NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

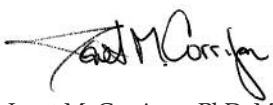
A CONSENSUS REPORT

Foreword

Healthcare-associated infections (HAIs) are a serious public health issue in the United States. An estimated 2 million HAIs occur each year in this country, accounting for an estimated 90,000 deaths and adding $4.5 billion to $5.7 billion in annual healthcare costs. Although healthcare facilities have collected data on HAIs for many years, these data have not been used to compare rates of infection among facilities, resulting in a paucity of publicly available data.

In recent years, demand has been growing for public reporting of HAI data, and approximately 20 states now require providers to report these data. Because the risk of contracting an HAI is so great and of such concern to providers, consumers, and purchasers of healthcare, the National Quality Forum (NQF) has long identified infections as an area ripe for performance measurement and quality improvement—starting with its initial publication of *Safe Practices for Better Healthcare.* Subsequently, NQF has endorsed voluntary consensus standards related to HAIs in several projects. This report represents an extension of that work by presenting a set of seven national voluntary consensus standards for reporting HAI data, including a framework for measurement and public reporting.

We thank the Texas Medical Institute of Technology, the Association for Professionals in Infection Control and Epidemiology, and the Society for Healthcare Epidemiology of America for their support of this project. We also thank the Healthcare-Associated Infection Steering Committee and its Technical Advisory Panels for their stewardship of this project and NQF Members for their active participation and longstanding commitment to combating HAIs.



Janet M. Corrigan, PhD, MBA
President and Chief Executive Officer

ISBN 1-933875-11-9

Printed in the U.S.A.

Permissions
National Quality Forum
601 Thirteenth Street, NW, Suite 500 North
Washington, DC 20005
Fax 202.783.3434
www.qualityforum.org

NATIONAL QUALITY FORUM

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Table of Contents

(continued)

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Executive Summary

Healthcare-associated infections (HAIs) have emerged as a topic of critical interest for healthcare consumers, purchasers, and other stakeholders. Approximately 20 states now require healthcare providers to report infection-related data, and 16 states make reports on HAI rates available to the public. Numerous public and private purchasers and quality oversight organizations require providers to report HAI data in various local and regional initiatives.

To date, only limited national standards for the public reporting of HAI data have been in use. In the absence of widely agreed-upon standards for public reporting, it is difficult to compare or aggregate the reported data on regional or national levels. The lack of nationally agreed-upon standards for reporting infection rates also increases the burden on providers, who must respond to multiple requests for these data.

The National Quality Forum (NQF) is a private sector, national voluntary consensus standards-setting organization enabled by the National Technology Transfer and Advancement Act. NQF-endorsed™ consensus standards are the standards of "first choice" by the federal purchasers, quality oversight organizations, and others.

This report presents the results of a 15-month NQF project to identify, evaluate, and endorse the "best-in-class" performance measures for the reporting of HAI data. This project, which was guided by a Steering Committee and assisted by six Technical Advisory Panels, focused on the following areas: 1) intravascular catheters and bloodstream infections; 2) indwelling catheters and urinary tract infections; 3) surgical site infections; 4) ventilator and respiratory infections; 5) pediatric infections; and 6) reporting and implementation issues. In addition to

presenting 7 newly NQF-endorsed measures in 4 areas and the 13 HAI reporting measures previously endorsed by NQF in other projects, this report also includes 5 principles for public reporting of HAI data and 8 research recommendations that provide guidance on where practices and measures will have the greatest impact on continuing quality improvement efforts. As with the NQF Hospital Care, Ambulatory Care, and other projects, these measures will be expanded and improved in the near future.

Newly Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Intravascular Catheter-Associated Bloodstream Infections

- Central line bundle compliance
- Surgical site infection rate
- Cardiac surgery patients with controlled 6 am postoperative serum glucose
- Surgery patients with appropriate hair removal

Ventilator-Associated Pneumonia and Respiratory Illness

- Ventilator bundle

Healthcare-Associated Infections in Pediatric Populations

- Late sepsis or meningitis in neonates
- Late sepsis or meningitis in very low birth weight neonates

Previously Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Intravascular Catheter-Associated Bloodstream Infections

- Central line-associated bloodstream infections

Surgical Site Infections

- Prophylactic antibiotic received within one hour prior to surgical incision
- Prophylactic antibiotic selection for surgical patients
- Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for coronary artery bypass graft [CABG] and other cardiac surgery)
- Deep sternal wound infection rates for CABG
- Postoperative sepsis

Catheter-Associated Urinary Tract Infections

- Catheter-associated urinary tract infection rate for intensive care unit patients

Ventilator-Associated Pneumonia and Respiratory Illness

- Rate of ventilator-associated pneumonia

Clinician-Level Perioperative Care

- Timing of prophylactic antibiotics, ordering physician
- Timing of prophylactic antibiotics, administering physician
- Selection of prophylactic antibiotic, first- and second-generation cephalosporin
- Discontinuation of prophylactic antibiotics, non-cardiac procedures
- Discontinuation of prophylactic antibiotics, cardiac procedures

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Introduction

Healthcare-associated infections (HAIs) are a serious public health issue in the United States. HAIs are a significant complication affecting hospitalized patients, with between 5 and 10 percent of inpatients acquiring one or more infections during their hospitalization.[1] An estimated 2 million HAIs occur each year in the United States, accounting for an estimated 90,000 deaths and adding $4.5 billion to $5.7 billion in healthcare costs.[2,3]

The risk of contracting an HAI is of great concern to providers, consumers, and purchasers of healthcare. As a result, demand has been growing for public reporting of HAI data. To date, 16 states have enacted legislation mandating public reporting of infection rates; 2 states require that infection rates be reported but not publicly released; and 2 states require the reporting of other infection-related information. Of the remaining states, all but five have introduced but have not yet enacted legislation to measure HAIs.[4]

Although hospitals and other healthcare facilities have routinely collected data on HAIs for many years, these data have been used to track internal performance over time, to analyze institution-specific

[1] Weinstein RA, Nosocomial infections update, *Emerg Infect Dis,* 1998;4:416-420.

[2] Ibid.

[3] Stone PW, Larson E, Kawar LN, A systematic audit of economic evidence linking nosocomial infections and infection control interventions: 1990-2000, *Am J Infect Control,* 2002;30:145-152.

[4] Consumers Union: Stop Hospital Infections Campaign. Available at www.consumersunion.org/campaigns/learn_more_background/003544indiv.html. Last accessed April 2007.

quality improvement, and to monitor infection trends for public health surveillance—not to compare rates of infection among facilities. Because methods for diagnosis and data collection on HAIs vary among institutions, the validity of data comparisons between facilities or across geographic areas is questionable. Through endorsed national standards for HAI measurement, states and other organizations gain a valuable resource for implementing nationally comparable standards rather than going forward with separate, potentially discordant measurement efforts, and consumers gain access to uniformly reported data that are reliable and useful for decisionmaking.

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

This report presents a set of national voluntary consensus standards for reporting HAI data, including a framework for measurement and public reporting, 7 newly recommended evidence-based performance measures, 13 previously endorsed measures, and 8 recommendations for measure development and research in the following clinical priority areas:

- intravascular catheter-associated bloodstream infections (BSIs);
- surgical site infections (SSIs);
- catheter-associated urinary tract infections (CA UTIs);
- ventilator-associated pneumonia (VAP) and respiratory illness;
- HAIs in pediatric populations; and
- clinician-level perioperative care.

Relationship to Other NQF-Endorsed Consensus Standards

This report does not represent the first foray into measurement of HAIs; metrics of infections and infection prevention processes appear in NQF-endorsed™ measure sets addressing nursing care,[5] nursing home quality,[6] cardiac surgery,[7] hospital care,[8] and physician specialty care.[9] In all, 13 measures of HAI have been previously endorsed through the NQF process.

Other national voluntary consensus standards have been endorsed to identify best practices in infection prevention and to spur reporting of adverse outcomes resulting from HAIs. *Safe Practices for Better Healthcare: 2006 Update*[10] presents 30 practices that should be universally utilized to reduce the risk of harm to patients; 5 of these practices are specific to HAIs, and 3 of the 5 (i.e., Safe Practice 19: Aspiration and Ventilator-Associated Pneumonia Prevention, Safe Practice 20: Central Venous Catheter-Associated Bloodstream Infection Prevention, and Safe Practice 21: Surgical Site Infection Prevention) correspond directly to priority areas for measurement identified in this report. These initiatives, along with the performance measures, recommendations, and the framework detailed in this report, promote safer, higher-quality patient care and facilitate meaningful, transparent public reporting of HAIs. All previously endorsed measures and safe practices have received continued endorsement.

Identifying the Initial Set

An NQF Steering Committee (appendix B) outlined the initial approach to identify, evaluate, and recommend measures for endorsement. This approach included defining a specific purpose and scope for performance measures and screening the candidate standards against NQF criteria for selection (box A). In some instances, the Steering Committee requested that the Technical Advisory Panel (TAP) for a given priority area make recommendations for defining the scope of measurement within that topic (see the commentary, appendix C, for further information on Steering Committee and TAP deliberations).

For the purposes of this report, the Steering Committee defined an HAI as an infection that develops in a patient who is cared for in any setting where healthcare is delivered and that originates from the delivery of healthcare (i.e., was not incubating or present at the time healthcare was provided). In ambulatory and home

[5] National Quality Forum (NQF), *National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set,* Washington, DC: NQF; 2004.

[6] NQF, *National Voluntary Consensus Standards for Nursing Home Care: A Consensus Report,* Washington, DC: NQF; 2004.

[7] NQF, *National Voluntary Consensus Standards for Cardiac Surgery: A Consensus Report,* Washington, DC: NQF; 2004.

[8] NQF, *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set – A Consensus Report,* Washington, DC: NQF; 2003.

[9] NQF, *National Voluntary Consensus Standards for Hospital Care: Specialty Physician Performance Measures – A Consensus Report,* Washington, DC: NQF; 2007.

[10] NQF, *Safe Practices for Better Healthcare: 2006 Update – A Consensus Report,* Washington, DC: NQF; 2007.

settings, the term *healthcare-associated infection* would apply to any infection that was associated with a medical or surgical intervention. Because the geographic location of infection acquisition is often uncertain, the preferred term is *healthcare-associated* rather than *healthcare-acquired*.

Purpose

The purpose of this project is to endorse a set of national consensus standards that promotes consistent definitions, language, and methodology relevant to surveillance and reporting data on infections. Utilization of the consensus standards should result in information that is useful to the public for making healthcare choices and to the healthcare community for reporting and continuous improvement of infection prevention processes.

Scope

The scope of this project encompasses performance measures to be used across the spectrum of outpatient and inpatient settings, including but not limited to dialysis units, trauma centers, intensive care units (ICUs), specialty units, rehabilitation centers, emergency rooms, ambulatory surgical units, hospitals, long-term care settings, and home health settings. All relevant patient populations, including pediatric, maternal/perinatal, and immunocompromised patients, were considered in the evaluation of measure usability. Endorsed measures appropriate for accountability and public reporting and measurement are at the provider or institution level. To ensure that measures would be appropriate for provider accountability, community-level measurement, community-acquired infections, and assisted living facility settings were excluded from the scope.

Priority Areas for Measurement and Reporting

Clinical priority areas for measurement were selected based on the incidence of the relevant infection, the severity of its impact on patient morbidity and mortality outcomes, and the resource burden they place on health systems. TAPs were convened to address measurement in each of these four priority areas:

- intravascular catheters and BSIs;
- SSIs;
- indwelling urinary catheters and urinary tract infections; and
- VAP and respiratory illness.

A fifth clinical TAP was convened to evaluate how measurement in each of these four clinical areas could be applied to the pediatric population, and a sixth TAP focusing on reporting and implementation was convened to provide guidance and recommendations for measurement implementation in all areas and to develop a framework for public reporting of HAI data.

Identifying Candidate Standards for Evaluation

Candidates for evaluation were identified through several complementary strategies:

- open solicitation of measures through NQF's "Call for Measures." From February 17, 2006, to March 17, 2006, the "Call" was distributed through the following avenues:
  - posted on NQF's web site,
  - e-mailed to NQF's Members and all project Steering Committee and TAP members, and
  - e-mailed to more than 1,300 individuals requesting to be kept apprised of NQF activities;
- review of NQF-endorsed measures and other related, ongoing NQF consensus work to identify infection measures within these other efforts; and
- active search of additional candidate standards from the Agency for Healthcare Research and Quality's National Quality Measures Clearinghouse and literature searches.

Criteria for Selection of Standards

Standards were evaluated against the criteria derived from the work of the NQF Strategic Framework Board and endorsed by NQF (box A). The following important characteristics also were considered in the selection of potential consensus standards:

- relevant to identified priority areas;
- address vulnerable populations;
- address all relevant populations;
- result in possible negative incentives or unintended consequences;
- have clear and complete specifications;
- have been pilot tested and validated or already are in use; and
- address high variation, including overuse and underuse.

The following principles also guided the selection of consensus standards:

- measures of outcomes are of highest priority because of their resonance with consumers and purchasers and their usefulness to providers for internal quality improvement;
- process measures (often preventive actions) linked to outcomes should be considered;
- the focus of the measures is primarily accountability as a driver of quality improvement; and
- measures should reflect an aspect of care that is substantially influenced by established practices of infection prevention.

Box A – Criteria for Evaluation and Selection of Measures

1. **Important.** The extent to which a measure reflects a variation in quality and low levels of overall performance and represents a significant burden of disease, suffering, or financial costs.
2. **Scientifically Acceptable.** The extent to which a measure provides consistent and credible results when implemented.
3. **Useable.** The extent to which intended audiences (e.g., consumers, purchasers, providers) can understand the results of a measure and are likely to find it helpful for decisionmaking.
4. **Feasible.** The extent to which data can be obtained within the normal flow of clinical care and an implementation plan can be achieved.

Ongoing Improvement of Initial Measure Set

This is an initial measure set. As new information becomes available and measure developers continue crafting and improving current measures related to HAIs, new measures for the set and updates will be considered.

Principles for Public Reporting of Healthcare-Associated Infection Data

As voluntary and mandatory public reporting programs gain in number, certain principles have emerged that should act as a framework for developing reporting programs. This framework includes elements that programs should plan to incorporate as they gain experience in reporting and seek to improve their reports. For example, the principle of risk adjustment to support performance comparisons acknowledges that although risk adjustment is important, it and other methodologies for accounting for risk (e.g., hierarchical modeling), although still in their infancy for HAI reporting, should be explored as current reporting efforts go forward.

The following principles for public reporting of HAI data were developed through the deliberations of the project's Reporting and Implementation TAP and include recommendations that address issues relevant to both the facility (e.g., hospital, clinic, outpatient surgical center) collecting data for measurement and the program (e.g., state-mandated public reporting programs, contractual requirement) reporting the data to the public. The majority of measures used for tracking HAIs originally were intended for surveillance by healthcare professionals rather than for public reporting, with greater precision in specifications preferred for measures used to compare performance. Most current HAI measures and reporting programs for accountability are in the earliest stages of development. Implementing initial measures within a carefully designed reporting program will facilitate continued improvement of current measures, identify gaps for future measure development, help in honing strategies for implementation, and improve the effectiveness of public reporting.

Overall, programs for reporting HAI data should encompass the following:

1. **Metrics should be chosen that are fully specified and generally accepted.**
   - *Measures should be applicable across care settings and facilitate the identification of attribution for outcomes.* They should be useful in all care settings where patients are at risk of infection and should take into account transitions between settings.
   - *Measures should rely on feasible and reliable data sources.* Data sources should be valid and feasible and usable for collection. Several data sources are being used and tested for use in reporting HAIs, including administrative and hybrid methodologies. To maintain feasibility and align with electronic health records, data sources and terminologies should be consistent with national efforts in this area.
   - *Measures should not create unintended consequences or negative incentives.* Inclusions and exclusions should not create the opportunity for providers not to report relevant cases, which would result in under reporting of infection rates. Furthermore, inclusions and exclusions should be clearly defined and use acceptable coding standards, where applicable.

Similarly, measures of compliance should provide the practitioner with discretion if practices are not in the patient's best interest—for example, measures of antibiotic use should not promote over- or underprescription of antibiotic agents. Additionally, measures should not create a disincentive to treat the sickest and most vulnerable patients.

- *If appropriate, measures should be reported using risk stratification to account for patient case mix and other factors.* Risk of infection can vary by patient population, the type of care provided (e.g., surgical versus medical), the type of healthcare facility (long-term care versus acute care hospital), or the kind of unit within the facility (e.g., trauma unit versus medical ICU). Furthermore, risk can be amplified by comorbid conditions or immune status. Adequate risk adjustment ensures that variations in quality are not obscured by variations in risk. Although no risk adjuster currently is adequate for program implementation, programs should compare denominators of similar risk (e.g., compare large academic centers to large academic centers, ICU data to ICU data). As risk adjusters are validated by investigators in the field and become available, programs should have strategies to incorporate them as an improvement to their reporting programs.
- *Measures should be included to address antimicrobial resistance.* When appropriate, include measures to monitor antimicrobial resistant infections and assess the effectiveness of practices to prevent their transmission. Rates of resistant infections should be reported only with sufficient risk adjustment. Thus, trends in HAIs caused by antimicrobial-resistant bacteria will be apparent within each category of HAI.

2. Those who collect and report data should assist providers in achieving a common understanding of their measurement roles and responsibilities.

- *Provide clear guidance for interpreting measure specifications to increase the accuracy of reporting.* When designing a measurement and reporting program, consideration should be given to how interpretation of the measure can affect the validity of results. For example, specifications that rely on clinical judgment as a criterion may yield highly variable data. Technical assistance should be available to ensure that providers have a clear understanding of HAI case finding and definitions as they pertain to measurement. In addition, to achieve greater accuracy in data collection and consistency of reporting across programs, standardized measurement terminology and clear measurement definitions are critical.
- *Educate data abstractors on the appropriate data collection methodologies for infection measurement.* Data may be collected from electronic and/or paper-based documents. However, those given the responsibility of abstracting/identifying HAI data, no matter what type, should be trained in identifying infection data and collecting them. Without clear guidance on what data should be collected, how to collect them, and their importance, different levels of effort and variation in interpreting specifications among institutions could artificially affect reported infection rates. Studies have shown

that there is significant variation in the quality and completeness of data collected between abstractors with no or little training and those with training.[11] In most healthcare facilities, trained infection control professionals (ICPs) are the most skilled and provide the most accurate data; however, for programs that do not have an ICP onsite, access to this expertise and to comprehensive training through consultation or collaboration could facilitate more accurate data collection. As the use of data in electronic format becomes more widely adopted and manual medical record review becomes a rarity, it will be important that those validating electronic data and using them for analysis and reporting be appropriately trained.

- *The collection timeframe should be appropriate to the anticipated infection rate.* Surgical site infection rates require a 30-day follow-up and a 1-year follow-up if prosthetic material is placed during the procedure. HAIs with low incidence rates will require longer data collection timeframes. The minimum number of time units (e.g., annual, monthly, weekly) for data collection should be clear and should be based on the consideration that some programs or institutions may need longer timeframes to collect a minimum number of cases.
- *Transitioning to electronic surveillance methodologies will bring greater consistency to data collection.* The use of electronic case finding and surveillance systems can reduce inconsistency in data collection and reduce burden on staffing; however, any implemented measures should yield the same results regardless of data collection methodology and should be overseen by trained infection control professionals and epidemiologists.
- *Participation in measurement is valuable for all institutions, including those with a small number of cases.* The minimum number of cases in the denominator should not exclude or discourage programs that fall below the threshold from collecting or submitting data for surveillance or quality improvement.

[11] Sherman ER, Heydon KH, St. John KH, et al., Administrative data fail to accurately identify cases of healthcare-associated infection, *Infect Control Hosp Epidemiol,* 2006;27:332-337.

3. **Evaluation of the measurement and reporting process—metric definition, data collection, analysis, and reporting—should be occurring at regular intervals.**
   - *Adopt an auditing/verification strategy for reported data as standard practice.* Public reporting programs (state mandated or voluntary) should pursue third-party verification of submitted data. Auditing/verification improves the accuracy of results, reduces the risk of gaming the system for self-reported measures, and increases public trust in reported data. For example, the state of New York, which began data collection for infections in January 2007 for public reporting in 2008, has incorporated mandatory data audits into its reporting program.
   - *As programs evolve, the benefits of public reporting should be evaluated.* The effects of the reporting program should be assessed to determine its utility to consumers, its impact on clinical outcomes and practices, and whether reductions in HAIs and associated costs have been achieved. Furthermore, evaluation should include examination for the occurrence of any unintended consequences (e.g., negative incentives or gaming of results).

4. **Those who report HAI rates for comparison across providers have the responsibility to explain to users the reliability of reported data and the uses that the achieved degree of reliability will support.**
   - *Potential users should be included when reporting programs are developed.* A diverse team of stakeholders—particularly consumers, purchasers, providers, and individuals with expertise and experience in healthcare epidemiology/infection control—should be included in program development to ensure the usability and accessibility of the reported information.
   - *During metrics development and selection, end users should be considered.* Patients may prefer or better understand summary measures; for example, a composite measure of all infection prevention measures and scope of the infection control program for a provider (facility) could convey to consumers the level of effort on the part of the provider to prevent infections. However, caution should be taken to ensure that important outcomes are not

obscured within a composite measure. Appropriate testing for the validity, reliability, and feasibility of each component as well as the measure as a whole is important for designing a useful composite measure.

- *Public reports should be easily read and interpretable.* Publicly reported data should be displayed in a manner that is in plain, clear language for the public and that provides information on how the data are to be used and interpreted.
- *Reliability of data and the uses that the degree of reliability will support should be communicated in reports.* In reports, the source of the data (e.g., medical records, claims, surveys), the statistical methodology, the level of accuracy (e.g., how good or "clean" the data are), the risk-adjustment method, if used, the comparability of the population being measured, and how these numbers can be interpreted should be made transparent to users.

5. Reporting programs should rely on carefully constructed statistical methodologies that are appropriate to HAI measurement.

- *Differences in sample sizes among institutions should be considered when analyzing data and designing reports.* The volume of procedures that result in infection may be as important as the rates of infection when evaluating performance. For example, two hospitals may have the same 10 percent rate of infection resulting from hip replacements, but one facility may perform 10 times as many procedures as the other.
- *As we move toward the goal of zero infections, the meaning of the rate of infections in comparison to zero infections and the significance of the rate to consumer decisionmaking should be clear.* In the early stages of measurement and quality improvement, zero percent infection rates may not be attainable; the use of "best-in-class" (i.e., an external benchmark) for reporting is the appropriate approach for driving quality improvement at this time. However, "best-in-class" as a comparable statistic should not remain a static benchmark. For measures of adherence to safe or best practices, 100 percent compliance should be the goal.

The NQF-Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

The measure set for HAIs will facilitate quality improvement efforts to improve infection outcomes in the identified priority areas. Table 1 at the end of this report presents each endorsed measure. Because consensus standards must be consistently specified to meet the goal of standardization, measure specifications are provided in appendix A. Given the limited number of fully suitable measures across all categories of HAIs, recommendations for measure development and research to address these gaps are outlined in the commentary (appendix C).

Recommendations for Research and Measure Development

Gaps in available metrics and supporting research were identified in all clinical priority areas; recommendations for measure development and research to supplement the endorsed set are listed below. The significant need for further measure development and supporting research was most striking in the urinary tract infection, pediatric infection, and VAP priority areas. Further research and measure development in these specific areas should be prioritized.

Recommendation 1: Case Definitions for VAP and CA UTI

Request that CDC reconsider case definitions for VAP and CA UTI in order to meet required measure maintenance for both VAP and CA UTI rate measures in the next 12 to 24 months.

Recommendation 2: BSI Research and Measure Development

There is a need for additional research and measure development in the following areas:

- research in the area of compliance levels with proper line maintenance procedures. Appropriate maintenance of central lines provides critical leverage for reducing healthcare-associated BSIs;
- research in the area of duration of catheter use and adherence to catheter maintenance protocols to monitor the appropriateness of central line utilization;
- research in the tracking of pediatric and adult infections identified after hospital discharge;
- development of an overuse measure for femoral vein insertion in those over 18 years of age;
- development of standard care practices for collecting and culturing patient samples based on established guidelines and evidence. Methods that do not adhere to guidelines expose the patient to unnecessary risk, such as drawing blood through catheters, taking two samples from the same draw, or excessive and unnecessary line entry;
- evaluation of how improper maintenance of intravascular catheters contributes to the risk of developing BSIs;
- development of guidelines that specify appropriate situations for inserting lines into femoral veins. Frequency of femoral line insertions should be monitored, and a benchmark should be established to determine if rates are too high;
- evaluation of the usefulness of a metric other than "central line days" (e.g., cases) as a denominator for calculating catheter-related BSI rates used in public reporting;
- evaluation of the effectiveness of enhanced (i.e., technologically advanced) central venous catheters for the prevention of infection and patient safety; and
- standardization of methods for categorizing ICU groups (e.g., standardized definition of a medical ICU). Although stratification by ICU is an appropriate mechanism to adjust for risk of catheter-related BSIs, ICU categorization should be standardized between hospitals.

Recommendation 3: SSI Research and Measure Development

Additional research and measure development is needed in the following areas:

- development of a composite measure comprising the three surgical care infection prevention measures addressing appropriate antibiotic use for surgical patients;
- development of additional SSI measures based on the recommendations with the highest evidence (i.e., level A-1 and A-2 evidence) from the Healthcare Infection Control Practices Advisory Committee guidance on HAI reporting;[12]
- modification of measures to include patients less than 18 years of age, when appropriate. Antibiotic timing should be consistent with care policies that allow parents to be present during anesthesia induction, and, for children, antibiotic timing prior to surgery should follow current evidence and guidelines relevant to that population;
- development of an outcome measure of SSI that includes specifications for identifying infections on readmission, because this may improve the capturing of infections that manifest postdischarge;
- inclusion of cesarean section infections;
- development of a reliable system for 30-day postdischarge surveillance and 1-year postdischarge surveillance when prosthetic material is placed during the procedure;
- construction of measures with exclusions to address temporary shortages of antibiotics that prevent compliance;
- research on risk-stratification methods and risk adjustment related to SSIs, particularly with regard to comorbidities and severity of illness at the time of surgery;
- research on the feasibility, reliability, and validity of the proposed SSI measures;
- research to identify opportunities for measurement of SSIs resulting from procedures in the ambulatory setting;

[12] McKibben L, Horan T, Tokars JI, et al., Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee, *Am J Infect Control,* 2005;33(4):217-226.

- research to identify additional procedures that could be included in the SSI outcomes measure, including those relevant to the pediatric population (<18 years); and
- research on the rate at which surgical patients are readmitted with serious infection at hospitals other than the one where they had their original procedures. In addition, research is needed to determine the validity and reliability of capturing deep incisional and organ/space SSIs upon readmission in general, as well as the proportion of infections diagnosed after discharge within 30 days after the procedure and 1 year after procedures during which prosthetic material is placed permanently.

Recommendation 4: Incorporation of Best Practices of Urinary Catheter Care into the NQF-Endorsed Safe Practices for Better Healthcare

Incorporate into the NQF-endorsed Safe Practices for Better Healthcare a practice that adheres to CDC guidelines for urinary catheter care; implements a written or computer-based reminder system that includes stop orders for catheters and regular reminders or prompts to assess catheter status; and obtains a urine culture before initiating antimicrobial therapy for UTI in a patient with a urinary catheter.

Recommendation 5: CA UTI Research and Measure Development

Although no measures of CA UTI were endorsed, the immediate need for quality improvement in CA UTI prevention is recognized, and it is recommended that best practices for urinary catheter care be incorporated into the HAI chapter of NQF's *Safe Practices.* A computer-based or written reminder system for catheter assessment and removal should be incorporated as an NQF safe practice. Studies have shown that reminder systems and prompts can significantly decrease duration of catheterization, a primary risk factor for CA UTI. Additionally, the development of measures to align with and support this safe practice is recommended. Any measure development would require supporting research on risk-adjustment and stratifi-cation methods to account for patient populations, comorbidities, unit type, and catheter type.

Research Recommendations

It is recognized that reliable, valid measures of outcomes of care remain an essential focus for quality measurement and accountability. In addition to recommendations for immediate process/structure measure development, further research is proposed to support the development and implementation of outcome measures, including research to expand clinical understanding of CA UTI and ways to prevent it:

- research is needed to define and specify outcome measures of symptomatic, indwelling CA UTI. Specifically, further research is needed on the diagnostic criteria specific to symptomatic CA UTI and inclusive of all patients at risk of contracting infection. A clarified definition of CA UTI with tested validity and reliability suitable for facility-to-facility comparison and a tested risk-adjustment strategy is needed to support outcome measurement; and
- further research is needed on optimal strategies for managing patients who need urinary catheters. Research to update and expand guidelines for catheter insertion and care should include information about the risks and benefits of various types of catheters and catheter materials, alternative catheterization strategies for different patient groups, and current knowledge of the pathogenesis, microbiology, and diagnosis of CA UTI.

Measure Development Recommendations

The following recommendations are offered for measure development:

- develop measures to assess urinary catheter utilization, such as utilization rates that have been appropriately stratified or risk adjusted or structural measures of whether a system is in place to accurately track duration of catheterization;
- develop measures to assess appropriateness of catheter insertion, such as rates of insertion order documentation in the patient record or structural measures of whether a system or protocol is in place to assess indications for catheter placement;
- develop measures to assess the appropriateness of continued catheterization to ensure that once catheters are placed, they are appropriately documented, maintained, and assessed for removal. Such measures could include structural measures of whether a system is in place to track patients with a catheter or rates of how frequently catheterization exceeds X days (threshold to be determined) without clearly documented indication;
- develop structural measures to assess appropriateness and timeliness of catheter removal, such as whether an institution uses automatic stop orders for catheters or has a standardized approach in place to identify and remove unneeded catheters; and
- develop measures to assess compliance with best practices of catheter insertion and care. Such measures could include process measures that assess compliance with good catheter care practices, including whether the catheter system remains closed, the urine collection bag is kept at an appropriate height, and the

catheter is appropriately anchored; structural measures could assess whether an institution has a system in place to train and support caregivers in compliance with best practices.

Recommendation 6: VAP Research and Measure Development

To broaden the scope of VAP measures, research on or development of measures in the following areas is recommended:

- development of an outcome measure based on a definition that requires laboratory results (e.g., histopathological exams, semi-quantitative and quantitative cultures), clinical criteria, and radiology results consistent with VAP;
- development of a measure to assess the appropriateness of ventilator weaning;
- development of a measure to evaluate whether antibiotic therapy administered to ventilated patients was appropriate for the organism identified in cultures;
- development of measures to identify VAP in patients with acute respiratory distress syndrome (ARDS);
- evaluation of the benefit of including oral care practices and the appropriate frequency of oral care practices in the VAP bundle;
- development of measures to encourage the use of trained infection control practitioners or hospital epidemiologists, with experience in VAP diagnosis and data abstraction, to collect and report VAP data;
- research to define and measure healthcare-associated pneumonia (HCAP);
- research to evaluate how frequently blood cultures, pleural fluid growth, and semi-quantitative cultures are used to diagnose VAP;
- research to evaluate the utility of elastin fiber (a marker for VAP) detection in lower lung aspirates using potassium hydroxide preparation as a diagnostic tool to identify bacterial VAP;
- evaluation of the methods to assess readiness to extubate in very low birth weight (VLBW) infants. Currently, assessing readiness to extubate in VLBW infants cannot be accurately and reliably evaluated unless a clinician with appropriate skills is present for the assessment;
- research regarding the effectiveness of stress ulcer disease/peptic ulcer disease prophylaxis in preventing VAP; and
- research of organisms that cause VAP in children.

Recommendation 7: Pediatric Infections

For pediatric infections, areas recommended for further research and measure development include the following:

- research on antimicrobial therapy monitoring, including tracking the frequency of appropriate initial selection, duration of agent/therapy, and number of courses given for positive cultures that may be contaminants (e.g., appropriate selection and use of vancomycin); outcome measures for healthcare-associated viral infections relevant to pediatrics, including rates of respiratory and gastrointestinal infections (no symptoms on admission with symptoms manifesting 72+ hours after admission); and rates of worker viral infections compared with patient infection rates;

- development of SSI outcome measures that include in the numerator implantable devices, surgery to correct congenital heart conditions, ventriculoperitoneal shunts, scoliosis corrections, and infections resulting from circumcision;
- development of central line-associated BSI measures that track infection rates after hospital discharge, because pediatric catheters are often managed in home or community settings;
- research of appropriate uses of chlorhexidine for cutaneous antisepsis for neonates less than two months of age and to identify whether current practices are evidenced;
- evaluation of the validity of the DVT component of the VAP Bundle for pediatric populations;
- significance of *C. difficile* infections in the pediatric population; and
- definition of VAP in children and appropriate prevention strategies.

Recommendation 8: Healthcare Disparities in HAI Rates and Management

Areas recommended for further research and measure development include the following:

- research to determine whether there are disparate rates of HAI and/or management disparities that are not related to access by stratifying performance measures by race/ethnicity; and
- research to determine whether stratification of HAI rates and management by race/ethnicity is appropriate for public reporting.

Acknowledgments

The Texas Medical Institute of Technology, a not-for-profit medical research organization dedicated to driving the adoption of clinical solutions in patient safety and healthcare performance improvement, provided the primary support for this project. The Association for Professionals in Infection Control and Epidemiology and the Society for Healthcare Epidemiology of America provided additional support.

Table 1 – NQF-Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

Intravascular Catheter-Associated Bloodstream Infections

Central line bundle compliance[13]

- Hand hygiene[14]
- Maximal barrier precautions upon insertion[15]
- Chlorhexidine skin antisepsis[16]
- Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older[17]
- Daily review of line necessity with prompt removal of unnecessary lines

Surgical site infection rate

- Deep wound and organ space infections as a result of elective surgery to include coronary artery bypass graft (CABG) and cardiac surgery; hip or knee arthroplasty; colon surgery; hysterectomy (abdominal and vaginal); and vascular surgery

Cardiac surgery patients with controlled 6 am postoperative serum glucose

Surgery patients with appropriate hair removal

Ventilator-Associated Pneumonia and Respiratory Illness

Ventilator bundle[18]

- Head of the bed elevation at least 30 degrees
- Daily sedative interruption and daily assessment of readiness to extubate
- Stress ulcer disease prophylaxis
- Deep vein thrombosis prophylaxis

Healthcare-Associated Infections in Pediatric Populations

Late sepsis or meningitis in neonates

Late sepsis or meningitis in very low birth weight neonates

[13] Aligns with NQF-endorsed Safe Practices 20 and 22.
[14] Aligns with Joint Commission 2006 NPSG 7A.
[15] Aligns with CDC *Guidelines for the Prevention of Intravascular Catheter-Related Infections.*
[16] Aligns with CDC *Guidelines for the Prevention of Intravascular Catheter-Related Infections.*
[17] Aligns with CDC *Guidelines for the Prevention of Intravascular Catheter-Related Infections.*
[18] Aligns with NQF-endorsed Safe Practices 19.

As shown below in table 2, NQF has previously endorsed 13 HAI-related measures, 5 within the last year as part of clinician-level measure sets.

Table 2 – Previously Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data[19]

Intravascular Catheter-Associated Bloodstream Infections

Central line-associated bloodstream infections
Endorsed in the NQF Hospital Care (2003) and Nursing-Sensitive Care (2004) projects[20]

Surgical Site Infections

Prophylactic antibiotic received within one hour prior to surgical incision
Endorsed in the NQF Hospital Care (2003) and Cardiac Surgery (2004) projects[21]

Prophylactic antibiotic selection for surgical patients
Endorsed in the NQF Hospital Care (2003) and Cardiac Surgery (2004) projects

Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for CABG and other cardiac surgery)
Endorsed in the NQF Hospital Care (2003) and Cardiac Surgery (2004) projects

Deep sternal wound infection rates for CABG (this can also be captured in the Surgical Site Infection Rate measure in Table 1)
Endorsed in the NQF Cardiac Surgery (2004) project

Postoperative sepsis
Endorsed in the NQF Nursing-Sensitive Care (2004) project

Catheter-Associated Urinary Tract Infections

Catheter-associated urinary tract infection rate for ICU patients
Endorsed in the NQF Nursing-Sensitive Care (2004) project

Ventilator-Associated Pneumonia and Respiratory Illness

Rate of ventilator-associated pneumonia
Endorsed in the NQF Hospital Care (2003) and Nursing-Sensitive Care (2004) projects

(more)

[19] It should be noted that NQF has requested maintenance updates for two of these endorsed measures, Catheter-Associated Urinary Tract Infections and Ventilator-Associated Pneumonia. These measures will remain endorsed while the owner is afforded a one-year period to update them so that they comport with current science and to improve the likelihood of comparable implementation across hospitals and other healthcare entities.

[20] NQF, *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set – A Consensus Report,* Washington, DC: NQF; 2003; NQF, *National Voluntary Consensus Standards for Nursing-Sensitive Care: An Initial Performance Measure Set – A Consensus Report,* Washington, DC: NQF; 2004.

[21] NQF, *National Voluntary Consensus Standards for Cardiac Surgery – A Consensus Report,* Washington, DC: NQF; 2004.

Table 2 – Previously Endorsed National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data[19] (continued)

Clinician-Level Perioperative Care
Timing of prophylactic antibiotics, ordering physician Endorsed in the NQF Physician Specialty (2007)[22] project
Timing of prophylactic antibiotics, administering physician Endorsed in the NQF Physician Specialty (2007) project
Selection of prophylactic antibiotic, first- and second-generation cephalosporin Endorsed in the NQF Physician Specialty (2007) project
Discontinuation of prophylactic antibiotics, non-cardiac procedures Endorsed in the NQF Physician Specialty (2007) project
Discontinuation of prophylactic antibiotics, cardiac procedures Endorsed in the NQF Physician Specialty (2007) project

[22] NQF, *National Voluntary Consensus Standards for Hospital Care: Specialty Physician Performance Measures – A Consensus Report,* Washington, DC: NQF; 2007.

Appendix A

Specifications of the National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

The following table summarizes the detailed specifications for each of the National Quality Forum (NQF)-endorsed™ national voluntary standards for the reporting of healthcare-associated infection data. All of the consensus standards contained in the following table are newly endorsed.

All information presented has been derived directly from measure sources/developers without modification or alteration (except when the measure developer agreed to such modification during the NQF Consensus Development Process) and is current as of January 2008.

All NQF-endorsed voluntary consensus standards are open source, meaning they are fully accessible and disclosed. Issues regarding any NQF-endorsed consensus standards (e.g., modifications to specifications, emerging evidence) may be submitted to NQF for review and consideration via the "Implementation Feedback Form" found at www.qualityforum.org/implementation_feedback.htm. NQF will transmit this information to the measure developers and/or compile it for consideration in updating the measure set.

Appendix A – Specifications of the National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

INTRAVASCULAR CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
CENTRAL LINE BUNDLE COMPLIANCE[2]	IHI	Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place.[3] The central line bundle elements include: ■ Hand hygiene[4,5] ■ Maximal barrier precautions upon insertion[6] ■ Chlorhexidine skin antisepsis[7] ■ Optimal catheter site selection, with subclavian vein as the preferred site for non-tunneled catheters in patients 18 years and older[8] ■ Daily review of line necessity with prompt removal of unnecessary lines.	Total number of intensive care patients with central lines on day of week of sample.	Exclude patients less than 18 years of age at the date of intensive care unit (ICU) admission and patients outside the ICU and patients whose lines were not placed in the ICU.	Medical record.

(more)

[1] Intellectual Property (IP) owner. For the most current specifications and supporting information please refer to the IP owner.

IP Owners
CDC - Centers for Disease Control and Prevention (www.cdc.gov)
CMS - Centers for Medicare & Medicaid Services (www.cms.hhs.gov)
IHI - Institute for Healthcare Improvement (www.ihi.org)
The Joint Commission (www.jointcommission.org)
Vermont Oxford Network (www.vtoxford.org)

[2] This is an "all or nothing" indicator. If any of the elements are not documented, do not count the patient in the numerator. If a bundle element is contraindicated for a particular patient and this is documented appropriately on the checklist, then the bundle can still be considered compliant with regard to that element.

[3] Aligns with Joint Commission 2006 NPSG 7A.

[4] Hand hygiene is the washing of hands or the use of alcohol-based hand rub prior to and after insertion or care of the central line.

[5] Aligns with *CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections.*

[6] Aligns with *CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections.*

[7] Aligns with *CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections.*

[8] Aligns with *CDC Guidelines for the Prevention of Intravascular Catheter-Related Infections.*

INTRAVASCULAR CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
SURGICAL SITE INFECTION (SSI) RATE[9]	CDC	Number of SSIs[10] occurring within 30 days after the operative procedure if no implant is left in place, or within 1 year if an implant is in place, in patients who had a National Healthcare Safety Network (NHSN) operative procedure[11] performed during a specified time period and the infection appears to be related to the operative procedure. Infections are identified on original admission or upon readmission to the facility of original operative procedure within the relevant timeframe (30 days for no implants; within 1 year for implants). Two types of CDC-defined SSIs are included: (1) A deep incisional SSI must meet the following criteria: ■ Infection occurs within 30 days after the operative procedure if no implant is left or within one year if implant is in place and the infection appears to be related to the operative procedure *AND* ■ involves deep soft tissues (e.g., fascial and muscle layers) of the incision	Number of NHSN operative procedures performed during a specified time period stratified by: ■ Type of NHSN operative procedure *AND* ■ NNIS SSI risk index: Every patient having the selected procedure is assigned one risk point for each of the following three factors: • Surgical wound classification = clean, contaminated, or dirty • American Society of Anesthesiologists (ASA) preoperative severity of illness score = 3, 4, or 5 • Duration of operation >t hours, where t varies by type of NHSN operative procedure and is the approximate 75th percentile of the duration of the procedure rounded to the nearest whole number of hours. *Note:* For operative procedures performed using laparoscopes and endoscopes, the use of a laparoscope is an additional factor that modifies the risk index.	Exclude procedures not included under the definition of NHSN operative procedure and excludes superficial SSI.	Medical record.

(more)

[9] Public reporting of this measure is recommended to be limited to deep incisional and organ space infections occurring as a result of elective procedures in the following categories: coronary artery bypass graft (CABG) and other cardiac surgery, hip or knee arthroplasty, colon surgery, hysterectomy (abdominal or vaginal), and vascular surgery. For surveillance purposes, organizations should collect and submit data on the measure as specified (all SSIs as defined by the NHSN SSI Event Protocol resulting from all included NHSN operative procedures).

[10] Refer to NHSN Patient Safety Component Protocol for definitions of SSIs. Available at www.cdc.gov/ncidod/dhqp/pdf/nhsn/NHSN_Manual_%20Patient_Safety_Protocol022307.pdf. Last accessed May 31, 2007.

[11] For ICD-9-CM codes, refer to operative procedure categories in NHSN Patient Safety Component Protocol. Available at www.cdc.gov/ncidod/dhqp/pdf/nhsn/ICD9cmCODES_V1_5.pdf. Last accessed September 2007.

INTRAVASCULAR CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
SURGICAL SITE INFECTION (SSI) RATE[9] *continued*		*AND* ■ patient has at least one of the following: a) purulent drainage from the deep incision but not from the organ/space component of the surgical site b) a deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least one of the following signs or symptoms: fever (>38°C) or localized pain or tenderness. A culture-negative finding does not meet this criterion c) an abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination d) diagnosis of a deep incisional SSI by a surgeon or attending physician. *Note:* There are two specific types of deep incisional SSIs: 1) Deep Incisional Primary (DIP) – a deep incisional SSI that is identified in a primary incision in a patient that has had an operation with one or more incisions (e.g., C-section incision or chest incision for CABG) 2) Deep Incisional Secondary (DIS) - a deep incisional SSI that is identified in the secondary incision in a patient that has had an operation with more than one incision (e.g., donor site [leg] incision for CBGB).			

(more)

INTRAVASCULAR CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
SURGICAL SITE INFECTION (SSI) RATE[9] *continued*		(2) An organ/space SSI must meet the following criteria: ■ Infection occurs within 30 days after the operative procedure if no implant is left or within one year if implant is in place and the infection appears to be related to the operative procedure *AND* ■ infection involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure *AND* ■ patient has at least one of the following: a) purulent drainage from a drain that is placed through a stab wound into the organ/space b) organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space c) an abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination d) diagnosis of an organ/space SSI by a surgeon or attending physician. Specific sites of an organ/space SSI may be identified.[11]			

(more)

INTRAVASCULAR CATHETER-ASSOCIATED BLOODSTREAM INFECTIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
CARDIAC SURGERY PATIENTS WITH CONTROLLED 6 AM POSTOPERATIVE SERUM GLUCOSE[12]	CMS/Joint Commission	Surgery patients with controlled 6 am serum glucose (</=200 mg/dl) on postoperative day (POD) 1 and POD 2.	Cardiac surgery patients with no evidence of prior infection. Include patients with an ICD-9-CM Principal Procedure Code of selected surgeries (refer to Appendix A, Table 5.10 for ICD-9-CM Codes)[13] *AND* An ICD-9-CM Principal Procedure Code of selected surgeries (refer to Appendix A, Table 5.11 for ICD-9-CM Codes).[14]	Exclude the following patients: ■ Patients who had a principal diagnosis suggestive of preoperative infectious diseases (refer to Appendix A, Table 5.09 for ICD-9-CM Codes) ■ Patients less than 18 years of age ■ Patients with physician documented infection prior to surgical procedure of interest ■ Burn and transplant patients (refer to Appendix A, Tables 5.14 and 5.15 for ICD-9-CM codes) ■ Patients whose ICD-9-CM principal procedure occurred prior to the date of admission.	Administrative data and medical records.
SURGERY PATIENTS WITH APPROPRIATE HAIR REMOVAL[15]	CMS/Joint Commission	Surgery patients with surgical hair site removal with clippers or depilatory or no surgical site hair removal.	All selected surgery patients. Include patients with an ICD-9-CM Principal Procedure Code or ICD-9-CM Other Procedure Codes of selected surgeries.[16]	Exclude the following patients: ■ Patients less than 18 years of age ■ Patients who performed their own hair removal *AND* ■ Patients whose mode of hair removal could not be determined.	Administrative data and medical records.

(more)

[12] Aligns with NQF Safe Practice 21.

[13] See Table 5.10, Appendix A, *National Healthcare Quality Measures Specifications Manual*. Available at www.qualitynet.org/dcs/ContentServer?cid=1163010419895&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page. Last accessed September 12, 2007.

[14] See Table 5.11, Appendix A, *National Healthcare Quality Measures Specifications Manual*. Available at www.qualitynet.org/dcs/ContentServer?cid=1163010419895&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page. Last accessed September 12, 2007.

[15] Aligns with NQF Safe Practice 21.

[16] See Table 5.10, Appendix A, *National Healthcare Quality Measures Specifications Manual*. Available at www.qualitynet.org/dcs/ContentServer?cid=1163010419895&pagename=QnetPublic%2FPage%2FQnetTier3&c=Page. Last accessed September 2007.

Appendix A – Specifications of the National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data

VENTILATOR-ASSOCIATED PNEUMONIA AND RESPIRATORY ILLNESS

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
VENTILATOR BUNDLE[17]	IHI	Number of ICU patients on mechanical ventilation at time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are:[18] ■ Head of bed elevation 30 degrees or greater (unless medically contraindicated); noted on 2 different shifts within a 24-hour period ■ Daily "sedation interruption" and daily assessment of readiness to extubate; process includes interrupting sedation until patient follow commands and patient is assessed for discontinuation of mechanical ventilation. Parameters of discontinuation include: resolution of reason for intubation; inspired oxygen content roughly 40%; assessment of patients ability to defend airway after extubation due to heavy sedation; minute ventilation less than or equal to 15 liters/minute; and respiratory rate/tidal volume less than or equal to 105/min/L (RR/TV ≤105) ■ Stress ulcer disease (peptic ulcer disease) prophylaxis ■ DVT (deep venous thrombosis) prophylaxis.	Total number of ICU patients on mechanical ventilation.	Patients less than 18 years of age at the date of ICU admission.	Medical record.

(more)

[17] Aligns with NQF Safe Practice 19.

[18] This is an "all or nothing" indicator. If any of the elements are not documented, do not count the patient in the numerator. If a bundle element is contraindicated for a particular patient (as defined by Joint Commission ICU-1-3) and this is documented appropriately in the medical record, then the bundle can still be considered compliant with regard to that element. The Joint Commission definitions and guidelines should be followed for specifications corresponding to Joint Commission ICU-1-3.

HEALTHCARE-ASSOCIATED INFECTIONS IN PEDIATRIC POPULATIONS

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
LATE SEPSIS OR MENINGITIS IN NEONATES	Vermont Oxford Network	Eligible infants[19] with one or more of the following criteria: **Criterion 1. Bacterial Pathogen**[20] A bacterial pathogen[21] is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life. **Criterion 2. Coagulase-Negative Staphylococcus** Coagulase-negative staphylococcus is recovered and the infant has all three of the following: ■ Coagulase-negative staphylococcus is recovered from a blood culture obtained from either a central line or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap, or ventricular drain *AND* ■ Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress, or hemodynamic instability) *AND* ■ Treatment with five or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or	■ Any infant who is born at the hospital and whose birth weight is between 401 and 1500 grams *OR* whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is eligible, regardless of where in the hospital the infant receives care ■ Any outborn infant who is admitted to any location in the hospital within 28 days of birth, without first having gone home, and whose birth weight is between 401 and 1500 grams *OR* whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is eligible, regardless of where in the hospital the infant receives care ■ Any infant whose birth weight is over 1500 grams and who is admitted to a neonatal intensive care unit (NICU)[22] in your hospital within the first 28 days of life, regardless of gestational age ■ Any infant whose birth weight is over 1500 grams and who dies at any location in your hospital within 28 days of birth without first having gone home. This includes inborn and outborn infants.	Exclude patients if: ■ The infant is discharged home or dies on or before Day 3 ■ The infant is transferred from your center to another hospital on or before Day 3 and either, a) is not readmitted to the center/hospital before discharge home, death, or first birthday, or b) is transferred a second time on or before Day 3.	Medical record review.

(more)

[19] Each of the late infection items is based on whether the infant had the infection *after* Day 3 of life. In determining the date of Day 3, the date of birth counts as Day 1 regardless of the time of birth. For an infant born at 11:59 pm on September 1, Day 3 is September 3. Use the criteria that follow when answering each of the late infection questions.

[20] If a bacterial pathogen and a coagulase-negative staphylococcus are recovered during the same sepsis work-up performed after Day 3, check only "Bacterial Pathogen" for that episode. If a bacterial pathogen is recovered during one episode of sepsis after Day 3, and coagulase-negative staphylococcus is recovered during another episode of sepsis after Day 3 (associated with the three clinical criteria listed below) check both "Bacterial Pathogen" and "Coagulase-Negative Staph."

[21] For included pathogens, see Appendix B, *Vermont Oxford Network Database Manual of Operations for Infants Born in 2007* (11.0). Available at www.vtoxford.org/tools/2007%20Manual%20of%20Operationswithindex.pdf. Last accessed April 2007.

[22] A NICU is any location within the hospital in which newborn infants receive continuous positive airway pressure (CPAP) or intermittent mandatory ventilation (IMV).

HEALTHCARE-ASSOCIATED INFECTIONS IN PEDIATRIC POPULATIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
LATE SEPSIS OR MENINGITIS IN NEONATES *continued*		transferred prior to the completion of five days of intravenous antibiotics, this condition would still be met if the intention were to treat for five or more days. **Criterion 3. Fungal Infection** A fungus was recovered from a blood culture obtained from either a central line or peripheral blood sample after Day 3 of life.			
LATE SEPSIS OR MENINGITIS IN VERY LOW BIRTH WEIGHT (VLBW) NEONATES	Vermont Oxford Network	Eligible infants[23] with one or more of the following criteria: **Criterion 1. Bacterial Pathogen**[24] A bacterial pathogen[25] is recovered from a blood and/or cerebral spinal fluid culture obtained after Day 3 of life. **Criterion 2. Coagulase-Negative Staphylococcus** Coagulase-negative staphylococcus is recovered and the infant has all 3 of the following: ■ Coagulase-negative staphylococcus is recovered from a blood culture obtained from either a central line or peripheral blood sample and/or is recovered from cerebrospinal fluid obtained by lumbar puncture, ventricular tap, or ventricular drain *AND*	■ Any infant who is born at the hospital and whose birth weight is between 401 and 1500 grams *OR* whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is eligible, regardless of where in the hospital the infant receives care ■ Any outborn infant who is admitted to any location in the hospital within 28 days of birth, without first having gone home, and whose birth weight is between 401 and 1500 grams *OR* whose gestational age is between 22 weeks 0 days and 29 weeks 6 days (inclusive) is eligible, regardless of where in the hospital the infant receives care.	Exclude patients if: ■ The infant is discharged home or dies on or before Day 3 ■ The infant is transferred from your center to another hospital on or before Day 3 and either, a) is not readmitted to the center/hospital before discharge home, death, or first birthday, or b) is transferred a second time on or before Day 3. The risk-adjustment process begins by using logistic regression to model the dichotomous measure with several case mix variables: gestational age and its quadratic term, APGAR score at 1 minute, maternal race, infant gender, multiple birth (Yes/No), vaginal delivery (Yes/No), birth	Medical record review. *(more)*

[23] Each of the late infection items is based on whether the infant had the infection *after* Day 3 of life. In determining the date of Day 3, the date of birth counts as Day 1 regardless of the time of birth. For an infant born at 11:59 pm on September 1, Day 3 is September 3. Use the criteria that follow when answering each of the late infection questions.

[24] If a bacterial pathogen and a coagulase-negative staphylococcus are recovered during the same sepsis work-up performed after Day 3, check only "Bacterial Pathogen" for that episode. If a bacterial pathogen is recovered during one episode of sepsis after Day 3, and coagulase-negative staphylococcus is recovered during another episode of sepsis after Day 3 (associated with the three clinical criteria listed below) check both "Bacterial Pathogen" and "Coagulase Negative Staph."

[25] For included pathogens, see Appendix B, *Vermont Oxford Network Database Manual of Operations for Infants Born in 2007* (11.0). Available at www.vtoxford.org/tools/2007%20Manual%20of%20Operationswithindex.pdf. Last accessed September 2007.

HEALTHCARE-ASSOCIATED INFECTIONS IN PEDIATRIC POPULATIONS (continued)

Measure	IP Owner[1]	Numerator	Denominator	Exclusions and Adjustments	Data Source
LATE SEPSIS OR MENINGITIS IN VERY LOW BIRTH WEIGHT (VLBW) NEONATES *continued*		■ Signs of generalized infection (such as apnea, temperature instability, feeding intolerance, worsening respiratory distress, or hemodynamic instability) *AND* ■ Treatment with five or more days of intravenous antibiotics after the above cultures were obtained. If the infant died, was discharged, or transferred prior to the completion of five days of intravenous antibiotics, this condition would still be met if the intention were to treat for five or more days. **Criterion 3. Fungal Infection** A fungus was recovered from a blood culture obtained from either a central line or peripheral blood sample after Day 3 of life.		location (Inborn/Outborn), birth defect severity (No Defect, Moderately Severe, Severe, Very Severe, Most Severe), and small for gestational age (Yes/No). From the logistic model, the number of expected cases and a standardized morbidity ratio (SMR) is calculated for each hospital. An estimate is made of the "systematic" variation associated with the hospital SMRs using the method suggested by Martuzzi and Hills.[26] This method assumes that the SMRs are distributed gamma, and that deviations from the gamma distribution are associated with random variation. The systematic variation is used to "shrink" center SMR values and their confidence limits based on the number of infants reported. The values for centers with a smaller number of infants shrink more toward the mean of all centers than do centers with more infants. Values for estimates of the number of observed cases minus the number of expected cases (O-E) and control limits for O-E values are also shrunken using the systematic variation value.	

[26] Martuzzi M, Hills M, Estimating the degree of heterogeneity between event rates using likelihood, *Am J Epidemiol,* 1995;141:369-374.

Appendix B
Steering Committee, Technical Advisory Panels, and Project Staff

Steering Committee

Kenneth W. Kizer, MD, MPH (Co-Chair)
Medsphere Systems Corporation
Aliso Viejo, CA

Daniel W. Varga, MD (Co-Chair)
SSM Health Care
St. Louis, MO

William B. Baine, MD
Agency for Healthcare Research and Quality
Rockville, MD

Hayley Burgess, PharmD, BCPP
Hospital Corporation of America, Inc.
Nashville, TN

Terry A. Clyburn, MD
University of Texas-Houston
Houston, TX
American Academy of Orthopedic Surgeons
Rosemont, IL

Duane Davis, MD
Geisinger Health Plan
Danville, PA
America's Health Insurance Plans
Washington, DC

Joyce Dubow
AARP Public Policy Institute
Washington, DC

Justin V. Graham, MD, MS
California Prison Health Care Receivership Corp.
San Jose, CA

Peter A. Gross, MD
Hackensack University Medical Center
Hackensack, NJ

Patricia A. Cacolice Hildebrand, MSN
CHRISTUS Hospital
Houston, TX

Patrick A. Hymel, Jr., MD
MedMined, Inc.
Vestavia Hills, AL

David Knowlton
New Jersey Health Quality Institute
Trenton, NJ

Elaine Larson, RN, PhD
Columbia University
New York, NY

Mark Levy, MD, MPH
Genesis Healthcare
Kennett Square, PA

Tammy Lundstrom, MD, JD
Detroit Medical Center
Detroit, MI

Lisa McGiffert
Consumers Union
Austin, TX

Edward Mendoza
Office of the Patient Advocate, State of California
Sacramento, CA

Daniel Pollock, MD
Centers for Disease Control and Prevention
Atlanta, GA

Louise Probst
St. Louis Area Business Health Coalition
St. Louis, MO

Michael T. Rapp, MD, JD
Centers for Medicare & Medicaid Services
Baltimore, MD

Jane D. Siegel, MD
University of Texas Southwestern Medical Center
Dallas, TX

Michael Tapper, MD
Lenox Hill Hospital
New York, NY

Robert A. Wise, MD
The Joint Commission
Oakbrook, IL

Liaison Members

Charles R. Denham, MD
Texas Medical Institute for Technology
Austin, TX

Denise Graham
Association of Professionals in Infection Control and Epidemiology
Washington, DC

Gary Noskin, MD
Northwestern University
Chicago, IL
Society for Healthcare Epidemiology of America
Washington, DC

Technical Advisory Panel for Indwelling Catheters and Urinary Tract Infections

William Claiborne Dunagan, MD (Chair)
BJC Healthcare
St. Louis, MO

Inga M. Himelright, MD
Blue Cross Blue Shield of Tennessee
Knoxville, TN

Ebbing Lautenbach, MD
University of Pennsylvania
Philadelphia, PA

Gina Pugliese, RN, MS
Safety Institute Premier, Inc.
Chicago, IL

Sanjav Saint, MD
University of Michigan Medical Center
Ann Arbor, MI

Sue Sebazco, RN, BS, CIC
Arlington Memorial Hospital
Arlington, TX

Arjun Srinivasan, MD
Centers for Disease Control and Prevention
Atlanta, GA

Richard A. Van Enk, PhD
Bronson Methodist Hospital
Kalamazoo, MI

Edward S. Wong, MD
McGuire Veterans Affairs Medical Center
Richmond, VA

Technical Advisory Panel for Intravascular Catheters and Bloodstream Infections

Gary A. Roselle, MD (Chair)
Department of Veterans Affairs
Cincinnati, OH

Kim Delahanty, RN
University of California, San Diego Medical Center
San Diego, CA

Steven M. Gordon, MD
Cleveland Clinic Foundation
Cleveland, OH

Henry Masur, MD
National Institutes of Health
Bethesda, MD

Rita D. McCormick, RN, CIC
University of Wisconsin Hospital and Clinics
Madison, WI

Leonard A. Mermel, DO, ScM
Brown Medical School
Providence, RI

Mary-Claire Roghmann, MD, MS
University of Maryland-Baltimore
Columbia, MD

Technical Advisory Panel for Pediatric Infections

Timothy G. Ferris, MD, MPhil, MPH (Chair)
Harvard Medical School and Massachusetts General Hospital Institute for Health Policy
Boston, MA

Susan Coffin, MD
Children's Hospital of Philadelphia
Philadelphia, PA

Craig Gilliam, BSMT, CIC
Arkansas Children's Hospital
Little Rock, AR

Stephen T. Lawless, MD, MBA
Nemours
Newark, DE

Wilbert Henry Mason, MD
Children's Hospital of Los Angeles
Los Angeles, CA

Nalini Singh, MD
Children's National Medical Center
George Washington University
Washington, DC

Kevin Slavin, MD
Joseph M. Sanzari Children's Hospital/Hackensack
Hackensack, NJ

Technical Advisory Panel for Reporting and Implementation

Dennis Shubert, MD, PhD (Chair)
Dirigo Health Agency
Augusta, ME

Katherine Browne
National Partnership for Women & Families
Washington, DC

David Carvalho
Illinois Department of Health
Springfield, IL

Don Goldmann, MD
Institute for Healthcare Improvement
Boston, MA

Eddie Hedrick, MT
Missouri Department of Health and Senior Services
Jefferson City, MO

Teresa C. Horan
Centers for Disease Control and Prevention
Atlanta, GA

Richard Johannes, MD
Cardinal Health Information Companies, MediQual
Marlborough, MA

Brian Koll, MD
Beth Israel Medical Center
New York, NY

Denise Love
National Association of Health Data Organizations
Salt Lake City, UT

Ellen Mangione, MD
Colorado Department of Public Health and Environment
Denver, CO

Michael Parry, MD
Stamford Hospital
Stamford, CT

Richard Platt, MD
Harvard School of Medicine and Brigham and Women's Hospital
Boston, MA

Jill Rosenthal
National Academy for State Health Policy
Portland, ME

Janet P. Stewart
Blue Cross and Blue Shield of Alabama
Birmingham, AL

Peggy Thompson, RN
Tampa General Hospital
Tampa, FL

Marc Volavka
Pennsylvania Health Care Cost Containment Council
Harrisburg, PA

Technical Advisory Panel for Surgical Site Infections

Robert S.D. Higgins, MD (Chair)
American Medical Association
Chicago, IL

Raymond Chinn, MD
SHARP Memorial Hospital
San Diego, CA

E. Patchard Dellinger, MD
University of Washington School of Medicine
Seattle, WA

Aaron S. Fink, MD
Atlanta Veterans Affairs Medical Center
Atlanta, GA

Anthony Harris, MD
Associate Professor of Medicine, University of Baltimore
Baltimore, MD

Keith M. Olsen, PharmD
University of Nebraska Medical Center
Omaha, NE

William E. Scheckler, MD
St. Mary's Hospital Medical Center
Madison, WI

Rachel L. Stricof, MT, MPH
New York State Department of Health
Albany, NY

Rodney Thompson, MD
Mayo Clinic
Rochester, MN

Robert A. Weinstein, MD
John H. Stroger Hospital of Cook County
Chicago, IL

Technical Advisory Panel for Ventilator and Respiratory Infections

Jay Deshpande, MD, MPH (Chair)
Vanderbilt Children's Hospital/Vanderbilt University Medical Center
Nashville, TN

Donald E. Craven, MD
Lahey Clinic
Burlington, MA

John Hensing, MD
Banner Health System
Phoenix, AZ

Thomas F. Keys, MD
Cleveland Clinic Foundation
Cleveland, OH

Raed Khoury, MA, MPH, MT(ASCP), CIC, CHSP, ARM, CPHQ
John Muir Health
Walnut Creek and Concord Campuses
Walnut Creek, CA

C. Glen Mayhall, MD
University of Texas Medical Branch
Galveston, TX

Beverly Mihalko
Oakwood Healthcare System
Dearborn, MI

Denise Murphy, RN
Barnes-Jewish Hospital
St. Louis, MO

Shannon Oriola, RN, CIC, COHN
Sharp Metropolitan Medical Campus
San Diego, CA

Project Staff

Janet M. Corrigan, PhD, MBA
President and Chief Executive Officer

Helen Burstin, MD, MPH
Senior Vice President, Performance Measures

Robyn Y. Nishimi, PhD
Senior Advisor

Dianne Feeney, BSN, MS
Senior Vice President, Operations

Lawrence D. Gorban, MA
Vice President, Operations

Rodger J. Winn, MD
Clinical Consultant

Kate C. Blenner
Program Director

Katherine D. Griffith
Research Assistant

Kristyne E. McGuinn, MHS
Program Director

Kendra Shanley
Research Assistant

Sabrina Zadrozny, MS
Program Director

Appendix C
Commentary

Introduction

In February 2006, the National Quality Forum (NQF) initiated a project to achieve consensus on a comprehensive set of national consensus standards for the public reporting of healthcare-associated infection (HAI) data in the United States. The Healthcare-Associated Infection Steering Committee (appendix B) was formed to oversee project activities and comprised representatives from key healthcare constituencies, including consumers, providers, purchasers, and researchers. Technical Advisory Panels (TAPs) in each priority area (appendix B) were formed to assist NQF staff on measure evaluations, advise the Steering Committee on the technical aspects of measures, and make recommendations for endorsement and supplemental research and measure development. This appendix summarizes the deliberations of the Steering Committee and the TAPs, which met in person and via conference call between April 2006 and March 2007.

Approach

Before measures could be recommended, an approach for defining the parameters and goals of the project was needed to determine the desired scope of measurement. To clarify terminology, it was necessary to standardize HAI definitions for measurement; the Steering Committee decided on a definition of HAI suitable to support accountability measurement and asked the TAPs to make recommendations for condition-specific definitions. The purpose of the project and the resulting set of national voluntary consensus standards were identified, and a scope of measurement was set based on the stated purpose. Once terminology, purpose, and scope had been clarified, measures

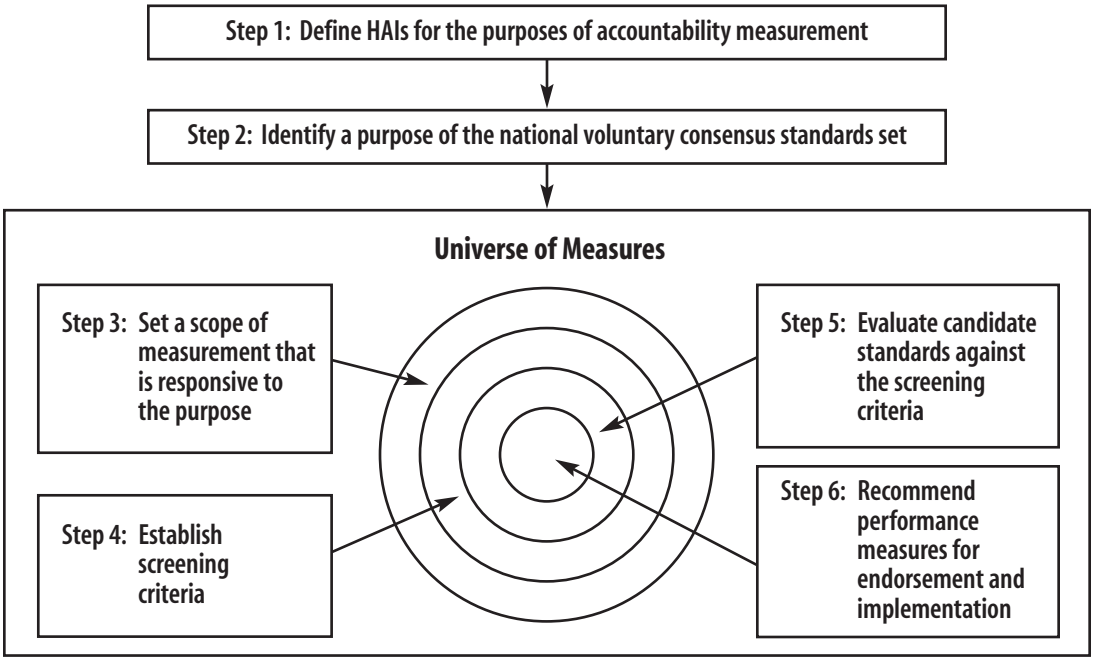
were identified and evaluated. An overview of the project approach is presented in figure 1.

Defining HAIs

Several different terms for infection that results from healthcare interventions (i.e., *healthcare-acquired infection, healthcare-associated infection, nosocomial infection*) are used by multiple organizations for varying purposes; furthermore, multiple definitions for each term are used interchangeably. To clarify what is meant by the measurement of infections resulting from the delivery of healthcare, Steering Committee members identified *healthcare-associated infection* as the preferred term for accountability measurement; it was noted that because of the difficulty involved in determining the geographic location of the acquisition of infection, the term healthcare-associated is preferred over *healthcare-acquired.* The following definition of HAI was selected to ensure that all settings are included in quality measurement relating to infections:

> An infection that develops in a patient who is cared for in any setting where healthcare is delivered and that originates from the delivery of healthcare (i.e., was not incubating or present at the time healthcare was provided). In ambulatory and home settings, the term *healthcare-associated infection* would apply to any infection that is associated with a medical or surgical intervention.[1]

Figure 1. HAI Consensus Project Approach



[1]This definition is based on the one used in the *Hospital Infection Control Practices Advisory Committee (HICPAC) Guideline for Management of Multi-Drug Resistant Organisms in Healthcare Settings* (2006). Available at www.cdc.gov/ncidod/dhqp/pdf/ar/mdroGuideline2006.pdf. Last accessed April 2007.

The Committee also decided that it was necessary to further clarify the specific infections encompassed by the term *healthcare-associated infection* in order to support outcome measurement of these infections. Outcome measures of HAIs have been evaluated and endorsed in previous NQF projects. During these projects, project committee members and NQF Members identified shortcomings with the definitions used for HAI case finding (i.e., the numerator and denominator) that had the potential to generate inaccurate HAI rates.

To ensure that condition-specific definitional issues were addressed, an ad hoc meeting of entities that had developed HAI definitions, overseen surveillance, or implemented performance measurement programs was convened to make recommendations regarding definitions to the HAI Steering Committee and TAPs. The group made the following recommendations to the clinical TAPs, which were approved by the Steering Committee:

- **Bloodstream Infections (BSIs).** It was recommended that the BSI TAP consider how to operationalize a definition of BSIs based on criterion 1 of the Centers for Disease Control and Prevention (CDC) definition and assess whether or not this definition/criteria is appropriate for public reporting.
- **Surgical Site Infections (SSIs).** The ad hoc group recommended that the broad CDC definition of an SSI as "an infection that occurs within 30 days after an operation" be accepted; however, the group recognized that some types of SSIs have little impact on patient outcomes. It was recommended that the SSI TAP determine how the definition could be implemented to optimize benefit for public reporting.
- **Urinary Tract Infections (UTIs).** The ad hoc group could not come to a conclusion on a definition of healthcare-associated UTIs appropriate for measurement; it recommended that the UTI TAP review definitions in use and make recommendations for a definition suitable to support accountability measurement.
- **Ventilator-Associated Pneumonia (VAP).** The ad hoc group concluded that a definition of VAP suitable to measurement does not exist. They recommended that the VAP TAP review definitions in use and make recommendations for a definition suitable to support accountability measurement.

Condition-Specific Definitions

With guidance from the ad hoc group and Steering Committee, clinical TAPs were asked to evaluate condition-specific definitions currently in use for their respective priority areas and to make recommendations on the definition most suitable for outcome measurement; if a fully suitable definition could not be identified, TAPs were asked to make recommendations for modifications or subsets of definitions. The Reporting and Implementation TAP noted that modifications to surveillance definitions for reporting purposes could have a negative impact on the level and consistency of surveillance and that any recommendations should be accompanied by language stating that definition modifications are for accountability measurement purposes only and that definitions and expectations for surveillance

are unchanged. Condition-specific definitions are addressed in the summary of deliberations by priority area at the end of this commentary.

Purpose

The Steering Committee identified the purpose of the project to be the endorsement of a set of national consensus standards that promotes consistent definitions and language relevant to reporting data on HAIs, that results in information that is useful to the public for making healthcare choices, and that is efficient for the healthcare community for reporting and continuous improvement of infection prevention processes. This purpose was selected to stress that consistency in definitions and language is critical in order to harmonize infection prevention efforts and will be necessary for meaningful and actionable measurement.

The Steering Committee elaborated that within the context of endorsing performance measures, the purpose of the project was to focus on measures of outcomes—specifically, rates of infection. Process measures were considered to be valuable and to require a strong correlation with improving outcomes as measured by an infection rate.

Overarching Scope

The scope of this project encompasses performance measures to be used across the spectrum of outpatient and inpatient settings, including but not limited to dialysis units, trauma centers, intensive care units (ICUs), specialty units, rehabilitation centers, emergency rooms, ambulatory surgical units, hospitals, long-term care settings, and home health settings. All relevant patient populations, including pediatric, maternal/perinatal, and immunocompromised patients, were considered in evaluating measures' usability. Endorsed measures were to be appropriate for accountability and public reporting, and measurement was to be at the institution level. (To ensure that measures are appropriate for accountability, community-level measurement, community-acquired infections, and assisted living facility care settings were excluded from the scope.)

To arrive at this scope, the Steering Committee discussed settings in which patients are at risk of infection and in which infection can be attributed to healthcare interventions, populations at considerable risk of infection or for whom outcomes of infection are serious, levels of measurement that accurately assign accountability, and consumer expectations of HAI reporting systems. Steering Committee discussions of appropriate care settings, populations, and levels of measurement for HAIs are described below.

Although this overarching scope would serve to guide the project as a whole, additional parameters for appropriate measurement within specific clinical areas were needed. The Steering Committee asked the TAPs to identify the scope of measurement for their respective clinical areas, with consideration given to the overarching scope of the project. Scope of measurement for each clinical condition, as identified by the TAPs and approved by

the Steering Committee, is detailed in the condition-specific discussions at the end of this document.

Care Settings

Public reporting initiatives to date have focused on hospital care, specifically ICUs, where a substantial number of HAIs originate. The Steering Committee agreed that the scope of measurement should include infections arising in multiple care settings in order to achieve greater transparency of quality practices across all healthcare entities, but acknowledged that the feasibility of data collection and correct attribution becomes problematic beyond the hospital setting. The Steering Committee decided that attributing community-acquired infections to healthcare interventions would not be feasible; community-acquired infections and assisted living facilities (a setting in which it would be difficult to determine if an infection was community acquired or healthcare associated) were excluded from the scope for this reason.

Populations

Pediatric, maternal/perinatal, and immunocompromised patients were identified as subpopulations that should be included in the project scope and as important because they are at significant risk for contracting infections and are often excluded from performance measurement. Although care for patients from these subpopulations differs significantly from care for other patients, Steering Committee members decided that this should not be a barrier for inclusion and that appropriate risk adjustment or stratification should be considered. Specifically, the Pediatric TAP was given guidance to evaluate the applicability of all measures to pediatric populations and to make recommendations for adjustments or stratification to accommodate the inclusion of pediatric patients.

Initially, healthcare workers were considered for inclusion in the scope, but it was determined that the safety of healthcare workers might be more fully addressed in an independent project dedicated to the topic. For the HAI project, measures involving healthcare workers are included only if they are used to evaluate infection prevention processes and patient safety.

Level of Analysis

The Steering Committee recommended facility-level measurement as the appropriate level of analysis for HAI accountability measures; it did not recommend measurement for individual clinicians, ambulatory care centers, or health plans, because there are confounding factors at these levels (e.g., community-acquired infection versus HAIs). The Steering Committee decided to exclude community-level measures of infection because of the absence of an accountable body and the inability to distinguish community-acquired infections from HAIs.

Evaluation of Candidate Standards

NQF staff prepared detailed measure evaluations using standard criteria established in NQF's *National Framework for Healthcare Quality Measurement and Reporting* and *A Comprehensive Framework*

for Hospital Care Performance Evaluation. Information for the measure evaluations was obtained from the measure developers, literature review, and independent research. The five clinical TAPs met in person and by conference call to review the candidate consensus standards in their respective priority areas. TAPs for each priority area conducted preliminary reviews of the measure evaluations prepared by NQF staff and made graded recommendations to the Steering Committee based on the perceived strengths and weaknesses of each measure, as well as technical reasons why a measure should or should not be recommended. Recommendations were based on the standard criteria for evaluation of measures (see box A in the report), as well as whether measures addressed the overarching scope set out by the Steering Committee and whether they fell into the specific scope for a priority area as defined by the TAP. A sixth TAP, for reporting and implementation, then met to review measure recommendations in all priority areas and develop a strategy for reporting and implementation.

Standardized Grading for TAP Recommendations

In September 2005, the NQF Board established an Ad Hoc Advisory Committee on Evidence and Performance Measure Grading to review a draft measure grading instrument. The purpose of the instrument is to standardize the TAPs' consideration of candidate consensus standards, thereby further increasing the transparency and reproducibility of the evaluative process. The draft grading tool focuses on a standardized grading system for TAP recommendations:

A - TAP strongly recommends this measure advance.

B - TAP recommends this measure advance, but with reservation.

C - TAP makes no recommendation for or against this measure.

D - TAP recommends against advancing this measure.

I - TAP concludes that the evidence is insufficient to make a recommendation for or against this measure.

Framework for Reporting and Implementation

The Reporting and Implementation TAP was convened to address strategies for effective reporting of HAI data that would improve the usefulness of measurement and reduce the risk of misinterpretation or misuse of public reports. Additionally, the Reporting and Implementation TAP was tasked with evaluating the clinical TAPs' and the Steering Committee's recommendations to formulate implementation guidance for the performance measure set.

Reporting and Implementation TAP members proposed the Framework Principles for Public Reporting to address the interests of all parties with a stake in HAI measurement. TAP members stressed that, above all, consumers' need for actionable data must be met and that although current measures are not ideal, it is through implementation within a carefully

constructed program that measures will improve over time to meet the needs of consumers and purchasers of healthcare.

The principles for reporting were also the product of discussions of the specific measures evaluated during this project. Using the evaluations and recommendations of the Steering Committee and clinical TAPs, the Reporting and Implementation TAP distilled overarching issues for implementation and developed a framework that would be responsive to the concerns and recommendations specific to this measure set and that would also serve as guidance for the design of a public reporting program using any measures of HAI. This framework was evaluated by the Steering Committee and approved to advance for endorsement as a national voluntary consensus standard.

General Issues

During the evaluation of candidate standards, Steering Committee and TAP members identified several general topics that were particularly important to consider for programs that are beginning HAI public reporting initiatives. These issues include identifying the purpose of the initiative—and in particular considering whether programs should be used for accountability or surveillance; incorporating measures of antimicrobial-resistant infections; and using electronic surveillance tools.

Surveillance Versus Accountability Measurement

The purpose of this project is to identify HAI measures that can be used for accountability measurement; however, many of the HAI measures that were available for review by TAPs were developed for surveillance. Although seven new measures for accountability were recommended, the research recommendations from the project illustrate the need for more robust and precisely defined measures for providing stakeholders with fully usable information.

Surveillance is defined by the World Health Organization as a systematic ongoing collection, collation, and analysis of data and the timely dissemination of information to those who need to know so that action can be taken. The rates of disease, infection, or activities provided by surveillance data serve as a basis for decisionmaking about issues of public health, health education, and health policy. Although surveillance data may be used to make high-level decisions, the data are not intended to be used to assign accountability to an organization, health plan, or individual.

By contrast, accountability measures are intended to identify the party responsible for providing quality care. The National Quality Measure Clearinghouse describes an accountability measure as one that requires a higher level of reliability and validity by insisting that each provider collect data in the same way using standardized, detailed specifications to ensure that comparisons are fair or that

predefined measure performance has been achieved.[2,3] Quality measures can be used for accountability to facilitate decisionmaking, accreditation, financial incentives, and external quality oversight. Most Committee members believed that, despite some of the shortcomings of the consensus standards received for review, it is by using the surveillance measures for this purpose that continued measure improvement will become a priority.

Antimicrobial-Resistant Infections

Steering Committee and TAP members acknowledged the public health importance of preventing, monitoring, and responding to antimicrobial-resistant infections. As a consequence of recent media attention, rates and outcomes for resistant infections are becoming of increasing interest to consumers. Accordingly, each TAP was asked to consider how to measure antimicrobial-resistant infections in a manner that was appropriate for accountability measurement. This project did not identify existing measures of antimicrobial-resistant infection rates; however, the SSI TAP reviewed and recommended three measures from the Surgical Care Improvement Project (SCIP) that addressed appropriate antibiotic use for surgical patients.

Although there were no additional measures addressing appropriate antibiotic use or resistant infections in the BSI, catheter-associated UTI (CA UTI), HAIs in pediatric populations (Pediatric), or VAP TAPs, Steering Committee and TAP members identified several principles to guide the development of public reporting measures for antimicrobial-resistant infections upon which the final recommendations were based.

- **Track rates of antimicrobial-resistant infections and identify case-mix adjustment that permits comparison between facilities.** Rates of antimicrobial-resistant infections vary greatly and can be influenced by the type of facility, geographic location, or unit. Also, although methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridium difficile (C. difficile)* infections are generally more prevalent in adults, vancomycin-resistant enterococci and resistant gram-negative bacteria infections are more prevalent in children. Given the high variability associated with acquiring an antimicrobial-resistant infection, a comparison of raw rates would not be meaningful data for the comparison and selection of healthcare facilities. Developing measures for similar patient populations (e.g., same type of surgery) may potentially be a way of taking into account facility-level effects. Although measuring rates for every type of resistant infection may not be appropriate for accountability purposes because of variable incidence rates, each facility should monitor rates of every antimicrobial-resistant infection for internal quality improvement.
- **Monitor the appropriate use of antimicrobial agents.** Evidence supports the theory that rates of antimicrobial-resistant

[2] National Quality Measure Clearinghouse, *Using Measures.* Available at www.qualitymeasures.ahrq.gov/resources/measure_use.aspx. Last accessed April 2007.

[3] Refer to the Framework for Public Reporting of Healthcare Associated Infection Data in the report body for further guidance on implementation in accordance with this definition.

infections have increased because of the practice of prescribing antibiotics inappropriately (i.e., treatment that does not specifically work for the infection of interest).[4,5,6] Measurement initiatives aimed at reducing antimicrobial-resistant infections should include a measure to evaluate antimicrobial prescribing practices in order to ensure that use is in accordance with guidelines.

- **Monitor antimicrobial resistance at the community and institution levels.** Tracking rates of antimicrobial-resistant infections in the community is important for identifying opportunities to implement interventions for specific organisms and to raise awareness about evaluating patients transferred from other hospitals in the same region to determine whether they have an antimicrobial-resistant infection.
- **The target for measuring rates of antimicrobial-resistant infections should be zero.** Steering Committee members agreed that the goal for antimicrobial-resistant infection rates should be zero; however, this goal may complicate meaningful comparisons among facilities, since risk adjustment would be required because of the high level of variability in antimicrobial-resistant infections based on patient population, type of hospital, and type of unit.

Electronic Surveillance Systems

Steering Committee and TAP members agreed that electronic surveillance systems are useful as tools for hospital infection control groups to track infections, identify the source of infection, and develop interventions to prevent future infections. One electronic surveillance system was evaluated during this project; however, it was believed that the system was not yet ready for national endorsement. Steering Committee and TAP members, however, agreed that the benefit provided by electronic surveillance should be further explored; that a set of minimum requirements should be identified for electronic surveillance systems that are useful for public reporting; and that a comparison of all available electronic surveillance systems could identify which systems are currently appropriate for comparison among healthcare facilities.

Discussion and Consensus Standard Recommendations

The Steering Committee considered each candidate consensus standard using the criteria listed below. Evaluations from the TAPs guided the deliberations; the comments and recommendations of each TAP are detailed in the next section. Performance measures and recommendations for research were advanced for endorsement by a straight majority of votes among Steering Committee members.

[4] Boyce JM, Opal SM, Chow JW, et al., Outbreak of multi-drug resistant Enterococcus faecium with transferable vanB class vancomycin resistance, *J Clin Microbiol,* 1994;32(5):1148-1153.

[5] McGowan JE Jr., Antibiotic resistance in hospital organisms and its relation to antibiotic use, *Rev Inf Dis.* 1983;5(6):1033-1048.

[6] Olson B, Weinstein RA, Nathan C, et al., Epidemiology of endemic Pseudomonas aeruginosa: why infection control efforts have failed, *J Infect Dis,* 1987;150(6):808-816.

Criteria for Recommending Measures

The Steering Committee selected measures to advance for endorsement using TAP evaluations of measures' technical merits and the standard criteria for selection identified by the NQF Strategic Framework Board and endorsed by NQF. In addition, the Steering Committee evaluated measures against the stated purpose and scope of the project and the following additional principles for selection:

- measures of outcomes are of highest priority;
- process measures will be considered secondarily;
- the focus of the measures is primarily accountability as a driver of quality improvement; and
- measures should reflect an aspect of care substantially influenced by established practices of infection prevention.

Intravascular Catheter-Associated Bloodstream Infections

Scope and Definitions

Scope of Measurement

TAP members expanded upon the project scope established by the Steering Committee to identify measurement areas for catheter-related BSIs that had the greatest opportunity for impact, were feasible to implement nationally, and were meaningful for consumer decisionmaking and public accountability.

TAP members determined that only measures addressing primary BSIs related to catheters would be considered. Also, peripheral line measures were excluded, because the risk of infection from peripheral lines is very low, and these infections do not represent a major healthcare problem. Although TAP members agreed that intravascular catheter-associated BSIs are an important issue for home health and nursing home settings, research on measurement and data collection for BSIs in the home health care and long-term care settings was unavailable. Because the majority of BSIs with adverse outcomes are related to *Staphylococcus* and *Candida* species, the TAP believed it may be helpful to pay particular attention to these organisms.

Reporting Catheter-Associated BSIs for Accountability Measurement

The ad hoc definitions group, the BSI TAP, and Steering Committee members reviewed the CDC definition of catheter-related BSIs used in the National Healthcare Safety Network (NHSN). TAP members agreed that the CDC definition was appropriate and useful for public health surveillance, yet they also identified concerns about using the entire CDC definition for public reporting. TAP members recommended that a subset of this definition be used for public reporting, because the full surveillance definition for catheter-related BSIs may overestimate the true incidence by including infections from an undocumented source (e.g., postoperative surgical sites, UTIs)[7]

[7] O'Grady NP, Alexander M, Patchen Dellinger E, et al., Guidelines for the prevention of intravascular cathether-related infections, *MMWR,* 2002;51(R-10):1-29.

and complicate comparison among institutions. This would mean that those collecting the data would use the full definition in the measure specification for their data collection efforts; however, only the subset would be publicly reported (those infections falling outside of the subset would be used for internal quality improvement).

The surveillance definition specified that one culture of common skin contaminants and physician administration of antibiotics was an acceptable criterion[8] for identifying BSIs. Evidence suggests that patients with suspected catheter-associated infections should have two blood cultures, with at least one culture from a percutaneously drawn blood sample.[9,10,11,12,13] TAP members agreed that this criterion, which relies on physician administration of antibiotics, was not appropriate for use as an accountability measure in adults, because one culture is not sufficient to distinguish whether an infection is from a different source (e.g., a wound or respiratory tract), and data are not replicable among institutions.

The Pediatric TAP recommended that for neonates and children, the criterion that permits diagnosis based on one culture and physician administration of antibiotics should be retained, despite the recommendation by the BSI TAP to exclude this criterion for adults. The Pediatric TAP made this recommendation because although coagulase-negative staphylococci in the blood culture would be excluded, it constitutes a relatively more common pathogen in the pediatric population than in adults, and even though the amount of blood necessary for culture is less than previously required, fewer children under age five will have two samples drawn. The Pediatric TAP also suggested that the term *vital sign instability* would be more appropriate than *hypotension* in pediatric cases. Furthermore, glucose instability, which is not included in the definition criteria, is an important sign of BSI, particularly in the neonatal intensive care unit (NICU).

Steering Committee members raised concerns about the validity of a subset of the definition being used for public reporting and recommended that if this definition is used in a measure for public reporting, the measure should be monitored to avoid unintended consequences.

[8] Criterion 2b of the CDC definition of catheter-related BSIs is as follows: "common skin contaminant (e.g., diphtheroids, Bacillus sp., Propionibacterium sp., coagulase-negative staphylococci, or micrococci) is cultured from at least one blood culture from a patient with an intravascular line, and the physician institutes appropriate antimicrobial therapy."

[9] DesJardin J, Clinical utility of blood cultures drawn from indwelling central venous catheters in hospitalized patients with cancer, *Ann Intern Med,* 1999;131(9):641-647.

[10] Siegman-Igra Y, Anglim AM, Shapiro DE, et al., Diagnosis of vascular catheter-related bloodstream infection: a meta-analysis, *J Clin Microbiol,* 1997;35(4):928-936.

[11] Mermel LA, Maki DG, Infectious complications of Swan-Ganz pulmonary artery catheters and peripheral arterial catheters, In: Seifert H, Jansen B, Farr BM, eds., *Catheter-Related Infections,* New York: Marcel Dekker; 1997:259-305.

[12] Dunne WM Jr, Nolte FS, Wilson ML, Blood cultures III, In: Hindler JA, ed. *Cumitech 1B,* Washington, DC: American Society for Microbiology; 1997:1-21.

[13] Blot F, Schmidt E, Nitenberg G, et al., Earlier positivity of central venous versus peripheral blood cultures is highly predictive of catheter related sepsis, *J Clin Microbiol,* 1998;36(1):105-109.

Previously Endorsed Measures

Central Line-Associated Bloodstream Infection (CLAB) (CDC) – Previously Endorsed

This measure was endorsed in both the Hospital and Nursing-Sensitive Care projects; it was recommended by the BSI and Pediatric TAPs with reservation, because the measure was developed for surveillance rather than accountability, and anecdotal use of these data for public reporting indicates that the measure may not be valid for comparison among hospitals. To improve the meaningfulness of this measure to consumers, the TAP suggested the public reporting of only a subset of the specifications (i.e., reporting of laboratory-confirmed infections) based on the implementation experience gained since the measure was initially endorsed. Although Steering Committee members raised concerns about the validity of a subset of the definition, they ultimately supported the recommendations of the BSI TAP, with the caveat that any measure based on this subset should be monitored to avoid unintended consequences.

Recommended New Measures

Central Line Bundle Compliance (Institute for Healthcare Improvement [IHI])

The Pediatric TAP and the Steering Committee recommended this measure from IHI, despite the recommendation of the BSI TAP, which preferred a similar measure from CDC. Although the measure proposed by IHI applies only to patients age 18 years and older, it was recommended by both the Steering Committee and the Pediatric TAP that the specifications be revised to include pediatric populations. Both measures specify the use of chlorhexidine antiseptic, which requires additional research for children less than 2 years old.

Measures Not Recommended—Intravascular Catheter and BSIs

Of the 10 measures evaluated by TAP members, 8 were not recommended for advancement:

- An additional similar measure of catheter-related BSI rate was not advanced, because TAP members preferred the measure based on the CDC definition, which was more precise and more widely used.
- Four measures were not included because of the TAP's concern about the validity of the administrative data, which could not be confirmed at this time. TAP members recommended additional research, because the efficiencies in data collection would be welcome. The four measures included Selected Infections Due to Medical Care (adults and children) and Postoperative Sepsis (adult and children).
- A measure addressing peripheral intravenous catheters was not recommended, because it was deemed to be outside of the project scope.
- TAP members recommended that two measures addressing central line insertion practices were suitable for public reporting; the Steering Committee preferred the measure that was more applicable to pediatric patients.
- An electronic surveillance tool to identify nosocomial infections was reviewed by two TAPs and the Steering Committee.

Although all reviewers agreed that HAI electronic surveillance should be explored because of its potential value, the tool that was reviewed was not ready for immediate use for national public reporting. Specifically, TAP members questioned whether the tool could produce comparable information among institutions because of the lack of a risk-adjustment methodology; they also questioned its utility for hospitals of varying sizes.

Research Recommendations

Although the Steering Committee recommended two BSI measures that could be used for public reporting, it also identified gaps in measurement and guidance for the implementation of public reporting initiatives:

- **Develop measures that assess compliance with proper line maintenance procedures.** Appropriate maintenance of central lines provides critical leverage for reducing healthcare-associated BSIs.[14,15,16] Measuring line maintenance may be useful to identify areas related to BSI rates in need of improvement.
- **Develop measures that assess adherence to evidence-based protocols for ensuring the competency of those inserting and maintaining central lines.** Healthcare facilities often select certain staff to perform central line insertions; however, currently no measures are available for determining whether those staff members are performing insertions in accordance with guidelines, whether they have continuing education, or whether they are routinely evaluated. Additional measures could include requirements for data on line placement, number of insertions for each inserter, whether training is current, and whether a facility has programs to establish competency in appropriate insertion techniques.
- **Develop measures of BSI rates that track infections identified after hospital discharge.** Pediatric TAP members recommended that measures be developed to address central line-associated BSI measures that track infection rates after hospital discharge, because pediatric catheters are often managed in home or community settings.
- **Modify the measure Central Line Bundle Compliance to discourage femoral vein insertion in those over 18 years of age.** This measure recommends subclavian insertion, which is based on observational studies. Although the risk of infection at the subclavian site is lower than that for the internal jugular site, the bundle should state that femoral catheterization should be avoided if at all possible in patients over 18 years of age, based on prospective, randomized data in adults showing that this site has higher infection and deep vein thrombosis (DVT) risks.[17]

[14] Mermel LA, Prevention of intravascular catheter-related infections, *Ann Intern Med,* 2000;132(5):391-402.

[15] Viale P, Politi E, Sisti M, et al., Impact of central venous catheters (CVC) management on infectious risk [Abstract], *J Hosp Infect,* 1998;40(Suppl A):8.1.8.

[16] Ena J, Cercenado E, Martinez D, et al., Cross-sectional epidemiology of phlebitis and catheter-related infections, *Infect Control Hosp Epidemiol,* 1992;13(1):15-20.

[17] Merrer J, De Jonghe B, Golliot F, et al., Complications of femoral and subclavian venous catheterization in critically ill patients, *JAMA,* 2001;286(6):700-707.

In addition to creating a research agenda for measure development, several gaps in research and approaches for addressing them were identified:

- **Develop clinical care guidelines for culturing patients.** Methods used to draw samples may vary among hospitals because samples are often drawn through catheters, which may introduce contaminants; two samples may be obtained from the same draw rather than during separate occurrences, as recommended; or the frequency of blood sampling and the reasons for culturing might be different across institutions. Guidelines from the IDSA, the American College of Critical Care Medicine, and the Society for Healthcare Epidemiology[18] and additional evidence[19,20,21,22,23] suggest that two cultures should be drawn from peripheral veins.
- **Evaluate how lapses in maintenance of intravascular catheters contribute to the risk of developing BSIs.** Improper maintenance of intravascular catheters (i.e., breaches in aseptic technique) has been identified as a contributing cause of catheter-associated BSIs, especially in intravascular catheters used for extended periods.[24,25,26] Identifying and measuring appropriate methods for line maintenance will provide leverage points for developing interventions and improving quality of care.
- **Identify guidelines that specify appropriate situations for inserting lines into femoral veins.** Frequency of femoral line insertions should be monitored, and a benchmark should be established to determine if rates are too high.
- **Evaluate the appropriateness of using "central-line days" as a denominator for calculating catheter-associated BSI rates.** Although CDC calculates rates based on patients with a central line, that is, "central-line days," regardless of how many lines a patient may have, TAP members suggested that *counting all lines* in each patient may be more suitable for public reporting, because each line represents a risk somewhat independently of the other lines inserted.
- **Implement more efficient mechanisms to count catheter days.** Evidence suggests that counting catheter days one time per week has a high degree of validity for

[18] Mermel LA, Farr BM, Sheretez RJ, et al., Guidelines for the management of intravascular catheter-related infections, *Clin Infect Dis,* 2001;32(9):1249-1272.

[19] DesJardin J, Clinical utility of blood cultures drawn from indwelling central venous catheters in hospitalized patients with cancer, *Ann Intern Med,* 1999;131(9):641-647.

[20] Siegman-Igra Y, Anglim AM, Shapiro DE, et al., Diagnosis of vascular catheter-related bloodstream infection: a meta-analysis, *J Clin Microbiol,* 1997;35(4):928–936.

[21] Mermel LA, Maki DG, Infectious complications of Swan-Ganz pulmonary artery catheters and peripheral arterial catheters, In: Seifert H, Jansen B, Farr BM, eds., *Catheter-Related Infections,* New York: Marcel Dekker; 1997:259-305.

[22] Dunne WM Jr, Nolte FS, Wilson ML, Blood cultures III, In: Hindler JA, ed., *Cumitech 1B,* Washington, DC: American Society for Microbiology; 1997:1-21.

[23] Blot F, Schmidt E, Nitenberg G, et al., Earlier positivity of central venous versus peripheral blood cultures is highly predictive of catheter related sepsis, *J Clin Microbiol,* 1998;36(1):105-109.

[24] Mermel LA, Prevention of intravascular catheter-related infections, *Ann Intern Med,* 2000;132:391-402.

[25] Viale P, Politi E, Sisti M, et al., Impact of central venous catheters (CVC) management on infectious risk [Abstract], *J Hosp Infect,* 1998;40(Suppl A):8.1.8.

[26] Ena J, Cercenado E, Martinez D, Bouza E, et al., Cross-sectional epidemiology of phlebitis and catheter-related infections, *Infect Control Hosp Epidemiol,* 1992;13(1):15-20.

denominator data, which would lessen the data collection burden.[27]

- **Standardize methods for categorizing ICU groups.** Although stratification by ICU is an appropriate mechanism to adjust for risk of catheter-related BSIs, ICU categorization should be standardized among hospitals.

Surgical Site Infections

Scope and Definitions

Scope of Measurement

The SSI TAP suggested that, in addition to the overarching scope for the entire project, the measures under consideration could be adapted for pediatric patients, with appropriate dosage modifications. TAP members recommended that trauma patients be excluded from SSI measures, because of the wide variation in surgical procedures, confounding factors (high degree of exposure to contaminants) for this population, and the difficulty of implementing prophylactic interventions for these patients. Measures that address antibiotic resistance specifically were not identified for SSIs in this project. However, the TAP took into consideration antibiotic resistance issues where appropriate when reviewing each measure.

Reporting of SSI for Accountability Measurement

Members of the ad hoc committee on definitions discussed the definition of SSIs used in the NQF-endorsed™ measure, which was developed by the Society of Thoracic Surgeons (STS). Members recommended that TAP members consider the more inclusive CDC definition of SSIs rather than the STS definition, which addresses only deep sternal wound infections.

Members of the SSI TAP recommended that for surveillance purposes, facilities should continue collecting all data for superficial incisional SSI, deep incisional SSI, and organ/space SSI, as specified by the current CDC definition, but for public reporting, only deep incisional and organ/space infections should be included (similar to the subset of definitions for reporting recommended for public reporting of BSIs). Deep incisional and organ/space infections were recommended for public reporting because these infections often require hospitalization and are associated with significant morbidity and mortality, in comparison with superficial infections, which are often treated in outpatient settings. These infections are high cost, high volume, and more relevant for consumer decisionmaking.

The Centers for Medicare & Medicaid Services (CMS) and CDC are working toward an agreement on which ICD-9-CM Codes will comprise the procedure categories included in the SSI measure. CMS is making plans to use a subset of the CDC SSI measure for public reporting. That subset is to include only deep incisional and organ/space infections, such as may occur with the following procedures: hysterectomy (abdominal and vaginal), coronary artery bypass graft (CABG) and

[27] Klevens RM, Tokars JI, Edwards J, et al., Sampling for collection of central line-day denominators in surveillance of healthcare-associated bloodstream infections, *Infect Control Hosp Epidemiol,* 2006;27(4):338-342.

other cardiac surgery, colon surgery, joint replacements (hip and knee), and vascular surgeries. In addition, infections related to these procedures can be captured upon readmission to the hospital after the initial operative procedure within the 30-day period during which there were no implanted devices and within 1 year for implanted devices (e.g., joint replacements).

Previously Endorsed Measures

Four of the measures reviewed by the SSI TAP were previously endorsed—three were endorsed in both the "Hospital Care" and "Cardiac Surgery" projects[28,29] and one from the Cardiac Surgery project. The three hospital care measures, which are part of the CMS SCIP, were advanced, addressing antibiotic timing, selection, and discontinuation for surgery patients. The fourth measure, from the Cardiac Surgery project, addressed deep sternal wound infection rates for CABG; it was not recommended for inclusion in this project, but it can be captured in the endorsed SSI measure. The SSI TAP identified several reasons for excluding this measure from this project:

- The measure counts only deep sternal wound infections that occur during the initial admission and within 30 days of surgery. It does not include patients who are readmitted for deep sternal infection, even if readmission occurs within 30 days. A substantial number of infections develop postdischarge and are found on readmission.
- The measure applies only to CABG patients and does not translate well to general surgery.
- The risk-adjustment methodology, which includes the collected 21 variables, has not been validated for procedures other than CABG.
- The numerator includes only deep sternal wound infections, while the CDC data can be used to report on deep incisional and organ/space infections for seven procedures.
- The STS definition requires a positive culture; however, not all surgeons may take a culture (i.e., it may not be necessary or possible).

Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision (CMS/Joint Commission)

TAP members recommended this measure because of the strength of the data on the relationship between the use of prophylactic antibiotics and SSIs for the included procedure categories, although data demonstrating the importance of the specific timing of antibiotics are weak. Although the measure specifications did not include persons under age 18 or the codes for pediatric procedures, the Pediatric TAP supported the use of this measure if the specifications were modified appropriately. The Steering Committee supported the SSI TAP recommendation.

[28] NQF, *National Voluntary Consensus Standards for Hospital Care: An Initial Performance Measure Set – A Consensus Report,* Washington, DC: NQF; 2003.

[29] NQF, *National Voluntary Consensus Standards for Cardiac Surgery: A Consensus Report,* Washington, DC: NQF; 2004.

Prophylactic Antibiotic Selection for Surgical Patients (CMS/Joint Commission)

TAP members recommended this measure based on the feasibility of data collection and strong supporting evidence for the relationship between the use of the recommended antibiotics and SSI for the specified procedure categories from randomized controlled trials; however, they noted that compliance is high, and therefore room for improvement in this area might be limited. Again, noting that the measure specifications did not include persons under age 18 or the codes for pediatric procedures, the Pediatric TAP supported the use of this measure if the specifications were modified appropriately. The Steering Committee supported the TAP recommendation.

SSI TAP members were concerned about the identification of appropriate situations in which to administer vancomycin in lieu of other antibiotics (i.e., when patient allergy is present or when high rates of methicillin-resistant *Staphylococcus aureus* [MRSA] or *Staphylococcus epidermidis* are reported). TAP members also believed that requiring documentation of a reason for use of vancomycin places an unreasonable burden on the physician. The Steering Committee supported the SSI TAP recommendation.

Prophylactic Antibiotic Discontinued Within 24 Hours after Surgery End Time, 48 Hours for CABG and Other Cardiac Surgery (CMS/Joint Commission)

TAP members recommended this measure after considering several factors, including whether administration of antibiotics beyond 24 (or 48) hours decreases infection rates; increases rates of *C. difficile*; or increases antibiotic resistance. Evidence indicates that prolongation of antibiotics beyond this period does not confer any anti-infection benefit, although the rates of *C. difficile* and antibiotic resistance increase. The specification to allow antibiotic continuation up to 48 hours in cardiac surgery is based on evidence from non-randomized trials with cardiac surgery patients that have shown higher rates of *C. difficile* and higher rates of antibiotic resistance when antibiotics are continued past 48 hours after surgery. Rates for this measure are generally not as high as the rates for the measures of prophylactic antibiotics prior to surgery and antibiotic selection. The Pediatric TAP supported the use of this measure if the specifications were modified appropriately, which is consistent with the two previous antibiotic timing and selection measures. The Steering Committee supported the SSI TAP recommendation.

Members were advised that their recommendation regarding this measure will be taken into consideration when the measure is updated by the developer as part of ongoing maintenance of NQF endorsement. The Steering Committee supported the TAP recommendation.

Recommended New Measures

Surgical Site Infection Rate (CDC)

SSI TAP members recommended this measure, as proposed by CDC, for endorsement, using the definition of SSI for public reporting described earlier. The TAP also recommended that the measure be revised

in the future to include improvement in the risk-adjustment methodology to ensure proper comparisons of institutions and that the SSI definition be broadened to include SSIs identified during hospital readmission to a hospital, in addition to SSIs identified during the initial hospital visit. The Pediatric TAP did not specifically review this measure, because the SSI TAP had not recommended it at the time of the Pediatric TAP meeting. The Pediatric TAP did, however, discuss this measure in the context of the antibiotic timing, prophylaxis, and discontinuance measures, noting that the measure specifications did not include persons under age 18 or the codes for pediatric procedures. The Steering Committee supported the SSI TAP recommendation.

Cardiac Surgery Patients with Controlled 6 am Postoperative Serum Glucose (CMS/Joint Commission)

TAP members recommended this measure after the CMS Technical Group noted that it was the best available measure that was feasible and that the 200 mg/dL postoperative serum glucose level was obtainable and was correlated with better outcomes. The TAP clarified that the use of two glucose determinations in the measure was based on the original tri-state audit, which showed the inability to gather data more frequently or to average glucose levels. Pediatric TAP members noted that although an altered measure may be suitable for older children and diabetic patients, this measure could be potentially dangerous for infants and young children. The Steering Committee supported the SSI TAP recommendation.

Surgical Patients with Appropriate Hair Removal (CMS/Joint Commission)

The TAP members recommended this measure, yet noted their concern about the conflicting evidence in this area. A Cochrane review included three randomized studies that have shown shaving to be inferior to clipping and seven studies that have shown shaving to be inferior to depilatories. Two other systematic reviews also have shown an advantage to not shaving. Additionally, the studies were all conducted more than 10 years ago (1971-1992) and they aggregated all types of SSIs. Some members of the TAP believed that the effort to document the type of hair removal process may be considerable, although others noted that hair removal was routinely captured in the operative note. TAP members indicated that aggregation would obscure the relationship between shaving and deep incisional or organ/space infections, which are the most important. CMS noted that in its preliminary testing, the use of shaving occurred in up to 30 percent of facilities, indicating that there is significant room for improvement. The Steering Committee supported the SSI TAP recommendation.

Measures Not Recommended—SSIs

Two additional measures were evaluated by TAP members, but were not recommended. The process measure—Colorectal Surgery Patients with Immediate Postoperative Normothermia— did not have a sufficient evidence base and applied to a very small population. The second was another SSI rate measure; it was not

recommended because of the requirement to have a trained data abstractor, the amount and breadth of quality data required, and the difficulty of collecting the measure for healthcare facilities without electronic data collection systems. Members also believed that risk-adjustment algorithms for the measure were inadequate and that the measure was developed and primarily used specifically for general and vascular surgeries in high-volume institutions. The TAP believed the CDC SSI rate measure was the better measure.

Research Recommendations

TAP members identified several areas for future measure development and opportunities to improve existing measures:

- **Develop a composite measure consisting of the three surgical care infection prevention measures addressing appropriate antibiotic use for surgical patients.** Three measures from the SCIP project were evaluated for inclusion in this measure set. The TAP recommended developing a composite measure for these three items because the data are collected at the same time, and this would increase the feasibility of creating a composite measure.
- **Include additional procedures in the antibiotic timing measures.** The recommended antibiotic timing measures were limited to high-volume, high-impact procedures because evidence is not strong enough to support the inclusion of other procedure categories and because the burden of surveillance for other procedures might be unreasonably high, given their importance. TAP members recommended further research to establish evidence for the importance of these measures for other procedures and the development of measures where evidence indicates they are appropriate (e.g., central nervous system procedures).
- **Develop additional SSI measures.** TAP members recommended using the recommendations with the highest evidence (i.e., levels A-1 and A-2 evidence) from the Healthcare Infection Control Practices Advisory Committee (HICPAC) report[30] as a resource to develop additional measures.
- **Modify SSI measures to include patients under 18 years of age.** The measure currently is not specified for patients under 18 years of age; however, the Pediatric TAP supported the modification of the three surgical infection prevention measures to include children, with the following considerations: antibiotic timing may conflict with care policies that allow parents to be present during anesthesia induction; antibiotic timing before surgery should be 30 minutes to 1 hour before the procedure; and antibiotic administration should be completed prior to incision, based on the American Academy of Pediatrics Red Book.[31] The Pediatric TAP also believed that these three measures should be modified to include the following procedures for pediatric patients: ventricular-peritoneal shunt procedures, circumcision, correction of scoliosis, and congenital cardiac surgery repair.

[30] McKibben L, Horan T, Tokars JI, et al., Guidance on public reporting of healthcare-associated infections: recommendations of the Healthcare Infection Control Practices Advisory Committee, *Am J Infect Control,* 2005;33(4):217-226.

[31] American Academy of Pediatrics (AAP), Antimicrobial prophylaxis, In: Pickering LK, Baker CJ, Long SS, McMillan JA, eds., *Red Book: 2006 Report of the Committee on Infectious Diseases,* 27th ed., Elk Grove Village, IL: AAP; 2006:824-828.

In the course of their evaluations, TAP members identified several factors that would add value to the information available for each recommended measure. The following TAP recommendations identify areas in need of additional research to facilitate standardized implementation of the measure set:

- **Identify valid risk-stratification and risk-adjustment methodologies for SSIs.** There is little research on risk-stratification methods and risk adjustment related to SSIs, particularly with regard to comorbidities and severity of illness at the time of the procedure.
- **Conduct additional research on the feasibility, reliability, and validity of SSI measures.** TAP members recommended that, as these measures are more widely implemented, an assessment of the reliability, validity, and feasibility of data collection should be conducted.

Catheter-Associated Urinary Tract Infections

Scope and Definitions

Scope of Measurement

In addition to evaluating and recommending measures for endorsement, the Steering Committee requested that the Indwelling Catheters and UTI TAP set an appropriate scope for outcomes measurement of healthcare-associated UTIs. During its deliberations, the TAP identified the parameters of measurement in terms of suitability for public accountability, opportunity for improvement, and burden of disease.

The TAP concluded that outcome measurement should focus on symptomatic bacteriuria occurring in patients with indwelling urethral catheters. This scope focuses measurement on a defined population at significant risk of contracting a preventable infection. Limiting measurement to this population has the following advantages:

- **Addresses significant burden of disease.** The great majority of healthcare-associated UTIs result from instrumentation of the urinary tract, usually catheterization.
- **Measures a commonly used modifiable risk factor.** Catheterization is a common practice; approximately 15 to 25 percent of hospital patients have a urinary catheter at some time during their stay, with rates of utilization varying by unit type within the hospital.[32] Indwelling urethral (Foley) catheters are the most frequently utilized catheter type. The risk of contracting CA UTI increases with the duration of catheterization.[33] Despite this risk, catheters are often overutilized and unnecessary, placing patients at needless risk of contracting infection.[34,35,36]

[32] Weinstein JW, Mazon D, Pantelick E, et al., A decade of prevalence surveys in a tertiary-care center: trends in nosocomial infection rates, device utilization, and patient acuity, *Infect Control Hosp Epidemiol,* 1999;20(8):543-548.

[33] Saint S, Kaufman SR, Thompson M, et al., A reminder reduces urinary catheterization in hospitalized patients, *Jt Comm J Qual Patient Saf,* 2005;31(8):455-462.

[34] Jain P, Parada JP, David A, et al., Overuse of the indwelling urinary tract catheter in hospitalized medical patients, *Arch Intern Med,* 1995;155(13):1425-1429.

[35] Harstein AI, Garber SB, Ward TT, et al., Nosocomial urinary tract infection: a prospective evaluation of 108 catheterized patients, *Infect Control,* 1981;2(5):380-386.

[36] Saint S, Wiese J, Amory JK, et al., Are physicians aware of which of their patients have indwelling urinary catheters? *Am J Med,* 2000;109(6):476-480.

- **Permits attribution to healthcare interventions.** In the absence of a catheter, susceptibility to infection is significantly modified by host defenses and anatomy, making it difficult to attribute infection to processes of care.
- **Measures a condition for which prevention, screening, and treatment are established.** Screening and prophylaxis for asymptomatic bacteriuria is generally not recommended, except in some special populations.[37]

Defining Healthcare-Associated UTIs for Accountability Measurement

TAP members also were asked to evaluate current definitions of healthcare-associated UTIs for their sensitivity and specificity within the identified project scope. Definitions considered were those used by the Association for Professionals in Infection Control and Epidemiology (APIC) for home health[38] and long-term care settings;[39] by CMS for the Minimum Data Set (MDS) measures of nursing home care;[40] by CMS for the Outcome and Assessment Information Set, Outcome-Based Quality Improvement, and Outcome-Based Quality Monitoring measures of home health agencies;[41] and by CDC/NHSN for infection surveillance.[42]

None of these definitions was identified as fully acceptable for supporting outcomes measurement. In general, definitions did not distinguish between infections in catheterized and non-catheterized patients; ideally, definition criteria should be specific to infections arising from a catheter and would be stratified by catheter type (i.e., Foley, condom, suprapubic). TAP members noted that diagnostic criteria listed in definitions may not be specific to CA UTIs. Recent literature suggests that diagnostic criteria such as accepted microorganism thresholds, "traditional" uropathogen designations, and certain symptoms (i.e., urgency, frequency, dysuria, suprabic tenderness, leukocytosis) are not useful for distinguishing between infected and non-infected catheterized patients.[43,44,45] Furthermore, these criteria may arbitrarily

[37] Nicolle LE, Bradley S, Colgan R, et al., Infectious Diseases Society of America guidelines for the diagnosis and treatment of asymptomatic bacteriuria in adults, *Clin Infect Dis,* 2005;40(5):643-654.

[38] Embry FC, Chinnes LF, APIC special communication: draft definitions for surveillance of infections in home health care, *Am J Infect Control,* 2000;28(6):449-453.

[39] McGeer A, Campbell B, Emori TG, et al., Definitions of infection for surveillance in long term care facilities, *Am J Infect Control.* 1991;19(1):1-7.

[40] Centers for Medicare & Medicaid Services (CMS), *Revised Long-Term Care Facility Resident Assessment Instrument User's Manual, Version 2.0, December 2002;* Revised January 2006, Chapter 3: Item by Item Guide to the MDS. Available at www.cms.hhs.gov/NursingHomeQualityInits/downloads/MDS20rai1202ch3.pdf. Last accessed May 2007.

[41] CMS, *OASIS - Based Home Health Agency Patient Outcome and Case Mix Reports.* Available at www.cms.hhs.gov/apps/hha/obqm3.pdf. Last accessed May 21, 2007.

[42] Horan TC, Gaynes RP, Surveillance of nosocomial infections, In: *Hospital Epidemiology and Infection Control,* 3rd ed., Mayhall CG, ed., Philadelphia: Lippincott Williams & Wilkins; 2004:1659-1702. Available at www.cdc.gov/ncidod/dhqp/pdf/nnis/NosInfDefinitions.pdf. Last accessed April 2007.

[43] Maki DG, Tambyah PA, Engineering out the risk of infection with urinary catheters, *Emerg Infect Dis,* 2001;7(2):342-347.

[44] Stark RP, Maki DG, Bacteriuria in the catheterized patient: what quantitative level of bacteriuria is relevant? *N Engl J Med* 1984;311(9):560-564.

[45] Tambyah PA, Maki DG, Catheter-associated urinary tract infection is rarely symptomatic: a prospective study of 1497 catheterized patients, *Arch Intern Med,* 2000;160(5):678-682.

exclude a significant proportion of the population at risk—reliance on symptoms requiring patient complaint excludes patients unable to communicate these symptoms, and provisions requiring symptoms to have "no other recognized cause" exclude patients with confounding comorbidities who may nonetheless have a CA UTI. Several definitions included clinician diagnosis of UTI or initiation of treatment for UTI as a criterion for case identification, which the TAP agreed were inappropriate for supporting outcomes measurement because of questionable sensitivity and specificity and potential unintended consequences. In addition to concerns about the specificity of criteria, TAP members were uncertain whether it would be feasible to collect definitions across institutions and whether data collection could be performed with consistent quality.

Of the definitions examined, the TAP agreed that the CDC/NHSN definition is the best of those currently in use and that with additional research and specification it holds the most potential for supporting outcome measurement. Although the TAP acknowledged that the criteria used are suitable for surveillance, their sensitivity and specificity in measuring CA UTI outcomes for facility-to-facility comparison are not established. Further research on this definition was strongly recommended.

The Pediatric TAP concluded that healthcare-associated UTI is not a priority for measurement in pediatrics because of the low frequency of catheter use and the difficulty of attributing UTIs in children to the receipt of healthcare.

Previously Endorsed Measures

The measure, Catheter-Associated Urinary Tract Infection Rate for ICU Patients, was previously endorsed in the Nursing-Sensitive Care project. TAP members had concerns about the measure and that attendant definitions had not been updated for several years. Therefore, it was strongly recommended that over the next year, the developer should revise the measure to reflect current science and standards.

Measures Not Recommended—CA UTIs

During its deliberations, the CA UTI TAP evaluated two measures and one set of paired measures, none of which was recommended for endorsement. Generally, concerns about definitions of CA UTI, absence of risk adjustments, and failure to discriminate between catheter- and non-device-associated infections were cited as reasons for measures to be withheld from endorsement.

- **Urinary Catheter Utilization (CDC).** The numerator for this measure is catheter days, and the denominator is patient days, with results stratified by unit type. The TAP concluded that the measure provides no mechanism for distinguishing appropriate catheter use from inappropriate catheter use, either by utilization, catheter type, or duration of catheterization—a primary risk factor for infection. In addition, the measure is not risk adjusted for patient populations or comorbidities, and it has not been tested for suitability as a comparative indicator. Absent any risk adjustment, stratification, or thresholds that could differentiate between appropriate and inappropriate care, this measure was deemed to be not useful for consumer

decisionmaking or meaningful comparison among institutions at this time. It was recommended that modification of this measure to distinguish between high- and low-quality utilization strategies and to appropriately adjust for risk (beyond stratification by unit type) be pursued.

- **Residents with a UTI (CMS/MDS).**[46] Numerator inclusions are identified with the MDS definition, which relies on initiation of treatment as a criterion for case identification. The measure does not distinguish between community-acquired or healthcare-acquired UTI, and it does not differentiate between catheterized and non-catheterized patients. Aside from the definitional issues, the measure lacks appropriate risk adjustment.
- **Residents Who Frequently Lose Control of Their Bowel or Bladder (Low-Risk) and Residents Who Have a Catheter in Their Bladder at Any Time During the 14-Day Assessment Period (paired measure) (CMS/MDS).**[47] Although the TAP agreed that the measure appears to be effective for assessing continence care and appropriate catheter utilization in low-risk elderly populations, it was unable to conclude whether it is effective relevant to infections. The group saw the logic in the concept that appropriate catheter utilization in cases of low-risk incontinence is a good proxy for infection prevention, but the measure has not been used or tested for this purpose and would require validation. Because the measure addresses catheter utilization in nursing home residents, a population for whom this is an important issue, the TAP concluded that this measure should be revisited and retested for use as a process measure.

Harmonization with the NQF-Endorsed Safe Practices for Better Healthcare

In October 2006, the NQF Board of Directors approved endorsement of the updated NQF *Safe Practices for Better Healthcare,* which includes five practices aimed at reducing nosocomial infections. Although these five practices address important issues in infection prevention, they do not include interventions or specifications addressing CA UTI. The TAP recommended that CDC guidelines for urinary catheter care and a specification for a written or computerized system for catheter stop orders and daily reminders to check catheter status be incorporated into the HAI chapter of *Safe Practices.* Studies have shown that good catheter care is critical for avoiding infection and that a reminder system or prompt can significantly decrease the duration of catheterization, a primary risk factor for CA UTI.[48,49,50]

[46] Previously endorsed in *National Voluntary Consensus Standards for Nursing Home Care.*

[47] Previously endorsed in *National Voluntary Consensus Standards for Nursing Home Care.*

[48] Saint S, Kaufman SR, Thompson M, et al., A reminder reduces urinary catheterization in hospitalized patients, *Jt Comm J Qual Patient Saf,* 2005;31(8):455-462.

[49] Cornia PB, Amory JK, Fraser S, et al., Computer-based order entry decreases duration of indwelling urinary catheterization in hospitalized patients, *Am J Med,* 2003; 114(5):404-407.

[50] Huang WC, Wann SR, Lin SL, et al., Catheter-associated urinary tract infections in intensive care units can be reduced by prompting physicians to remove unnecessary catheters, *Infect Control Hosp Epidemiol,* 2004;25(11):974-978.

Recommendations for Measure Development and Research

Recognizing the lack of measures for CA UTI, TAP members generated the following recommendations for measure development. These measure concepts are for process and structure measures to be reported in conjunction with an infection rate outcome measure; measures in any of the following areas could be developed and implemented relatively quickly and could facilitate public reporting and quality improvement while a suitable outcome measure is developed and refined. Any measure development would require supporting research on risk-adjustment and stratification methods to account for patient populations, comorbidities, unit type, and catheter type.

- **Develop measures to assess urinary catheter utilization.** Because catheter use is the most significant modifiable risk factor for CA UTI, risk-adjusted, well-stratified measures of catheter utilization in all settings where catheters are used will be critical for reducing CA UTI.
- **Develop measures to assess the appropriateness of initial catheterization.** Overuse of catheters and unnecessary catheterization are significant problems; examples of measures that could address this issue include the proportion of catheterized patients with a documented order for insertion, whether a protocol is in place to assess indications for a catheter, or whether a facility has programs to establish provider competency in the appropriate use of catheters.
- **Develop measures to assess the appropriateness of continued catheterization.** Measures should be developed to ensure that once catheters are placed, they are appropriately documented, maintained, and assessed for removal; for example, measures of whether a facility has a system to track patients with catheters or measures of the frequency with which catheter status is documented could help avoid forgotten catheters.
- **Develop measures to assess the appropriateness and timeliness of catheter removal.** Measures should be developed to identify institutions with protocols in place to ensure the timely removal of catheters and whether these protocols are followed—for example, whether or not a facility has a system for catheter automatic stop orders.
- **Develop measures to assess compliance with best practices of catheter care.** Institutions should be measured on compliance with guidelines and whether programs are in place to train and support staff and caregivers on best practices.

Reliable, valid measures of outcomes of care remain an essential focus for quality measurement for accountability; however, TAP evaluations of CA UTI measures were complicated by the lack of information in the literature specific to CA UTI pathogenesis, risk, and diagnosis. In addition to its recommendations for immediate process/structure measure development, the TAP proposed further research to support the development and implementation of outcome measures, including research to expand clinical understanding of CA UTI and the means to prevent it.

- **Pursue research to define outcome measures of symptomatic CA UTI.** Additional work is needed to clarify the utility of the CDC/NHSN definition for this purpose. The sensitivity and specificity of criteria as they pertain to symptomatic CA UTI should be tested, and research into modifications for risk adjustment, special populations, and catheter types should be pursued to maximize the utility of the measure output.
- **Pursue research to clarify optimal strategies for managing patients who need urinary catheters.** Best practices, such as CDC's *Guideline for the Prevention of Catheter-Associated Urinary Tract Infections,*[51] should be re-evaluated and updated regularly to incorporate advancements in technology and care practices. Additional research is needed to identify and standardize practices to improve care, to provide further information about the risks and benefits of new catheters and alternative catheterization strategies, and to expand knowledge of the pathogenesis, microbiology, and diagnosis of CA UTI.

Ventilator-Associated Pneumonia and Respiratory Illnesses

Scope and Definitions

Scope of Measurement

In addition to the scope established by the Steering Committee members for the entire project, the VAP TAP identified a scope of measurement for accountability. TAP members specified the following parameters for VAP measurement:

- **Consider measures of VAP and respiratory illnesses in all care settings.** Although measures in non-inpatient care settings were not identified for this project, TAP members indicated that measurement may be feasible in long-term care settings, yet hospital definitions would not be appropriate because of the different diagnostic criteria, care methods, and patient characteristics. For example, long-term care patients are more likely to have non-ventilator-associated HCAP, yet the appropriate method for distinguishing this population from VAP patients has not been established.
- **Any outcome measures identified or developed should focus on ICU patients.** TAP members suggested that the greatest return from measuring VAP would result from measuring VAP in ICUs. This would target high-risk patients and offer the greatest leverage to improve quality of care.

Defining VAP for Accountability Measurement

Steering Committee members did not agree on a new definition of VAP that could be used in an outcome measure for accountability. TAP members made recommendations to develop an acceptable VAP definition for public reporting, based on guidelines from the American Thoracic Society (ATS) and the Infectious Diseases Society of America (IDSA).[52]

[51] CDC, *Guideline for Prevention of Catheter-Associated Urinary Tract Infections;* 1981. Available at www.cdc.gov/ncidod/dhqp/gl_catheter_assoc.html. Last accessed December 2007.

[52] American Thoracic Society (ATS)/Infectious Diseases Society of America (IDSA), Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia, *Am J Respir Crit Care Med,* 2005;171(4):388-416.

TAP members thoroughly discussed the implications of changing a definition that has been the foundation of VAP data collection for more than 30 years. Although NHSN data are widely collected, TAP members noted that the data cannot be meaningfully used for accountability measurement because of inconsistencies in the use of the VAP algorithms for diagnoses among institutions; however, they agreed that the data are meaningful for diagnosis and surveillance. TAP members suggested that a new definition should be identified for public reporting in order to collect data more accurately to compare the incidence of VAP across settings. The incidence of VAP varies from 4 to 48 percent, depending on which criteria are used to diagnose it.[53] Although a new definition would preclude comparison with previous data, TAP members indicated that the unintended consequences would be great if data that are not replicable were used for accountability, decisionmaking, and reimbursement.

TAP members identified the following criteria to be included in a VAP definition that would provide objective, meaningful data for an outcome measure that could be used for accountability:

- **Microbiological test criteria should be a necessary component for defining VAP, in addition to radiology results and clinical signs and symptoms, for use in an outcome measure for accountability.** TAP members agreed that laboratory data (e.g., semi-quantitative cultures of endotracheal aspirates, bronchoscopic methods, non-bronchoscopic methods, histopathologic exams) should be enlisted to confirm pneumonia diagnosis and assure a standard, objective definition. Inclusion of laboratory data was recommended for the following reasons:
  - Although bronchoscopy and quantitative microscopy will identify nearly all VAP cases, for organizations that either do not have the resources for quantitative methods or that prefer non-invasive methods, a spectrum of diagnostic criteria should be available. Semi-quantitative analysis of endotracheal aspirates would offer acceptable, less-expensive, and relatively easy-to-implement diagnostic criteria. Utilization rates of semi-quantitative cultures have not been studied, although current evidence[54,55,56] suggests that moderate to heavy growth of a pneumonia-causing organism correlates well with quantitative methods.
  - Categorizations of moderate or heavy growth should be standardized for use across hospital laboratories. Using a specific threshold, such as 10^5 colony-forming units per sample, may result in better agreement between semi-quantitative and quantitative methods.

[53] Minei JP, Hawkins K, Moody B, et al., Alternative case definitions of ventilator-associated pneumonia identify different patients in surgical intensive care units, *Shock,* 2000;14(3):331-336.

[54] Middleton R, Broughton WA, Kirkpatrick MB, Comparison of four methods for assessing airway bacteriology in intubated, mechanically ventilated patients, *Am J Med Sci,* 1992;304(4):239-245.

[55] Baughman RP, Diagnosis of ventilator-associated pneumonia, *Microbes Infect,* 2005;7(2):262-267.

[56] Fujitani S, Yu VL, Diagnosis of ventilator-associated pneumonia: focus on nonbronchoscopic techniques (nonbronchoscopic broncheoalveolar lavage, including min-BAL, blinded protected specimen brush and blinded bronchial sampling) and endotracheal aspirates, *J Intensive Care Med,* 2006;21(1):17-21.

- Endotracheal aspirates can be collected even from critically ill patients before any type of antibiotic course is initiated; sample collection may not be as feasible with bronchoscopic methods.
- If a patient has been on antibiotics for 72 or more hours before the development of VAP, then the causative organism is likely to be antimicrobial resistant, and a lower threshold should be used to confirm the VAP diagnosis.

- **Exclude positive blood cultures and positive growth in pleural fluid.** Positive blood cultures and growth in pleural fluid are currently listed in the CDC definition as acceptable methods for confirming VAP diagnosis, yet TAP members agreed that these methods are less reliable because they do not reliably identify the source of infection. These methods should be phased out as acceptable ways to collect data for a publicly reported VAP measure.[57,58]
- **Include only bacterial pathogens.** TAP members recommended including only criteria related to bacterial pathogens for diagnosing VAP, even though the CDC definition for diagnosing pneumonia contains criteria for including uncommon pathogens (e.g., spores, virus). The interventions and preventive measures (e.g., the IHI ventilator bundle[59] and appropriate antibiotic use) recommended to decrease VAP rates are primarily effective for reducing rates of bacterial pneumonia, not viral or fungal pneumonia.[60,61,62] These criteria should be applicable only for public reporting, not clinical decisionmaking.
- **Include only the first episode of VAP.** TAP members discussed whether the definition should include only the first episode of VAP in a patient, because subsequent episodes introduce confounding variables.[63] Because the definition would be used in a measure intended for public reporting, if a patient has multiple cases, only the first case should be counted.
- **Specify the timeframe for VAP diagnosis.** A pneumonia case that occurs in a healthcare setting should be defined as ventilator associated only if it occurred ≥48 hours after intubation and met all other criteria of the pneumonia definition.

[57] Luna CM, Videla A, Mattera J, et al., Blood cultures have limited value in predicting severity of illness and as a diagnostic tool in ventilator-associated pneumonia, *Chest,* 1999;116(4):1075-1084.

[58] ATS/IDSA, Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia, *Am J Respir Crit Care Med,* 2005;171(4):388-416.

[59] See information in the measure specification table (appendix A).

[60] Craven DE, Steger KA, Epidemiology of nosocomial pneumonia: new perspectives on an old disease, *Chest,* 1995;108(2 Suppl):1S-16S.

[61] Tablan OC, Anderson LJ, Besser R, et al., Guidelines for preventing health-care-associated pneumonia, 2003: recommendations of the CDC and the Healthcare Infection Control Practices Advisory Committee, *MMWR,* 2004; 53(RR-3):1-36.

[62] ATS/IDSA, Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia, *Am J Respir Crit Care Med,* 2005;171(4):388-416.

[63] Eggimann P, Hugonnet S, Sax H, et al., Ventilator-associated pneumonia: caveats for benchmarking, *Intensive Care Med,* 2003;29(11):2086-2089.

TAP members based their recommendations on the CDC surveillance definition[64] and the ATS/IDSA[65] guideline on managing VAP. Because the guideline was written for use across all types of medical centers with varying resources, allowances are built in to account for variation in organizations' access to certain diagnostic tests. It is the most recent guideline, and it incorporates recommendations that address the challenges that were encountered with the implementation of the CDC diagnostic criteria and other VAP definitions.

Pediatric TAP members evaluated whether the recommended definition would be applicable to children and identified a few areas that should be highlighted:

- Diagnosing VAP in neonates is confounded by other pulmonary conditions, including respiratory distress syndrome and bronchopulmonary dysplasia.
- Clinicians should be educated about the risk of collecting tracheal aspirates in neonates. If tracheal aspirates will be used to diagnose VAP in neonates, suctioning should not extend below the endotracheal tube because this can cause damage to the lung tissue.
- Criteria need to be identified to differentiate "new," "progressive," and "persistent" infiltrates.
- Use of the term *tracheal aspirate* rather than *sputum* for neonates should be considered, because neonates do not produce sputum.
- Regarding the definition for VAP in children age 1 to 12, it is not clear that the upper age cutoff is the most appropriate one for differentiating VAP in children versus adults, because some children younger than 13 may manifest VAP in the same way that adults do; there is little literature available, however, for establishing the most appropriate age cutoff.

Members of the Steering Committee could not agree on whether changing the definition to require microbiological results and to introduce semi-quantitative cultures as an acceptable diagnostic criterion would help to reduce the amount of variability of diagnosis if used in an outcome measure. Moreover, the use of this practice has not been established as a clinical practice guideline, and although TAP members recommended that semi-quantitative methods be used more widely, Steering Committee members were hesitant to make this recommendation. Additionally, Steering Committee members were concerned that no adequate mechanism exists to monitor gaming by auditing whether a culture should have been taken and was not.

Considering the continued debate regarding the diagnosis of VAP (and non-VAP pneumonia as well) the Steering Committee recommended that NQF convene a meeting of experts in this field, including CDC, the Joint Commission, CMS, and members of the VAP and

[64] Horan TC, Gaynes RP, Surveillance of nosocomial infections, In: *Hospital Epidemiology and Infection Control,* 3rd ed., Mayhall CG, ed., Philadelphia: Lippincott Williams & Wilkins; 2004:1659-1702. Available at www.cdc.gov/ncidod/dhqp/pdf/NNIS/NosInfDefinitions.pdf. Last accessed May 2007.

[65] ATS/IDSA, Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia, *Am J Respir Crit Care Med,* 2005;171(4):388-416.

Reporting and Implementation TAPs. The three organizations are currently completing work to harmonize their definitions for pneumonia.

Previously Endorsed Measures

Three of the 10 measures considered by the VAP TAP have been endorsed in previous NQF projects. Two vaccination measures, endorsed in the NQF "Hospital Care" project, were reviewed by this TAP. Both measures were considered to be tools to measure and improve quality care and were deemed to be outside the scope of this project because of the limited impact patient vaccination has had on reducing rates of VAP in hospitals.

VAP Rate

A measure of the rate of VAP was previously endorsed in the NQF "Hospital Care" and "Nursing-Sensitive Care" projects. The recommendation by the TAP, after much deliberation, was for the measure developer to revise the specifications within a specified timeline to increase the consistency of how the measure is implemented across institutions. In addition, this measure should be revised in order to improve its usefulness to consumers.

Recommended Measures—VAP and Respiratory Illnesses

Ventilator Bundle (IHI)

The measure evaluates the number of ICU patients on mechanical ventilation at the time of survey for whom all four elements of the ventilator bundle are documented and in place. The ventilator bundle elements are as follows: head of bed elevation at least 30 degrees; daily sedation interruption and daily assessment of readiness to extubate; peptic (stress) ulcer disease (PUD) prophylaxis; and DVT prophylaxis. TAP members were divided about recommending this measure. They indicated that it should be used in conjunction with a reliable outcome measure in order to evaluate whether compliance with processes measured by the bundle improves VAP rates. In addition to concerns about using this measure without an outcome measure, TAP members noted that two of the elements that the bundle measures are not directly related to improving VAP incidence (PUD prophylaxis and DVT prophylaxis).[66] The bundle also does not include a measure of appropriate oral care, which has been proven to decrease VAP rates.[67,68,69] Benefits of using this measure for public reporting include an improvement in team work and a reduction in VAP rates in hospitals that

[66] ATS/IDSA guidelines recommend two components of the bundle with good evidence (i.e., weaning and HoB elevation) and recommend one (PUD/stress ulcer disease prophylaxis) with less solid evidence and only for use in certain situations.

[67] Rodriguez-Roldan JM, Altuna-Cuestra A, Lopez A, et al., Prevention of nosocomial lung infection in ventilated patients: use of an antimicrobial pharyngeal non-absorbable paste, *Crit Care Med,* 1990;18(11):1239-1242.

[68] Abele-Horn M, Dauber A, Bauernfeind A, et al., Decrease in nosocomial pneumonia in ventilated patients by selective oropharyngeal contamination (SOD), *Intens Care Med,* 1997;23:187-195.

[69] Bergmans DC, Bonten MJ, Gaillard CA, et al., Prevention of ventilator-associated pneumonia by oral decontamination: a prospective, randomized, double-blind, placebo-controlled study, *Am J Respir Crit Care Med,* 2001;164(3):382-388.

have implemented and measured all of the elements of the bundle.

Pediatric TAP members unanimously agreed that this measure should not be used in the NICU and that insufficient evidence is available for use of this measure in the pediatric ICU, because no evidence exists to verify whether these practices are helpful or harmful to children. Members of the Steering Committee recommended that this measure advance because process measures for VAP are important, and this ventilator bundle, although not entirely related to VAP, was correlated with an improvement in VAP rates. The Steering Committee agreed with the VAP TAP recommendation.

Measures Not Recommended—VAP and Respiratory Illnesses

Eight of the 10 measures evaluated by TAP members were not recommended for inclusion in the HAI reporting measure set because they were deemed to be either not well specified or outside of the scope of the project. The Steering Committee agreed with the TAP recommendations. Four of the measures considered were similar to elements of the Ventilator Bundle, and Steering Committee members preferred to recommend the bundle rather than measures addressing individual processes. However, after re-examination, the decision was made to put the bundle and the individual components to a vote. Based on discussions with the measure developers, NQF will conduct an addendum vote on the individual measures within the ventilator bundle.

Number of Healthcare Personnel Who Receive Influenza Vaccination[70]

Although the measure was approved by the membership, the Consensus Standards Approval Committee (CSAC) expressed concern about the exclusions in this measure for medical or religious contraindication or personnel who refuse vaccination. The Steering Committee recommended that the exclusions be moved to numerator exclusions. The CSAC did not recommend endorsement of this measure.

Ventilator Weaning Orders

TAP members did not recommend a process measure evaluating the number of ventilated surgery patients in the ICU whose medical record contained documentation of an order for a ventilator-weaning program (protocol or clinical pathway) any time during the initial episode of ventilation. TAP members strongly agreed that ventilator weaning is a meaningful method to decrease VAP rates and that a quality measure should be developed to measure whether the need for ventilation was assessed every day; however, the measure considered was clearly specified, and documentation of whether or not there is a plan in the medical record may not measure whether the process of interest

[70] Pearson ML, Bridges CB, Harper SA, Influenza vaccination of healthcare workers, recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP), *MMWR,* 2006;55(RR-2):1-16.

actually was accomplished. In addition, the measure denominator only includes surgery patients, although it is critical for all ICU patients on ventilators.

Vaccination Measures

The TAP reviewed two vaccination measures; both have been endorsed in the NQF "Hospital Care" project. Although TAP members agreed that vaccination is a venerable practice that continues to receive support and protect people from infections, the measures were not recommended because vaccinating patients is not directly related to a significant reduction in VAP rates. The Steering Committee supported the TAP recommendation.

Research Recommendations

Although only one new VAP measure was recommended for use as an accountability measure, TAP members identified four specific areas for measure development. These "measure concepts" were considered to be areas that offer leverage to improve quality care and areas in which the development of valid and reliable measures is feasible:

- **Develop an outcome measure with a definition of VAP that can be used for measuring accountability.** TAP members recommended that a VAP outcome measure should be based on a standard definition that requires objective, verifiable criteria (i.e., laboratory results), clinical criteria, and radiology results consistent with VAP.
- **Develop a measure of ventilator weaning.** TAP members agreed that the ventilator weaning order measure was not precisely specified and was not reliable, but they recommended that a new measure be developed to more accurately capture appropriate weaning for ventilator patients.
- **Develop a measure evaluating whether appropriate antibiotic therapy was administered to ventilated patients.** The incidence of microbial-resistant infections increases when antimicrobials are not appropriately prescribed.[71,72,73] If appropriate antibiotic administration for ventilated patients is measured, explicit instruction should be included to obtain a diagnosis of an organism prior to adjusting antibiotic therapy to treat pneumonia.
- **Develop measures to identify VAP in patients with acute respiratory distress syndrome (ARDS).** Patients with ARDS have multiple symptoms that may complicate the diagnosis of VAP. A quality measure for patients with ARDS may provide a mechanism to identify VAP in this population, because VAP often is underdiagnosed in ARDS patients.

[71] Boyce JM, Opal SM, Chow JW, et al., Outbreak of multi-drug resistant Enterococcus faecium with transferable vanB class vancomycin resistance, *J Clin Microbiol,* 1994;32(5):1148-1153.

[72] McGowan JE Jr., Antibiotic resistance in hospital organisms and its relation to antibiotic use, *Rev Inf Dis,* 1983;5(6):1033-1048.

[73] Olson B, Weinstein RA, Nathan C, et al., Epidemiology of endemic Pseudomonas aeruginosa: why infection control efforts have failed, *J Infect Dis,* 1987;150(6):808-816.

The following areas were identified as in need of additional research for quality measurement relating to VAP. Conducting research may provide additional information for future quality measurement endeavors related to VAP.

- **Evaluate the benefit of including oral care practices in the ventilator bundle.** Current evidence[74,75,76] suggests that certain oral care practices are correlated with a decrease in the incidence of VAP and that an oral care component should be considered as an addition to the ventilator bundle.
- **Trained infection control practitioners or hospital epidemiologists with experience in VAP diagnosis and data abstraction should be responsible for collecting and reporting VAP data.** TAP members believed that it was feasible to collect reliable data, provided an infection control practitioner or a hospital epidemiologist was responsible for collecting and reporting them. This was particularly recommended for collecting VAP data, because diagnosis is difficult, but it also may be relevant for other priority areas.
- **Define and measure HCAP.** Although VAP is a subset of HCAP, the incidence of HCAP, unrelated to VAP, is unknown and has not been widely studied.
- **Additional research is needed to determine how frequently blood cultures, pleural fluid growth, and semi-quantitative cultures are used to diagnose VAP.** TAP members wanted to know the impact that a recommendation to eliminate the use of blood cultures and pleural fluid to diagnose VAP would have and whether the inclusion of semi-quantitative methods would affect current practice. Quantifying how frequently these procedures are used to diagnose VAP may elucidate possible unintended consequences that may arise from the recommendations.
- **Explore the efficacy of potassium hydroxide wet preps as a diagnostic tool for VAP.** Because evidence evaluating the utility of potassium hydroxide preparation is older and conflicted, additional research in this area should explore whether this diagnostic tool can serve as an objective measure for VAP. This laboratory test of lung aspirates has shown promise in detecting elastin fibers, which are diagnostic of bacterial VAP and could increase the accuracy of diagnosis.[77]
- **Develop methods to assess readiness to extubate in very low birth weight (VLBW) infants.** Currently, assessing readiness to extubate in VLBW infants cannot be accurately and reliably evaluated unless the appropriately trained clinician(s) is present.

[74] Bergmans DCJJ, Bonten MJM, Gaillard CA, et al., Prevention of ventilator-associated pneumonia by oral decontamination, *Am J Respir Crit Care Med,* 2001;164(3):382-388.

[75] Treloar DM, Stechmiller JK, Use of a clinical assessment tool for orally intubated patients, *Am J Crit Care,* 1995;4(5):355-360.

[76] Hideo M, Hiroyuki H, Shigeto O, et al., Oral care reduces incidence of ventilator-associated pneumonia in ICU populations, *Inten Care Med,* 2006;32(2):230-236.

[77] Cook D, Mandell L, Endotracheal aspiration in the diagnosis of ventilator-associated pneumonia, *Chest*, 2000;117(4 Suppl 2): 195-197.

- **Evaluate the usage of SUD/PUD prophylaxis and its relation to VAP.** Some evidence[78,79] has shown that organisms causing VAP cannot be tracked back to the stomach, implying that the stomach may not be an important source for VAP.
- **Identify which organisms are responsible for VAP in children.** TAP members suggested that non-bacterial pneumonia may be a causative agent in children more frequently than in adults. In light of the recommendation of the VAP TAP to limit a reporting definition to bacterial pathogens, further research should be conducted to determine how frequently uncommon agents are responsible for VAP in children.

Healthcare-Associated Infections in Pediatric Populations

Scope and Definitions

Scope of Measurement

The Pediatric TAP was charged with reviewing the pediatric-specific HAI measures, making recommendations to the Steering Committee, and reviewing all the candidate measures under consideration in the other content-specific TAP areas. The Pediatric TAP was charged with reviewing whether for the measures initially reviewed by the BSI, CA UTI, SSI, and VAP TAPs, the recommended definitions are applicable, in whole or in part, to children, and for discussing the appropriateness of incorporating children into at least a subset of the measures to be reviewed for this project, particularly because there are few pediatric-specific measures currently identified.

The definition subsets recommended for reporting and measures considered did not account for the different settings in which children with devices (e.g., intravascular catheters) may receive care. Many children are cared for in the community or at home rather than in the hospital. Pediatric TAP members made the following recommendations for measuring pediatric HAIs in various settings of care:

- because rates of outpatient surgery utilization are increasing, this setting should be included in performance measurement;
- step down units, nursing homes and long-term care settings should be addressed, because these facilities are a significant source for resistant infections to originate and grow; and
- data on transfers from other hospitals and between units are important to track in order to correctly attribute infections.

Several special pediatric subpopulations represent a proportion of patients that are at risk for HAIs. Current age cutoffs for reporting HAIs may not be optimal. The age at which children developmentally achieve full immunocompetence may inform the CDC use of the age bands for infants and children, but there does not

[78] Bonten MJ, Gaillard CA, de Leeuw PW, et al., Role of colonization of the upper intestinal tract in the pathogenesis of ventilator-associated pneumonia, *Clin Infect Dis,* 1997;24(3):309-319.

[79] Prod'horm G, Leuenberger P, Koerfer J, et al., Nosocomial pneumonia in mechanically ventilated patients receiving antacid, ranitidine, or sucralfate as prophylaxis for stress ulcer: a randomized controlled trial, *Ann Intern Med,* 1994;120(8):653-662.

appear to be a biological basis for the age cutoff of 13 years in terms of child immunocompetence. During puberty, there may be some changes that impact HAIs and increase their risk (e.g., the rate of meningococcemia is much higher in adolescents than in infants), although evidence does not exist to substantiate this. Specifying different criteria for children under age one was acceptable, because there may be more immune system variance for children under the age of one, with the neonatal period constituting the time of highest risk.

TAP members noted that children affected with the following conditions or diseases have higher risk for infection and HAIs: cystic fibrosis, cancer, severe cerebral palsy (these children often have recurring aspiration pneumonia), use of suprapubic catheters, use of central lines in the community (these line infections are not systematically tracked and reported), and use of catheters in children with special needs and those who are device dependent (e.g., children on transfusion protocols, home ventilator programs, chelation protocols).

Pediatric TAP members also recognized several procedures that are performed frequently in children, which are not included in the CDC definition, including insertion of a ventriculo-peritoneal shunt, circumcision, correction of scoliosis, and congenital cardiac surgery repair.

Recommended Measures

Pediatric TAP members reviewed measures that were recommended from the BSI, CA UTI, SSI, and VAP TAPs. Specific recommendations related to children for each priority area are discussed in the respective sections. One of the two pediatric-specific measures that were reviewed was recommended by the Pediatric TAP.

Late Sepsis or Meningitis in Neonates (Vermont Oxford Network)

Late Sepsis or Meningitis in Very Low Birth Weight Neonates (Vermont Oxford Network)

TAP members recommended these measures, although they identified several problematic areas, including the numerator exclusion for cerebrospinal fluid for fungal infection and several aspects of the risk-adjustment methodology. The risk-adjustment model includes race as a variable in the regression model, but TAP members believed that stratification may be a better method to adjust for race. Also, although the variables included in the model are statistically significant, TAP members questioned the clinical relevance of each factor in calculating a rate of sepsis and meningitis for neonates. In addition, the birth weight categories used for this measure differ from the categories used by NHSN. The Steering Committee agreed with the TAP recommendation.

Measures Not Recommended

One of the two pediatric-specific measures was not recommended by TAP members for inclusion in the HAI measure set. This measure assesses whether central line infection prevention policies have been adopted in the pediatric ICU setting. TAP members agreed that the measure was not clearly specified and that the elements of the measure could be interpreted subjectively. The Steering Committee agreed with the TAP recommendation.

Research Recommendations

TAP members identified several gaps in current research for HAIs in children. Recommendations from the Pediatric TAP that specifically addressed BSI, CA UTI, SSI, and VAP appear in their respective sections. The following additional pediatric-specific measure recommendations were identified:

- Develop measures to monitor antimicrobial therapy, including tracking the frequency of appropriate selection, duration of agent/therapy, and the number of courses given for contaminated cultures (e.g., appropriate selection and use of vancomycin) for children undergoing surgical procedures.
- Develop outcome measures for HAIs caused by viruses that are relevant to pediatrics, including rates of respiratory and gastrointestinal infections (no symptoms on admission with symptoms manifesting 72+ hours after admission) and rates of worker viral infections compared with patient infection rates.

TAP members also identified areas for future research to support measurement of HAIs in pediatric patients (recommendations specific to BSI, CA UTI, SSI, and VAP are found in the appropriate sections):

- Research is needed to identify appropriate uses of cutaneous antisepsis for children, particularly neonates and infants, and to identify whether current practices are evidence based.
- The endorsed VAP bundle measure includes DVT prophylaxis, but its relevance to children is not clear; more research is needed on the incidence of DVT in this population.
- Research is needed regarding the significance of *C. difficile* infections in the pediatric population.
- Research is needed regarding the definition of VAP in children and appropriate prevention strategies.

Appendix D
Consensus Development Process: Summary

The National Quality Forum (NQF) is a unique, multistakeholder organization dedicated to improving healthcare quality through performance measurement and public reporting. NQF's Consensus Development Process (CDP) is the formal process through which it achieves consensus on the standards it endorses, including performance measures and other standards to improve healthcare quality.

Through this multistep process, NQF brings together diverse healthcare stakeholders who are represented in eight Member Councils: Consumer Council; Purchaser Council; Health Professional Council; Provider Organization Council; Supplier and Industry Council; Quality Measurement, Research, and Improvement Council; Health Plan Council; and Public/Community Health Agencies Council.

Members of the public with particular expertise in a given topic also may be invited to participate in the early identification of draft consensus standards, either as technical advisors or as Steering Committee members. In addition, the NQF process explicitly recognizes a role for the general public to comment on proposed consensus standards and to appeal healthcare quality consensus standards endorsed by NQF. Information on NQF projects, including information on NQF meetings open to the public, is posted at www. qualityforum.org.

NQF's CDP process begins with the formation of a Steering Committee that guides the project and that includes critical expertise and represents a balance of perspectives on the matter(s) under consideration. The purpose of the Steering Committee is to develop and carry out, in conjunction with NQF staff and technical advisors, as needed, a work plan that will result in a recommended product for endorsement by NQF membership, the Consensus Standards Approval

Committee (CSAC), and the NQF Board of Directors. Priority will be given to nominations for Steering Committees members that are made by NQF Members.

The next step involves a "Call for Measures." NQF invites the owners or stewards of performance measures or other types of candidate standards to submit their measures for consideration. Organizations do not need to be NQF Members to participate. Once NQF issues a "Call for Measures," organizations have 30 days to submit the requisite information. Organizations are asked to adhere to NQF Measure Submission Guidelines and must agree to provide free, public access to measures, including technical specifications, if they are endorsed by NQF.

The proposed consensus standards are distributed for review and comment by NQF Members and non-members. After NQF review and comment of the candidate consensus standards, member organizations are provided with a revised draft, on which they generally have 30 days to vote. Each organization has one vote.

Next, the candidate consensus standards and the voting results are submitted to the CSAC to consider in making its decision. Although the CSAC makes most of the final decisions regarding approval, on occasion, it may defer decisionmaking and request additional consensus building, and Member Council chairs are given an opportunity to provide input. As is the case with the Board of Directors, consumers and those who purchase services on their behalf constitute a simple majority on the CSAC.

After approval by the CSAC and ratification by the Board of Directors, NQF Members and non-members are provided 30 days to file an appeal. All appeals are reviewed by the CSAC and are forwarded with their recommendation to the Board of Directors for final consideration.

Once a set of voluntary consensus standards has been approved, the federal government may utilize it for standardization purposes in accordance with the provisions of the National Technology Transfer and Advancement Act of 1995 (P.L. 104-113) and the Office of Management and Budget Circular A-119. Consensus standards are updated as warranted.

For this report, the NQF CDP, version 1.8, was in effect. The complete process can be found at www.qualityforum.org.

National Quality Forum Publication Information

National Voluntary Consensus Standards for the Reporting of Healthcare-Associated Infection Data—A Consensus Report

Document No.	Description	Member Price*#	Non-member Price#
NQFCR-20-08	Paperback, 84 pages	$00.00 each, incl. shipping & handling (additional 10% discount on bulk orders of 10 or more copies shipped to one address)	$00.00 each, incl. shipping & handling (10% discount on bulk orders of 10 or more copies shipped to one address)

*Primary contacts for NQF member organizations will receive two complimentary copies.

#Orders directed to organizations or individuals in Washington, DC, must add 5.75% sales tax or provide a copy of your tax-exempt certificate with your order. For deliveries outside the United States, please contact us (202.783.1300 or fax below) for pricing information.

No. of copies _____ Cost of reports _____ Sales tax (5.75% DC) _____ **Total cost** _____

METHOD OF DELIVERY

☐ U.S. Postal Service (included)

☐ FedEx (Priority / Standard / 2-day / 3-day) [circle one]
(FedEx used ONLY if a valid FedEx Acct. No. is provided)

Your FedEx Acct. No. _____

METHOD OF PAYMENT

☐ Payment enclosed (check or money order, U.S. dollars only)

☐ Please invoice me (option ONLY for NQF Members)

Credit Card: ☐ Visa ☐ Mastercard ☐ Amex

Card # _____ VCODE _____ Expiration Date _____
FOUND ON SIGNATURE PLATE OR ABOVE AMEX CC#

Billing Address (for this credit card) _____

Total Amount $ _____ Signature _____

INVOICE AND PUBLICATIONS TO BE SENT TO

Name _____

Organization _____

Address _____

City State ZIP _____

Phone _____

Fax and E-mail _____

DIRECT ORDERS TO National Quality Forum
ATTN: Publications Unit
601 Thirteenth Street, NW, Suite 500 North, Washington, DC 20005

FAX Publications Unit – 202.783.3400

ALL SALES FINAL

The National Quality Forum (NQF) is a private, nonprofit, open membership, public benefit corporation whose mission is to improve the American healthcare system so that it can be counted on to provide safe, timely, compassionate, and accountable care using the best current knowledge. Established in 1999, NQF is a unique public-private partnership having broad participation from all parts of the healthcare industry. As a voluntary consensus standards setting organization, NQF seeks to develop a common vision for healthcare quality improvement, create a foundation for standardized healthcare performance data collection and reporting, and identify a national strategy for healthcare quality improvement. NQF provides an equitable mechanism for addressing the disparate priorities of healthcare's many stakeholders.

National Quality Forum
601 Thirteenth Street, NW, Suite 500 North
Washington, DC 20005

ISBN 1-933875-11-9