

Successful Disinfection of Needleless Access Ports: A Matter of Time and Friction

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Abstract

Background: There is controversy as to whether the design of the needleless access port or the method used to clean it prior to access impacts successful disinfection. The authors studied the disinfection effectiveness for needleless access ports. **Method:** The ports of 4 models of needleless access ports were inoculated with bacteria. The ports were disinfected for 15 seconds with 70% alcohol alone or 3.15% chlorhexidine/70% alcohol (Chlorascrub, PDI, Orangeburg, NY). Saline flush solutions were collected and cultured. **Results:** Disinfection with either 70% alcohol alone or with 3.15% chlorhexidine/70% alcohol for 15 seconds was effective. **Conclusions:** All models of needleless access ports were effectively disinfected using these two methods.

It is estimated that 250,000 episodes of central venous catheter-related bloodstream infection (CRBSI) occur annually in U.S. hospitals; these infections have an estimated additional cost of \$25,000 per episode and an attributable mortality as high as 25%.¹ Quality improvement organizations have used the U.S. Centers for Disease Control and Prevention's (CDC's) CRBSI prevention guidelines as the foundation of their quality improvement initiatives.^{2,3} Most of the recommended guidelines address catheter-site preparation, catheter insertion, and care and maintenance of the insertion site.^{1,4} Despite impressive gains in the reduction of insertion-related CRBSIs,^{3,5} they continue to occur later in the indwelling period of the central catheter.^{6,9} Observation of nursing practices prior to accessing needleless access ports (NAPs) vary greatly in the amount of contact time used with the disinfectant.

An observational study in one institution determined that approximately 31% of health care workers did not disinfect the ports prior to access.¹⁰ The duration of cleansing and the degree of friction that was used were not further specified. The CDC Guideline for Prevention of CRBSI recommends wiping the access port with 70% alcohol or an iodophor, but there is no recommendation as to the amount of time needed for disinfection to be effective.¹ In 2005, the Child Health Corporation of America provided its members a CRBSI reduction strategy that included a 30-second scrub of the port prior to access as part of their change package to reduce CRBSIs. A recent study demonstrated that disinfection with 70% alcohol alone for three to five seconds was not effective in sterilizing access ports that were

inoculated with bacteria.¹¹

There are sporadic reports of institution-specific increases of CRBSIs temporally related to the introduction of NAP access ports.^{6,9,12,13} Given the absence of data, it is difficult to ascertain the role the individual design of each NAP plays in CRBSI when there is so much individual variability in practices of disinfecting the membranous septum before accessing.

Chlorhexidine/alcohol has been shown to be more effective in preventing CRBSI antisepsis compared with alcohol alone for skin antisepsis.¹⁴ It was shown to be an effective NAP disinfectant when contained in an antiseptic-barrier cap.¹¹ In 2006, chlorhexidine/alcohol on a pledget (Chlorascrub; PDI, Orangeburg, NJ) became available, providing another disinfectant option to consider for use prior to NAP access.

Consequently, there remained many questions regarding best practice for those responsible for drafting policies on maintenance care of central catheters. Therefore, a study to compare the efficacy of 70% alcohol alone versus 3.15% chlorhexidine/70% alcohol (Chlorascrub; PDI, Orangeburg, NY) as a disinfectant before access was conducted, using recommendations provided by vascular access professionals of cleansing for 15-20 seconds. Additionally, to enhance growth of any microorganisms that remained in the internal fluid path of the NAPs, a standard hyperalimentation solution was instilled (20% hypertonic glucose, fat emulsion, amino acids) and then incubated for 24 hours, followed by quantitative culture of the flushed downstream solution.

Method

A standard 0.5 MacFarland suspension (10^5 colony forming units [CFU]) in a brain-heart infusion (BHI) broth of *Staphylococcus epidermidis* (ATCC 12228), *Staphylococcus aureus* (ATCC 29213), *Pseudomonas aeruginosa* (ATCC27853), and *Candida albicans* (ATCC66027) was used to inoculate the mem-

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branous septa of 25 of each NAP model and allowed to air dry for 18 hours. These microorganisms were chosen because they are frequently implicated in CRBSI. The inoculation size used was based on methods cited in a previous report.¹¹ Four NAPs from three manufacturers were selected for the study: Smartsite (Alaris, San Diego, CA; negative displacement), Smartsite Plus (Alaris; positive displacement), CLC2000 (ICU Medical, San Clemente, CA; positive displacement), and BD Q-syte™ (Becton-Dickinson, Franklin Lakes, NJ; neutral displacement).

Although 10⁵ CFU of all four organisms were in the initial inoculum, *C. albicans* was not recovered from any of the positive control agar plates. We postulate that *C. albicans* was unable to grow competitively in the presence of 10³ *S. aureus*, *S. epidermidis*, and *P. aeruginosa*. To determine if the disinfection process was effective against *C. albicans*, a 0.5 MacFarland inoculum of *C. albicans* alone was substituted for the bacterial suspension and the protocol repeated.

After the membranous septa were inoculated and allowed to air dry for 18 hours, 20 access ports of each NAP model were disinfected for 15 seconds with 70% alcohol alone or 3.15% chlorhexidine/70% alcohol pledgets using friction (twisting motion). Then, the access ports were flushed with 0.5 ml of 0.9% sterile nonbacteriostatic saline (NS; Westcon Medical Industries, Concord, CA), and the flush was collected downstream from the access port for quantitative culture onto a sheep-blood agar plate and incubated at 35°C/CO₂ for 48 hours.

To encourage the growth of any microorganisms that remained in the internal fluid path of the NAPs, 10 ports of each model, after the initial flush, were injected with 1 mL of hyperalimentation solution (20% hypertonic glucose, fat emulsion, amino acids) and allowed to remain at room temperature for eight hours. Ten ports of each type were not exposed to hyperalimentation fluid.

After eight hours of incubation, all 20 membranous septum of the access ports from each model were disinfected for 15 seconds using either 70% alcohol alone or chlorhexidine/alcohol and then flushed with NS solution that was collected downstream from the access port for quantitative culture. After the NS flush, the same 10 NAPs of each model that were instilled with hyperalimentation solution were again flushed with 1 mL of hyperalimentation fluid and incubated for an additional 16 hours.

To determine if chlorhexidine/alcohol provided for a 24-hour residual antiseptic activity, as described in studies on skin antiseptics,¹ the entire process was repeated again at 24 hours. All 20 NAPs from each model were disinfected for 15 seconds with 70% alcohol alone or chlorhexidine/alcohol and then flushed with 0.5 ml of NS solution. The flush was collected downstream from the access port for quantitative culture, incubated at 35°C/CO₂ for 48 hours.

Negative Controls

Five sterile NAPs from each model were flushed with 0.5 ml of NS solution at Time 0 hours and again at 24 hours after the initial flush and collected downstream for quantitative culture.

Positive Controls

Five access ports from each NAP model were inoculated, air dried overnight, accessed, and flushed with 0.5 ml of NS solution at Time 0 (after 18 hours of incubation) and again at 24

hours and collected downstream for quantitative culture.

Results

All inoculated access ports that were not disinfected (positive control) grew 10³ organisms (*S. aureus*, 400-500 CFU; *S. epidermidis*, 400-500 CFU; and *P. Aeruginosa*, 50-100 CFU) and, separately, 100 CFU of *C. albicans* when only the yeast was inoculated onto the access ports. The microorganisms were recovered in similar numbers when the NS flush was cultured at Time 0 and at 24 hours after the inoculum was allowed to air dry for 18 hours.

The flushes from sterile access ports that were not inoculated (negative control) did not grow any microorganisms. No microorganisms were recovered from any of the access ports that were disinfected for 15 seconds with either alcohol alone or chlorhexidine/alcohol. This also was true of all the access ports that were flushed with hyperalimentation solution and allowed to dwell for 8 and 16 hours.

Discussion

The efficacy of various disinfectants and duration of exposure time needed to disinfect access ports have not been studied adequately. Previous disinfection attempts using 70% alcohol alone for three to five seconds was not shown to be effective in sterilizing access ports that were inoculated with bacteria.¹¹ This study provided evidence that when access ports are subjected to a disinfection time of 15 seconds with friction, alcohol alone or chlorhexidine/alcohol is equally effective in sterilizing NAP ports inoculated with a 10⁵-CFU suspension of microorganisms, regardless of whether the NAPs were constructed using positive, negative, or neutral displacement technologies. It was observed that the membranous septum becomes “sticky” when chlorhexidine/alcohol is used as the disinfectant; whether continued use may result in a residue build up and make continued accessing difficult is unknown.

Limitations of our study include the applicability of such in vitro observations to clinical settings. This study did not provide information as to whether blood products in the ports would have represented an additional risk that would be permissive to replication of the microorganisms. Furthermore, it remains to be determined whether the access ports in the study would have the continued resilience and structural integrity after being accessed numerous times during the provision of care.

Many strategies to prevent CRBSIs have been promulgated by various organizations,^{1,4} but the focus has been on insertion. Because a number of CRBSIs occur late in the indwelling period and the hub becomes contaminated with continued use (which may introduce microorganisms into the lumen of the catheter), is urged the inclusion of appropriate disinfection of the membranous septum before access and appropriate site maintenance as part of a comprehensive program to decrease the risk of CRBSIs.

Disclaimer

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Intermittent Intravenous Administration Sets: Survey of Current Practices

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Abstract

The practice of using intravenous (IV) administration sets for intermittent infusion is subject to much controversy and there is no scientific data to validate the practice. To get an idea of this practice, an online survey was sent to approximately 4000 nurses, with 361 responding. The results highlight the vast differences in practice between the clinical settings of the available studies and how these sets are currently used. Although no recommendations for practice can be drawn from these data, they emphasize the urgent need for research on the use of intermittent administration sets and their contribution to the incidence of catheter-related bloodstream infection.

The frequency for changing intravenous (IV) administration sets is a controversial issue. When the studies are examined closely, more questions arise about the application of that data to clinical practice. The majority of questions focus on administration sets used for intermittent medication infusion.

In December 2006, Lynn Hadaway Associates, Inc., Milner, Georgia, conducted an online survey of nurses concerning how intermittent sets were used and how they were managed between uses. Although this was a convenience sample and not a scientific sample, the responses revealed a definite need for more clinical studies on this issue and more attention to the methods used to manage these administration sets.

Current Evidence About Administration Sets

A nationwide epidemic of intrinsic fluid contamination in 1971 prompted the U.S. Centers for Disease Control (CDC) to recommend that all administration sets be routinely changed every 24 hours.¹ Over the next 30 years, several studies demonstrated that extending the life of the administration set did not increase the risk of bloodstream infection. The life of a set was extended to 72 hours,^{1,2} whereas others found the optimal change frequency was 96 hours,³ and still others recommend extending set use to seven days.^{4,6}

In 2002, the CDC's *Guidelines for Prevention of Intravascular Device-Related Infections* stated, "Replace administration sets, including secondary sets and add-on devices, *no more frequently than at 72-hour intervals*, unless catheter-related infection is suspected or documented" (italics added). This was given the highest rating of Category 1A or strongly recommended for implementation.⁷ This allows health care facilities to choose an

extended period for using these sets. The authors of these guidelines did not make any attempt to distinguish among the varieties of ways administration sets are actually used.

The published studies have examined administration sets connected to the catheter hub for the infusion of continuous fluids. A study by Maki et al described IV medications being given in syringes or in small-volume infusions attached to the primary set and diluted with the backfilling or backpriming method, thus indicating that all sets remained connected. This study collected data on the purpose of the infusion, types of containers and solutions, all additives to the containers, medications injected into the administration sets, and the number of hours that the set was in continuous use.¹ Raad et al conducted a randomized study in a university-based cancer center.⁴ The collected data were very similar to the data collected by Maki, described above. Raad did not provide details about medication administration, listing "infusate variables" as antibiotics, anticoagulants, chemotherapy, and total parenteral nutrition (TPN). Gillies et al conducted a systematic review of 12 studies on administration sets. A table of these studies provided exclusion criteria, with one study excluding "heparin locks" and another study excluding "disconnection of the set without sterile gauze coverage for > 4 hours."² In the study by Rickard et al, aseptic technique was used when changing sets and "disconnection sites were decontaminated with chlorhexidine."⁵

Several studies have included oncology and critical care patients and stressed the high risk for infection in these groups. Most study criteria included TPN, lipids, and lipid-based medications, along with data for central and peripheral catheters.

The one element that is missing from these studies is the use of administration sets on an intermittent basis. The Infusion Nursing Society's *Standards of Practice* defines *intermittent IV therapy* as being "administered at prescribed intervals with periods of infusion cessation."⁸

Through the years, infusion nurses have made many attempts to enhance patient comfort with infusion therapy, including the

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ability to move about freely without being encumbered by connection to sets, fluid containers, and pumps. Toward that end, the use of intermittent IV therapy has greatly increased. In addition, the expansion of infusion therapy to alternate settings places a greater emphasis on intermittent rather than the continuous infusion more commonly seen in critical care settings.

In addition, the Infusion Nursing Society's *Standards of Practice* have always drawn a distinct difference between administration sets used for continuous infusion versus sets used for intermittent infusion. In the 2006 edition of these standards, the language for primary and secondary continuous set changes duplicated the language of the CDC guidelines: "no more frequently than 72 hours [emphasis added] and immediately upon suspected contamination or when the integrity of the system has been compromised."⁸ This standard is well supported by the studies already discussed.

These same studies did not provide any information about administration sets used for intermittent IV therapy. Therefore, the standard for changing intermittent sets has remained constant for the past 30 years, for changing at 24-hour intervals.⁸ Intermittent sets are manipulated on both ends with each use because a full fluid container replaces the empty one from the previous dose and the male Luer end of the set is connected to the catheter with each dose. This frequent handling increases the risk of contamination. For this reason and in the absence of studies demonstrating equal risk with longer use under these conditions, a conservative approach to the length of time intermittent sets are in use appears to be the safest approach to the issue.

Survey Process

A set of survey questions was designed and placed on an online survey service. In November 2006, an email message was sent to a group of 15 nurses from several specialties requesting that they complete the survey, paying attention to anything that might be confusing or unclear within the structure of each question. Through this validation process, a few wording changes were made in the questions to enhance clarity.

An email message was sent to approximately 3000 addresses in our company database (Lynn Hadaway Associates, Inc., Milner, GA) with a message going to online listservs of nurses interested in infusion therapy, infection control, and staff development. This message requested participation in this online survey, and it was estimated that the message would reach approximately 4000 nurses in a variety of clinical settings. The survey was open for a three-week period, with 361 nurses completing it.

Survey Results

Participants in this survey came from 42 states in the United States and from 9 other countries, including Australia, Brazil, Canada, England, Scotland, Saudi Arabia, Singapore, Spain, and Sweden. The majority of respondents worked in a hospital setting; however, ambulatory care, home care, and long-term care

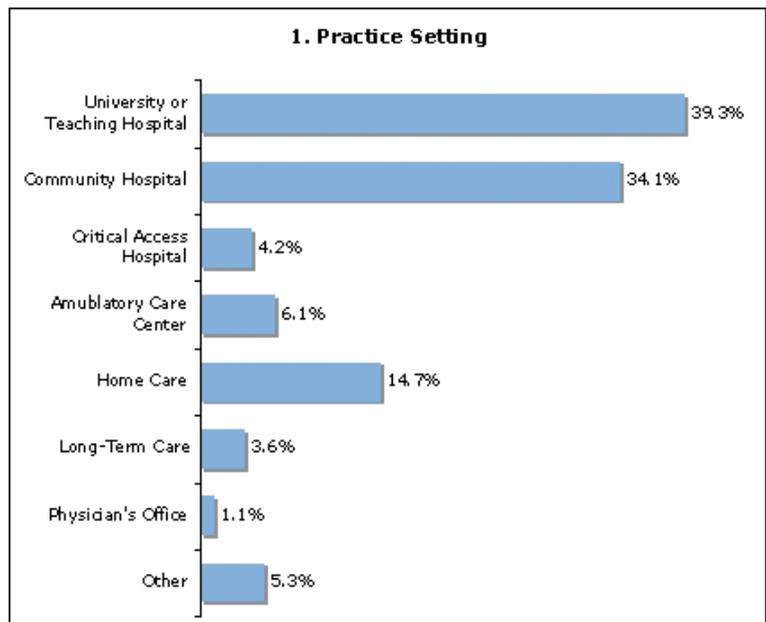


Figure 1. Practice Setting of Survey Respondents.

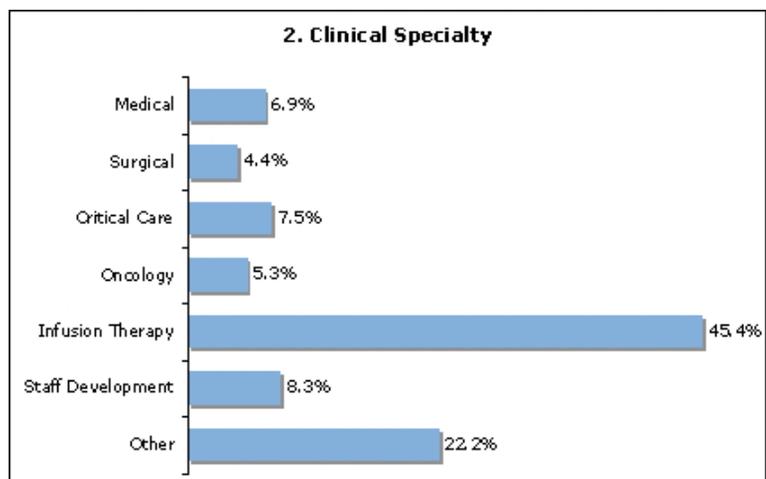


Figure 2. Clinical Specialty of Survey Respondents

nurses also participated (see Figure 1).

Almost half of the participants worked in infusion therapy (45.4%), with "other" being the second largest category (Figure 2), which included pediatrics and neonatal, vascular access or peripherally inserted central catheter (PICC) insertion, other critical care and emergency services, maternal or postpartum, nursing supervision, infection control, and educational services.

When giving intermittent IV medications with compatible continuous primary IV fluids, the most common practice (66.8% of respondents) was to leave the administration set for the intermittent medication connected to the primary continuous administration set for use with the next dose. Only 16.6% reported disconnecting and reconnecting the intermittent medication set with each dose. Among the remaining 16.6% of respondents, prac-

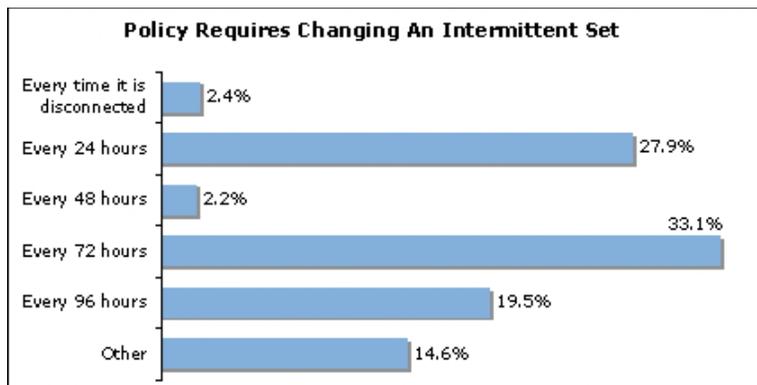


Figure 3. Change Intervals for Intermittent Sets

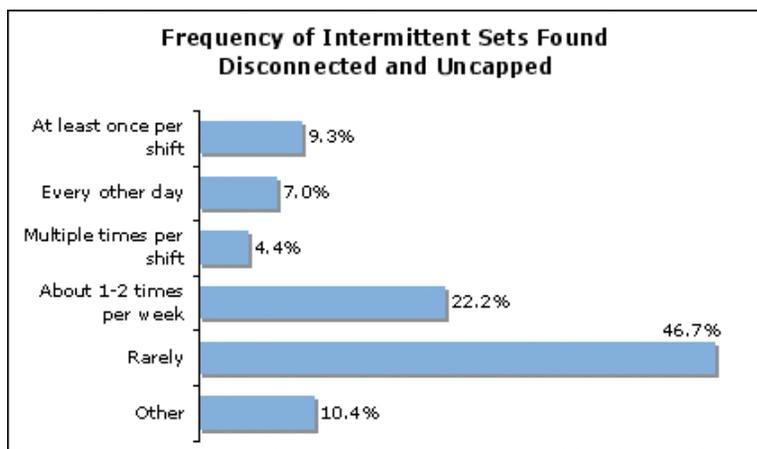


Figure 4. Frequency of Intermittent Sets Found Disconnected and Uncapped

tices differed among nursing units, from one nurse to the next, and with varying circumstances (eg, when more than one intermittent medication must be administered, when syringe pumps were used, or depending on the frequency of intermittent doses).

The use of “carrier” fluids, usually 0.9% sodium chloride, was a common practice, chosen by 60% of the respondents. Intermittent medications may be piggybacked into carrier fluids, thus allowing the nurse additional time when the intermittent medication has infused. Of those who answered affirmatively to using carrier fluids, 39% reported that these fluids remained connected to the patient between intermittent doses, and 35% disconnected the carrier fluid when the medication dose is complete. The remaining 26% checked “other,” with the decision to connect or disconnect depending on nurses’ preference, the presence of primary continuous fluids, or the health care setting.

Sixty-two percent (62.3%) reported that they disconnect primary continuous infusions from the catheter hub for some period of time. Typical reasons for disconnecting the continuous infusion included allowing patients to shower (75.7%) or to allow for ambulation (47.1%). Allowing playtime for children and eating were the third and fourth reasons for disconnection. Other reasons included transportation to other departments, various

types of therapy or other procedures, elimination of the pump while having magnetic resonance imaging (MRI), laboratory draws, blood transfusion, infusion of incompatible medications, and troubleshooting problems with the catheter.

The length of time that primary continuous fluids were temporarily disconnected ranged from a few minutes to unlimited periods. The largest percentage (29.3%) reported that the temporary disconnection may be unlimited, and 22.9% said that 30 minutes was the maximum. Only a few nurses wrote notes that this should never be done, and a few more indicated that it was dependent on physician orders. Most written comments indicated this was a nursing decision that was based on the needs of the patient. When asked about the presence of a policy addressing the disconnection of primary fluids, 76.2% reported that no policy was available. When written policies for this situation were available, they focused on maintaining the sterility of the tubing while disconnected, appropriate reasons for disconnection, and patient identification and proper procedure for reconnecting.

According to the survey, organization policies varied widely on the time periods required for changing an intermittent set. The largest percentage reported change intervals every 72 hours (33.1%). The smallest percentage (2.4%) reported their policy is to change an intermittent set every time it is disconnected. Another 2.4% said they were required to change intermittent sets every 48 hours (Figure 3).

Slightly more than half (52%) of respondents said that their organizational policies and procedures did not include instructions for the management of the male Luer end of the administration set. Those responding favorably (48%) were asked to provide information about the components of their policy. The overwhelming majority included the need for opening a new sterile end cap or blunt plastic cannula, applying it to the end of the administration set, and leaving the paper wrap on it as an indicator to the next nurse that it had been changed. Others wrote about avoiding the practice of connecting the male Luer end of the set to another injection port on the same set.

Two hundred and eighty-nine participants answered the question, “Is there ever a need to clean the tip of the male Luer end of the administration set with a disinfecting agent?” One hundred and twenty-six (43.6%) responded yes, whereas 163 (56.4%) answered no. An alcohol swab was the disinfectant chosen by 82.6%. Gauze soaked in chlorhexidine or a chlorhexidine swab was chosen by less than 10%. Several participants commented that if the set was contaminated, it should be changed rather than cleaned.

The next question was open ended and asked respondents to describe when the male Luer end of the intermittent set should be cleaned. There were 122 responses and all were easily categorized in four groups. Sixty (49%) indicated that the male Luer end of the set should be routinely cleaned with each connection and disconnection to the catheter. Accidental contamination such as touching the tubing on clothing or linens, or even dropping it

Discussion

on the floor, was the response from 21 (17%). Another 20 (16%) of respondents indicated that the presence of blood in or on the set required cleaning. Last, 21 (17%) respondents wrote that there was never an indication to clean the set, but that it should be discarded. The written responses from some participants signified that the question may have been misinterpreted, as a few responses seemed to be referring to the connection surface on the needleless connector rather than the actual administration set.

The open-ended question of the action(s) that should be taken if blood was found on the outside of the male Luer end of the administration set produced responses in two major categories. The majority of participants—119 of 265 or 45%—provided strong comments about replacing the entire administration set, whereas an additional 4% stated they would replace the Luer-locking threads, extension set, or any component contaminated with blood. One hundred and thirteen (42.6%) chose cleaning the external side of the set, and many wrote complex steps to wick the blood out of Luer-locking threads with antiseptic pads. Alcohol and chlorhexidine were both included as antiseptic agents. Other actions included flushing the tubing or cleaning with alcohol and flushing. Some of these 113 respondents indicated that the action would depend on the amount of blood, the location of the blood, or the length of time it had been on the tubing.

The action that would be taken if blood were found within the lumen of the male Luer end of the set produced such a variety of answers that we concluded that most respondents did not understand the question. The majority responded that they would flush the blood back into the catheter or vein if the administration set remained connected to the catheter. The question was trying to elicit their actions if an intermittent set was found to have blood back up into the lumen after it was disconnected from the catheter.

More than 90 percent of respondents acknowledged that they have observed IV sets used to administer intermittent medications left disconnected and uncapped. Although the largest percentage said it happened “rarely,” a surprising number said that it happened at least once or twice a week. Of the 91.3% of respondents who said they had found intermittent sets disconnected and uncapped, nearly half (47.7%) said it occurred “rarely.” Still, a significant percentage reported that it occurred about one to two times per week (22.2%), and another 9.3% reported incidences “at least once per shift” (Figure 4).

Furthermore, nurse respondents reported an extreme range of experience when asked, “Out of 100 sets used for intermittent IV infusion, what would be your estimated percentage of those left uncapped after disconnection?” Verbatim responses to the survey item ranged from “less than one percent” to “more than 90 percent.” Survey respondents were nearly unanimous, however, in reporting that the action taken when an uncapped and disconnected set was discovered, it was discarded and replaced with a new set.

Typically, a sterile tip cap is used to close the male Luer end of the administration set when disconnected from the needleless injection cap. The largest percentage of respondents (68.1%) said a sterile tip cap was used, whereas 31.2% reported using other sterile needleless components such as a blunt plastic cannula.

Clinical practice with administration sets differs greatly. Sets used for primary, continuous fluids may be temporarily disconnected for various time periods. Sets used when only intermittent medications are prescribed may be connected to carrier fluids or connected directly to the needleless connector on the catheter hub. Patients receive frequent intermittent therapy in a variety of alternative settings, and continuous connection to the administration set is inconvenient or even disruptive to their plan of care.

Virtually all research in the use of IV administration sets has focused on the acute or critical care setting, demonstrating that the extended use of these sets did not increase the risk of catheter-related bloodstream infections. Many of these studies have described the exclusion of catheters used for intermittent infusion therapy (eg, heparin locks). The use of gauze soaked in chlorhexidine gluconate solution to wrap around the set is also described; however, this is not common practice in the United States.

Our data show that administration sets used for primary, continuous infusion are disconnected for a variety of reasons and for varying lengths of time. This practice could be debated because continuous infusions may contain medications (eg, electrolytes, insulin, heparin), and temporary disconnection could alter the patient’s therapeutic outcomes. If these fluids do not contain any medications and the patient can be maintained without this infusion for a certain period of time, is there truly a clinical indication for the fluid at all? Can the fluids be stopped and the catheter used for only intermittent medications such as antibiotics?

The use of a carrier fluid does not address the issue of how to manage the male Luer end of the administration set. Although the medication administration set may remain connected to the set used for the carrier fluid, the primary set for the carrier fluid may be disconnected from the catheter hub when the intermittent medication has infused.

The majority of nurses responding to this survey categorized their clinical practice as infusion therapy. This group would be expected to pay closer attention to the details of managing administration sets, and this could account for the majority that emphasized discarding any administration set if there is any question of contamination.

Clearly, there is no prevailing consensus on the frequency for changing an intermittent set. More than 40% of respondents in our survey believed that there were times when it was appropriate to clean the male end of the administration set, yet there is no scientific evidence that supports this practice. In addition, comments describing cleaning rituals based on the length of time blood was in or on the administration set, the location of the blood, or the amount of blood are not supported by research.

All respondents reported having found administration sets disconnected and uncapped, although their estimates of the frequency varied greatly. However, this does raise the issue of how these sets should be handled for the next dose of medication: cleaned and then connected, connected without cleaning, or discarded and replaced?

Data on the number and types of microorganisms that can be isolated from the male Luer ends of intermittent administration sets are not available. How frequently are these sets contaminated but still in use?

There is mounting concern that needleless injection devices or needleless connectors may be increasing the risk of bloodstream infection. The design of these devices and the nursing practices of cleaning these devices before use are the focus of much attention, research, and serious discussion. However, the needleless devices are only one piece of the entire system.

Intermittent infusion therapy is a prevalent method for administering fluids and medications in all clinical settings. There are vast differences in how intermittent administration sets are handled between users and the length of time they are used. The absence of data should raise serious concern that these factors may be overlooked as propagators of catheter-related bloodstream infections.

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