Does the Evidence Support the SHEA-IDSA Recommendation on the Use of Positive-Pressure Mechanical Valves?

To the Editor—Few, if any, issues related to bloodstream infections and invasive devices have inspired such divergent opinions as that of needleless access connectors (ie, mechanical valves [MVs]). In a situation in which product choice is often decided on the basis of recommendations of societies such as the Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA), the obligation to ensure that such recommendations find support in empirical studies is paramount.

In the article titled “Strategies to Prevent Central Line–Associated Bloodstream Infections in Acute Care Hospitals” by Marschall et al. that was recently published in this journal, the following “recommendation” (section 4, subsection III, point 3) is made:

3. Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risks, benefits, and education regarding proper use (B-11).88-91

   a. Routine use of the currently marketed devices that are associated with an increased risk of CLABSI [central line–associated bloodstream infection] is not recommended.1(pS26)

The part of this recommendation that reads “before a thorough assessment of risks, benefits, and education regarding proper use” is a broad statement that should be in practice at all patient care facilities that have implemented the use of any new medical device. However, if read in conjunction with the rest of this recommendation, then a reasonable interpretation can lead to the conclusion that use of positive-pressure MVs are associated with an increased rate of CLABSI and, therefore, are not recommended for use. The authors’ recommendations are overly broad and not very inclusive in suggesting that (1) the use of all positive-pressure MVs lead to increased risk of CLABSI and (2) the use of only positive-pressure MVs are associated with this risk.

Indeed, only 2 (ie, Maragakis et al. and Rupp et al.) of the 4 studies cited in support of the recommendation demonstrated an increased rate of CLABSI when only a positive-pressure MV was used. Moreover, in both of those studies, the same brand of positive-pressure MV was implicated. Second, the evidence used to support the recommendation is limited and lacks the scientific rigor necessary to make such a strong recommendation.

The recommendation lists only positive-pressure MVs and omits negative-pressure MVs, even though 2 (ie, Field et al. and Salgado et al.) of the 4 studies cited to make the recommendation used negative-pressure devices (Figure). Thus, the recommendation summarized the evidence incorrectly.

Each of the 4 studies identifies deficits related to the design of the MV that may be associated with an increase in the rate of catheter-related bloodstream infection (CRBSI). The following quotations from each of the 4 studies describes these specific design deficits:

MV devices have intricate access surfaces that are more difficult to disinfect than simpler split-septum models. The fluid path in the MV devices has moving parts, and at least 1 of the MV devices has internal corrugations that may serve as reservoirs and foster the growth of microbial contaminates…Some of the devices have been noted by healthcare personnel to have incomplete flushing of blood from the fluid channel, and some are opaque, so that this would not be readily apparent to the user.

We speculate that risk of colonization of the connector device may be higher for MV devices because of the potential difficulty in sterilizing the gap between the valve and the hub.

[O]ur findings, along with the findings of other investigators, suggest that the mechanical valve system could be more difficult to disinfect because of the complicated nature of the multipart device.

Upon close inspection of the valve (figure 2), one can observe a shallow depression and a rim between the diaphragm and the plastic housing. It is possible that microbes and debris could

<table>
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<th>Reference</th>
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<td>Maragakis et al.</td>
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<td>Salgado et al.</td>
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<td>Rupp et al.</td>
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Figure. The positive- and negative-pressure devices associated with an increase in the rate of catheter-related bloodstream infection, according to the 4 studies cited.
collect in this area, which would be relatively resistant to cleansing or disinfection. The internal mechanism of the valve contains moving parts which introduces irregularities in the fluid flow and may promote areas of stagnation and create potential reservoirs for microbial growth. Also, the plastic housing is opaque, which prohibits visual inspection of the connector valve. Therefore, it is possible that blood or infusion products could collect within the valve and, because of its opaque nature, go unnoticed by healthcare workers.\textsuperscript{5,p1412}

In addition, the evidence used to support the recommendation was limited and lacked the proper control for variables that possibly influenced the results. The following limitations apply to all 4 studies:

1. The data were based on observation and were collected without randomization or proper control for variables.
2. The data were “retrospective, observational, and uncontrolled”\textsuperscript{5,p1412} and were collected during different periods of time, with likely differences in staff, patient populations, and level of care.
3. Each of the 4 studies reports on observational data from only a single healthcare facility.\textsuperscript{2-5}
4. No data were presented that were related to the homogeneity of the patient population, assuming that the patient populations were the same, because they could have been, and very well may have been, dramatically different.
5. No specific data were presented that were related to the homogeneity of the specific catheter types used, the length of catheterization, or the insertion and maintenance techniques used.
6. The MVs studied were not utilized according to the manufacturer’s instructions for use.

Finally, the recommendation fails to cite 2 studies\textsuperscript{67} that demonstrate positive outcomes associated with the use of a positive-pressure connector. In the first study, by Garcia et al.,\textsuperscript{a} the use of a positive-pressure connector was compared with the use of a split-septum device (ie, the split-septum device associated with lower CRBSI rates in Field et al.,\textsuperscript{3} Salgado et al.,\textsuperscript{4} and Rupp et al.\textsuperscript{5}) for its impact on BSI rates in a 427-bed tertiary care hospital. Garcia et al.\textsuperscript{a} found that, at 95% confidence intervals, the $P$ values did not indicate a statistically significant difference in the BSI rates between the split-septum device group and the Luer activated device group of patients with peripheral and central lines. However, the Luer activated device group was associated with a lower occurrence of sharps injuries related to intravenous port access. The second study, by Costello et al.,\textsuperscript{4} reported on a systematic intervention to reduce CLABSI rates in a pediatric cardiac intensive care unit from 7.8 to 2.3 cases of CLABSI per 1,000 catheter-days. Costello et al.\textsuperscript{7} reported:

For access to the CVLs [central venous lines], we converted our needleless connector system from a Luer lock-activated valve system...to a device that has a flat access surface and contains a positive-displacement valve....The positive-displacement valve has a fully cleanable surface and eliminates retrograde flow into the catheter when an infusion device is disconnected from an infusion port.\textsuperscript{7,p913}

A compendium is a summary or abstract containing the essential information in brief form. This portion of this compendium left out essential information by omitting negative-pressure MVs and the specific, well-documented deficits of MVs known to increase the risk of BSI. Because of the failure to include this relevant information and because of the lack of scientific rigor in the studies cited, we are asking that this recommendation be removed from the compendium. A critical assessment of all of the available literature on the efficacy of needleless access devices are needed; until then, recommendations related to the use of these devices should be limited to suggesting a thorough assessment of risks, benefits, and education regarding proper use of all devices in this category.

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\textbf{REFERENCES}


\textbf{Reply to Edgar}

The journal recently printed our supplement article: “Strategies to Prevent Central Line–Associated Bloodstream Infec-
tions in Acute Care Hospitals,"\textsuperscript{11} and we appreciate the attention of Kerry J. Edgar to this article.\textsuperscript{2} It appears that the greatest concern expressed in the letter reflects the fact that we restricted our comments in section 4, subsection III, point 3 to positive-pressure needleless connectors with mechanical valves rather than addressing needleless connectors with mechanical valves in general. The letter reviews 4 studies that note an increased incidence of catheter-related infection with use of mechanical valves. These are the studies we referenced in the compendium.\textsuperscript{1} As noted in the letter, of these 4 recently published studies in the peer-reviewed literature about the association of mechanical valves with an increased incidence of catheter-related infections, 3 involved positive-pressure devices. Thus, on the basis of the literature review performed while drafting the compendium, the recommendation as written is accurate in that it represents a summary of the evidence available at that time. The letter refers to the abstract by Garcia and Jendresky\textsuperscript{3} that did not find a difference in the rate of central line–associated bloodstream infection with the use of positive-pressure connectors, compared with the use of split-septum connectors. However, we did not include another abstract by Karchmer et al.\textsuperscript{4} that showed a significantly higher rate of central line–associated bloodstream infections with the use of mechanical valve connectors, some of which were positive-pressure connectors, because the methodology of the compendium included citations of peer-reviewed publications only.

The letter notes that “The mechanical valves studied were not utilized according to the manufacturer’s instructions for use,” suggesting that a breach in aseptic technique when handling the device, rather than the device itself, is associated with an increased risk of infection. This is a crucial point in the use of any medical device, and we addressed this issue by including the importance of education in section 4, subsection III, point 3: “Do not routinely use positive-pressure needleless connectors with mechanical valves before a thorough assessment of risks, benefits, and education regarding proper use.” Nevertheless, it is hoped that manufacturing of such devices in the future will involve fail-safe engineering advances aimed at further mitigation of the risk of infection in the complex hospital environment in which they are used. Both SHEA and the IDSA remain committed to keeping the compendium in alignment with current published evidence, and, together, the societies are undertaking a formal review and updating process.

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\section*{References}

\section*{Strategies to Prevent Catheter-Associated Urinary Tract Infection}

\textit{To the Editor}—We commend the Society of Healthcare Epidemiologists of America (SHEA) and the Infectious Disease Society of America (IDSA) for developing the recently published Compendium of Strategies to Prevent Healthcare-Associated Infections,\textsuperscript{1} which offers practical approaches for developing comprehensive infection prevention programs. Unfortunately, the methodology used for literature search or data extraction is not mentioned. It appears that some relevant articles were not reviewed, and that data from some reviewed articles were misinterpreted, particularly for the article by Lo et al.\textsuperscript{2} on strategies to prevent catheter-associated urinary tract infection.

Lo et al.\textsuperscript{2} offer 3 references\textsuperscript{3-5} for their statement that “Reviews and meta-analyses of silver-coated urinary catheters... consistently conclude [italics added] that evidence does not support a recommendation for the uniform use of such devices.”\textsuperscript{2(p43)} In the first reference, however, Brosnahan et al.\textsuperscript{3} conclude that silver alloy catheters “significantly” reduce the rates of both symptomatic and asymptomatic catheter-associated urinary tract infection,\textsuperscript{3(p21)} and that “results suggest that the use of silver alloy indwelling catheters for catheterizing hospitalized adults reduces the risk of catheter-acquired urinary tract infection.”\textsuperscript{3(p21)} Johnson et al.\textsuperscript{4} conclude that “according to fair-quality evidence, antimicrobial urinary cath-
etters can prevent bacteriuria in hospitalized patients during short-term catheterization.”

Lastly, Niel-Weise et al.\(^6\) do conclude that there are insufficient data to support the use of silver-coated catheters because of the paucity of well-controlled studies.\(^7\) However, in another meta-analysis (not referenced in the compendium), Saint et al.\(^8\) conclude that “this meta-analysis clarifies discrepant results among trials of silver-coated urinary catheters by revealing that silver alloy catheters are significantly more effective in preventing urinary tract infections than are silver oxide catheters.”

Lo et al.\(^2\) also state that “silver-alloy catheters may decrease bacteriuria but have not been shown to decrease symptomatic infection or other undesirable outcomes.” This statement contradicts the statement by Brosnahan et al.\(^4\) that “the risk of symptomatic urinary tract infection was also found to be reduced with the use of silver alloy catheters.”\(^9\) Other unreferenced publications, such as those by Newton et al.\(^7\) and Karchmer et al.,\(^9\) offer similar conclusions. In addition, the value of reducing bacteriuria is described in section 1.4 of the article by Lo et al.,\(^2\) wherein references are provided to support statements that bacteriuria can serve as a reservoir for organisms that can be transmitted to other patients or lead to sepsis.

Finally, section 4.2 of the article by Lo et al.\(^2\) lists many recommendations for implementing prevention and monitoring strategies. The great majority of these are people dependent and resource intensive. Nursing staff constraints and fatigue can lessen the impact of people-dependent measures, especially over time and during off-hour shifts. The use of silver-alloy-coated catheters offers a strategy that is independent of infrastructure and bedside practices. Although cost-effectiveness data are limited, the data that exist support the use of these catheters.\(^9,10\)

Device manufacturers share with clinicians a common goal dedicated to reducing the risk of healthcare-associated infection. We want to ensure that Foley catheters are used only when clinically indicated. For patients who need a Foley catheter, we want to reduce the risk of infection. The decision to use an antimicrobial-coated catheter should be based on the best available evidence, and we believe that the evidence supports the use of silver-alloy-coated Foley catheters in patients at risk of a catheter-associated urinary tract infection.

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**References**


**Reply to Ciavarella and Ritter**

To the Editor—Ciavarella and Ritter\(^1\) discuss 4 meta-analyses in their letter questioning the recommendation that addresses routine use of antimicrobial-coated indwelling urethral catheters in the recently published compendium of strategies to prevent healthcare-associated infections.\(^2\) They acknowledge Niel-Weise et al.\(^3\) concluded that evidence does not support the use of antimicrobial catheters and that there are substantial problems with the quality of most reported studies. The Cochrane review of Brosnahan et al.,\(^4\) as Ciavarella and Ritter\(^1\) note, concluded that silver-alloy catheters are associated with a decrease in asymptomatic bacteriuria and symptomatic infection, but it also concluded that “further economic evaluation is required to confirm that the reduction of infection compensates for the increased cost.” This Cochrane review was updated in 2008, subsequent to the publication of the compendium.\(^5\) The updated review again concluded that catheters coated with silver alloy or antibiotics may decrease asymptomatic catheter-acquired bacteriuria but that study quality is generally poor and further economic analysis is needed. Symptomatic urinary infection was addressed in only one study in the update, with no benefit...
reported. The meta-analysis of Saint et al. is an early publication that incorporated clinical trials only to 1993, which were also incorporated into the later meta-analyses. The meta-analysis by Johnson et al. concluded that there is only “fair quality evidence” that antimicrobial catheters can prevent bacteriuria in hospitalized patients during short-term catheterization and that there is no evidence for prevention of symptomatic infection. Johnson et al. concluded that the poor quality of published studies and the lack of valid economic analysis mean that further studies are required to clearly define the role of these catheters. The articles by Newton et al. and Karchmer et al. referred were considered in the systematic review of Johnson et al. As noted in the compendium, several more-recent publications not included in these meta-analyses raise further questions about the effectiveness of antimicrobial catheters.

Thus, the recommendation in the compendium to “not routinely use silver-coated or other antibacterial catheters” is appropriate, given the evidence. This topic, however, remains controversial, and this is acknowledged by the inclusion of “use of antimicrobial-coated catheters for selected patients at high risk for infection” as an unresolved issue in the compendium.

The ultimate solution for catheter-acquired urinary infection seems to require the development of catheter materials that are biofilm resistant. Device manufacturers certainly have an important role to play in achieving this goal. The introduction of potentially beneficial devices, however, must be accompanied by clinical trials that are methodologically rigorous, evaluate important clinical outcomes, and support the use of the devices.

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Importance of Postoperative Factors in the Study of the Epidemiology of Surgical Site Infection Due to Methicillin-Resistant Staphylococcus aureus

We read the recent article by Anderson et al. with interest and commend their effort to shed light on the timely topic of surgical site infection (SSI) due to methicillin-resistant Staphylococcus aureus (MRSA). However, we wish to comment on some of the limitations and conclusions of their study.

With regard to surgical site isolates, the definition of MRSA and the method for identifying MRSA were not stated. Since this was a multicenter study, it would have been desirable to have used a uniform definition and method for identifying MRSA across the entire network of participating hospitals. In addition, the frequency with which polymicrobial results were detected (ie, MRSA and other organisms growing concurrently from the same specimen) and how they were handled in the data analysis (if at all) were not presented.

It was interesting that the postulate by Anderson et al. that preoperative patient debility is a risk factor for MRSA colonization—and therefore infection—was not consistently supported by their own data. Specifically, they failed to find a significant association between MRSA SSI and admission from outside facilities that are likely to house debilitated patients (eg, a nursing home or a rehabilitation facility). Is the failure to confirm such an association due to a type 2 error,
or does debility impact SSI rate indirectly through factors not examined by the study (eg, stay at a long-term care facility or hospital within the previous year or postoperative factors)?

Even though the authors cited 2 references in support of their argument linking functional status with MRSA colonization, they failed to mention that the population of both of these studies was limited to nursing home patients whose risk of exposure to MRSA is expected to be higher than that of the general population. Whether debility is an independent predictor of MRSA colonization outside of nursing homes deserves further study.

Data with regard to postoperative variables were largely ignored. For example, no data were presented with regard to the number of days (both inpatient-days and days after discharge) between surgery and the diagnosis of SSI for patients with SSI due to MRSA, compared with that for patients with SSI not due to MRSA. Similarly, Anderson et al. did not discuss the setting (outpatient, in a hospital, or in a long-term care facility) where the diagnosis of SSI was made, how frequently wound drains were used, the duration of antibiotic therapy after surgery, or the postdischarge destination of patients (eg, long-term care facility vs others). Consideration of these and other postoperative factors is important before invoking only a preoperative mechanism of association between debility and MRSA SSI. Although intraoperative wound contamination is considered to be a common cause of SSI, inoculation of the surgical site either directly or through hematogenous routes during the postoperative period may also occur.

The sole study cited by the authors to support their view that MRSA colonization in surgical patients increases SSI risk due to the same organism involved primarily patients with non-surgical site infections (eg, pneumonia, urinary tract infection, bacteremia, and vascular access–related infection). Of interest, 2 other relevant studies have failed to find an association between preoperative MRSA colonization and SSI due to the same organism. Thus, preoperative colonization with MRSA may play a lesser role in causing SSI than in causing infections that do not involve the surgical site.

Even though the study by Anderson et al. was not a randomized controlled study, it would have been useful for the authors to present data on the potential impact of vancomycin prophylaxis on the risk of MRSA SSI, as some of their patients almost certainly received vancomycin prophylaxis. Was this issue studied but never reported, or was it not studied at all?

Anderson et al. suggest screening of patients “with decreased functional status” for MRSA colonization as well as decolonization of carriers or a change in their perioperative antibiotic regimen to include an agent with activity against MRSA. We believe such recommendations are premature for the following reasons: (1) it has not been clearly demonstrated that preoperative MRSA carriage is a predictor of MRSA SSI, (2) lack of demonstration of several preoperative factors (eg, American Society of Anesthesiologists risk category, diabetes, dialysis, or older age) that may be associated with functional impairment as independent predictors of MRSA SSI when studied simultaneously with selected postoperative factors, (3) the benefit of preoperative vancomycin prophylaxis with respect to MRSA SSI has not been clearly demonstrated, and (4) the benefit of mupirocin nasal decolonization therapy in preventing S. aureus SSI has not been clearly demonstrated, despite several randomized controlled studies (in fact, the benefit of mupirocin nasal decolonization therapy in preventing S. aureus SSI has not been demonstrated even in nonrandomized studies, in the case of general surgery procedures).

In conclusion, the weight of the evidence to date suggests that when investigating the epidemiology of MRSA SSI, the potential impact of postoperative variables should not be ignored. Indeed, if corroborated as independent predictors of MRSA SSI, postoperative factors such as how frequently wound drains are used or the duration of antibiotic prophylaxis may be more amenable to intervention than preoperative variables such as Medicaid insurance coverage or debility.

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Pseudoinfection Due to Mislabling

To the Editor—Pseudoinfections and pseudooutbreaks are mainly caused by transfer of organisms between patient specimens (cross-contamination) and by contamination of patient specimens with environmental organisms.1,2 Other causes are clinical misdiagnosis and surveillance artifacts.2-4 The following example shows that further causes must be considered.

Salmonella enterica serovar Hadar was isolated on the same day from a stool specimen of patient A and from an intestinal biopsy specimen of patient B. The patients were hospitalized in the same hospital but in different wards. An investigation was prompted, revealing that the patients had gone to the endoscopy suite concurrently on the day of specimen collection. An ileocoloscopy had been performed on patient A, including collection of mucosal biopsy specimens, whereas patient B had undergone gastroscopy without biopsy. No specimens at all had been collected from patient B that day to be sent to the microbiology laboratory. A stool specimen had been collected for microbiological examination from patient A, before patient A went to the endoscopy suite that day. Patient B did not show clinical signs of salmonellosis, and a pseudoinfection was suspected. However, the pseudoinfection obviously could not have been caused by specimen contamination or cross-contamination. Observations of the work flow within the endoscopy suite led us to conclude that specimen mislabeling was the most likely cause of the pseudoinfection. The charts of the 2 patients had been deposited on the same desk. When the biopsy specimen was taken to the desk to be marked with a patient label, a label of patient B was erroneously used for the biopsy specimen of patient A.

As in other cases published, this case of a pseudoinfection was noticed because of the unusual pathogen involved. Coincidentally, no biopsy specimen had been obtained from patient B on the day of specimen collection. If this had not been the case, the pseudoinfection would not have been noticed at all, or cross-contamination would have been regarded as the most likely cause of pseudoinfection, leading to a costly analysis of endoscope processing as well as of each step in specimen collection and processing.1,5 Taking into account frequent errors in daily routine work, we hypothesize that pseudoinfection due to mislabeling of specimens is not an infrequent event.

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