Protecting Against Needle Sticks

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I. Introduction

Diagnostic and therapeutic medical procedures routinely involve the need to penetrate the patient’s tissues with a sharp needle, syringe or lancet, commonly called sharps, through which medicines are injected and/or specimens are withdrawn or extracted for analysis. This practice has the potential to expose medical personnel to various biological hazards [Ref. 1]. The primary hazard and an important component of the risk associated with this procedure is an unintended secondary stick. This problem has been well documented by healthcare professionals [Refs. 2-7].

While there are factors which are not entirely under the control of the healthcare provider, such as an agitated patient, [Ref. 8] secondary sticks are most often the result of lapses in procedural control [Refs. 7-9]. The opportunity for mishandling to occur is increased the longer the sharp needle or lancet point is exposed.

Various means of minimizing secondary needle/sharps sticks have been explored utilizing both procedural techniques and hardware devices. One early attempt at control was to immediately recap the used needle. This practice however actually created a greater potential for a secondary stick to occur and was quickly abandoned [Refs. 8, 10-14]. Hardware related solutions now range from needleless syringe devices to needle destructive mechanisms to simple waste containers [Refs. 9, 15 & 16].

Needleless syringes and other derivative devices such as spring loaded needles which retract back into the syringe are now in common use. However, practical limitations restrict their use to certain well-defined applications such as vein access and parenteral solutions administration. Intramuscular injections and biopsy needles remain among those sharps applications which still pose the hazard of a secondary needle stick.

Ultimately, these biologically contaminated products find their way into a sharps disposal container (SDC) which is currently the waste receptacle of choice. The design of the sharps container must also consider that nonsharps waste, even gloves and sponges, will probably be inserted into the container.

Historically, stick scenarios involved not only the technicians but also personnel handling trash containing inadequately protected sharps [Ref. 9]. The early containers, randomly devised by hospitals, were not standardized and offered about as much resistance to sharps penetration as a cardboard milk carton [Refs. 17, 18]. An industry was waiting.

Currently, a number of companies are producing biohazardous material containers (SDC) and design standards have evolved to address such issues as penetration resistance, visibility of the waste, and security of the opening and lid mechanisms [Ref. 19].

Hospitals and clinics now have a variety of sharps containers available to protect healthcare workers from needle sticks. The SDC has become an important element in a safety strategy which seeks to minimize the exposure time to sharps after use by locating SDC’s for easy access.

SDC’s have evolved to their present form as a result of certain parameters of application. These include: an unimpeded opening sized for a range of syringes and needles; containers sized to

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accommodate a sufficient volume of material to avoid frequent replacement; visibility of the contents of the container to permit an assessment of their fullness, and biohazard markings [Ref. 19]. Because these requirements can vary throughout the hospital, there is no single container design which hospitals accept as best for all circumstances.

If the use of sharps were confined to areas frequented only by medical personnel, the required design objectives for SDC's would be easier to standardize. However, examining rooms, hospital wards and outpatient facilities are areas where medical personnel often share with the general public. Openly visible contents, for example, are sometimes distracting or distressing to patients or might invite the curious or malicious visitor. The visibility advantage becomes a disadvantage under these conditions. There are circumstances, therefore, when the contents of an SDC should not be casually visible and access to the contents should be restricted. Restricting access does not discriminate between medical and nonmedical personnel, however, and can make the disposal task more difficult for the intended user of this product.

A decade of use has not given the SDC complete immunity from criticism. The presence of sharps container systems has not eliminated needle sticks completely and the SDC's very presence provides a "defective design" target for stuck hospital workers who subsequently test positive for HIV or hepatitis infections.

A primary hazard associated with disposal is being stuck by the sharp as it is being disposed of, or by one previously disposed. To be stuck by a sharp already in the container requires the hand(s) to be in or near the container. The act of disposal requires carrying a sharp to the container during which time safe handling is the only protection.

Risk of stick increases with the length of time the sharp is exposed for possible contact. This general relationship between contact and exposure time underlies the concerns about location and accessibility of the SDC. Manufacturers have no direct control over these factors. However, they can react to design parameters such as size, color, and mounting fixtures as having a compatible or optimal association with location.

In practice it is desirable to underfill the container. The objective is to maintain a space barrier or volume void margin as a factor of safety. The irregularity which is common to most sharps in terms of physical size and shape geometry means that the disposed articles do not stack well. The result is that there is no absolute horizontal plane which can be controlled by design in a manner which assures the safety margin is not violated by the practice of the ultimate users of the product and the variations inherent in the stacking problem.

Product designers employ a fill level mark on the container as a reference point to identify a container which is full and needs to be replaced. A full container by this criteria is not full by the usual criteria employed in filling most ordinary containers. In order for this approach to be effective, healthcare workers must understand this and replace containers which have reached their design capacity as defined by the markings on the container.

Healthcare workers are trained professionals who are well aware of their proximity to the HEP/HIV risk which has been steadily increasing since the mid-seventies. The nursing profession in particular has given significant attention to the needle stick problem in journals and publications [Refs. 15, 20].

Given this awareness, how then do containers become "over filled?" One can only suspect at this point that it is simply a natural tendency with many subtle root causes:

- The mental distractions of a time schedule.
- The mark is perceived as a guideline; there is room for "one more."
- The user becomes trapped between an overfilled container and a "hot" syringe.
- Visibility of interior contents is a spatial judgement relative to the external fill level mark.
- Careless disposal technique.

II. Design Factors

If we can assume the container wall is adequate to resist an outward penetration then any other connection which might exist between a needle stick and container design involves a stick during transfer or a stick after transfer. In terms of container design, both problems are somewhat interactive.

Design concepts such as a mailbox chute or rotating tray mechanism are methods of transferring articles from the hand into a container. The mechanism itself acts as a barrier between the hand and a sharp edge or point after release.

There is a downside to this approach. If the container fills to a point where the mechanism either will not operate properly or will not transfer the sharp to the container, a nurse may feel compelled to retrieve the sharp and to look for a back up means of disposal, with a corresponding increase in exposure.

Another "torturous path" approach combines the safety margin with a slightly serpentine path which does not favor normal hand articulation. However, the momentum of a straight vertical drop is diminished by the existence of a lateral component of the drop velocity vector, increasing the possibilities for a snag or hang-up to occur. A direct line of sight to monitor fill level may also be affected.

With respect to the medical community, the rationale for such design considerations is unclear. Given the level of awareness and training that we expect in the healthcare professional it is difficult to envision that the hand would be improperly inserted beyond the plane of the drop opening. Even then the distance margin would also have to be violated by overfilling.

As we acknowledge the importance of maintaining the fill level safety margin we automatically draw in the issue of visibility. This aspect presents a special challenge to product design. On the side of the healthcare professionals who must interface with the SDC, a clear see-through container would be most advantageous. These workers are also unlikely to be repelled by the agglomeration of syringes readily visible. From the point of view of the custodial/disposal crew, however, a solid red container is best to signal the biohazardous nature of the materials. To reconcile these competing points of view, a semitransparent red color is often used combined with the standard biohazard symbols. With this compromise some visibility of contents is retained.

The use of the SDC in the patient's room or exam room prompts further design constraints which tend to restrict visibility. The visual appearance of the contents tends to undermine the wellness philosophy inherent in recovery, a principle to which hospitals are now sensitive. Designers, again, cannot dismiss the possibility that visible contents may draw the unwelcome attention of visitors or unattended patients.
There is another special application which must also be considered; the SDC which is designed for use on the phlebotomy tray. This container moves from room to room with the technician who draws blood samples for laboratory analysis. Small, usually solid red in color, and designed with a needle unwinder, this SDC is intended solely for the safe accumulation of used needles.

Needles attach to syringe barrels with the aid of a special hub design commonly called a Luer-Lok. After use, the syringe is used to wedge the needle hub into a slot through the top of the SDC which is secured to the tray. A counterclockwise twist of the syringe barrel loosens the needle to drop into the container. If this does not succeed as intended, the phlebotomist must devise an alternate safe disposal strategy.

Needle sticks while using this specialized container have occurred when the lid is closed forcefully against the unyielding point of a protruding needle. Again, an overfilled condition must precede this type of injury, but it is also coupled with a reckless disregard for the potential consequences.

III. The Hospital’s Role

Hospitals and clinics are both employers and consumers. As consumers they help to set design goals which are defined through experience with the use and disposal of sharps.

As employers, hospitals have a duty to protect employees from workplace dangers. Although this is federally mandated by OSHA, hospitals are not typical workplaces and hepatitis and AIDS are not typical dangers. Most who are exposed are highly trained and knowledgeable. Coping with these dangers is not something for which OSHA alone must promote concern. The medical community has been a proactive partner in addressing this risk [Ref. 21]. It is the source of a high volume of published discussion and analysis of the needlestick/sharps disposal problem and its management. Medical personnel use their experience and knowledge to instruct and train their staff and they seek to define and employ the best means available to safely dispose of sharps materials.

The one factor which dominates in a Pareto analysis of collected data is carelessness in handling [Ref. 6]. It seems to be one which is inherently difficult to affect by increasing focus and attention. This is exactly the reason that motivates manufacturers to concentrate on technology which obviates the use of sharps entirely.

Hospital rules are that needle sticks must be reported and preventive measures taken to ward off infection to the extent allowed by available treatment. If perceived as a medical device failure, the hospital is required to report this to the manufacturer and the FDA since it necessitates medical intervention. Manufacturers, in turn, must record and investigate each incident. This is not an option, it is federal law.

When a container is involved with a needle stick, it is usually disposed of. Consequently, any future investigation of the needlestick incident cannot include a direct examination of the SDC. With an apparent lack of more definitive data, concerns about inadequate SDC design are easily overstated. Even so, they cannot be dismissed in any responsible effort to improve the sharps disposal process and the products involved. The marketplace, experience, competition and technology are forces which tend to optimize performance when issues are understood. Because the many opportunities for needle sticks to occur must also admit the possibility of incidents not directly coupled with the container, attempts to establish a sound correlation with design factors is a challenge.

IV. Health Watch Agencies

Organizations other than OSHA and hospitals have given much attention to the problem of sharps containment and needle sticks. The Emergency Care Research Institute (ECRI) is an organization in Plymouth Meeting, Pennsylvania which assists member hospitals in making informed choices with respect to the purchase of capital equipment and medical devices. Product evaluation reports are published by ECRI in Health Devices.

The Center for Disease Control (CDC) in Atlanta, Georgia convened a panel of experts with a broad range of interest to study the sharps disposal problem. This effort resulted in guidelines and a basis for general standards [Ref. 19]. Even so, SDC designs remain fundamentally unchanged.

Current SDC designs are essentially a product of an evolutionary optimization in this healthcare environment as design practice attempts to fold user requirements into the product. Since absolute adherence to the CDC proposed standards can produce a design conflict, SDC designers must keep their eyes on several goals intended by the standards simultaneously and optimize compliance in the final design. For example, restricting hand insertion is incompatible with nonrestrictive sharps insertion.

The history of SDC designs and their application tends to indicate that there are no violative products in the marketplace based on noncompliance with these consensus standards. By this, it is reasonably accurate to conclude that there is no fundamental disagreement in the community of knowledgeable users over the results that the optimization of design goals has achieved in the final products.

V. Research Directions

From the accumulated knowledge and experience based on actual hospital practices, product design efforts and the circumstances of litigation, there are two general observations:

- Manufacturers of SDC’s have a continuing interest in looking for product improvements which could increase safe use and still preserve utility.

- Hospitals’ concerns with current SDC’s appear to relate more to ease of use. They acknowledge the advantages of visibility and fill limitations but tend to ascribe needle sticks to a procedural handling problem.

The concept of intentional under filling as a safety strategy survives without criticism. If we assume then that the preservation of a safety margin would provide some benefit as a safety goal regardless of how tenuous its connection is to the total number of needle sticks, it is natural to continue to look for ways to assure that this safety margin is maintained.

In this context we explored the use of electronic sensor technology which would remove most of the burden from the user to decide when the plane defining the maximum fill level had been breached to solve what has been characterized as the overfilling problem.

Before evaluating this approach we made a general list of requirements which we felt were reasonable expectations for the application of sensor technology:
adaptable to current products.
- Minimal reconfiguration of the SDC.
- Self-contained battery power.
- 30-60 days continuous use life.
- Disposable.
- Simple attachment/optional use.
- Minimal cost.
- Reusable with SDC replacement.
- Temperature stable range 0E- 40E C.
- Water resistant.
- Reagent sterilizable.
- Shock resistant - 5 ft. drop test.
- EMI/ESD protected.
- In-use indicator light (red) 2-second blink.
- Full level indication - constant on light (red).
- Self-test with failure indicator diagnostics.
- Battery end-of-life detection.

Essentially, the electronic sensor technology employed must detect some change in a transmitted signal relative to a steady state condition. We first considered the container as a chamber which would resonate at a certain base line signal frequency. Changes in resonance would occur as the volume diminished with material accumulation. A variation of this would be to measure the time for an ultrasonic acoustic signal to be reflected between an emitter and detector.

Disadvantages of the acoustic echo approach are power consumption and the averaging effects problem which would smooth out an irregular surface and ignore a potentially significant single irregularity. The longer acoustic wave length is also potentially less sensitive to small changes in volume (see Figure 1).

A better choice of technology seemed to be a relatively high frequency infrared signal which would scan across a fixed level in the container. A detectable change in signal would consist of a momentary or constant interruption of the signal path (see Figure 2).

Infrared signals can be focused, reflected and detected with low power consumption and emitter, detector, battery and circuitry can be packaged into a size of several cubic centimeters.

In addition, scanning across the full-level plane does not aver-

![Figure 1 - Sharps Disposal Container with Acoustic Echo Signal](image1)

![Figure 2 - Sharps disposal Container with Infra Red Signal](image2)

age the depth of the contents. A simple errant shape protruding into the buffer zone will be picked up by this method. All volume errors will therefore be on the safe side.

In order to test the feasibility of the horizontal infrared signal, a typical, Sage SDC unit was adapted to accept an emitter detector system assembled with currently available off-the-shelf electronic components. The IR emitter was positioned to aim the signal diagonally through the drop opening and reflect across the selected fill level and follow the same path back and out to the detector (see Figure 3). In our experimental device, a constant ON light indicated an uninterrupted signal path.

A variety of syringe sizes with attached needles were then disposed of in the usual manner until the light went out indicating an interrupted signal path. This experiment was repeated a number of times always with the same result. The success of this method was eventually rewarded with a patent [Ref. 22].

The ultimate refinement and interface of this method with SDC products would obviously require collaboration with the SDC industry to prove, or disprove, its value. Several key factors are involved with respect to this interface:

**IR Signal Reflection**
Small reflective surfaces must be located within the container.

**Emitter Detector Location**
The location used for the experiments was simply convenient to demonstrate the feasibility of the approach. Improvements exist here also. Locations within the container would require the device to be single use only. However, smaller battery size, miniaturization, and exteriorization of the signal light by optical methods are attractive possibilities.

**Interface With Container Mounting Brackets**
Any configuration must be compatible with current hospital practice with respect to location and mounting without significant changes to existing hardware.

**Areas of Maximum Impact**
Some low volume, well controlled areas such as exam offices could
have low priority. Marketing input is required to determine if a cost/benefit trade-off exists in such locations.

Container Size
The method outlined would not appear viable for use with containers such as are found on the phlebotomy tray. There may be other such exceptions.

VI. Conclusions

Sharps disposal containers may not have caused the needle stick problem to disappear, but healthcare workers are safer because of their use and the secondary trash handlers are at far less risk than they were when plastic trash bags also contained unprotected sharps materials.

The very presence of sharps disposal containers in the hospital setting has yet another benefit less well recognized. They are subtle daily reminders of a hazard that healthcare workers must use caution and training to avoid.

Until the time arrives when technology eliminates the sharp, or sharps disposal container design can embody some viable, innovative feature which gives greater assurance against mishap, the general rule of using one-hand, two-eyes and one sharp is the best defense against unintended sticks during the sharps disposal process.

References


