



# Disinfection of central venous access device needleless connectors: A human factors analysis

Frank A. Drews PhD<sup>1</sup> <sup>(6)</sup>, Richard A. Martinello MD<sup>2,3</sup> <sup>(6)</sup>, Joan N. Hebden MS, RN<sup>4</sup>, Keith H. St. John MT(ASCP), MS<sup>5</sup> <sup>(6)</sup>

and David A. Pegues MD<sup>6</sup>

<sup>1</sup>Department of Psychology, University of Utah, Salt Lake City, Utah, <sup>2</sup>Departments of Internal Medicine and Pediatrics, Yale School of Medicine, New Haven, Connecticut, <sup>3</sup>Department of Infection Prevention, Yale New Haven Health, New Haven, Connecticut, <sup>4</sup>IPC Consulting Group, Baltimore, Maryland, <sup>5</sup>North Star IPC Consulting Services, Newark, Delaware and <sup>6</sup>Division of Infectious Diseases, Department of Medicine, Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania

## Abstract

Objective: Evidence-based central-line-associated bloodstream infection (CLABSI) prevention guidelines recommend the use of an antiseptic scrub to disinfect needleless connectors before device access. Guideline noncompliance may render disinfection ineffective. The goal of this study was to observe needleless-connector disinfection practices and to identify perceived facilitators and barriers to best practices of needleless-connector access.

Methods: A human factors mixed-methods study involving nursing focus groups of perceived barriers and facilitators and clinical observations of compliance with instructions and protocols for use of 3.15% chlorhexidine gluconate/70% isopropyl alcohol (CHG/IPA) and 70% isopropyl alcohol (IPA) antisepsis products for central venous access device (CVAD) needleless-connector disinfection was conducted in intensive care units (ICUs) at 2 academic medical centers.

Results: Access to the antiseptic product and lesser workload were identified as best-practice facilitators. Barriers were the time required per needleless-connector access and knowledge deficits. Of the 48 observed access events, 77% resulted in needleless-connector disinfection. The observed mean needleless-connector scrubbing times when using IPA were substantially below the recommended time. Drying time after product use was negligible.

Conclusions: Lack of access to the disinfection product, emergency situations, and high workload were barriers to needleless-connector disinfection. Observed scrubbing and drying times were shorter than recommended, especially for IPA wipes. These needleless-connector disinfection deficits may increase the risk of CLABSI. Ongoing education and periodic competency evaluation of needleless-connector disinfection, improvement of supply management, and staffing workload are required to imbed and sustain best practices. Further study involving a larger sample size in diverse patient populations is warranted.

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Patients requiring vascular catheters are at increased risk for bloodstream infections (BSIs), particularly those with central venous access devices (CVAD) in an ICU setting due to the need for frequent administration of medications, fluids, and blood products. A common mode of transmission and pathogenesis for these infections is microbial contamination of the needleless connector from the patient's skin and/or the hands of healthcare professionals (HCP). Inadequate disinfection of needleless connectors, which are accessed multiple times by HCPs in the delivery of patient care, can result in intraluminal bacterial colonization of the needleless connector, tubing, and vascular catheter, leading to bloodstream infections (BSI) and potential metastatic infectious

Corresponding author: Frank A. Drews; Email: drews@psych.utah.edu

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complications. (Here, the use of the term disinfect/disinfection is consistent with the SHEA 2022 Compendium, as well as the SHEA/IDSA Guidelines published July 2014 in ICHE.)

A systematic review by Moureau et al<sup>1</sup> revealed that an estimated 50% of CVAD infections are caused by bacterial colonization of needleless connectors.<sup>1</sup> Despite this known risk, compliance with needleless-connector disinfection remains suboptimal, with observed rates as low as 10%.<sup>1</sup> The optimal needleless-connector disinfection product as well as the duration of needleless-connector disinfection remain unclear, and practice varies among healthcare facilities and HCPs.

Evidence-based CLABSI prevention guidelines recommend the use of an approved antiseptic, such as alcoholic chlorhexidine or 70% alcohol, for needleless-connector disinfection.<sup>2,3</sup> Seventy percent isopropyl alcohol (70% IPA) needleless-connector disinfection caps reduced CLABSI rates when compared to active disinfection with alcohol swabs alone in a quasi-experimental



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study of cancer patients.<sup>4</sup> However, to be effective, these passive disinfection caps require active needleless-connector disinfection when the disinfection cap has been on the needleless connector for less than a minimal duration (ie, 1 minute), between sequential needleless-connector accesses, and when the needleless connector is visibly soiled, or left exposed. Current recommendations and clinical data suggest that active needleless-connector disinfection should be performed following these steps<sup>5</sup>:

- Vigorously scrub the threads and septum of the needleless connector with a wipe.
- Twist the wipe over the connector threads and scrub the septum with pressure.
- Alternate between twisting the wipe on the threads and scrubbing the septum for at least 15 seconds (s) (or other duration for scrub and dry as noted by the manufacturer of the product used).
- Let needless connector air dry.
- Every additional access of the needleless connector requires a new 15-s scrub.

Although laboratory and clinical data suggest that a disinfection time of 15 s is sufficient to eliminate contamination with 70% IPA,<sup>6,7</sup> other data suggested that 5 s is sufficient.<sup>8</sup> Data suggesting an optimal drying time for alcohol are limited. One study suggested that 5 s is sufficient to let the 70% IPA alcohol dry,<sup>9</sup> but laboratory work to evaluate different needleless connectors used a 30-s drying time after a 15-s disinfection time.<sup>10</sup> Another study recommended disinfecting the needleless connector before and after access with a 15-s scrub.<sup>11</sup>

We investigated current practices of needleless-connector disinfection (ie, compliance with recommendations for use of chlorhexidine/alcohol and alcohol-based antisepsis products) and perceived facilitators and barriers to needleless-connector-access best practices. We conducted a multimethod study using focus groups and clinical observations in 2 academic healthcare systems including 4 intensive care units (ICUs) and 1 step-down unit.

#### Methods

## Setting

This study was conducted at 2 large, academic, acute-care hospitals caring for adult patients in November and December of 2021. Hospital 1 has 1,541 licensed beds including 210 ICU beds, and the hospital cares for ~80,000 hospitalized patients annually. Hospital 2 has 1,200 licensed beds, including 132 ICU beds, and has >38,000 admissions annually. Needleless-connector disinfection observations were conducted over a 2-day period at each site, including two 28-bed medical and surgical ICUs and a 28-bed medical step-down unit at hospital 1 and a 24-bed medical ICU and 24-bed general surgical ICU at hospital 2. Hospital 1 uses Baxter ONE-LINK needle-free IV connectors (Baxter, Deerfield, IL), and hospital 2 uses RyMed Invision Plus needle-free IV connectors (RyMed, Franklin, TN).

## Data collection

Direct, structured observations were performed by a trained observer shadowing HCPs accessing needleless connectors of CVADs. All HCPs on each unit were eligible for participation, using a convenience sample recruitment, with no individual refusing to be observed. Study participation was voluntary, and observations occurred on weekdays between 7 A.M. and 7 PM.

Table 1.	Questions	for the	Focus	Groups
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Questions	
<ol> <li>Describe the process for needleless-connector disinfection (c scrubbing time and drying time).</li> </ol>	ite
2. What makes it easier or harder to always scrub the needleles connector?	S
3. At your hospital, is disinfecting the catheter needleless-conner of the safety discussion? Where is it prioritized overall?	ector part
4. What is the availability of materials needed?	
5. What would you change if you could?	

A trained observer collected standardized data on an electronic tablet using coding software.<sup>12</sup> The data points collected were related to HCP activities that constitute events associated with needleless-connector access. Among them were the product used for hub disinfection, cleaning approach, and duration of cleaning and drying after hub cleaning. Duration was measured using a dedicated timer on the observation tool for each relevant variable. Behavioral categories were implemented in the observation tool for real-time coding and time measurement. Observations were performed opportunistically, with no more than 2 observations performed per participant per observation day. Observer training included review of vascular access procedures<sup>13</sup> followed by practice in the use of the electronic tool by coding of 28 video-recorded and 12 in vivo vascular access procedures.

Both institutions, when using 70% sterile IPA wipes, had a standard operating procedure of 15-s scrubbing times, but they differed in how they stated the recommended drying time. Hospital 1 recommended a 15-s drying time, whereas hospital 2 recommended "wait until dry," which was  $\sim$ 5 s. Therefore, the standard to evaluate practice for both hospitals was 15 s scrubbing time or 5 s drying time. When CHG/IPA wipes were used to disinfect a needleless connector, observations focused on compliance with manufacturer's instructions for use: 5 s scrubbing time plus 5 s drying time (10 s total time).

Focus groups comprised a convenience sample of 21 registered nurses working in the ICUs of the participating hospitals: 12 from hospital 1 and 9 from hospital 2. The duration of the focus groups ranged from 30 to 45 minutes, and the number of participants ranged from 2 to 5. The groups were facilitated by one team member (F.D.) and were held in a conference room or in a break room. Semistructured interview questions were used for the discussion in the focus group (Table 1). All focus groups were audio-recorded for later digital transcription and analysis.

Participants for both observations and focus groups were recruited via e-mail messages and announcements at daily meetings. There was little overlap between participants for both (only 5 participants were involved in focus groups and observations).

## Ethics

This study was approved by our institutional review board as exempt research under category 2 45 CFR 46.104(d)(2).

## Data analysis

The observational data were exported from the data collection tablet and were separated into individual files, specific to each observation. Next, the data from each file were combined into a Table 2. Needleless-Connector Access Events (AEs) with Average (SD) and Median (IQR) Needleless-Connector Disinfection, Scrubbing and Drying Times for Sites and Antiseptic Products<sup>a</sup>

	_						
	_	AE Hospital 1			AE Con	AE Combined	
Time (seconds)	IPA (n=7)	CHG/IPA (n=9)	Total (n=16)	IPA (n=21)	Combined IPA (n=28)	Combined All (n=37)	
Scrubbing time, s (SD)	7.2 (3.2)	5.0 (2.8)	6.0 (3.1)	5.2 (2.7)	5.7 (2.9)	5.5 (2.8)	
Median, s (IQR)	5.7 (2.7)	5.1 (2.0)	5.4 (3.3)	5.0 (2.2)	5.0 (1.8)	5.1 (2.2)	
Drying time, s (SD)	3.2 (2.6)	1.3 (1.5)	2.1 (2.2)	1.2 (1.8)	1.7 (2.2)	1.6 (2.0)	
Median, s (IQR)	3.7 (4.4)	1.0 (2.2)	1.8 (3.8)	0.7 (1.3)	0.7 (1.9)	0.8 (2.2)	
Disinfection time, s (SD) <sup>b</sup>	10.4 (4.2)	6.3 (3.9)	8.1 (4.4)	6.4 (3.4)	7.4 (4.0)	7.1 (3.9)	
Median, s (IQR)	12.0 (6.1)	5.35 (2.9)	6.4 (7.3)	5.4 (3.4)	6.0 (6.4)	5.4 (6.5)	

Note. SD, standard deviation; IQR, interquartile ratio.

<sup>a</sup>For both hospitals, IPA compliance was 0% for both scrubbing and drying times. For CHG/IPA, scrubbing time was 100% compliant, but 0% compliant with a 5-s drying time. <sup>b</sup>Scrubbing plus drying times.

single file for later statistical analyses using R version 4.1.2 software.  $^{\rm 14}$ 

For focus groups, a thematic analysis approach was used, allowing identification of common categories and a contextualized interpretation of the findings.<sup>15</sup> After the completion of the focus groups, 2 team members (F.D. and J.H.) read the first transcript and began developing a code book. Next, each line of the transcript was read, and the codes based on the code book were applied. The 2 team members independently coded all the training transcripts and subsequently reconciled coding discrepancies. Reconciliation involved discussion until consensus between coders was reached. After completion of the coding, reports were compiled and analyzed to check for consistency in coding and to identify and define the categories that emerged.

## Results

## **Observational study**

Hospital 1 utilized either IPA or CHG/IPA disinfection products for needleless-connector disinfection with the product choice based on unit. Hospital 2 utilized IPA exclusively for needlelessconnector disinfection. Both hospitals used IPA impregnated needleless-connector caps to protect the needleless connector when not in use. Overall, 48 needleless-connector access events were observed, including 19 (40%) at hospital 1 and 29 (60%) at hospital 2. In 11 instances (23%), no disinfection of the needleless connector occurred before device access, including 3 (16%) of 19 observations in hospital 1 and 8 (28%) of 29 observations in hospital 2. These missed opportunities were excluded from the analysis of needleless-connector disinfection scrubbing and drying times, resulting in a total of 37 access events performed by 31 nurses.

The average needleless-connector scrub, dry, and total disinfection (scrubbing plus drying) times for each hospital and disinfectant product used for the 37 access-event observations are presented in Table 2. The average needleless-connector scrubbing time across both hospitals and disinfectants was 5.5 s (SD, 2.8), with an average drying time of 1.6 s (SD, 2.0) and total needleless-connector disinfection time of 7.1 s (SD, 3.9).

The average scrub, dry, and disinfection times varied by disinfectant product, hospital, and specific access event action. At hospital 1, comparing IPA to CHG/IPA needleless-connector disinfection, the observed times were longer for scrubbing (7.2 s vs 5.0 s), drying (3.2 s vs 1.3 s), and total disinfection time (10.4 s vs 6.3 s). For IPA, the average needleless-connector scrubbing, drying, and disinfection times were each longer at hospital 1 than hospital 2 by 28%, 62%, and 38%, respectively. The needleless-connector disinfection time also varied by whether an IPA needleless-connector cap was used. The disinfection time when an IPA needleless-connector cap was removed was 6.6 s (SD, 4.2), which was slightly less time than the 8.3 s (SD, 3.2) disinfection time to scrub and dry a needleless connector without an IPA cap.

The results of the observational study showed that the recommended time for needleless-connector disinfection using IPA wipes was not met. For both hospitals combined, the observed needleless-connector disinfection times were at least 60% lower for target scrubbing (15 s vs 5.7 s), drying (5 s vs 1.7 s) and total disinfection time (20 s vs 7.4 s) for IPA. Although IPA needleless-connector disinfection times were on average longer at hospital 1 than hospital 2, neither approached recommended scrubbing nor drying times. For CHG/IPA needleless-connector disinfection, the average observed scrubbing time of 5 s was consistent with the manufacturer instructions for use (5 s), but the drying time was only 1.3 s compared to the recommended 5 s.

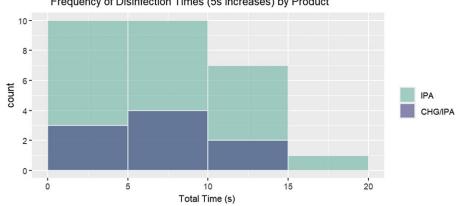
Figure 1 shows the distribution of disinfection times in intervals of 5 s. The mode for disinfection times for IPA fell into the 0–10-s timeframe (71% of all observations), while it fell in the 5–10-s timeframe for the CHG/IPA product (44%). In addition, 22% of the disinfection times using CHG/IPA exceeded the recommended time, as opposed to none for the IPA product. These results suggest that, overall, nurses were closer to the recommended disinfection time when using CHG/IPA.

## Focus groups

Several factors were identified as affecting HCP needlelessconnector disinfection practices and the ability to adhere to recommendations for use. These factors were classified by themes, and illustrative quotes are provided in Table 3.

## Procedures

Participants demonstrated knowledge about the method of needleless-connector disinfection. However, the discussions at both sites revealed occasional confusion about disinfection time



Frequency of Disinfection Times (5s increases) by Product

Fig. 1. Frequency of disinfection times in 5s increases by product.

Table 3.	Illustrative	Quotes	Identified	From	the f	focus	Groups	With	Healthcare	Professionals
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Category	Quote
Procedures	<ul> <li>" For the alcohol it is 15 seconds."</li> <li>"3 seconds, maybe 5 seconds, 10 seconds. Okay."</li> <li>"I put my gloves on, I take the CHG/IPA, I scrub for 5 seconds, I let it dry."</li> <li>"I've never heard of a drying time for alcohol."</li> <li>"Well, I mean, we still have to scrub the hub, even if we're taking the alcohol cap off?"</li> <li>"So, when there's multiple accesses of the same hub That's when I think it [adherence] goes down."</li> </ul>
Facilitators and barriers	<ul> <li>"We have all the supplies that we need by the bedside."</li> <li>"Alcohol caps on strip."</li> <li>"Not being busy—decreased workload."</li> <li>"Absence of supplies, for example, makes it harder."</li> <li>"Everything is so spread out that you have to leave to get supplies and leave your patient."</li> <li>"There are sometimes where it's difficult to meet the 15-sec timeframe."</li> <li>"If your assignment is not super busy, then you have a lot of time to spend in somebody's room doing everything exactly the way you're supposed to, not cutting corners."</li> <li>"Like even opening the packages sometimes can be difficult."</li> <li>"Unless you have the packet open, ready to go, then you have to put it down, and then it's dirty, and then you're kind of starting over again."</li> <li>"Patient body habitus."</li> <li>"In a code, I think those are the scrubs that get missed."</li> </ul>
Culture	[Management] "They're very clear and very transparent when it comes to our infection rates." "In the MICU it is on our bulletin board. It'll say CLABSI rate for the month, or I want to say somewhere else. I read it. Maybe it's the email." "Data would be helpful but would not change what I do personally." "Don't know if we get the data on that [infection rates]. I couldn't tell you. We don't see it. Yeah, I know that our managers get that data." "If I see someone going to access the central line and I see they don't have a disinfectant in their hands. I'm immediately grabbing something and just handing it to the HCP." "Since COVID-19, we always have heard of CLABSIs and central line issues—I think we were getting more." "Our rate [CLABSI] went up, and we had to come up with a plan to address that issue."
Supplies	<ul> <li>"Finding supplies"—Patient care technicians "are supposed to restock Get product ourselves—It's easier."</li> <li>Not having product in the supply room: "Not sure who establishes par level.</li> <li> If you have a really sick patient, you might fly through stuff and then you're spending 20 minutes restocking your cart."</li> </ul>
Changing practice	"I'll state an unpopular opinion. Get rid of the caps so that people feel uncomfortable with lines being exposed forcing them to scrub the hub." "Bigger wipe with more saturation for better coverage." "Shortened time for scrub the hub." "Limit the frequency of scrubbing."

requirements for IPA wipes. For IPA wipes, some participants stated required scrubbing times of 15 s, and others provided times ranging from 3 s to 10 s. In addition, there was uncertainty about the requirement and time for alcohol drying before needleless-connector access.

To meet the disinfection and drying times during access events, participants provided several strategies, including use of room clocks, watches, or simply counting to themselves. However, numerous participants did not use a strategy, or just guessed the proper duration.

Finally, participants expressed some confusion about the need to disinfect the needleless connector after removal of an alcoholimpregnated needleless-connector cap that was in place for <1 minute, and about situations when sequential needlelessconnector access events were necessary, which is defined in the hospital protocol.<sup>16</sup> Many participants stated that removing the IPA hub cap was sufficient disinfection and that no additional disinfection was required for sequential needleless-connector accesses.

## Facilitators and barriers

Accessibility of disinfection products was identified as an important facilitator, particularly when the product was available at the IV pole or in a standardized location within the room.

HCP workload created challenges with adherence to recommended practice, especially when caring for patients with high acuity, as well as the overall busyness of the unit. Additional barriers included difficulty opening product packaging, the physical complexity of manipulating the needleless connector to prevent contamination, difficult needleless-connector access with large body-habitus patients, and during resuscitation efforts.

#### Culture

Participants were aware of ongoing patient safety discussions regarding CLABSI rates, and the focus on CLABSI reduction. CLABSI rate data dissemination at the unit level contributed to awareness, however, not all participants were aware of efforts to share these data. In addition, participants questioned whether availability of data would result in behavior change.

Another aspect related to culture was the perceived shared goal of supporting each other regarding CLABSI prevention and needleless-connector disinfection.

Finally, several participants pointed out that the COVID-19 pandemic had a negative impact on CLABSI prevention efforts due to the higher workload and movement of infusion pumps into the hallway.

#### **Supplies**

Among the facilitators promoting recommendation adherence was product availability at the bedside. Lack of product created a barrier to adherence, especially when patients were in isolation precautions or when the unit layout required long walking distances to obtain supplies.

## Changing practice

Practice changes that would improve needleless-connector disinfection practice focused on improving workflow by reducing scrubbing duration and frequency. In addition, the size of the wipes was too small. The introduction of alcohol-impregnated caps may have led to a false sense of safety, eroding the practice of needlelessconnector disinfection. Also, the need to place alcohol sanitizer and gloves on the IV pole as gloved hands may have been contaminated by performing other interactions with the environment and not changed before needleless-connector disinfection. Participants felt that product innovation, such as adding color to the disinfectant that revealed a change when drying was achieved, would promote practice. Visual reminders to perform needlelessconnector disinfection, rather than more education, was cited as a promoter of best practice.

## Discussion

The results of this study suggest that disinfection time for needleless connectors was less than recommended, with the larger discordance when using IPA wipes, whereas the use of CHG/IPA wipes resulted in smaller practice deviations. Importantly, most HCPs know about the manufacturers' instructions for use or hospital policy; however, when faced with time-challenged and/or high acuity workloads, they may reduce needleless-connector disinfection time, resulting in a greater risk for BSI/CLABSI. Using a product that will allow for faster disinfection may reduce the impact of time-challenged and/or high-acuity workloads on practice adherence. Our observations support the need for ongoing education and periodic competency evaluation of needlelessconnector disinfection to imbed and sustain best practice in accordance with manufacturers' instructions for use and/or hospital policy.

An interesting finding of the focus groups was the contribution that alcohol-impregnated caps made on adherence to needlelessconnector disinfection. The use of caps with a recommended contact time for disinfection (>1 minute) and need for repeated needleless-connector disinfection following sequential access events, led to HCP confusion and practice deviations.

Overall, the observed deviations from manufacturers' instructions for use or hospital policy for needleless-connector disinfection raise the potential risk of BSI and CLABSI, and efforts are required to reduce this adverse outcome risk for patients. Auditing and optimizing both needleless-connector scrubbing and drying times, visual reminders, workload management and bedside supply management are efforts that will promote needleless-connector practice adherence.

Although the data generated from these observations are susceptible to confounding by a Hawthorne effect,<sup>17</sup> it is concerning that the observed needleless-connector disinfection practices were consistently suboptimal and deviated significantly from the recommended manufacturers' instructions for use or the hospital policies for needleless-connector disinfection. As revealed by the focus groups, some HCPs performing needleless-connector disinfection had an incomplete understanding of the importance and proper application of the recommended practice.

This study had several limitations. The relatively small sample size did not allow for a generalizability of our results outside ICU or teaching-hospital settings. As a result, future work should include an additional range of hospitals and geographic areas, allowing for an increase in observations of needleless-connector access events and focus-group participation. The goal of this expanded work would be the development of national guidelines for best practices regarding needleless-connector access. The direct observations of needleless-connector disinfection were conducted in an inpatient care setting during routine daily care and therefore were not able to be blinded. Nursing staff were aware that the investigator was observing infection prevention practices and behaviors. In addition, participation was voluntary, which may have contributed to a self-selection bias. The strengths of this study include the performance of the study across multiple inpatients units at 2 academic medical centers, and the use of accurate time measurements to determine disinfection times.

In conclusion, needleless-connector disinfection products requiring longer scrubbing and drying times may be associated with greater nonadherence compared with products requiring more abbreviated scrubbing and/or drying durations. Compliance with scrubbing and drying requirements may be improved by ensuring (1) point of care availability of the antiseptic product, (2) staff are knowledgeable about product use, and (3) staff understand the implications of noncompliance with needlelessconnector disinfection. Additional research is required to confirm these findings and determine whether they are generalizable to other clinical settings.

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