On the bleeding edge

Advances in technology, concerns about safety, and newly enacted legislation are thrusting blood collection procedures, and those who perform them, into a white-hot spotlight.

By Dennis J. Ernst MT(ASCP)

Nearly every aspect of blood collection is making progress, if not headlines, as the healthcare industry focuses on blood collection procedures and those who perform them. Current hot topics include safety needles, conversions to plastic tubes, the order of draw, phlebotomy certification, tube holder reuse, and phlebotomy-related lawsuits.

Safety

Perhaps the most revolutionary development in the history of blood collection since disposable needles was the anxiously anticipated signing of the Needlestick Safety and Prevention Act in 1999. This measure mandated those employers who are subject to the provisions of the Bloodborne Pathogens Standard to put safer needles into the hands of those who collect blood specimens. The act not only changed forever the way blood collection procedures are performed, but impacted nearly every facet of blood specimen collection in the United States.

Phlebotomists

Because safer needles require one or more additional steps to activate a safety feature (there are currently no passive sharps for blood collection by venipuncture), those who draw blood specimens must adapt to new equipment — no small task for the hundreds of thousands of phlebotomists and blood collectors from other healthcare professions who have grown comfortable with a technique standardized to conventional syringes and tube holders for more than 30 years. Even though the General Accounting Office estimates the legislation will prevent up to 69,000 accidental needlesticks annually, change — for better or worse — invariably meets with resistance.¹ ²

Laboratory managers

Some employers were ahead of the curve when the legislation took effect and had implemented the safeguards in their facilities while they could afford the luxury of selecting and implementing on their own timetable. When the act became effective on April 18, 2001, however, most had 90 days to orchestrate the necessary steps to become compliant: organizing committees, selecting the products to be evaluated, evaluating the products, collating the results, selecting the safety device(s), and implementing them facilitywide. Not much time considering the magnitude of the task. Managers who were not proactive to the legislation were hard-pressed to comply before enforcement began, and many are still mired in the process.
Manufacturers

Anticipating the demand that legislation promised to bear upon the market, manufacturers have been gearing up for years. The U.S. Patent and Trademark Office issued more than 1,000 patents for safety products in the last 10 years.\(^3\) The scramble to satisfy the mandated hunger for safer systems has only intensified since the legislation has become effective. With conventional needles on their way out, the playing field for the blood collection supply market has leveled, allowing innovative designs and companies to emerge and compete for dominance of an entirely new market on an even footing with those who have dominated the conventional needle market.

Currently, at least 11 companies offer safety products in four categories for facilities to evaluate: modified tube holders, modified needles, winged infusion sets, and skin puncture devices (see page 13). Many others provide products that facilitate needle concealment, incineration or disposal. But of all the types of blood collection supplies, no category has seen more new products in the last 12 months than that of winged-infusion (butterfly) sets. Long awaiting safety modification, winged infusion sets have been associated with an inordinately high rate of accidental needlesticks — 18 percent of all those incurred by healthcare workers and 32 percent of those sustained by phlebotomists.\(^4,5\) Shunned by the safety- and cost-conscious, the device, nevertheless, continues to be preferred by many for its maneuverability and for use on small and fragile veins.

Plastic tubes

Concern over exposure has spread to non-needle injuries as well. Since broken glass injuries have resulted in documented cases of HIV infection, facilities nationwide are looking hard at converting from glass collection tubes to plastic.\(^6\) Besides the obvious benefits of reducing broken-glass exposures, managers are further enticed by the reduction in the cost of disposing of plastic specimen tubes over their glass counterparts.

Plastic tubes and the order of draw

The industry-wide conversion from glass to plastic tubes, however, is forcing the reconsideration of one of the most basic principles of blood specimen collection: the order of draw. Often referred to as “phlebotomy’s best-kept secret,” the order of draw has its origins in the literature as far back as 1977 when additive carryover from one tube to the next was observed independently at two hospitals, St. Barnabas Medical Center in Livingston, N.J. and Hillcrest Medical Center in Tulsa, OK.\(^7\) Subsequent observations of similar spurious results related to the order in which tubes are filled led the National Committee for Clinical Laboratory Standards (NCCLS) to institute an order of draw designed to prevent erroneous results due to additive carryover in their standard, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, published in 1991.\(^8\) In that document, the standards organization established two distinct orders of draw: one for syringes and one for vacuum-assisted draws. However, the separate order for syringes was repealed when NCCLS revised the standard in 1998 due to the lack of supportive evidence that syringes required a separate order. According to the 1998 standard, the most current, NCCLS recommends the following order:

Continues on page 12
First: Sterile tubes for cultures.
Second: Nonadditive tube.
Third: Sodium citrate tube.
Fourth: Gel separator tube.
Fifth: Heparin tube.
Sixth: EDTA tube.
Seventh: Oxalate-fluoride tube.

With so many facilities now converting from glass to plastic tubes, those who draw blood specimens must now consider the composition of the tube they are using. Since plastic does not activate clotting like glass does, plastic tubes for serum testing, e.g., red-stoppered tubes, must contain a clot activator. The problem arises when drawing plastic red-stoppered tubes (which contain a clot activator) in the same place in the order of draw as red-stoppered tubes made of glass (without an additive). During tube exchange, if even minute amounts of the blood/clot activator mixture carries over into the next tube, which according to the current order of draw is the sodium citrate tube (blue top) for coagulation testing, the clot activator can alter the results and lead a physician to adjust the patient's anticoagulant therapy based on erroneous results.

Therefore, it stands to reason that facilities using plastic tubes should draw the red-stoppered tubes with the clot activator after the blue top if coagulation studies are also being drawn. If no blue top is drawn, the plastic red top can precede a heparin (green top) or EDTA (lavender top) tube without concern for carryover. (The current thinking is that any carryover of the clot activator into tubes other than blue tops is irrelevant since the minute amount of clot activator will be consumed by the excess heparin or EDTA and will not compromise their ability to anticoagulate the specimen.)

**Tube holder reuse**

One of the more controversial issues affecting the blood collection industry is the reuse of tube holders. This practice has come under increased scrutiny over the last several years for two reasons: contamination and safety. Studies show that a high percentage of tube holders are contaminated with blood even after one use. Some facilities are reacting to these concerns by soaking their used tube holders in a dilute bleach solution daily instead of the costly practice of discarding them after each use. However, the Occupational Safety and Health Administration (OSHA) is sending strong signals that it is becoming increasingly intolerant of removing needles and, therefore, reusing tube holders for safety reasons.

Through compliance directive, inspectors are reminded that needle removal is prohibited unless employers can meet both of two conditions: 1) that needle removal is required for the procedure or that no feasible alternative is available and 2) that needle removal is performed by some method other than two-handed recapping.
As if to underscore the difficulty in justifying needle removal from tube holders, the latest directive, issued in January 2002, includes the following statement: “The practice of removing the needle from a used blood-drawing/phlebotomy device is rarely, if ever, required by a medical procedure. Because such devices involve the use of a double-ended needle, such removal clearly exposes employees to additional risk.”

With this statement, OSHA clearly challenges employers to prove that no alternative is feasible. Employers that make this claim are required to back up such a policy with written justification supported by reliable evidence, a caveat many consider impossible to satisfy.

Another change in the language of the new directive, however, could easily be interpreted as OSHA’s long awaited ban on needle removal and, hence, tube holder reuse. The prior directive, issued in 1999, stated “Needles are expected to be used and immediately discarded.” However, the new directive states “Devices with needles must be used and immediately discarded after activation of the safety feature.” Industry watchers see this change in the language from “needles” to “devices with needles” as significant step toward banning tube-holder reuse completely.

This firmer stance calls into question the legitimate use of an entire class of modified tube holders — those that employ a...
release mechanism to allow the operator to drop the contaminated needle into a nearby sharps container one-handedly — and automatic unthreading devices built into sharps containers. Since releasing the needle through these mechanical means constitutes removing the needle, laboratory managers who want to continue using them will have their work cut out to justify the practice in their exposure control plan.

**Certification**

No single act subjected phlebotomists to more scrutiny than that of the California phlebotomist who was caught rinsing and reusing contaminated butterfly needles on multiple patients. An unconceivable act that appalled the phlebotomy community on every level, the incident became the flashpoint for California to enact legislation mandating certification of all phlebotomists. Two other states also have certification legislation on the books, although their measures are less sweeping than California’s. Louisiana requires certification for phlebotomists unless they are under the direct supervision of a physician or employed by a licensed clinical laboratory; Nevada mandates that all laboratory assistants obtain phlebotomy certification.

Although New York and Florida legislatures are considering certification measures, the lack of initiatives in other states suggests that the California incident is being considered an isolated one that couldn’t happen elsewhere.14

The OSHA directive refers to a federal program change to which state adoption is not required. “A dangerous complacency,” says Sheila Clover BS CPT(ASCP)(NCA)(NPA), executive director of Phlebotomy West, a phlebotomy advocacy group that lobbies for the profession. “With the growing regulatory focus on safety and error reduction in the lab and in healthcare generally, interest in phlebotomy certification is likely to grow,” he says.

**References**


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This test was prepared by Jeanne M. Isabel, M.S.Ed., CLSpH(NCA), MT(ASCP), associate professor, School of Allied Health Professions, Northern Illinois University, DeKalb, IL.

1. **The Needlestick Safety and Prevention Act was signed in the year 2000.**
   - True
   - False
2. **Over the past 10 years, issued patents for safety products have exceeded:**
   - a. 50
   - b. 100
   - c. 500
   - d. 1,000

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CE test on PHLEBOTOMY: ON THE BLEEDING EDGE
3. The most numerous type of safety products offered by manufacturers are:
   a. modified tube holders
   b. modified blood collection needles
   c. winged infusion sets
   d. skin puncture devices
4. Phlebotomy products available for needles include devices that facilitate concealment, incineration, and disposal.
   True
   False
5. The phlebotomy product most associated with a high rate of accidental needlesticks is:
   a. tube holders
   b. skin puncture devices
   c. winged infusion sets
   d. none of the above
6. Broken glass injuries resulting in cases of HIV infection are influencing facilities to convert to plastic tubes.
   True
   False
7. Concerns relating to the order of draw for vacuum tubes developed from:
   a. additive carryover
   b. hemolysis
   c. vacuum
   d. none of the above
8. The standard for order of draw of tubes was instituted by:
   a. ASCLS
   b. NAACLS
   c. NCCLS
   d. FDA
9. If multiple vacuum tubes are to be filled at the time of venipuncture, the current standard recommended order of draw should be:
   a. nonadditive, sodium citrate, gel separator, EDTA
   b. nonadditive, EDTA, gel separator, sodium citrate
   c. EDTA, sodium citrate, gel separator, nonadditive
   d. sodium citrate, gel separator, EDTA, nonadditive
10. Glass tubes do not activate clotting and must contain a clot activator.
    True
    False
11. Carryover of clot activator to which tube may alter coagulation testing results?
    a. EDTA
    b. Sodium citrate
    c. Heparin
    d. Sodium oxalate
12. When using multiple plastic tubes in venipuncture, the order of draw should include drawing tubes with clot activator before the sodium citrate tube.
    True
    False
13. OSHA has issued directives that ban reuse of vacutainer tube holders.
    True
    False
    True
    False
15. Eclipse, Puntur Gard, and Saf Point Vac are all examples of:
    a. modified tube holders
    b. modified blood collection needles
    c. winged infusion sets
    d. skin puncture devices

TEST ANSWER FORM
PHLEBOTOMY: ON THE BLEEDING EDGE — April 2002
(This form may be photocopied; it is no longer valid for CEUs after April 30, 2003)

1. TRUE FALSE
2. a. b. c. d.
3. a. b. c. d.
4. TRUE FALSE
5. a. b. c. d.
6. TRUE FALSE
7. a. b. c. d.
8. a. b. c. d.
9. a. b. c. d.
10. TRUE FALSE
11. a. b. c. d.
12. TRUE FALSE
13. TRUE FALSE
14. TRUE FALSE
15. a. b. c. d.

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   Excellent         Good         Fair         Poor
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   Excellent         Good         Fair         Poor
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   a. hospital > 500 beds
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   b. hematology
   c. microbiology
   d. immunology
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