

Bloodstream Infection Associated with Needleless Device Use and the Importance of Infection-Control Practices in the Home Health Care Setting

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The influence of infection-control practices on bloodstream infection (BSI) risk was examined in a home health care setting in which three needleless devices were used consecutively. A case-control study and a retrospective cohort study were conducted. Risk factors for BSI included lower education level, younger age, having a central venous catheter (CVC) with multiple ports, or having a tunneled CVC. Among patients with a tunneled CVC, those at greatest risk had been allowed to shower rather than bathe and to get their exit site wet ($P < .01$). A high proportion (49%) of isolates were hydrophilic gram-negative bacteria, suggesting water sources of infection. In the cohort study, the BSI rate decreased as the frequency of changing the needleless device end cap increased from once weekly up to every 2 days, suggesting that the mechanism for BSI may involve contamination from the end cap. These findings may help to develop infection-control measures specific to home health care.

Over the past few decades, efforts to contain rising medical care costs have resulted in considerable changes in the health care delivery system in the United States. Many types of medical care traditionally provided in the hospital may now be provided in the patient's home. The use of home health care (HHC) has become prevalent, with ~2.1 million Medicare enrollees receiving home care in 1990 [1]. From 1991 to 1992, spending on HHC increased ~30%, compared with 12% for hospital care [2]. Within HHC, home infusion therapy is the most rapidly growing component [3, 4].

As HHC expands, new challenges are emerging regarding the care of patients in a setting that is less controlled than the hospital setting. One challenge is developing effective infection-control measures, especially as new technologies or patient care practices are introduced into HHC. An example is the use of needleless intravenous (iv) access devices, which have been designed to reduce the risk of health care workers' occupational exposure to bloodborne pathogens. Although the potential benefits to health care workers have been shown [5–7], few data

are available to assess the potential risk of adverse effects to patients and how to minimize that risk.

Two previous outbreaks of bloodstream infection (BSI) in HHC patients have illustrated some problems that can occur as needleless devices are introduced into the HHC setting [8, 9]. In each of those outbreaks, BSI risks can be compared only between one manufacturer's needleless device and the antecedent needle device. As a result, the focus of concern has been on the BSI risk intrinsic to the needleless devices rather than on the infection-control practices used with these devices. To evaluate the influence of infection-control practices on BSI associated with the use of needleless devices in the HHC setting, we examined BSI risk factors and compared the BSI rates associated with the consecutive use of three different needleless devices at Coram Healthcare in Houston.

Background

In February 1994, Coram Healthcare was using the Clave (ICU Medical, Irvine, CA) needleless device (figure 1). Because of an increasing number of reports regarding iv fluid leaking through the Clave device, it was discontinued, and the Safsite device (Braun Medical, Bethlehem, PA) was introduced at the end of May 1994. Several weeks after the introduction of the Safsite device, reports of BSIs increased, with a high number of BSIs due to hydrophilic gram-negative bacteria. However, an extensive culture survey of iv flushes and infusates failed to document intrinsic or extrinsic contamination. In response to the increased number of BSIs, some of the Coram nurses began instructing their patients to change the needleless device end cap more frequently. In November 1994, the Safsite device was replaced by the Interlink device (Baxter, Deerfield, IL). Because of continued concerns about the association of BSIs with the

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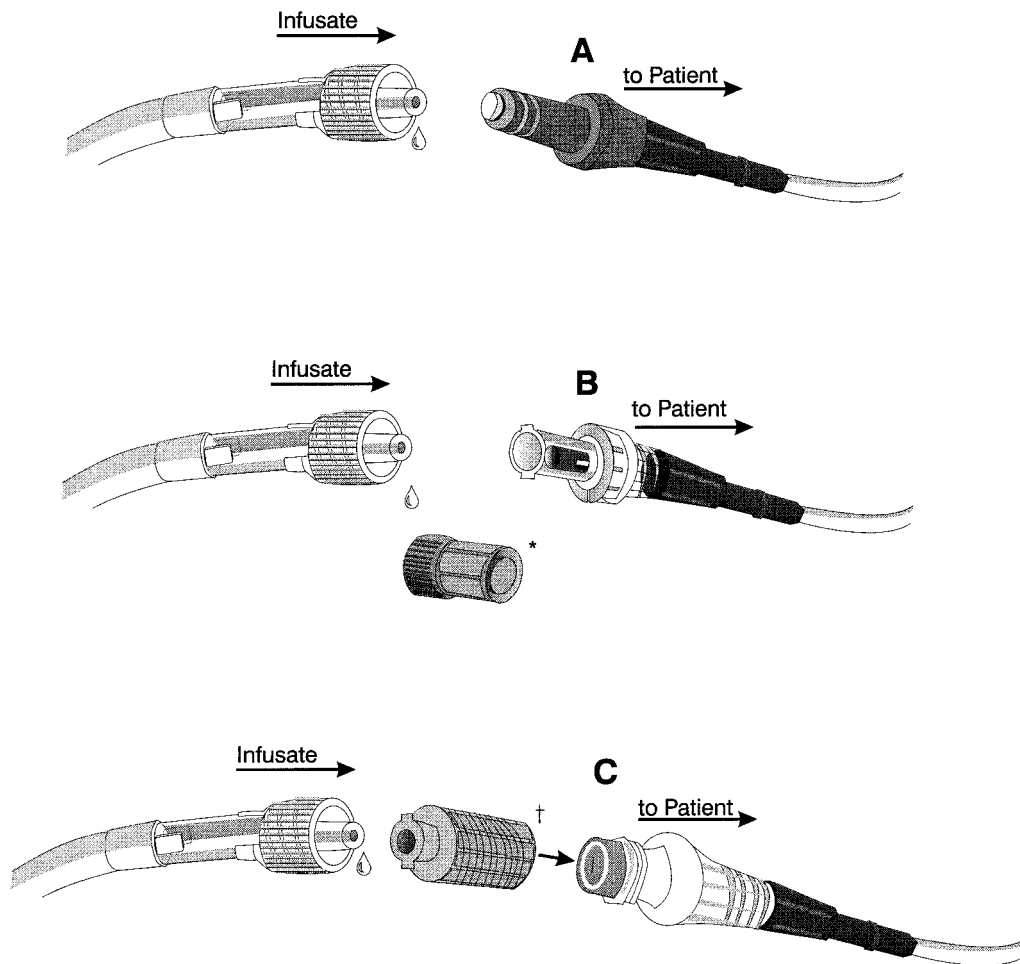


Figure 1. Needleless device end caps and attachments, Coram Healthcare, Houston, February 1994–April 1995. *A*, Clave end cap; *B*, Safsite end cap with *protective cover; *C*, Interlink end cap with †blunt cannula (adapter for continuous infusion).

use of needleless devices, the Centers for Disease Control and Prevention and the Texas Department of Health were asked to assist in an epidemiologic investigation. The objective of the investigation was to identify risk factors for BSI in this HHC setting.

Patients and Methods

Definitions. A case-patient was defined as a Coram Healthcare patient with a central venous catheter (CVC) or midline catheter who acquired a primary BSI during the study period, February 1994 through April 1995. Primary BSI was defined as the presence of clinical sepsis (one or more of the following signs or symptoms: temperature $\geq 38^{\circ}\text{C}$, subjective fever and chills, or systolic blood pressure < 90 mm Hg) in association with a positive blood culture, receipt of iv antimicrobials in response to the episode, and no apparent focus of infection. The association with HHC was defined

as the receipt of care from Coram Healthcare for ≥ 3 days before onset of a BSI.

Case ascertainment. To ascertain potential case-patients, we reviewed patient reports provided by private physicians, positive blood culture results from microbiology laboratories, and pharmacy records of iv antimicrobials used during the study period. Medical records were reviewed to determine if potential case-patients met the case definition.

iv catheter-days. Because the dates of insertion and removal of CVC or midline catheters were not readily available, the number of iv catheter-days was estimated by reviewing billing records and determining the number of days patients were charged for iv catheter supplies (e.g., dressing kits, flushes, iv medications, total parenteral nutrition) during the study period.

Procedural review. The iv therapy policies and practices at Coram Healthcare were assessed by interviewing the nursing supervisor and field nurses, observing infection-control practices, and reviewing the organizational policies and written instructions given to patients.

Table 1. Comparison of potential risk factors for primary BSIs, Coram Healthcare, Houston, February 1994–April 1995.

Potential risk factor	Case-patients (n = 53)	Control-patients (n = 71)	Odds ratio (95% confidence interval)	P
Categorical variables				
Sex (male)	26 (49)	31 (44)	0.8 (0.4–1.8)	.7
Chronic renal disease	3 (6)	2 (3)	2.1 (0.3–18.8)	.7
Only one caregiver	25 (47)	38 (54)	0.8 (0.4–1.7)	.6
Diabetes	6 (11)	5 (7)	1.7 (0.4–6.9)	.5
Race (not Caucasian)	16 (30)	14 (20)	1.8 (0.7–4.4)	.3
Human immunodeficiency virus	15 (28)	12 (17)	1.9 (0.8–5.1)	.2
Malignancy	14 (26)	28 (39)	0.6 (0.2–1.3)	.2
Educational level (<college) ^a	22 (47)	18 (27)	2.4 (1.0–5.7)	.05
Central venous catheter ≥2 ports ^b	18 (69)	31 (44)	3.5 (1.1–11.6)	.03
Continuous variables				
Duration of home health care, days ^c	43 (4–783)	61 (11–822)	—	.3
Age, years	42 (12–74)	46 (11–78)	—	.04

NOTE. Data for categorical values are no. (%) and for continuous variables are median (range).

^a Information available for 114 patients (47 case-, 67 control-patients).

^b Information available for 67 patients (26 case-, 41 control-patients).

^c From start of home intravenous therapy until BSI (for case-patients) or until end of therapy (for control-patients).

Case-control study. To determine the risk factors for HHC-associated primary BSI, we conducted a case-control study. Control-patients were randomly selected from 961 Coram Healthcare patients with a CVC or midline catheter who did not acquire a BSI during the study period. Data collected included patient demographics, educational level, underlying diagnoses, primary caregivers at home, type of and reason for the iv catheter, the length of time receiving HHC, instructions given to the patients regarding bathing or showering practices, and the type and duration of each needleless device used.

Cohort study. To examine the secular trends of BSI during the study period, we conducted a cohort study to determine the BSI rate during each period after an alteration was made either in the type of needleless device used or in the frequency the end cap was changed. To determine rates, we calculated the number of BSIs per 1000 iv catheter-days.

Statistical analysis. Univariate analysis was done with Epi Info 6.03 [10]. Categorical variables were compared by the likelihood ratio χ^2 or Fisher's exact test; continuous variables, with the Wilcoxon rank sum test; and BSI incidence rates, with the *z*-distribution as a large-sample test [11]. Multivariate analysis was done by stepwise logistic regression on PC-SAS [12]. For the models in our multivariate analysis, we selected variables that were significantly associated with BSI ($P \leq .05$) in the univariate analysis.

Results

Case-patient characteristics. We identified 53 case-patients with 65 BSI episodes during the study period. Some of the characteristics of the case-patients can be seen in table 1. In

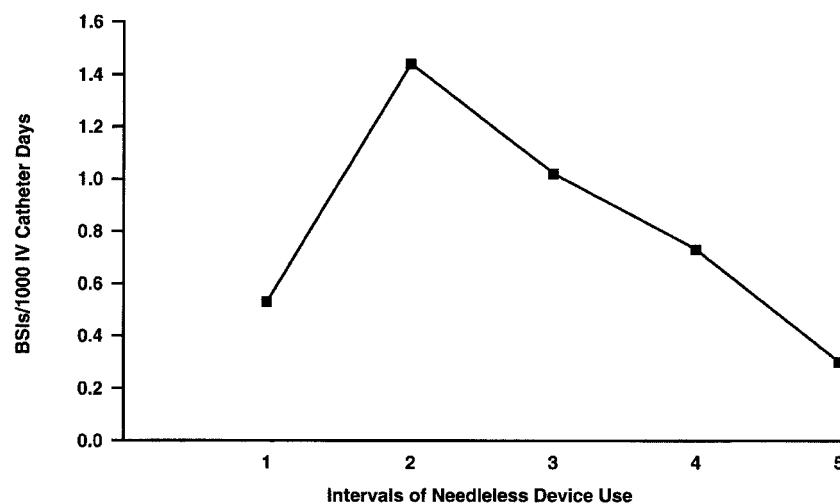


Figure 2. BSI rates during different intervals when needleless devices were used, Coram Healthcare, Houston: 1, Clave device with end cap change twice per week (February–May 1994); 2, Safsite device with end cap change once per week (June 1994); 3, Safsite device with end cap change twice per week (July–August 1994); 4, Safsite device with end cap change every 2 days (September–October 1994); 5, Interlink device with end cap change every 2 days (November 1994–April 1995).

Table 2. Comparison of risk for BSI by intravenous catheter type, Coram Healthcare, Houston, February 1994–April 1995.

Catheter type	Case-patients (n = 53)	Control-patients (n = 71)	Odds ratio (95% confidence interval)	P
Central venous catheter (CVC) with implanted ports	4 (8)	8 (11)	3.3 (0.4–34.1)	.6
Peripherally inserted CVC	10 (19)	20 (28)	3.3 (0.5–26.0)	.3
Tunneled CVC (overall)	24 (45)	12 (23)	13.0 (2.2–100.0)	<.01
Instructed not to shower ^a	2 (4)	5 (9)	2.6 (0.2–39.0)	.6
Allowed to shower ^a	13 (25)	6 (11)	14.1 (2.0–130.4)	<.01
Midline	2 (4)	13 (19)	Reference ^b	Reference ^b
Other/unknown	13 (20)	18 (34)	4.7 (0.8–36.2)	.1

NOTE. Data are no. (%).

^a Instructions on showering unknown for 10 patients with tunneled CVC (9 case-patients and 1 control-patient).

^b Patients who used midline catheter served as reference for comparison with each other group shown.

addition, 35 case-patients (66%) were hospitalized at least once for BSI. For 12 case-patients who died (23%), the death was attributed to the underlying disease rather than to the BSI acquired during HHC.

Procedural review. Needleless device end caps were connected to the external end of the patient’s iv catheter (figure 1). Patients were instructed to wipe the end cap with alcohol before flushing or administering iv medications. During different time intervals, the end cap was changed with different frequency, varying from once per week up to once every 2 days (figure 2). Most of the alterations in the frequency of changing the end cap were made informally by individual nurses and, therefore, were not done uniformly and were not documented in medical records. However, the nurses reported that as the number of BSI increased, they felt increasingly inclined to have their patients change the end cap more frequently.

Except for patients with a tunneled CVC, those with other types of CVCs or midline catheter usually were advised to bathe instead of shower at home and were taught a sterile technique, which included wearing sterile gloves and, optionally, a surgical mask, during dressing changes. These patients were told to leave the dressing in place while bathing.

Patients with a tunneled CVC, in contrast, were allowed to take showers at home, once the insertion site was well-healed after catheter placement and if deemed appropriate by their physicians. These patients were not required to use a sterile technique to change their dressings and were permitted to remove the dressings while showering to wash around the insertion site with soap and water. All patients, regardless of catheter types, were told to keep their dressings dry and clean.

Case-control study. Case- and control-patients did not differ significantly by sex, race, presence of multiple caregivers at home, underlying illnesses, or duration in HHC until either the end of iv therapy (control-patients) or development of a BSI (case-patients). However, compared with control-patients, case-patients were significantly younger, less likely to have attended college, and more likely to have had a CVC with multiple (≥2) ports (table 1).

Compared with patients with a midline catheter, those with a tunneled CVC with an external port were more likely to have had a BSI (table 2). Among patients with tunneled CVCs, only

those who were allowed to shower at home had an increased risk for BSI. Patients with other types of iv catheter did not have an increased risk for BSI.

Compared with the Interlink device (table 3), the Safsite device was associated with an increased BSI risk. The Clave device also was associated with an increased BSI risk, but this association did not reach statistical significance.

In multivariate analysis, independent risk factors for BSIs were use of a tunneled CVC with external port (odds ratio [OR] = 4.5; *P* < .01) or use of the Safsite device (OR = 3.1; *P* < .01). Because the frequency of changing the end cap was not documented for individual patients, we could not assess its potential impact on the risk for BSI in the case-control study (univariate or multivariate analysis).

Cohort study. During the study period, 1014 Coram Healthcare patients accrued 98,483 iv catheter-days. The highest BSI rate was seen during the early Safsite period, when the end cap was changed only once per week (figure 2). The BSI rate decreased steadily as the end cap was changed more frequently, from twice per week (i.e., middle Safsite period) to every 2 days (i.e., late Safsite period). The lowest BSI rate was seen during the Interlink period, several weeks after the Coram nurses began instructing patients to change the end cap every 2 days. Compared with the BSI rate during the Interlink period (0.3 BSI/1000 iv catheter-days), the rates during the early Safsite period (1.4), the middle Safsite period (1.0), and the late Safsite period (0.7) were higher (*P* ≤ .01). The rate seen during the Clave period also was higher than that seen during the Interlink

Table 3. Comparison of risk for BSI by needleless device type, Coram Healthcare, Houston, February 1994–April 1995.

Needleless device ^a	Case-patients (n = 53) ^b	Control-patients (n = 71)	Odds ratio (95% confidence interval)	P
Clave	11 (21)	17 (24)	2.2 (0.7–6.5)	0.2
Safsite	41 (77)	31 (44)	4.5 (1.9–10.5)	<0.01
Interlink	13 (25)	44 (62)	Reference ^c	Reference ^c

NOTE. Data are no. (%).

^a For case-patients, needleless devices associated with BSI; for control-patients, all needleless devices used while receiving home care.

^b 53 case-patients with 65 BSI episodes.

^c Patients who used Interlink device served as reference for comparison with each other group shown.

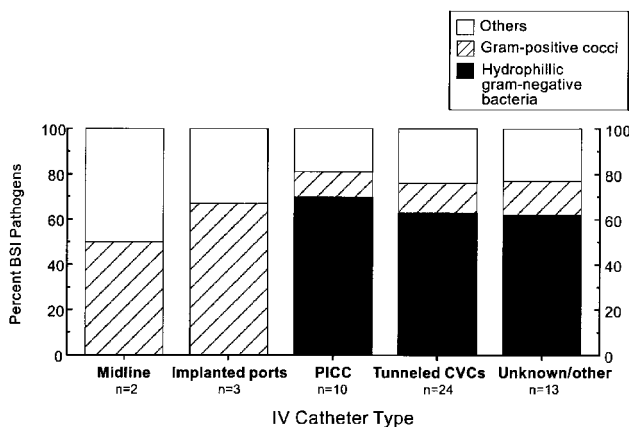


Figure 3. Distribution of case-patient BSI pathogens by intravenous (iv) catheter type, Coram Healthcare, Houston, February 1994–April 1995. CVC, central venous catheter; PICC, peripherally inserted CVC.

period, but this difference did not reach statistical significance (0.5 vs. 0.3; $P = .07$).

Pathogens associated with BSIs. The BSI pathogens isolated from our case-patients were hydrophilic gram-negative bacteria (i.e., *Pseudomonas*, *Stenotrophomonas*, *Acinetobacter*, and *Serratia* species) (49%), *Staphylococcus* species (17%), other gram-negative bacteria (12%), fungi (8%), other gram-positive bacteria (3%), and mixed organisms (11%). The distribution of pathogens was similar for case-patients with a peripherally inserted CVC (PICC) and those with a tunneled CVC with an external port—predominantly hydrophilic gram-negative bacteria (figure 3). In contrast, no hydrophilic gram-negative bacteria were isolated from case-patients with either a midline catheter or CVC with implanted port. The distribution of pathogens was similar among patients with different needleless device types (figure 4).

Discussion

Our results suggested that the risk for BSI in Coram HHC patients was related to changing the end cap of the needleless device on the iv catheter. Although an increased BSI risk was seen with the Safsite device in the case-control study (table 3), this increased risk was probably associated more with how frequently the end cap was changed than with the Safsite device itself. Indeed, in our cohort study, we observed a trend of decreasing BSI rate as the end cap was being changed more frequently (figure 2). The highest BSI rate was observed during the early Safsite period, when the end cap was changed only once per week, and the lowest rate was observed during the Interlink period, long after the Coram nurses had already begun to instruct their patients to change the end cap every 2 days. These findings suggested that the mechanism for BSI may involve colonization of the end cap with microorganisms that

eventually reached the intravascular segment of the iv catheter [8]. Changing the end cap more frequently might have served to reduce the load of potential pathogens that could enter the bloodstream whenever the iv catheter was accessed.

The difference in BSI rates during the Interlink and late Safsite periods probably was not related to the intrinsic risk of the devices themselves. Rather, as time progressed, more nurses may have instructed their patients to change the end cap every 2 days. Interestingly, although the Interlink device was associated with the lowest BSI rate in our study (end cap changed every 2 days), it was associated with an increased BSI risk in a previous study (end cap changed once per week) [8].

In addition to needleless device use, iv catheter-related BSI risks in HHC also may depend on a number of other factors. Training of the caregiver is crucial, because medical care at home is given primarily by the patient or family members, who usually are not medical professionals and may not understand the importance of good infection-control practices. Findings from one of the previous studies [9] and from our study suggest that socioeconomic factors may affect BSI risk in HHC patients. BSI risk was influenced by ethnicity in the previous study and by educational level in our study. Infection-control strategies in the HHC setting, therefore, should include teaching methods that are consistent with the educational levels and cultural backgrounds of the primary caregivers in the home.

The distribution of BSI pathogens also suggests the influence of infection-control practices on BSI risk. There was a high proportion (49%) of hydrophilic gram-negative bacteria and a low proportion (17%) of gram-positive cocci among BSI isolates from our HHC patients. These findings are unusual when compared with data from Center for Disease Control and Prevention's National Nosocomial Infections Surveillance system, which show a lower proportion (6%) of hydrophilic gram-negative bacteria and a higher proportion (60%) of gram-positive cocci among BSI isolates from hospitalized patients [13]. The differences in the pathogens causing BSI in hospitalized patients and in our HHC patients suggest that the sources of infection

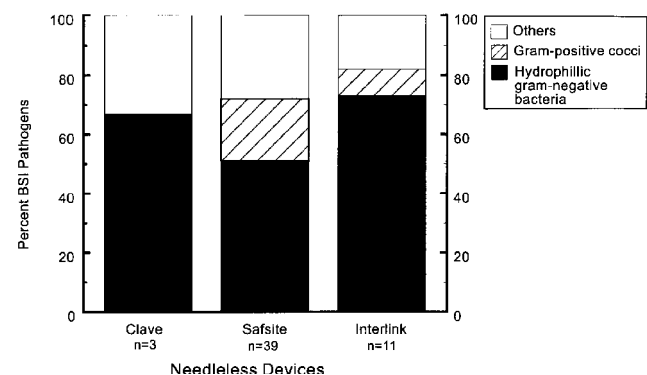


Figure 4. Distribution of case-patient BSI pathogens by needleless device type, Coram Healthcare, Houston, February 1994–April 1995.

are different in these two populations. Gram-positive cocci are mostly skin organisms, such as *Staphylococcus aureus* and coagulase-negative staphylococci [13–18]. Hydrophilic gram-negative bacteria, in contrast, are usually found in water sources, including contaminated iv infusates and tap water from whirlpools or hot tubs [19–25]. Because a culture survey did not show that contaminated flushes or infusates were used in our study patients, a more likely mode of transmission of hydrophilic gram-negative bacteria might have been exposure to tap water in the home setting, such as during showering or swimming.

In our study, although the distribution of BSI pathogens is similar by needleless device type, it differs by iv catheter type (figures 3 and 4), suggesting that the source of infection varies by iv catheter but not by needleless device type. There is a predominance of hydrophilic gram-negative bacteria in patients with a PICC or CVC with an external port, in contrast to the predominance of staphylococci and absence of hydrophilic gram-negative bacteria observed in patients with a midline catheter or CVC with an implanted port. These findings suggest that the PICC and the CVC with an external port are more susceptible to contamination from tap water exposures than are other types of iv catheters. Among all iv catheters, however, only the tunneled CVC is associated with an increased BSI risk, indicating that there may be contributing factors other than inadvertent exposures to tap water in the home setting. Because only the patients with tunneled CVCs are allowed some options regarding showering and changing the dressing, we hypothesize that a lenient attitude toward water exposure (i.e., removing dressing during shower), along with less rigorous care for the iv catheter (i.e., non-sterile technique for changing dressing), may have contributed to an increased BSI risk in these patients.

Information on the actual infection-control practices of patients was not available to directly assess the impact of showering and other water exposures on BSI risk. Nevertheless, the distribution of BSI pathogens in our study strongly suggests water sources of infection. Restricting tap water exposures from showering or recreational water use, along with the consistent practice of sterile technique for dressing changes, may be important in minimizing the risk of BSI to HHC patients.

As health care reform proceeds and the need for medical cost containment is emphasized, the reduction of costs from hospitalization will continue to be a major concern. The number of patients entering the HHC system will increase; as this occurs, the potential for HHC-related infections also will increase. This and two previous studies evaluating the BSI risk in HHC patients have raised a number of issues regarding infection control in the HHC setting, including the frequency of changing the needleless device end cap, iv catheter insertion and maintenance procedures, and educating the in-home primary caregivers. These findings demonstrate the need to establish effective surveillance systems and to develop infection-control

standards specific to needleless device use and to the HHC setting.

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