

Accidental needle stick prevention: an important, costly, unsafe policy revisited

The article by Wolf et al¹ in this issue of the *Annals* addresses important mediceconomic and disease transmission and safety issues. Because of the number of injections administered at an allergy practice, sharp object containers are usually kept within immediate reach of the employee giving shots. Activating a needle guard mechanism after giving the injection adds an additional action, thereby potentially increasing the opportunity for accidental needle sticks (ANSs).

In 1984, the first case of needle stick-transmitted human immunodeficiency virus (HIV) was reported.² In 1986, the Occupational Safety and Health Administration (OSHA) was petitioned by various unions representing health care employees to develop a standard that protects employees from occupational exposure to bloodborne diseases.³ The US Congress subsequently passed the Needlestick Safety and Prevention Act. This act, which passed on January 18, 2001, and became effective on April 18, 2001, directed OSHA to revise the bloodborne pathogens standard.⁴ This revision specifies that "safer medical devices, such as sharps with engineered sharps injury protections and needle-less systems" constitute "an effective" engineering control and must be used where feasible.⁵ There was no definition of "effective" or "safer" or the need to validate before use.

The Centers for Disease Control and Prevention estimate that 600,000 percutaneous injuries occur annually.⁶ The most significant bloodborne pathogens in needle stick injuries are HIV, hepatitis virus B, and hepatitis virus C.⁷ Certainly, there are other potential bloodborne pathogens, such as malaria, syphilis, and leptospirosis, that should be considered.⁵ It is estimated that health care workers exposed to hepatitis C virus through a needle stick or other percutaneous device have a serologic conversion rate of 1.8% (range, 0%–7%) per injury.⁸ HIV transmission appears to be greater when there is exposure to a larger quantity of blood as indicated by a visibly bloody device, a procedure that involves placing a needle in a vein, or a deep injury.⁹ Database review has shown that only a few types of needles and other sharp object devices are associated with most injuries.^{10,11} The greatest percentages of needle sticks occurred with hypodermic needles (29%) and winged-steel needles.^{10,12} The true incidence of needle sticks in an office setting is unknown, because most data are hospital reported.^{5,13}

In an excellent review, Porta et al¹³ cited 16 articles on needle stick issues. These needle sticks were not specific to small-gauge needles used in intradermal (ID) injections or

subcutaneous allergy extract administration.^{5,13} Theoretically, injecting with a small-bore needle subcutaneously or intradermally should create a relatively bloodless field, because the volume of blood conveyed from a 20-gauge needle is 30 times greater than the amount from a 27-gauge needle.¹² OSHA workplace standards have many requirements, including an exposure control plan and engineering work practice controls.^{14,15} The latter specifically addresses proximity of sharp object containers, handling of contaminated needles and other contaminated sharp objects, and notes that bending, recapping, or breaking of needles is prohibited.⁵ In the event of an injury with potential for transmission of a bloodborne pathogen, the employer is required to implement an immediate evaluation of the occurrence.

Since 1984 more than 1,000 patents have been issued for devices designed to theoretically prevent ANSs. Concern has been raised about sufficient data to determine the effectiveness of a protective device.¹⁶ The specific incidence of needle sticks in office-based allergy practices is unknown; however, it is estimated that 270 million allergy injections (both allergy injection treatment [AIT] and ID testing) are given annually.⁵

In their article in this issue of the *Annals*, Wolf et al write, "In compliance, our practice switched to using safety needles (for subcutaneous shots) as mandated by OSHA and in response to a final recommendation by the JCAAI [Joint Council of Allergy, Asthma, and Immunology] in December 2003." They had an increased ANS rate within 3 months, and employees were reluctant to use the new needles. Wolf et al then raise an important issue: are the new (new technology safety-engineered device) syringes really safer? They then decided to conduct a national survey to answer this question. The survey asked if allergy practices had switched to the new syringes when performing skin testing and/or administering allergy injections.

In their study, Wolf et al analyzed 1.54 million AITs given with the traditional needle and found an incidence of 17 ANSs or a rate of 0.00178%. The data with the new syringe was 0.807 million AITs with 32 ANSs or a rate of 0.00396%. Both the Terumo SurGuard and BD Safety Glide new syringes were used, and approximately 50% of the new syringes were safety actuated after use. Similarly with ID testing, 1.08 million tests were performed, with 23 ANSs or a rate of 0.00212% using the traditional syringe. The new syringe performed 293,508 ID tests with 11 ANSs or a rate of 0.00374% or almost double the rate of ANSs.

In a retrospective survey that included 7.026 million 26- or 27-gauge needles, of which 4.93 million were used for AITs and 2.229 million for ID tests, Kanter and Siegel⁵ found a total of 45 ANSs and no disease transmission for an ANS rate of 0.00064%. It was similarly noted that there was an increase in ANSs in 3 large practices that switched from the traditional to the new syringe.⁵ One could logically combine the data from Kanter and Siegel with the data from Wolf et al, because they are both survey derived. This would total 7.64 million for the traditional syringe and a combined number of ANSs of 95 or a rate of 0.000985%. Similarly, combined data with the new syringe shows 1.138 million uses with 50 ANSs or a rate of 0.00439%. Both data sets show similar results. Review of this combined data shows that although the ANS rate in the study by Wolf et al was somewhat higher, the data are consistent with one another, which validates both data sets.

Data are limited regarding the efficacy of the new syringe and extremely limited in the outpatient setting. In 1995, Ornstein et al¹⁷ performed a prospective hospital-based study that showed a reduction in ANSs from 33 to 14 during the 6-month study period with the new syringe. Nursing staff members who were using hollow-bore needles and manipulating intravenous lines accounted for the greatest number of needle stick injuries in the preintervention period. Needle-stick injury rates associated with intravenous line manipulation, procedures with 3-mL syringes, and sharp object disposal were reduced by 50%; however, reductions in these subcategories were not statistically significant. No seroconversion to HIV-1 or hepatitis B virus occurred among those with needle stick injuries. The direct cost for each needle stick evaluated is \$789. The authors concluded that despite an overall reduction in needle stick injury rates, no statistically significant reductions could be directly attributed to the protective devices. In 1996, Mulherin et al¹⁸ prospectively evaluated a new syringe at the University of California San Diego Medical Center. Only 59.5% of 390 syringes were activated, and user acceptance and satisfaction were unfavorable. They concluded that development of safety devices should preferably incorporate passive activation and consider end-user satisfaction. In 1992, Younger et al¹⁹ evaluated a new 3-mL syringe on ANSs in 3 medical centers. The total number of needle sticks from all sources increased from 134 during the baseline period to 140 during the study phase. However, the overall rate of needle sticks that involved 3-mL syringes decreased from 14 per 100,000 inventory units to 2 per 100,000, and the frequency declined substantially at each of the participating medical centers. It was concluded that the results are encouraging, but more clinical experience with this new device and longer follow-up are essential to provide the data necessary for a definitive evaluation of efficacy.

There is no doubt that OSHA's implementation of universal precautions in 1992 has greatly reduced health care workers' exposure to bloodborne pathogens. However, in the outpatient setting, no such data exist. In contrast, Kanter and Siegel⁵ showed that approximately a 2-fold increase in ANSs was reported when safety needles were used to give allergy

injections in allergy offices. Most (83%) of the offices had instructed their employees in the use of the safety needles, so failure to educate is an unlikely explanation for the higher reported rate of ANSs. The employer is required to have a written exposure plan and evidence that "frontline" employees were involved in its creation. The employer may be asked to show evidence of training in the use of safety devices and to show how employee compliance is monitored. This suggests that employees may not individually choose between safety devices or conventional devices and that the employer has a duty to promote the use of new needles.

The paradox exists that new syringes with small bores (26 or 27 gauge) used in the outpatient setting for giving AITs and ID tests may in fact be less safe than the traditional syringe. The surveys by both Wolf et al and Kanter and Siegel showed that traditional syringes were safer for subcutaneous injections in the allergy setting. This finding is contrary to the OSHA guidelines and regulations. A plausible explanation for this discrepancy is that the extra step required to secure the needle adds another potential error for the user. On the other hand, there was no apparent safety difference between new safety and traditional syringes when it came to ID testing. Wolf et al conclude, "Intention to avoid injury in the workplace is a noble goal, but to accept the inertia of guidelines without corroborating evidence may ultimately do more harm than good. Just as clinicians' feet are held to the fire to practice evidence-based medicine, the government should also be responsible to show favorable outcomes as a result of imposed guidelines."

In the late 17th century, Sir Isaac Newton promoted the use of the scientific method as fundamental to the investigation and acquisition of new knowledge based on physical evidence. Scientists use observations, hypotheses, and logic to propose explanations for natural phenomena in the form of theories. Predictions from these theories that can be reproducibly tested by experiment are the basis for developing new technology. It is apparent that the hypothesis that the new syringes would provide greater safety than the traditional syringes has only been tested in hospital settings and not evaluated in the office setting. Similarly, no differentiation of large-bore from small-bore needle ANSs has been undertaken, even though data support that there are differences in probable disease transmission with an ANS.¹²

I believe that outpatient practices should be exempt from mandatory use of the new small-bore safety syringes when administering ID tests or AITs until a prospective trial suggests that one of the multiple available new syringes is truly safer in this setting. Wolf et al conclude, "A little more than half of the allergists surveyed have switched to safety needles when giving allergy shots. Half of the users do not cap the needles, so essentially only one fourth of allergists surveyed are using safety needles according to OSHA guidelines. Based on current OSHA guidelines, most allergy practices are currently at risk of substantial fines but may, in truth, be practicing in a safer environment. Our limited survey findings do not change that fact. We clearly need a multicenter pro-

spective trial to examine the impact of safety needles in outpatient (allergy) practices to further investigate this important issue.”

LEWIS KANTER, MD
USC-LAC Keck School of Medicine
Los Angeles, California

REFERENCES

1. Wolf BL, Marks A, Fahrenholz JM. Accidental needle sticks, the Occupational Safety and Health Administration, and the fallacy of public policy. *Ann Allergy Asthma Immunol.* 2006; 97:52–54.
 2. Needlestick transmissions of HTLV III from a patient infected in Africa. *Lancet.* 1984;2:1376–1377.
 3. Occupational Safety and Health Administration. Revision to OSHA’s blood-borne pathogens standard technical background and summary. Washington DC, April 2001. Available at www.osha-scl.gov/needlesticks/needlefact.html. Accessed November 1, 2005.
 4. Occupational Safety and Health Administration. Occupational exposure to blood borne pathogens; needlesticks and other sharps injuries; finale rule. *Federal Register.* 2001;66:5317.
 5. Kanter LJ, Siegel C. Needle sticks and adverse outcomes in office-based allergy practices; *Ann Allergy Asthma Immunol.* 2003;90:389–392.
 6. Occupational Safety and Health Administration. Revision to She’s Blood-borne Pathogens Standard Technical Background and Summary. Washington, DC, April 2001. Available at: www.osha-scl.gov/needlesticks/needlefact.html. Accessed November 1, 2005.
 7. Association for Professionals in Infection Control and Epidemiology, Inc. APIC position paper: prevention of device mediated blood-borne infections to health care workers. *Am J Infect Control.* 1998;26:578–580.
 8. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. Centers for Disease Control and Prevention. *MMWR Recomm Rep.* 1998;47(RR-19):1–39.
 9. Cardo DM, Culver DH, Ciesielski CA, et al; Centers for Disease Control and Prevention Needlestick Surveillance Group. A case-control study of HIV seroconversion in health care workers after percutaneous exposure. *N Engl J Med.* 1997;337: 1485–1490.
 10. *National Institute for Occupational Safety and Health Alert: Preventing Needlestick Injuries in Health Care Settings.* Rockville, MD: Department of Health and Human Services; 1999. Publication 2000–108.
 11. EPINet. *Exposure Prevention Information Network dta Reports.* Charlottesville: University of Virginia International Health Care Worker Safety Center; 1999.
 12. Shirazian D, Herzlich BC, Mokhtarian F et al. Needlestick injury: blood, mononuclear cells, and acquired immunodeficiency syndrome. *Am J Infect Control.* 1992;20:133–137.
 13. Porta C, Handelman E, McGovern P. Needlestick injuries among health care workers: a literature review. *Am Assoc Occup Health Nurs J.* 1999;47:237–244.
 14. *Federal OSHA Blood-Borne Pathogen Directive: A Resource Primer.* Washington, DC: BD Advanced Protection Technologies; November 1999.
 15. Occupational Safety and Health Administration. Labor regulation (CFR 1910.1030). Washington, DC, Dec 6, 1991.
 16. Jagger J. Reducing occupational exposure to bloodwork pathogens: where do we stand a decade later? *Infect Control Hosp Epidemiol.* 1996;17:573–575.
 17. Orenstein R, Reynolds L, Karabaic M, Markowitz SM, Wong ES. Do protective devices prevent needlestick injuries among health care workers? *Am J Infect Control.* 1995;23:344–351.
 18. Mulherin S, Rickman LS, Jackson MM. Initial worker evaluation of a new safety syringe. *Infect Control Hosp Epidemiol.* 1996;17:593–594.
 19. Younger B, Hunt EH, Robinson C, McLemore C. Impact of a shielded safety syringe on needlestick injuries among healthcare workers. *Infect Control Hosp Epidemiol.* 1992;13:349–353.
-