Reducing Occupational Exposure to Bloodborne Pathogens: Where Do We Stand a Decade Later?

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It has been 12 years since the first case of needlestick-transmitted human immunodeficiency virus (HIV) was reported in the medical literature and 10 years since the Occupational Health and Safety Administration (OSHA) began the process of enacting a standard for the protection of healthcare workers from exposure to bloodborne pathogens. These seminal events triggered widespread efforts to educate healthcare workers, to improve workplace conditions, and to eliminate the causes of exposure risk. After a decade of sustained effort, there is little doubt that important advances have been made in creating a safer healthcare setting and in increasing awareness of workplace risks.

Healthcare workers whose careers have spanned the past decade can remember practices and equipment that once were commonplace but that are unacceptable, or even shocking, by today's standards. A decade ago, one could find an array of makeshift or poorly designed needle disposal containers, such as paper cups, flimsy plastic jugs, or thin-walled cardboard pop-up boxes, from which needles regularly spilled or protruded. In most hospitals, disposal containers were located far from the point of use, forcing healthcare workers to travel the corridors of patient-care areas carrying used, exposed needles. Recapping of contaminated needles was a standard, even recommended, practice. Blood generally was not thought of as a hazardous substance, and frequent hand contact with blood was viewed as just part of the caregiver's job. A surgeon's red badge of honor was the blood-saturated surgical gown. And, the absent-minded act of leaving a used needle at a patient's bedside drew little attention. Today, the same act could be grounds for a lawsuit.

In addition to better disposal systems, safer workplace practices, and the increased use of personal protective equipment that occurred with the implementation of the OSHA Bloodborne Pathogen Standard, medical product manufacturers have responded to the need for new products designed to prevent exposure to blood and other potentially infectious body substances. A new array of barrier products with greater fluid resistance and improved garment design are available. Advances in the design of needle devices and sharp instruments finally have gone beyond the issue of patient safety and have addressed the problems of user safety.

Clear evidence of the response of inventors and manufacturers can be found in the records of the US Patent and Trademark Office. Since 1984, more than 1,000 patents have been issued for devices designed to prevent needlesticks. There has been a parallel introduction of new safety devices into the healthcare marketplace. Although the acceptance of this new technology varies among hospitals, most healthcare workers in the US have had the opportunity of evaluating or using one or more safety devices now on the market. Of the new generation of devices, needleless or protected-needle intravenous (IV) systems are the

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most widely used, with more than 50% of US hospitals converting from hypodermic needle connections for piggybacks and intermittent IVs by January 1995. Despite many obvious and encouraging signs of progress during the past decade, documenting the impact of these changes has been more elusive. The major barrier to making “before-and-after” comparisons is the distinct shortage of data from “before.” Although old data exist, methods of data collection have changed, such that old data cannot be compared readily to more recent data. Of particular importance, the identification of devices causing injuries is lacking in old data.

There is strong evidence on one point, however: recapping as a cause of needlesticks, first described by McCormick and Maki, has declined dramatically in recent years. In a 1986 study conducted at the University of Virginia Hospital, one third of needlesticks from hollow-bore needles occurred during recapping, whereas in 1994 and 1995, only 4% of needlesticks from hollow-bore needles occurred while recapping. A similar result was found in 64 US hospitals collaborating with the University of Virginia in a data-sharing network (the Exposure Prevention Information Network, or EPINet) during the same time period. This finding was consistent across all hospitals in the network. Although these data suggest that an important and widespread change had taken place, it is not clear which change or changes made such a difference. Were healthcare workers responding to recommendations to avoid recapping of needles? Were disposal boxes closer to the point of use, reducing the incentive to recap? Were there fewer needles eligible for recapping because of the introduction of some safety devices? Is some combination of these factors responsible? Most importantly, does a reduction in recapping-related needlesticks mean there has been an overall decrease in needlesticks, or are healthcare workers injured more frequently by exposed needles? The answers remain unclear.

Another finding sheds some light in our quest for answers about what is effective in reducing exposure risk from needlesticks. Data from the 1986 study conducted at the University of Virginia Hospital showed that the injury rate from IV catheter styles was 18.4 per 100,000 catheters purchased. In September 1992, a safety catheter with a retractable shielded stylet was introduced into the hospital and also into two other hospitals in the EPINet data-sharing network. For 12 months, the three hospitals used the safety IV catheter and simultaneously used the same brand of conventional catheter in areas where the new catheter could not be used. The overall injury rate in 1992 and 1993 for the conventional catheter was 7.5 per 100,000 catheters purchased. For the safety catheter, the overall injury rate was 1.2 per 100,000 catheters purchased, representing an 84% reduction in comparison to the conventional catheter. Although a number of factors may have contributed to the lower rates observed with the safety catheter, these data nevertheless suggest that education and improved disposal systems can reduce injury rates of conventional devices (a 59% reduction from the 1986 rate), but that an effective safety device potentially can reduce injury rates far more (84%) than can be accomplished by education and good disposal systems alone.

Over the past decade, an enormous investment has been made by healthcare institutions, government agencies, medical product manufacturers, professional associations, and researchers to make the healthcare workplace safer from the risk of blood-borne pathogen transmission. We have learned that it takes considerable time to invent, manufacture, market, pilot-test, evaluate, and disseminate into widespread use the new technology that holds the most hope for effective protection of healthcare workers. We also have learned that, despite massive efforts and visible progress, getting an answer to the elusive question “What works?” is a long-term prospect.

There are several sobering facts to keep in mind during the process of sorting out what works from what does not. Although at first sight these observations may appear daunting, they can help set the stage for a realistic outlook.

(1) Most safety devices are subject to “the honeymoon phenomenon,” as evidenced in the adjoining article by Mulherin, Rickman, and Jackson. The first reaction to a new device designed to prevent needlesticks often is enthusiasm and praise, which usually is followed by a more practical and critical assessment when the device is put into use.

(2) If you search for a problem, you are more likely to find one than if you don’t search. New safety devices are scrutinized more closely than the products they are intended to replace ever were. Consequently, more problems are likely to be found. All potential problems are of concern and should be investigated and addressed, but it is also important that, when comparisons to conventional technology are made, such information be balanced to include a discussion of the potential issues that accompany the use of conventional products. A case in point: in the ongoing evaluations of whether needleless IV systems increase the incidence of bloodstream infec-
tions, other equally important patient safety questions related to the use of conventional hypodermic needle IV line connections never have been addressed. For instance, in institutions where conventional hypodermic needle IV connections are used, what is the frequency of inadvertent IV line disconnection, with consequent discontinuation of vital IV medications in postoperative patients? Ask the nearest anesthesiologist. Why has this never been factored into the equation of patient safety issues?

(3) The more successful we become at preventing needlesticks, the longer it will take, and the more difficult it will be, to demonstrate the efficacy of safety devices. Needlestick injuries are, from a statistical perspective, rare events occurring roughly in the range of from 40 injuries per 100,000 devices used to 1 or fewer injuries per 100,000 devices used. To demonstrate that one device has a lower injury rate than another, statistical sample size requirements must be met, and a sufficient number of devices must be used to detect a statistical difference, if one exists. The lower the injury rate, the greater the number of devices required to demonstrate a statistical difference. Depending on the devices being compared and the statistical parameters set, most such trials conducted today would require a minimum of 100,000 devices. The annual usage of specific types of needles in the average hospital is likely to be less than the number required to conduct a needlestick efficacy trial. As prevention becomes more effective and devices become safer, the required numbers will increase proportionately.

(4) The more widespread safety devices become, the more injuries will be caused by them. Many available safety devices still require a needle for penetration of skin or tissue. They provide a safety feature that can be activated after use of the needle. With this type of device, a residual fraction of needlesticks must be expected and does not represent a device failure if that fraction of injuries is appropriately low. But, as the number of injuries from safety devices accumulates, even if the devices work well, there is the strong possibility of observing a phenomenon well known to other areas of safety. Opponents of the technology use injury reports to declare the technology inherently dangerous (deaths caused by seatbelts; brain damage caused by motorcycle helmets, needlesticks caused by safety needles). Count on it, but remember, the relevant statistic is how many injuries a device prevents. If it prevents more than it causes, it is better than the alternative.

These observations are not intended to be discouraging, but rather to provide a realistic perspective in preparation for the long haul. With the increasing availability of safer medical devices and the rapid communication of effective prevention measures, we can expect even greater reductions in risks to healthcare workers in the decade to come; but we should not think that it will be easy.

REFERENCES


https://doi.org/10.2307/30141942 Published online by Cambridge University Press