ORIGINAL ARTICLE

Contribution of a Winged Phlebotomy Device Design to Blood Splatter

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BACKGROUND. Despite a proliferation of phlebotomy devices with engineered sharps injury protection (ESIP), the impact of various winged device designs on blood splatter occurring during venipuncture procedures has not been explored.

OBJECTIVES. To evaluate the potential for blood splatter of 6 designs of winged phlebotomy devices.

DESIGN. A laboratory-based device evaluation without human subjects, using a simulated patient venous system.

METHODS. We evaluated 18 winged phlebotomy devices of 6 device designs by Terumo, BD Vacutainer (2 designs), Greiner, Smith Medical, and Kendall (designated A-F, respectively). Scientific filters were positioned around the devices and weighed before and after venipuncture was performed. Visible blood on filters, exam gloves, and devices and measurable blood splatter were the primary units of analysis.

RESULTS. The percentages of devices and gloves with visible blood on them and filters with measurable blood splatter ranged from 0% to 20%. There was a statistically significant association between device design and visible blood on devices ($P < .0001$) and between device design and filters with measurable blood splatter ($P < .0001$), but not between device design and visible blood on gloves. A wide range of associations were demonstrated between device design and visible blood on gloves or devices and incidence of blood splatter.

CONCLUSIONS. The results of this evaluation suggest that winged phlebotomy devices with ESIP may produce blood splatter during venipuncture. Reinforcing the importance of eye protection and developing a methodology to assess ocular exposure to blood splatter are major implications for healthcare personnel who use these devices. Future studies should focus on evaluating different designs of intravascular devices (intravenous catheters, other phlebotomy devices) for blood splatter.

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In accordance with the Needlestick Safety and Protection Act and the resultant revision of the Occupational Safety and Healthcare Administration's Bloodborne Pathogens Standard (BPS), numerous devices with engineered sharps injury protection (ESIP) have been made available for use by healthcare personnel (HCP).[1,2] According to section 1910.1030 (c) (1) (v) of the BPS, "An employer, who is required to establish an Exposure Control Plan, shall solicit input from nonmanagerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan."[2]

In an effort to develop a complementary and more objective approach to sharps evaluation and selection, a sharps safety evaluation laboratory was developed at the James A. Haley Veterans Administration (VA) Medical Center's Research Center of Excellence in Tampa, Florida. The VA Office of Public Health/Occupational Health supported this project. A multidisciplinary team including an infection preventionist and a mechanical engineer consulted with HCP and medical practitioners to develop methods for detecting blood splatter from intravascular devices. The method used in this evaluation was developed and validated with the intention of following clinical procedures in a simulated laboratory setting, maximizing the opportunity to capture any blood splatter, and implementing instructions for single-handed use of a butterfly device (see below) whenever possible. Development and validation of this method was previously described in detail.[3,4]

When a method for detecting blood splatter was developed, the team was asked to conduct laboratory-based testing and evaluation of the most commonly used phlebotomy devices in the VA system, starting with steel winged-tip phlebotomy devices, which are often referred to as "butterfly" devices. A variety of such devices are commercially available, with dif-

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TABLE 1. Master List of Devices by Name, Needle Gauge, Length of Needle and Tubing, whether Activated in Vein, and Timing of Simulated Phlebotomy

Design, device	Device specifications	Activated in vein	Timing (s)
A: Terumo Surshield Safety Winged Blood Collection Set			
1	21-gauge × 3/4″ × 12″	No	10
2	23-gauge × 3/4″ × 12″	No	20
3	23-gauge × 3/4″ × 7″	No	20
B: BD Vacutainer Push-Button Blood Collection Set			
4	21-gauge × 3/4″ × 7″	Yes	10
5	23-gauge × 3/4″ × 12″	Yes	20
6	23-gauge × 3/4″ × 7″	Yes	20
7	21-gauge × 3/4″ × 12″	Yes	10
C: BD Vacutainer Safety-Lok Blood Collection Set			
8	23-gauge × 3/4″ × 12″	No	20
9	21-gauge × 3/4″ × 12″	No	10
10	21-gauge × 3/4″ × 7″	No	6
D: Greiner Vacuette Safety Blood Collection Set			
11	21-gauge × 3/4″ × 12″	Yes	8
12	23-gauge × 3/4″ × 12″	Yes	20
13	23-gauge × 3/4″ × 7.5″	Yes	18
E: Smith Medical Saf-T-Wing Blood Collection and Infusion Set			
14	23-gauge × 3/4″ × 12″[a]	While exiting arm	18
15	21-gauge × 3/4″ × 12″[a]	While exiting arm	7
F: Kendall[b]/Angel Wing Blood Collection Set			
16	21-gauge × 3/4″ × 12″	Yes	9
17	23-gauge × 3/4″ × 12″	Yes	18
18	23-gauge × 3/4″ × 12″[a]	Yes	18

NOTE. Unless otherwise noted, the device connection at the distal end of the tubing is a vacuum-tube connection without a tube holder.

[a] Connection at distal end of tubing is a vacuum-tube connection included in a tube holder.

[b] Now known as Covidien-Kendall.

ferent designs to integrate ESIP and attached to lengths of tubing between 6 and 12 inches.

The team conducted objective testing and subjective evaluations of the devices. This article focuses on the objective evaluation, which was designed to answer the following questions: Do the devices produce blood splatter when activated? If so, what is the amount of splatter produced?

METHODS

Materials

Twenty-five each of 18 types of butterfly devices were tested between August 2008 and September 2009. The 18 devices were chosen as representative samples of the designs and specifications commercially available at the date of the onset of evaluation. From 5 brands, the device designs of a total of 6 different blood collection sets were tested, including 2 gauge sizes (21 and 23 gauge), a consistent needle length (3/4 inch), and 2 tubing lengths (7 inches and 12 inches). The brand names and trade names, and the number of different devices of each design (in parentheses) are as follows: design A, Terumo Surshield (3); design B, Becton Dickinson (BD) Vacutainer Push-Button (4); design C, BD Vacutainer Safety Lok (3); design D, Greiner Vacuette (3); design E, Smith Medical Saf-T-Wing (2); and design F, Kendall Angel Wing (3). These are referred to hereafter as designs A–F. The butterfly devices included a vacuum adapter for blood collection at the distal end of the tubing. Blood collection tubes (without additive, 7 mL, Becton-Dickinson) were used for blood collection by insertion into the vacuum adapter. See Table 1 for a complete list of these devices by design and specifications and Figure 1 for a photograph of all 18 devices tested.

To examine blood splatter during blood collection procedures, objective testing was performed in a controlled laboratory setting intended to simulate the health care setting while also controlling for potential confounding variables. A mock venous blood system was established according to the manufacturer's specifications (Limbs & Things), using an injectable extended antecubital fossa (ACF) pad (a soft tissue pad used for venipuncture that represents the ACF of the human arm) attached to infusion tubing and containing

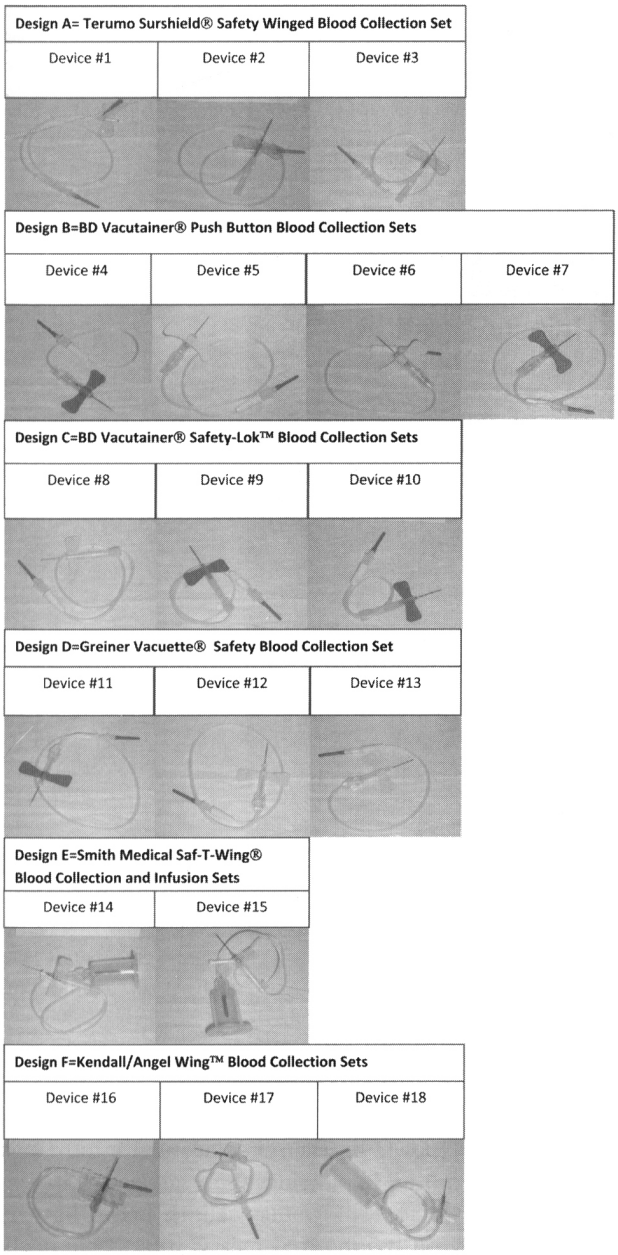

FIGURE 1. Photograph of the 18 devices tested, by design group.

mock venous blood. For each device, a protocol was devised to maximize capture of peripheral blood splatter from the butterfly needle (360° around the venipuncture site), using 1–2 scientific filters composed of Kimberly Clark heavy-duty coverall particulate arresters (tested at ≥0.3 μm, prelabeled). The filters were weighed on a scale calibrated to 0.001 g (Daigger Analytical Scale APX 100) before and after performing the venipuncture procedure, which included activation of the safety device. The venipuncture procedure, activation of the safety feature, and measurement of the filters occurred inside a tissue culture hood, which provided a controlled environment that was free from contamination and protected from any sudden changes in air pressure.

Procedure

A pilot protocol to measure blood splatter from butterfly devices had previously been validated by researchers associated with this study team.[3,4] Using this pilot protocol as a template, specific protocols for each device design (A–F; ranging from 60 to 100 steps) were developed to ensure consistent procedures between devices, incorporate the manufacturer's instructions for use, allow for single-handed use when feasible, and capture any potential blood splatter generated during the venipuncture procedure and the activation of the safety device. Subsequently, a validation trial of 10 attempts was completed for each device to confirm and adjust the steps. Once the validation attempts were completed, no further adjustments were made to the protocol for that specific device. Twenty-five reiterations of the validated protocol were performed for each of the 18 devices.

The tester was a HCP with more than 15 years of experience with phlebotomy and intravenous catheter insertion, using a variety of conventional devices and in several types of health care settings. Prior to validating each of the 18 protocols, the tester practiced 10–20 times with each device until the protocol could be followed without deviation.

For each protocol or device, the ACF pad was premarked with 25 injection sites. These sites were numbered in a rotating fashion so that each was neither predictable nor adjacent to the injection site immediately preceding or following. After each venipuncture procedure was performed, medical tape was placed over each insertion site to prevent seepage of blood during subsequent venipuncture trials. The level of mock blood in the blood bag was maintained at between 400 and 500 mL. Protocols for device designs A, B, C, E, and F used 2 filters to collect blood splatter. To follow the manufacturer's instructions for use and to maximize the capture of blood splatter, the configuration of design D necessitated the use of only 1 filter. For protocols requiring 2 scientific filters, these filters were designated A and B. Filters were placed in specific locations to maximize the capture of blood splatter. See Figure 2 for an illustration of the experimental setup and filter placement.

The time between the release of the clamps in the mock venous blood system and the insertion of the needle and the time between the engagement of the vacuum blood tube and withdrawal of the needle were vigilantly monitored and standardized between trials for each protocol or device. See Table 1 for the timing used for each device design.

For each trial, the filter(s) were measured on the analytical scale immediately before and after the venipuncture procedure, which included activation of the safety device. The difference in post- and preactivation filter mass was the primary unit of analysis for detecting measurable blood splatter. In addition to detecting measurable blood on the filters, the

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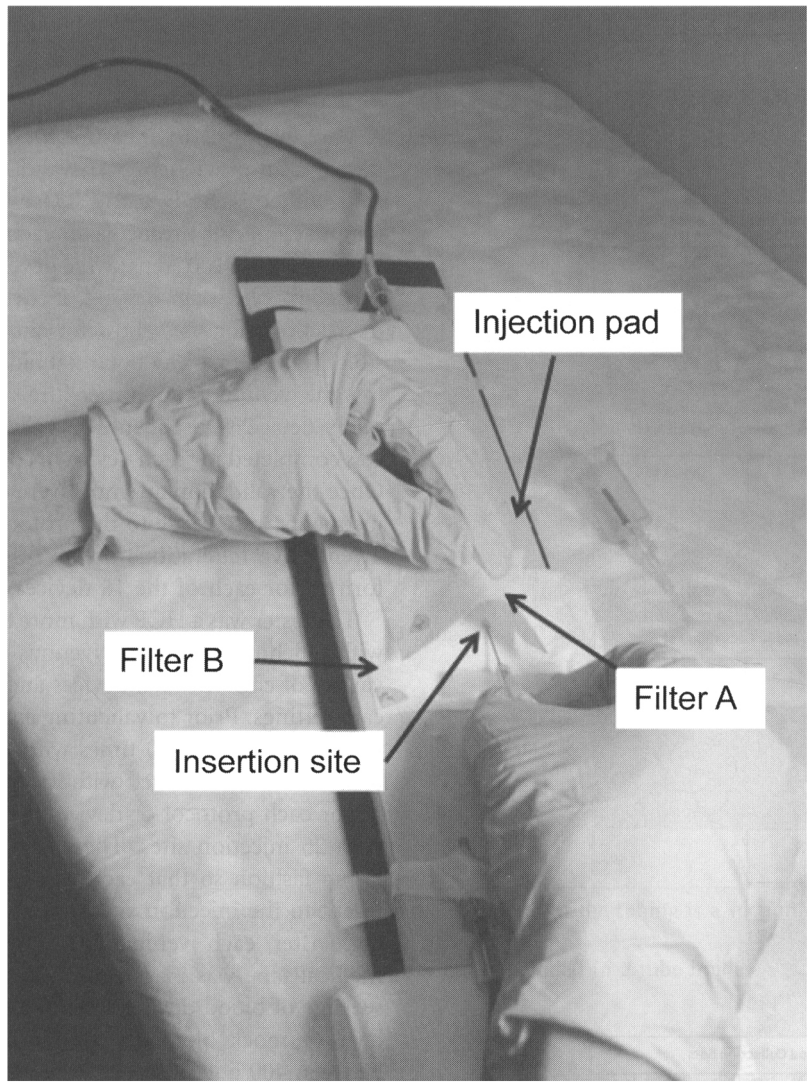

FIGURE 2. Photograph of the experimental setup, with filters, injection pad, and insertion sites indicated.

absence or presence of visible mock blood on the filters, the tester's gloves, and a filter used to wipe the device were noted and recorded on an Excel spreadsheet. A visual inspection for visible blood splatter was conducted after each trial, and findings were recorded for each of the parameters as a dichotomous response (yes or no).

Statistical Methods

Pre- and postactivation filter weights as well as the presence or absence of visible blood on filters, devices, and the tester's gloves were noted and recorded on an Excel spreadsheet. Data were analyzed using descriptive statistics, Fisher exact test of association, complementary log-log transformation (prevalence ratios), and odds ratios to determine whether there was a difference in blood splatter between designs.

RESULTS

For the primary unit of analysis, designs C and E were the only devices that produced measurable blood splatter. Design E had 1 instance of measurable blood splatter, which measured 0.0011 mg. Design C had 15 instances of measurable blood splatter, the amount of which ranged from 0.0010 to 0.0060 mg. When compared with all other design groups, design C was the only design to demonstrate a statistically significant difference between post- and preactivation filter weights, indicating measurable blood splatter ($P < .0001$).

Visible blood on filters, gloves, the device, and filter B after the device was wiped were recorded as objective findings. Frequencies and percentages of observed visible blood varied widely (see Table 2). First, there was a wide range of values for the frequency of visible blood on filters, from 0% of the

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TABLE 2. Objective Findings after Completion of Simulated Venipuncture Procedure

Device design and number	Visible blood				Measurable blood on filters
	On gloves	On device	On filters (A and B)	On filter B after wiping device[a]	
Total A[b]	1 (1.33)	36 (48.00)	7 (9.33)	1 (1.33)	0 (0.00)
A1	1 (1.33)	7 (9.33)	6 (8.00)	0 (0.00)	0 (0.00)
A2	0 (0.00)	15 (20.00)	0 (0.00)	1 (1.33)	0 (0.00)
A3	0 (0.00)	14 (18.67)	1 (1.33)	0 (0.00)	0 (0.00)
Total B[c]	4 (4.00)	77 (77.00)	60 (60.00)	16 (16.00)	0 (0.00)
B4	0 (0.00)	23 (23.00)	19 (19.00)	8 (8.00)	0 (0.00)
B5	1 (1.00)	16 (16.00)	11 (11.00)	1 (1.00)	0 (0.00)
B6	1 (1.00)	16 (16.00)	8 (8.00)	4 (4.00)	0 (0.00)
B7	2 (2.00)	22 (22.00)	22 (22.00)	3 (3.00)	0 (0.00)
Total C[b]	3 (4.00)	68 (90.67)	16 (21.33)	14 (18.67)	15 (20.00)
C8	0 (0.00)	19 (25.33)	1 (1.33)	1 (1.33)	0 (0.00)
C9	3 (4.00)	24 (32.00)	1 (1.33)	6 (8.00)	4 (5.33)
C10	0 (0.00)	25 (33.33)	14 (18.67)	7 (9.33)	11 (14.67)
Total D[b]	0 (0.00)	0 (0.00)	0 (0.00)[d]	0 (0.00)	0 (0.00)
D11	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
D12	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
D13	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)
Total E[e]	1 (2.00)	29 (58.00)	4 (4.00)	2 (4.00)	1 (2.00)
E14	0 (0.00)	10 (20.00)	0 (0.00)	0 (0.00)	0 (0.00)
E15	1 (2.00)	19 (38.00)	4 (4.00)	2 (4.00)	1 (1.00)
Total F[b]	2 (2.67)	38 (50.67)	11 (14.67)	4 (5.33)	0 (0.00)
F16	0 (0.00)	6 (8.00)	6 (8.00)	2 (2.67)	0 (0.00)
F17	1 (1.33)	15 (20.00)	2 (2.67)	1 (1.33)	0 (0.00)
F18	1 (1.33)	17 (22.67)	3 (4.00)	1 (1.33)	0 (0.00)

NOTE. Data are no. (%).

[a] Additional blood, in excess of that on filter B prior to wiping device.

[b] $N = 75$.

[c] $N = 100$.

[d] Only 1 filter was used.

[e] $N = 50$.

time for design D to 60% for design B. The values for the frequency of visible blood on gloves had a much smaller range, from a low of 0% for design D to 4% for designs B and C. For frequency of visible blood on the device, designs A, E, and F had similar values (48%, 58%, and 50.67% of trials, respectively). Design D produced no visible blood on the device, whereas device B produced visible blood in 77% of the trials and device C did so in 90.67% of the trials. The frequency of finding blood on filter B after postactivation wiping of the device ranged from 0% for design D to 16% and 18.67% for designs B and C, respectively. The use of design D produced no visible blood on gloves, the device, or filters.

Using Fisher exact tests, statistically significant associations ($\alpha = 0.05$) were identified between device design groups and observing visible blood on the device ($\chi^2 < 0.0001$, $P < .0001$) and between device design groups and filters having measurable blood splatter ($\chi^2 < 0.0001$, $P < .0001$). There was no statistically significant association between device design group and visible blood on gloves ($\chi^2 = 0.5351$, $P = .5077$).

An analysis of the data with complementary log-log transformation revealed statistically significant differences in prevalence rates for measurable blood on filters for design C (83%) and for visible blood on the device for designs A (0.13%), B (2.82%), and C (3.26%). There were no significant differences for the prevalence rates of visible blood on gloves. These results were replicated using odds ratios (see Table 3).

DISCUSSION

The objectives of this article were to determine whether the devices produced blood splatter when activated and, if so, the amount of splatter produced. In this study, 1 of the 6 device designs statistically significantly demonstrated measurable blood splatter. Several designs had multiple instances of visible, but not measurable, blood splatter. The finding that visible blood splatter on the device, gloves, or filter did not always result in measurable blood splatter might indicate measurement error or the need for a more sensitive scale. Differences in the findings of visible and measurable blood splatter between device designs suggest that the device design

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TABLE 3. Results of Analysis Using Log Transformation and Odds Ratios

Outcome, predictor	Prevalence ratio (95% CI)	*P*	Odds ratio (95% CI)	*P*
Measurable blood on filter(s)				
Design C versus other	83.57 (11.04–632.80)	<.0001*	93.50 (12.13–720.87)	<.0001*
Design E versus other	0.53 (0.07–4.00)	.537	0.52 (0.07–4.05)	.536
Visible blood on device				
Design A versus other	0.13 (0.02–0.97)	.047**	0.13 (0.02–0.94)	.044**
Design B versus other	2.82 (1.47–5.40)	.002**	2.98 (1.49–5.97)	.002**
Design C versus other	3.26 (1.68–6.35)	<.0001*	3.51 (1.71–7.20)	.001*
Design E versus other	0.45 (0.11–1.85)	.267	0.43 (0.10–1.86)	.262
Design F versus other	0.60 (0.21–1.68)	.327	0.58 (0.20–1.70)	.324
Visible blood on gloves				
Design A versus other	0.50 (0.06–3.88)	.505	0.49 (0.06–3.91)	.504
Design B versus other	2.02 (0.59–6.90)	.262	2.04 (0.59–7.12)	.263
Design C versus other	1.89 (0.50–7.14)	.346	1.91 (0.50–7.38)	.347
Design E versus other	0.80 (0.10–6.23)	.83	0.80 (0.10–6.35)	.829
Design F versus other	1.11 (0.24–5.15)	.891	1.11 (0.24–5.26)	.891

NOTE. Log transformation was a comparison of the prevalence of blood splatter between designs. It was used because of low numbers of positive observations. Odds ratios allowed for comparisons of the odds of splatter between designs.

* $P < .0001$.

** $P < .05$.

itself contributes to or mitigates blood splatter during venipuncture.

There are reports of HCP acquiring infections with bloodborne pathogens as a result of experiencing a blood splash to the conjunctiva.[5-8] While our study did not demonstrate statistically significant amounts of blood spatter with some of the device designs or on devices and gloves, this clinically significant issue warrants mention. In terms of potential for blood exposure to HCP, the bloodborne pathogens HIV, hepatitis C virus, and hepatitis B virus (HBV) are present at concentrations of 10^0–10^3, 10^0–10^6, and 10^9–10^9 viral particles per milliliter of serum or plasma, respectively.[9,10] Thus, it is possible that the mucous membranes of HCPs could be exposed to blood splatter in small amounts not visible to the naked eye. In such instances, if the HCP is not aware of the exposure, the opportunity for HIV or HBV postexposure prophylaxis would be missed.[11] Evaluation of devices with ESIP is essential before they are to be purchased by healthcare facilities; various evaluative criteria are available.[12-15] Occupational infection control issues such as the potential for needlestick injury or blood contamination should be included in these criteria.

There are reports in the literature that describe procedures that generate blood splashes or splatters, such as general surgery;[16] orthopedic surgery;[17] ear, nose, and throat surgery;[18] and angiography.[19] However, articles that describe the evaluation of blood splatter with the use of sharps devices are not as prevalent. In 2002, Asai et al[20] compared the safety and efficacy of 2 intravascular catheters that had safety features with a conventional (non-ESIP) catheter during intravenous and intra-arterial cannulation of patients. The presence or absence of blood contamination on the researcher, assistant, patient, or tray where the withdrawn device was placed was evaluated by counting the number of bloodstains. The incidence of blood contamination was significantly greater with the use of the conventional catheter and one of the devices with ESIP compared with the other device with ESIP.[20] In the only report of its kind of which we are aware,[21] 3 phlebotomy devices were evaluated both with benchtop assessments and by HCP using the devices in the clinical setting. One of these devices was the Becton Dickinson Vacutainer Push-Button device (design B in this study). Fluid splatter was measured by using a blood substitute containing a fluorescein dye and placing colored paper beneath the device. The paper and the investigator's gloves were examined under ultraviolet light to detect fluid droplets. For this device, in the 20 trials conducted, blood splatter was detected on the gloved hand positioned behind the device in 7 instances (35%).[21] Compared with the results of that study, in 100 trials in our study, design B produced visible blood splatter on gloves 4% of the time, on the device 77% of the time, on filters 60% of the time, and on filter B after wiping the device 16% of the time, but it did not produce measurable blood splatter. It is important to note that the tubing length was not mentioned in the other study.[21]

This study has several limitations. First, products were tested in a laboratory setting and not on humans or with real blood. Second, the evaluations did not measure the distance or direction of blood splatter. In addition, collapsing 18 devices into 6 design categories may have resulted in less device-specific information. Finally, the confidence intervals for prevalence and odds ratios may indicate the need for larger sample sizes.

The potential for blood exposure exists with certain designs

of steel winged-tip phlebotomy devices with ESIP, and this has implications for both future research and clinical practice. Suggestions for future inquiry in this area are to analyze each device separately (not in design groups), use a pumping venous system to more closely simulate the human system, use a more sensitive scale to measure blood splatter on the filters, develop additional methods for capturing blood splatter that can characterize direction and distance of blood splatter, and use larger sample sizes.

The implications of our findings for clinical practice are that HCP should anticipate the possibility of blood splatter when using such phlebotomy devices. The following excerpts from the OSHA Bloodborne Pathogens Standard[2] warrant emphasis: "All procedures involving blood shall be performed to decrease splashing, spraying, spattering, & generation of droplets of these substances" (1910.1030 [d] [2] [xi]). "Gloves shall be worn when it can be reasonably anticipated that employee may have hand contact with blood; when performing vascular access procedures & when handling or touching contaminated items or surfaces" (1910.1030 [d] [3] [ix]). And finally, "masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood may be generated & eye, nose, or mouth contamination can be reasonably anticipated" (1910.1030 [d] [3] [x]). The clinically significant risk of ocular exposure that was demonstrated in this study warrants further investigation.

The results of this study reinforce the importance not only of wearing personal protective equipment such as masks and eye protection (face shields, goggles, safety glasses) when performing venipuncture procedures but also that blood splatter should be anticipated when using the devices evaluated in this study. In addition, surfaces near the venipuncture site (such as armrests) should be decontaminated after each procedure is performed.

It is likely that the design of phlebotomy devices that have ESIP will continue to evolve. It is imperative that device evaluations be performed as new or modified devices become available. We suggest that evaluation of blood splatter serve as one of the prerequisites for purchasing decisions about steel winged-tip phlebotomy devices.

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