
Accidental needle sticks, the Occupational Safety and Health Administration, and the fallacy of public policy

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Background: Current Occupational Safety and Health Administration (OSHA) guidelines mandate the use of safety needles when allergy injections are given. Safety needles for intradermal testing remain optional. Whether safety needles reduce the number of accidental needle sticks (ANSs) in the outpatient setting has yet to be proven.

Objective: To determine the rate of ANSs with new (safety) needles vs old needles used in allergy immunotherapy and intradermal testing.

Methods: Allergy practices from 22 states were surveyed by e-mail.

Results: Seventy practices (28%) responded to the survey. Twice as many ANSs occurred in practices giving immunotherapy when using new needles vs old needles ($P < .01$). The rate of ANSs was roughly the same for intradermal testing with new needles vs old needles.

Conclusions: These findings further question whether OSHA's guidelines for safety needle use in outpatient practice need revision and if allergy practices might be excluded from the requirement to use safety needles.

Ann Allergy Asthma Immunol. 2006;97:52–54.

INTRODUCTION

With the advent of the human immunodeficiency virus, awareness of the possibility of transmissible disease from occupational accidental needle sticks (ANSs) was heightened. This led to the implementation of the Bloodborne Pathogen Standard in 1991.¹ This legislation was chiefly aimed at ANSs in hospitals. Then, in November 2000, the Needlestick Safety and Prevention Act was passed into law.² This act expanded the definition of “engineering control” to include mechanisms with sharp object injury protection and needleless systems. In addition, health care professionals were required to involve workers exposed to sharp objects in the development of an exposure plan and maintain a sharp object injury log of percutaneous injury information. In April 2001, the Occupational Health and Safety Administration (OSHA) revised its Bloodborne Pathogen Standard in accordance with this act. Since most hospitals were already using sharp object safety devices when the revised OSHA standard went into effect, many physicians were left uncertain about the law's applicability to an office setting.

Allergy practices were especially reluctant to incorporate safety needles into their practices. Aside from the additional cost of the safety syringes, it seemed intuitively obvious that safety needles might increase the employee's risk of injury, because such devices increase the employee's contact with the needle before the needle's disposal. Because of the number of injections administered by an allergy practice, sharp object containers are usually kept within immediate reach of the employee giving shots. Having to activate a needle guard

mechanism after giving the injection adds another action, thereby potentially increasing the opportunity for ANSs.

The Joint Council of Allergy, Asthma, and Immunology (JCAAI) asked to be exempted from the new legislation but met with resistance from OSHA. Then, in June 2002, the JCAAI published a memo stating that practices “**MUST** shift to the newly engineered safety syringe/needle combinations unless using a safer medical device compromises either patient safety or medical integrity.”

In 2003, the JCAAI clarified that OSHA's rule mandated that safety needles be used for immunotherapy injections. For intradermal testing, however, individual practices could opt to continue use of old needles if, after testing and documentation, safety engineered needles were thought to be less safe.³ The American Academy of Pediatrics asked that an exception be made for ambulatory settings where childhood vaccines were given, but this exception was summarily rejected by OSHA.

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 in December 2003. Within 2 months, 3 of our employees experienced self-inflicted ANSs. One of the employees had worked for 15 years without a previous needlestick. Subsequently, that employee refused to continue using the safety needles. We, as employers, were hesitant to potentially endanger our employees with needles that might be less safe.

This experience motivated us to reexamine our choice of safety needles. We conducted a nationwide survey to determine the rate of ANSs with new (safety) needles vs old needles used in allergy immunotherapy and intradermal testing. Previously, a retrospective survey of ANSs, in most allergy practices in California and in 3 large practices across the country, had shown a much lower rate of ANSs in allergy

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Received for publication October 7, 2005.

Accepted for publication in revised form October 17, 2005.

practices vs general medical practice. Further, in the 3 large allergy practices, there was a 10- to 100-fold increase in ANSs during trials with safety needles.⁴

METHODS

In summer 2004, a 15-question survey was sent via e-mail to allergists from 22 randomly chosen states: Alabama, Arizona, Colorado, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, and Virginia. Two hundred fifty-two surveys were sent to active e-mail addresses. Three weeks later, the survey was resent to nonresponders.

The survey asked if allergy practices had switched to safety needles when performing intradermal skin testing and/or administering allergy injections. Response to the survey determined how many intradermal tests and injections were performed in a given month and how many ANSs resulted per year. Respondents were able to write in numbers when answering questions, eliciting some range of response (eg, 1 to 2). The offices were also asked which safety device they preferred, if formal training on how to use the new needles was offered, and their opinion of whether the new needles were safer.

RESULTS

Seventy practices (28%) responded to the survey. A total of 29% of responding allergists had switched to using safety needles for intradermal testing; 59% had switched to safety needles when giving allergy injections. Of those using safety needles for allergy injections, 57% reported using BD Safety Glide needles (Becton, Dickinson and Company, Franklin Lakes, NJ) and 29% used Terumo SurGuard needles (Terumo Medical Corporation, Elkton, MD). Roughly, only 50% cap the safety needles before disposing of them. Of responders, 34 (83%) of 41 reported that their staff had undergone specific training on the use of the new safety syringes.

The total combined number of all allergy injections given by practices with old needles was 128,376 per month, accounting for 1.54 million allergy shots in a year. The total number of ANSs from using old needles to give allergy shots was 27.5 or an incidence rate of 0.00178%. The total combined number of all allergy injections given by practices with the new needles was 67,272 per month, accounting for 807,000 shots per year. The total number of ANSs from using new safety needles was 32 or an incidence rate of 0.00396%. In regard to intradermal testing, old needles accounted for 1.08 million tests per year with subsequently 23 ANSs (0.00212% of the time).

New needles performed 293,508 tests, leading to 11 ANSs or a corresponding rate of 0.00374% (Table 1).

The ANS rates specifically for practices that had switched to safety needles were tabulated. The ANS rates with safety needles used for allergy injections was 0.00374% vs 0.00317% with the old needles. Likewise, ANS rates for intradermal testing were 0.00397% with safety needles and 0.00211% with the old needles (Table 2).

When the practices were asked if they deemed the new syringes to be more or less safe than the older syringes, only 9% of the responders thought they offered more safety. Twenty-nine (48%) of the 60 who answered the question thought the new needles were less safe (Table 3).

Using a simple *t* test, no statistical difference was found comparing ANSs in intradermal testing with the group as a whole or in those practices that switched needles. Statistical significance was seen in the group as a whole when comparing ANSs during the administration of allergy shots with old vs safety needles ($P < .01$). Statistical significance was also seen comparing ANSs during administration of allergy shots with old vs safety needles in the practices that had switched ($P < .05$).

DISCUSSION

There is no doubt that OSHA's implementation of universal precautions in 1992 has greatly reduced health care workers' exposure to bloodborne pathogens. Two prospective studies have also reported fewer ANSs in the hospital setting after implementation of safety needles at an estimated cost of \$789 per ANS prevented.^{5,6} However, in the outpatient setting, no such data exist. In contrast, we found approximately a 2-fold increase in ANSs reported when safety needles were used to give allergy injections in allergy offices. Most of the offices (83%) had instructed their employees in use of the safety needles, so failure to educate is an unlikely explanation for the higher reported rate of ANSs. Our use of a retrospective e-mail survey may be questioned; however, there appears to be no intrinsic bias in how the information was solicited or how the results were obtained. Kanter and Siegel⁴ have also reported in a survey of allergy practices the possibility of increased ANSs with the use of safety needles.

Since the Needlestick Safety and Prevention Act became effective, OSHA has issued an increasing number of citations for violations of the law. A citation issued to a Pennsylvania nursing home led to a maximum \$70,000 fine for failing to use safety devices. This was the first citation issued for failing to use safety devices and was a maximum penalty because the violation was deemed to be willful (ie, "commit-

Table 1. Accidental Needle Stick Rates for All Practices Surveyed*

	No. of injections per year	No. of needle sticks	Rate of needle sticks, %
Intradermal, old needle	1.08 million	23	0.00212
Intradermal, safety needle	293,508	11	0.00374
Allergy injury, old needle	1.54 million	27.5	0.00178
Allergy injury, safety needle	806,784	32	0.00396

* Intradermal, old vs safety needle: $P > .05$. Allergy injection, old vs safety needle: $P < .01$.

Table 2. Accidental Needle Stick Rates for Those Practices That Switched to Safety Needles*

	No. of injections per year	No. of needle sticks	Rate of needle sticks, %
Intradermal, old needle	535,776	17	0.00317
Intradermal, safety needle	293,508	11	0.00374
Allergy injury, old needle	935,988	19.75	0.00211
Allergy injury, safety needle	806,784	32	0.00396

* Intradermal, old vs safety needle: $P > .05$. Allergy injection, old vs safety needle: $P < .05$.

Table 3. Survey Responses Regarding the Safety of the New Syringes

Response	No. (%) of respondents (N = 70)
More safe	6 (9)
Just as safe	25 (36)
Less safe	29 (41)
Unknown	10 (14)

ted with an intentional disregard of, or plain indifference to, the requirements of the Occupational Safety and Health Act"). OSHA's issuance of citations for failure to have safety needle devices in use demonstrates how OSHA requires that the employer is responsible for more than just keeping a box of safety needles in a cabinet somewhere on the premises. 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 using safety devices or conventional devices and that the employer has a duty to promote employee compliance in using safety devices.

The matter of safety needle use creates an interesting dilemma for the office practice. In response to increased needle handling, an employee may wish to elect not to use the safety needles or to use the safety needles without actuating the safety mechanism. What should the employer do in this situation? Would the employer be subject to citation by OSHA for providing safety needles but allowing an employee to voluntarily choose not to use them?

The paradox exists that small bore (26- or 27-gauge) safety needles used in the outpatient setting for giving allergy shots and performing intradermal testing may, in truth, not be safer at all. Our survey revealed that old syringes were safer for subcutaneous injections, contrary to OSHA's dictum. A plausible explanation for this discrepancy is that the extra step required to secure the needle interjects another (mis)step for the user. On the other hand, no apparent safety difference exists between safety and nonsafety engineered syringes when it comes to intradermal testing. The lack of demonstrable difference in ANSs might be attributable to a more "controlled environment" and stationary aspect of the user in intradermal testing.

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 for showing favorable outcomes as a result of imposed guidelines. We believe that outpatient practices should be exempt from mandatory use of small-bore safety needles when administering intradermal testing or allergy injections until a prospective trial suggests that one of the multiple available safety needles is truly safer.

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 prospective trial to examine the impact of safety needles in outpatient (allergy) practices to further investigate this important issue.⁷

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