

**Box C. Three Facts and Myths about CLABSIs.**

1. **Fact?** According to the CDC's *MMWR* published in March 1, 2011: "Decreases in CLABSIs have been attributed to various factors, including increased financial and leadership support for CLABSI prevention, improved education and engagement of clinicians in prevention efforts, packaging of prevention recommendations into practice bundles, increased data monitoring and feedback on progress, improvement of the safety culture in health-care, and local and statewide collaborative prevention efforts."<sup>25</sup>

**Response:** These factors reportedly have contributed to measured reductions in CLABSIs, but this list is incomplete. Other considerations, too—namely, biases and confounding factors, including measurement bias, feedback bias, publication bias, confounding bias, confirmatory bias, and changes in clinical behaviors—as much as these factors listed by the CDC, may be responsible for measured decreases in the number of CLABSIs in ICUs.

Moreover, discussed in this newsletter's *October-November-December, 2010*, issue, although feedback among staff about the intent, progress and effectiveness of an intervention is often lauded as a benefit of the study, such dialogue can create feedback bias, which can introduce error into the study's results.<sup>27</sup> Indeed, like a blinded drug study, limiting the staff's knowledge of the intervention and its intent is important to the study's validity.

2. **Fact?** The infection data published by the CDC in its report about CLABSIs featured in the March 1, 2011, issue of *MMWR*, like most published rates of CLABSIs, are sound and have been independently validated for quality, accuracy and completeness.

**Response:** The majority of all reported HAI data have *not* been validated, including the CLABSI data used by the CDC in this report in *MMWR*. This is a potentially problematic finding, as independent audits of medical records have demonstrated under-reporting of the true incidence of CLABSIs (see: main article).<sup>32,37</sup>

Several biases and factors, including confounding, confirmatory, sampling, and feedback biases, may cause not only published CLABSI rates to under-report the true incidence of infection, but also prospective cohort studies (and retrospective comparisons of infection data; see: main article) to over-exaggerate the effectiveness of an evaluated intervention and to misattribute to this intervention observed reductions in the CLABSI caused instead by one or more confounding factors (e.g., changes in behavior, such as reductions in the sensitivity of the surveillance methods used to detect, record and report CLABSIs; or, the more aggressive use of antibiotics).

3. **Fact?** In 2009 the CDC published a study in the *Journal of the American Medical Association* (JAMA) that

examined trends in the incidence of CLABSIs caused by methicillin-resistant *Staphylococcus aureus*, or "MRSA."<sup>42</sup> Using for its analysis infection data that hospitals reported to the CDC between 1997 and 2007, this study reported that the incidence of CLABSIs due to MRSA decreased by at least 50% since 2001 in the 6 most common types of adult ICUs. The CDC concludes in this report that this finding "means that the risk of primary MRSA bloodstream infections among patients with central line in these ICUs has substantially decreased in recent years."

**Response:** This conclusion may not be valid. The infection data used by the CDC for this analysis were self-reported and were not validated. Identifying the under-reporting of infection rates, audits have demonstrated that *reported* data suggesting reductions in infections do *not* necessarily reflect (or "mean") *actual* infection reductions.<sup>32,37</sup>

Due to a number of factors discussed in both this newsletter's main article and its *January-February-March-April, 2011*, issue, the CDC's conclusions that the incidence of CLABSIs due to MRSA in these adult ICUs decreased by at least 50% may be in error, and the possibility cannot be ruled out that the risk of these infections actually *increased* in recent years—the CDC's conclusions notwithstanding. A number of biases and uncontrolled confounding factors—such as reductions in the sensitivity of surveillance methods used since 2001 to measure, record, and report infections—could result in significant under-reporting of CLABSIs due to MRSA in these 6 types of adult ICUs. ●

➔ REFERENCES to this newsletter are available at:  
[www.myendosite.com/htmlsite/2011/refs05-0711.pdf](http://www.myendosite.com/htmlsite/2011/refs05-0711.pdf)

➔ Note that the **BOX ARTICLES** in the mailed version of this newsletter were abridged. The complete version of each box article is available only in this **ON-LINE** version of this newsletter.

Thank you for your interest in this newsletter, which I founded. *I have addressed each topic to the best of my ability. Respectfully,* **Lawrence F. Muscarella, Ph.D.**  
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# The Q-Net™ Monthly

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## What's News

Several recommendations for the prevention of infections associated with improperly reprocessed gastrointestinal endoscopes and other types of reusable medical equipment—including instructions for reprocessing the [Olympus MAJ-855 Auxiliary Water Tube](#)—are featured in this newsletter's January-February-March-April, 2011, issue. Next issue: Q-Net's popular [annual quiz](#).

## Editor-in-Chief

This newsletter/journal's articles are written by its editor-in-chief, [Lawrence F. Muscarella, Ph.D.](#)  
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## What is 'Q-Net'?

**Q-Net** is a technology assessment, infection control-based network of questions, answers, and perspectives. Its newsletter, or journal, 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.

## Review of a CDC Report about Healthcare-Associated Infections

*Have state and federal initiatives to prevent infections been as effective since 2001 as the CDC claims?*

◆ This article reviews a report published by the Centers for Disease Control and Prevention (CDC) in the March 1, 2011, issue of "Morbidity and Mortality Weekly Report" (MMWR).

◆ This article—which is the second in a series entitled "Dear CDC,"—concludes that this CDC report is more conjectural than scientific.

◆ The first article in this series was published in this newsletter's August-September, 2002, issue.



**INTRODUCTION:** PUBLISHED STUDIES, NEWSPAPER articles, and federal reports frequently focus on healthcare-associated infections (HAIs), sentinel events, or medical errors as a metric to evaluate health care in the U.S.<sup>1-16</sup> Measured reductions in these or another "patient harm" are often reported to indicate quality and safety improvements.

Discussed in the *October-November-December, 2010*, issue of this newsletter, a number of recently published studies evaluated the effectiveness of a checklist,

initiative, or bundle of "best practices" for the prevention of central line-associated bloodstream infections (CLABSIs) in the intensive care units (ICUs) of hospitals.<sup>17-24</sup> Several of these studies observed reductions in the incidence of CLABSIs over a period of time, reporting that these results demonstrate the success of the studied intervention.

*The Centers for Disease Control and Prevention:* The Centers for Disease Control and Prevention (CDC) has published a number of reports in the past few years discussing quality improvements in U.S. healthcare facilities.<sup>3,4,12,24-26</sup>

One of these reports published in May, 2010, provides a summary of "state-specific" CLABSI data that acute-care hospitals reported to the *National Health-*

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care Safety Network (NHSN)—an Internet-based surveillance system that is managed by the CDC and to which healthcare facilities in every state report HAIs.<sup>11,12</sup> According to this state-specific report, more than 1,500 hospitals in 17 states “observed” 18% fewer CLABSIs during the first 6 months of 2009 than “predicted.” Based on these results, the CDC concluded that patient care in U.S. hospitals is “getting safer.”<sup>12</sup>

**MORBIDITY AND MORTALITY WEEKLY REPORT:** ANOTHER CDC REPORT focusing on the safety of U.S. healthcare facilities was published in the March 1, 2011, issue of *Morbidity and Mortality Weekly Report*† (MMWR).<sup>25</sup> The findings of this CDC report, which is entitled “Vital Signs: Central line-associated bloodstream infections—United States, 2001, 2008 and 2009,”<sup>25</sup> are summarized in Box A.

This CDC report in *MMWR*, which is a retrospective analysis, estimates (without direct measurements) that the number of CLABSIs in the ICUs of U.S. hospitals decreased by 58% during the past decade—from an estimated 43,000 infections (reported by approximately 260 hospitals participating in NHSN’s predecessor, the *National Nosocomial Infections Surveillance System*, or NNIS) in 2001 to an estimated 18,000 infections (reported by approximately 1,600 hospitals participating in NHSN) in 2009.<sup>25,26</sup>

According to the CDC, these results (which are based on a number of assumptions):<sup>25,26</sup> (a) demonstrate significant improvements in the quality of health care in the ICUs of U.S. hospitals; (b) are “likely” due to state and federal efforts, coordinated and supported by the CDC (among others), to prevent HAIs; and (c) indicate that “the cumulative excess health-care costs of all CLABSIs prevented in ICUs (from 2001 to 2009) could approach \$1.8 billion, and the number of lives saved could be as high as 27,000” (see: Box A).

**CLABSIs:** Like a number of other reports that discuss the quality of health care in ICUs,<sup>13-15,17-24</sup> this CDC report in *MMWR* focuses on CLABSIs, which are associated with a mortality rate of as high as 25%.<sup>20,21,24,25</sup> Whether valid or not, the use of CLABSIs as a metric not only to rate and compare the safety of hospitals, but also to evaluate the impact of initiatives, projects, and both state and federal efforts to prevent HAIs has become commonplace.<sup>13-15,27</sup> This newsletter’s *October-November-December, 2010*, issue discusses these uses in detail, and Box B lists several of this issue’s key points.

**The American Recovery and Reinvestment Act (ARRA):** Discussed in this CDC report in *MMWR*, the federal government

† A series of reports prepared by and sometimes referred to as the “voice” of the CDC, *MMWR* is this agency’s “primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information.”<sup>40</sup> (The *Joint Commission* recommends reading *MMWR* to prevent HAIs.<sup>41</sup>)

**Box A. Summary of the CDC’s findings published in the March 1, 2011, issue of MMWR.<sup>25</sup>**

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- Each year 5% of hospitalized patients in the U.S. contract a healthcare-associated infection (HAI), one type of which is a central line-associated bloodstream infection (CLABSI). The mortality rate associated with CLABSIs is reported to be as high as 25%.
- This report by the CDC in *MMWR* compares national estimates of the number of CLABSIs among patients in intensive care units (ICUs), inpatient wards and outpatient hemodialysis facilities in 2008 and 2009 with estimates of CLABSI data recorded in ICUs in 2001.
- Estimates of CLABSI data in ICUs were determined by the CDC: (a) in 2001 from approximately 260 hospitals participating in the National Nosocomial Infections Surveillance System (NNIS); and (b) in 2009 from the approximately 1,600 hospitals participating in the CDC’s National Healthcare Safety Network (NHSN).
- The CDC estimates that the number of CLABSIs in ICUs (in the U.S.) dropped from 43,000 in 2001 to 18,000 in 2009—a reported reduction of 25,000 (i.e. 58%).<sup>α</sup>
- The CDC writes that this report’s data suggest that “the cumulative excess health-care costs of all CLABSIs prevented in ICUs could approach \$1.8 billion, and the number of lives saved could be as high as 27,000.”<sup>α</sup>
- *The CDC report in MMWR also concludes that:*
  - (major) “reductions in CLABSIs in ICUs likely reflect the impact of a coordinated effort by state and federal agencies, professional societies, and health-care personnel to implement proven best practices for the insertion of central lines”;
  - this effort, which likely has “helped drive these reductions,” has been coordinated and supported by the CDC, among others; and
  - this “model of federal, state, facility, and health-care provider collaboration that has proven so successful in CLABSI prevention should be applied to other HAIs and other health-care-associated conditions.” ●

in 2009 established the goal of a 50% reduction in CLABSIs, nationwide, by 2013.<sup>25,28</sup> Also noted in this CDC report, the *American Recovery and Reinvestment Act (ARRA)* of 2009

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<sup>α</sup> The CDC’s estimates and conclusions presented in this issue of *MMWR* are based on self-reported CLABSI data that have not been validated for quality.<sup>25,34</sup> As the CDC acknowledges, these data are subject to “reporting biases.”<sup>25</sup>

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appropriated \$40 million for the CDC to support efforts by state health departments to monitor and prevent HAIs.<sup>11,25</sup>

*“National success”*: An expert committed to the prevention of CLABSIs described the CDC’s findings presented in this report in *MMWR* as “the first national success we have for patient safety in this country.”<sup>26</sup> Similarly, one of this report’s co-authors stated that the CDC’s estimated 58% reduction in the number of CLABSIs “stands out in terms of a national, large-scale, dramatic reduction in healthcare-associated infections,” adding that there are few, if any, “other examples like this in the quality improvement literature.”<sup>26</sup>

**AIM AND RESULTS:** THIS REVIEW EVALUATED and calls into question the estimates, conclusions, and scientific rigor of this CDC report published in *MMWR*.

**DISCUSSION:** THIS CDC REPORT in *MMWR* suggests significant improvements—at least in enhanced leadership and targeted funding by the federal government (e.g., the ARRA of 2009) to support state-based efforts for the prevention of HAIs (see: Box A).<sup>25,26,28</sup> Moreover, this report in *MMWR* highlights laudable initiatives by the CDC to improve the quality and safety of health care.<sup>25,26</sup> This review found this CDC report to be more conjectural than scientific, however, and as salient for its estimates and conclusions as for its limitations and oversights.

➔ *Other types of HAIs are also important to monitor and prevent. This newsletter’s January-February-March-April, 2011, issue provides a number of recommendations to prevent HAIs associated with improperly reprocessed gastrointestinal (GI) endoscopes—including how to reprocess the Olympus MAJ-855 auxiliary water tube.*

*“Reporting biases”*: Like that of any publication that rates, ranks and compares the safety of hospitals based on reported rates of HAIs, this CDC report assumes—indeed, its validity requires—that the infection data it used for its analysis is accurate and complete.<sup>11-15,25,27</sup> Notably, however, the majority of all reported CLABSI data have not been validated<sup>β</sup> for accuracy and completeness—including this CDC report’s data (which were self-reported to the NNIS in 2001 and to the CDC’s NHSN in 2009 and were not reported by a random sample of healthcare facilities).<sup>11,13,14,27,29-36</sup>

As a consequence, the U.S. Government Accountability Office (GAO), among others, has concluded that there is a

<sup>β</sup> Validation evaluates the quality of reported infection data. Without confirmation of the data’s validity, infections may have been missed or not counted and their incidence under-reported.<sup>13,14,27,29</sup>

### Article at a Glance: Review of a CDC report

- ◆ **BACKGROUND:** A report published by the CDC in the March 1, 2011, issue of *Morbidity and Mortality Weekly Report* (MMWR) concludes that from 2001 to 2009 the estimated number of central line-associated bloodstream infections (CLABSIs) in the ICUs of U.S. hospitals was reduced by 58%, adding that coordinated state and federal efforts were “likely” responsible for this result.
- ◆ **IMPLICATIONS:** According to the CDC, this report’s findings indicate that “the cumulative excess health-care costs of all CLABSIs prevented in ICUs could approach \$1.8 billion,” with as many as 27,000 “lives saved.”
- ◆ **AIM:** The validity of this CDC report was evaluated.
- ◆ **CONCLUSIONS:** This review questions the soundness of this CDC report, finding its estimates and conclusions to be more conjectural than scientific and to be based on self-reported infection data the majority of which have not been validated and may be in error. ●

“substantial risk” that these published infection data (which have not been validated) may be “misleading,” yield unreliable national estimates of HAIs, and under-report the true incidence of infection (one consequence of which can be to over-exaggerate the success of initiatives and other interventions that are evaluated based on these HAI data).<sup>11,13,14,27,29-35</sup>

The CDC’s report in *MMWR* acknowledges as much, agreeing that the CLABSI data on which its analysis is based are subject to “reporting biases.”<sup>25</sup> (Examples of such biases would include measurement, sampling, publication, and confounding biases.<sup>27</sup>) Additionally, the CDC concedes in its state-specific report about CLABSIs that infection data that have not been validated may lack quality and completeness.<sup>11</sup>

Similarly, the *American Hospital Association* (AHA) has expressed “serious concern” about the public reporting of HAI data through the CDC’s NHSN, concluding that these data, which generally lack validation, may not be a sound indicator of a hospital’s quality and performance.<sup>35</sup> These concerns of the GAO and AHA, and, too, of the CDC, raise questions about the validity of this CDC report in *MMWR*.

*A retrospective comparative analysis:* In addition to its infection data being prone to biases\* (e.g., measurement inaccuracy

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\* The reader is referred to this newsletter’s *October-November-December, 2010*, issue, which discusses a number of biases and confounding factors that can cause both CLABSI rates to under-report the true incidence of infection and the performance of a studied intervention for the prevention of CLABSIs to be over-exaggerated.

**Box B:** *Key points of this newsletter's October-November-December, 2010, issue about CLABSIs.*<sup>27</sup>

1. Whereas the CDC reports that hospitals in the U.S. may be “getting safer,”<sup>12</sup> other researchers have found the quality of health care to be lacking and to display “little evidence” of improvement, reporting that concerning lapses in infection control (at least among dozens of inspected ambulatory surgical centers) were “common.”<sup>2,3</sup>

2. A CDC “state-specific” study published in May, 2010, found that the number of CLABSIs reported by almost two thirds of 17 (U.S.) states whose laws mandate the reporting of CLABSI data to the CDC’s NHSN (see: main article) was significantly fewer than “predicted.”<sup>11</sup> The CDC interpreted this finding to suggest that the quality of health care in the ICUs of hospitals is improving<sup>12</sup> (notwithstanding the findings of others<sup>2,3</sup>).

3. The majority of reported CLABSI rates—including those listed in both the CDC’s state-specific report<sup>11</sup> and an article by *Consumer Union* about CLABSIs<sup>15</sup>—have not been validated and, like the estimates and conclusions that are based on them, may be in error.

4. Like report cards that children might write to grade their own academic performance, the majority of reported CLABSI rates are measured, interpreted and reported (to, for example, the CDC’s NHSN or another database) by hospitals themselves (some as mandated by state law, others voluntarily) without these rates having been independently audited by, for example, federal or state public health officials (i.e., data validation) to ensure the data’s quality, accuracy and completeness.

5. The use of reported CLABSI data and rates by the CDC, consumers, Consumer Union, and public and private health insurers, among others, to evaluate, compare, and rate the relative safety and quality of hospitals is often invalid. Nevertheless, public and private health insurers may condition reimbursement on a hospital’s tracking and reporting of its CLABSI rates (e.g., *value-based purchasing*, *pay for performance*, and the Centers for Medicare and Medicaid’s *pay-for-reporting* program<sup>27</sup>).

6. A list is provided of several biases—including sampling, publication, feedback (see: [Box C](#)), and confounding biases—that can cause measured CLABSI rates to under-report the true incidence of infection and the performance of an associated infection-control intervention, initiative, or program of “best practices,” evaluated using, for example, a prospective cohort study (or a retrospective comparison of infection data), to be over-exaggerated.

7. A review of two prospective-cohort studies that evaluated the effectiveness of a bundle of “best practices” for the prevention of CLABSIs is provided. ●

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cies), this CDC report in *MMWR* is a retrospective study that compares the number of CLABSIs reported in 2001 to those reported in 2009. Unlike randomized controlled studies, which are significantly more scientifically robust,<sup>27</sup> such retrospective comparisons, like prospective cohort studies, are limited in strength and cannot control or eliminate unrecognized confounding factors.\* As a result, these studies cannot demonstrate causal (i.e., cause-and-effect) relationships between an intervention and observed reductions in CLABSIs.<sup>27</sup>

*Note:* The reader is referred to [Box C](#), which provides a number of *facts* and *myths* about CLABSIs and their reporting.

*Questions raised:* Therefore, primarily because this CDC report in *MMWR* is retrospective, not controlled, and compares CLABSI data that, although they are prone to biases and to under-reporting the true incidence of infection, have not been validated for accuracy and completeness, this review questions this CDC report’s estimates and conclusions that:<sup>25</sup>

- the number of CLABSIs in the ICUs of U.S hospitals was reduced by 58% between 2001 and 2009;

- state and federal efforts coordinated by the CDC (among others) to prevent HAIs—such as those for which the *ARRA* of 2009 allocated \$40 million in targeted funding—were “likely” responsible for this reduction in CLABSIs; and

- “the cumulative excess health-care costs of all CLABSIs prevented in ICUs (since 2001) could approach \$1.8 billion, and the number of lives saved could be as high as 27,000.”

*This review questions this CDC report’s analysis, estimates and conclusions about CLABSIs.*

*The Pittsburgh Regional Healthcare Initiative and the Michigan Keystone Project:* This CDC report in *MMWR* asserts that: “in recent years, large-scale regional and state-wide projects, such as the *Pittsburgh Regional Healthcare Initiative* and the *Michigan Keystone Project*, have demonstrated roughly 70% reductions in CLABSI rates (in ICUs) by increasing adherence to recommended best-practices for the insertion of central lines,” adding that: “the successes of (this) *Initiative* and (this) *Project* demonstrate the impact of regional and state-based CLABSI prevention programs.”<sup>25</sup>

This review found, however, that these assertions by the CDC are seemingly overly simplistic, if not over-reaching. First, both the CDC in an earlier study published in 2005<sup>24</sup> and Pronovost et al. (2006)<sup>20</sup> evaluated this *Initiative* and *Project*, respectively, using CLABSI data that had not been validated (the laws in neither Pennsylvania nor Michigan require such data validation<sup>11</sup>)—therefore, the claim that either study demonstrated roughly a 70% reduction in CLABSI rates may be inaccurate. Second, these studies by the CDC in 2005<sup>24</sup> and Pronovost et al. (2006)<sup>20</sup> were of a prospective-cohort design, not of a randomized controlled design—therefore, this

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CDC report's assertion<sup>25</sup> that the successes of this *Initiative* and *Project* demonstrate their effectiveness for the prevention of CLABSIs (i.e., a cause-and-effect relationship) may be more conjectural than scientific.<sup>8</sup>

*This review suggests that this CDC report's conclusions about the number of CLABSIs prevented since 2001, the money saved, and the successes of coordinated efforts to prevent HAIs are overly simplistic and more conjectural than scientific.*

Pronovost et al. (2006) would seemingly agree, acknowledging that: (1) the infection data (used to evaluate the *Michigan Keystone Project*) were incomplete (i.e. these data had not been validated) and could have "exaggerated" the study's results due to a measurement bias;<sup>20</sup> and (2) their study's prospective-cohort design "reduces the ability to make a causal connection between the intervention and reduced rates of (CLABSI)."<sup>20</sup> So, too, might the GAO and AHA agree, having both concluded that infection data that have not been validated may lack quality and yield faulty conclusions.<sup>34-36</sup>

*Confirmed adherence to "best" practices?* The soundness of these assertions by the CDC in this report in *MMWR* is questioned for a third reason, too. At odds with the CDC's claim that such efforts as this *Initiative* and *Project* have reduced CLABSI rates "by increasing adherence to recommended best-practices,"<sup>25</sup> neither the CDC's study in 2005<sup>24</sup> nor Pronovost et al.'s (2006)<sup>20</sup> evaluated staff adherence to the studied practices. According to the CDC's study in 2005:<sup>24</sup> "data on implementation of and adherence to the promoted practices or other facility-specific interventions were not systematically reported; therefore, determining the relationship between adherence and the observed decrease in infection rate was not possible." Pronovost et al. (2006) similarly wrote that their study did not evaluate staff adherence to the studied intervention's practices because of "limited resources."<sup>20</sup>

Although not discussed in this CDC report in *MMWR*,<sup>25</sup> unless not only validated CLABSI data and a controlled study are used, but also staff adherence to an evaluated intervention or "promoted practices"<sup>24</sup> is confirmed (among other criteria), conclusions that the intervention—including such state and federal efforts as those that are the focus of this CDC report in *MMWR*, or for which the *ARRA* of 2009 appropriated targeted funding<sup>25</sup>—caused or was likely responsible for achieving a percentage reduction in HAIs would be speculative.<sup>27</sup>

*Confirmatory bias?* The aforementioned CDC's state-specific

report states that HAI data reported to the CDC's NHSN are the "primary data" used to evaluate the impact of federal funds allocated by this *ARRA* of 2009 and administered by the CDC to prevent HAIs.<sup>11</sup> Similarly the CDC's report in *MMWR* states that the CDC is using the NHSN's data to monitor progress toward achieving the national goal of a 50% reduction in CLABSIs by 2013.<sup>25,28</sup>

This review provides a cautionary note about the use of the NHSN's infection data for these purposes. Not only can the NHSN's self-reported infection data (a majority of which have not been validated) yield misleading estimates of HAIs, but also such a prospective comparison of these data to evaluate quality improvements and progress is prone to misinterpretations and faulty conclusions about the incidence of CLABSIs and the impact of interventions to prevent them.<sup>27</sup>

The CDC's use of the NHSN's infection data for these purposes raises an additional issue for debate: whether this CDC's administration of targeted funding by the *ARRA* of 2009 to prevent HAIs, as well as the CDC's evaluation of the progress toward a national goal of a 50% reduction in CLABSIs, might have inadvertently introduced *confirmatory bias*<sup>9</sup> (among other biases<sup>27</sup>), causing this CDC report's conclusions to have unintentionally advanced an auspicious outcome, assigned more validity to the NHSN's data than scientifically warranted, and described the impact of coordinated state and federal efforts for the prevention of CLABSIs (such as those currently funded by the *ARRA* of 2009) more favorably than empirically demonstrated.

*A recent study wrote that: "the politics of measuring HAIs may have outpaced the science."<sup>43</sup> That the role of the CDC vis-à-vis HAIs has become more political than scientific could be argued.*

*Data validation:* Consistent with conclusions that infection data that have not been validated (e.g., the NHSN's) can yield misleading results and unreliable estimates of HAIs, cases of under-reporting the true CLABSI rate have been identified during independent audits,<sup>11,13,14,27,29-35,37</sup> one consequence of which can be to over-exaggerate the actual impact of an evaluated initiative or project to prevent CLABSIs.

For example, the Connecticut Department of Public Health (C-DPH) found that during its (blinded) retrospective audit in 2009 of the medical records of this state's 30 acute-care hospitals, more than half of the infections the C-DPH confirmed to be CLABSIs had not been reported (to the NHSN).<sup>32</sup> Similar cases of the under-reporting of HAIs have

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<sup>8</sup> The CDC authored another report in 2009 that discusses the incidence of CLABSIs due to MRSA. This report, too, advances conclusions about reductions in these infections that may not be sound.<sup>42</sup>

<sup>9</sup> *Confirmatory bias* in this context favors an advantageous outcome (or discourages an undesirable conclusion). Unless eliminated or controlled, confirmatory bias could result in a study overlooking or ignoring factors that might invalidate or jeopardize its hypothesis.

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been reported by the New York State Health Department.<sup>37</sup>

A conclusion that is in agreement with this review's questioning of this CDC report's use of infection data that have not been validated, the C-DPH wrote that data validation is "essential if data from performance measurement systems are to be *credible*,"<sup>32</sup> adding that "a method to validate data must be considered in any mandatory reporting system" (to ensure the reported HAIs' accuracy and completeness).<sup>32</sup>

*Validation of their accuracy and completeness is  
"essential" if infection data are to be "credible."*

**Clarification:** This review lauds the diligent efforts of federal and state agencies, infection-control researchers, and health-care facilities to prevent and publicize awareness about HAIs. It questions, however, the validity of reports claiming quality improvements and the likely responsible interventions that are based on: (1) the use and comparison of self-reported HAI data (e.g., the CDC's NHSN), the majority of which have not been validated; are prone to inaccuracies; lack statistical soundness; and may under-report the true incidence of HAIs; and (2) a retrospective (or, a prospective-cohort<sup>27</sup>) study design or methodology, the scientific rigor of which is limited.<sup>π</sup> An example is this CDC report in *MMWR*, which concludes significant reductions in its estimated number of CLABSIs likely due to state and federal efforts.<sup>11,13,14,27,29-35</sup>

Echoing concerns previously expressed in this newsletter about published prospective cohort studies that evaluated the impact of an intervention on the incidence of CLABSIs in ICUs,<sup>27</sup> retrospective studies, even more so, are not sufficiently robust to determine whether an intervention caused an observed reduction in HAIs. Indeed, retrospective studies comparing un-validated HAI data (e.g., this CDC report in *MMWR*) are prone to misinterpretations of their results; to over-exaggerations of the actual impact of associated interventions on observed reductions of HAIs (e.g., state and federal efforts to prevent CLABSIs); and to misattributing to the intervention reductions in CLABSIs that might have been caused instead by one or more unrecognized confounding factors (e.g., reduced sensitivity of the surveillance methods used to detect, measure, and record a true infection; or, the more aggressive use of antibiotics).<sup>27</sup>

**CONCLUSIONS: UNDERSCORING THE IMPORTANCE** of the publication of accurate and circumspective depictions of both the quality of health care and of the incidence of HAIs in the U.S., this review calls into question the findings of the CDC report published in the March 1, 2011, issue of *MMWR*,

primarily because this report's retrospective methodology is limiting, and its results are based on infection data that have not been validated, possibly causing its national estimates of, and conclusions about, CLABSIs to be in error.<sup>34</sup>

Due to a number of limitations, oversights, and other factors, the possibility cannot be ruled out that this CDC report: (i) under-reported and underestimated the true incidence and risk, respectively, of CLABSIs in ICUs; (ii) over-exaggerated the percentage by which the estimated number of CLABSIs might have been reduced since 2001; (iii) overstated not only the validity of the NHSN's data but also (e.g., by millions of dollars) the cumulative amount of money saved and (e.g., by the thousands) the number of patient deaths prevented by efforts to prevent CLABSIs; and (iv) misattributed to these efforts an estimated reduction in CLABSIs caused instead by one or more biases and/or confounding factors.

**FINAL WORDS: THIS REVIEW RAISES** the additional concern that publication of (un-validated) HAI data that are prone to biases and under-reporting the true incidence of CLABSIs might cause: opportunities to prevent HAIs to be missed; less vigilance and attention to infection control; and, therefore, an increased risk of CLABSIs in ICUs.<sup>13,14,27</sup> In truth, HAIs remain a "danger" and are "far more common and deadly than many people understand."<sup>38</sup> (Whether the estimates of other CDC reports, such as one recently published concluding that colorectal cancer incidence and mortality have declined in recent years in the U.S., are scientifically sound is unclear.<sup>39</sup>)

In closing, validation of the accuracy, completeness, quality and statistical soundness of reported HAI data is recommended, without which analyses, estimates and conclusions that are based on these data—such as the conclusion of this CDC report in *MMWR* that the estimated number of CLABSIs in ICUs of U.S. hospitals has decreased since 2001 by 58% likely due to coordinated state and federal efforts to prevent HAIs,<sup>25,26</sup> or claims of the touted safety of one health-care facility compared to another<sup>15,27,35</sup>—may be questioned.

A circumspective approach is also recommended whenever a retrospective comparison (or prospective cohort study) is used to evaluate quality improvements in health care or the percentage by which an initiative might have reduced CLABSIs, lest the study's results be misleading and observed reductions in infections caused instead by one or more confounding factors be misattributed to the initiative. A number of additional recommendations are provided in this newsletter's *October-November-December, 2010*, issue. ■ **The End**  
[Article by: Lawrence F. Muscarella Ph.D.]

<sup>π</sup> The completeness of reports that lack adequate discussions and disclosures of the potential impact of these two noted limitations on their results and conclusions about HAIs is also questioned.

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