



REVIEW

The impact of U.S. policies to protect healthcare workers from bloodborne pathogens: The critical role of safety-engineered devices

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Received 2 October 2008; received in revised form 16 October 2008; accepted 17 October 2008

KEYWORDS

Needlestick
injuries/sharps injuries;
Occupational exposures;
Safety-engineered sharp
devices;
Bloodborne pathogens
regulations;
Healthcare worker
safety

Summary In the United States (U.S.), federal legislation requiring the use of safety-engineered sharp devices, along with an array of other protective measures, has played a critical role in reducing healthcare workers' (HCWs) risk of occupational exposure to bloodborne pathogens over the last 20 years. We present the history of U.S. regulatory and legislative actions regarding occupational blood exposures, and review evidence of the impact of these actions. In one large network of U.S. hospitals using the Exposure Prevention Information Network (EPINet) sharps injury surveillance program, overall injury rates for hollow-bore needles declined by 34%, with a 51% decline for nurses. The U.S. experience demonstrates the effectiveness of safety-engineered devices in reducing sharps injuries, and the importance of national-level regulations (accompanied by active enforcement) in ensuring wide-scale availability and implementation of protective devices to decrease healthcare worker risk.

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The protection of healthcare workers (HCWs) from exposures to bloodborne pathogens, a life-threatening occupational risk in healthcare settings, was tragically neglected in the pre-AIDS era. Such exposures, particularly to hepatitis B, long exacted a deadly toll among HCWs worldwide. But it was not until the global AIDS epidemic captured the attention of the healthcare community that efforts to reduce this grave occupational risk were set in motion. United States (U.S.) federal agencies introduced and then mandated a comprehensive array of countermeasures, and succeeded in achieving significant reductions in occupational risk to the national healthcare workforce. The actions taken in the U.S. over the past 20 years can thus provide a useful model, with caveats, for other countries that are presently at earlier stages of progress.

The first case of needlestick-transmitted HIV was reported in the *Lancet* in 1984, alerting the healthcare community to this new threat [1]. In 1987, the Centers for Disease Control and Prevention (CDC) documented six cases of occupationally acquired HIV infection in the U.S. [2], a report that sent shock waves through the healthcare community. Pressure was applied to government agencies to take protective action, and a large healthcare worker union formally petitioned the Occupational Safety and Health Administration (OSHA), an agency of the U.S. Department of Labor with authority over employers, to set a new standard requiring healthcare employers to upgrade protective measures provided to employees. This began a process that lasted more than a decade, during which many policy actions were initiated in the complicated regulatory and legislative environment of the U.S.

The CDC was the first federal agency to respond. In 1987, it issued guidelines for Universal Precautions for workers at risk of exposure to the blood or body fluids of patients [3]. The guidelines applied to all bloodborne pathogens, and recommended: (1) increased use of personal protective equipment (PPE) such as gloves, fluid-resistant gowns, protective eyewear, masks and other barrier garments to reduce contact with blood and contaminated body fluids; (2) safer handling and disposal of sharp med-

ical devices; (3) hepatitis B vaccine offered at no cost to employees; (4) use of puncture-resistant sharps containers, placed as close as possible to the point-of-use; and (5) annual training of all at-risk workers in the protective measures included in the guidelines [3].

OSHA issued an advisory notice to employers in 1987 which incorporated the CDC guidelines [4]; in that same year, it initiated procedures for establishing a regulatory standard covering employee exposures to bloodborne pathogens [5]. After several years of hearings and public comment, and intense congressional pressure, the standard was promulgated in 1991 [6]. To this day, the OSHA Bloodborne Pathogens Standard (BPS) remains the principal authority protecting U.S. HCWs from bloodborne pathogens.

Pathogen-specific prevention and interventions

The 1987 recommendations from the CDC and OSHA were followed by a rapid increase in hepatitis B vaccination rates. The incidence of occupational HBV infections declined dramatically, from more than 17,000 cases in 1983, before the availability of the vaccine, to 400 in 1995 – a 95% decline [7].

OSHA's 1987 advisory notice and the 1991 BPS both included provisions requiring employers to record and track occupational blood exposures, and to offer exposed employees follow-up counseling and treatment, including post-exposure chemoprophylaxis (PEP), when medically appropriate [4,6]. The use of anti-retroviral (ARV) drugs for HIV PEP was a significant advance in preventing occupational transmission of HIV. In 1997, the CDC, reporting on the results of a case-control study, said "the odds of HIV infection among health care workers who took zidovudine prophylactically after exposure were reduced by approximately 81 percent" [8]. The following year, the CDC issued clinical guidelines on the use of combination ARV therapy (believed to be more effective than treat-

ment with zidovudine alone) for PEP to reduce HCWs' risk of infection after an exposure to HIV [9].

The rapid adoption of ARV drugs by HIV/AIDS patients also had a profound effect on HCWs' HIV exposure and infection risk: hospital admissions of HIV/AIDS patients declined dramatically [10,11], and those on ARV therapy who were hospitalized posed less infection risk to HCWs, since they usually have low (in some cases undetectable) viral loads. The combination of these factors resulted in a marked decrease in HIV transmission risk to hospital-based HCWs. Through 1997, 54 documented and 132 possible cases of occupational HIV infection were reported in the U.S.; after 1997, only three additional documented and five possible cases were reported. Since 2001, there has been only one possible case of occupationally transmitted HIV/AIDS reported in the U.S. [10–12].

Prevention of sharps injuries

The safety-related work practices outlined in the CDC's Universal Precautions and OSHA's joint advisory in 1987 were the first steps towards reducing sharps injury risk to U.S. HCWs [3,4]. These work practices included a prohibition (with a few exceptions) on the recapping of contaminated needles, and provision of puncture- and fluid-resistant sharps disposal containers at the point-of-use, preferably within arms' reach of the user. Placement of sharps containers in patient rooms and other point-of-use locations reduced the incentive of HCWs to recap used needles: one study reported that the implementation of point-of-use sharps containers lowered recapping-associated needlesticks from 23% of all needlesticks in 1986 to only 5% in 1992–1994 [13].

The greatest impact on sharps injury risk, however, resulted from the adoption of safety-engineered needles and sharp devices designed to reduce the incidence of sharps injuries to users. From their first appearance on the market around 1988 to the passage of a national needlestick law in the U.S. in 2000, a progression of policies were implemented by government agencies, state legislatures and the U.S. Congress that first recommended, then required, their use. As early as 1987, OSHA specified that "engineering controls" were the preferred method of hazard reduction to prevent HCWs' exposure to blood [4]. Safety-engineered needles and sharp devices are considered engineering controls; however, they were not available in 1987, and therefore were not

specified in the joint advisory. But by 1990, the major medical device manufacturers had embraced the concept of safety-engineered needles and sharps, resulting in the rapid development of new sharps safety technology. By 1996, there were more than 1000 U.S. patents issued for medical devices with sharps safety features [14]. The new technology addressed the full spectrum of sharp devices, including injection devices, vascular access and blood-drawing devices, surgical instruments and laboratory equipment. The investment of U.S. medical device manufacturers in the development of this technology was critical to efforts to create a safer healthcare workplace.

The national movement to require the use of safety-engineered devices began around 1990, with numerous advocacy groups pulling all possible legal and regulatory levers to see which ones would have the desired effect. Healthcare worker unions, nursing and infection control professional associations, medical device manufacturers, state government officials, and academic researchers all embraced the common goal.

The first government policy with noticeable impact on the use of needle devices was a "Safety Alert" issued by the Food and Drug Administration (FDA) in 1992, following a request from the healthcare community [15]. The safety alert advised healthcare institutions to stop using hypodermic needles for accessing I.V. ports and connecting I.V. lines (piggyback needles), and to preferentially adopt needleless I.V. connectors and I.V. access syringes (usually used for heparin/saline flushes). Although compliance with an FDA safety alert is voluntary, they are taken seriously by hospitals. Following publication of the 1992 alert, the medical device industry reported a dramatic increase in demand for needleless I.V. equipment. And a report of trends in needlestick injuries among nurses showed that between 1993 and 2001 there was a 100% drop in injuries from I.V. line connectors, previously one of the most common causes of injury, and a 62% drop in injuries from prefilled syringes (used for heparin/saline flushes) [16].

The FDA alert was also significant because it provided language that became the foundation for defining devices designed to reduce needlestick injuries, including:

- A fixed safety feature to provide a barrier between the hands and the needle after use; the safety feature should allow or require the hands to remain behind the needle at all times.
- The safety feature [is] an integral part of the device, and not an accessory.

- The safety feature [is] in effect before disassembly and [remains] in effect after disposal, to protect users and trash handlers, and for environmental safety.
- The safety feature [is] as simple as possible, and [requires] little or no training to use effectively [15].

In 1999, the FDA also issued a "Safety Advisory" on the hazards of glass microhematocrit capillary tubes, which were prone to breakage and presented a serious risk of injury and blood exposure to HCWs. The advisory, issued jointly with OSHA and the National Institute for Occupational Safety and Health (NIOSH), warned against the use of glass capillary tubes and recommended instead plastic or plastic-wrapped tubes [17]. The safety advisory had a significant impact. In U.S. sharps injury data from 1994 to 1998 (prior to the advisory being issued), the total number of reported injuries from glass capillary tubes was 33; for the period 2000–2004, after the advisory was issued, the total number of injuries from glass capillary tubes dropped to 6 [18].

Pressure in the U.S. to legally require devices with sharps injury protection grew as more safety devices were introduced to the health-care market and evidence of their effectiveness became available. Clinical trials and product evaluations were published on safety-engineered blood-drawing devices, vascular access devices, blunt suture needles, syringes, and needleless I.V. equipment, all of which demonstrated the effectiveness of the new technology in reducing needlestick injury risk. The degree of efficacy varied but was generally high, ranging from two-thirds reduction in injuries for safety phlebotomy devices to more than 80% reduction for safety I.V. catheters [19–28].

Healthcare worker unions became a driving force in introducing legislation at the state level, part of a larger strategy to ultimately achieve a single federal law. In 1998, California passed the first state law requiring employers to provide safety-engineered sharp devices in all relevant device categories [29]. Medical device manufacturers had to scale up production of safety devices to meet market demand for the most highly populated U.S. state [30]. Sixteen additional states passed similar laws in the next two years [31]; this patchwork of state laws created havoc for manufacturers and hospital procurement organizations, and provided further incentive to pass a uniform national law.

The federal government recognized the need to assess potential costs and benefits of mandating safety-engineered sharp devices at a national

level. To this end, OSHA issued a "Request for Information" (RFI) in 1998 soliciting comments and documentation on workplace experiences with engineering controls designed to minimize occupational exposure to bloodborne pathogens from percutaneous injuries. A summary of responses from more than 400 healthcare facilities was published in May 1999; OSHA concluded that "safer medical devices are an effective and feasible method of hazard control [32]."

The federal government's Office of Management and Budget was commissioned to perform a cost/benefit assessment of the national impact of adopting safety-engineered sharps. This report, issued in 2000, provided further support for the benefits of the technology and its cost-effectiveness if adopted nationwide [33].

As a result of the supporting evidence provided by the RFI, OSHA revised the compliance directive for the BPS, giving OSHA inspectors the authority to issue citations and levy fines against healthcare employers who failed to provide safety-engineered sharps in their facilities [34]. The 1999 revised compliance directive stated that "Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, *they must be used*" [emphasis added]; it said further that "Significant improvements in technology are most evident in the growing market of safer medical devices that minimize, control or prevent exposure incidents [34]."

The Needlestick Safety And Prevention Act of 2000

The U.S. Congress determined that language in the OSHA BPS relating to needlesticks and sharps safety needed to be expanded for greater clarity. The Needlestick Safety and Prevention Act (NSPA) of 2000, which required OSHA to revise the BPS for this purpose, was unanimously passed by both Houses of Congress, and was signed into law by President Clinton on November 6, 2000 [35]. The law required that: (1) frontline HCWs (those providing direct patient care) be included in the process of evaluating and selecting safety-engineered needles and sharps; (2) employers document evaluation and implementation of safety-engineered devices; (3) employers update their evaluation plan annually to reflect the availability of new technology; and (4) employers maintain a sharps injury log documenting the types of devices causing injuries and an explanation of the circumstance of each incident. OSHA made these revisions to the BPS in compliance with

the new law, and the revised standard took effect in April 2001 [36].

Definition of “safety-engineered” sharp devices; exemptions; training

The 2001 revised BPS defined a “sharp with engineered sharps injury protection” (SESIP) as a “non-needle sharp or needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident [36].” This definition allowed for a variety of injury-prevention design solutions and avoided mandating specific features or brands. It also encouraged the broad participation of industry in designing a wide range of innovative products.

Under the revised standard, safety-engineered devices are not required for applications which do not involve direct patient contact (e.g., mixing drugs in the pharmacy) [37]. Also, exemptions from using safety devices are allowed in specific clinical circumstances. OSHA states that “No one medical device is appropriate in all circumstances of use. For purposes of this standard, an ‘appropriate’ safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated” [36]. OSHA further explains: “If a safer device is not available in the marketplace, the employer is not required to develop any such device. Furthermore, the revised requirements are limited to the safer medical devices that are considered to be ‘effective’ [...] a device that, based on reasonable judgment, will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used” [36].

Although safety devices are usually more expensive than conventional ones, OSHA does not allow exemptions based solely on cost. In a letter to the American Academy of Pediatrics, OSHA stated: “The standard does not give the employer the option to forgo appropriate, commercially available, and effective engineering controls” [38]. Elsewhere OSHA says, “[S]electing a safer device based solely on the *lowest* cost is not appropriate. Selection must be based on employee feedback and device effectiveness” [39].

Regarding training of employees on the use of safety devices, OSHA emphasized that training should include “an explanation of the use and limitations of [...] appropriate engineering controls”

and “instruction in any new techniques and practices” [36].

The chief importance of the federal law was to give high-profile visibility to the requirement to use safety-engineered devices, and to provide a single standard of protection for all U.S. HCWs. The law, combined with active enforcement by OSHA, resulted in high levels of compliance by healthcare institutions nationwide.

Enforcement and compliance

Between 2001 and 2005, the number of citations issued by OSHA for failure to use engineering and work practice controls was four times that issued for this class of violation in the previous decade. Between 2001 and 2007, OSHA issued 144 citations and levied \$389,800 in fines against healthcare facilities for failure to comply with the requirement to use safety devices (personal communication, Dionne Williams, Office of Health Enforcement, OSHA, 2008). Such punitive enforcement actions are taken very seriously by U.S. hospitals, since OSHA citations are made public and a hospital’s reputation can be adversely affected by bad publicity.

A dramatic surge in adoption rates of safety-engineered devices occurred in 2000 and 2001. The only national data available that reflect overall compliance with the requirement to use safety devices come from the medical device industry; industry data (from sources reflecting all manufacturers and the total U.S. device market) show national market trends for adoption of safety devices in three device categories (Fig. 1) [40]. From 1990 to 2000, there was a gradual adoption of safety devices, but the voluntary rate of adoption was generally low – 25% or less for most device categories [41]. Adoption rates climbed sharply after 2000, with safety-engineered devices becoming the predominant technology over the following three years [40]. Encouragingly, adoption rates were particularly high for the types of devices with the highest risk of bloodborne pathogen transmission: blood collection needles and I.V. catheters.

Impact of the law on injury rates

Assessing the overall impact of the U.S. law is complicated by the fact that, in most cases, a clear-cut before-and-after comparison of data cannot be made, since the adoption of safety technology occurred gradually during the 1990s. However, one hospital in the U.S., Memorial Sloan-Kettering Can-

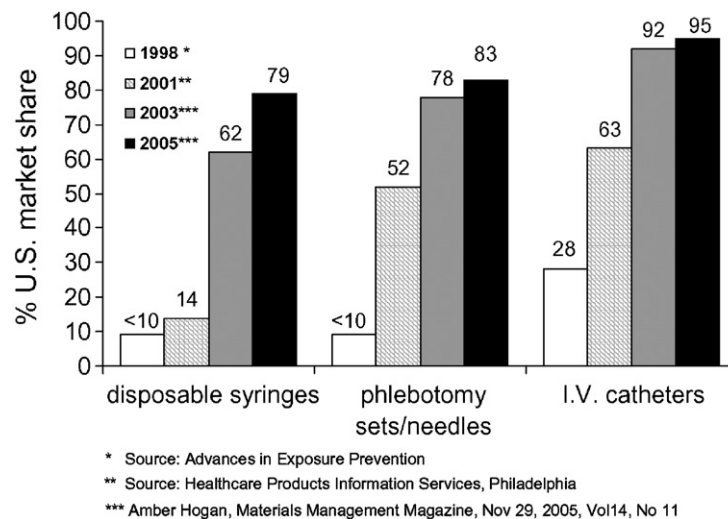


Figure 1 Increase in percent market share of three safety devices, U.S., 1998–2003. 1998–2005 data represents all U.S. hospitals; data for 1998 and 2001 additionally includes alternate sites (clinics, offices, labs).

cer Center (MSK) in New York City, documented an experience in which no safety devices were in use before the law was passed, followed by a near-total conversion to safety-engineered devices after the law took effect [42]. The MSK study showed an overall reduction in sharps injuries of 58%, with a 71% reduction in injuries from hollow-bore needles, and a 75% reduction among nurses, the occupational group that typically sustains the highest proportion of injuries.

A group of U.S. hospitals using the Exposure Prevention Information Network (EPINet) program for surveillance of occupational blood exposures has participated in a data-sharing network with the University of Virginia since 1993; these hospitals, like most in the U.S., gradually adopted various safety-

engineered devices between 1993 and 2000. For this reason, EPINet network data from before and after the NSPA do not reflect as sharp a distinction as in the MSK study. Fig. 2 shows annual injury rates from hollow-bore needles in the EPINet network during the period 1993–2004 (cumulative total of 87 U.S. hospitals contributing data); injury rates dropped by 34% after passage of the NSPA in 2000. Consistent with the MSK study, nurses as an occupational group showed the largest reduction in injury rates (51%) [16].

Device-specific injury rates (Fig. 3) show that the largest reductions in rates were seen for the devices with the highest market penetration, including phlebotomy needles (59% reduction) and I.V. catheter stylets (53% reduction). These two

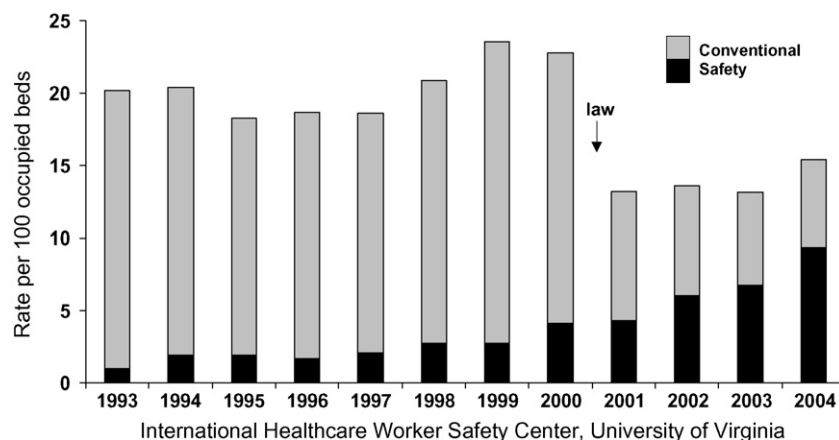


Figure 2 Injury rates from hollow-bore needles: safety versus conventional, U.S. EPINet 1993–2004. 87 hospitals; total injuries = 18,975 (excludes injuries occurring before use of device).

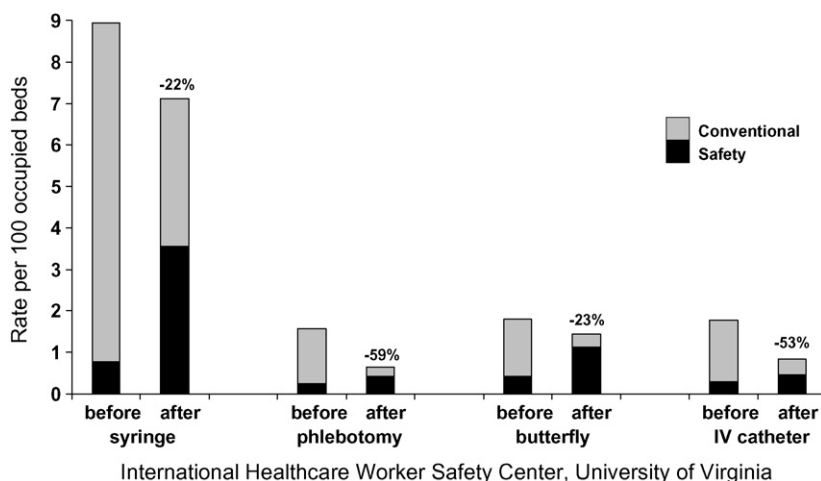


Figure 3 U.S. EPINet: device-specific injury rates before (1993–2000) and after (2001–2004) passage of Needlestick Safety and Prevention Act (November 2000). 87 hospitals; total injuries = 10,778 (excludes injuries occurring before use of device).

device categories are among those with the highest risk of bloodborne pathogen transmission; converting to safety in these categories is likely to have the greatest impact on reducing transmission risk to HCWs. Fig. 3 also shows that there is residual use of conventional devices; injury rates would decline further with 100% conversion to safety in device categories where that goal is feasible. (There remain legitimate non-patient applications for conventional syringes, for example.)

Fig. 4 compares the injury rate for surgical settings with the combined rate for all other hospital settings; it shows that the surgical sharps injury rate remained unchanged after passage of the NSPA in 2000, and that the law almost exclusively

impacted (and benefited) non-surgical settings. Lack of adoption of safety-engineered devices, such as blunt suture needles and shielded scalpels, largely accounts for this phenomenon.

It is important to underscore that global reductions in U.S. sharps injury rates were observed only after safety devices became the predominant technology; the low level of safety-device adoption before 2000 did not produce a large-scale reduction in rates. For device categories (suture needles and scalpels) in which adoption of safety alternatives has remained low – blunt-tip suture needles and safety scalpels both have less than 5% market share – injury rates have not declined at all [43,44].



Figure 4 U.S. EPINet: comparison of surgical and non-surgical injury rates, 1993–2003. 87 hospitals; total injuries = 28,895 (excludes injuries occurring before use of device).

Conclusions

U.S. government regulations and legislation, first initiated by OSHA in 1987, have been critical to the successful implementation of prevention measures that protect U.S. HCWs from life-threatening bloodborne pathogens. The U.S. is unique in fostering the development of a new generation of safety-engineered sharp medical devices, and is the first country to nationally mandate their adoption. The U.S. experience demonstrates the importance and effectiveness of safety-engineered needles and sharps in reducing sharps injuries and bloodborne pathogen exposures in healthcare settings.

The U.S. experience also showed that voluntary adoption of safety technology, without a legislative mandate, was ineffective in producing a large-scale reduction in sharps injury rates. A significant drop in rates occurred only after an enforceable law was enacted and safety-engineered devices became the predominant technology.

U.S. legislation requiring safety-engineered devices has notable strengths. First, it recognizes that safety devices are not available for every medical application, and permits clinical judgment to be used in such cases. Second, it requires the input of HCWs in the process of evaluating and selecting safety devices, which is key to their acceptance and also results in valuable feedback for device manufacturers. User input in each institution is important because different devices may be appropriate for different healthcare facilities. Third, the law requires in-service training to ensure that new devices are used consistently and correctly; the emphasis on appropriate training has been critical to implementing a new generation of devices. Fourth, the legislation does not favor any specific company or device design, but instead provides a performance-based definition of safety-engineered devices that allows for a variety of approaches. This has been important in encouraging industry-wide participation, and has resulted in a range of product designs and choices, which is necessary given the diversity of medical procedures that are performed.

Although compliance with the requirement to use safety devices, as reflected in market data, has been high, there remain areas of weakness. While HCWs in non-hospital settings (clinics, private doctors' and dentists' offices, long-term care facilities, free-standing laboratories, etc.) account for approximately 60% of the healthcare workforce in the U.S. [45], adoption levels of safety-engineered devices in these settings are generally about 25–35% below hospitals [40]. There is a lower level of enforcement in these independent facilities

as well, and the consequences of not complying are perceived to be less. Within the hospital environment, the surgical setting is least likely to adopt safety-engineered devices, such as blunt suture needles and shielded scalpel blades. Surgeons and anesthesiologists generally have been resistant to new safety equipment. In 2007, however, the American College of Surgeons issued a "Statement on Sharps Safety" that recommended, among other practices, the use of blunt-tip suture needles and devices with engineered sharps injury-prevention features [46]. It remains to be seen whether the ACS recommendation will have an impact.

The cost of safety technology is an issue in every country, rich or poor. In the U.S., healthcare employers cannot use cost arguments to justify continued use of conventional needles and sharp devices. They may, however, use cost as one criterion among others in choosing between different safety-engineered alternatives.

The legislation passed in the U.S. created a large and permanent market for safety-engineered devices. Major device manufacturers around the world are producing safety-engineered sharp devices as a result of the demand created by the U.S. market. The initial costs for developing this new technology have been borne largely by the U.S. market. Manufacturing efficiencies have been achieved and the cost of safety devices continues to decline; new and more cost-effective products are being designed as the market for safety devices expands globally. The greatest cost efficiencies will be achieved when safety-engineered devices become the standard in every country. It is a goal worth pursuing.

Conflict of interest statement

Funding: No funding sources.

Competing interests: None declared.

Ethical approval: Not required.

Acknowledgements

The authors wish to acknowledge and thank the hospitals that contribute data to the U.S. EPINet Sharps Injury Surveillance Network. These hospitals voluntarily participate in a research network coordinated by the International Healthcare Worker Safety Center at the University of Virginia. A list of the participating hospitals can be found on the Center's website, at: <http://healthsystem.virginia>.

[edu/internet/epinet/EPINetHospitalList.cfm](http://www.cdc.gov/od/ohrt/epinet/EPINetHospitalList.cfm). E.P. is supported by a grant from the National Institute for Occupational Safety and Health/CDC (award #: 1 K01 OH009140-01A1).

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