

HealthBeat

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Inherent Dangers of Phlebotomy Needles & Available Solutions

BY LLOYD FISCHER

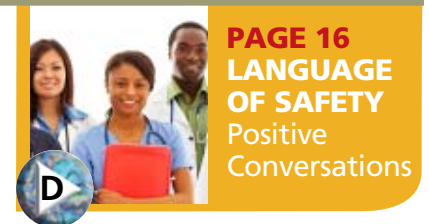
In announcing CDC's National Sharps Injury Action Plan in 2005, the U.S. made an absolute commitment to the American people to jettison dangerous needles by ensuring adoption of the safest needle devices. If Americans cannot experience routine blood collection safely, if this fundamental and elemental procedure of modern medicine cannot be performed reliably, then there is no way to eliminate accidents stemming from engineered yet dangerous needle devices and to reach true safety—the optimum characteristic of a technological society and therefore CDC's target of zero accidents stemming from inadequate safety designs.

Note: This is Part I of a two-part series.

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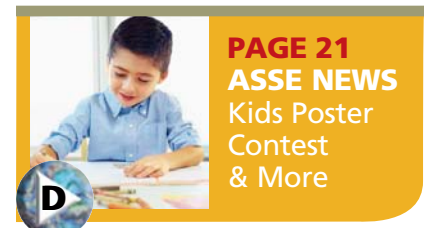
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issues are one of the key factors Congress enacted with the historic safety legislation, the Needlestick Safety and Prevention Act of 2000. Yet, a decade after the legislation became law, Americans continue to suffer hundreds of thousands—if not millions—of accidents annually due to design shortcomings in medical needle devices. By comparison, after a mere few dozen vehicle part failures, automobile manufacturers are swiftly hit with major recalls. Don't people deserve at least the same standard of care in medicine?

This survey explores for the first time the technological issues surrounding the practice of drawing blood using the ubiquitous vacuum-based system, and it documents the U.S. government's policy and interest to solve the dangers designed into phlebotomy needles that are used in the U.S. more than 400 million times annually. The issues are well known to needle manufacturers, but they have not made the information readily available, so this may be the first time that the little-known but potentially life-threatening technical designs have been provided to the general public—to those who come in contact with the needles either as a patient or as someone who uses these dangerous devices in phlebotomy practice.

Phlebotomy needle designs point to our nation's limited success rate in ridding society of dangerously

engineered medical devices (DEMDs). The design issues these tools present are in large part of the reason why we as a nation are having trouble achieving success in mitigating to any respectable degree the suffering and cost of needlestick accidents. The safer blood collection needles produced and made available in other countries and regions of the world serve to demonstrate that manufacturers are disregarding the safety legislation, and as a result, we will continue to experience large numbers of accidents, suffering and enormous hidden healthcare costs associated with their use.

Dr. Russell Bessette is a former chair of the U.S. Department of Homeland Security in science and technology. As a nationally known professor of industrial standards, he served as keynote speaker at the National Standards Institute's Annual Meeting in 2006, and shortly before his address as director of the New York State Technology and Research program, the safety expert recognized the dangers in phlebotomy needles as a serious national health hazard when he approved funding research relative to technological solutions to the design deficiencies of vacuum-based, multiple-sample blood collection technology (Bessette, 2006).

Since the San Francisco Chronicle's investigative article "Epidemic Ravages Caregivers" first exposed the needlestick accident epidemic in 1998, needle companies have improved their safety designs, but the safest needles are not offered in America. American Nurses Association (ANA) surveys and other reports confirm that blood collection needles continue to take a huge toll in both financial cost and suffering. Therefore, the act is focused on improving technology, not procedures. To support intent of the historic federal legislation in providing the safest needles to Americans, CDC created the country's first National Sharps Injury Action Plan (2005) to root out dangerous needle devices and to move the profession toward employing truly safe needles and sharp-related devices.

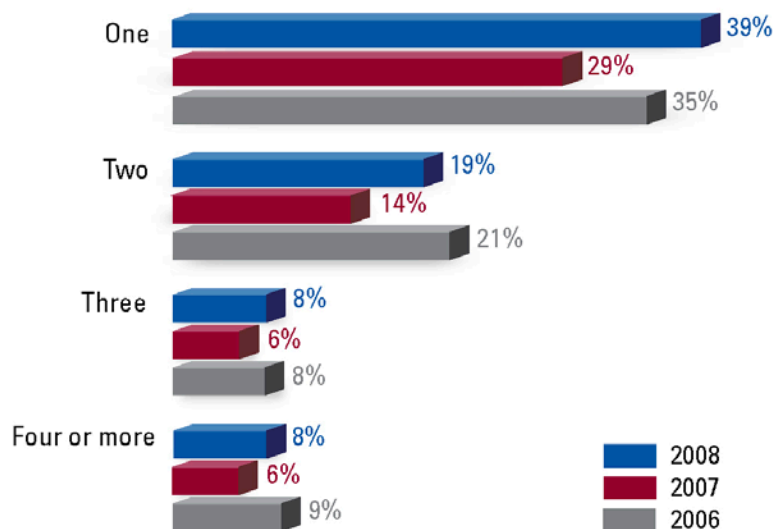
As of 2011, the rate of accidental sticks continues at epidemic levels. This fact prompted ANA to launch yet another campaign: "Safe Needles Save Lives." While the campaign's literature warns of the dangers of poorly designed needle devices, the material does not cover the acute challenges posed by dangerous needle designs. It is interesting to note that ANA's needle safety campaign is sponsored by Becton Dickinson and Company (BD), the world's largest needle manufacturer. With headquarters in New Jersey, BD invented the vacuum-based phlebotomy needle trademarked as the BD Vacutainer System®.

The industry publication, *Infection Control and Hospital Epidemiology*, published a recent study of needlestick injuries, and it concludes that the rate of accidental needlesticks due to technology—not errors in practice—has remained virtually unchanged and that exposure to blood and body fluid through sharps and needlestick injuries is all too common since the

Figure 1

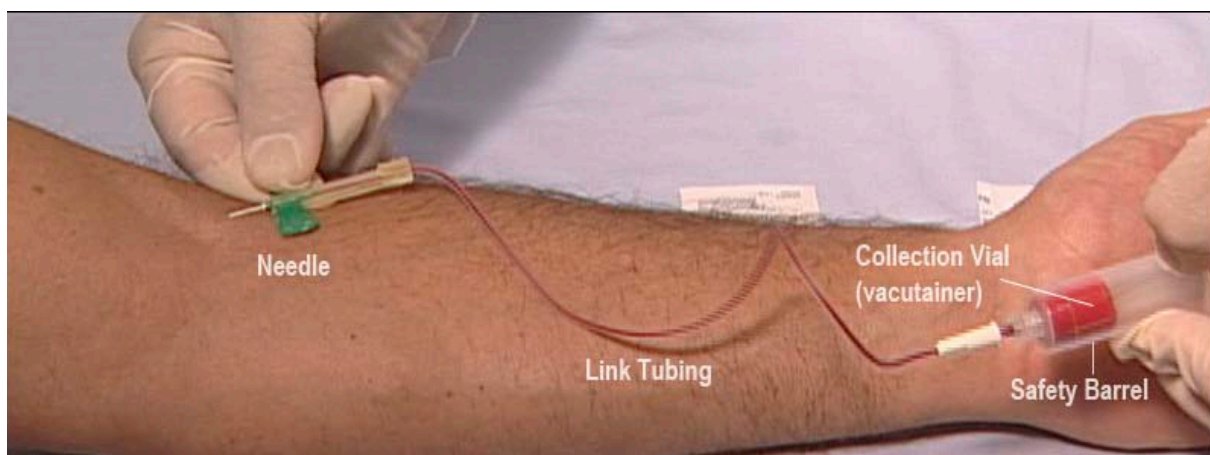
Needlestick Injuries

74% of nurses say they would not consider working for an employer that does not provide safety syringes. Nearly two-thirds (**64%**) report being accidentally stuck by a needle while working, and a staggering **74%** report being stuck by a contaminated needle. Over the course of their career, nurses have experienced contaminated needlesticks:



legislation was enacted. According to Infection Control Today, “A recent study shows that needle-stick injuries actually have increased 6.5%” (see Figure 1; Author, 2011).

ANA’s research concurs with Infection Control and Hospital Epidemiology’s recent report that accidental needlesticks continue to take a heavy toll on healthcare workers. All phlebotomy and syringe injection needles have after-the-draw safety mechanisms that function to blunt, cap, sheath or retract the needle—yet, the crisis continues due to other technological deficiencies, especially in blood collection needles, which do not provide the safety function of vein entry indication (VEI). By contrast, injection syringe and catheter needles provide positive visual verification that the needle is inside the vein (via VEI flashback) prior to complicating the procedure by attempting an injection or by starting an IV drip.



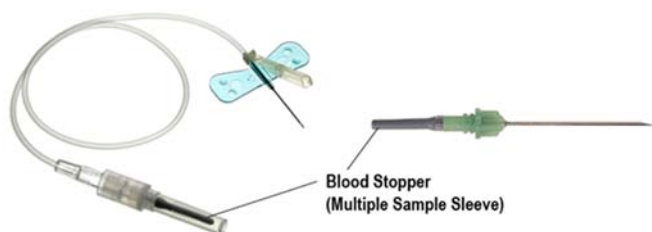
The standard components of the conventional winged set. Note the needle is inserted and the collection vial is attached, so blood is flowing through the link tubing. The rear sharp is not visible—the red collection vial cap is slid over it.

is pulled off the rear sharp, and the plastic sleeve automatically reseals. Vials can be attached and detached from the needle device, but blood does not leak from the rear sharp when the sample vial is removed because the blood stopper is made of elastomeric plastic that automatically closes the hole (that is made by the pressure of being pushed against the sharp it covers). The stopper also works to keep the inside of the metal needle cannula sanitary. A plastic hub holds the needle and guide tube and serves as a surface for the operator to hold with one hand and to control the needle while sample tubes are inserted, filled and removed with the other hand.

The other phlebotomy design used routinely is the winged set (a.k.a., butterfly needle), and the design is based on the IV injection catheter but engineered to work with the same plastic blood stopper that keeps blood from leaking and flowing between draws. The blood stopper is the heart of the vacuum tube-based system, and all multiple-draw blood collection needles in both syringe (a.k.a., straight needle) and winged sets (a.k.a., butterfly needle) use this same plastic part. The butterfly needle has two separate sharps: a front needle that is inserted into the patient and a second needle that is separated from the front needle by transparent link tubing 6 in. to 12 in. in length. The blood stopper is located at the end of the second needle. The front needle is encapsulated by plastic housing that provides a wide butterfly wing-shaped surface that the operator holds to use the needle, thus the name “butterfly needle.”

When the collection vial is pushed into position, the vial’s cap pushes the elastomeric sleeve against the end of the sharp, puncturing and compressing the sleeve. Once the sharp penetrates the cap and reaches the open area of the evacuated vial, blood begins to flow freely. When a suitable amount of blood has been drawn, the sample vial is removed, allowing the elastomeric blood stopper to assume its original shape over the rear sharp and reseal automatically, preventing blood leakage into the environment.

On its face, the blood stopper seemed like a good solution to the problem of preventing blood leakage. But, the fact is that this one tiny piece of plastic (that costs only 1/8 of a penny) is responsible for much suffering.



THE VACUUM-BASED PHLEBOTOMY SYSTEM **Phlebotomy Needles: Two Designs That Pose Different, Dangerous Technical Problems**

The blood collection system in both designs is based on a blood stopper that sits over the rear sharp and prevents blood leakage. The design prevents vein entry indication or “flashback.”

In phlebotomy straight needle design, the blood collection vial (a.k.a., sample tube, vacuum tube) is attached to the rear of the needle cannula. The sealed sterilized vial is pushed onto the device’s rear sharp, which is located inside a guide tube (a.k.a., safety barrel), thereby connecting the collection vial to the needle. The pressure required to push the stoppered vial onto the rear sharp must break two seals; first, the vacuum tube’s seal, and second, the seal created by a small plastic sheath (a.k.a., multiple-sample sleeve, blood stopper or cap) that covers the rear sharp. This tiny piece of plastic has been adopted by all phlebotomy manufacturers and is designed to prevent blood from leaking or flowing out of the needle’s rear cannula when the sample tube is attached and removed from the needle device.

When blood has filled the chamber, the sample vial

While it keeps blood from leaking and enables multiple draws, it also blocks flashback—indication that a needle is properly seated inside a vein.

Such flashback indication is a vital safety function found in syringe and hypodermic blood collection needles, and designed into all injection syringes and catheter needles used in the U.S. Without flashback, there is no way to know for certain that the needle is inside a vein when the collection vial is attached and the negative pressure inside begins the suction action. Infants, seniors, obese patients, those with hard-to-find-veins and the operators themselves are at risk of injury if the vial is attached but the needle is not inside a vein.

TECHNOLOGICAL DIFFICULTIES EXPOSED: THE LITTLE-KNOWN DANGERS

It might seem obvious, but danger to both operators and patients is reduced when the operator is certain of correct needle placement before attaching the collection vial to the device assembly. Indeed, according to the safety expert at Premier, Inc., the world's largest provider of needles to hospitals, VEI is a safety function that informs the operator, through flashback, that the needle is inside a vein (Gosnell, 2009).

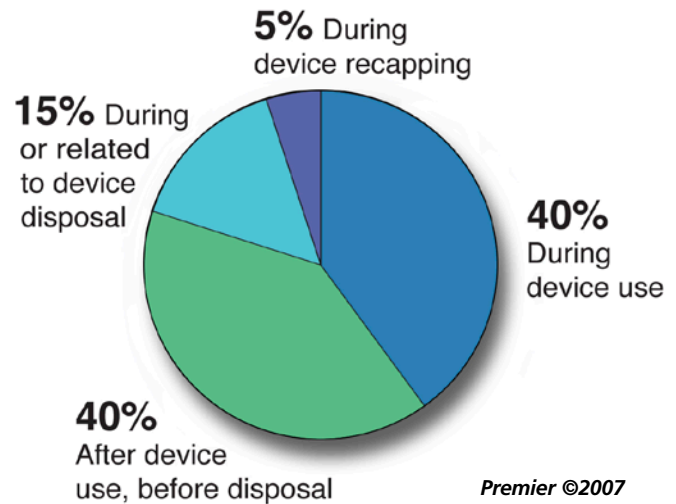
VEI through flashback is an essential safety function designed into injection syringe and catheter needles. The vacuum-based blood collection needle design used in the U.S. (a.k.a., conventional blood collection needle) is not designed to provide this vital indication of correct needle placement. Flashback is a much-used medical term for the “flash” of blood that occurs at the moment a vein has been penetrated (e.g., blood is released from the closed vena system in a “flash”). VEI through flashback is a safety function because flashback designed into an injection syringe, catheter or phlebotomy needle means that a vein can be located before complicating the procedures and endangering people.

Injection, catheter and phlebotomy needles all require placing the needle's tip inside a vein, not muscle or fat tissue, before either injecting medicine, removing the needle to set a catheter or collecting blood. And, certainty of needle placement in the vena system is vital for safety in these three types of procedures.

In routine blood collection procedures, VEI functionality allows the procedure to be accomplished safer than without the function, which can be the cause of serious consequences. Why? With flashback, the sample vial under negative pressure is attached after the operator knows for certain that the needle's tip is inside a vein. Without flashback, the vacuum action begins regardless of needle position and is therefore dangerous.

Consider when the collection vial is attached and no blood flows due to the needle not being inside a vein, the operator begins prodding to locate a vein. Making matters worse, this manipulation of the sharp inside the patient occurs with vacuum action taking place. This is a dangerous practice for the patient because the vacuum

Timing of Needlestick Injuries



action can cause damage and pain to the patient as the evacuated tube draws in through the needle whatever the tip is in contact with—delicate tissues, nerves or veins.

And, it is dangerous practice for the device operator. According to Premier, Inc., a great percentage of needle accidents occur during the probing phase, when the operator is attempting to locate a vein. Each week, thousands are accidentally stuck with a contaminated sharp while the operator attempts to control a phlebotomy device. It is dangerous designs like these that caused a former president of the nation's largest worker amalgamation, the Service Employees International Union, to label these devices “killer needles” (Stern, 1998).

The problems presented by the conventional blood collection system without VEI safety are well-known to needle manufacturers, and several are producing vacuum-based phlebotomy needles designed with the function of vein entry indication. Few if any are used in the U.S., and not one manufacturer provides educational material that instructs on the dangers to both operators and patients from the needles they make available in the U.S. that do not provide VEI. In fact, this report is the first time that the inherent design issues in multiple-sample, vacuum tube-based needles have been made available to the public and the masses of healthcare workers who use these devices (Perry, 2003).

BD owns more than 20 designs invented to provide VEI safety functionality. Apparently, many of these are either unreliable or too costly to put into commerce, but BD has made one available, the BD Flashback Vacutainer® needle that is available in Europe and other regions but not in the U.S.—even though BD has received patent protection for a clip that shields the needle similar to other post-collection safety mechanisms. Other leading needle companies are producing VEI safety designed into their phlebotomy needles. As of this writing, none of these are in use in the U.S. where BD is

the market leader. For more information on these passive safeties phlebotomy needles made available worldwide but not in the U.S., click [here](#).

The vacuum-based system routinely used today requires skill and focus, two factors that are not always available in modern medicine. In the standard straight and winged-set designs of all brands, the collection vial (invented by BD) is inserted into the guide tube with enough pressure to break two seals in order to connect the vial to the needle. One seal is the seal on collection tube, and the second is the seal the blood stopper makes over the rear sharp.

The design requires the operator to accomplish the attachment process without moving the needle's tip while not knowing needle placement. Even a small movement can cause the embedded needle to nick or pierce a vein. When veins are cut, they tend to collapse as the body's defense mechanism kicks in to ward off internal bleeding. Collapsed veins are not suitable for blood collection, so additional sticks are then required. Not only can this be harmful to patients, especially infants, but a second, third or fourth needle stick to locate a vein provides greater chance that the healthcare professional might experience a contaminating event.

Further, vacuum-based needle systems are designed to "draw" as soon as the collection vial's seal is broken by the action of pushing it against the rear sharp. However, should the embedded needle not be inside a vein, the collection vial's vacuum action along with "prodding" to find a vein can result in discomfort or pain, causing the body's involuntary nervous system to pull away from the pain's source. Even when an adult is told to not move, the body's uncontrollable subconscious impulse is to pull away, a reaction that can dislodge an embedded needle. When this occurs, the conscientious operator instinctively grabs for the needle, trying to regain control, and risks getting stuck by a contaminated sharp.

WINGED SET COMPLEXITIES WORK AGAINST PERFORMING PHLEBOTOMY SAFELY

The butterfly design is based on the IV catheter design, and over the past several decades, tens of billions of these needles have been produced with link tubing measuring 6-in. to 12-in. long. The IV catheter was never meant to take fluids from the body as is evident in its patent. This long tubing makes phlebotomy procedures more difficult to perform because many find it difficult to control the front needle, which is separated from the rear assembly where the collection vial is attached.

The winged set's rear assembly consists of a guide tube that surrounds the rear sharp, and both the guide tube and rear needle are attached to a plastic hub, also called an adapter. Link tubing connects the rear sharp assembly to the frontal hub assembly that holds the needle. The collection vial must be pushed by one hand into the guide tube with sufficient force to break the two seals

and without moving the embedded needle while doing so. The pressure required to break the two seals will cause the guide tube/sharp assembly to collapse upon contact unless the second hand, or some other method, keeps the unwieldy apparatus secured.

Manufacturers do not explain how to best accomplish this practice while keeping the embedded needle and also the guide tube steady with only two hands. In actuality, an unavailable third hand is needed to grab hold of a collection vial and then push it on the needle or pull it off the rear of the device that is connected to the long tubing likely resting on the same surface where the patient's limb is stationed. Therefore, because only two hands are available, it is common practice to actually release the embedded needle in order to free a hand necessary to secure and steady the rear apparatus so the vial can be attached. This practice, however, leaves the needle inside the patient but without manual control of the sharp.

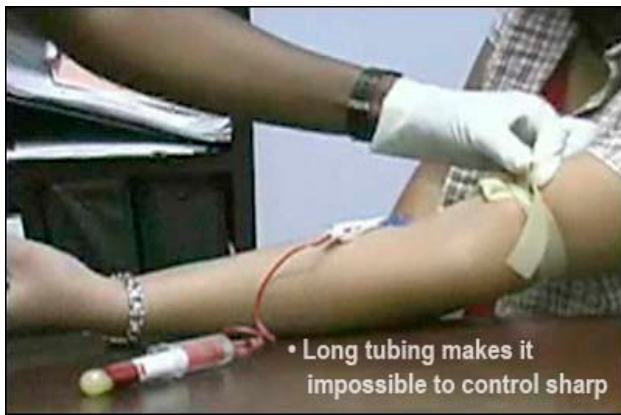
Note: The word "sharp" may be considered a euphemism that should not be allowed to lessen appreciation for its potential as a dangerous and potentially contaminated needle.

Without a second hand to stabilize the rear assembly containing the rear sharp, it is not easy to get the vial properly attached. Doing so safely is impossible because the exposed rear needle must be manipulated into position with one hand that then must lend pressure to support the rear needle assembly while the other hand controls the collection vial; all the while there is no hand controlling the embedded needle. The device is designed for one hand to hold the embedded needle in place and another hand to hold, attach and detach the collection vial. But, without a third hand to steady the guide tube at the end of many inches of link tubing, the action of breaking the two seals and affixing the collection vial to the hub is ripe for error.

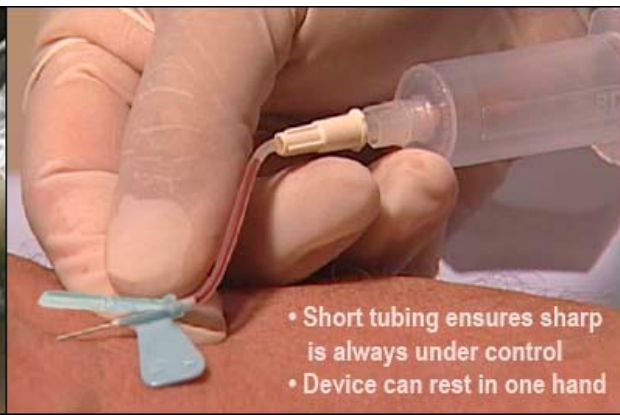
Perhaps, the dangerous design is why there is little if no instruction in any safety journal, school book, demonstration video or product manual that describes how to conduct the procedure without releasing control of the sharp embedded in the patient. Needless to say, releasing control of the sharp to free a hand to support the rear sharp during attachment of the collection tube is an extremely dangerous action to take. Clearly, the butterfly phlebotomy needle design leads users to release control of the sharp and to practice a potentially deadly risk.

What is the reason for the link tubing being 6 in. to 12 in. when a length of 2 in. to 3 in. allows the entire device to rest easily in one hand, freeing the other hand to attach and detach specimen vials without risking being stuck by an uncontrolled contaminated needle?

The head of safety designs at medical device company Smiths Medical says the long tubing provides a cushion, or "bounce," from the unwanted movement that results from pushing the collection vial in place in the rear of the device (Miller, 2011).



• Long tubing makes it impossible to control sharp



• Short tubing ensures sharp is always under control
• Device can rest in one hand

Photos 2 and 3: Long and short butterfly needles

However, 3 in. of tubing will provide the same simple cushion while the needle is held securely in place as the second hand attaches the vial to the rear of the device.

Shorter link tubing enables the collection vial to rest naturally in the cupped palm. Having the device held in the palm is a solution that stops any forward motion that is exerted on the embedded needle as the sample vial is affixed at the opposite end with adequate force to break two seals. With shorter tubing, the needle is manually controlled at all times during the procedure, therein making the practice safe, and following OSHA's safety regulations. Common sense dictates that a device that fits in the palm of the hand and has only a few inches of tubing is less cumbersome than a device with 6 in. to 12 in. of tubing that must be organized and stationed somewhere or otherwise hung in mid-air. Leaving the long tubing hanging is not a sound option as the weight of the tubing and blood inside will pull on the front and rear sharps. Shortening the tubing will also lower material, packaging, shipping and storage costs.

The phlebotomy butterfly needle's 6-in. link tubing makes it difficult, perhaps impossible, to maintain control of the sharp. The caregiver in Photo 2 is shown removing the tourniquet with one hand, while the second hand is handling tape or collection vials. The embedded needle is dangerously not under manual control.

Photo 2 is taken from a manufacturer's product-use instruction video. MYCO Medical's demonstration shows the issues presented by the vacuum-based system applied to winged set designed needles. All brand of phlebotomy butterfly needles have the same technological design, and because of the length of link tubing, the practice requires all (but the most experienced) to release control of the needle to free a hand required to attach the vacuum tube. At any time, a slight movement (cough, laugh, itch, etc.) can dislodge the contaminated sharp. Furthermore, infants cannot be cautioned not to move, as they do not understand or have the ability to comply with language commands.

The butterfly device in Photo 3 has 2 in. of link tubing, and the entire device rests naturally in the same cupped hand that is securely controlling the embedded sharp. The sharp is the focus of control as visible flashback is identified, and then the second hand is free to attach and detach the collection vial(s) safely. The sharp is always

under precise manual control, and the cupped hand provides the back pressure to steady the guide-tube while the collection vial is inserted and removed.

When questioned about the need for 6-in. to 12-in. link tubing,

BD's medical director and chief of Vacutainer® worldwide, Dr. Anna Stankovic, claims the long tubing exists to allow for shallow angle penetration upon percutaneous entry. However, as seen in the photograph comparison, the same angle can be obtained with considerably shorter tubing (Stankovic, 2009).

A few engineers say the link tubing provides the safety function of visual indication, while most company executives shy away from discussing this idea, perhaps for a number of reasons. However, it seems that one reason for hesitancy is that by propounding the safety of VEI early in the phlebotomy procedure, there is admission that the vacuum-based system without visual indication promotes dangerous practice. This would be true for those who have difficulty maneuvering collection vials in and out of the rear assembly without releasing control of the embedded sharp.

Further, safe practice is especially difficult to establish when collecting blood from an infant. In all cases, there is no certainty the infant will not suddenly move and dislodge a contaminated needle that is not under manual control. However, winged sets do not always provide flashback in the link tubing because sometimes the vena pressure lacks the force required for blood to overcome the tubing's air pressure and to travel up the cannula shaft to a point where identification of vein entry is possible. Technology that solves this problem has been invented and is available, but such solutions are not made available to the U.S. population.

Some say that the long link tubing that saddles safety in hospitals and labs is a leftover from the 1970s when food companies made cereal boxes oversize to give the appearance of greater content. The idea is that the long tubing on wing sets requires a larger package, and the size creates a perception the device costs more to manufacture, and therefore, the product commands a higher price. The butterfly is sold at two to three times higher than straight phlebotomy needles (Robinson, 2009).

The cost to manufacture these blood collection needles has not been made public by the needle companies until recently when one major producer disclosed that the cost of manufacturing either a winged set or a straight needle is mere pennies (Robinson, 2009). In terms of cost comparison, the straight needle and

the winged-set are both sterilized and packaged—the straight needle comes in a strong double-capsule airtight plastic container and the butterfly in a larger but paper-thin plastic bag enclosure. The butterfly with its 6-in. to 12-in. link tubing increases shipping and handling costs, but the straight needle uses a bit more metal than the butterfly design because the needle cannula is continuous, whereas the butterfly device has two shorter pieces of metal comprising the front and rear sharps. Both devices have the same sealing mechanism, the blood stopper. But for the narrow plastic tubing and the butterfly's one or two rather ordinary plastic parts (adapters) that do not cost much in mass production, direct material costs for both devices are fairly close. **Note:** The adapter holds the link tubing that, depending on the adapter, can attach to a syringe or a sample vial.

By comparison, pharmaceutical products have huge development costs; testing, insurance, marketing, government compliance. However, needle companies produce billions of needles year after year with virtually no development costs. For example, one company produces 1 billion phlebotomy needles annually, and this is accomplished with only two-dozen employees working less than two 8-hour shifts 5 days a week in a small factory. The large profits for the few companies making blood collection needles might be considered obscene because these devices are vital to medical care.

From a safety perspective, the butterfly's design encourages all but the very experienced to release control of the embedded needle in order to free one hand to support the rear sharp assembly as the other hand pushes and pulls the collection vial on rear of the device. Releasing the embedded sharp violates both OSHA regulations and common sense, which demand that control of an industrial tool (and medical needles are classified as such) should never be relinquished while the device is in operation. Despite the dangers, the practice is indeed widespread and is taught as an acceptable practice by U.S. manufacturers.

A **demonstration video** produced by MYCO Medical graphically illustrates the fact that long link tubing requires that two hands are needed to attach and detach the specimen vial during the collection process. The company's butterfly is designed very similarly to all other winged sets on the market, so the training video illustrates a universal safety problem. MYCO Medical's demonstrated practice—to keep some control of an embedded sharp—is that the operator tapes the link tubing to the patient to help stabilize the embedded needle. Whether followed by tapping practices or not, the design requires one hand to control an unsecured rear assembly while working vials in and out, while the other hand

controls the needle inside the patient.

In actuality, little stabilization appears to result from taping the tubing to the patient. In fact, when the tubing is taped down to the skin's surface in the video, torque is visibly generated along the length of the tubing to the embedded needle. Depending on needle placement, forces like this can eject an embedded needle that has been released from manual control.

As dangerous as it is, the video demonstration is meant to teach how best to operate the winged set phlebotomy needle.

Note: MYCO Medical's winged set is produced by Hindustani Medical Devices (HMD)—the largest needle company in India—whose owner is also the chair of India's medical device manufacturer trade association with close ties to the country's leadership that has developed trade alliances with U.S. government officials. BD's chair sits on a U.S.-Japan Needle Council, the Japanese governing body that oversees the sale of all of the 150 million needles HMD imports from Japan annually, as well as the 350 million phlebotomy needles assemblies purchased by Smiths Medical and Greiner Bio-One, to name a few.

If operator error were the reason for a majority of the accidents that happen year after year, then the historic U.S. safety legislation would be directed to operator practices. But, the Needlestick Safety and Prevention Act is directed to improve technology because all of the studies leading up to the legislation

Shortcomings of the butterfly design—not the inadequacy of safe practice—compel operators to release control of embedded contaminated sharps.

drove home to the U.S. Congress that poorly designed technology was at fault, not nurse practices. In private discussions, company leaders admit that it is the shortcomings of the butterfly design—not the inadequacy of safe practice—that compel operators to release control of embedded contaminated sharps. Yet, manufacturer-driven marketing campaigns are often designed to look like educational services, but they actually reinforce notions that accidents occur due to operator error.

The system design requires adding the collection vial without knowing the needle's placement in the body, and this allows significant potential for an unintended event. Sudden patient movements—cough, fear, itch, pain, sneeze, etc.—can cause an unforeseen movement that can work to dislodge a needle that is not under manual control. Or, such movements can change an embedded device's position, especially if the embedded sharp is not held firmly in place. It is natural to not hold a needle firmly in place when the operator has no idea if the sharp is or is not placed properly in the first place. With this uncertainty, human factors dictate that a user will naturally be less diligent to keep the needle's position exactly sure since there is a probability the needle not embedded

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correctly will require manipulation movement or “prodding,” an industry euphemism, to locate a vein.

In truth, the inability to predict sudden patient movements and uncertainty about the needle’s placement are both human factor and physics-design issues. In the end, because there is no way to control a patient’s movement, along with insensible design issues especially inherent in the winged set, these medical tools are unreliable.

There are other reasons why taping the link tubing to the patient’s arm is not safe practice. The process of taping the tubing down requires releasing the hand holding the embedded sharp so that the hand is free to help affix the tape to the patient. As a result, the practice of taping can itself lead to unintended consequences should the patient move even slightly. Therefore, the butterfly device as engineered with long tubing promotes the practice of releasing manual control of the needle in order to secure it. It would be difficult to find a better example of design contradiction in modern medicine.

Another profound design issue in the system is evident when using the device in infant draws because babies cannot understand the words “do not move.” As soon as the needle pierces an infant’s skin, his or her automatic response is uncontrollable crying and thus shaking, making prodding for a vein even more problematic. Furthermore, once the collection tube is attached, it begins to draw in whatever tissue the needle tip is in contact with, and veins collapsing from vacuum suction are not uncommon. Collapsed veins means the infant has to be stuck again in an attempt to find a new vein. As a result, infant blood collection using a winged set is not an enjoyable healthcare practice.

Some institutions do not allow the use of a vacuum-based vial in pediatric blood collection procedures. Instead, a syringe is attached to the rear of the tubing so that the draw can be manually controlled. OSHA’s bloodborne pathogen standard provides no guidance on this matter—even though the government’s chief industrial safety organization is required to protect all citizens, including the most vulnerable.

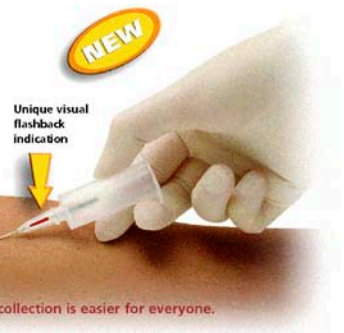
A basic OSHA tenant is that for an industrial tool to be safe, it must work in a reliable manner. Imagine if you operated a paint gun that could explode even if it were used according to standard procedures? Or, what if x-rays, which output a safe amount of radiation most of the time, suddenly put out many times that amount if the patient moved slightly?

Reliability must be supported and controlled by strict regulations in medical device safety. There are several reasons for this, most notably common sense. Operators

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- Faster procedures

BD Vacutainer® Flashback needle

Ref.	Gauge	Length	Colour Coding	Packaging
301746	21G – 0.8 mm	1" – 25 mm		50 /box 1000/case
301747	22G – 0.6 mm	1" – 25 mm		50 /box 1000/case
301748	22G – 0.6 mm	1.25" – 32 mm		50 /box 1000/case

BD Vacutainer® Flashback needle ideally complements our range of blood collection devices and accessories. Ask your BD representative for more information.



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can, over time, learn to use dangerously designed sharps, such as the vacuum tube-based system (first sold in the U.S. as the BD Vacutainer System®), and establish a good margin of safety. But, the high rate of phlebotomy accidents during the probing stage shows that everyone is susceptible to an accident while using these tools.

It is notable that while a well-trained and experienced operator can use even a dangerous device, the less experienced can produce epidemic-level accidents. A recent study of accidents in medical schools reveals needlestick accidents occur often in that special environment. By the time medical students are required to draw blood, they have studied the human anatomy in-depth, and they have proven their interest in medical care through rigorous commitment and excellence. Even with such educated and talented persons—aided by rigorous instruction from the best phlebotomy teachers—these unreliable needles are the cause of accidents among students studying to become physicians. Most states require little or no training to obtain a license to practice phlebotomy. Getting a license to cut hair requires more training (Sharma, et al., 2009).

All in all, controlling a conventional winged set requires years of experience and ample dexterity. But, at the end of the day, there is no guarantee that a patient will not suddenly move, causing the unattended but embedded needle to be ejected with potentially

tragic results, regardless of the operator's proficiency.

BD's European catalogue showing its Vacutainer Flashback® Needle begins with the telling truth, "Reliable results start with reliable samples."

•**Better specimen quality.** BD's research has determined that the Vacutainer System® without VEI can influence laboratory results, i.e., lower quality of the specimen. BD provides no further explanation as to what occurs to the blood during the collection process that can cause such a change in the quality of the specimen.

•**Less redraws, less manipulations, less exposure to blood.** This means that the function of flashback safety in the vacuum-based system reduces these dangerous events. In other words, flashback indication reduces the potential for adverse events when compared to the same system without VEI functionality. Furthermore, suffering to the patient is decreased because positive confirmation that the needle is in the vein means less probing and fewer sticks and therefore less opportunity for the vacuum action to do long-term damage.

•**Closed collection system,** BD's use of these words seems to indicate that safety functions are operating passively in the background. "Passive" refers to medical device functions that do not require manual activation. All research agrees that safety functions that occur passively during procedures are more likely to provide safety than those that require the user to manually activate a mechanism to provide the safety function. According to *Infection Control Today*, scientifically engineered medical devices that provide "passive" safety functions are primary to safety and "...should involve no button-pressing, no lever-pushing, no needle-shearing and no post-clinical procedural activation" (Mitchell, 2008).

The entire group of companies that produce the majority of conventional systems worldwide, including BD, Covidien, Greiner, HMD, Kawasumi, Misawa, Nipro, Sarstedt, Smiths, Terumo, et al., have similar product demonstrations to MYCO Medical's or descriptions indicating the process of attaching and detaching the collection vial requires two hands, whether shown explicitly as in MYCO's video, or inferred.

The system's design requires relinquishing control of the embedded needle—an industrial tool in use. No one would suggest that it is safe to start up a jackhammer and then leave it lying on the pavement while its operator uses both hands to handle another task. The same goes for a bone saw, dentist drill or surgical laser. All industrial tools—no matter the manufacturer—under the Department of Labor's direction, must be controlled and not left unattended during use. This is the law of the land, and it protects all of us equally. ☺

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Note to References: A 2009 interview with the president of a major needle company disclosed the true cost of plastic and metal needle components. Interview participants are under a confidential agreement to not disclose their identity. Copyrights and trademarks are the property of their respective manufacturers, patent-holders, individuals and intellectual property companies.

Lloyd S. Fischel has been a public advocate for several decades. In the late 1980s, at the height of the Cold War, Fischel worked to bring the U.S. and Soviet Union closer by converting high-tech military resources to produce consumer goods. A collaboration with president Mikhail Gorbachev resulted in the publication of *Dear Mr. Gorbachev*, published in three countries. Fischel operates a commercial orchid farm in Hawaii where he cofounded the *Farmers Union* to reduce food importation there. He may be contacted at lloyd@lsfischel.info.

Occupational Health Nurses & Safety

Do you recall having a job description that focused on a single area of responsibility? With today's challenging business environment, responsibilities have increased for most SH&E professionals. The role of the occupational health nurse (OHN) is no exception. Certified occupational health nurses (COHNs) and certified occupational health nurse-specialists (COHN-Ss) demonstrate professionalism and competency on a daily basis. COHNs impact business decisions in various business sectors. Companies who employ these highly trained and skilled professionals often look to OHNs for leadership not only in the occupational health, treatment and wellness arenas, but also in accident/injury prevention. Because of their unique background and skills, OHNs are a natural fit for safety. In fact, many OHNs have responsibilities in areas that fall within the safety arena. Examples include responsibility or oversight for:

- OSHA recordkeeping;
- Conducting accident investigations and root-cause analysis, and recommending corrective and preventive actions;
- PPE hazard assessments;
- assisting with respiratory protection: selection, fit-testing and training;
- performing noise area monitoring/personal sampling to determine exposure; recommending engineering or administrative controls to reduce that exposure and assisting with PPE selection and training;
- conducting ergonomic assessments to identify hazards, assess risk and recommend control methods (following the hierarchy of controls) to reduce risk to tolerable levels.

It makes sense for OHNs who work in safety to demonstrate professionalism, expertise and competency.

For safety professionals, this means qualifying for credentialing, such as the associate safety professional (ASP), certified safety professional (CSP) or occupational and safety technologist (OHST) offered through the Board of Certified Safety Professionals (BCSP). To promote the same level of professionalism in safety for occupational health nurses, the American Board for Occupational Health Nurses (ABOHN) partnered with BCSP to develop the Safety Manager (SM) professional safety specialty credential.

Safety Manager Professional Safety Specialty Credential

The safety manager (SM) credential is the premier safety specialty credential offered by ABOHN. Achieving the SM credential reflects expertise and competency of the OHN with safety responsibility. To qualify to sit for the board certification exam, applicants must hold the core credential (COHN or COHN-S), earn 50 contact hours related to safety, demonstrate work experience related to safety domains and have a minimum of 25% of safety responsibilities in their job. The SM credential:

- is the same level as the ASP offered by BCSP;
- may serve as a terminal certification (does not expire if renewed—CEU requirements are applied)
- is accepted by BCSP for qualification to sit directly for the CSP professional certification.

If you are an OHN with safety responsibility or have an OHN working for you who does, the SM specialty credential is essential to demonstrate competency. For more information, visit the **ABOHN website**.

Submitted by Peggy Ross, R.N., M.S., COHN-S/CM/SM, CSP, ABOHN Directors.