For: *Infection Control, Operating Room, Endoscopy, Instrument Reprocessing, Risk Managers, et al.*

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What's News

Happy Holidays and New Year. Note that this is the *complete* version of this article. A shorter version was mailed to subscribers. This article, like all others published in this newsletter, can be downloaded at: http://**www.MyEndoSite.com**

The risk of disease transmission during ERCP is a topic that will be discussed soon in this newsletter.

Editor-in-Chief

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What is 'Q-Net'?

Q-Net is a technology assessment, infection control-based **net**work of **q**uestions, answers, and perspectives. Its newsletter is *The* **Q-Net™** *Monthly*.

The main goal of **Q-Net** is to encourage the infection control, endoscopy, and operating room communities to improve patient care by not only asking good questions but also by demanding well referenced, evidence-based answers.

Q-Net addresses the needs of both the healthcare provider, whose goal is to provide the best care possible, and the patient, who deserves affordable quality health care.

Published Infection Rates: More Conjectural than Scientific?

A focus on central line-associated bloodstream infections

This article assesses the validity of reported rates of bloodstream infections associated with central venous catheters, or CLABSIs. Though its discussion focuses on the rates of these infections in the intensive care units (ICUs) of acute-care hospitals, this article may also be applied to the prevention of infections associated with flexible endoscopes used in out-patient endoscopy centers or in ambulatory surgical centers.

INTRODUCTION: EVERY WEEK A newspaper article, federal report, or scientific study discusses the quality of health care in the U.S.[1-17] Many of these publications focus on efforts to prevent healthcare-associated infections (HAIs), often in intensive care units (ICUs). Recently enacted state laws that mandate the reporting of certain types of HAIs are examples of such efforts.[1,5,6,8,9]

The use of patient outcomes to measure the success of many of these efforts is of considerable interest and debate. Although some recent reports suggest that hospitals in the U.S. may be "getting safer,"[7] others have found the quality of health care to be lacking.[14,15] A federal study by Schaeffer et al. (2010), for example, found infection-control lapses among dozens of inspected ambulatory surgical centers (ASCs) to be common[14] (*see:* this newsletter's July, 2010, issue).

Raising additional questions about

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➡ **CONCLUSION:** *This article questions the validity of the majority of publicly-reported rates of bloodstream infections associated with central lines (CLABSIs). In general, these rates have not been validated for accuracy. The validation of these rates is recommended, to ensure their sound comparisons.*

the quality of health care in the U.S., Landrigan et al. (2010) found "harms" to patients to be similarly common among 10 randomly-selected hospitals in North Carolina, with "little evidence" of improvement (over the 6-year period ending in 2007).[15] Examples of such harming events discussed by Landrigan et al. (2010) are "CLABSIs," which are a type of HAI and an acronym for *bloodstream infections associated with central venous catheters* (or "central lines"; *see*: Box A).

According to Landrigan et al. (2010), their findings (that harming events were common) "validate" concerns about the quality of health care, at least in hospitals in North Carolina.[15] Their findings also underscore the importance of developing more effective strategies to prevent CLABSIs and other types of HAIs. A growing number of such strategies are based on models of greater accountability and transparency, namely, on rating schemes that grade and rank the quality of hospitals.

Such rating schemes facilitate convenient (although not necessarily valid) comparisons of, in addition to other metrics,[13] HAI rates among hospitals in the same or different cities, states and countries, all but compelling hospitals to become more competitive, to improve their care, and to report reduced infection rates.[6,10,12,16] That such comparisons of infection data are not limited to hospitals but may also apply to other types of medical facilities, including ASCs, is noted.

"CLABSIs": Articles, reports and studies frequently laud a hospital's claimed safety, or publicize how effectively a specific intervention, checklist, or bundle of best practices might have reduced the rates of CLABSIs in adult or pediatric ICUs.[1-7,10-12,17-24] CLABSI rates in ICUs have become a popular patient outcome used by consumers, federal and state agencies, and both public and private insurers to assess, rate, and compare the quality of hospitals.[1,6,8-12,25-32] According to one report, the public reporting of CLABSI and other HAI rates will help to "save countless lives and dollars."[25]

A hospital's public reporting of a low CLABSI rate might imply to the consumer the safety not only of its ICUs, but also of the hospital's other departments, including its gastrointestinal (GI) endoscopy and respiratory therapy departments. A hospital reporting a relatively high, if uncompetitive, CLABSI rate, however, may be viewed as potentially unsafe and be publicly labeled by a consumer magazine as a "poor performer"[12]—a moniker that, whether fair or not, could cause the hospital to experience consumer backlash and encounter financial, legal, and accreditation hardships.

A first-of-its-kind CDC report: The first of its kind, the *Centers for Disease Control and Prevention* (CDC) published a report in June (2010) that summarizes CLABSI data reported by more than 1500 (short stay, acute-care) hospitals in 17 (U.S.) states[6,7] whose laws mandate the reporting of CLABSI data to a network within the CDC (*see*: Box B).

This report found that the number of CLABSIs provided

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Box A: ***A few facts about central venous catheters.***

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1] Central venous catheters, or simply *central lines*, are long, narrow intravascular catheters (tubes) that are inserted into one of the patient's large peripheral veins, typically terminating at or near the heart, or in one of the body's "great vessels" (e.g., the superior vena cava).[21]

2] Among other functions, these intravascular devices may be used to draw samples of blood to evaluate patients for bloodstream infections (e.g., bacteremia), including those that may be associated with the central line itself, namely, CLABSIs, which have become a popular metric to assess and gauge a hospital's safety and quality.

3] CLABSIs are *primary* bloodstream infections that are associated with inserted central lines and, satisfying certain criteria, are *not* related to infection at another body site. (*Secondary* bloodstream infections, in contrast, are those in patients with central lines that *are* associated with a primary infection at *another* body site.)[20,21,23,30]

4] Central lines are reportedly responsible for approximately 80,000 bloodstream infections (CLABSIs) in intensive care units (ICUs) each year in the U.S.[18-24] These infections may be associated with: prolonged hospitalization; an average cost of $42,000 per infection (or an annual cost estimated to be as high as $2.3 billion in the U.S.); and an attributable mortality rate of as high as 25% to 35%.[17-24,42]

5] In pediatric ICUs, CLABSIs are reported to be the most common type of healthcare-associated infection.[18,19] No doubt, the prevention of CLABSIs in hospitals is crucial not only to improving public health and reducing healthcare costs, but also to promoting both awareness and an evidence-based culture in all types of healthcare settings. ●

Box B. ***State mandated reporting of CLABSIs.***

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As part of a national initiative to increase awareness about healthcare-associated infections (HAIs), several states in the U.S. require hospitals (and sometimes other types of medical facilities, including ASCs[31]) to report their rates of CLABSIs, among one or more other types of HAIs, one or more times a year to, for example, the state's department of public health, a hospital association, or website.[6,8,9,29-32]

Such legislation, like the requirements of CMS's (Medicare's) new reimbursement rules (effective 01-01-2011), is part of a growing effort to prevent HAIs and reduce costs through greater accountability, financial incentives to improve patient care, and the reporting of CLABSI rates.[4,5,8,9,25-27,31,32] But caution is advised when using these rates to compare hospitals (*see*: *main article*). ●

by almost two thirds (n=11) of these states was significantly (18%) fewer than "predicted,"[6] which the CDC suggests demonstrates that care in hospitals is becoming "safer"[7] (notwithstanding the concerning findings of Schaeffer et al.'s [2010][14] study and Landrigan et al.'s [2010] report[15]).

Direct hospital comparisons: Although the CDC notes in this state-specific report that its CLABSI data are "not put forth … for direct comparisons between states,"[6] this report's formal, impressive, and easy-to-read listing of infection data certainly facilitates, if not ensures, just that: direct comparisons of CLABSI data (in different states).[4,5,8-10,12,29,30]

Comparisons of the CLABSI data listed in this state-specific report are similar to those encouraged by Consumers Union, whose March (2010) issue of *Consumer Reports* lists the CLABSI data reported by 43 hospitals in 10 states.[12] This magazine urges consumers to "protect" themselves and (when given a choice) select a hospital it labels a "top performer"[12] for having reported a comparatively low CLABSI rate.*

Data validation: As with any metric or patient outcome used to evaluate a hospital's quality, the reporting of infection rates can only be as valid as the measured data are accurate. That these measured CLABSI rates—which may be reported by hospitals to the state's department of health, a hospital association, web-based software, or the CDC, either voluntarily or as mandated by a state law[6,8,9,30-32]—be accurate, therefore, is necessary and underscored, because, in addition to these rates being used to compare hospitals,[6,12,32] both public and private insurers may condition reimbursements on hospitals tracking and reporting CLABSI rates. Examples of such incentivizing programs include *value-based purchasing*,[26,33] *pay for performance*,[10,12,33,34] and the Centers for Medicare and Medicaid Services' (CMS) *pay-for-reporting* program.[25,27,28]

Otherwise, if reported CLABSI rates have not been validated, then: (a) the public's presumption of their accuracy might be *incorrect*; (b) the use of these rates to compare hospitals might not be "*credible*";[32] (c) claims that these rates demonstrate improved health care might be *in error*;[7] (d) instructions urging consumers to use these rates to select a "top" performing hospital might be *unsound*;[12] (e) state laws mandating the reporting of these rates would be arguably *incomplete*;[8,9,30-32] (f) payments or reimbursements to hospitals based on these rates could be *problematic*;[25-28] and (g) conclusions about the effectiveness of an intervention designed to reduce CLABSI rates in ICUs might be *flawed*.[17-24]

PURPOSE, METHODOLOGY: THIS ARTICLE AIMS to reconcile reports suggesting health care in U.S. hospitals is becoming safer[6,7] with dissimilar reports that found concerning lapses and harms to be common.[14,15] Specifically, this article's *primary* aim is to assess: (a) the validity of reported CLABSI rates, which may be used by consumers, governmental agencies, and insurers to evaluate and compare a hospital's relative safety, or to incentivize improved health care;[26-28,30-32] and (b) the completeness of state laws mandating the reporting of these infection rates.[8,9,30-32] As part of this aim, this article seeks to confirm that the CLABSI data listed in the CDC's aforementioned state-specific report[6] and in *Consumer Reports'* March (2010) issue[12] have been validated.

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ABSTRACT: INFECTION RATES: *FACT OR FICTION?*

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◆ **BACKGROUND:** CLABSI rates have become a popular metric for consumers, magazines, reports, governmental agencies, and insurers to compare hospital safety.

◆ **PURPOSE:** To assess the validity of reported rates of CLABSIs.

◆ **RESULTS:** The validity of the majority of reported CLABSI rates is questioned. With only a few exceptions, their accuracy, completeness, and reliability have not been independently confirmed.

◆ **RECOMMENDATIONS:** *Validation of the accuracy of reported CLABSI rates is recommended.* Also recommended is: the revision and completion of state laws to require that these reported rates be validated; and the revision of programs and rules that financially reward, pay, or reimburse hospitals, based on their reporting of CLABSI rates, to require that these reported rates be validated.

◆ **CAUTION:** The cautious use of reported CLABSI rates is advised. The use of reported CLABSI rates that have not been validated may be unsound.

* The reader is requested to review the "*Dear Consumer Reports*" article on p. 4 of this newsletter's Jan-Feb-Mar, 2010, issue.

Box C: *Data Validation: A clear necessity*

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Validation of reported rates of CLABSIs ensures their accuracy, reproducibility, completeness, and sound use. One method of validation is to confirm that the CLABSI rate measured and detected by, for example, state health officials (during a retrospective review of the medical records of patients with positive blood cultures associated with a central line) is not significantly different from the CLABSI rate reported by the hospital.[30,32,36]

Whereas negligible differences between the detected and the reported CLABSI rates would seemingly validate their accuracy, significant differences between these two CLABSI rates might suggest "missed" infections (i.e., the failure of the employed surveillance methods to detect and count every *bona fide* CLABSI) and the under-reporting of an ICU's true CLABSI rate.[10,11,21,22,32,36,37,40] ●

Table 1: ***Factors that might cause: (A) the CLABSI rate to be under-reported; (B) the over-exaggeration of an intervention's effectiveness; and/or (C) a reduced CLABSI rate to be misattributed to an intervention:***

1. *Measurement bias*, which may result from, among other factors, the employment of surveillance methods that lack the necessary sensitivity to measure, interpret, and report CLABSIs.[10,11,46] Such methods might "miss," or not count, a CLABSI due to, for example:
   a. not culturing the blood samples of patients suspected of a CLABSI for all types of recognized pathogens, including fungi and aerobic *and* anaerobic bacteria;
   b. misinterpreting ambiguous definitions of CLABSIs;[46]
   c. using too low a blood volume for culturing;[11] and
   d. misclassifying *primary* bloodstream infections associated with central lines, namely, *bona fide* CLABSIs, as false positives (e.g., a common skin contaminant such as coagulase-negative staphylococci) or as *secondary* infections attributed to another site.[11,18,19,30,36,37]
2. *Financial bias*, which may result from, for example, reimbursing or financially rewarding hospitals that report a reduced CLABSI rate (e.g., CMS's *pay-for-reporting* program);[10,21,22,25-27] or from one or more potential financial conflicts of interest associated with a hospital reporting a reduced CLABSI rate.[32,39]
3. *Feedback bias*, resulting from clinicians and staff members being, not blinded, but instead provided with "feedback" about a study's intent and the success of their efforts to reduce CLABSI rates in ICUs.[18-24,35,43,45]
4. *Publication bias*, resulting from, for example, the tendency to report only favorable CLABSI data; or, to report or publish incomplete data.[19,22,35,36,38,45]
5. *Sampling bias,* resulting from ICUs treating diverse patient populations that have not been randomized or adjusted for different risks of CLABSI (e.g., high-risk populations, varying birth weights in neonatal ICUs[45]).
6. *Confounding bias*, resulting from such *factors* as:
   a. administration of antimicrobial therapy without having first obtained a blood culture to confirm a CLABSI (such therapy should be started, when possible, *after* a blood culture has confirmed infection);[41]
   b. use of different medical supplies, such as catheter dressings or insertion-site antiseptics, or the use of catheters impregnated with antimicrobial agents; and
   d. other changes in infection-control techniques or behaviors,[20] including changes in the catheter's use;[45] use of more experienced physicians to insert and maintain central lines (as opposed to less skilled residents); or, changing catheter dressings more often.

This article's *secondary* aim is to review and assess the soundness of several published prospective cohort studies that conclude that an intervention, collaborative, checklist, or bundle of best-practice strategies reduced the rate of CLABSIs in one or more ICUs by a specific percentage.[12,17-24]

These aims were achieved by reviewing several newspaper articles, state laws, federal reports, prospective cohort studies and, among other publications, both the CDC's state-specific report and *Consumer Reports'* article about CLABSIs in its March (2010) issue. (*Note*: This article's discussion may also be applied to the prevention of HAIs in other types of health care settings, including GI endoscopy units and ASCs.)

Results: This review questions the validity of the *majority* of reported rates of CLABSIs. With only a few exceptions, reported CLABSI rates—including those listed in the CDC's state-specific report[6] and in *Consumer Reports'* article about CLABSIs in its March (2010) issue[12]—have not been validated for accuracy and completeness.[6,8,9,30,32] This finding suggests that the ubiquitous use of reported CLABSI rates to evaluate and compare the relative safety and quality of hospitals by consumers; by the CDC and other federal and governmental agencies; by Consumer Union; and by public and private insurers, among others, may be unsound.[14,15]

Advancing the use of data that may be in error, the CLABSI data listed in the CDC's state-specific report were *not* validated in the majority (n = 12) of the 17 listed states—even though the CDC used these rates to conclude that care in hospitals is getting safer.[7] (According to this CDC report, the laws in only the remaining 5 states require that the reported CLABSI rates be validated for accuracy and completeness).[6]

In addition, the CLABSI rates reported by more than half (n = 23) of the 43 hospitals listed in the *Consumer Reports'* article about CLABSIs similarly were not validated—even though Consumers Union used these rates to provide advice, grade hospitals, and to label some *poor* or *top* performers.[12]

Several prospective cohort studies were identified during this review that evaluate how effectively an intervention, checklist, collaborative, or bundle of practices might reduce CLABSI rates in adult or pediatric ICUs.[17-24] Compared to randomized controlled (and "blinded") studies, these (prospective cohort) studies are less scientifically rigorous; limited to yielding correlations and associations; and more prone to misinterpretations and to misattributing to the studied intervention observed reductions in CLABSI rates that are caused by one or more unrecognized and un-controlled confounding factors, some of which are listed in Table 1.

Nevertheless, their design limitations notwithstanding, several of these reviewed studies, in addition typically to not validating the accuracy of their published CLABSI rates, suggest, imply, or conclude (possibly in error) that the studied intervention *caused* the reduction in the CLABSI rate.[17-24]

Table 1 also lists several biases that can cause: (a) measured CLABSI rates to *under*-report the true incidence of

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infection and (b) prospective cohort studies, including those identified during this review, to *over*-exaggerate the percentage by which an intervention might have reduced the CLABSI rate.[8-11,21,30,32] Several characteristics that these prospective cohort studies share in common are discussed in Box D and Table 2 (*see*: pages 24S$_1$ and 24S$_2$, respectively).[17-24]

DISCUSSION: WITH POTENTIALLY CONCERNING implications, this review found that the majority of reported CLABSI rates have not been independently validated for accuracy, completeness, and reliability. That many of these published rates may be in error, therefore, is a possibility.

Like report cards that children might write themselves to grade their own school performance without the accuracy of their grades having been confirmed by their teachers,[8-10] published CLABSI rates, with only a few exceptions, are measured, interpreted and reported by hospitals themselves (some as mandated by a state's laws, others voluntarily) without these rates having been independently audited by, for example, state or federal public-health officials.

Questioning the ubiquitous use of CLABSI rates: By questioning the validity of the majority of reported CLABSI rates, this review inextricably also questions the soundness of their use by: (1) *consumers*, among others, to compare the relative safety of hospitals[32] (having reasonably, though erroneously, presumed that all reported CLABSI rates have been validated); (2) the *CDC*, to conclude, based on its state-specific report,[6] that hospitals are becoming safer;[7] and (3) *Consumer Union*, to rate hospitals, label some *poor performers*, and to urge consumers in its March (2010) issue of *Consumer Reports* to choose a hospital it labels a *top performer*.[12]

Questioning the validity of the majority of reported CLABSI rates also raises doubts about the soundness of their use by: (4) private and public *insurers*, as well as government agencies and federal rules, programs, and policies, to incentivize improved health care by providing to hospitals reimbursements, financial rewards, and other forms of compensation that are conditioned on their reporting (at times, reduced) CLABSI rates (e.g., CMS's *pay-for-reporting* program);[10,24,25-28,33,34] (5) *state laws*, to reduce the risk of HAIs via greater accountability and transparency;[1,5,6,8-10,30,32] and (6) *clinicians*, as a metric to evaluate the effectiveness of interventions implemented in ICUs to reduce CLABSI rates.[17-24,35]

Incomplete state laws and federal rules: Similarly questioned is the completeness of state laws that mandate the tracking and reporting of CLABSI rates, and of public and private insurance programs, federal rules, and reimbursement policies that condition financial payments on the reporting of these rates, *without* requiring that these rates be validated.

Several states currently do not mandate the reporting of CLABSI rates,[6,10] so that an increasing number do demonstrates progress. But, as long as state laws, among other statutes, programs, rules and policies, do not require that these reported rates be checked to confirm that every CLABSI was counted, in addition to these rates and their comparisons potentially lacking credibility,[8,9,32] the cogency and relevance of these laws may be reasonably questioned.[32] According to one state's report on HAI initiatives, the validation of infection data, including reported CLABSI rates, "must be considered in any mandatory reporting system to ensure that HAIs are being accurately and completely reported."[32]

Prospective cohort studies: The soundness of the conclusions of several reviewed prospective cohort studies, including one published by the CDC in 2006,[35] is similarly questioned. In general, their conclusions, first, are based on CLABSI data that have not been validated; and, second, suggest or imply that their measured data indicate a causal relationship between the implementation of a studied intervention or bundle of practices and a reduction in the CLABSI rate by a specific percentage.[17-24,35] While these are most insightful studies, their limiting designs, however, preclude their advancement of such a conclusion, namely, that the studied intervention *was responsible for* the reduced CLABSI rate (*see*: Box D and Table 2 on pages 24S$_1$ and 24S$_2$, respectively).[17-24]

Admittedly, several of these prospective cohort studies acknowledge that their data are limited to yielding correlations and associations. But this limitation is typically not emphasized and, in some instances, is overlooked.[17-24,35] Most notably, these prospective cohort studies are not blinded[20,22] and cannot exclude the possibility that behavioral changes[20] or one or more other unrecognized and un-controlled factors—*not* the studied intervention—caused the observed CLABSI rate reduction. Moreover, discussed in Table 2 (p. 24S$_2$), confidence in the suggestions of several of these studies that the evaluated intervention reduced the CLABSI rate is further weakened, because such an observation would require that which these studies typically fail to verify: that clinicians rigorously adhered to the intervention's practices.[17-24]

Under-reporting, over-exaggerating? Table 1 lists several biases that, among others, can cause the measured CLABSI rates to under-report the true incidence of infection and to over-exaggerate a studied intervention's actual effectiveness in ICUs.[8-11,17-24,32,35] A possible display of the effects of these biases, significant discrepancies have been identified between the (lower) rates of reported CLABSIs and the (higher) CLABSI rates validated during independent audits (*see*: Box C).[6,8-11,30,32,36-38] Possibly also displaying the effects of these factors, that the national aggregate of CLABSI data listed in the CDC's state-specific report might, too, under-report the true infection rate cannot be ruled out (*see*: Box E on p. 24S$_1$).

Biases: Listed in Table 1, *measurement bias* resulting from, for example, variations in and reduced sensitivities of the surveillance methods used to measure, interpret, and report CLABSI rates can cause under-reporting of the true CLABSI

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rate.[10,11,21] Small changes in the sensitivity of these methods, like subtle differences in the subjective interpretation of the CDC's definition of a CLABSI,[30] can cause noticeable inaccuracies in reported CLABSI rates.

Other biases listed in Table 1 that can similarly cause reported CLABSI rates to under-report the true incidence of infection include *financial bias*, which may result from, for example, providing hospitals with a financial incentive to report reduced CLABSI rates,[22,25-28,39] and *feedback bias*.[18-24]

Like an open-label drug study, feedback bias can cause behavioral[20] changes that affect the measurement of the CLABSI rate (*see*: Table 2 and Box D).[18-24] Indeed, the designs of several of the reviewed prospective cohort studies ensure that the clinicians are (not blinded and are) told of the intent of the study and of the progress and success of their efforts to reduce the rates of (and costs associated with) CLABSIs in ICUs.[18-24]

That reported CLABSI rates may be inaccurate and their ubiquitous use less scientific and meaningful than subjective and conjectural is one of this review's unexpected and concerning findings.[8,9]

But, while it may be important to reduce CLABSI rates quickly and for as many patients as possible (*see*: Table 2), such feedback can compromise the study's scientific integrity and introduce bias that can cause the conclusions of a study evaluating how effectively an intervention might have reduced CLABSI rates in ICUs to be misleading.[10,11,17-24,35]

Confounding factors: Similarly, *confounding factors* can introduce *confounding bias* (*see:* Table 1), resulting in misinterpretations of the CLABSI data. Unlike randomized controlled studies, prospective cohort studies evaluating the percentage by which an intervention might reduce CLABSI rates can not generally eliminate or control for confounding bias.

Consequently, in addition to being prone to under-reporting the true CLABSI rate, these studies can misattribute to the intervention an observed reduction in the CLABSI rate that was actually caused by one or more confounding factors. Table 1 lists some examples of confounding factors that may vary not just in one ICU but also in a number of different ICUs during the study of an intervention's effectiveness.[10,11,24]

Posing an increased risk of infection? CLABSI data that have not been validated and under-report the true incidence of CLABSIs can mischaracterize the safety and quality of hospitals and under-estimate the true risk of HAIs in ICUs and in other hospital departments and units, including the GI endoscopy department. Such misleading infection data could also cause the CDC and other federal agencies to conclude erroneously that health care in the U.S. is becoming safer.[6,7]

Most important, as a consequence of such faulty data, ICUs may forgo the implementation of crucial interventions, "miss" important opportunities to prevent HAIs,[32] and reallocate limited financial resources and staff hours to other labors appearing (in error) to require more attention, paradoxically posing an *increased* risk of CLABSIs. *That the publication, use and advancement of inaccurate infection data can, therefore, pose harm to patients stresses the importance of validating reported CLABSI (and other HAI) rates.*[8,9,32,38]

CONCLUSIONS, RECOMMENDATIONS: ALTHOUGH INCREASINGLY USED as a metric to evaluate, rate, and compare the safety and quality of hospitals,[6,8,9,12] the majority of reported CLABSI rates have *not* been independently validated for accuracy, completeness, and reliability. That these reported CLABSI rates, therefore, may be inaccurate, not credible,[32,40] pose a risk of harm to patients, and their ubiquitous use less scientific and meaningful than subjective and conjectural is a concerning finding.[8,9]

A number of factors, some of which are listed in Table 1, can affect reported CLABSI rates, causing them to under-report the true incidence of infection and, if these rates are associated with a studied intervention, to over-exaggerate its clinical effect on CLABSI rates in ICUs.[8-11,21,30,32] The cautious use of reported CLABSI rates is, therefore, advised, whether published in a CDC report or consumer magazine, or used by, among others, consumers, a state law, governmental agency, federal rule, or health insurer.

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The **REFERENCES** to this article are available *on-line* at:
www.myendosite.com/htmlsite/2010/refs10111210.pdf

Thank you for your interest in this newsletter. *I have addressed each issue and topic to the best of my ability. Respectfully, Lawrence F. Muscarella, Ph.D.*
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Box D: Case Study: ***Review of two studies that, like several others, discuss the effectiveness of a bundle of best practices for reducing the rate of CLABSIs.***

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In 2006 a prospective cohort study evaluated the effectiveness of a bundle of practices on the rate of CLABSIs in ICUs in Michigan.[21] This bundle included a popular checklist of five evidence-based infection-control practices. Published in the *New England Journal of Medicine*, this study found, first, that the rate of CLABSIs was significantly reduced within 3 months (compared to the baseline infection rate); and, second, that this reduction was sustained for 15 more months after the intervention's implementation. Published in the *British Medical Journal* in early 2010, a second study evaluating this same bundle's effectiveness found that this reduced CLABSI rate (published in 2006) was sustained for an additional 18 months.[22]

These two studies, however, like several others evaluating the effectiveness of an intervention,[18-24,25] were not randomized, controlled, or blinded. Like an open-label drug study (which does not "blind" the researchers or the participants from the study's intent or the administered drug), many prospective cohort studies evaluating the effectiveness of an intervention on the CLABSI rate are not sufficiently rigorous to either avoid bias or to control for the impact that one or more unrecognized confounding factors might have on the measured outcome (*see*: Table 1).

Nor did either study evaluate or confirm the staff's adherence to the bundle's practices.[21,22] As a consequence of these (and other) considerations (*see*: Table 2), these prospective cohort studies (as some of their authors acknowledge[21,22]) cannot exclude the *null* hypothesis—namely, that one or more confounding factors—*not* the (staff's adherence to the) bundle of studied practices—caused the measured reduction in the rates of CLABSI, notwithstanding the common intimation by these studies that the bundle's implementation was responsible for the observed reduction in the CLABSI rates (*see*: Table 2).

Examples of factors that can cause the measured rate of CLABSI to under-report the true incidence of infection are listed in Table 1 and include: "feedback"[21,22] provided to clinicians about the study's progress and their efforts to reduce the rate of CLABSI in ICUs; (b) rewarding ICUs reporting a reduced infection rate with "incentive payments";[22] and (c) the use of surveillance methods that do not remain fixed and, not only are not standardized among participating ICUs, but also may become less sensitive after the bundle's implementation in ICUs and fail to detect and count every CLABSI[10,11] (*see:* Table 1).

Indeed, none of the data collected by either study was independently validated for accuracy. Therefore, that the conclusions of these and other similar prospective cohort studies might have unwittingly over-exaggerated the percentage by which the studied intervention reduced the CLABSI rate, and assigned to the intervention an effect caused instead by a confounding factor (a "false-positive" result) cannot be ruled out (*see*: Table 1 and Table 2). ●

Box E: ***A display of inaccurate CLABSI rates?***

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The CDC's state-specific report found the national aggregate rate of reported CLABSIs to be 18% lower than expected. Interestingly, *none* of the states listed in this report that observed its number of CLABSIs to be *lower* than predicted requires by law that CLABSI data be validated for accuracy and completeness, whereas every state that validates its CLABSI rate reported *higher* than "predicted"[6] infection data. That these findings may suggest, not necessarily that hospitals are becoming safer,[7] but that reported CLABSI rates that have not been validated may underreport the true incidence of infection, due less to improvements in infection control than the effects of such factors as those listed in Table 1, is debatable. ●

In closing, the validation of reported CLABSI rates is recommended and "essential,"[32] to ensure that they are accurate, complete, and can be used soundly and without hesitation. It is also recommended that state laws—as well as public and private insurance and reimbursement programs, rules, and policies that condition financial rewards, payments, or bonuses on the reporting of CLABSI data—be updated and completed to require the validation of reported CLABSI rates.

Whether both the CDC's state-specific report on CLABSI data and Consumers Union's article about CLABSI rates in its *Consumer Reports'* March (2010) issue will be updated to emphasize more clearly that the majority of their listed CLABSI data have not been independently validated and that, because these data may therefore be inaccurate, their use to compare the safety of hospitals may be unsound is unclear, though such clarification is encouraged, if not urged.

Finally, the standardization of surveillance methods used to detect and interpret CLABSI rates is also encouraged, and the importance of statistically adjusting these rates for risk factors to account for differences in patient populations (e.g., "patient-mix"[6]) is noted, so that CLABSI rates, their reporting, and their comparisons are more scientifically sound.[10,11] Finally, performing randomized controlled studies to evaluate how effectively an intervention might reduce CLABSI rates in ICUs is recommended, as is also the clearer disclosure by prospective cohort studies that their designs restrict their observations to associations and correlations. (*Note*: Table 2 is on the next page.) ● ~ **The End** ~ (This article was written by: *Lawrence F. Muscarella, Ph.D.*)

Table 2: ***Factors shared in common by several of the reviewed prospective cohort studies that evaluate how effectively (e.g., the percentage by which) an intervention reduced the CLABSI rate in ICUs.***

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1. *Limited to associations*: Many of the prospective cohort studies evaluating the impact of an intervention on the rate of CLABSIs in ICUs suggest, intimate, or conclude that the studied intervention *resulted in, was responsible for,* or *caused* a reduction in the CLABSI rate by, for example, 66%, 50% or 74%.[17-24,35,43,44] In general, however, such conclusions are questioned (*see:* main article), because the limitations of the designs of these studies restrict them to observing instead only an *association* between the implementation of the studied intervention and a reduction in the rate of CLABSI (*see:* #6, below, on same page).

2. *Adherence to the intervention not confirmed*: Moreover, these studies may *not* verify adherence by staff members to the intervention, which raises fair questions about whether, not the intervention, but other factors, such as measurement, feedback, publication, or confounding biases (*see*: Table 1) might themselves have been responsible for the observed reduction in the CLABSI rate.[35,44]

3. *Confounding factors*: The reviewed prospective cohort studies do not control for every relevant confounding factor (*see:* Table 1), which itself, independent of the studied intervention, might have had a substantive effect on the measured CLABSI rate reduction. The use during (but *not* prior to) the studied "intervention period" of well-trained attending physicians instead of less experienced medical residents to insert and maintain central lines is an example of such a confounding factor, which is typically unrecognized, un-controlled, not a component of the studied intervention, and could itself cause a reduction in the CLABSI rate (*see*: Table 1 and Box D) that might be misattributed to the intervention (a "false-positive" effect or result).

4. *Biases:* The reviewed prospective cohort studies do not eliminate the effects that biases may have on the measured outcome. For example, because staff members are not blinded during these studies, but rather are usually told of the study's intent to reduce the rate of CLABSIs and provided with "feedback" and progress reports about the effectiveness of the intervention, the measured infection rates may inadvertently and unwittingly become inaccurate due to feedback bias (*see*: Table 1).[21] If the ICUs were additionally provided with financial incentives to report reduced CLABSI rates, then the measured infection rates may be prone, too, to financial bias.[22] Further, the use during the intervention period of a less sensitive surveillance method may introduce even more error into the reported rate of CLABSI due to measurement bias.[10,11]

Such biases can cause the observed incidence of CLABSIs in one or more ICUs to under-report the *true* infection rate—for example, bacteremia associated with a central line (a *primary* CLABSI) might not be counted, having been subjectively assigned in error to (or reclassified as) a *secondary* infection due to an unrelated source or site, such as an urinary tract infection.[11,18,19,30,36,37] Consequence, these prospective cohort studies can be prone to over-exaggerating the percentage by which a studied intervention might have reduced the CLABSI rate.[17-24,35,43]

5. *Lack of validation*: These reviewed prospective cohort studies[17-24,35,43] generally base their conclusions on CLABSI rates that are detected, interpreted, and reported by the participating hospitals themselves (*see*: main article). In general, these studies do *not* independently validate the accuracy and completeness of these CLABSI rates to ensure that none were missed and every CLABSI was counted (*see:* Box D). This omission raises reasonable questions about the actual CLABSI rates and the true effectiveness of the studied intervention on them.[32,40]

6. *Immediate impact:* It is recognized that the reviewed prospective cohort studies[17-24,35,43] are generally quality improvement projects seeking to achieve prompt reduction in CLABSI rates for as many patients as possible. Rather than perform a controlled and randomized (and blinded) study that might admittedly benefit only the "treatment" (or "intervention") group of patients (and not also the "control" or "non-intervention" group[24]), these studies expose *all* patients to the intervention, gauging the intervention's effectiveness by comparing the respective CLABSI rates measured *before* and *after* the intervention's implementation, instead of the more rigorous comparison of the treatment group's CLABSI rate to that of the control group's.

Although these prospective cohort studies are most insightful, their goals most admirable, and their results potentially having immediate impact for the treatment group of patients, their designs—in addition to rendering them prone to under-reporting the true incidence of infection and to over-exaggerating an intervention's true effectiveness on CLABSI rates (*see*: Table 1)—necessarily preclude them from concluding a causal relationship between the studied intervention and an observed reduction in CLABSI rates in ICUs, some of these studies' conclusions notwithstanding *(see:* #1, above, on same page).[17-24,35,43] ●

~ Happy Holidays and New Year. ~

The **REFERENCES** to this article are available *on-line* at:
➔ www.myendosite.com/htmlsite/2010/refs10111210.pdf