Evidence Report/Technology Assessment
Number 9

Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies

Volume 6—Prevention of Healthcare-Associated Infections

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-02-0017

Prepared by:
Stanford University-UCSF Evidence-based Practice Center, Stanford, CA

Series Editors
Kaveh G. Shojania, M.D., *University of California, San Francisco*
Kathryn M. McDonald, M.M., *Stanford University*
Robert M. Wachter, M.D., *University of California, San Francisco*
Douglas K. Owens, M.D., M.S., *VA Palo Alto Health Care System, Palo Alto, California; Stanford University*

Investigators

Sumant R. Ranji, M.D.
Kanaka Shetty, M.D.
Keith A. Posley, M.D.
Robyn Lewis, M.A.
Vandana Sundaram, M.P.H.
Cristina M. Galvin, M.S., M.A.
Lisa G. Winston, M.D.

AHRQ Publication No. 04(07)-0051-6
January 2007

This report is based on research conducted by the Stanford-UCSF Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 290-02-0017). The findings and conclusions in this document are those of the author(s), who are responsible for its contents, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

Suggested Citation:
Ranji SR, Shetty K, Posley KA, Lewis R, Sundaram V, Galvin CM, Winston LG. Prevention of Healthcare-Associated Infections. Vol 6 of: Shojania KG, McDonald KM, Wachter RM, Owens DK, editors. Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies. Technical Review 9 (Prepared by the Stanford University-UCSF Evidence-based Practice Center under Contract No. 290-02-0017). AHRQ Publication No. 04(07)-0051-6. Rockville, MD: Agency for Healthcare Research and Quality. January 2007.

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to **epc@ahrq.gov.**

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Beth A. Collins Sharp, Ph.D., R.N.
Director, EPC Program
Agency for Healthcare Research and Quality

Marian D. James, Ph.D., M.A.
EPC Program Task Order Officer
Agency for Healthcare Research and Quality

Acknowledgments

We thank Jessie McGowan and the Cochrane Effective Practice and Organisation of Care (EPOC) group for their help with the literature searches, Peter Pronovost, M.D., Ph.D. for providing a draft copy of an unpublished study, and Paul Cornia, MD for providing additional data from one study. We also acknowledge with much gratitude our expert advisors and peer reviewers who are listed in Appendix D*.

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/hainfgaptp.htm

Structured Abstract

Objective: To determine the effects of quality improvement strategies on promoting adherence to interventions for prevention of selected (surgical site infections (SSI), central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), and catheter-associated urinary tract infections (CAUTI)) healthcare-associated infections (HAIs), and on HAI rates.

Data Sources: MEDLINE® and Cochrane Collaboration's Effective Practice and Organisation of Care registry. We also reviewed the reference lists of systematic reviews and included studies, and contacted experts.

Search Strategy and Inclusion Criteria: We included randomized and quasi-randomized controlled trials, controlled before-after studies, interrupted time series, and simple before-after studies that reported either HAI rates or rates of adherence to target preventive quality improvement (QI) interventions for any of the four target HAIs. QI strategies were classified as clinician education, patient education, audit and feedback, clinician reminders, organizational change (including revision of professional roles, staffing changes, and total quality management/continuous quality improvement), and financial or regulatory incentives. We targeted hand hygiene as a preventive intervention for all HAIs. The target preventive interventions specific to SSI were appropriate perioperative antibiotic prophylaxis (including appropriate antibiotic selection, timing, and duration), perioperative glucose control, and decreasing shaving of the operative site. For CLABSI, we targeted adherence to maximal sterile barrier precautions, use of chlorhexidine for skin antisepsis, and avoidance of femoral catheterization. For VAP, we targeted semirecumbent patient positioning and daily assessment of readiness for ventilator weaning. For CAUTI, we targeted reduction in unnecessary catheter use and adherence to aseptic catheter insertion and catheter care. Our primary outcomes were the rate of HAI (defined as infections per 100 cases for SSI and infections per 1,000 device-days for CLABSI, VAP, and CAUTI) and the rate of adherence to preventive interventions (defined as the percentage of patients at risk who received the preventive intervention). Secondary outcomes included effects on costs and adverse effects associated with the interventions.

Data Collection and Analysis: Two reviewers independently abstracted data. Due to heterogeneity in study populations, QI strategies, preventive interventions, and outcomes, no formal quantitative analysis was attempted. We assessed study quality based on prespecified criteria for internal and external validity.

Main Results: Sixty-four studies met all inclusion criteria; 28 studies addressed prevention of SSI, 19 CLABSI prevention, 12 VAP prevention, and 10 CAUTI prevention. Three studies targeted prevention of multiple HAIs. The study methodologic quality was generally poor, as 52 of 64 included studies were simple before-after studies, and most of these (33 of 52) reported data at only one time point before and after the intervention. The majority of included studies reported infection rates, but did not report rate of adherence to preventive interventions.

Baseline HAI rates were generally above the median rates reported by the Centers for Disease Control and Prevention's National Nosocomial Infection Surveillance System (NNIS).

Studies addressing surgical site infections: The majority of studies targeted provision of appropriate antibiotic prophylaxis (22 of 28 studies), using combinations of educational interventions, audit and feedback, and clinician reminders. Sixteen of these studies reported data on adherence to appropriate antibiotic prophylaxis guidelines. Clinician reminders were effective at improving appropriate prophylaxis in two controlled studies; educational interventions with audit and feedback were effective in three multicenter studies (two interrupted time series and one simple before-after study.) No QI strategies were clearly effective at reducing SSI rates or improving adherence to other targeted preventive interventions.

Studies addressing central line-associated bloodstream infection: Active educational interventions for clinicians appeared effective at reducing CLABSI rates, based on two controlled before-after studies, one interrupted time series, and four simple before-after studies of relatively good methodologic quality. Two of these studies combined education with an explicit checklist for adherence to insertion site practices and allowed nurses to stop the procedure if the checklist was not followed, a strategy worthy of future study.

Studies addressing ventilator-associated pneumonia: Active educational interventions (including use of web-based and video tutorials) appeared to reduce VAP rates, based on evidence from two simple before-after studies. Conclusions in this area are especially limited as we did not identify any controlled studies.

Studies addressing catheter-associated urinary tract infection: Printed or computer-based reminders to physicians, coupled with an "automatic stop order", appear to be effective at reducing the duration of urethral catheterization (based on two controlled studies and three simple before-after studies.)

Conclusion: The evidence for quality improvement strategies to improve adherence to preventive interventions for healthcare-associated infections is generally of suboptimal quality, consisting primarily of single-center, simple before-after studies of limited internal and external validity. Thus, we were unable to reach any firm conclusions regarding actionable QI strategies to prevent HAIs. Based on the limited available data, we suggest that the following strategies are worthy of future study, and possibly wider implementation: use of printed or computer-based reminders with automatic stop orders to reduce unnecessary urethral catheterization, printed or computer-based reminders to improve surgical antibiotic prophylaxis, active educational interventions with use of of checklists to improve adherence to central line insertion practices, and active educational interventions such as tutorials to improve adherence to preventive interventions for ventilator-associated pneumonia. Higher quality studies of QI strategies for HAI prevention are urgently needed.

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Appendices and Evidence Tables for this report are provided electronically at http://www.ahrq.gov/downloads/pub/evidence/pdf/qualgap6/hainfgap.pdf

Executive Summary

Overview

Healthcare-associated infections (HAIs) are considered to be the greatest risk posed to hospitalized patients; up to two million patients experience a healthcare-associated infection every year in the U.S., leading to approximately 88,000 deaths per year. Active efforts to curb HAIs have increased in recent years, thanks to the growing emphasis on patient safety and quality; these efforts include public reporting of infection rates in some states, and widely publicized campaigns to promote adherence to HAI preventive interventions (such as the Institute for Healthcare Improvement's "100,000 Lives" campaign).

Within the hospital, surgical site infections (SSI) and three types of infections common in intensive care unit (ICU) patients are particularly prevalent—central-line associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), and catheter-associated urinary tract infections (CAUTI). Together, these infections account for more than 80 percent of all HAIs. In this report, we systematically review the evidence supporting quality improvement strategies to reduce the incidence of these key healthcare-associated infections. We intend to identify strategies that successfully increase adherence to effective preventive practices for each of these infections and reduce infection rates. Our specific research questions are:

1. **Do quality improvement strategies increase adherence to evidence-based preventive interventions for healthcare-associated infections?**
2. **What are the critical components of effective QI strategies?**
3. **What are the limitations of current research in this field, and what areas require further study?**

We defined a "preventive intervention" as a specific infection control practice that has been demonstrated to reduce the incidence of a HAI. To identify target preventive interventions, we reviewed the CDC guidelines for prevention of surgical site infection, prevention of intravascular catheter-related infections, prevention of healthcare-associated pneumonia, and prevention of catheter-associated urinary tract infection. Hand hygiene was identified as an important preventive intervention for all HAIs. The disease-specific target preventive interventions we identified are as follows:

- Surgical site infection: appropriate perioperative antibiotic prophylaxis (including appropriate antibiotic selection, timing, and duration), perioperative glucose control, and decreasing shaving of the operative site.

- Central line-associated bloodstream infection: adherence to maximal sterile barrier precautions, use of chlorhexidine for skin antisepsis, and avoidance of femoral catheterization.

- Ventilator-associated pneumonia: semirecumbent patient positioning and daily assessment of readiness for ventilator weaning.

- Catheter-associated urinary tract infection: reduction in unnecessary catheter use and adherence to aseptic catheter insertion and catheter care

As in previous reviews in this series, we performed a rigorous search of the published literature using the MEDLINE® database, supplemented by targeted searches of the Cochrane Collaboration Effective Practice and Organisation of Care (EPOC) database. We included studies with contemporaneous control groups (randomized controlled trials and controlled before-after studies) and quasi-experimental studies without a contemporaneous control group (interrupted time series and simple before-after studies). We classified QI interventions according to a modification of a taxonomy used in previous volumes of this series. The QI strategies were classified as follows:

1. Clinician education
2. Patient education
3. Audit and feedback
4. Clinician reminder systems
5. Organizational change
6. Financial or regulatory incentives for patients or clinicians

We included studies that used one or more of the above QI strategies to implement or increase use of any of the target preventive interventions. Included studies were required to report data on the rate of adherence to recommended preventive interventions and/or the rate of healthcare-associated infection. Trials that reported related outcomes, such as costs, health services utilization (e.g., length of stay), patient or provider satisfaction with care, or adverse events associated with the intervention, were included only if they included data on infection rates or adherence measures.

We assessed study quality based on prespecified criteria for assessing study internal and external validity. These criteria were not used to determine study inclusion or exclusion. For simple before-after studies, we applied the following criteria:

1. Was the intervention performed independent of other QI efforts or other changes?
2. Did the study report data at more than one time point before and after the intervention?
3. If the study reported infection rates, were process measurements also reported?
4. If the study reported infection rates, did the study use CDC/NNIS methodology for measuring infections?
5. (For CLABSI, VAP, and CAUTI) If the study reported infection rates, were reported rates adjusted for device utilization?
6. (For SSI) If the study reported infection rates, was surveillance for infections performed after hospital discharge?

Studies reporting process measures (rate of adherence to target preventive interventions) were considered to have greater external validity, as these measures are universally applicable. For controlled studies, we also applied the following study quality criteria, as used in previous volumes of this series:

1. Were study subjects randomized, and if so, was the randomization process described?
2. For non-randomized studies, was the rationale for selection of the comparison group explained, and a baseline observation period included (to assess selection bias)?
3. Were the outcome assessors blinded to treatment group assignment?
4. Was a unit-of-analysis error present? If so, were appropriate statistical methods used for correction?

We did not perform quantitative analysis, instead using our study quality criteria as a framework to identify studies of relatively stronger internal and external validity.

Results

Our search strategy identified a total of 4,847 citations, and one additional unpublished citation was identified from our peer review panel. Of these, 434 underwent full-text review, and 64 articles met all criteria for inclusion. In general, baseline rates of HAIs were higher than rates reported by the Centers for Disease Control and Prevention's National Nosocomial Infection Surveillance System (NNIS).

Surgical Site Infections

Twenty-eight studies met all inclusion criteria and addressed prevention of surgical site infections. Most (19) of the studies were performed outside of the United States. Several QI strategies were used: 23 studies used clinician education, 15 used audit and feedback, 15 used organizational change strategies such as creation of multidisciplinary teams or adding additional staff, and five used clinician reminder systems. The methodological quality of studies was generally poor; 22 of 28 used a quasi-experimental simple before-after (SBA) design. Even within the limits of the study design, most SBA studies had poor internal and external validity, as most reported data on only one time point before and after the intervention, and most did not perform post-discharge surveillance. Ten studies used surgical site infection rate as the primary outcome, eight used process measures as primary outcomes, and eight both infection rates and process measures. The majority of studies (16 of 28) reported data on adherence to appropriate antibiotic prophylaxis protocols. Limited data indicate that educational interventions coupled with audit and feedback may be effective at improving adherence to appropriate antibiotic prophylaxis. Clinician reminders may also improve perioperative antibiotic prophylaxis, especially when incorporated into a CPOE system. No conclusion can be reached regarding the effectiveness of QI strategies at promoting perioperative glucose control, perioperative normothermia, or decreasing operative site shaving. We were unable to determine any strategies effective at reducing SSI rates. In studies that did not have important methodologic flaws, surgical site infection rates were not consistently reduced, even when process measurements were improved.

Central Line-Associated Bloodstream Infections

Our literature search identified 19 studies that met our inclusion criteria that specifically addressed prevention of central line-associated blood stream infection (CLABSI). Ten were

from centers within the United States. All but one of the studies was from a single center. All of the studies reported rates of CLABSI; nine of the studies also reported data on adherence measures. All studies but one targeted hand hygiene; five studies targeted hand hygiene alone, four targeted hand hygiene and maximal sterile barrier precautions, and seven studies targeted hand hygiene, maximal sterile barrier precautions, and at least one other preventive strategy. All but one of the studies employed educational strategies for health care providers as part of their intervention, targeting nurses and physicians. The majority of educational interventions were active in nature. Eight studies employed audit and feedback, five employed strategies that included organizational change, and four used clinician reminders. The majority of studies used a multifaceted approach, incorporating more than one QI strategy. The methodological quality of studies was also poor, as all but two used an SBA design, and the majority of these reported data at one time point before and after the intervention and failed to report both infection rates and adherence measures. Seven studies (including two controlled studies) used active educational interventions, including demonstrations and self-study tutorials to improve adherence to preventive practices during catheter insertion and reduce CLABSI rates. Two of these studies used an explicit checklist during central line insertion, with nurses empowered to stop the procedure if all preventive interventions were not used, and documented marked reductions in CLABSI rates. These educational interventions have been evaluated in teaching and non-teaching hospitals, and in U.S. and European institutions, increasing their generalizability. We were unable to judge the effectiveness of any other QI strategies at either improving adherence or reducing CLABSI rates.

Ventilator-Associated Pneumonia

We identified 12 articles meeting our inclusion criteria that assessed prevention of ventilator-associated pneumonia. Studies were mostly performed in the United States, primarily in a single institution. All but one included studies explicitly promoted hand hygiene, and eight promoted semirecumbent patient positioning; two studies promoted daily assessment of readiness to wean from the ventilator. Many other preventive interventions were used in the studies, including aseptic drainage of ventilator circuit condensate, appropriate suctioning technique, and provision of oral care. All studies primarily used educational interventions targeted at providers (physicians, nurses, and respiratory therapists.) Most of these combined use of written materials and lectures, with six studies implementing an explicit clinical guideline for preventive care. Three studies used audit and feedback of infection rates, and two used a continuous quality improvement intervention. The methodologic quality of studies was generally poor, as all used a SBA design, and (similar to CLABSI studies) most reported data at one time point before the intervention and did not report both adherence measures and infection rates. Two studies used an active educational intervention with use of a self-study module for ICU staff, and documented significant reductions in VAP rates; this appears to be a promising strategy for reducing VAP. These studies implemented explicit clinical guidelines for preventing VAP. No conclusion can be reached on the effectiveness of audit and feedback of VAP rates, or on the effectiveness of any other QI strategies.

Catheter-Associated Urinary Tract Infection

Our search identified ten articles that addressed prevention of catheter-associated urinary tract infections, six of which were performed outside the United States. Of the included studies, six addressed reduction in placement of catheters or removal of unnecessary catheters once already placed, four addressed aseptic insertion and catheter care, and two hand hygiene. Six studies used a printed or computer-based reminder to attempt to reduce unnecessary catheter use. Six studies used provider education, two used audit and feedback, and two used an organizational change strategy whereby nurses were authorized to remove urethral catheters without a physician order. Seven studies measured CAUTI rate (symptomatic CAUTI or asymptomatic bacteriuria). Four studies measured catheter usage, reported as the percentage of inpatients catheterized or the average duration of catheterization. We identified three controlled before-after studies and seven simple before-after studies. The CBA studies were generally of fair methodologic quality, and the SBA studies were generally of relatively poor quality, with similar problems with internal and external validity as for the other HAIs. Within these limitations, reminders to clinicians appear to be effective at reducing unnecessary catheter usage, primarily by reducing the duration of catheterization. Three of these studies incorporated an "automatic stop order" mandating removal of the catheter after 48 to 72 hours unless countermanded by the physician, and all documented a reduction in catheter use and CAUTI rate. We were unable to assess the effectiveness of any other QI strategies.

Across all four target HAIs, the quality of the included studies was generally poor, as 52 of 64 included studies used a SBA design. Even within the limitations of this study design, most studies had poor internal validity, chiefly due to reporting data at only one time point before and after the intervention. Generalizability was also poor, as the baseline level of HAI rates were well above the pooled NNIS mean for CLABSI, VAP, and CAUTI. The relatively high baseline rates raise the concern that the observed improvement could be due to regression to the mean (especially in SBA studies). Most studies also reported infection rates without reporting accompanying adherence measures. Publication bias is likely, as most (30 of 39) of the studies reporting adherence to preventive interventions reported a statistically significant improvement in adherence. Other methodologic problems in the included studies are similar to those identified in previous volumes in this series, such as inadequate reporting of intervention details and failure to report the reach of an intervention. No studies performed a formal cost-benefit analysis, and few studies reported on any potential adverse effects of the intervention. We were unable to perform any quantitative analyses.

Conclusions

We are unable to make firm recommendations for organizations seeking to implement quality improvement interventions to reduce healthcare-associated infections. Based on the limited data available, we reach the following conclusions:

1. Preliminary data indicates that several strategies are worthy of future study, and possibly wider implementation.

There is insufficient data to support universal implementation of these strategies, but they may be suitable for implementation if an appropriate plan is in place to monitor their effectiveness and potential adverse effects:

- Printed or computer-based reminders with use of automatic stop orders to reduce unnecessary urethral catheterization (the only strategy supported by multiple controlled trials);

- Printed or computer-based reminders for improving adherence to recommendations for timing and duration of surgical antibiotic prophylaxis;

- Staff education, including use of interactive tutorials (including video and web-based) and checklists, to improve adherence to insertion practices for placement of central venous catheters;

- Staff education, including use of interactive tutorials, to improve adherence to preventive interventions to prevent ventilator-associated pneumonia.

2. Higher quality studies of QI strategies to implement preventive interventions are urgently needed.

Investigators should attempt to perform controlled trials of QI strategies when possible, and should report both adherence measures and infection rates. If performing a controlled trial is impractical, investigators should perform interrupted time series studies, involving reporting data for at least 3 time points before and after the intervention and formal time series statistical analysis. Given the burden of disease caused by healthcare-associated infections, prioritizing study of methods to implement effective preventive interventions should greatly benefit hospitalized patients.

Technical Review

Chapter 1. Introduction

Healthcare-associated infections (HAIs) are considered to be the greatest risk patients face in the hospital environment. HAIs can occur in any patient care setting, but infections in hospitalized patients account for the vast majority of HAIs. Hospitalized patients are additionally susceptible to experiencing serious consequences of HAIs due to comorbid illnesses. According to estimates from the Centers for Disease Control and Prevention (CDC), up to two million patients (nearly one in 20 hospitalized patients) experience a healthcare-associated infection every year in the U.S., leading to approximately 88,000 deaths and $4.5 billion in extra costs per year. Moreover, the incidence of HAIs appears to have increased over the last three decades,[1] despite the fact that the majority of HAIs are thought to be preventable.[2]

Efforts to monitor and prevent HAIs have existed for decades. These efforts have followed the public health methodology of surveillance and prevention. The effectiveness of such methods was provided by the Study of the Effectiveness of Nosocomial Infection Control (SENIC) study,[3] which demonstrated that hospitals with structured infection control programs achieved sustained reductions in HAI rates, whereas hospitals with less comprehensive programs saw increased infection rates.

The growing focus on improving patient safety over the past few years has catalyzed even greater efforts to curb HAIs. Public reporting of infection rates has been proposed as a means of educating patients and encouraging preventive efforts;[4] currently, six states require reporting of HAIs, and legislation requiring some type of reporting has been proposed in the majority of states. The Healthcare Infection Control Practices Advisory Committee (HICPAC) recently published guidance on the public reporting of healthcare associated infections, which suggested that central line insertion practices and infection rates, surgical antimicrobial prophylaxis and infection rates, and influenza vaccination coverage among patients and healthcare personnel are areas that may be appropriate for public reporting.[5] These efforts are in parallel to those already being undertaken by many national and international organizations. The Joint Commission for Accreditation of Healthcare Organizations (JCAHO) has made prevention of HAI one of their Patient Safety Goals for 2007.[6] The Institute for Healthcare Improvement (IHI) made the institution of practices to prevent HAIs (specifically surgical site infections, central line-associated bloodstream infections, and ventilator-associated pneumonia) three of the six ”planks” of their “100,000 Lives” campaign.[7] These preventive interventions were organized into “bundles”, in an effort to promote complete adherence with all of the recommended interventions for all eligible patients. The IHI’s recent press statements that over 122,000 “lives were saved” at hospitals participating in the campaign, though methodologically controversial, is likely to increase the enthusiasm for implementing these and the other recommended practices. Finally, prevention of HAIs was recognized as one of the 20 “Priority Areas for National Action” in the 2003 Institute of Medicine report, “*Transforming Health Care Quality*”.[8]

Major Healthcare-Associated Infections

Within the hospital, infections in surgical patients and infections in intensive care unit (ICU) patients are particularly prevalent. The Harvard Medical Practice Study II[9] found that surgical site infections (SSI) were the second most common overall adverse event (behind only adverse drug events) in all hospitalized patients. The incidence of HAI in ICU patients has been

estimated to be as high as 30 percent,[10] and 25 percent of all HAIs are estimated to occur in ICU patients.[11] Surgical site infections (SSI) and three other types of infections commonly seen in ICU patients—central-line associated bloodstream infections (CLABSI), catheter-associated urinary tract infections (CAUTI), and ventilator-associated pneumonia (VAP)—account for more than 80 percent of all HAIs.[10]

Data on the incidence of HAIs in U.S. hospitals primarily comes from the CDC's National Nosocomial Infection Surveillance System (NNIS). The NNIS consists of over 300 hospitals which voluntarily report data on several types of nosocomial infections (including SSI, CLABSI, VAP, and CAUTI), using standardized reporting criteria. Data from NNIS are important for use in benchmarking,[12] although the data are not intended for use in direct hospital-to-hospital comparison of infection rates. The pathogenesis, incidence, and prevention of these HAIs are briefly outlined below.

Surgical Site Infections

Surgical site infections (SSIs) frequently complicate operations, with an estimated annual incidence of 780,000 cases per year.[13] The Centers for Disease Control and Prevention (CDC) publishes a widely used set of diagnostic criteria for each type of SSI: superficial incisional, deep incisional and organ space infections (Table 1). The 2004 NNIS report published mean SSI rates that ranged from 0.45 per 100 cases for low-risk cholecystectomy to 11.25 per 100 cases for high-risk colorectal surgery.[14] For example, in coronary artery bypass graft (CABG) operations, the rate for average-risk patients was 3.45/100 cases. In the same group of patients, the rate of superficial infections was 1.87/100 cases, the rate of deep incisional infections was 0.89/100 cases and the rate of organ space infections was 0.68/100 cases. SSIs increase length of stay and costs substantially. One study estimated that each SSI increased hospital charges by $4,768 (2006 dollars).[15] Another study estimated that patients diagnosed with SSIs after discharge incurred $3,696 in additional outpatient costs (2006 dollars).[16]

Several organizations, including the CDC, the National Surgical Infection Prevention Project (NSIPP) and the Surgical Care Improvement Project (SCIP), have proposed preventive interventions to reduce the incidence of SSIs. The CDC strongly recommends several preventive measures that are well supported in the literature (Table 2) and are also recommended by NSIPP and SCIP.[13] However, adherence to these practices remains suboptimal, including that of the best-studied preventive practice, antimicrobial prophylaxis. The current guidelines recommend three aspects of antimicrobial prophylaxis: appropriate timing, appropriate selection, and appropriate duration.

Appropriate timing consists of administration of antimicrobial prophylaxis within one hour before the surgical incision (or within two hours if a flouroquinolone or vancomycin is used); appropriate selection refers to using antibiotics effective against the pathogens likely to be encountered in a specific type of surgery (e.g., cefazolin for hip or knee arthroplasty); and appropriate duration of therapy mandates discontinuing antibiotics within 24 hours after surgery.[13, 17] Adherence to these measures in practice is suboptimal. A retrospective study of over 30,000 Medicare patients published in 2005 found that prophylaxis was given within one hour of incision in only 55.7 percent of patients and discontinued within 24 hours of surgery in 40.7 percent of patients; guideline-concordant therapy was appropriately used in 92.6 percent of patients.[18] These data indicate that improving antimicrobial prophylaxis practices, particularly antibiotic timing, has the potential to positively impact SSI rates. Several groups, including the

Institute for Healthcare Improvement (IHI) and the Surgical Care Improvement Project (SCIP) have tried to promote use of these practices nationwide.[19]

Table 1. CDC/NNIS definitions for nosocomial infections, 2004

Infection	Definition
Surgical site infections (SSI)	***Superficial Incisional Infections:*** A superficial SSI must meet the following criteria: Infection occurs within 30 days after the operative procedure **and** involves only skin and subcutaneous tissue of the incision **and** patient has at least **one** of the following: a. Purulent drainage from the superficial incision b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision c. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat, **and** superficial incision is deliberately opened by surgeon, **unless** incision is culture-negative d. Diagnosis of superficial incisional SSI by the surgeon or attending physician ***Deep Incisional SSI*** A deep incisional SSI must meet the following criteria: Infection occurs within 30 days after the operative procedure if no implant is left in place 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 **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 when the patient has at least one of the following signs or symptoms: fever (>38°C) or localized pain or tenderness, **unless** incision is culture-negative 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 ***Organ/Space SSI:*** An organ/space SSI involves any part of the body, excluding the skin incision, fascia, or muscle layers, that is opened or manipulated during the operative procedure. An example is appendectomy with subsequent subdiaphragmatic abscess, which would be reported as an organ/space SSI at the intraabdominal specific site. An organ/space SSI must meet the following criteria: Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 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
Central line-associated bloodstream infections (CLABSI)	**Patient must have had an indwelling central venous catheter in place at the time of, or within 48 hours of the onset of the event.** Laboratory Confirmed Bloodstream Infection (LCBI) **LCBI criteria may be used for all patients. LCBI must meet at least one of the following three criteria:** **Criterion 1:** Patient has a recognized pathogen cultured from one or more blood cultures **and** organism cultured from blood is not related to an infection at another site.

Table 1. CDC/NNIS definitions for nosocomial infections, 2004 (continued)

Infection	Definition
Central line-associated bloodstream infections (CLABSI)	**Criterion 2:** Patient has at least one of the following signs or symptoms: fever (>38°C), chills, or hypotension **and** signs and symptoms and positive laboratory results are not related to infection at another site **and at least** one **of the following:** a. common skin contaminant (e.g., diphtheroids, *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci, or micrococci) is cultured from **two** or more blood cultures drawn on **separate** occasions b. 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 physician institutes appropriate antimicrobial therapy c. positive antigen test on blood (e.g., *H. influenzae*, *S. pneumoniae*, *N. meningitidis*, or Group B *Streptococcus*). **Criterion 3:** Patient ≤ 1 year of age has at least one of the following signs or symptoms: fever (>38°C, rectal), hypothermia (<37°C, rectal), apnea, or bradycardia **and signs and symptoms and positive laboratory results are not related to an infection at another site** and **at least one of the following:** a. common skin contaminant (e.g., diphtheroids, *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci, or micrococci) is cultured from **two** or more blood cultures drawn on separate occasions b. 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 physician institutes appropriate antimicrobial therapy c. positive antigen test on blood or urine (e.g., *H. influenzae*, *S. pneumoniae*, *N. meningitidis*, or Group B Streptococcus). Clinical Sepsis (CSEP): **CSEP may be used only to report a primary BSI in neonates and infants. To report a CSEP, the following criterion must be met:** **Patient ≤ 1 year of age** has **at least one** of the following clinical signs or symptoms with no other recognized cause: fever (>38°C, rectal), hypothermia (<37°C, rectal), apnea, or bradychardia **and** blood culture not done or no organisms or antigen detected in blood **and** no apparent infection at another site **and** physician institutes treatment for sepsis.
Ventilator-associated pneumonia (VAP)	**PNU 1: Clinically defined pneumonia (in mechanically ventilated patient)** ***Radiographic criteria:*** Two or more serial chest radiographs with at least *one* of the following: New or progressive *and* persistent infiltrate Consolidation Cavitation Pneumatoceles, in infants <1 year old NOTE: In patients without underlying pulmonary or cardiac disease, *one definitive* chest radiograph is acceptable. ***Clinical Criteria:*** For any patient, at least **one** of the following: a. Fever (>38°C or >100.4°F) with no other recognized cause b. Leukopenia (<4,000 WBC/mm3) *or* leukocytosis (>12,000 WBC/mm3) For adults >70 years old, altered mental status with no other recognized cause **and** at least **two** of the following: c. New onset of purulent sputum, or change in character of sputum, or increased respiratory secretions, or increased suctioning requirements d. New onset or worsening cough, or dyspnea, or tachypnea e. Rales or bronchial breath sounds f. Worsening gas exchange, increased oxygen requirements, or increased ventilation demand)
Catheter-associated urinary tract infection (CAUTI)	***Symptomatic urinary tract infection:*** **Criterion 1:** Patient has at least *one* of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness **and** patient has a positive urine culture, that is, $>10^5$ microorganisms per cm^3 of urine with no more than two species of microorganisms.

Table 1. CDC/NNIS definitions for nosocomial infections, 2004 (continued)

Infection	Definition
	Criterion 2: Patient has at least **two** of the following signs or symptoms with no other recognized cause: fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness **and** at least **one** of the following: a. Positive dipstick for leukocyte esterase and/or nitrate. Pyuria (urine specimen with >10 WBC/mm^3 or >3 WBC/high power field of unspun urine) c. Organisms seen on Gram stain of unspun urine d. At least **two** urine cultures with repeated isolation of the same uropathogen (gram-negative bacteria or *S. saprophyticus*) with >10^2 colonies/mL in nonvoided specimens e. >10^5 colonies/mL of a single uropathogen (gram-negative bacteria or *S. saprophyticus*) in a patient being treated with an effective antimicrobial agent for a urinary tract infection f. Physician diagnosis of a urinary tract infection g. Physician institutes appropriate therapy for a urinary tract infection **Criterion 3:** Patient <1 year of age has at least **one** of the following signs or symptoms with no other recognized cause: fever (>38°C), hypothermia (<37°C), apnea, bradycardia, dysuria, lethargy, or vomiting **and** patient has a positive urine culture, that is, >10^5 microorganisms per cm^3 of urine with no more than two species of microorganisms. **Criterion 4:** Patient <1 year of age has at least **one** of the following signs or symptoms with no other recognized cause: fever (>38°C), hypothermia (<37°C), apnea, bradycardia, dysuria, lethargy, or vomiting **and** at least **one** of the following: a. Positive dipstick for leukocyte esterase and/or nitrate b. Pyuria (urine specimen with >10 WBC/mm^3 or >3 WBC/high power field of unspun urine) c. Organisms seen on Gram stain of unspun urine d. At least *two* urine cultures with repeated isolation of the same uropathogen (gram-negative bacteria or *S. saprophyticus*) with >10^2 colonies/mL in nonvoided specimens e. >10^5 colonies/mL of a single uropathogen (gram-negative bacteria or *S. saprophyticus*) in a patient being treated with an effective antimicrobial agent for a urinary tract infection f. Physician diagnosis of a urinary tract infection g. Physician institutes appropriate therapy for a urinary tract infection ***Catheter-associated asymptomatic bacteriuria:*** **Criterion 1:** Patient has had an indwelling urinary catheter within 7 days before the culture **and** patient has a positive urine culture, **and** patient has **no** fever (>38°C), urgency, frequency, dysuria, or suprapubic tenderness.

Table 2. Recommended preventive interventions

Healthcare-associated infection	Preventive intervention	Definition	Level of supporting evidence	Notes
All target HAIs	Hand hygiene	Washing hands before and after each patient contact	I	Universally recommended as key strategy to present HAIs of all types. Current recommendations encourage use of waterless, alcohol-based hand rubs.
Central line-associated bloodstream infections (CLABSI)	Maximal sterile barrier precautions	Use aseptic technique including the use of a cap, mask, sterile gown, sterile gloves, and a large sterile sheet for the insertion of all central venous catheters (CVC)	I	
	Chlorhexidine skin antisepsis	Use 2% chlorhexidine gluconate solution for skin disinfection at the CVC insertion site	I	
	Appropriate insertion site selection	Avoid femoral site for non-emergency CVC insertion	I	CVC insertion at the internal jugular or subclavian site is preferred.
	Prompt removal of unnecessary catheters	Removal of CVC that is no longer essential for care	I	Routine removal of CVC and routine replacement of CVC over guidewire are explicitly discouraged.
Surgical site infection (SSI)	Appropriate use of perioperative antibiotics	Administration of appropriate prophylactic antibiotic with correct timing and duration	I	Generally defined as 1st generation cephalosporin administered within 1 hour prior to surgical incision and discontinued within 24 hours
	Avoidance of shaving of the operative site		I	Use of clippers encouraged when necessary
	Perioperative glucose control	Maintenance of blood glucose <150mg/dl during postoperative period (tighter control may be more beneficial in specific patient populations)	I	Especially important for patients undergoing coronary artery bypass grafting
Ventilator-associated pneumonia (VAP)	Semirecumbent positioning	Elevation of the head of the bed to more between 30 and 45 degrees	I	
	Daily assessment of readiness for weaning	Minimize duration of mechanical ventilation by minimizing sedative administration (including daily “sedation holidays”) and/or using protocolized weaning	II	

Table 2. Recommended preventive interventions (continued)

Healthcare-associated infection	Preventive intervention	Definition	Level of supporting evidence	Notes
Catheter-associated urinary tract infection (CAUTI)	Aseptic insertion and catheter care	Use of skin antisepsis at insertion and proper aseptic technique for maintenance of catheter and drainage bag; use of closed urinary drainage system	I	
	Reduction in unnecessary catheter use	Avoiding use of catheter unless clinically indicated; prompt removal of catheters when indications for use are no longer present	I	Generally accepted indications for urethral catheterization include bladder outlet obstruction, urinary incontinence, need for frequent urine output monitoring, and postoperative state. Duration of catheterization is a significant risk factor for CAUTI, and unnecessary catheterization is common.

Level of supporting evidence:
I: Level IA recommendation by Centers for Disease Control and Prevention, or Level I recommendation by Infectious Diseases Society of America/American Thoracic Society.
II: Level II recommendation by Infectious Diseases Society of America/American Thoracic Society.

Central Line-Associated Bloodstream Infections

More than five million central venous catheters (CVC) are inserted into patients in the U.S. every year.[20] Several types of infections can occur in patients with CVCs. The skin at the insertion site of the catheter may become infected (so-called exit-site infection). The internal surface of the device itself may become colonized with bacteria, which occurs in 25 percent of catheters left in place for five days. The clinical significance of colonization alone is unclear, but (along with migration of skin flora along the external surface of the catheter) it predisposes to the most serious consequence of catheter-related infection—central-line associated bloodstream infection (CLABSI),[21] when a patient develops bacteremic infection associated with the presence of a CVC. It is estimated that one of the two types of infection above (exit-site infection or CLABSI) occur in 3-7 percent of catheters,[21] resulting in approximately 80,000 episodes of CLABSI in the U.S. every year.[11] Most of these infections occur in patients with temporary central venous catheters, often placed in ICU patients. CLABSI are estimated to result in an absolute increase in mortality of 10-30 percent for ICU patients,[10, 22, 23] and the total yearly costs to the U.S. health care system are between $300 million and $2 billion.[11]

CLABSI are measured according to criteria established by the CDC's National Nosocomial Infection Surveillance System (Table 1). For CLABSI, VAP, and CAUTI, rates of infections are adjusted for the individual hospital's rate of use of the associated device (catheter or mechanical ventilator), and the infection rates are reported as infections per 1,000 device-days. The NNIS reports an average CLABSI rate of 4.1-6.1 infections per 1,000 catheter-days in medical-surgical ICUs, and even higher rates in other types of ICUs (e.g., burn units, 10.0 per 1,000 catheter-days).[14]

Prevention of CLABSI involves close attention to several factors. Basic rules of infection control should be followed, principally involving appropriate hand hygiene.[24] Ensuring a sterile environment at the time of insertion of the catheter (through use of maximal sterile barrier precautions and skin disinfection with chlorhexidine) has been demonstrated to reduce the rates of infection in controlled studies,[25, 26] and specific insertion practices have been recommended by the CDC and other major organizations (Table 2). Appropriate dressing and handling of the catheter is clearly important, but no specific strategy has been unequivocally associated with reduction of infections (apart from hand hygiene).[21] Removal of catheters that are no longer necessary is another important step, as increasing duration of catheterization predisposes to catheter colonization and subsequent CLABSI.[21] Despite extensive research on methods to prevent CLABSI, adherence to recommended preventive practices is suboptimal. A recent survey found that ICU policies regarding insertion and care of CVCs varied widely, with only 28 percent requiring maximal sterile barrier use and 36 percent requiring hand hygiene prior to catheter insertion.[27] Due to the close link between insertion practices and infections, and the suboptimal rate of adherence to these practices, the CDC's Healthcare Associated Infection Practices Committee suggested CVC insertion practices as a candidate quality measure for states considering public reporting programs.[5]

Ventilator-Associated Pneumonia

Ventilator-associated pneumonia (VAP) is a common and morbid condition affecting ICU patients. The diagnosis of VAP can be difficult. The CDC definition is widely used, but the current diagnostic criteria are entirely clinical in nature,[28, 29] and a standard for invasive or microbiologic diagnosis has yet to be established (Table 1). Nevertheless, VAP is estimated to occur in 9-27 percent of patients intubated for more than 48 hours,[29] and patients with VAP have a higher risk of dying in the ICU than similar patients without VAP, though the magnitude of this risk is controversial.[30] Patients with VAP remain hospitalized for 7-9 excess days, and costs are estimated to be between $12,000 and $40,000 per patient.[30]

The pathogenesis of VAP is dependent on the duration of mechanical ventilation, colonization of the aerodigestive tract with bacteria, aspiration of contaminated secretions, and impaired host defenses.[31] Prevention of VAP thus focuses on reducing the duration of intubation and various strategies to prevent colonization and aspiration. Multiple practice guidelines for prevention of VAP have appeared in the last 5 years,[28, 31-33] reflecting the rapidly evolving body of research on prevention of VAP.

Catheter-Associated Urinary Tract Infection

Urinary tract infections associated with urethral catheters (CAUTI) are the most common HAI in hospitals in the U.S., and account for approximately 40 percent of all HAIs.[34] Over 30 million urinary catheters are inserted in hospitalized patients in the U.S. each year,[35] and in these patients, colonization of the catheter resulting in asymptomatic bacteriuria occurs in approximately 3-10 percent of patients per day. Once bacteriuria develops, approximately 25 percent develop symptomatic UTI, and approximately three percent develop bacteremia.[11] Though the attributable morbidity, mortality, and costs of CAUTI are much lower than CLABSI, VAP, and SSI on a per-patient basis, due to the frequency of urethral catheterization in

hospitalized patients, asymptomatic bacteriuria and CAUTI often precipitate antibiotic therapy and may serve as a reservoir for resistant pathogens.[36, 37]

Preventive strategies for CAUTI have been evaluated since the 1960s, and (like CVC prevention) focus on reducing unnecessary catheter use and reducing colonization of the insertion site and catheter apparatus. Use of a closed urinary drainage system was the first intervention proven to prevent CAUTI, and these systems are now in standard use.[36, 37] Avoiding obstruction of the drainage system and using aseptic insertion practices (Table 2) are also recommended. While urinary catheters are needed in certain common situations (principally, postoperative states, urinary incontinence, need for frequent urinary output monitoring, and bladder obstruction),[38] evidence shows that catheters are frequently kept in place when no indications are present, resulting in up to 50 percent of urinary catheter-days being unnecessary.[39] This unnecessary catheter use predisposes to colonization and eventual symptomatic CAUTI.

Research Questions

In this report, we will systematically review the evidence supporting quality improvement strategies to reduce the incidence of healthcare-associated infections. We will focus our attention on strategies to reduce HAIs in the inpatient setting, specifically addressing prevention of surgical site infections, central line-associated bloodstream infection, ventilator associated pneumonia, and catheter associated urinary tract infection. Our intent is to identify strategies that successfully increase adherence to effective preventive practices for each of these infections and reduce infection rates. Our specific research questions are:

1. Do quality improvement strategies increase adherence to evidence-based preventive interventions for healthcare-associated infections?

a. Which QI strategies increase use of interventions known to prevent surgical site infections?
b. Which QI strategies increase use of interventions known to prevent central venous catheter-associated bloodstream infections?
c. Which QI strategies increase use of interventions known to prevent ventilator-associated pneumonia?
d. Which QI strategies increase use of interventions known to prevent urinary catheter-associated urinary tract infections?
e. In each of these areas, are QI strategies associated with reductions in the incidence of infections (as well as improving adherence)?
f. Are QI strategies associated with adverse effects?
g. Are QI strategies cost-effective?

2. What are the critical components of effective QI strategies?

a. What is the evidence for QI strategies targeting the simultaneous implementation of multiple preventive interventions ("bundling")?
b. What strategies are effective at increasing use of preventive interventions across different disease processes?

3. What are the limitations of current research in this field, and what areas require further study?

Chapter 2. Methods

Scope

This report focuses on healthcare-associated infections contracted in acute care hospitals. Specifically, we focused on prevention of four types of infections that collectively account for more than 80 percent of all HAIs in hospitals[10]: surgical site infections (SSI), central line-associated bloodstream infections (CLABSI), ventilator-associated pneumonia (VAP), and catheter-associated urinary tract infection (CAUTI). Prevention of these HAIs has become increasingly important not only due to the burden of disease, but because an increasing number of states are mandating or considering mandating public reporting of rates of some or all of these infections. National organizations such as the Centers for Disease Control and Prevention[5] and Institute for Healthcare Improvement[7] also recommend focusing on prevention of these HAIs as a high-impact method of reducing iatrogenic morbidity and mortality.

Definitions of QI Terms Used in This Report

We used quality improvement terminology in accordance with prior volumes of the *Closing the Quality Gap* series, as follows:

- **Quality gap:** The difference between health care processes or outcomes observed in practice and those potentially achievable on the basis of current professional knowledge. The difference must be attributable in whole or in part to a deficiency that could be addressed by the health care system.

- **Quality improvement strategy:** Any intervention strategy aimed at reducing the quality gap for a group of patients representative of those seen in routine practice.

- **Quality improvement target:** The outcome, process or structure that the QI strategy targets, with the goal of reducing the quality gap.

Classification of Interventions and Quality Improvement Strategies

The intervention(s) used in a study sometimes included more than one QI strategy. Each intervention was characterized in terms of the QI strategy (or strategies) employed. Interventions containing two or more different QI strategies (as defined by the categorization listed below) were considered multifaceted interventions. For example, an intervention using (a) audit and feedback and (b) clinician education was defined as a multifaceted intervention, using two QI strategies.

We used a taxonomy of quality improvement strategies as defined in previous volumes of the series (Table 3).

Table 3. Quality improvement strategies

QI strategy	Examples
Provider reminder systems	• Reminders in charts for providers • Computer-based reminders for providers • Computer-based decision support
Facilitated relay of clinical data to providers	• Transmission of clinical data from outpatient specialty clinic to primary care provider by means other than medical record, e.g., phone call or fax
Audit and feedback	• Feedback of performance to individual providers • Quality indicators and reports • National/state quality report cards • Publicly released performance data • Benchmarking – provision of outcomes data from top performers for comparison with provider's own data
Provider education	• Workshops and conferences • Educational outreach visits (e.g., academic detailing) • Distribution of educational materials
Patient education	• Classes • Parent and family education • Patient pamphlets • Intensive education strategies promoting self-management of chronic conditions
Promotion of self-management	• Materials and devices to promote self-management
Patient reminder systems	• Postcards or calls to patients
Organizational change	• Case Management, Disease Management • Total Quality Management, Cycles of Quality Improvement • Multidisciplinary teams • Change from paper to computer-based records • Increased staffing • Skill mix changes
Financial incentives, regulation, and policy	*Provider Directed:* • Financial incentives based on achievement of performance goals • Alternative reimbursement systems (e.g., fee-for-service, capitated payments) • Licensure requirements *Patient Directed:* • Copayments for certain visit types • Health insurance premiums, user fees *Health System Directed:* • Initiatives by accreditation bodies (e.g., residency work hour limits) • Changes in reimbursement schemes (e.g., capitation, prospective payment, salaried providers)

For the purposes of this report, each intervention-control comparison within a study was abstracted separately. Thus, if an article reported a three arm trial, in which distinct interventions were delivered to participants in two of the arms and the third arm constituted a control group, then we considered such a *study* to contain two *trials* (the separate comparisons of the two intervention arms against the control group).

Targeted Preventive Interventions

We defined a "preventive intervention" as a specific infection control practice that has been demonstrated to reduce the incidence of a HAI. For each of our target HAIs, a wide variety of preventive interventions have been evaluated. We chose to focus on the implementation of preventive interventions that are recommended for universal use in target patient populations by

professional societies and governmental organizations. We selected these target preventive interventions by reviewing evidence-based HAI prevention guidelines compiled by authorities in the field. Specifically, we reviewed the CDC guidelines for prevention of surgical site infection (1999),[13] prevention of intravascular catheter-related infections (2002),[24] prevention of healthcare-associated pneumonia (2003),[32] and prevention of catheter-associated urinary tract infection (1983).[40] In order to obtain the most current information on recommended preventive interventions, we also reviewed the 2005 Surgical Care Improvement Project[41] recommendations, the 2005 American Thoracic Society/Infectious Disease Society of America guidelines for the management of patients with healthcare-associated pneumonia,[31] the recommendations of the Institute for Healthcare Improvement's "100,000 Lives" campaign, and solicited input from our peer review panel.

We primarily considered for inclusion preventive interventions that received a grade of IA (strongly recommended for implementation and supported by well-designed experimental, clinical, or epidemiological studies) or IB (strongly recommended for implementation and supported by some experimental, clinical, or epidemiological studies and strong theoretical rationale) from the CDC prevention guidelines, or an equivalent rating from another professional society guideline. We emphasized interventions that were broadly applicable to as large a patient population as possible, had a strong evidence base, had a known quality gap (i.e., a suboptimal rate of use in practice had been documented), and whose use was potentially modifiable through patient-, provider- or system-focused QI strategies. Given this focus, we did not address implementation of some strategies whose utility remains controversial (e.g., continuous aspiration of subglottic secretions to prevent VAP), and we did not address implementation of effective strategies whose use is not under the control of an individual provider (e.g., use of antimicrobial-coated central venous or urinary catheters).[42, 43] The preventive interventions we focused on were determined through consensus, including discussion with our group of technical experts and peer reviewers; they are summarized in Table 2.

The IHI has recommended "bundles" of preventive interventions for targeting SSI, CLABI, and VAP. These bundles are intended to be applied to all eligible patients. Implementation of the "bundles" should be measured in an "all-or-none" format, whereby institutions should measure and report their adherence to all components of the bundle, and successful implementation is defined by adherence to all preventive interventions simultaneously.[44] The IHI also encourages audit and feedback of the "all-or-none" measurements, as well as specific implementation strategies. Our target interventions are similar to those included in the bundles advocated in the IHI's 100,000 Lives campaign, with three exceptions. We did not target implementation of perioperative normothermia, as this intervention is not recommended by the CDC, and its overall effectiveness remains controversial.[45] We also did not target universal stress ulcer prophylaxis and deep venous thrombosis (DVT) prophylaxis for ventilated patients. Universal stress ulcer prophylaxis has not been shown to reduce VAP (and may in fact increase it[28]), and DVT prophylaxis, while appropriate ICU care, is not directly linked to the prevention of VAP.

Inclusion and Exclusion Criteria

Included studies were required to:

- Report the effect of an intervention on the incidence of healthcare-associated infection (SSI, CLABSI, VAP, or CAUTI), *or* report the effect of an intervention on adherence to evidence-based preventive interventions.

- Use either an experimental design with a control group (randomized or quasi-randomized controlled trial, controlled before-after study) *or* a quasi-experimental design (interrupted time series or simple before-after study). Quasi-experimental studies were required to have a clearly defined intervention time period; interrupted time series designs required reporting of at least three time points of data before and after the intervention.

Thus, we included studies that reported either infection rates or process measures (e.g., rate of adherence to handwashing protocols). Trials that reported related outcomes, such as costs, health services utilization (e.g., length of stay), patient or provider satisfaction with care, or adverse events associated with the intervention, were included only if they included data on infection rates or process measures. We included studies whose QI strategy targeted implementation (or increased use of) any of the target preventive interventions, with one exception. A prior systematic review[46] has addressed the effectiveness of QI strategies to promote appropriate hand hygiene; thus, we did not include studies that reported purely on hand hygiene adherence, but did include studies that targeted improving hand hygiene adherence and also reported the incidence of one or more of our target HAIs.

In contrast to previous volumes of this series,[47, 48] we expanded our study design inclusion criteria to include simple before-after (SBA) studies, quasi-experimental studies in which there was no contemporaneous control group and fewer than three data points before and after the intervention. We did so after preliminary literature searches revealed a dearth of controlled trials in this field. We planned to separately analyze data from controlled trials, when possible.

Literature Search and Review Process

To identify studies for possible inclusion, we conducted a systematic search of the MEDLINE® database, using a combination of search terms specific to each target HAI. The full search strategy is shown in Appendix A*. We supplemented this search with a search of the Cochrane Collaboration's Effective Practice and Organisation of Care (EPOC) database, which includes the results of periodic searches of EMBASE®, CINAHL®, and MEDLINE® as well as hand searches of specific journals and article bibliographies.[49] The MEDLINE® search was completed through January 2006 and the EPOC search through December 2005. We also screened the bibliographies of included articles to identify additional references.

A trained research assistant screened titles and abstracts [Appendix B*], and a physician investigator reviewed all exclusions. Articles that reported the effect of a quality improvement strategy on HAI rates or adherence to preventive interventions underwent full-text abstraction

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/hainfgaptp.htm

using a standardized form [Appendix B*]. Two independent reviewers, including at least one physician investigator, performed full-text reviews. The abstraction form recorded information on study design, methodological characteristics, quality improvement strategies, and outcomes; all disagreements were resolved by consensus.

Outcome Measures

Included studies reported two types of outcomes: rate of adherence to recommended preventive interventions, or rate of healthcare-associated infection. For adherence measures, we abstracted the data on adherence to our target preventive interventions (generally reported as the percentage of patients who received the intervention), or the adherence to an explicit clinical guideline (or "bundle") for prevention of HAIs.

For studies reporting infection rates, we abstracted data using the definition of infection as defined in the study. The specific subtypes of infection varied slightly for each target HAI:

- For surgical site infection, we abstracted information on all infections. When possible, we planned to analyze infection rates separately for the different classes of SSI, as defined by the CDC[14]: organ/space infections, deep incisional infections, and superficial incisional infections.

- For central line-associated bloodstream infections, we were primarily interested in the effects of QI strategies on laboratory-confirmed bloodstream infection (LCBI), and separately abstracted information on catheter colonization or exit-site infection.

- For ventilator-associated pneumonia, we abstracted information on all VAP.

- For catheter-associated urinary tract infection, we abstracted information separately for symptomatic UTI and asymptomatic bacteriuria.

Measurement Issues Specific to Studies of Healthcare-Associated Infections

In comparison to previous reviews in this Series, unique measurement issues arise when evaluating quality improvement studies of efforts to reduce HAIs. The most widely accepted diagnostic criteria for HAIs are the NNIS definitions.[14, 50] NNIS definitions for SSI, CLABSI, and CAUTI are summarized in Table 1. As can be seen, HAIs are not entirely objective measurements, unlike outcomes used in previous volumes such as laboratory values or antibiotic consumption; also, there are different subtypes of specific HAIs. Studies have demonstrated that slight differences in the interpretation of SSI definitions can lead to widely differing infection rates[51, 52] even when the same subtype of SSI (e.g., only deep incisional infections) are being measured. Also, a given study might measure CLABSI using only NNIS-defined laboratory confirmed bloodstream infections (LCBI), or also include infections meeting the "clinical sepsis" criteria. While these differences in measurement should not affect the internal validity of a

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/hainfgaptp.htm

study, assuming measurement standards remain constant throughout the study, they may limit the ability to compare infection rates across studies.

Measurement of ventilator-associated pneumonia poses additional challenges. Currently, there is no easily applicable clinical definition for VAP. Recent research has focused on development of a gold standard for diagnosis using invasive methods, but these methods have not been widely implemented and remain under evaluation. Thus, studies performed at different times may have used slightly different diagnostic criteria, further limiting the comparability of infection rates across studies.

In this review, we will provide the data on incidence of HAIs as measured by the NNIS. Given the above limitations, these data are not intended for direct comparison to the incidence found by individual studies. However, NNIS data may be useful for identifying studies that have an unusually high (or low) baseline incidence of HAI.

Quality Issues Specific to Studies of Healthcare-Associated Infections

Quasi-experimental or simple before-after (SBA) studies are commonly used in quality improvement,[53] but are prone to problems that limit establishing causality when determining the effect of an intervention. SBA studies are common in the infection control literature.[54] Harris[55] identified three factors that most often result in alternative explanations in quasi-experimental studies of infection control: (1) difficulty in controlling for important confounding variables, (2) results that are explained by the statistical principle of regression to the mean, and (3) maturation effects, secular trends that can affect either baseline or post-intervention measurements (e.g., seasonal variation in infection rates). We recognized that many of our included studies were likely to use SBA designs, and thus defined specific quality criteria for these studies to identify studies that would be less prone to the above flaws. Our goal was to identify studies where (within the limitations of the study design) causality could more reliably be attributed to the intervention. We used these criteria to gauge the internal and external validity of study results in order to identify studies of the greatest utility for stakeholders. We did not exclude studies based on the presence or absence of these quality criteria. The quality criteria are outlined below:

Factors Affecting the Internal Validity of the Studies

- *Was the intervention performed independent of other QI efforts or other changes?*

Non-randomized studies are inherently limited in their ability to account for confounding variables. In the complex hospital environment, many quality improvement efforts are generally underway that could affect the care and outcomes of diverse groups of patients. Failure to report on cointerventions or other contemporaneous QI measures could result in falsely attributing a change in infection rates to the effect of the QI intervention.

- *Did the study report data at more than one time point before and after the intervention?*

Infection control interventions are frequently implemented when infection rates are noted to be increasing or to exceed a recognized benchmark.[55] Given this context, one would

expect subsequent infection rates to decrease simply on the basis of regression to the mean (i.e., even without a specific intervention). If data are presented at a single time point before and after the intervention, this expected decrease due to regression to the mean could be interpreted as a beneficial effect of the intervention. Use of an interrupted time series design can determine if a true intervention effect exists; such a design requires at minimum three time points of data before and after the intervention, and use of time series regression models or autoregressive integrated moving-average (ARIMA) models for data analysis.[49] In the absence of such a design, reporting of more than one time point before and after the intervention can at least indicate if the pre-intervention infection rate was consistent or abruptly increasing, and indicate if the post-intervention rate was sustained.

- *If the study reported infection rates, were process measurements also reported?*

Measuring adherence to process measures (i.e., adherence to the target preventive interventions) provides important complementary information to measurement of infection rates for several reasons. First, high-quality data links increased adherence to process measures to lower infection rates for SSI[41] and CLABSI,[23] but adherence in general practice is known to be suboptimal. Second, as mentioned above, elevated infection rates within a given hospital could be due to secular trends, such as outbreaks (e.g., with a genotypically distinct resistant bacteria) that may not be directly tied to poor infection control practices. If a simple before-after study documents both lower infection rates and improved adherence to process measures after an intervention, that provides more (albeit indirect) support for concluding that the intervention was truly effective. Finally, process measurements do not require adjustment for a patient's underlying risk of infection.[5] This allows for greater inter-hospital and inter-study comparability than infection rates alone, and thus reporting of process measures can improve the external validity of a study as well as its internal validity. For these reasons, the CDC's Healthcare Infection Control Practices Advisory Committee suggested measurement of central venous catheter insertion practices and surgical antimicrobial prophylaxis for public reporting, in conjunction with reporting CLABSI and SSI rates.[5]

Factors Affecting the External Validity of the Studies

As process measures are unambiguous measurements with universal applicability, studies reporting process measures were considered to have greater external validity. We posed the following questions to assess study external validity for studies reporting infection rates.

- *If the study reported infection rates, did the study use CDC/NNIS methodology for measuring infections?*

NNIS definitions for nosocomial infections are the accepted standard in infection control, and their accuracy for case finding has been validated.[56]

- *(For CLABSI, VAP, and CAUTI) If the study reported infection rates, were reported rates adjusted for device utilization?*

HAI rates should be adjusted for potential differences in risk factors.[5] Device-associated infections must be adjusted for the rate of use of the device in question, and in the NNIS system rates are reported as infections per 1,000 device-days.[14] This does not take into account many other potential risk factors, but failure to perform this basic level of risk stratification would markedly limit the utility of a study's results.

- *(For SSI) If the study reported infection rates, was surveillance for infections performed after hospital discharge?*

Depending on the surgical procedure in question, a large proportion of infections may occur after discharge from the hospital. In fact, some studies have demonstrated that for common surgeries such as knee arthroplasty and abdominal hysterectomy, the majority of SSI may not manifest until after discharge.[57, 58] Case-finding methods that do not perform post-discharge surveillance could thus substantially underestimate the incidence of SSI.

We used the same criteria as above to address the external validity of controlled studies. For internal validity of controlled studies, we used the following criteria, as used in previous volumes in the Series:

- Method of treatment assignment
  - *Were study subjects randomized, and if so, was the randomization process described?*
  - *For non-randomized studies, was the rationale for selection of the comparison group explained, and a baseline observation period included (to assess selection bias)?*

- Blinding
  - *Were the outcome assessors blinded to treatment group assignment?*

- Statistical analyses
  - *Was a unit-of-analysis error present? If so, were appropriate statistical methods used for correction?*

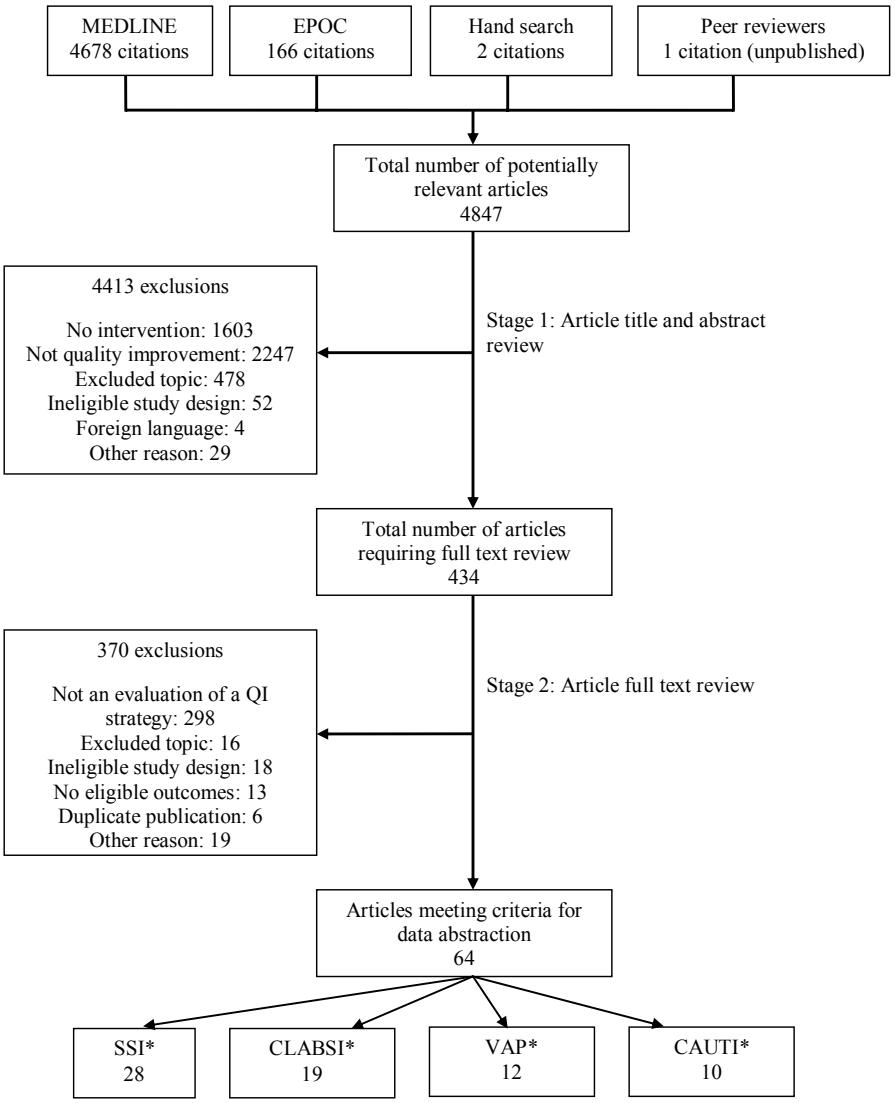
Analysis

In previous volumes in this Series, we have noted marked variation in study populations, intervention characteristics, and methodologic features of the included studies, which have contributed to statistical heterogeneity.[47, 48] We expected to encounter similar issues in this review, given the inherent issues in measurement outlined above (and the variation in interventions). In addition, we expected to find many simple before-after studies based on our preliminary literature searches. Thus, we did not plan to perform quantitative analysis, instead planning to summarize studies qualitatively. Using our study quality criteria as a framework, we planned to identify studies of relatively stronger internal validity and external validity for more detailed discussion. We opted not to use a scoring system for formally determining study quality, as the utility of these scores is controversial.[59] In general, studies meeting both criteria for external validity and two of three criteria for internal validity were considered to be of stronger internal validity and external validity, and studies with serious flaws affecting internal validity (0 of 3 criteria met) were considered to have poor internal validity.

Chapter 3. Results

Our search strategy identified a total of 4,847 citations, and one additional unpublished citation was identified from our peer review panel (Figure 1). Of these, 434 underwent full-text review, and 64 articles met all criteria for inclusion. Of these, three reported data on more than one target HAI.[60-62] All included studies utilized a single intervention arm. The results are summarized according to each target HAI below. Appendix C* lists the excluded studies and the reason for exclusion.

Figure 1. Search results and article triage



*Includes studies reporting prevention of more than one HAI.
EPOC: Effective Practice and Organisation of Care; SSI: surgical site infections; CLABSI: central line-associated bloodstream infections; VAP: ventilator-associated pneumonia; CAUTI: catheter-associated urinary tract infections.

* Appendixes cited in this report are provided electronically at http://www.ahrq.gov/clinic/tp/hainfgaptp.htm

Surgical Site Infections

Included Studies: Settings, Goals, and Target Populations

Our search strategy identified 28 articles that met our inclusion criteria and addressed prevention of surgical site infections (Tables 4a-4h). One of these[60] reported data on SSI, but its intervention primarily targeted VAP; thus, it will be discussed in the VAP section. Most (15) studies were conducted in single tertiary care hospitals, but seven were completed in multiple hospitals,[19, 61, 63-67] and one at a community hospital;[68] the hospital type was unclear in five studies.[69-73]

Many studies took place in a defined location in the hospital, with nine occurring the operating room,[64, 73-80] six in the intensive care unit,[60, 61, 66, 72, 81, 82] and two on the general inpatient ward.[83, 84] The remainder took place in multiple areas of the hospital. Ten of the studies took place in the past decade[19, 64, 67, 71-74, 83, 85, 86] but the remainder took place before then or did not have a stated time period. Among those reporting follow-up periods, the range was one month to four years, with a median of one year.

Baseline Infection Rates in U.S. and Non-U.S. Studies

Most of the studies were performed outside of the United States, with 11 in Europe, Australia, and New Zealand,[61, 63, 64, 66, 71-73, 75, 80, 84, 86] nine in the United States,[19, 69, 70, 76-79, 82, 85] and eight in other countries.[60, 65, 67, 68, 74, 81, 83, 87] The NNIS 2004 report published mean surgical site infections rates for surgeries performed in the United States that ranged from 0.44 per 100 cases for low-risk cholecystectomy, 3.45/100 for all coronary artery bypass surgery patients, and 11.53/100 for high-risk colorectal surgery.[14] By comparison, among our included studies, the sixteen studies that used surgical site infection rates as an outcome reported a median of 5.4 per 100 cases and a range of 1.1–24.4 per 100 cases. This range represents the wide range of geographic areas, time periods, and types of surgeries among included studies.

Baseline surgical site infection rates in the United States-based studies were 4-12.4 percent in four studies involving QI in cardiac surgery patients[70, 79, 82, 85] and 2.3 percent in a large multicenter trial.[19] In studies from Europe, New Zealand and Australia, the baseline infection rates ranged from 5.4 to 13.9 percent in studies with multiple types of surgeries[61, 71, 86] and 4.1 percent in one study of cardiac surgery patients.[72] A German study reported a surgical site infection rate of 48/1,000 patient-days that cannot be directly compared to the NNIS report.[66] Studies conducted in other countries (including Israel, Brazil, and Guatemala) reported baseline surgical site infection rates of 13.5 percent,[81] 24.4 percent,[68] 5 percent,[60] 4.2 percent, [74] and 0.33/1,000 patient days.[87] Overall, studies conducted in Europe, Australia, and New Zealand had similar infection rates as those of United States studies, although these rates were higher than those reported in the NNIS 2004 report. Studies conducted in all other countries showed much higher infection rates than in comparable United States studies, which decreased their translatability to United States QI efforts.

Preventive Interventions and Outcomes Measured

We identified several preventive interventions for review: appropriate provision of perioperative antibiotics (including appropriate timing, selection and duration of antibiotics), hand hygiene, perioperative glycemic control, and avoidance of preoperative shaving. Eleven studies targeted more than one process measure, including at least one of the above.[19, 61, 63, 66, 68, 69, 72-75, 82] Promotion of the appropriate use of perioperative antibiotics was used in 23 of the 28 studies;[19, 61, 63-69, 72-80, 82-86] in ten of these, other preventive interventions were advocated as well.[19, 61, 63, 66, 68, 69, 72-75] Sixteen of the 23 studies targeting perioperative antibiotics reported data on appropriate antibiotic use before and after the intervention; the other seven studies reported only SSI rates. Hand hygiene promotion was used in seven of the studies,[60, 66, 69, 72, 74, 81, 87] often as part a comprehensive infection control program.[66, 69, 72, 74] Four studies targeted improved perioperative glycemic control[19, 66, 74, 85] and eight studies promoted avoidance of shaving at the operative site[19, 61, 66, 69, 72, 74, 82, 85] as part of a comprehensive infection control program, but no studies used either intervention alone. Overall, both U.S. and non-U.S. studies used similar preventive interventions.

Ten studies used surgical site infection rate as the primary outcome,[61, 66, 68, 70-72, 74, 79, 81, 82] eight used process measures as primary outcomes, [63-65, 73, 77, 78, 80, 84] and eight used surgical site infection rate and at least one included process measure as a primary or secondary outcome.[19, 60, 67, 69, 76, 85-87] We did not attempt quantitative synthesis of the results because of the heterogeneity of outcomes, preventive methods, and baseline surgical site infection rates.

Quality Improvement Strategies

Included studies directed audit and feedback methods, educational interventions or clinical reminders at providers (Tables 4a-4h). Physicians were specifically targeted in ten studies,[63-65, 71, 73, 75-78, 80] nurses in one,[69] and both physicians and nurses in seven studies;[60, 61, 66, 68, 79, 84, 86] the remainder targeted all clinical staff.[67, 70, 72, 74, 81-83, 85, 87] Clinical reminder systems were explicitly used in five studies targeting appropriate antibiotic use; two used a computerized physician order entry (CPOE) system,[78, 79] and three others used a preprinted reminder sticker or forms.[64, 76, 83] Every study that did not use a clinical reminder system used some type of educational program. Seven studies employed consensus-building sessions,[19, 60, 64, 65, 70, 75, 83] and the remaining studies distributed information using lectures or written materials. One study used academic counterdetailing.[63] Fourteen studies explicitly used audit and feedback[19, 61, 66, 69-73, 75, 82-84, 86, 87] as a means of directly decreasing infection rates or of promoting specific interventions (see above). Fifteen used organizational change strategies such as creation of multidisciplinary teams or adding additional staff to existing teams to monitor and promote changes in infection control practices, along with either audit and feedback or consensus building sessions.[19, 61, 63, 67, 69, 71, 72, 77, 80-86]

Methodological Quality of Included Studies

The methodological quality of studies was generally poor because 22 of 28 used a quasi-experimental simple before-after design (Tables 4a-4h). We identified two interrupted time series,[67, 86] three controlled before-after studies,[63, 64, 66] and one randomized control trial (RCT)

(Tables 4a, 4b, 4f).[79] Most of the simple before-after studies had limited internal validity (Table 5). Five simple before-after studies reported data on more than one time point before and after the intervention;[60, 61, 69, 74, 85] most (14/23) reported at least one process measurement.[19, 60, 65, 69, 73, 75-78, 80, 83-85, 87] No study clearly stated that the intervention was conducted independent of any other quality improvement effort. Three simple before-after studies met two criteria for internal validity.[60, 69, 85] Despite difficulties with internal validity, some studies exhibited good external validity as they used standard NNIS/CDC methods to track infections and performed post-discharge surveillance.[74, 75, 82] Among those studies reporting surgical site infection rates, most reported an overall infection rate, but two studies separately reported superficial incisional, deep incisional, and organ/space infection rates.[61, 82]

Given the generally poor methodological quality of the results and the heterogeneity of the methods used, we will summarize the results according to their study design, internal and external validity, and give less detail on lower quality studies. We further divided the studies into the 16 studies that reported compliance with appropriate antibiotic prophylaxis as an outcome measure,[19, 61, 63-65, 67, 73, 75-80, 83, 84, 86] and those that reported other outcome measures, including the surgical site infection rate.

Studies Addressing Use of Appropriate Antibiotic Prophylaxis

Controlled Trials. One controlled study was conducted in six pairs of matched hospitals (four teaching, two suburban, and six rural hospitals), and focused on improving appropriateness of perioperative antibiotic timing and duration (Table 4a).[63] The educational effort centered on academic counterdetailing, a process in which pharmaceutical marketing techniques are used to promote academic goals (suggest moving this definition up to where the term is first used). Investigators used promotional gifts, posters, lectures, videos, and targeted letters to inform the physician staff about appropriate perioperative antibiotic use. The study showed improvement in appropriate duration (absolute improvement of 20.0 percent, p=0.04) and in appropriate timing (absolute improvement of 13.0 percent, p=0.12). The study employed a crossover design, and similar results were seen in the second (crossover) phase of the study. This improvement reverted to baseline after the QI effort was stopped during the final phase of the study. The study's generalizability to current U.S. hospital practices is moderate despite the multicenter design because the study took place in Australia 20 years ago.

Table 4a. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): controlled studies

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Landgren 1988[63]	Australia Multiple hospitals of different types	1985-1986	2 years	Appropriate use of perioperative antibiotics	*QI strategies: Clinician education, audit and feedback, clinician reminder* Counter-detailing program designed to counter efforts of pharmaceutical representatives and align behavior more closely with antibiotic guidelines booklet, widespread in Victoria, Australia. 1) All surgeons, anesthetists, and residents received pen, notepads similar to that of drug companies, each carrying rational prescribing message. 2) 2 posters focused on proper antibiotic use, and 1 offering positive reinforcement. 3) Audit of results 4) lecture organized for surgical staff, discussing results of audit. 5) 10 minute satirical videotape was produced specifically for staff, mocking drug reps, surgeons, RNs, microbiologists: aimed to stimulate discussion. 6) Academic representative met with select number of surgeons, especially those unable to attend.	Adherence to appropriate timing of perioperative antibiotics: Net effect size (change in intervention – change in control) = 20%; p=0.04 Adherence to administering perioperative antibiotics for the appropriate duration: Net effect size (change in intervention – change in control) = 14%; p=NS

Table 4a. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): controlled studies (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Ritchie 2004[64]	United States Multiple hospitals of different types	9/1999	1 month	Appropriate use of perioperative antibiotics	*QI strategies: Clinician education, clinician reminder* Investigators used a retrospective audit to characterize use of antibiotics in pre-intervention period. After a consensus building session with orthopedic surgeons, anesthetists and investigators, all agreed that they would use preprinted sticker placed to remind anesthesiologist and surgeon to use cefazolin at induction, and for no more than 2 doses after surgery.	Adherence to appropriate timing of perioperative antibiotics: Net change in adherence (change in intervention group – change in control group): 15% p value not supplied Adherence to administering perioperative antibiotics for the appropriate duration: Net change in adherence (change in intervention group – change in control group): 56% p value not supplied
Zanetti 2003[79]	United States Tertiary care or universi-ty hospital	Not specified	1 month	Appropriate use of perioperative antibiotics	*QI strategies: Clinician reminder* Computer-generated automatic alert for redosing prophylactic antibiotics in prolonged cardiac surgery.	Infection rates: Net change in infection rate (change in intervention group – change in control group) = 2.0%; p=NS Appropriate redosing of antibiotics: Net change in frequency of appropriate redosing (change in intervention group – change in control group) = 28%; p<0.01

A second controlled study was also directed at providers: a preprinted sticker was placed to remind providers to limit the duration of prophylactic antibiotics (cefazolin) to three doses total (Table 4a).[64] The policy in the control group was usual care. In the intervention hospital, appropriate cefazolin use rose from 29 percent to 74 percent ($p<0.001$). However, the study's internal validity is moderate. The authors failed to explain how the control hospital was chosen; in addition, the improvement in cefazolin use occurred in all intervention hospital patients regardless of whether the sticker was used. This suggests a possible Hawthorne effect (i.e., physicians changed their behavior due to awareness that a study was ongoing) or spillover of the educational effect of the sticker to other clinical situations.

A randomized controlled trial took place in a major teaching hospital that had a preexisting integrated computerized physician order entry system (Table 4a).[79] Patients were randomized to receive a computerized reminder if prophylactic antibiotics needed redosing during a long operation. The study reported significantly more frequent intraoperative redosing in the intervention group (68 percent vs. 40 percent, $p<0.001$) though no statistically significant differences in the secondary outcome (surgical site infection rate was four percent in the treatment group vs. six percent in the control group, $p=0.42$). The study was likely underpowered to detect difference in infection rates. The study was a well-designed RCT, but has only moderate

applicability because the study hospital's provider characteristics (which include familiarity with CPOE) are uncommon.

Interrupted Time Series Studies. One study[86] was conducted in a diverse group of 13 Dutch hospitals (both teaching and non-teaching) that were already participating in a national surveillance network (Table 4b). A supervising committee received surveillance data from the individual hospitals, and supplied feedback to the hospital based on process and outcome measures. They also organized educational meetings for both nurses and physicians, emphasizing guideline adherence and appropriate use of prophylactic antibiotics. The precise content of both the feedback and the educational content were not discussed. The study exhibited good internal and external validity. It was a prospectively designed study where the pre-intervention baseline was established in multiple hospitals over one year. In addition, the committee collected data on several process measurements as well as on surgical site infections. Given that these hospitals were part of a surveillance network, it seems likely that other QI interventions were ongoing but it is unclear whether these would have affected surgical site infections. The distribution of surgeries remained stable between hospitals, but the proportion of orthopedic and gynecological surgery increased after the intervention; the authors adjusted for this change in their comparison. The study's results are translatable to other settings because the investigators followed CDC recommendations for surgical site infection post-discharge surveillance and standard prophylactic antibiotic protocols. Results revealed statistically significant increases in appropriate duration (55.8 percent to 68.6 percent), selection (4.9 percent to 62.5 percent) and timing of antibiotic administration (49.5 percent to 60.6 percent). The study showed a non-significant trend toward reduced surgical site infections: 5.4 percent pre-intervention and 4.6 percent post-intervention.

Another study[67] used continuous quality improvement (CQI) methodology to target postoperative infections among women undergoing cesarean section at two maternity hospitals in Colombia (Table 4b). At each hospital, multidisciplinary teams were formed that underwent training in CQI methods by outside facilitators; these teams then researched the problem of SSI and formulated a structured approach using multiple cycles of interventions and measurement. The intervention focused on streamlining the process of ordering and administering perioperative antibiotics, along with feedback of infection rates to hospital administrators. The study's internal and external validity were excellent, as the investigators collected at multiple time points, performed appropriate ITS statistical analysis, measured both process measures (use of perioperative antibiotic prophylaxis and appropriate timing of prophylactic antibiotics) and infection rates, and used CDC/NNIS measurement standards. The intervention achieved statistically significant improvements in administration of antibiotics (i.e., whether or not antibiotics were given at all) and appropriate timing of antibiotics at both hospitals; SSI rates were significantly reduced as well.

Table 4b. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): interrupted time series

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Weinberg, 2001[67]	Colombia Two academic maternity hospitals	1996-1998	Hospital A: 12 months Hospital B: 21 months	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site	*QI strategies: Audit and feedback, organizational change* A CQI intervention was performed targeting surgical site infections in women undergoing cesarean section at 2 hospitals in Bogota, Colombia. At both hospitals, multidisciplinary teams were formed consisting of an obstetrician, resident, nurse, pharmacist, and administrator. The teams reviewed the literature to identify risk factors for SSI. The teams underwent training in CQI methods by outside facilitators, then used PDSA methods to identify the problem and formulate an approach. SSI rates were fed back to administrators and (at one hospital) to individual physicians.	Infection rate prior to intervention: Hospital A, 10.5%; Hospital B, 6.1% Infection rate after intervention: Hospital A, 0%; Hospital B, 4.4%; p<0.001 for hospital A, p=0.042 for hospital B Compliance with appropriate timing of antibiotic prophylaxis: Compliance before intervention: hospital A, 24%; hospital B, 70% Compliance after intervention: hospital A, 96%; hospital B, 96%; p<0.001 for both
Van Kasteren 2005[86]	Netherlands Tertiary care or university hospital	7/2001 – 10/2002	16 months	Appropriate use of perioperative antibiotics	*QI strategies: Clinician education, audit and feedback, clinician reminder* Implementation of a national guideline for surgical antimicrobial prophylaxis at 13 Dutch hospitals. The guideline recommends single-dose prophylaxis with a cephalosporin (plus metronidazole if indicated) to be administered within 30 minutes before incision. Each hospital received feedback on their baseline compliance rate to the guideline. The study group formulated recommendations for improving adherence at each hospital, and discussed them with physicians and nurses. Additional educational meetings were held.	Infection rate prior to intervention: 5.4% Infection rate after intervention: 4.5%; p=NS Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 44.2% after intervention: 31.4%; p<0.01 Adherence to appropriate selection of antibiotics: before intervention: 3.9% after intervention: 63.5%; p<0.01 Adherence to appropriate timing of perioperative antibiotics: before intervention: 49.5% after intervention: 61.6%; p<0.01

Before-After Studies With Good Internal and External Validity. A large study was conducted in Italy between 1987 and 1989 in which a group of 12 hospitals convened a series of meetings with surgeons and nurses in each of the participating wards to discuss nosocomial infection rates and promote best practices (Table 4c).[61] Targeted practices included avoiding preoperative shaving, using appropriate, short-term antibiotic prophylaxis, limiting invasive procedures and drains, implementing respiratory exercises, and using optimal disinfection procedures. Several time points were measured, and multiple hospitals were used, strengthening both internal and external validity. The authors reported small but statistically significant improvements for all process measures, including a drop in prolonged antibiotic prophylaxis (36.9 percent to 27.2 percent, $p<0.001$). The surgical site infection rate was unchanged (7.8/100 to 6.7/100 cases, $p>0.05$); in addition, the authors reported non-significant changes in both the superficial infection rate (6.7/100 to 5.7/100 cases) and the deep infection rate (1.9/100 to 1.05/100 cases) but they did not state which definitions were used for these outcomes.

Table 4c. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with good methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
*Greco 1991[61]	Italy Multiple hospitals of different types	12/1988 – 6/1989	19 months	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Audit and feedback of infection rates to hospitals or individual clinicians	*QI strategies: Clinician education, audit and feedback, clinician reminder* Series of meetings with surgeons and nurses from each of participating wards. Data on infection incidence and practices were discussed and best practices reviewed including: appropriate use of perioperative antibiotics (pre-operative, limited duration, appropriate selection), avoidance of preoperative shaving, closed drainage of urinary catheters and surgical drains, implementation of respiratory exercises, use of hygienic measures for urinary catheters.	Infection rate prior to intervention: 7.8% of patients Infection rate after intervention: 6.2% of patients p=NS

* This study addresses prevention of surgical site infections and catheter-associated urinary tract infections.

Before-After Studies With Moderate Internal and External Validity. A large multi-hospital study was conducted to examine implementation of several process measures, including appropriate use of prophylactic antibiotics, prevention of hyperglycemia, normothermia, avoidance of shaving, and optimization of oxygen tension (Table 4d).[19] Fifty-six hospitals participated in the effort, where teams of clinical leaders from each hospital attended learning sessions. They shared strategies and implemented them at their respective hospitals, but details regarding local implementation strategies were not available. Outcomes were analyzed by hospital, as patient level data was unavailable. Internal validity was strengthened by the reporting of outcomes for process measures and for surgical site infection. The surgical site infection rate showed a non-significant improvement from 2.3 per 100 cases to 1.7 per 100 cases. The improved adherence to all preventive interventions was statistically significant, including timing

Table 4d. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Dellinger 2005[19]	United States Multiple hospitals of different types	4/2002-2/2003	11 months	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Improving perioperative glucose control	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Collaboration among 56 hospitals to study implementation of 1 or more quality initiatives. Each facility created team of "clinical champion" - surgeon or anesthesiologist - along with day-to-day coordinators. Learning sessions performed every 4 months. Subsequently, information was brought back to individual facilities. Exact means of diffusion of information for specific measures were not stated.	Infection rate prior to intervention: 2.28% of cases Infection rate after intervention: 1.65% of cases; p=NS Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 72% after intervention: 92%; p<0.01 Adherence to appropriate selection of perioperative antibiotics: prior to intervention: 90% after intervention: 95%; p<0.01 Adherence to protocols for perioperative shaving of the surgical site: prior to intervention: 59% after intervention: 95%; p<0.01 Adherence to protocols for perioperative normothermia: prior to intervention: 57% after intervention: 74%; p<0.01 Adherence to protocols for perioperative glucose control: prior to intervention: 46% after intervention: 54%; p<0.01
Larsen 1989[76]	United States Tertiary care or university hospital	6/1986 – 11/1986	6 months	Appropriate use of perioperative antibiotics	*QI Strategies: Audit and feedback, clinician reminder* Authors used pre-existing information system (Health Evaluation through Logical Processing -HELP) to monitor patients. Subsequently, computer decision analysis tool implemented to prepare reminder stickers to be placed in chart. Reminder stickers focused on provision of appropriate antibiotic prophylaxis.	Infection rate prior to intervention: 1.1% of cases Infection rate after intervention: 0.7% of cases p value not supplied Adherence to appropriate timing of perioperative antibiotics: before intervention: 40% after intervention: 58% p<0.01

of antibiotics within one hour (72 percent to 92 percent), appropriate selection of antibiotics (90 percent to 95 percent), and discontinuation of antibiotics within 24 hours (67 percent to 85 percent). However, the authors could not adjust for differences in patient or provider characteristics as they only had access to hospital level data, and they did not report data on multiple time points prior to the implementation. Mitigating these concerns, the broad range of participating hospitals gave the data good external validity and reduces the possibility that the improvement represented regression to the mean.

One study implemented a computerized reminder using a preexisting computer decision analysis system to improve antibiotic prophylaxis (Table 4d).[76] The study was conducted prospectively, with baseline prescribing habits established during the first year and the intervention implemented during the second year. Computer generated reminders were placed in the chart during the intervention period. Antibiotics were given within two hours of incision in 40 percent of the sample prior to the intervention, and 58 percent of the sample after the intervention ($p<0.001$ for the difference). The infection rate declined from 1.8 percent to 0.9 percent, but the external validity of this outcome is diminished because the authors did not use CDC criteria to diagnose infections and did not conduct post-discharge surveillance.

Before-After Studies With Poor Internal and External Validity. Eight studies in this category met our inclusion criteria but had methodological flaws that seriously limited their internal external validity (Table 4e).[65, 73, 75, 77, 78, 80, 83, 84] An Italian study examined the impact of a preoperative antibiotic prophylaxis protocol, but included one time point before and after the intervention and gave few details as to the nature of the QI intervention.[75] In a 1988 study, a multidisciplinary program was used to promote use of single dose cefazolin in obstetrical and gynecological surgical procedures.[77] However, other QI interventions were ongoing, making the results less reliable; the authors also reported several results where the numbers were inconsistent. A study using a CPOE system to remind providers to redose prophylactic antibiotics during long surgeries showed a great improvement after institution of the protocol (20 percent to 58 percent)[78] but only reported data immediately before and after the intervention. A French study examined the effect of local guideline development on antibiotic usage but reported data in terms of a composite outcome (using indication, selection, dosage, timing, dosing interval, and duration), which limits our ability to discern the effect of the QI strategy.[73] In addition, only two time points were analyzed, which limits internal validity. A Brazilian hospital program used preprinted order forms to promote appropriate use of surgical antibiotic prophylaxis and demonstrated a statistically significant improvement in this process measurement; however, only two time points were analyzed.[83]

Two studies (conducted at the same hospitals in the Netherlands) measured compliance with guidelines regarding the selection and duration of antibiotics[84] or timing of prophylactic antibiotics[80] before and after an intervention (Table 4e). However, the intervention and pre-intervention measurement periods were two years apart and the intervention took place over one year in between measurements, making it difficult to infer causality in either study. Another study measured the effect of having control of antimicrobial drugs by an infectious disease specialist.[65] The average prophylactic drug course in the study was four days (range 1-34 days), limiting applicability to current practice.

Table 4e. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with poor methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Brusaferro 2001[75]	Italy Tertiary care or university hospital	12/1998	6 months	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education, audit and feedback* A protocol for perioperative antibiotic prophylaxis was developed by a group consisting of a microbiologist, chemist, anesthetist, clinical pharmacologist and three surgeons. Compliance with the protocol was measured before and after the intervention. Follow-up focus groups were conducted with the group and the surgical units after the data were collected.	Compliance to guideline for perioperative antibiotic prescribing: before intervention: 4.3% after intervention: 17.4% p<0.01
Smith 1988[77]	United States Tertiary care or university hospital	5/1988 – 11/1988	16 months	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education, clinician reminder* 1) Direct education programs (in-service) were presented to anesthesia and OR staff. 2) Change in OR drug stocks to change provider use 3) In-service education by director of obstetrics and gynecology directed at specific attendings 4) Eventually hospital required that formal Infectious Diseases consultation and approval for all disfavored antibiotics.	Compliance with using single dose cefazolin as preoperative antibiotic prophylaxis, percent compliance before intervention: 0% after intervention: 42.8% p value not supplied
St. Jacques 2005[78]	United States Tertiary care or university hospital	Not specified	1 month	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician reminder* Used computer reminder system to assist in intraoperative redosing of prophylactic antibiotics.	Adherence to appropriate timing of perioperative antibiotics: before intervention: 20% after intervention: 57% p<0.01

Table 4e. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Talon 2001[73]	France Hospital type not specified	6/1998 - 7/1998	2 months	Appropriate use of perioperative antibiotics Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Clinician education, audit and feedback* A survey of antibiotic prescribing practices was performed and used to develop local guidelines for antimicrobial prophylaxis by a multidisciplinary team. Diffusion of guidelines to all surgeons and anesthetists, as well as display of guidelines.	Adherence to appropriate timing of perioperative antibiotics: before intervention: 89% after intervention: 98% Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 76% after intervention: 94% Adherence to appropriate selection of perioperative antibiotics: before intervention: 74% after intervention: 96% Overall percentage of inappropriate prescriptions (timing, duration, and selection): Before intervention: 69% After intervention: 18%; p=0.01
Prado 2002[83]	Brazil Tertiary care or university hospital	10/1999	1 month	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education, clinician reminder* Multiple interventions were instituted: 1) Created a multidisciplinary leadership team with representatives from surgical, infection control, pharmacy, and hospital epidemiology and quality-improvement departments. 2) Creation of a preprinted perioperative antibiotic prophylaxis form indicating only type of surgery. 3) Review of form by all parties involved (RNS, MDs) 4) initiation of perioperative antibiotic prophylaxis protocol.	Infection rate prior to intervention: 4.1% Infection rate after intervention: 4.2%; p=NS Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 21.4% after intervention: 95.8%; p<0.01 Adherence to appropriate selection of perioperative antibiotics: before intervention: 74.5% after intervention: 97.2%; p<0.01

Table 4e. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Gyssens 1996[80]	Netherlands Tertiary care or university hospital	1990 - 1992	14 months	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education, clinician reminder* A guideline for standard surgical antimicrobial prophylaxis was introduced, which called for standard single-dose prophylaxis with a cephalosporin to be delivered within 1 hour prior to surgical incision. The guideline was introduced after a preintervention period in which the rates of appropriate antimicrobial prophylaxis were measured and reported to the department chairpersons. The protocol was developed in concert with the surgeons. The guideline was presented to the surgical department and junior pharmacists introduced it to the nursing staff (no other details on the implementation process are provided.)	Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 21% after intervention: 85% p<0.01 Adherence to appropriate timing of perioperative antibiotics: before intervention: 42% after intervention: 73% p<0.01
Gyssens 1996[84]	Netherlands Tertiary care or university hospital	1 month	Not specified	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education, audit and feedback, clinician reminder* The principal goal was to universally have a single-dose of cephazolin at incision. Recommendations were adapted into new protocols and presentations were held on these new protocols. Junior pharmacists organized briefings for nurses and prophylaxis guidelines were displayed in the wards and operating rooms. Pharmacy techs discussed protocol violations with prescribers and nurses on their twice weekly visits to wards.	Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 79% after intervention: 92% p<0.01

Table 4e. Articles addressing prevention of surgical site infections (studies addressing use of appropriate antibiotic prophylaxis): before-after studies with poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Shapiro 1981[65]	Israel Multiple hospitals of different types	Not specified	Not specified	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education* Introduction of a protocol involving changing the perioperative antibiotics used previously, initiating prophylaxis shortly before the operation, and encouraged the curtailment of prophylactic administration of antimicrobial drugs in the early postoperative period.	Adherence to administering perioperative antibiotics for the appropriate duration: before intervention: 39% after intervention: 97% p value not supplied

Studies Not Using Appropriate Antibiotic Prophylaxis as an Outcome

Controlled Trials. One controlled before-after study was conducted in multiple hospitals (including several teaching hospitals) and evaluated if a quality management project could reduce all types of nosocomial infections (Table 4f).[66] The investigators used 'quality circles' which consisted of a committee with at least one physician and one nurse representative from each study hospital. These committees actively reviewed infection control practices and surveillance data from each institution and guided modification of infection control practices. Surgical site infections declined from 2.2/100 cases to 1.6/100 cases (not statistically significant) and overall nosocomial infections declined from 7.5/100 cases to 5.3 cases/100 cases (a significant decrease). Several factors undermine the internal validity of the study. The control group was not randomly assigned, but instead consisted of those hospitals that declined to participate in the quality management project. In addition, the surgical site infection rate (but not the overall nosocomial infection rate) reverted back to baseline by the end of the study. The QI strategy ('quality circles') did not have a clear mechanism for improvement so it is difficult to infer causality between the intervention and the primary outcome, especially considering that all of the hospitals were interested in quality improvement and may have had concurrent QI projects.

Table 4f. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): controlled studies

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Gastmeier 2002[66]	Germany Multiple hospitals of different types	10 months	2 years	Hand hygiene Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Improving perioperative glucose control	*QI strategies: Clinician education, audit and feedback* Intervention hospitals introduced quality circles and surveillance activities. The quality circles consisted of at least 1 physician and 1 nurse from the surgical unit and ICU, and infection control personnel. The quality circles were structured groups that used continuous quality improvement (CQI) methodology to decide on a problem focus, reach a consensus on solving a given problem, and execute the solution. Each QC focused on hand hygiene, but otherwise each intervention hospital individualized their focus. Thus, each hospital focused on different aspects of SSI, CAUTI or CLABSI prevention; the specific preventive interventions targeted appear to vary between hospitals, but generally belonged to CDC category I. After a 10-month period in which the quality circles were set up, outcomes were measured, and subsequently ongoing surveillance was performed by infection control nurses according to NNIS protocols. Outcomes were measured again after another 10 months.	Infection rate prior to intervention: 2.6% of cases Infection rate after intervention: 2.0 % of cases p=NS

Before-After Studies With Moderate Internal and External Validity. A study conducted in Israel measured infection rates for permanent cardiac antiarrhythmic devices before and after the implementation of comprehensive infection control program (Table 4g).[74] The investigators combined education on antiseptic techniques, avoidance of preoperative shaving, preoperative antiseptic showers, optimization of perioperative hyperglycemia, improvement in ventilation, and promotion of perioperative prophylaxis. The authors noted a decrease in the rate of infections from 4.2 percent in the immediate pre-intervention period to 0 percent. However, the rate of SSI had been 0.5 percent for three years prior to the increase to 4.2 percent, so the decrease could simply represent regression to the mean.

Two studies in this category investigated quality improvement in cardiac surgery (Table 4g).[70, 85] One study developed a protocol based on local committee literature search and consensus-building session after investigators realized that their hospital's infection rate was far above the NNIS mean at 7.58 percent.[70] The protocol consisted of encouraging all of the following: (1) perioperative glucose control; (2) maintenance of strict sterility of the graft and sternal wound sites; (3) use of intranasal mupirocin during the perioperative period; (4) post-operative use of a sports bra for women with a cup size of C or larger to reduce pull on the incision site; (5) reduction of traffic in and out of the operative suite; (6) administration of the prophylactic antibiotic within one hour of incision; (7) a preoperative shower with chlorhexidine.

Specific educational programs emphasized each one of the above to the nursing staff. The authors reported a decrease in the surgical site infection rate to 3.47 percent (from 7.58 percent), but did not report results for process measures. The study findings are generalizable to other interested hospitals because the hospital used standard CDC diagnostic criteria for surgical site infections. However, some of the interventions are atypical, and the effectiveness of any one of the measures is indeterminate. The other study[85] employed a 'Plan-Do-Check-Act' continuous quality improvement model, and a dedicated infection control practitioner was responsible for ensuring compliance. They emphasized several interventions: (1) perioperative glucose control; (2) segregation of instruments for graft and sternal wound sites; (3) reduction of traffic in and out of the operative suite; (4) administration of the perioperative antibiotic in the holding area; (5) a preoperative shower with chlorhexidine. The authors did not report results for these process measures. They did note pre-intervention infection rates, and also reported that the mediastinitis rate declined from 2.1 percent to 1.5 percent (non-significant trend) and the leg wound infection rate declined from 1.93 percent to 0.47 percent (a significant improvement). However, mediastinitis rates had risen from 0.8 percent four years prior to the study to 2.1 percent during the pre-implementation period without explanation; the subsequent decrease could represent regression to mean. The external validity of the study was diminished to some extent because the authors did not report the diagnostic criteria for surgical site infections.

The last study in this group examined whether a handwashing promotion program decreased nosocomial infection rates in a neonatal intensive care unit (Table 4g).[87] After a prospective observational period established baseline infection rates, a special educational program which explained the merits of hand washing began for all clinical staff in the neonatal intensive care unit, and compliance was subsequently monitored by observers. Hand hygiene compliance improved from 43 percent to 80 percent during the promotional period, but surgical site infection rates did not show a statistically significant change. External validity was improved because the study used CDC criteria for the diagnosis of infection. However, the stated surgical site infection rate of 0.33/1,000 patient-days is difficult to interpret, as the number of surgical cases was not reported.

Table 4g. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Borer 2004[74]	Israel Tertiary care or university hospital	1997 - 9/2001	24 months	Hand hygiene Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Improving perioperative glucose control	*QI Strategies: Clinician education* A check list of infection control items was devised. These consisted of hand hygiene, appropriate use of perioperative antibiotics, glycemic control, and decreasing use of shaving of the operative site. In addition to these interventions, there was strict aseptic techniques used to scrub the surgical site; staff couldn't wear fake nails or jewelry; staff received education and active surveillance was performed.	Infection rate prior to intervention: 4.2% of cases Infection rate after intervention : 0% of cases p<0.01

Table 4g. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of moderate methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Lutarewych 2004[70]	United States Not specified	1/2002 – 2/2002	1 year	Improving perioperative glucose control	*QI Strategies: Clinician education, audit and feedback, patient education* Multiple interventions were implemented: 1) perioperative glucose control 2) maintenance of strict sterility of the graft and sternal wound sites. 3) use of intranasal mupirocin during the perioperative period 4) use of a sports bra for women with a cup size of C or larger to reduce pulling on the incision site 5) reduction of traffic in and out of the operative suite 6) administration of the preoperative antibiotic l<1 hour before incision 7) a consistent preoperative shower with chlorhexidine Improvement in compliance was directed to staff to reinforce education about other measures.	Infection rate prior to intervention: 7.58% of cases Infection rate after intervention: 3.47% of cases p value not reported
Rao 2004[85]	United States Tertiary care or university hospital	1/1999 – 4/1999	20 months	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Improving perioperative glucose control	*QI Strategies: Clinician education, clinician reminder* ICP was assigned to the open-heart surgery program. ICP followed patient from admission to discharge and implemented the following program: prospective surveillance of superficial and deep chest and leg infections; post discharge follow up of patients readmitted within 30 days; chlorhexidine showers by pts the night before/morning of surgery; hair removal by clippers only; administration of antibiotics 2 hours before surgical incision; segregation of surgical instruments; improved glycemic control.	Infection rate prior to intervention: 2.1% Infection rate after intervention: 1.5% p=NS Adherence to protocols for perioperative antibiotic prophylaxis: before intervention: 70% after intervention: 92% p value not reported

Table 4g. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of moderate methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Won 2004[87]	Taiwan Tertiary care or university hospital	9/1998 - 8/2000	22 months	Hand hygiene	*QI Strategies: Clinician education, audit and feedback* A multifaceted campaign to encourage hand hygiene was implemented. All health care workers received lectures on appropriate use of hand cleansing agents, correct hand washing techniques, and importance of hand washing. This information was incorporated into regular resident orientation sessions. Cartoon reminders were posted above each sinks along with printed reminders in easily visible sites. Observations of hand washing were made by other NICU nurses, and results posted in the NICU each month. One-on-one feedback was privately given to individual healthcare workers who did not perform hygiene appropriately, and positive reinforcement was given at NICU staff meetings. Financial incentives were given to nurses as an extra monthly bonus, individualized by the number of correct observed hand washing opportunities. The formal lectures were discontinued after 2 years, but the other measures continued for an additional 16 months.	Infection rate prior to intervention: 0.33% per 1,000 patient days Infection rate after intervention: 0.84 per 1,000 patient days p=NS Adherence to protocols for hand hygiene: before intervention: 43% after intervention: 81% p<0.01

Before-After Studies With Poor Internal and External Validity. Several studies met our inclusion criteria but had methodological flaws that seriously limited their internal validity or applicability (Table 4h).[68, 69, 71, 72, 81, 82] One study attempted to reduce the nosocomial infection rates using educational programs directed at handwashing but did not use CDC or NNIS criteria for measuring surgical site infections and did not conduct post-discharge surveillance.[81] Another study measured the effect of a comprehensive program of infection control practices but only reported one time point before and after the intervention and also did not report the effect on process measures.[68] In addition, the study's results translate poorly to current practices because the surgical site infection rate was 24.4 percent prior to the intervention and standard CDC definitions for wound infections were not used. Two studies involving surgical site infections in cardiothoracic surgery patients reported data only immediately before and after the intervention, and did not include outcomes for the various prevention interventions.[72, 82] One of these studies did not report using standard NNIS or CDC criteria to diagnose wound infections;[72] the other study did not comment on the higher infection rates seen in the middle years of study.[82] Another study in this category investigated quality improvement in cardiac surgery patients but did not

clearly define pre-intervention period, and defined outcomes in terms of observed/expected infection rates but did not state how these were created.[69] In addition, pre-intervention compliance was not discussed for most interventions in the study.

A United Kingdom (UK) study examined if using audit and feedback methods could reduce surgical site infection rate in the UK.[71] The authors extended post-discharge surveillance to 30 days, and then reported the results to participating surgeons. The overall surgical site infection rate significantly declined over 29 months from 13.9 percent to 7.9 percent. However, the authors did not report how the surgeons used the information or if concomitant QI efforts were underway. In addition, there was significant variation in the monthly infection rate, which was not reflected in the before-after statistical analysis. External validity is also limited by the relatively high pre-intervention surgical site infection rate.

Finally, a study conducted in an intensive care unit in a tertiary care center in Guatemala examined the effect of an educational program on hand hygiene, aseptic technique and multiple nosocomial infections.[60] The study included surgical site infection as an outcome, but focused on ventilator-acquired pneumonia primarily, and will be discussed in more detail in the VAP section.

Table 4h. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of poor methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Atukorala 1998[81]	Sri Lanka Tertiary care or university hospital	1 month	Not specified	Hand hygiene	*QI Strategies: Clinician education, organizational change* The strategy consisted of a broad-based increase in infection control measures. The number of infection control nurses was increased and all health care workers underwent educational programs on infection control, which stressed hand washing as a priority. A liaison nurse was identified on each ward to assist the infection control nurse. A policy of replacing IV catheters every 3 to 4 days was instituted and guidelines for urinary catheter changes were instituted. Proper disposal of clinical waste was initiated.	Infection rate before intervention: 4.44% of patients Infection rate after intervention: 2.72% of patients p<0.01
Cavalcante 1991[68]	Brazil Community hospital with residents	1986-1989	4 years	Appropriate use of perioperative antibiotics	*QI Strategies: Clinician education* "The most important measures recommended by the infection control committee to decrease the infection rates were antibiotic policies, isolation precautions, education programs, a change to reusable instead of disposable material, no routine change of ventilators, no local and systemic antibiotic prophylaxis, and device procedure policy". Education involved 19 basic courses in infection control and informal in-services.	Infection rate prior to intervention: 24.4% of patients Infection rate after intervention: 3.4% of patients p value not reported

Table 4h. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
McConkey 1999[82]	United States Tertiary care or university hospital	4/1991-12/1994	3 years	Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Audit and feedback, clinician reminder* Prospective effort to reduce SSI using comprehensive infection control program. The following interventions were instituted: 1) prospective surveillance; 2) quarterly reporting of surgeon and assistant specific SSI rates; 3) chlorhexidine shower by pt preoperative; 4) Hair removal by clipping on morning of surgery; 5) antibiotic prophylaxis 1/2 to 2 hours prior to incision; 6) elimination of open ice baths for cooling of cardioplegia solution; 7) limitation of OR traffic; 8) minimization of intraoperative flash sterilization; 9) elimination of tap-water wound bathing within 96 hours post-op; 10) sterile wound dressing for first 96 hours post-op; 11) use of dedicated infection control practitioner.	Infection rate prior to intervention: 12.4% of cases Infection rate after intervention: 8.2% of cases p<0.01
Schelenz 2005[72]	UK Hospital type not specified	9/2000 – 12/2001	16 months	Hand hygiene Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Investigators implemented a bundle of different interventions aimed at decreasing MRSA wound infections, using education, audit and feedback, improvements in surgical skin preparation, improved antibiotic prophylaxis and several measures to limit the spread of MRSA.	Infection rate prior to intervention: 4.1% of cases Infection rate after intervention: 2.1% of cases p=NS

Table 4h. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Haycock 2005[69]	United States Hospital type not specified	4 months	1 year	Hand hygiene Appropriate use of perioperative antibiotics Decreasing use of preoperative shaving of the operative site Perioperative normothermia Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Identified best practices for preventive practices and gaps in current practice. Formed process teams and implemented pilot protocol. Then implemented change and modified strategy based on results. Intervention targeted antibiotic prophylaxis, skin preparation, hand hygiene, blood glucose control, and wound case management for cardiac surgery patients.	Infection rate prior to intervention: 1.5% of cases Infection rate after intervention: 0.3% p<0.05 Adherence to protocols for hand hygiene: Percentage change in compliance rate (post % - pre %): 11% Adherence to administering perioperative antibiotics for the appropriate timing: before intervention: NR after intervention: 87% Adherence to appropriate selection of perioperative antibiotics: before intervention: NR after intervention: 98% Adherence to protocols for perioperative shaving of the surgical site: before intervention: NR after intervention: 100%

Table 4h. Articles addressing prevention of surgical site infections (studies not using appropriate antibiotic prophylaxis as an outcome): simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Reilly 2001[71]	UK Not specified	Not speci-fied	28 months	Audit and feedback of infection rates to hospitals or individual clinicians	*QI Strategies: Audit and feedback, clinician reminder* Surveillance including individual risk assessment for wound infection, daily visits perioperatively, final assessment 4 weeks post-op. Results collected and reported to participating physicians.	Infection rate prior to intervention: 13.9% of cases Infection rate after intervention: 7.9% of cases p<0.05
*Berg 1995[60]	Guatemala Tertiary care or university hospital	Not speci-fied	1 year	Hand hygiene	*QI Strategies: Clinician education* A multifaceted intervention was used to target nosocomial infections in the ICU, with both general measures and measures targeting VAP and CAUTI. Nurses and physicians received 15 educational sessions on aseptic technique, stressing proper hand washing. The educational sessions used lectures and demonstrations, and individual clinicians also received positive and negative feedback and reminder signs at the bedside. The VAP intervention targeted proper use of sterile rinse water and improvement in aseptic technique for suctioning. Providers received more than 15 interactive conferences on the detection, management, and prevention of nosocomial pneumonia; these included lectures, demonstrations, individual instruction and feedback, and contests. The CAUTI intervention consisted of changing open urinary drainage systems to closed systems (aseptic catheter care), with an educational session on the new catheter. The intervention did not specifically target CLABSI, but those outcomes are reported.	Infection rate before intervention: 4% of patients Infection rate after intervention: 5% of patients p=Non-significant (NS) (Note: denominator for above is all patients in ICU; number of surgical cases was not provided.)

*This study addresses prevention of surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections.

Table 5. Quality criteria for simple before-after studies addressing surgical site infections

	Internal Validity			External Validity	
Author	**Did the study report data on more than one time point before and after the intervention?**	**If the study reported infection rates, did it also report process measurements?**	**Was the intervention performed independent of other QI efforts or other changes?**	**Did the study use NNIS/CDC methods for measuring infections?**	**Did the study perform surveillance for infections after hospital discharge?**
Atukorala 1998[81]	○	○	▲	▲	▲
Berg 1995[60]	●	●	▲	●	▲
Borer 2004[74]	●	○	▲	●	●
Brusaferro 1991[75]	○	●	▲	●	●
Cavalcante 1991[68]	○	○	○	○	▲
Dellinger 2005[19]	○	●	▲	▲	●
Greco 1991[61]	●	○	○	▲	▲
Gyssens 1996[84]	○	Not applicable	▲	Not applicable	Not applicable
Gyssens 1996[80]	○	●	▲	Not applicable	Not applicable
Haycock 2005[69]	●	●	▲	○	▲
Larsen 1989[76]	○	●	○	▲	●
Lutarewych 2004[70]	○	○	○	●	●
McConkey 1999[82]	○	○	▲	●	●
Prado 2002[83]	○	●	○	○	▲
Rao 2004[85]	●	●	▲	○	●
Reilly 2001[71]	○	○	▲	○	●
Schelenz 2005[72]	○	○	○	○	▲
Shapiro 1981[65]	○	Not applicable	○	Not applicable	Not applicable
Smith 1988[77]	○	Not applicable	○	Not applicable	Not applicable
St Jacques 2005[78]	○	Not applicable	▲	Not applicable	Not applicable
Talon 2001[73]	○	Not applicable	▲	Not applicable	Not applicable
Won 2004[87]	○	●	▲	●	Not specified

● Yes ○ No ▲Unclear

Central Line-Associated Bloodstream Infections

Included Studies: Settings, Goals, and Target Populations

Our literature search identified 19 studies that met our inclusion criteria that specifically addressed prevention of central line-associated blood stream infection (CLABSI) (Tables 6a-6e). One of the studies[60] reported data on CLABSI rates, but primarily addressed VAP prevention. This study will be discussed in detail in the section on VAP but will not be included in the analysis of CLABSI. This left 18 studies for analysis. Ten of the 18 studies were from centers within the United States[88-97] and eight were from outside the United States.[62, 98-104] Seventeen of the studies specifically targeted reduction of CLABSI, while one[62] targeted CLABSI and VAP. All but one of the studies was from a single center. One study[96] reported data from multiple hospitals that varied from tertiary teaching centers to community non-teaching hospitals. Of the remaining studies, 14 were from tertiary care medical centers and three from community hospitals. One of these community hospitals had residents,[100] while the other two were non-teaching centers.[92, 102] One study[104] did not report the type of hospital. Most studies took place in ICUs. One study was from a bone marrow transplant unit[90] and two did not state the type of unit that was studied.[91, 104] One study was located in a neonatal ICU[62] and the remaining studies were from adult medical or surgical ICUs.

All of the studies reported rates of CLABSI; nine of the studies also reported data on process measurements.[89-93, 96, 100, 101, 103] The study populations were highly variable, with baseline CLABSI ranging from 2.7 episodes of CLABSI/1,000 catheter-days[96] to 45.9 CLABSI/1,000 catheter-days.[102] The range of study duration was 4-39 months, with the median being 23 months. Four studies[62, 96, 98, 104] did not report duration.

Preventive Interventions and Outcomes Measured

We identified hand hygiene, use of maximal sterile barrier precautions, appropriate insertion site selection, chlorhexidine skin disinfection, and prompt removal of unnecessary catheters as target preventive interventions for this review (Tables 6a-6e). All studies but two[92, 97] targeted hand hygiene; the next most common targeted strategy was maximal sterile barrier precautions. Five studies targeted hand hygiene alone,[62, 88, 98, 100, 104] four targeted hand hygiene and maximal sterile barrier precautions,[90, 91, 101, 103] and seven studies targeted hand hygiene, maximal sterile barrier precautions, and at least one other preventive strategy[89, 93-96, 99, 102] (Tables 6a-6e). A number of included studies also attempted to reduce CLABSI by improving nursing care of catheters already in situ.[88, 89, 99] We did not consider in situ catheter care as a target preventive intervention as there is a stronger evidence base supporting proper insertion practices as effective means of preventing CLABSI, but these interventions may have contributed to the observed effects in these studies.

Quality Improvement Strategies Used

Tables 6a-6e list the QI strategies employed in each study and provide details on the QI intervention. All but one of the studies employed educational strategies for health care providers as part of their intervention (Lam[62] did not include provider education). Most of the educational

programs were for nurses and physicians;[88, 89, 91-94, 96, 97, 99-104] one study only provided education for nurses[90] and another only for physicians.[95] One study[98] did not specify who was given education. Most educational interventions involved distributed educational material[88, 89, 92, 94-96, 99, 102-104] or lecture format.[89, 91-94, 96, 97, 100-102, 104] Three particularly intensive educational programs combined distributed material, lectures, and interactive workshops.[92, 93, 102] Other modes of provider education used in the studies were consensus-building sessions,[88] distribution of "promotional materials",[89] and academic detailing.[90, 101] The majority of studies that used education used more than one modality for delivery of educational content.

In addition to provider education, the strategies of audit and feedback, clinical reminders, and organizational change were employed to encourage behavioral change. Eleven studies employed audit and feedback,[88, 90, 92-97, 100-102] five employed strategies that included organizational change,[62, 90, 96-98, 100] and four used clinical reminders.[62, 90, 96, 101] Seven studies used two different strategies,[62, 88, 92, 93, 95, 98, 102] five used only provider education,[89, 91, 99, 103, 104] three studies employed three of the strategies,[97, 100, 101] and two studies used all four strategies to encourage behavioral change.[90, 96]

Study Methodologic Quality

The methodological quality of studies was limited, as all but two used a quasi-experimental, before-after design (Tables 6a-6e). In addition, there was extensive variability in the duration of studies and whether the intervention ran in series or coincident with the period measuring the intervention's effect. To help facilitate comparison between studies and qualitative analysis, we developed criteria to characterize internal and external validity for simple before-after studies (Table 7). One study met all three criteria for internal validity.[100] Eight studies met two out of three,[88, 89, 91-93, 96, 101, 103] three studies met one out of three,[90, 95, 97] and five studies met none.[62, 98, 99, 102, 104] Most studies met criteria for external validity. Only three studies did not measure CLABSI by NNIS/CDC definitions,[90, 95, 98] and three studies did not report infection rates in terms of days of device utilization.[90, 102, 104]

Given the heterogeneous study groups, the variety of specific interventions, and the significant methodological limitations of all the included studies, we were not able to perform quantitative analysis of the data. We will summarize the studies that we considered to have generally stronger internal and external validity.

Controlled Before-After Studies. One study[94] measured the effect of their intervention in an ICU that cares for patients undergoing general, orthopedic, transplant, trauma, and vascular surgery, and compared the results to a concurrent control ICU that cares for patients undergoing cardiac surgery (Table 6a). An interdisciplinary team of physicians, nurses, and infection control practitioners implemented five interventions over a period of nearly two years: (1) education of staff to increase provider awareness of evidence-based infection control practices (a hospital-wide intervention which also targeted providers in the control ICU). All physicians or physician extenders who inserted CVCs were required to complete a Web-based training module and 10-question posttest. Completion of the module was required for physicians. Infection control staff also provided 16 lectures for nurses and five for physicians to reinforce the guidelines. Monthly CLABSI rates were posted in the SICU; (2) a central catheter insertion cart containing all the materials needed to properly insert a CVC was introduced on the study unit; (3) the ICU team began asking whether catheters could be removed every day during rounds, and added this

Table 6a. Articles addressing prevention of central line-associated bloodstream infections (CLABSI): controlled studies

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Berenholtz 2004[94]	United States Tertiary care or university hospital	2/1999-12/2001	2 years	Hand hygiene Maximal sterile barrier precautions Appropriate insertion site selection Chlorhexidine skin disinfection Prompt removal of unnecessary catheters	*QI Strategies: Clinician education, audit and feedback* Multiple interventions to reduce CLABSI were introduced in a staggered fashion. 1) Beginning 2/1999, all physicians or physician extenders who inserted CVCs were required to complete a Web-based training module and 10-question posttest. The training module emphasized hand hygiene, maximal sterile barrier precautions, chlorhexidine skin sterilization, and subclavian site as the preferred insertion site. It also addressed the care of central lines after insertion. In 2002, completion of the module was required for physicians. Infection control staff also provided 16 lectures for nurses and five for physicians to reinforce the guidelines. Monthly CLABSI rates were posted in the SICU. 2) A central catheter insertion cart containing all the materials needed to insert a CVC was introduced in 6/1999. 3) Beginning 6/2001, the ICU team began asking whether catheters could be removed every day during rounds, and added it to the daily goals form for each patient. 4) A standardized checklist for CVC insertion, completed by nurses, was introduced in 11/2001. 5) Beginning 12/2001, nurses were empowered to stop insertion of a CVC if the checklist was not followed (except in an emergency.)	Intervention group: Before intervention: 11.3 CLABSI per 1,000 catheter-days After intervention: 0 CLABSI per 1,000 catheter-days Control group: Before intervention: 5.7 CLABSI per 1,000 catheter-days After intervention: 1.6 CLABSI per 1,000 catheter-days p value for comparison of change in intervention group versus change in control group = NS

Table 6a. Articles addressing prevention of central line-associated bloodstream infections (CLABSI): controlled studies (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Eggimann 2000[99]	Switzerland Tertiary care or university hospital	3/1997 - 4/1997	8 months	Hand hygiene Maximal sterile barrier precautions Chlorhexidine skin disinfection Prompt removal of unnecessary catheters	*QI Strategies: Clinician education* A multiple-approach intervention strategy targeted at the reduction of vascular-access infections was implemented in March 1997. An educational campaign consisting of 30-min slide-shows and practical demonstrations was developed for all medical ICU staff (21 fellows or residents, 82 nurses, and 15 nursing assistants), and was completed by individual in-service training. The guidelines covered the following: preparation of the material to avoid any interruption during insertion; skin preparation (hair-cutting instead of shaving) and disinfection (alcohol-based solution of chlorhexidine gluconate 0·5%, with 2 min drying time); maximum barrier precautions (sterile gloves and gown, cap, mask, and a large sheet) used for all but peripheral lines; subclavian or wrist vein as standard insertion sites; and dressings (dry gauze covered by a non-occlusive adhesive band). Administration sets, devices, and dressings were replaced every 72 h, except for lines receiving lipid or blood products, and for the first dressing after catheter insertion 24 h. Hand disinfection was strongly emphasized before and after the insertion, replacement, or manipulation of any vascular device. Central lines were not routinely replaced, but were changed over a guidewire in cases of clinical sepsis without documented source of infection. Prompt removal of any device not intended for use was strongly recommended.	Infection rate prior to intervention: 3.1 microbiologically documented CLABSI per 1,000 catheter-days Infection rate after intervention: 1.2 CLABSI per 1,000 catheter-days p<0=0.04

prompt to the daily goals form for each patient; (4) a standardized checklist for CVC insertion, completed by nurses, was implemented; (5) nurses were empowered to stop procedures if guidelines contained in the checklist were not followed. The cumulative intervention targeted hand hygiene, maximal sterile barrier precautions, chlorhexidine skin disinfection, and subclavian vein as the preferred insertion site. It also addressed the care of central lines after insertion. Cases were defined by NNIS criteria, and the data were normalized to days of device usage. CLABSI rates in the study unit decreased from 11.3/1,000 catheter-days in the quarter before the beginning of the intervention to 0/1,000 catheter-days in the quarter when nurses were empowered to stop the procedure if guidelines were not followed. The control unit also saw a decrease in rates of CLABSI, from 5.7/1,000 catheter-days to 1.6/1,000 catheter-days over the same time period. Study data were analyzed by using a Poisson regression model to model the

change in infection rates over time and by comparing the slopes and intercepts of the regression lines for the intervention and control groups. There was no significant difference between the regression lines for either slope or intercept. This raises the possibility that the educational intervention (which was delivered to both groups) may have entirely accounted for the intervention effect. No process measures were reported. A subsequent report documented sustained reductions in CLABSI over an additional 18 months of followup.[105]

An educational campaign aimed at reducing CLABSI was the main intervention in another controlled study out of the medical ICU of a large tertiary medical center in Geneva, Switzerland (Table 6a).[99] The program consisted of 30-minute slide shows and practical demonstrations and was given to all medical intensive care unit (MICU) staff (fellows, residents, nurses, nursing assistants). Among our targeted interventions, proper hand hygiene, use of chlorhexidine for skin preparation, maximal sterile barrier precautions, and use of the subclavian vein as the preferred site were specifically addressed. Rates of CLABSI before and after the educational campaign were compared to rates in the surgical ICU (SICU) of the same hospital; the authors do not comment how isolated the units are, and it is possible that there was crossover among unit personnel. The study did not report data at multiple time points and did not report process measures. Data for arterial and central venous lines were reported in aggregate. Rates of CLABSI decreased from 11.3/1,000 catheter-days to 3.8/1,000 catheter-days in the MICU (study unit), while they were unchanged during the same period in the control SICU (10.3/1,000 catheter-days before and 11.6/1,000 catheter-days after the educational campaign). A subsequent report documented a sustained reduction in CLABSI over six years of follow-up.[106]

Interrupted Time Series Studies. A yet to be published study employed a complex multiple time series design.[96] This project took place in 107 separate ICUs in the state of Michigan over a one-year period. Study ICUs were diverse, ranging from small non-teaching community hospitals to large tertiary academic centers; both surgical and medical ICUs were included. In addition to an intervention to reduce CLABSI, participating ICUs sequentially introduced a "Daily Goals Sheet" to improve communication among healthcare personnel, a multi-faceted intervention to reduce ventilator-associated pneumonia, and a comprehensive unit-based safety program to improve safety culture.

The implementation period for each of the four interventions was estimated to take three months. Hospitals were asked to start with the comprehensive unit-based safety program, and then choose the implementation order for the remaining three patient safety interventions during the 12-month period. The included manuscript comments only on the intervention to reduce CLABSI; it does not give details of the nature or outcomes of the other patient safety programs.

Before implementing any patient safety intervention, each ICU designated at least one physician and nurse as team leaders. For CLABSI, interventions were washing hands prior to the procedure, using full barrier precautions, cleaning the skin around the insertion site with chlorhexadine, avoiding the femoral site if possible, and removing unnecessary catheters. A bundle of six strategies was used to increase adherence to these targeted interventions, similar to those used in a prior study:[94] (1) ICU clinicians were educated to increase their awareness of evidence-based infection control practices and to review the harm caused by CLABSI; (2) A central catheter insertion cart containing all the materials needed to properly insert a CVC was introduced on the study unit; (3) the ICU team began asking whether catheters could be removed every day during rounds, and added it to the daily goals form for each patient; (4) A standardized checklist for CVC insertion, completed by nurses, was implemented; (5) Nurses were

empowered to stop procedures if guidelines contained in the checklist were not followed; and (6) teams were provided with monthly feedback regarding the number of CLABSI and quarterly feedback regarding rates of CLABSI in their ICU.

Data was acquired at baseline and at three-month intervals. The sequential nature of the implementation and time frame of the study meant that no single center had a complete data set; data from all of the study centers was analyzed in aggregate. As a result, the population of centers included in the baseline data set and subsequent post-intervention data sets had significant overlap, but were not identical. Cases of CLABSI were defined by NNIS criteria and reported normalized to days of device utilization. Data reported as median CLABSI/1,000 catheter-days for each time period among the ICUs included at each time point. The median pre-intervention rate of CLABSI was 2.8/1,000 catheter-days. This decreased to 1.7 during the three-month peri-intervention period, and then to zero during each of the subsequent periods post-intervention. Thus, more than half of the study ICUs reported no cases of CLABSI up to nine months following implementation of their quality improvement strategy. The difference between the pre- and post- intervention rates of CLABSI was statistically significant ($p=0.002$); multi-level Poisson regression model (time series analysis) demonstrated a significant decrease in CLABSI rates during all observation periods (versus pre-intervention baseline).

Though the reported results are impressive, aspects of the study design and data collection limit the interpretability of its results. Most significantly, the current study focuses on an intervention to prevent CLABSI, but in reality the intervention involved a variety of interventions targeting patient safety and HAIs, which could have contributed to the observed effect in addition to the CLABSI-specific intervention. There were also problems with internal validity. Of the 1,176 ICU-months of data, 25 percent were not available. While a sensitivity analysis was performed and statistical significance was maintained, this is a large amount of data unaccounted for; it might be expected that those centers not reporting data have a higher rate of CLABSI. In addition, as described above, the population of ICUs included in the baseline data is not the same as that studied after implementation of the intervention, introducing the potential for sampling error.

Table 6b. Articles addressing prevention of central line-associated bloodstream infections: interrupted time series

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Pronovost (unpublished)[96]	United States Multiple hospitals of different types	3/2004 – 2/2005	3 months	Hand hygiene Maximal sterile barrier precautions Appropriate insertion site selection Chlorhexidine skin disinfection Prompt removal of unnecessary catheters	*QI Strategies: Clinician education, audit and feedback, clinician reminder, organizational change* Using a multiple time series design, Keystone ICU involved individual ICUs implementing several different patient safety interventions and monitoring the impact of these interventions on specific safety measures. In addition to the multi-faceted intervention to reduce CLABSI, ICUs implemented a "Daily Goals Sheet" to improve communication between clinicians in the ICU, a multi-faceted intervention to reduce ventilator-associated pneumonia, and a comprehensive unit-based safety program (CUSP) to improve safety culture. The implementation period for each intervention was estimated to take three months. Hospitals were asked to start with CUSP and then choose the implementation order for the remaining three patient safety interventions during the 12-month period. Before implementing any patient safety intervention, each ICU designated at least one physician and nurse as team leaders. These team leaders were given detailed training and then were responsible for disseminating the interventions to their colleagues. Team leaders participated in biweekly conference calls and attended two state-wide meetings during the year. For each intervention, teams were provided a manual of operations that included details regarding the efficacy of the intervention, evidence supporting the intervention, suggestions for implementing the intervention, and methods of data collection. Interventions were: washing hands prior to the procedure, using full barrier precautions, cleaning the skin around the insertion site with chlorhexadine, avoiding the femoral site if possible, and removing unnecessary catheters. The strategy to increase the use of these evidence-based interventions had six components, as described in detail elsewhere. First, ICU clinicians were educated to increase their awareness of evidence-based infection control practices and to review the harm caused by CLABSI. Second, a cart with all supplies and equipment necessary for central line insertion was created to reduce the number of steps necessary in preparing for safe and sterile line insertion. Third, a central line insertion checklist was used by the ICU bedside nurse to help ensure a safe and sterile procedure. Fourth, nurses were empowered to stop a central line insertion (in non-emergency situations) if providers did not comply with evidence-based infection control practices. Fifth, ICU staff discussed whether central lines could be removed during daily physician rounds. Finally, monthly feedback was provided to teams regarding the number of CLABSIs and quarterly feedback regarding rates of CLABSI in their ICU.	Median infection rate prior to intervention: 2.8 CLABSI per 1,000 catheter-days Median infection rate after intervention: 0 per 1,000 catheter-days $p<0.01$

Before-After Studies With Good Internal and External Validity. Only one study met all of our criteria for internal and external validity (Table 6c).[100] This study, out of Mexico City, used a combination of education, audit and feedback, and organizational change to encourage behavioral change in a medical-surgical ICU and a neurologic-ICU. The education component consisted of one-hour classes given by an infection control nurse to unit nurses and residents. The investigators performed active surveillance of hand hygiene and catheter care practices; performance feedback consisted of charts posted in the units with unit level data on hand hygiene and invasive device care. Cases of CLABSI were defined by NNIS criteria. The intervention led to a reduction of CLABSI from 46.3 events/1,000 catheter days to 19.5. The authors also demonstrated an improvement in process measures, with optimal hand hygiene improving from 62 percent to 85 percent of observed cases. A major limitation to the study was the high baseline rate of CLABSI, which likely was related to resource availability at the study center. Part of the hand hygiene component of the study involved a hospital-wide switch from non-antiseptic soap to alcohol hand rub or povidone-iodine soap.

A pair of studies carried out in a surgical ICU in a single teaching hospital reported consecutive interventions to reduce CLABSI (Table 6c). The first study[88] was an educational program targeted primarily at nurses. The main intervention was a 10-page self-study module that every nurse was expected to complete, along with a pre- and post-test. Unit-level monthly feedback of rates of CLABSI was posted, along with fact sheets and posters. Of note, housestaff did not receive the educational program but were responsible for placing all central lines under supervision of faculty and/or fellows. The educational module covered background information about CLABSI and methods to decrease risk. Of our targeted interventions, optimal hand hygiene and preferred insertion site (subclavian vein optimal, femoral vein only in emergency situations) were specifically addressed. Other techniques to reduce the risk of CLABSI focused on catheter maintenance. This study was not a time series analysis but did report data at multiple time points before and after the intervention. Process measures were not reported. CLABSI rates decreased from 10.8 cases/1,000 catheter-days before the intervention to 3.7 cases/1,000 catheter-days afterward. Subsequent to this study, the same group attempted another intervention to improve adherence to optimal risk reduction behaviors.[89] Using a series of bedside audits to define current practice patterns, a multifactorial behavioral intervention was designed. Pictures demonstrating each step of CVC maintenance and insertion were placed at every patient's bed, throughout the ICU, and in the manual each resident receives when they rotate through the ICU. Nurses received lectures and hands-on demonstrations were given to nurses as part of their annual skills sessions. Lectures were given to the entire resident staff, and monthly lectures were given to all residents rotating through the ICU. A second set of bedside audits was performed to assess the success of the behavioral intervention, and CLABSI rates were monitored concurrently with the study. Data was reported at multiple time points before and after the intervention, but a formal time series analysis was not performed. Only ten central line insertions were actually audited after the intervention, limiting the findings regarding behavioral change improvement. The intervention was associated with improved adherence to appropriate hand hygiene (17 percent to 30 percent), maximal sterile barrier precautions (50 percent to 80 percent) and appropriate catheter site selection (53 percent to 60 percent). No other process measures were reported. The rate of CLABSI was 3.4/1,000 catheter-days before the intervention and 2.8/1,000 catheter-days afterward.

Two other studies out of the same integrated healthcare system as the previous two reports used a similar educational intervention to reduce CLABSI (Table 6c).[92, 93] One of these[92] was

distinguished by the fact that it was in non-teaching, community hospital and included a medical and surgical ICU. For this intervention, all ICU nurses and physicians had to complete a 10-page self-study module on the prevention of CLABSIs; the module was similar to the one described above.[88] Nursing and medical staff received a 45 minute lecture on CLABSI, and grand rounds on prevention of CLABSI were presented to the medical staff. Among our targeted interventions, maximal sterile barrier precautions and appropriate catheter site selection were covered in the educational program. Posters and fact sheets were placed in the ICU. A pretest and posttest was administered to ICU nurses; the pretest was optional but the posttest was mandatory. All physicians completed the posttest as well. Rates of CLABSI were 4.9/1,000 catheter-days before the intervention, and 2.1/1,000 catheter-days afterward. Rates of adherence to appropriate catheter site selection improved from 25 percent to 41 percent. All catheters used in this study were impregnated with chlorhexidine and silver-sulfadiazine. The same investigators also reported the results of an intervention in the MICU of a large tertiary academic medical center.[93] A multidisciplinary committee made local modifications to the educational module already described;[88] the program was administered to all nurses and physicians working on the unit. In addition, a promotional campaign was carried out that included distribution of lapel buttons, fact sheets, posters; photographic guidelines demonstrating proper insertion and catheter care techniques were placed in prominent locations in the ICU. Feedback was provided in the form of monthly reports of CLABSI rates, which were posted in multiple locations throughout the unit. Data were reported from multiple time points before and after the intervention, but a formal time-series analysis was not performed. CLABSI rate improved from 9.4 cases/1,000 catheter-days before the intervention to 5.5 cases/1,000 catheter-days after the procedure. The education did not change provider behaviors regarding catheter site selection; 26 percent of insertion sites were deemed appropriate before the intervention compared to 20 percent afterward. Notably, there was a QI program targeting Ventilator-Associated Pneumonia running concurrently with this study. There could have been significant crossover in effect between the interventions, making the results less reliable.

This study, like the three others from this healthcare system,[88, 89, 93] is subject to a certain amount of bias due to the fact that there was intense system-wide effort to reduce overall health-care associated infections, a fact which by itself might influence the findings.

Another study using an educational intervention targeted medical students and interns (Table 6c).[91] As part of a half-day course on performing a variety of medical procedures, interns and students received a one-hour lecture on basic infection control principles, including hand washing and appropriate use of barrier garments. Attendees then went through a series of one-hour workstations, one of which was dedicated to proper insertion of arterial and central venous catheters. This module specifically addressed hand hygiene and maximal sterile barrier precautions. Data on the effectiveness of the intervention was collected in six medical-surgical ICUs and their associated step-down units and was reported at multiple time points. Cases were defined by CDC criteria. Use of full-sized drapes was assessed by measuring the surrogate marker of purchasing records and improved from 44 percent to 65 percent after the intervention. Rate of CLABSI decreased from 4.51 to 2.92 cases/1,000 patient-days. Rates of infection normalized to catheter days were estimated, but not actually measured.

Table 6c. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of good methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Higuera 2005[100]	Mexico Commu-nity hospital with residents	phase 1 6/ 2002 – 8/ 2002; phase 2 9/ 2002 - 5/2003	9 months	Hand hygiene	*QI Strategies: Clinician education, audit and feedback, organizational change* The overall strategy was referred to process control. Targeted processes were hand hygiene and catheter care. The study was in Mexico, where routine maintenance catheter was very substandard compared to US practice. The investigators reported using education, process control, performance feedback, and direct observation. The education process was led by an infection control nurse who presented one hour classes to nurses and residents. Performance feedback consisted of charts posted in the units with unit level data on hand hygiene and invasive device care.	Infection rate prior to intervention : 46.3 CLABSI per 1,000 catheter-days Infection rate after intervention: 19.5 CLABSI per 1,000 catheter-days p<0.01 Adherence to protocols for hand hygiene: before intervention: 62% after intervention: 84.9% p<0.01
Coopersmith 2002[88]	United States Tertiary care or university hospital	7/1999 - 12/2000	18 months	Hand hygiene	*QI Strategies: Clinician education, audit and feedback* This was an educational intervention targeted primarily at nurses, but also at physicians. The main intervention was a 10-page self study module that every nurse was supposed to complete, along with a pre- and post-test. Specific risk reduction strategies addressed included: handwashing & aseptic technique, methods for detection potential clinical signs & symptoms of local infection, technique for sending catheter-tip culture, routine catheter site care, replacing administration sets & fluids, cleaning & changing injection ports & luer lock caps, how to handle parenteral fluids & multidose vials & procedure for drawing blood cultures. The program also involved verbal inservice raining at staff meetings. Each participant took a pretest before the study module and an identical test upon completion. Fact sheets & posters reinforcing this information were posted throughout the ICU.	Infection rate prior to intervention: 10.8 CLABSI per 1,000 catheter-days Infection rate after intervention: 3.7 CLABSI per 1,000 catheter-days p<0.01

Table 6c. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of good methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Coopersmith 2004[89]	United States Tertiary care or university hospital	11/2000 - 2/2002		Hand hygiene Maximal sterile barrier precautions Appropriate insertion site selection	*QI Strategies: Clinician education* Used a literature-based determination of risk factors involved in catheter infections to develop an audit tool to determine whether randomly checked CVCs were properly maintained or whether new insertions were performed under sterile conditions. After these bedside audits, a behavioral intervention was designed. The intervention was multifactorial. Pictures demonstrating each step of CVC maintenance (aimed at nursing staff) and insertion (aimed at physicians) were placed at every patient's bed, throughout the ICU, and in the manual each resident receives when they rotate through the ICU. Lectures and hands-on demonstrations were given to nurses as part of their annual skills sessions by two of us (C.S.S. and M.E.S.). Lectures were given to the entire resident staff in the departments of surgery and emergency medicine by one of us (C.M.C.), and monthly lectures were given to all residents rotating through the ICU. To assess the success of the behavioral intervention, a second set of bedside audits was performed from November 2001 through February 2002.	Infection rate prior to intervention: 3.4 CLABSI per 1,000 catheter-days Infection rate after intervention: 2.8 CLABSI per 1,000 catheter-days p=NS Adherence to protocols for hand hygiene: before intervention: 17% after intervention: 30% Adherence to appropriate use of maximal sterile barrier precautions: before intervention: 50% after intervention: 80% Adherence to appropriate catheter site selection: before intervention: 53% after intervention: 60% p=NS for all process measures

Table 6c. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of good methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Warren 2003[92]	United States Non-teaching community hospital	7/1999 - 9/1999	2 years	Maximal sterile barrier precautions Appropriate insertion site selection	*QI Strategies: Clinician education, audit and feedback* An educational intervention targeting CLABSI was administered to the clinical staff in a community hospital ICU. Nursing and medical staff received a 45 minute lecture on CLABSI, and grand rounds on prevention of CLABSI were presented to the medical staff. Posters and fact sheets were placed in the ICU (the content of these was not specified.) CLABSI rates were reported to all ICU staff. All ICU nurses and physicians had to complete a 10-page self-study module on the prevention of CLABSIs, based on the 1996 HICPAC guidelines. These emphasized maximal sterile barrier precautions, preference for subclavian vein insertion, and guidelines for changing intravenous tubing and administration sets as well as proper technique for blood cultures. A pretest and posttest was administered to ICU nurses; the pretest was optional but the posttest was mandatory. All physicians completed the posttest as well.	Infection rate prior to intervention: 4.9 CLABSI per 1,000 catheter-days Infection rate after intervention: 2.1 CLABSI per 1,000 catheter-days P<0.01 Adherence to appropriate catheter site selection: before intervention: 25% after intervention: 41% p<0.01

Table 6c. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of good methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Warren 2004[93]	United States Tertiary care or university hospital	1/ 2002 - 12/2003	2 years	Hand hygiene Maximal sterile barrier precautions Appropriate insertion site selection	*QI Strategies: Clinician education, audit and feedback* An educational intervention targeting CLABSI was administered to the clinical staff in a medical ICU at a teaching hospital. The ICU infection control team developed policies and procedures for catheter insertion and site maintenance and developed a strategy for education and implementation. The intervention consisted of the following: Nursing and medical staff received a 45 minute lecture on CLABSI. Posters and fact sheets were placed in the ICU at computer terminals (the content of these was not specified.) All ICU nurses and physicians had to complete a 10-page self-study module on the prevention of CLABSIs, based on the HICPAC guidelines. These emphasized the following: hand hygiene, maximal sterile barrier precautions, avoidance of femoral catheterization, hair removal with clippers, avoidance of antimicrobial ointment at the insertion site, avoidance of changing catheters over guidewires, and guidelines for changing intravenous tubing and administration sets. A pretest and posttest was administered to nurses and physicians. CLABSI rates were reported to all ICU staff. A promotional campaign was also launched with distribution of lapel buttons, fact sheets, posters, and photographic guidelines demonstrating proper insertion and catheter care techniques in prominent locations in the ICU.	Infection rate prior to intervention: 9.4 CLABSI per 1,000 catheter-days Infection rate after intervention: 5.5 CLABSI per 1,000 catheter-days Adherence to appropriate catheter site selection: before intervention: 26.3% after intervention: 20.4% p=NS

Table 6c. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of good methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Sherertz 2000[91]	United States Tertiary care or university hospital	06/1996 and 06/1997	6 months	Hand hygiene Maximal sterile barrier precautions	*QI Strategies: Clinician education* PGY-1 residents and medical students underwent a 1/2-day educational session on infection control practices for procedures. Infection control practitioners and an epidemiologist gave a 1-hour lecture on basic infection control principles, including hand washing. The subjects then rotated through a series of 1-hour stations at which they received didactic and hands-on instruction on the following procedures: insertion of central venous and arterial catheters, blood draws through vascular lines, arterial puncture, urinary catheter insertion, lumbar puncture, peripheral venous catheter insertion, and phlebotomy. The hands-on stations used mannequins.	Infection rate prior to intervention: 4.51 CLABSI per 1,000 patient-days Infection rate after intervention: 2.92 CLABSI per 1,000 patient-days p<0.01 Adherence to appropriate use of maximal sterile barrier precautions: before intervention: 44% after intervention: 65% p<0.01

Before-After Studies With Moderate Iinternal and External Validity. A study from Korea used a combination of education and intensive surveillance and active feedback to reduce the rate of CLABSI (Table 6d).[103] The infection control committee held "Infection Control Week", during which new guidelines for central line care, aseptic technique, and hand washing were distributed. Details of the educational program were not provided. Infection control staff conducted daily surveillance of all central lines to monitor for appropriate catheter care, including hand washing, occlusive dressing, and aseptic application of povidone iodine, and gave direct feedback if protocols were violated. Rates of CLABSI decreased from 4.2/1,000 catheter-days before the intervention to 1.3/1,000 catheter-days afterward, but these results are non-significant due to the very small size of the study. The data reflect only six actual cases of CLABSI.

A study conducted in a surgical intensive care unit of a tertiary care hospital used corporate "Six Sigma" methodology, which focuses on minimizing variability and improving efficiency, to target CLABSI (Table 6d).[97] A multidisciplinary team consisting of SICU staff and hospital epidemiologists developed an educational module for residents and guidelines for catheter care and changing catheters over guidewires. Additionally, attending staff were required to supervise non-emergent catheter insertion, and infection rates were fed back to SICU staff. The study had good external validity and reported data at more than one time point before and after the intervention, but did not measure adherence. CLABSI were significantly reduced, however, the results of the QI intervention were likely significantly confounded by the simultaneous introduction of antibiotic-coated catheters[42] for patients requiring long-term (greater than four days) mechanical ventilation; these had not been used in the baseline phase of the study.

Table 6d. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Yoo 2001[103]	Korea Tertiary care or university hospital	10/1998 – 1/1999	3.5 months	Hand hygiene Maximal sterile barrier precautions	*QI Strategies: Clinician education* An intensive surveillance and catheter care education program was instituted at an ICU in Korea. The infection control committee held "Infection Control Week", during which new guidelines for central line care, aseptic technique, and hand washing were distributed. Infection control staff conducted daily surveillance of all central lines to monitor for appropriate catheter care, including hand washing, occlusive dressing, and aseptic application of povidone iodine. Infection control staff gave direct feedback if protocols were violated, and recommended catheter removal and blood cultures if the patient has symptoms of CLABSI.	Infection rate prior to intervention: 4.2 CLABSI per 1,000 catheter-days Infection rate after intervention: 1.3 CLABSI per 1,000 catheter-days p=NS
Frankel, 2005[97]	United States Tertiary care or university hospital	5/2001 - 5/2002	2 years	Maximal sterile barrier precautions	*QI Strategies: Clinician education, audit and feedback, organizational change* The study used Six Sigma methods to reduce CLABSI in a surgical ICU. Trained facilitators met with clinical stakeholders to instruct them in Six Sigma methodology, which focus on minimizing variability and improving efficiency. The stakeholder groups (SICU staff and hospital epidemiologists) determined risk factors for CLABSI and formulated a stepwise intervention. This consisted of a standardized video tutorial for residents on insertion site practices, development of new policies for changing catheters over wires, development of a standardized kit with insertion materials, new policies for catheter care, and inserting antibiotic-coated catheters in patients expected to be ventilated for >4 days. Also, all central lines were inserted under direct supervision of an attending physician except in an emergency. Feedback on infection rates was posted in the ICU.	CLABSI rate: Infection rate before intervention: 10.5/1,000 catheter-days After intervention: 1.7/1,000 catheter-days p<0.001

Before-After Studies With Poor Internal and External Validity. We identified seven simple before-after studies with poor internal and external validity which are listed in Table 6e. One of these[60] will be discussed under the section addressing prevention of VAP.

Table 6e. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of poor methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Bijma 1999[98]	The Netherlands Tertiary care or university hospital	Not specified	6 months	Hand hygiene	*QI Strategies: Clinician education; organizational change* The following fivefold intervention was consecutively implemented during a 12-month period: 1. A propanol/isopropanol solution containing a quaternary ammonium compound and an emollient to prevent excessive drying of the skin was introduced as a hand disinfecting agent. 2. An adhesive, non-woven, island-type gauze was introduced as CVC dressing. 3. A "one bag" TPN system was introduced. 4. A small needleless closed IV connection device was incorporated in every SICU patient's IV system. 5. Implementation of the aforementioned measures was carried out by and under continuous surveillance of the SICU's infection control practitioner (ICP). Checking protocol compliance required the ICP's daily presence on the SICU.	Infection rate prior to intervention: 15.0 CLABSI per 1,000 catheter-days Infection rate after intervention: 8.0 CLABSI per 1,000 catheter-days P=NS
*Lam 2004[62]	Hong Kong Tertiary care or university hospital	Not specified	10 months	Hand hygiene	*QI Strategies: Clinician reminder; organizational change* Nurses and physicians received an educational program targeting hand hygiene. A hand hygiene protocol was implemented as part of the orientation for new staff. Face-to-face educational seminars were conducted for nurses and physicians where solutions to overcome obstacles to hand washing were provided; 2 sessions were provided for physicians and 10 for nurses. A task-oriented analysis was performed to identify strategies for hand washing during complex procedures. Demonstrations were conducted at regular intervals, and reminder pictures were posted at each hand washing basin.	Infection rate prior to intervention: 6.8 CLABSI per 1,000 catheter-days Infection rate after intervention: 1.2 CLABSI per 1,000 catheter-days p=NS Compliance with hand hygiene: Before intervention: 40% After intervention: 53% p<0.01

Table 6e. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Lobo 2005[101]	Brazil Tertiary care or university hospital	1/01 through 12/02	20 months	Hand hygiene Maximal sterile barrier precautions	*QI Strategies: Clinician education; audit and feedback, clinician reminder* An education program was developed by a multidisciplinary task force focusing on CVC insertion, manipulation, and care. 3 infection control nurses, a physician, and the entire unit staff were on the task force.	Infection rate prior to intervention: 20 CLABSI per 1,000 catheter-days Infection rate after intervention: 11 CLABSI per 1,000 catheter-days p value not reported Adherence to appropriate use of maximal sterile barrier precautions: Before intervention: 91% after intervention: 100% p=NS
Penne 2002[90]	United States Tertiary care or university hospital	January 1997-July 1998, August 1998-March 2000	Not specified	Hand hygiene Maximal sterile barrier precautions	*QI Strategies: Clinician education; audit and feedback; clinician reminder; organizational change* A nurse educator performed individual education sessions with each staff member and demonstrated dressing change to ensure sterile technique and proper application of dressing to prevent risk of infection	Number of CLABSI before intervention: 39 Number of CLABSI after intervention: 24 Note: number of catheter-days not supplied
Puntis 1991[104]	UK Not specified	Not specified	Not specified	Hand hygiene	*QI Strategies: Clinician education* The nutritional care team at a children's hospital instituted an education program for care of catheters used for parenteral nutrition. Hand hygiene was emphasized, and new guidelines for catheter care were drawn up emphasizing use of aseptic technique and proper technique for changing feeding bags. Demonstrations of line care and bag changing were organized for nursing staff at which attendance was compulsory. A video of proper technique was also shown. This educational intervention was delivered to junior medical staff and nurses.	Infection rate prior to intervention: 45% of catheters infected Infection rate after intervention: 8% of catheters infected

Table 6e. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Rosenthal 2003[102]	Argentina Non-teaching community hospital	Bernal Medical center: 4/1999-5/1999; Colegiales Medical Center, 9/2000-12/2000	22 months	Hand hygiene Maximal sterile barrier precautions Appropriate insertion site selection Prompt removal of unnecessary catheters	*QI Strategies: Clinician education; audit and feedback* A surveillance and educational intervention was implemented at 2 ICUs in Argentina. Health care workers in the study ICUs underwent training for central venous catheter care based on CDC guidelines (at the time, these included hand hygiene, maximal sterile barrier precautions, appropriate insertion site selection and prompt removal of unnecessary catheters; however, chlorhexidine skin sterilization was not part of the guidelines.) Subsequently, performance feedback on catheter site care was provided to the ICU staff on a monthly basis. Compliance rates with catheter care were also provided to ICU administrators. This intervention was referred to as phase 2 (phase 1 being the pre-intervention period.) A separate intervention to encourage hand washing was implemented simultaneously; all health care workers received a comprehensive infection control manual. Hand washing compliance was observed covertly in the ICU by an infection control practitioner and monthly meetings were held at which hand washing rates were displayed and fed back to providers. Hand washing rates were also posted monthly in the ICUs and reported to the ICU manager and administrator. The hand washing guideline was also posted in the ICU. Educational classes were given in 1-hour group sessions for each shift daily for 1 week (attendance was voluntary). Participants underwent a posttest to evaluate retention of the educational material. In addition, infection control review classes were held to answer questions and share surveillance data.	Infection rate prior to intervention: 45.94 CLABSI per 1,000 catheter-days Infection rate after intervention: 9.90 CLABSI per 1,000 catheter-days p<0.01 Adherence to protocols for hand hygiene before intervention: 23.1% after intervention: 64.5% p<0.01

Table 6e. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Wall 2005[95]	United States Tertiary care or university hospital	began 11/2002	2 years	Hand hygiene Maximal sterile barrier precautions Chlorhexidine skin sterilization	*QI Strategies: Clinician education; audit and feedback* A continuous quality improvement intervention was conducted in a medical intensive care unit. An interdisciplinary team consisting of the MICU director and nurse manager, MICU nurses and physicians, epidemiologist, infection control practitioner and QI experts was assembled and decided to focus on central line insertion practices (after reviewing relevant prevention literature). The intervention primarily targeted house staff physicians. A nurse observed central line insertions to determine the baseline quality gap. A checklist for central line insertion was developed that mandated: hand hygiene, maximal sterile barrier precautions, chlorhexidine skin preparation, and proper supervision of trainees. (These steps could be skipped if the insertion was considered an emergency.) Providers were educated on the checklist and supporting evidence through a web-based tutorial with self-assessment exam; house staff was required to complete the tutorial. Infection rates and rates of compliance with process measures were fed back to the front line staff.	Infection rate prior to intervention: 7.0 CLABSI per 1,000 catheter-days Infection rate after intervention: 3.8 CLABSI per 1,000 catheter-days

Table 6e. Articles addressing prevention of central line-associated bloodstream infections: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
**Berg 1995[60]	Guatemala Tertiary care or university hospital	3 months	1 year	Hand hygiene	*QI Strategies: Clinician education* A multifaceted intervention was used to target nosocomial infections in the ICU, with both general measures and measures targeting VAP and CA-UTI. Nurses and physicians received 15 educational sessions on aseptic technique, stressing proper hand washing. The educational sessions used lectures and demonstrations, and individual clinicians also received positive and negative feedback and reminder signs at the bedside. The VAP intervention targeted proper use of sterile rinse water and improvement in aseptic technique for suctioning. Providers received more than 15 interactive conferences on the detection, management, and prevention of nosocomial pneumonia; these included lectures, demonstrations, individual instruction and feedback, and contests. The CA-UTI intervention consisted of changing open urinary drainage systems to closed systems (aseptic catheter care), with an educational session on the new catheter. The intervention did not specifically target surgical site infections, but those outcomes are reported.	Infection rate prior to intervention: 14% of patients Infection rate after intervention: 13% of patients p=NS Adherence to protocols for hand hygiene: before intervention: 5% after intervention: 63% p<0.01

*This study addresses prevention of central line-associated bloodstream infections and ventilator-associated pneumonia.
**This study addresses prevention of surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections.

Table 7. Quality criteria for simple before-after studies addressing central line-associated bloodstream infections

	Internal Validity			External Validity	
Author	**Did the study report data on more than one time point before and after the intervention?**	**If the study reported infection rates, did it also report process measurements?**	**Was the intervention performed independent of other QI efforts or other changes?**	**Did the study use NNIS/CDC methods for measuring infections?**	**Did the study report infection rates in terms of device utilization?**
Berg 1995[60]	○	●	▲	●	●
Bijma 1999[98]	○	○	▲	○	●
Coopersmith 2002[88]	●	○	●	●	●
Coopersmith 2004[89]	●	●	▲	●	●
Frankel, 2005[97]	●	○	○	●	●
Higuera 2005[100]	●	●	●	●	●
Lobo 2005[101]	○	●	●	●	●
Lam 2004[62]	○	○	▲	●	●
Penne 2002[90]	○	●	▲	○	○
Puntis 1991[104]	○	○	▲	●	○
Rosenthal 2003[102]	○	○	○	●	○
Sheretz 2000[91]	●	●	▲	●	●
Wall 2005[95]	●	○	▲	○	●
Warren 2003[92]	○	●	●	●	●
Warren 2004[93]	●	●	▲	●	●
Yoo 2001[103]	○	●	●	●	●

●: Yes ○: No ▲: Unclear

Ventilator-Associated Pneumonia

Included Studies: Settings, Goals, and Target Populations

Our search strategy identified a total of 12 articles meeting our inclusion criteria that assessed prevention of ventilator-associated pneumonia (Tables 8a-8c). Of these, ten specifically targeted VAP, and two[60, 62] addressed prevention of multiple types of HAIs including VAP. Studies were mostly performed in the United States.[107-114] Ten studies took place in a single institution and two[107, 113] in multiple hospitals. Studies primarily evaluated prevention of VAP in adult medical-surgical ICUs;[60, 107-111, 114-116] results were reported separately for medical and surgical patients in two studies.[109, 110] One study[62] was conducted in a neonatal ICU and one study[107] evaluated an intervention conducted in both adult and pediatric ICUs. Six[107, 109, 110, 113, 115, 116] of the nine studies reporting the study period were conducted within the last decade. The follow-up periods ranged from six months to 2.5 years, with a median of one year. The median baseline rate of VAP was 19.5 per 1,000 ventilator-days, but varied widely across the studies (range 5.5 – 113

episodes/1,000 ventilator-days.) By comparison, the median rate of VAP in medical-surgical ICUs at NNIS hospitals in 2003 was 4.6 per 1,000 ventilator days (interquartile range, 2.6 – 7.2) for major teaching hospitals and 5.6 per 1,000 ventilator-days at all other hospitals (IQR 2.9 – 6.7).[14]

Preventive Interventions and Outcomes Measured

We identified hand hygiene, semirecumbent patient positioning, and daily interruption of sedation and assessment of readiness to wean as target preventive interventions for this review. All included studies explicitly promoted hand hygiene, and eight[107-111, 113-115] promoted semirecumbent patient positioning; two studies[107, 113] promoted daily assessment of readiness to wean from the ventilator. Overall, many other preventive interventions were used in the studies (Table 9).

Aseptic drainage of ventilator circuit condensate, appropriate suctioning technique, and provision of oral care (including chlorhexidine mouthwash) were frequently incorporated into preventive strategies. Some studies made use of interventions that remain controversial, such as universal peptic ulcer disease prophylaxis[113] or use of heat and moisture exchangers.[107, 111, 115]

All studies focused specifically on prevention of VAP and instituted preventive interventions targeting it, with the exception of one study[62] which implemented an intervention targeting hand hygiene and measured its effects on multiple HAIs in an ICU.

Quality Improvement Strategies

All studies primarily used educational interventions targeted at providers (Tables 8a-8c). Nurses and physicians were specifically targeted in all 12 studies, and respiratory therapists in six;[107, 108, 110, 111, 115, 116] three studies[60, 113, 116] targeted all clinical staff in the ICU. Most studies combined use of written materials and lectures, with six studies[60, 107, 108, 111, 113, 115] using an explicit clinical guideline for preventive care. Three studies[109, 111, 116] used audit and feedback of infection rates to ICU staff or ICU managers, and two[108, 112] used a continuous quality improvement intervention. One[113] incorporated other organizational change strategies (establishment of multidisciplinary team rounds daily and daily assessment of patient goals on rounds). No other QI strategies were used in any included study.

Methodologic Quality of Included Studies

The methodologic quality of studies was generally poor, as all used a quasi-experimental, before-after design (Tables 8a-8c). With this limitation, the external validity of studies was generally good, as all but one[110] used CDC/NNIS definitions to diagnose VAP and all reported infection rates adjusted for device utilization (Table 10). However, the studies exhibited limitations with internal validity. Only five studies[107, 108, 110, 111, 115] reported infection rates at more than one time point before and after the intervention, and only two studies[107, 109] specifically stated that no other QI interventions took place contemporaneously. Three studies[60, 62, 111] reported both infection rates and process measures (in each case, compliance with hand hygiene protocols), and one study[114] measured only process measures (adherence to semirecumbent patient positioning). Because of the lack of controlled studies, variety of

preventive interventions used, and the wide differences in baseline rates of VAP, we did not attempt quantitative synthesis of the results. Given the generally poor methodologic quality of the results and the homogeneity of QI strategies used, we will summarize the studies that we considered to have generally stronger internal and external validity.

Before-After Studies With Good Internal and External Validity. Two studies[107, 110] conducted within the same integrated health system used an educational intervention centered around a self-study module for physicians, nurses and respiratory therapists (Table 8a). The paper-based module consisted of a comprehensive tutorial on the epidemiology, risk factors, diagnosis, and prevention of VAP, accompanied by a 20-question pretest and posttest. The preventive interventions discussed included semirecumbent patient positioning and hand hygiene. Completion of the module and passing the post-test was required for all respiratory care practitioners (RCPs) in one study[110] and was strongly encouraged for nurses in both studies. Of note, both of these studies documented the reach of the intervention by documenting the percentage of nurses and RCPs completing the module. These studies were both of similar methodologic quality, with good external validity; both studies also reported data at more than three time points before and after the intervention, but did not conduct a formal time series statistical analysis. One study[110] used the American College of Chest Physicians diagnostic criteria for VAP rather than the NNIS definition, but as the ACCP criteria are slightly more stringent, it is unlikely that this affects the applicability of the results significantly. Results revealed a statistically significant decrease in the incidence of VAP in three of the four hospitals evaluated in the two studies (one community hospital, one adult tertiary care hospital and one pediatric tertiary care hospital). Another community hospital failed to note a decrease in VAP rates but also had the lowest rate of completion of the module among RCPs. The baseline rates of VAP were lower than other included studies (8.75/1,000 ventilator days and 12.6/1,000 ventilator days respectively), but still above the pooled NNIS median during that time period.

An educational intervention targeting semirecumbent patient positioning was carried out in another study at a tertiary care hospital.[114] The study used a multifaceted intervention using clinician reminders (incorporating an order for semirecumbent positioning into standardized order sets) and interactive education for physicians and nurses; adherence was measured at baseline and at two and six months after the intervention. As VAP rate was not measured, we could not fully apply our study quality criteria. The study achieved a statistically significant improvement in the proportion of patients with the head of the bed elevated above 30 degrees (from 26 percent pre-intervention to 88 percent post-intervention.)

Table 8a. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of good methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Babcock 2004[107]	United States Multiple hospitals of different types (1 adult tertiary care, 1 pediatric tertiary care, 2 community hospitals)	1/2000-1/2001	18 months	Hand hygiene Head of bed elevation above 30 degrees Daily interruption of sedation	*QI Strategies: Clinician education* All nurses and respiratory care practitioners working in the ICU at 4 hospitals received a self-study module on preventing VAP, accompanied by pre- and post-test examinations. The self-study module contained information on the epidemiology, risk factors, clinical and economic consequences, etiology, definitions, diagnostic procedures, and risk reduction methods for VAP. All participants had to complete the module and score >80% on the post-test. The module was mandated for nurses at 3 of the 4 hospitals. The key messages were also used in posters and fact sheets in the ICU. Nursing and respiratory care staff also underwent in-service training (at scheduled training times and staff meetings). At the adult teaching hospital, respiratory care practitioners received 2 1-hr lectures on VAP.	Infection rate prior to intervention: 8.75 VAP per 1,000 ventilator-days Infection rate after intervention: 4.74 VAP per 1,000 ventilator-days p<0.01

Table 8a. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of good methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Zack 2002[110]	United States Tertiary care or university hospital	10/2000 - 9/2001	1 year	Head of bed elevation above 30 degrees	*QI Strategies: Clinician education* ICU nurses and respiratory therapists received an educational intervention targeting VAP prevention. Participants completed a 10-page self-study module with information on the epidemiology, risk factors, etiology, diagnosis, consequences, and prevention of VAP. The specific preventive interventions included: head of bed elevation >30 degrees, encouraging orotracheal intubation and orogastric tubes, early extubation and use of NIV when needed, provision of adequate sedation, avoidance of gastric over distention, provision of oral hygiene, avoiding overuse of antibiotics, and appropriate disposal of ventilator circuit condensates. Participants were required to complete a 20 question pretest and posttest before and after completing the educational module. Infection control practitioners also conducted in-services at scheduled meeting times, and respiratory therapists also received two 1-hour lectures on VAP. The RCPs completed the posttest again 6 months after completing the self-study module. The module was mandatory for all RCPs, but was not mandatory for nurses. Individuals who scored <80% on the posttest were required to repeat the module. Additionally, fact sheets and posters were posted in the ICU.	Infection rate prior to intervention: 12.6 VAP per 1,000 ventilator days Infection rate after intervention: 5.7 VAP per 1,000 ventilator days p<0.01
Helman 2003[114]	United States Tertiary care or university hospital	Not reported	6 months	Head of bed elevation above 30 degrees	QI Strategies: Clinician education, clinician reminder An intervention to improve compliance with elevation of the head of the bed above 30 degrees was carried out at a teaching hospital. The first intervention consisted of adding an order to the standardized admission order set to keep the HOB elevated. The second intervention (which took place 2 months after the first) was an educational intervention targeting all physicians and nurses. The educational session was a group discussion based on a prepared poster on HOB elevation. The session was mandatory for all physicians.	Compliance to head of bed elevation > 30 degrees: Compliance before intervention: 26% After intervention: 88% p<0.01

Before-After Studies With Moderate Internal and External Validity. A continuous quality improvement intervention was conducted in a study[111] in a community hospital, focusing on hand hygiene and semirecumbent patient positioning. The study also used audit and feedback of VAP rates to practitioners (Table 8b). Although this study had reasonable internal validity, the applicability of its results is questionable. The study was conducted in 1989, and many aspects of ICU care have changed since then, as have VAP diagnostic criteria. Nevertheless, the study did document improvement in hand hygiene after the intervention as well as a reduction in VAP rates.

A staggered educational intervention consisting of semirecumbent patient positioning and interventions targeting suctioning technique,[109] along with audit and feedback of infection rates to staff, was also successful in reducing VAP rates in both a surgical and medical ICU in a tertiary care hospital (Table 8b). The study also conducted a cost analysis showing that nearly $350,000 was saved as a result of preventing a total of 66 episodes of VAP. However, only one time point of data was provided pre-intervention, limiting the internal validity of the results.

A study conducted in two Argentinean ICUs[116] used a brief educational intervention consisting of a 1-hour lecture to all ICU staff, along with implementation of a nosocomial infection surveillance system using NNIS methodology. The study also had a markedly high rate of VAP (51.3 episodes/1,000 ventilator-days) and did document a significant reduction.

A prevention guideline recommending hand hygiene and semirecumbent patient positioning was disseminated in a study from Pakistan[115] that used a focused educational intervention, but without use of a self-study module. This study was of good internal validity, also documenting infection rates at three time points before and after the intervention. The intervention was associated with a 51 percent relative decrease in the incidence of VAP, but the authors noted that an outbreak of *Acinetobacter* VAP took place immediately before implementation of the intervention. Thus, part of the observed results may have represented regression to the mean rather than a true intervention effect.

Table 8b. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Kelleghan 1993[111]	United States Community hospital	Spring 1989-Spring 1990	18 months.	Hand hygiene Head of bed elevation above 30 degrees	*QI Strategies: Clinician education, audit and feedback, regulatory incentives* A CQI-based intervention was performed by a multidisciplinary Nosocomial Pneumonia Prevention Team consisting of members from nursing, infection control, physicians, and respiratory care. The team developed a prevention guideline for nurses and RTs consisting of hand washing, HOB elevation, ventilator care (scheduled circuit changes, suction catheter changes etc), neurologic assessment, and oral care. The guideline was presented to RNs and RTs in educational meetings including feedback on infection rates and demonstrations using equipment and mannequins. Nurses received continuing education credit for attendance. Note, new equipment (heat and moisture exchangers) were also introduced after the educational campaign was completed.	Infection rate prior to intervention: 17 VAP per 1,000 ventilator days Infection rate after intervention: 5 VAP per 1,000 ventilator days Adherence to protocols for hand hygiene: before intervention: 40% after intervention: 58% p values not reported
Lai 2003[109]	United States Tertiary care or university hospital	Second quarter of 1997 - First quarter of 1998	18 months	Head of bed elevation above 30 degrees	*QI Strategies: Clinician education, audit and feedback* A team consisting of the hospital epidemiologist, infection control practitioners, ICU directors and ICU managers developed and implemented preventive interventions. The interventions consisted of elevation of the head of the bed and changes in maintenance of nasogastric feeding tubes and prolongation of the time between changing of inline suction catheters. Infection rates were presented quarterly to ICU staff at staff meetings and via charts.	Infection rate prior to intervention: Surgical ICU: 45.1 VAP per 1,000 ventilator-days; Medical ICU: 22.4 VAP per 100 ventilator-days Infection rate after intervention: Surgical ICU: 27.9 VAP per 100 ventilator-days; Medical ICU: 11.6 VAP per 100 ventilator-days p values not supplied

Table 8b. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of moderate methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Rosenthal 2006[116]	Argentina Two non-teaching community hospitals	11/2001-12/2002	1 year	Hand hygiene	*QI Strategies: Clinician education, audit and feedback* All clinical staff received 1-hour educational sessions on VAP, discussing the epidemiology and pathogenesis, hand hygiene, proper handling of secretions and catheters, and percussion and postural drainage to stimulate coughing. Feedback of VAP rates was provided to ICU staff monthly at infection control meetings, and to ICU administrators.	Infection rate prior to intervention: 51.28 VAP per 1,000 ventilator days Infection rate after intervention: 35.52 VAP per 1,000 ventilator days p<0.01
Salahuddin 2004[115]	Pakistan Tertiary care or university hospital	1/2003-12/2003	1 year	Hand hygiene Head of bed elevation above 30 degrees	*QI Strategies: Clinician education* A clinical guideline was developed for VAP prevention by physicians and the ICU head nurse. The elements of the guideline were: hand washing, protective gown/glove use for specific groups of patients, head of bed elevation >30 degrees, avoiding gastric over distension, use of NIPPV to avoid intubations and facilitate early extubation, use of OG tubes instead of NG tubes, provide adequate sedation, prevent accidental extubation, perform oral hygiene with chlorhexidine, and removal of inline humidifiers from ventilators. An educational program, based on the guideline, was administered to ICU nursing and junior medical staff through weekly lectures, departmental presentations, "reinforcement at the bedside and visual aids posted in the ICU."	Infection rate prior to intervention: 13.2 VAP per 1,000 ventilator days Infection rate after intervention: 6.5 VAP per 1,000 ventilator days p=0.02

Before-After Studies With Poor Internal and External Validity. Five studies met all our inclusion criteria, but had methodologic flaws that seriously limited the internal or external validity of the results (Table 8c).[60, 62, 108, 113, 116] One study[108] incorporated scheduled changes of the ventilator circuit as one of the main preventive interventions; this is explicitly discouraged by both the ATS/IDSA and CDC guidelines. Another[113] restricted reporting of infection rates to studies that documented improvement in process outcomes. One study[112] provided virtually no details on the QI intervention that was conducted. Finally, a study conducted in an ICU in Guatemala combined an educational intervention on hand hygiene with an intensive educational intervention focusing on aseptic suctioning technique.[60] The hospital had no formal infection control mechanisms in place prior to the study and had a remarkably high baseline rate of VAP (113/1,000 ventilator-days). Although the rate was reduced substantially, it remained high

(40/1,000 ventilator-days) post-intervention. The study did document markedly improved compliance with hand hygiene. The rates of other HAIs (CAUTI, SSI, and CLABSI) did not change.

Table 8c. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of poor methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
*Berg 1995[60]	Guatemala Tertiary care or university hospital	Not specified	1 year	Hand hygiene	*QI Strategies: Clinician education* A multifaceted intervention was used to target nosocomial infections in the ICU, with both general measures and measures targeting VAP and CAUTI. Nurses and physicians received 15 educational sessions on aseptic technique, stressing proper hand washing. The educational sessions used lectures and demonstrations, and individual clinicians also received positive and negative feedback and reminder signs at the bedside. The VAP intervention targeted proper use of sterile rinse water and improvement in aseptic technique for suctioning. Providers received more than 15 interactive conferences on the detection, management, and prevention of nosocomial pneumonia; these included lectures, demonstrations, individual instruction and feedback, and contests. The CAUTI intervention consisted of changing open urinary drainage systems to closed systems (aseptic catheter care), with an educational session on the new catheter. The intervention did not specifically target surgical site infections, but those outcomes are reported.	Infection rate prior to intervention: 113 VAP per 1,000 ventilator-days Infection rate after intervention: 40 VAP per 1,000 ventilator-days p<0.01 Adherence to protocols for hand hygiene: Before intervention: 5% After intervention: 63% p<0.01
Joiner 1996[108]	United States Tertiary care or university hospital	5/1992-9/1992	2.5 years	Hand hygiene Head of bed elevation above 30 degrees	*QI Strategies: Clinician education, organizational change* A QI team (including physicians, respiratory therapists, ICU nurses, infection control practitioners, and quality managers) brainstormed to develop practice guidelines for preventing VAP. These guidelines were developed into a standardized protocol and presented to staff in a presentation and at staff meetings. VAP rates were reviewed monthly and shared with departments. A continuous quality improvement method was used to review data and revise the intervention as needed.	Infection rate prior to intervention: 26 VAP per 1,000 ventilator-days Infection rate after intervention: 16 VAP per 1,000 ventilator-days p value not reported

Table 8c. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Resar 2005[113]	United States Multiple hospitals of different types	2002-2004	6 months	Head of bed elevation above 30 degrees Daily interruption of sedation	*QI Strategies: Clinician education, organizational change* Report of 61 hospitals who participated in the IHI IMPACT network. Teams of critical care physicians from each organization attended collaborative meetings, beginning with a half-day introductory course on change concepts. The "ventilator bundle", consisting of PUD prophylaxis, DVT prophylaxis, HOB elevation, and sedation vacation, were the key concepts targeted for implementation, and the collaborative meetings sere devoted to implementation methods. ICU's implemented multidisciplinary rounds and daily patient goals at a minimum.	For medical-surgical ICUs Infection rate prior to intervention: 5.5 VAP per 1,000 ventilator days Infection rate after intervention: 2.7 VAP per 1,000 ventilator days p value not reported
Nicotra 1996[112]	United States Single hospital, type not specified	12/1991-5/1994	18 months	Hand hygiene	*QI Strategies: Clinician education, organizational change* A continuous quality improvement style intervention was implemented to reduce VAP. A multidisciplinary task force developed a process improvement plan consisting of implementation of a closed suction device, and changes in cleaning and maintenance of ventilator units. A survey was performed which revealed a lack of knowledge among nurses about preventive interventions for VAP. Thus, an educational program on VAP was conducted for nurses, consisting of information about hand washing, suctioning, other preventive measures (such as patient mobilization, respiratory care, maintaining hydration, assessing nutritional status, and review of drugs for stress ulceration), as well as general infection control measures.	Infection rate prior to intervention: 22 VAP per 1,000 ventilator days Infection rate after intervention: 8.3 VAP per 1,000 ventilator days p values not reported

Table 8c. Articles addressing prevention of ventilator-associated pneumonia: simple before-after studies of poor methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
**Lam 2004[62]	Hong Kong Tertiary care or university hospital	Not specified	10 months	Hand hygiene	*QI Strategies: Clinician reminder; organizational change* Nurses and physicians received an educational program targeting hand hygiene. A hand hygiene protocol was implemented as part of the orientation for new staff. Face-to-face educational seminars were conducted for nurses and physicians where solutions to overcome obstacles to hand washing were provided; 2 sessions were provided for physicians and 10 for nurses. A task-oriented analysis was performed to identify strategies for hand washing during complex procedures. Demonstrations were conducted at regular intervals, and reminder pictures were posted at each hand washing basin.	Infection rate prior to intervention: 16.9 VAP per 1,000 ventilator days Infection rate after intervention: 6.4 VAP per 1,000 ventilator days p=NS Adherence to protocols for hand hygiene: before intervention: 40% after intervention: 53% p<0.01

*This study addresses prevention of surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections.
**This study addresses prevention of central line-associated bloodstream infections and ventilator-associated pneumonia.

Table 9. Other preventive interventions used in studies addressing ventilator-associated pneumonia

Author	Continuous aspiration of subglottic secretions	Avoidance of scheduled ventilator circuit changes	Use of heat and moisture exchangers	Universal peptic ulcer disease prophylaxis	Aseptic suctioning technique	Aseptic drainage of ventilator circuit condensate	Oral care	Other interventions
Babcock 2004[107]	○	●	●*	○	●	●	●	Avoid gastric overdistension; provide immunizations for influenza and pneumococcus
Berg 1995[60]	○	○	○	○	●	●	○	
Joiner 1996[108]	○	○	○	○	●	●	●	
Lai 2003[109]	○	○	○	○	○	○	○	Replacement of stopcocks with enteral valves for nasogastric feeding tubes; changing of in-line suction catheters as needed instead of every 24 hours
Lam 2004[62]	○	○	○	○	○	○	○	
Salahuddin 2004[115]	○	○	●	○	○	○	●	Monitor gastric residual volume; use noninvasive positive pressure ventilation (NIPPV) to avoid intubation and facilitate extubation; use orogastric tubes
Zack 2002[110]	○	○	○	○	○	●	●	Use orogastric tubes; avoid gastric overdistension; use NIPPV when possible; provide immunizations for influenza and pneumococcus
Kelleghan 1993[111]	○	○	●	○	●	●	●	Avoid gastric overdistension
Nicotra 1996[112]	○	○	○	○	▲*	▲*	○	
Resar 2005[113]	○	○	○	●	○	○	○	Multidisciplinary rounds in ICU; daily patient goals; DVT prophylaxis
Rosenthal 2006[116]	○	○	○	○	●	●	○	Percussion and postural drainage to stimulate coughing

●: Yes ○: No ▲: Unclear

* - Babcock 2004[107]: heat and moisture exchangers contraindicated in patients with "excessive secretions", but otherwise recommended.

* - Nicotra 1996[112]: nurses "received information" on suctioning and handling of ventilator tubing, but does not specifically state that aseptic technique was discussed.

Table 10. Quality criteria for simple before-after studies addressing ventilator-associated pneumonia

	Internal Validity			External Validity	
Author	**Did the study report data on more than one time point before and after the intervention?**	**If the study reported infection rates, did it also report process measurements?**	**Was the intervention performed independent of other QI efforts or other changes?**	**Did the study use NNIS/CDC methods for measuring infections?**	**Did the study report infection rates in terms of device utilization?**
Babcock 2004[107]	●	○	●	●	●
Berg 1995[60]	○	●	▲	●	●
Helman, 2003[114]	○	Not applicable	●	Not applicable	Not applicable
Joiner 1996[108]	●	○	▲	●	●
Lai 2003[109]	○	○	●	●	●
Lam 2004[62]	○	●	▲	●	●
Salahuddin 2004[115]	●	○	▲	●	●
Zack 2002[110]	●	○	▲	○*	●
Kelleghan 1993[111]	●	●	▲	●	●
Nicotra 1996[112]	○	○	▲	●	●
Resar 2005[113]	○	○	▲	▲†	●
Rosenthal 2006[116]	○	○	▲	●	●

●: Yes ○: No ▲: Unclear

* - The study used the American College of Chest Physicians criteria for diagnosis of VAP.
† - 84% of participating hospitals used CDC/NNIS definitions for measuring VAP rates. The methods used by the remaining hospitals were not specified.

Catheter-Associated Urinary Tract Infection

Included Studies: Settings, Goals, and Target Populations

Our search identified ten articles that addressed prevention of catheter-associated urinary tract infections (Tables 11a-11e). All explicitly sought to reduce the incidence of CAUTI and/or reduce unnecessary urethral catheterization, with the exception of one study (discussed previously[60] in the VAP section) that introduced a hand hygiene intervention and reported its effects on VAP, SSI, and CAUTI. Six of ten included studies[60, 61, 117-120] were performed outside the U.S. An equal number of studies targeted CAUTI in ICU patients[60, 61, 119-121] and general inpatient ward patients.[117, 118, 122-124] All studies targeted adult patients. The baseline rate of CAUTI varied from 10.3 to 36 UTI per 1,000 urethral catheter-days (median, 15.1/1,000 catheter-days). By comparison, the NNIS mean for medical-surgical ICUs in 2003 was 3.3 CAUTI per 1,000 catheter-days (IQR 2.1 – 5.2/1,000 catheter-days) in major teaching hospitals and 3.1 (IQR 1.6 – 5.1) per 1,000 catheter-days in non-teaching hospitals.

Preventive Interventions and Measured Outcomes

We identified reduction in unnecessary catheter use, aseptic insertion and catheter care, and hand hygiene as key preventive interventions for CAUTI. Of the included studies, six[118, 119, 121-124] explicitly addressed reduction in placement of catheters or removal of unnecessary catheters once already placed, four[61, 117, 120, 121] addressed aseptic insertion and catheter care, and two[60, 120] hand hygiene. Among the four studies addressing insertion and catheter care, three[117, 120, 121] implemented specific guidelines for catheter care after insertion, and one[121] addressed catheter insertion technique.

The measured outcomes varied across studies. Seven studies measured CAUTI rate, measured as rate of symptomatic CAUTI in six studies[60, 61, 119-122] and asymptomatic bacteriuria in one.[123] Five studies measured catheter usage,[118, 119, 122-124] reported as the percentage of inpatients catheterized in three studies[118, 122, 124] and the average duration of catheterization in two others.[119, 123] Two studies, both of which implemented a catheter care policy[117, 120] reported the rate of adherence to the policy (Tables 11a-11e).

Quality Improvement Strategies

Provider reminders were used in six studies,[61, 118, 119, 122-124] all of which sought to reduce unnecessary catheter use through a printed[61, 118, 119, 122] or computerized[123, 124] reminder to physicians (Tables 11a-11e). Six studies[60, 61, 117, 120-122] used provider education, specifically targeting nurses in one study[117] and all clinical staff in the others. Two studies[61, 120] used audit and feedback and two[121, 122] used an organizational change strategy by allowing nurses to remove urethral catheters without a physician order.

Methodologic Quality of Included Studies

We identified three controlled before-after (CBA) studies[117, 123, 124] and seven simple before-after studies.[60, 61, 118-122] The CBA studies were generally of fair methodologic quality. With

regards to factors affecting internal validity, the rationale for selection of the control group was not explained in any of the three studies, and no study reported if outcomes assessors were blinded to treatment group assignment. None of these studies reported CAUTI rate as a primary outcome, instead focusing on process measures (duration of urethral catheterization in two studies[123, 124] and adherence to a guideline for urethral catheterization in one[117]). This likely serves to increase their external validity, given the inherent difficulty in comparing CAUTI rates between hospitals.

The methodologic quality of the SBA studies was moderate within the limits of the study design. All studies reporting infection rates reported rates (Table 12) adjusted for device utilization, and all but one[61] used NNIS definitions. However, only two studies reported data at more than one time point before and after the intervention[61, 121] and three of seven studies reporting infection rates[60, 119, 120] reported process measures as well.

We will separately discuss the results of the studies addressing reduction in catheter usage and the studies addressing catheter care.

Studies Addressing Reduction in Catheter Usage

Seven studies[61, 118, 119, 121-124] sought to reduce urethral catheter usage, 5[118, 119, 122-124] through use of a paper- or computer-based reminder to clinicians (Table 11a). Two[123, 124] were controlled studies and five[61, 118, 119, 121, 122] were simple before-after studies.

Reminders incorporated into an existing computerized physician order entry system were used in two studies,[122, 123] one CBA[123] and one SBA.[122] In a controlled crossover trial at an academic medical center,[123] the intervention consisted of a computerized order requiring an indication for catheter placement and a default 72-hour stop date for the catheter. The intervention successfully reduced the duration of catheterization on the study ward, but was not powered to detect a difference in CAUTI. A similar CPOE reminder with a 48-hour automatic stop date was used in another study,[122] but in addition, nurses were empowered to discontinue catheters independent of a physician order according to a prespecified protocol. Significant reductions in both catheter use and CAUTI rates were demonstrated, albeit in the setting of a relatively high baseline rate of CAUTI (36/1,000 catheter-days.)

Three studies[118, 119, 124] used a paper-based reminder. A controlled trial[124] used a chart prompt to physicians after a catheter had been in place for 48 hours, asking for a specific clinical indication to continue catheterization. Although hampered by initial implementation problems, the study did significantly reduce the percentage of days patients were catheterized compared to control. There was no difference in the need for urethral re-catheterization after catheter removal between intervention and control groups. A similar indication sheet was used in another before-after study[118] requiring documentation of the indication for catheterization before it could be placed, but this failed to reduce the overall rate of catheterization. Nurses were required to remind physicians to remove unnecessary catheters five days after insertion in a before-after study;[119] this intervention significantly reduced both the mean duration of catheterization and CAUTI rates in ICU patients.

Finally, one study[121] conducted in ICU patients empowered nurses to remove catheters without a physician order if prespecified indications were met. Nurses also received an educational intervention on catheter care. The intervention reduced CAUTI rates in all three ICUs studied.

Table 11a. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing reduction in catheter usage): controlled studies

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Cornia 2003[123]	United States Tertiary care or university hospital	11/2000 - 3/2001	8 weeks	Removal of unnecessary catheters	*QI Strategies: Clinician reminder* Resident physicians were required to enter an order for urinary catheter placement in the hospital's computerized physician order entry (CPOE) system. The computer study order required that an indication be selected for placement, provided routine catheter care instructions, and had a default stop date of 72 hours after placement. A reminder appeared after 72 hours asking the ordering physician to renew or discontinue the catheter order. Physicians had the option of using the computer order, a written order, or no order.	Mean duration indwelling catheter in place (first study period): Control: 6.63 days Intervention: 4.72 days p<0.01 Mean duration indwelling catheter in place (second study period): Control group: 8.53 days Intervention group: 5.56 days p<0.01
Saint 2005[124]	United States Tertiary care or university hospital	6/2001-12/ 2002	8 months	Removal of unnecessary catheters	*QI Strategies: Clinician reminder* A printed reminder was attached to the physician notes in the charts of patients who had a urinary catheter in place for >48 hours. The reminder required the physician to either order removal of the catheter or check a specific reason for continuing the catheter (among 6 reasons that were specified.) Initially, the reminders were frequently ignored, so plastic tape flags asking physicians to "sign here" and alphanumeric reminder paging were used to increase compliance with the reminder.	Rate of use of indwelling urinary catheters *Control*: prior to intervention: 27.8% of patients after intervention: 32.0% of patients *Intervention:* before intervention: 14.4% of patients after intervention: 13.3% of patients p value not reported

Table 11b. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing reduction in catheter usage): simple before-after studies of moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
*Greco 1991[61]	Italy Multiple hospitals of different types	12/1988 – 6/1989	19 months	Aseptic insertion and catheter care	*QI Strategies: Clinician education, audit and feedback, clinician reminder* Series of meetings with surgeons and nurses from each of participating wards. Data on infection incidence and practices were discussed and best practices reviewed including: appropriate use of perioperative antibiotics (pre-operative, limited duration, appropriate selection), avoidance of preoperative shaving, closed drainage of urinary catheters and surgical drains, implementation of respiratory exercises, use of hygienic measures for Urinary catheters.	UTI associated with indwelling catheters: Infection rate prior to intervention: 12.9 per 100 urinary catheters Infection rate after intervention: 11.9 per 100 urinary catheters p=NS
Danchaivijitr, 1992[118]	Thailand Multiple hospitals of different types	Not specified	Not specified	Reduction in placement of catheters	*QI Strategies: Clinician reminder* An "indication sheet" was attached to charts. This sheet listed indications for urethral catheterization and was to be filled out by prescribers. It listed 5 specific indications for catheterization (urinary retention, recording hourly urine output, injury to urethra, irrigation of urinary bladder, and "other"); prescribers were to order catheterization only for one of the specific indications.	Rate of use of indwelling catheters: before intervention: 8.1% of patients after intervention: 8.6% of patients p=NS
Huang 2004[119]	Taiwan Tertiary care or university hospital	1/2002-12/2002	1 year	Removal of unnecessary catheters	*QI Strategies: Clinician reminder* Nursing staff reminded physicians daily to remove urinary catheters if they were no longer needed five days after being inserted. Catheters were placed or removed at the discretion of the physicians in charge.	Rate of symptomatic urinary tract infection: Infection rate prior to intervention: 11.5 per 1,000 catheter-days Infection rate after intervention: 8.3 per 1,000 catheter-days p<0.01 Mean duration indwelling catheter in place: before intervention: 7.0 days after intervention: 4.6 days p<0.01

Table 11b. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing reduction in catheter usage): simple before-after studies of moderate methodologic quality (continued)

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Dumigan 1998[121]	United States Community hospital with residents	5/1996-10/1997	18 months	Aseptic insertion and catheter care Removal of unnecessary catheters	*QI strategies: Clinician education, organizational change* Multidisciplinary effort used to reduce CAUTI was implemented according to plan-do-check-act methodology. Multidisciplinary committee (including physicians, nurses, and infection control practitioners) created protocols for physicians, nurses, and the laboratory regarding urinary catheter use and procedures. Physicians were targeted by creating a list of indications for catheter use. Nurses received a video presentation on insertion technique and standardized protocols for catheter care. Indications for removing catheters were developed, and nurses were allowed to remove catheters without a physician's order if they were present. After protocols were developed, an extensive educational campaign was used to disseminate them to nurses, housestaff, and attending physicians. Note: an audit/feedback intervention (feedback of CAUTI infection rates) was in place prior to the intervention.	Rate of symptomatic urinary tract infection: Infection rate prior to intervention (CAUTI per 1,000 catheter-days): SICU: 10.3, MICU, 15.8, CICU, 15.1 Infection rate after intervention: SICU: 8.6; MICU: 11.2; CICU: 8.3. p value 0.03 for CICU only; NS for others
Topal 2005[122]	United States Tertiary care or university hospital	Fall 2002-Spring 2003	18 months	Reduction in placement of catheters / Removal of unnecessary catheters	*QI strategies: Clinician education, clinician reminder, organizational change* Three interventions were implemented to reduce urinary catheter use and CAUTI. Physicians were prompted (using the computerized physician order entry system) to discontinue catheters, maintain catheters for 48 hours, or maintain catheters chronically each time a catheter was placed in the ED. Physician and nursing staff were educated on lower-risk alternatives to indwelling devices. A nurse-driven protocol was introduced to allow nurses to discontinue catheters independent of a physician's order when patients no longer met criteria for catheter use. Bladder scanners were purchased to allow nurses to assess for urinary retention.	Rate of symptomatic urinary tract infection: Infection rate prior to intervention: 36 per 1,000 catheter-days Infection rate after intervention: 11 per 1,000 catheter-days $p<0.01$

* This study addresses prevention of surgical site infections and catheter-associated urinary tract infections

Studies Addressing Catheter Care

Two studies conducted educational interventions on catheter care with implementation of a clinical guideline in order to reduce CAUTI (Tables 11c-11e). A controlled before-after trial in general ward patients[117] introduced an infection control liaison nurse to conduct the intervention and found an improvement in adherence to the guideline for catheter care on the study wards compared to the control wards. The study did not measure CAUTI rates. The other study[120] was a simple before-after trial in ICU patients that also used audit and feedback of infection rates. The intervention was associated with increased guideline adherence, increased compliance with hand hygiene, and a reduced rate of CAUTI.

Finally, one study discussed previously in the VAP section[60] introduced an educational intervention targeting hand hygiene in an ICU in Guatemala (Table 11e). No effect on CAUTI was found, although adherence to hand hygiene protocols did improve.

Table 11c. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing catheter care): controlled studies

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Ching 1990[117]	Hong Kong Tertiary care or university hospital	Not specified	Not specified	Aseptic catheter care	*QI Strategies: Clinician education* An infection control liaison nurse was selected for each ward in the intervention group, with another nurse appointed as their assistant. The ICLNs and the assistants received a 3-hour interactive training session from the infection control team on a new guideline for appropriate urinary catheter care. The guideline recommended proper securing of the catheter, preventing the catheter and tube from kinking, and emptying the draining spigot into a collecting container. The ICLNs then presented demonstration tutorials and lectures to regular ward nurses in the intervention wards. The tutorials were in small groups and attendance was mandatory; the lecture was a 30-minute lecture on the new guideline. The control wards received only the lectures.	Adherence to a clinical guideline for preventing UTI: *Control:* before intervention: 32.2% after intervention: 51.8% *Intervention:* before intervention: 37.9% after intervention: 64.0% p value for comparison <0.01

Table 11d. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing catheter care): simple before-after studies of moderate methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
Rosenthal 2004[120]	Argentina Private hospital	1/2001-9/2002	22 months	Hand hygiene Aseptic catheter care	*QI Strategies: Clinician education, audit and feedback* An educational intervention with performance feedback was delivered to ICU staff. The education focused on compliance with handwashing before catheter insertion, and positioning the catheter to avoid compression of the catheter by the patient's leg. It is not clear if the intervention targeted nurses, physicians, or both. Feedback on compliance with these practices was provided to ICU staff (through posters in the ICU) and at infection control meetings. Compliance rates and CAUTI rates were fed back to the ICU administrators.	Rate of symptomatic urinary tract infection: Infection rate prior to intervention: 21.3 per 1,000 catheter-days Infection rate after intervention: 12.39 per 1,000 catheter-days p<0.01 Adherence to protocols for hand hygiene: before intervention: 23.1% after intervention: 65.2% Compliance with aseptic insertion and catheter care guidelines: before intervention: 83% after intervention: 96% p<0.01 for both process measures

Table 11e. Articles addressing prevention of catheter-associated urinary tract infections (studies addressing catheter care): simple before-after studies of poor methodologic quality

Author	Setting and Hospital Type	Study period	Length of follow-up	Preventive Interventions	Quality improvement intervention	Results
*Berg 1995[60]	Guatemala Tertiary care or university hospital	Not specified	1 year	Hand hygiene	*QI Strategies: Clinician education* A multifaceted intervention was used to target nosocomial infections in the ICU, with both general measures and measures targeting VAP and CAUTI. Nurses and physicians received 15 educational sessions on aseptic technique, stressing proper hand washing. The educational sessions used lectures and demonstrations, and individual clinicians also received positive and negative feedback and reminder signs at the bedside. The VAP intervention targeted proper use of sterile rinse water and improvement in aseptic technique for suctioning. Providers received more than 15 interactive conferences on the detection, management, and prevention of nosocomial pneumonia; these included lectures, demonstrations, individual instruction and feedback, and contests. The CAUTI intervention consisted of changing open urinary drainage systems to closed systems (aseptic catheter care), with an educational session on the new catheter. The intervention did not specifically target CLABSI, but those outcomes are reported.	Rate of symptomatic urinary tract infection: before intervention: 18 per 1,000 catheter-days after intervention: 13 per 1,000 catheter-days p=NS Adherence to protocols for hand hygiene: Before intervention: 5% After intervention: 63% p<0.01

*This study addresses prevention of surgical site infections, central line-associated bloodstream infections, ventilator-associated pneumonia and catheter-associated urinary tract infections.

Table 12. Quality criteria for simple before-after studies addressing catheter-associated urinary tract infections

	Internal Validity			External Validity	
Author	**Did the study report data on more than one time point before and after the intervention?**	**If the study reported infection rates, did it also report process measurements?**	**Was the intervention performed independent of other QI efforts or other changes?**	**Did the study use NNIS/CDC methods for measuring infections?**	**Did the study report infection rates in terms of device utilization?**
Berg 1995[60]	○	●	▲	●	●
Danchaivijitr, 1992[118]	○	N/A	▲	N/A	N/A
Greco 1991[61]	●	○	○	○	●
Huang 2004[119]	○	●	●	●	●
Rosenthal 2004[120]	○	●	●	●	●
Topal 2005[122]	○	○	▲	●	●
Dumigan 1998[121]	●	○	▲	●	●

●: Yes ○: No ▲: Unclear

Chapter 4. Discussion

Although many studies have been published documenting the effect of quality improvement initiatives on prevention of healthcare-associated infections, the published literature is of poor methodologic quality overall and does not consistently demonstrate the effectiveness of any specific strategy to either reduce infection rates or improve adherence to recommended preventive interventions. The available evidence does identify several promising strategies that merit more rigorous evaluation and may be appropriate for wider implementation. In the following sections, we will summarize our findings for prevention strategies for each target HAI, based on the few controlled studies and simple before-after studies with moderate to good methodologic quality.

Surgical Site Infection

Limited data (consisting of two interrupted time series[67, 86] and one before-after study[19]) indicate that educational interventions coupled with audit and feedback may be effective at improving adherence to recommended strategies for SSI prevention, specifically appropriate antibiotic prophylaxis. Importantly, these strategies resulted in significant improvements in appropriate antibiotic timing, which has been documented to be deficient in U.S. hospitals. Clinician reminders may also improve perioperative antibiotic prophylaxis (one RCT, one CBA, one SBA), especially when incorporated into a computerized physician order entry system. No conclusion can be reached regarding the effectiveness of educational interventions alone on improving antibiotic prophylaxis practices. We also could not determine the effectiveness of QI strategies at promoting perioperative glucose control, perioperative normothermia, or decreasing operative site shaving, as very few studies reported data on these process measures.

We were also unable to determine any strategies effective at reducing SSI rates. Overall, SSI rates were statistically significantly reduced in five of 18 studies reporting this measure. In studies that did not have important methodologic flaws, surgical site infection rates were not consistently reduced, even when process measurements were improved. One study using an explicit "bundle" of interventions did improve process measures[19] but not infection rates. Audit and feedback of SSI rates has been widely advocated, but the effect on surgical site infection rates is not clear. This strategy was evaluated in three multicenter studies (two ITS, one CBA[66]), with inconsistent results.

Central Line-Associated Bloodstream Infections

Two controlled studies,[94, 99] one interrupted time series,[96] and four simple before-after studies[88, 89, 92, 93] of relatively good methodological quality used active educational interventions to significantly reduce the incidence of CLABSI. These interventions used demonstrations and self-study tutorials to improve adherence to preventive practices during catheter insertion. These educational interventions have been evaluated in teaching and non-teaching hospitals, and in U.S. and European institutions, increasing their generalizability. Two studies[94, 96] used an explicit checklist to be filled out during line insertion, with nurses empowered to stop the procedure if all preventive interventions were not used, and documented marked reductions in CLABSI rates. This strategy may be worthy of wider implementation given its apparent success

in a large population of ICUs in one study.[96] We were unable to determine which QI strategies are effective at improving specific preventive interventions, as the studies documenting reduced CLABSI rates did not consistently report process measures.

Ventilator-Associated Pneumonia

Active educational interventions with use of a self-study module for ICU staff appear to be a promising strategy for reducing VAP rates, based on two SBA studies.[107, 110] These studies used explicit clinical guidelines for preventing VAP, incorporating promotion of semirecumbent patient positioning and hand hygiene along with oral care, handling of ventilator condensate, and other interventions. No conclusion can be reached on the effectiveness of audit and feedback or other QI strategies on VAP rates. One SBA study effectively improved adherence to semirecumbent patient positioning using an educational- and reminder-based intervention.[114]

Catheter-Associated Urinary Tract Infection

Reminders to clinicians appear to be effective at reducing unnecessary catheter usage, primarily by reducing the duration of catheterization (two CBA studies[123, 124] and two SBA studies[119, 122]). A key element of these studies was the use of an "automatic stop order" mandating discontinuation of the catheter after a specific time period (48 to 72 hours) unless the physician countermands the order. Three SBA studies using automatic stop orders were also associated with reduced CAUTI rates.[119, 121, 122] Two of these studies[121, 122] allowed nurses to remove catheters without a physician order if prespecified indications were met, an intervention worthy of future study. We could not determine the effect of other QI strategies on either infection rate or process measures. The safety of these interventions—i.e., the need for urethral re-catheterization—has not been adequately assessed; however, although re-catheterization is undoubtedly uncomfortable and inconvenient for patients, it is unlikely to lead to lasting harm. There is insufficient evidence supporting the utility of guidelines for catheter care.

Limitations

The quality of included studies was poor. Across all four target HAIs, 52 of 64 included studies used a quasi-experimental, before-after design. Even within the limitations of this study design, most studies had poor internal validity, chiefly due to reporting data at only one time point before and after the intervention (33 of 52 studies). Whether the study reported infection rates or process measures (or both), it is very difficult to attribute an improvement in outcomes to the intervention on the basis of two data points. The baseline level of HAI rates were generally relatively high in most studies, and were above the pooled NNIS median for CLABSI, VAP, and UTI. While the NNIS data is not recommended for direct inter-hospital comparisons, the relatively high baseline rates raise the concern that the observed improvement (especially in before-after studies) could be due to regression to the mean, or even that institutions were motivated to study interventions to decrease HAI because of their unusually high infection rates. This may simply reflect the fact that many included studies were likely performed as documentation of ongoing quality improvement efforts, and not with a specific research agenda. Reporting of more time points of baseline data would provide assurance that an acute outbreak

had not temporarily elevated baseline infection rates, and reporting of more data points after the intervention would provide greater assurance about the true intervention effect and its sustainability. Studies generally used NNIS definitions and used appropriate adjustment for device utilization, but given the problems with internal validity, the vast majority of studies cannot be considered generalizable.

We identified only one randomized controlled trial, eight controlled before-after trials, and three interrupted time series. These studies also exhibited problems with methodologic quality, especially among the CBA studies, in which the majority did not document the rationale for the selection of the control group. None of the controlled trials documented blinding of the outcomes assessors.

Reporting of infection rates without reporting accompanying process measures was common in our included studies. Of the 47 before-after studies reporting infection rates, only 24 reported data on the process measures targeted by the intervention. Accomplishing full adherence to recommended care can be difficult even in a clinical trial setting; a recent randomized trial of semirecumbent patient positioning found that the target elevation of the head of the bed (45 degrees) was not achieved in 85 percent of patients randomized to semirecumbent positioning,[125] even with the presence of a dedicated research nurse assisting with intervention implementation. Given the inherent difficulties present in measuring HAI rates, and the lack of validated methods for inter-hospital comparisons of HAI rates, it is very important for process measures to be documented and reported. However, many of our included studies implemented an intervention with the intention of improving process measures, found a reduction in infection rates, and reported that the intervention must have been effective at improving the process, without actually documenting so. This is a particular concern in studies using passive interventions such as guideline dissemination and lectures. Past research has demonstrated that passive interventions are unlikely to achieve significant improvements in provider behavior,[126] and thus it is unlikely that significant improvement in infection rates should occur as a result of such interventions if the appropriate process measures are not in fact improved.

Although several studies used an explicit clinical guideline for preventing HAIs (particularly the studies using educational interventions with self-study tutorials to target CLABSI and VAP), only two studies[19, 113] directly assessed implementation of the "bundles" recommended by the IHI. The organization makes the point that setting the target of complete adherence to a bundle of processes "sets the bar high" and motivates overall system redesign rather than targeted single-process interventions,[44] but there are no data to support this theoretically attractive claim. The IHI also recommends specific QI strategies for implementing the "bundles", such as audit and feedback of infection rates and all-or-none measurements, and use of multidisciplinary rounds and setting daily patient goals for ICU patients.[7] The very limited published data does not allow evaluation of the effectiveness of these strategies. The recommendations of the "100,000 Lives" campaign are being widely implemented in U.S. hospitals, providing an excellent opportunity for conducting higher-quality studies to determine effective implementation strategies.

In this review, the vast majority (30 of 39) of the studies reporting adherence to process measures reported a statistically significant improvement in adherence. This striking lack of reporting of negative results is highly likely to be a manifestation of publication bias. Although this trend was not as evident among studies reporting infection rates, 21 of 33 studies reporting CLABSI, VAP, or CAUTI rates found a statistically significant improvement. Thus, even the

limited conclusions we are able to draw from the evidence may not be representative of overall experience with these strategies.

Other methodologic problems in the included studies are similar to those identified in previous volumes in this series. While most studies identified a baseline quality gap (generally an elevated HAI rate compared to benchmark standards), the majority did not specifically identify barriers to implementation of evidence-based practices or tailor their intervention to overcome barriers. Most studies provided few details on the intervention, particularly with regards to the intensity of the intervention and its reach (the extent to which those targeted by the intervention actually received it). Most studies did not state if other QI interventions were underway simultaneously. The median length of follow up was approximately one year across all studies, which is likely too short to confirm a sustained improvement in either infection rates or process measures.

Because of the limited number of controlled trials, we were unable to perform any quantitative analyses such as median effects analysis. We are thus unable to obtain any estimate of the magnitude of the effect that hospitals implementing these strategies may hope to achieve. Very few studies reported on any potential adverse effects of the intervention, and no high-quality studies assessed the cost-benefit of the intervention.

Conclusions

Due to the extensive limitations in the primary data outlined above, we are not able to make any firm recommendations for organizations seeking to implement quality improvement interventions to reduce healthcare-associated infections. Quality improvement efforts in infection control are active, and thus we make the following recommendations for further study in this area.

1. Preliminary data indicates that several strategies are worthy of future study.

Based on limited evidence, the following quality improvement strategies to reduce healthcare-associated infections could be considered for wider implementation, if higher-quality studies confirm their effectiveness:

- Printed or computer-based reminders with use of automatic stop orders to reduce unnecessary urethral catheterization. This is the only strategy we identified that is supported by more than one controlled study.

- Printed or computer-based reminders for improving adherence to recommendations for timing and duration of surgical antibiotic prophylaxis;

- Staff education using interactive tutorials (including video and web-based) and checklists, to improve adherence to insertion practices for placement of central venous catheters;

- Staff education, including use of interactive tutorials, to improve adherence to preventive interventions to prevent ventilator-associated pneumonia.

2. Higher quality studies of QI strategies to implement preventive interventions are urgently needed.

Given the prevalence of HAIs and the associated morbidity and mortality, there is a great need for information on how to improve adherence to preventive interventions. We recognize that conducting controlled trials may not be practical for many investigators for cost and feasibility reasons; as well, it may be unethical to randomize subjects to receive or not receive preventive interventions. If performing a controlled trial is impractical, investigators should perform interrupted time series analyses to demonstrate that a QI intervention is truly effective. At least three time points of data should be reported before and after a clearly defined intervention time period, and a formal ITS statistical analysis should be conducted. Studies should ideally report the effect of the intervention on both process measures (adherence to recommended preventive interventions) and infection rates. Studies should also document if other QI efforts were underway simultaneously, and use standardized definitions for measuring and reporting HAIs. Formal evaluation of the cost-benefit of the intervention should be conducted, and adverse events should be documented.

We acknowledge that even conducting higher-quality nonrandomized trials may pose logistical challenges. Monitoring infection rates over a sustained period of time requires adequate infection control resources, which may not currently be in place at many U.S. hospitals.[127, 128] In an era of public reporting of infection rates, hospitals may feel pressured to respond quickly to increases in measured infection rates, even if these rates may not be directly tied to poor adherence to preventive practices. Measuring adherence to preventive interventions is resource intensive,[129] and requires additional trained personnel. If public reporting of infection rates becomes more widespread, as seems likely, investment in infection control resources will be necessary in order to adequately monitor infection rates and process measures and continue study of implementation of effective preventive measures.

We also believe that there are potential cross-cutting opportunities, in which interventions proven to work for one target should be considered for others. For example, empowering nurses to remove urinary catheters when patients met prespecified criteria, when coupled with earlier studies that demonstrated the value of respiratory-therapist-driven ventilator weaning algorithms,[130] may point the way to more interventions managed by nonphysician providers, working under carefully crafted protocols. Another example is empowering nurses to stop central venous catheter insertion if a checklist of preventive interventions is not followed; empowering nonphysician providers in this fashion could be applied to preventive interventions for many HAIs.

We emphasize that the level of evidence supporting these strategies is below that supporting the recommendations made in prior volumes of this series.[47, 48] Thus, we are unable to recommend strongly that these QI strategies be more widely implemented, as--in addition to the poor quality of supporting evidence--the potential adverse consequences and cost-benefit of these strategies has not been assessed. Wider implementation of these measures (most of which do not appear to be complex or costly) should be feasible, but should only be performed if a formal plan for evaluating their effectiveness is in place.

The lack of strong evidence supporting use of specific QI strategies should not be taken to mean that ongoing QI efforts in HAI prevention have been uniformly unsuccessful, or that current strategies should not be continued. Population-level data from Europe shows that HAI incidence can be reduced through use of infection control surveillance,[131] and some institutions

have documented sustained reductions in specific HAI.[105, 106] The mechanisms behind these successes and the best means of translating them into other settings remain to be determined. High-quality evidence exists to support many preventive interventions that are very effective at reducing HAI incidence. Given the huge toll in human lives, antibiotic use (leading to more resistant infections) and costs caused by hospital-acquired infections, efforts to better understand how to implement these interventions should be prioritized.

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List of Acronyms/Abbreviations

Acronym/Abbreviation	Meaning
ARIMA	Autoregressive integrated moving-average
CAUTI	Catheter-associated urinary tract infection
CABG	Coronary artery bypass graft
CDC	Centers for Disease Control and Prevention
CLABSI	Catheter line-associated blood stream infection
CPOE	Computerized physician order entry
CVC	Central venous catheter
DVT	Deep vein thrombosis
EPOC	Cochrane Effective Practice and Organisation of Care
ICU	Intensive care unit
IHI	Institute for
ITS	Interrupted time series
HAI	Healthcare-associated infection
HICPAC	Healthcare Infection Control Practices Advisory Committee
JCAHO	Joint Commission for Accreditation of Healthcare Organizations
LCBI	Laboratory Confirmed Bloodstream Infection
MICU	Medical intensive care unit
NNIS	National Nosocomial Infection Surveillance System
NSIPP	National Surgical Infection Prevention Project
QI	Quality improvement
RCP	Respiratory care practitioners
SBT	Simple before-after
SCIP	Surgical Care Improvement Project
SENIC	Study of the Effectiveness of Nosocomial Infection Control
SICU	Surgical intensive care unit
SSI	Surgical site infection
VAP	Ventilator-associated pnemonia

APPENDIXES:

to

"Closing the Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 6—Prevention of Healthcare-Associated Infections"

Prepared by the Stanford University-UCSF Evidence-based Practice Center
(Contract #290-02-0017)

Appendix A. Literature Search Strategy

Date: 2/13/06

#1 *targets QI strategies that tend to be multi-factorial using relevant MeSH terms and title words*	Patient-Centered Care [mh] or Progressive Patient Care [mh] or Critical Pathways [mh] or Delivery of Health Care, Integrated [mh] or Patient Care Team [mh] or Behavior Control [mh] or ((coordination [tw] or coordinated [tw] or Multifactorial [tw] or Multi-factorial [tw] or Multicomponent [tw] or Multi-component [tw] or multidisciplinary [tw] or multi-disciplinary [tw] or interdisciplinary [tw] or inter-disciplinary [tw] or integrated [tw] or community-based [tw] or organized [tw] or comprehensive [tw]) and (program*[tw] or care [tw] or approach [tw] or intervention [tw] or strategy [tw] or strategies [tw] or management [tw] or managing [tw] or center*[tw])) or Organization and Administration [mh] or bundle*[tw]	813885
#2 *targets TQM and CQI*	Total Quality Management [mh] OR Quality control [mh] OR TQM [tw] OR CQI [tw] OR (quality [tw] AND (continuous [tw] OR total [tw]) AND (management [tw] OR improvement [tw]))	41902
#3 *targets provider education*	Education, Continuing [mh] OR Education, Nursing [mh] OR Education, Medical [mh] OR Inservice Training [mh] OR Programmed Instruction [mh] OR ((Education [tw]AND Continuing [tw]) AND (medical [tw] OR professional* [tw] OR nursing [tw] OR physician* [tw] OR nurse* [tw])) OR (outreach [tw] AND (visit* [tw] OR educational [tw]) OR (academic [tw] AND detailing [tw]))	170009
#4 *targets diffusion of innovation*	Diffusion of Innovation [mh] OR (Diffusion [ti] AND (Innovation [ti] OR technology [ti]))	6710
#5 *targets audit & feedback, reminder systems, and financial incentives*	Medical audit [mh] OR ((Audit [tw] OR feedback [tw] OR compliance [tw] OR adherence [tw] OR training [tw]) AND (improvement* [tw] OR improving [tw] OR improves [tw] OR improve [tw] OR guideline* [tw] OR practice* [tw] OR medical [tw] OR provider* [tw] OR physician* [tw] OR nurse* [tw] OR clinician* [tw] OR academic [tw] OR visit* [tw])) OR Reminder Systems [mh] OR Reminder* [tw] OR ((financial [tw] OR economic [tw] OR physician* [tw] OR patient*) AND incentive* [tw]) OR Reimbursement Mechanisms [mh] or Guideline Adherence [mh] OR practice guidelines [mh]	184663
#6	Medical Informatics [mh] OR computer [tw] OR (decision [tw] AND (support [tw] or analysis [tw))	345989
#7 All QI studies	#1 or #2 or #3 Or #4 or #5 or #6	1326026
#8 Surgical site infection terms	Surgical wound infection[mh] OR surgical site infection*[tiab] OR postoperative infection*[ti] OR postsurgical infection*[ti] OR wound infection*[ti] OR sternal wound infection*[tiab] OR postoperative[ti] OR post-surgical[ti]	59870

#9 Combination of QI terms with SSI terms	#7 AND #8	3438
#10 RCT search	Randomised [ti] OR Randomized [ti] OR Controlled [ti] OR intervention [ti] OR evaluation [ti] OR impact [ti] OR effectiveness [ti] OR Evaluation [ti] OR Studies [ti] OR study [ti] Comparative [ti] OR Feasibility [ti] OR Program [ti] OR Design [ti] OR Clinical Trial [pt] OR Randomized Controlled Trial [pt] OR Epidemiologic Studies [mh] OR Evaluation Studies [mh] OR Comparative Study [mh] OR Feasibility Studies [mh] OR Intervention Studies [mh] OR Program Evaluation [mh] OR Epidemiologic Research Design [mh]	2702355
#11 Meta-analysis, systematic review search	((meta-analysis [pt] OR meta-analysis [tw] OR metanalysis [tw]) OR ((review [pt] OR guideline [pt] OR consensus [ti] OR guideline* [ti] OR literature [ti] OR overview [ti] OR review [ti] OR Decision Support Techniques [mh]) AND ((Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])) OR (handsearch* [tw] OR search* [tw] OR searching [tw]) AND (hand [tw] OR manual [tw] OR electronic [tw] OR bibliographi* [tw] OR database* OR (Cochrane [tw] OR Medline [tw] OR CINAHL [tw] OR (National [tw] AND Library [tw])))) OR ((synthesis [ti] OR overview [ti] OR review [ti] OR survey [ti]) AND (systematic [ti] OR critical [ti] OR methodologic [ti] OR quantitative [ti] OR qualitative [ti] OR literature [ti] OR evidence [ti] OR evidence-based [ti]))) BUTNOT (editorial [pt] OR comment [pt] OR letter [pt])	89605
#12 All original research	#10 OR #11	2766210
#13 Combination of QI terms with SSI terms, limited to original research only	#9 AND #12	1837
#14 #SSI/QI search limited to English only	#13 AND Limits: English	1532
#15 CLABSI search (restrict to English only)	(Catheterization, Central Venous [MeSH] OR central line*[ti] OR central venous catheter*[ti]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “healthcare associated”[tiab] OR “hospital acquired”[tiab] OR bundle[tiab])	829
#16 VAP search (restrict to English only)	(Respiration, Artificial[mh] OR mechanically ventilated*[ti] OR intubated*[ti] OR mechanical ventilation*[ti] or ventilator associated*[ti]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “healthcare associated”[tiab] OR “hospital acquired”[tiab] OR bundle[tiab])	1034
#17 UCUTI search (restrict to English only)	(Urinary catheterization[mh] OR urinary catheter*[tiab]) AND (Cross infection [mh] OR bacteremia [mh] OR nosocomial [tiab] OR “hospital-acquired”[tiab] OR “healthcare-associated”[tiab] OR bundle[tiab])	602

Supplemental searches

#S1 Nosocomial infection systematic reviews (limited to English only)	Cross infection[mh] AND systematic[sb]	401
#S2 Handwashing systematic reviews (limited to English only)	Handwashing[mh] AND systematic[sb]	60
#S3 Author searches	Pronovost p[au] OR Gastmeier P[au] OR Gyssens IC[au]	220
TOTAL CITATIONS (#14 +#16 +#18 + #20 +#S1 +#S2)	#14 OR #15 OR #16 OR #17 OR #S1 OR #S2 OR #S3	4678

Appendix B. Sample Data Abstraction Forms

Stage 1 (Screening Title and Abstract) Form

1. Does this article report or evaluate the results of an intervention (whether performed by the investigators or not)?
- o Yes
- o No
- o Can't tell

2. Does the article involve quality improvement or a QI strategy?
- o Yes - involves quality improvement or a QI strategy
- o Yes - systematic review of evaluations of a QI strategy
- o No
- o Can't tell

3. Should this article proceed to article abstraction stage for this topic?
- o Yes - evaluates a QI strategy involving nosocomial infections
- o No – ineligible topic* (focused on community-acquired infections, outpatient care, or specific nosocomial infection other than CLABSI, VAP, SSI, or UCUTI)
- o No - not an evaluation or not QI
- o Can't tell - need article
- o No - but useful background article
- o No - foreign language article

4. What type of study design was used?
- o RCT or quasi-RCT
- o CBA** or ITS ***
- o Simple before-after study or time series not meeting ITS definition
- o Observational (e.g., cohort study, cross-section, case-control)
- o Systematic review or meta-analysis
- o Economic or decision analysis, modeling
- o Non-research (commentary, review, news)
- o Qualitative research (e.g., focus groups)
- o Guideline or consensus statement
- o Can't tell (need article)

** Note that at this stage, err in favor of including articles unless they clearly address infections other than those listed below. Also, if an article addresses general nosocomial infection prevention, err in favor of including it at this stage.*

CLABSI = central line associated blood stream infection (synonyms: central venous catheter associated infection, central venous catheter sepsis, central line sepsis)
VAP = ventilator associated pneumonia
SSI = surgical site infection (synonyms: surgical wound infection, postoperative infection)

UCUTI = urinary catheter associated urinary tract infection (synonyms: foley catheter associated urinary tract infection, urinary catheter related infection, urinary catheter associated cystitis)

*** Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgment that control represents a comparable group or setting*

**** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND at least three time points both before and after*

Note: At this stage of triage, if there is a reasonable chance article is a clinical trial, CBA or ITS, err on the side of inclusion at that level. Stricter criteria can be applied more reliably at next stage of abstraction using full text of article. Similarly, if there is a reasonable chance article is a systematic review, designate it as such so article can be pulled.

5. What category of study question is addressed by the article?
   - o Can the incidence of CBSI be reduced?
   - o Can the incidence of SSI be reduced?
   - o Can the incidence of VAP be reduced?
   - o Can the incidence of UCUTI be reduced?
   - o Can nosocomial infections in hospitals be reduced?
   - o Not applicable – excluded above [answer only if excluded at Q1 or Q2 above]
   - o Can't tell (need article)

Stage 2 (Full Text) Abstraction Form

1. Does this article merit full text abstraction?
   - o Yes
   - o No – not QI or not an evaluation of a QI strategy* ***[exclusion]***
   - o No – ineligible study design (i.e., not RCT, CBA, or ITS) ***[exclusion]***
   - o No - excluded topic (Focus on evaluation of infections which are not hospital acquired or not CLABSI, SSI, VAP, or UTI) ***[exclusion]***
   - o No – no eligible outcomes** ***[exclusion]***
   - o No- other ***[exclusion]***

**Treatment evaluation studies (studies of the effect of a specific preventive intervention or therapy on nosocomial infection rates) should not be included. To be included, studies should explicitly attempt to promote use of a particular intervention, rather than evaluating the effect of the intervention itself.*

***Eligible outcomes include physician or staff adherence to recommended practices, or improvement in rate of SSI, CLABSI, VAP, or UTI. Article must report at least one of these two outcomes to be eligible for full text abstraction. Studies that addressed general nosocomial infection prevention should be abstracted ONLY if they report outcomes pertaining to SSI, CLABSI, VAP or UTI.*

2. Does this article present data overlapping with another article?
   - o Exclude this article as a duplicate publication (identify included citation being duplicated) ***[exclusion]***

- o Include this article, but obtain listed citation to help with abstraction (e.g., separate methods paper; identify required citation)
- o No or N/A

3. Does abstraction of this study require information from methods or results reported in other citations?
- o Yes (specify)
- o No

4. Does the article report data for more than one comparison (i.e., should it be abstracted as more than one study)?
- o Yes (specify which comparison is being abstracted here and which others will be abstracted elsewhere)
- o No

5. What category of study question is addressed by the article? [check all that apply]
- o Surgical Site Infections
- o Central Line Infections
- o Ventilator Acquired Pneumonia
- o Urinary Catheter-related UTI
- o Other [describe; discuss with Sumant before proceeding]

6. For studies addressing Surgical Site Infections: which of the following specific preventive interventions were targeted?
- o Hand hygiene
- o appropriate use of perioperative antibiotics
- o decreasing use of preoperative shaving of the operative site
- o improving perioperative glucose control
- o perioperative normothermia
- o audit and feedback of infection rates to hospitals or individual clinicians
- o None of the above (discuss with Sumant before proceeding)
- o N/A – article does not address surgical site infections

7. For studies addressing central line-associated bloodstream infections: which of the following specific preventive interventions were targeted?
- o hand hygiene
- o maximal sterile barrier precautions
- o appropriate insertion site selection
- o chlorhexidine skin disinfection
- o prompt removal of unnecessary catheters
- o None of the above (discuss with Sumant before proceeding)
- o N/A – article does not address central line-associated bloodstream infections

8. For studies addressing ventilator-associated pneumonia: which of the following specific preventive interventions were targeted?
- o hand hygiene
- o head of bed elevation above 30 degrees
- o daily interruption of sedation
- o None of the above (discuss with Sumant before proceeding)
- o N/A – article does not address ventilator-associated pneumonia

9. For studies addressing urinary catheter-associated urinary tract infections: which of the following specific preventive interventions were targeted?
- o hand hygiene
- o elevation of the head of the bed
- o aseptic insertion and catheter care

- o None of the above (discuss with Sumant before proceeding)
- o N/A – article does not address urinary catheter-associated urinary tract infections

10. Describe the QI strategy used and its salient features. **[text box]**

A) Study Setting and Participants

11. In what country did the study take place?
    - o US
    - o Non-US [specify]

12. When did the study take place?
    - o If supplied, give exact dates of study period (beginning to end of intervention period)
    - o Not reported

13. In what type of hospital did the study take place?
    - o Tertiary care or university hospital
    - o Community hospital with residents
    - o Non-teaching community hospital
    - o More than one hospital of different types (specify)
    - o Other or unclear (specify)

14. Who was targeted by the intervention? (check all that apply)
    - o All clinical staff
    - o Physicians
    - o Nurses
    - o Respiratory therapists
    - o Other ancillary staff [specify]
    - o Patients
    - o Other [specify]

15. In what clinical setting did the study take place? (check all that apply)
    - o Intensive care unit (specify if medical, surgical, pediatric or other)
    - o Operating room
    - o General inpatient ward (non-ICU)
    - o Other [specify]

16. Were patients in the study selected on the basis of specific clinical characteristics? (check all that apply)
    - o Postoperative patients (specify type of surgery, if supplied)
    - o Patients with specific disease process (specify)
    - o Intubated (mechanically ventilated) patients
    - o Other (specify)
    - o No specific clinical characteristics

17. Were patients in the study selected on the basis of specific demographic characteristics? (check all that apply)
    - o Children (specify age groups)
    - o Elderly (specify age groups)
    - o Specific type of insurance (i.e., patients within a particular HMO) (describe)
    - o Other demographic characteristic (describe)
    - o No specific demographic targeted

18. What type of intervention was provided to the control population?
    - o No intervention or usual care
    - o Some form of low intensity intervention (describe)
    - o No true control - just two or more different types of intervention (discuss with other reviewers; study may need to be excluded)

B) Study Design

19. What was the study design?
    - o Randomized trial (state method of randomization if described)
    - o Quasi-randomized trial (state basis for treatment allocation, e.g.,alternating patients, calendar date, even or odd identification numbers)
    - o Controlled before-after study*
    - o Interrupted time series**
    - o Simple before-after***

**Controlled Before After (CBA) requires contemporaneous observation periods for control and intervention groups AND judgment that control represents a comparable group or setting*

*** Interrupted time series (ITS) requires statement of well-defined time period for intervention implementation AND measurement of data at three or more time points both before and after intervention.*

**** Simple before-after (SBA) requires defined observation period for control and intervention periods.*

20. What was the unit of randomization or treatment allocation?
    - o Patient
    - o Provider
    - o Hospital ward or unit
    - o Entire hospital
    - o Firm (describe)
    - o Institution
    - o Other
    - o Not applicable—ITS or simple before-after study (skip to question 24)

21. For the unit of treatment allocation above, state sample size in each group:
    - o control group
    - o intervention group
    - o Not stated or not clear (explain)

**If sample size differs for outcomes, detail differences in "Not stated or not clear" text box. For simple before-after studies, enter pre-intervention sample size in "control group" box and post-intervention sample size in "intervention group" box*

22. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient outcomes analyzed), state sample size in each group:
    - o control group
    - o intervention group
    - o Not stated or not clear
    - o Not applicable (unit of analysis same as unit of treatment allocation above)

23. If unit of analysis differed from unit of treatment allocation, did authors acknowledge this issue and/or make appropriate adjustments?

- o Yes (describe)
- o No
- o Not applicable (unit of analysis did not differ from unit of treatment allocation)

24. Were the patients and providers in the control site (or pre-intervention period for SBA or ITS studies) comparable to the intervention site?

- o Yes (skip to question 26)
- o No (explain why not)
- o Unclear (describe)

25. If "no", were efforts made to adjust outcomes for underlying baseline differences in patient and provider characteristics?

- o Yes
- o No (explain why not)
- o Unclear (describe)

Design criteria for randomized and quasi-randomized trials
(If study is a CBA, skip to question 31; if SBA, skip to question 33; if ITS, skip to question 35)

26. Did the study have a cross over design? (Patients randomized to a sequence of interventions such as treatment A followed by treatment B in one group and treatment B followed by treatment A in the other group).

- o Yes (describe)
- o No
- o Not sure - clarify with other reviewers before proceeding

27. Was there adequate concealment of treatment allocation?

- o Yes *(unit of allocation was institution, team or professional and randomization process explicity described,OR unit of allocation was patient or episode of care and some form of centralized randomization scheme or sealed envelopes used)*
- o Not clear (only partially meets above criteria) or not stated - specify which
- o No - inadequate concealment *(enrollment of patients in alternation or through use of even/odd identifying numbers OR unit of allocation was patient or episode of care and reported use of any allocation process that is entirely transparent before assignment (e.g., open list of random numbers) OR allocation was altered byinvestigators, professionals or patients)*

28. Were patients blind to intervention/treatment allocation?

- o Yes
- o No
- o Not sure (explain)
- o Not applicable (patients not actively involved in study - e.g., provider-focused intervention with patient level data obtained retrospectively from charts)

29. Were providers blind to intervention/treatment allocation?

- o Yes
- o No
- o Not sure (explain)
- o Not applicable (explain)

30. Were outcomes assessors blinded to intervention/treatment allocation?
    - o Yes
    - o No
    - o Not sure (explain)
    - o Not applicable (explain)

Design criteria for CBA trials

31. Were measurements in the control group performed at the same time as the intervention group?
    - o Yes
    - o No
    - o Unclear

32. Were the criteria used for selecting the control site explained?
    - o Yes (describe)
    - o No

Design criteria for SBA trials

33. Was the data for the "before" period collected during the same time of the year as the "after" period (e.g., data collected from June-November, but during different years)?
    - o Yes
    - o No (describe)

34. If the data was collected at different times of the year, were efforts made to correct for this?
    - o Yes (describe)
    - o No

Design criteria for ITS trials

35. Was the data analyzed using a formal test for trend (time series ANOVA or regression)?
    - Yes
    - No
    - Unclear

36. **(For all studies)** Do any methodologic aspects of the study design not captured above seriously undermine
appropriateness of inclusion?
    - Yes (explain)
    - No (use text box to document any non-fatal, but still noteworthy methodological features)

C) Quality Improvement Attributes of Intervention

37. Was the intervention performed independent of other quality improvement efforts or other changes?
    - Yes
    - No (specify other interventions that took place)
    - Unclear

38. Did the investigators identify a specific quality gap (a difference between optimal and actual care) in the study population?
    - Yes (describe)
    - No

39. Did the QI strategy involve PATIENT EDUCATION?
    - o Yes
    - o No patient education (skip to question 43)

40. Which of the following educational strategies was used? (check all that apply)
    - o One-on-one session, in person or via telephone
    - o Group session (e.g., classes)
    - o Distribution of printed or audiovisual materials (e.g., pamphlets or poster in waiting room)
    - o Interactive computer-based learning
    - o Provision of clinical data to patient (e.g., test results)
    - o Not sure or other (describe)

41. In what setting was the educational content delivered? (check all that apply)
    - o Clinical setting (e.g., office or emergency department)
    - o Other or unclear (describe)

42. Who was responsible for delivery of the educational content? (check all that apply)
    - o Physician
    - o Nurse or nurse practitioner
    - o Other ancillary health provider (describe)
    - o No specific delivery person (e.g., entirely mailed, computer-based, or passively distributed content)

43. Did the intervention involve PROVIDER EDUCATION?
    - o Yes
    - o No (skip to question 49)

44. Who was the target of the educational intervention? (check all that apply)
    - o Attending (staff) physicians
    - o Residents or fellows
    - o Medical students
    - o Nurse practitioners
    - o Nurses
    - o Respiratory therapists
    - o Other (specify)

45. Which of the following educational strategies was used? (check all that apply)
    - o Distribution of educational materials (published or printed recommendations for clinical care, including clinical practice guidelines, audio-visual materials and electronic publications)
    - o Meetings or lectures (e.g., traditional CME)
    - o Educational outreach visits (e.g., “academic detailing”—a trained person who met with providers in their practice settings to give information with the intent of changing the provider's practice)
    - o Interactive in-person education (e.g., workshops or procedure demonstrations)
    - o Computer- or internet-based interactive tutorials (e.g., self-study modules)
    - o Consensus-building sessions (e.g.,for development of guideline)
    - o Not sure or other (describe)

46. Were all components of the educational intervention delivered to all targets of the intervention?
    - o Yes
    - o No (specify which targets received which components of the intervention)
    - o Unclear or not specified

47. In what setting was the educational content delivered? (check all that apply)
    - o Regularly scheduled staff meeting (specify)
    - o Specially scheduled on-site educational meeting (i.e., in-service class)
    - o Off-site meeting (e.g., CME)

- o Independent study (e.g., computer- or paper-based tutorial)
- o Other (describe)
- o Not clear or not specified

48. Who was responsible for delivery of the educational content? (check all that apply)
    - o Physician expert opinion leader (describe how selected)
    - o Other physician (including colleagues)
    - o Infection control practitioner
    - o Nurse
    - o Pharmacist
    - o Other (describe)
    - o Not clear or not specified
    - o No specific delivery person (entirely independent study or passively delivered content)

49. Did the QI strategy involve a PROVIDER REMINDER system*?
    - o Chart based decision support or reminder system*
    - o Computer based decision support or reminder system
    - o Not sure
    - o No or N/A

** Patient or provider encounter specific information, provided verbally, on paper or on a computer screen, which is intended to prompt provider to recall information at the time of the patient encounter (e.g., reminder to remove catheter)*

50. Did the QI strategy involve provider AUDIT AND FEEDBACK*? (check all that apply)
    - o feedback of infections (or infection rates) to individual provider
    - o feedback of infections/infection rates to practice or hospital
    - o feedback of rate of adherence to preventive interventions to individual provider
    - o feedback of rate of adherence to preventive interventions to practice or hospital
    - o Public reporting of performance data (state if individual data or data for a group or institution)
    - o Benchmarking**
    - o Not sure or other
    - o No or N/A

**Any summary of clinical performance of health care over a specified period of time, e.g., reporting of surgical site infection rates.*
***Benchmarking refers to the provision of performance data from institutions or providers regarded as "leaders in the field." These data provide targets for other providers and institutions to emulate.*

51. Did the QI strategy involve ORGANIZATIONAL CHANGE?
    - o Changes in team structure (e.g., creation of a dedicated procedure team) (specify)
    - o Revision of professional roles among health professionals (e.g., authorizing nurse to stop a procedure if proper infection control procedures were not followed) (specify)
    - o Increased staffing without changes in roles (e.g., adding more nurses) (specify)
    - o TQM/CQI - cycles of measurement of quality problems, design of interventions, implementation and remeasurement
    - o Changes in medical records systems -- e.g.,changing from paper to computerized records, patient tracking systems (specify)
    - o Communication and case discussion between distant health professionals (e.g., telemedicine)
    - o Not sure or other (describe)
    - o No or N/A

52. Did the intervention involve FINANCIAL OR REGULATORY INCENTIVES DIRECTED AT PROVIDERS?
- o Financial incentives for achievement of performance goals (describe)
- o Regulatory mandates (e.g., need for completion of educational module before performing procedures) (describe)
- o Other (describe)
- o No component of provider-directed financial or regulatory incentives

53. Did the intervention involve FINANCIAL OR REGULATORY INCENTIVES DIRECTED AT A PRACTICE OR HEALTH SYSTEM?
- o Yes (describe)
- o No component of health-system-directed financial or regulatory incentives

54. Did the study use an explicit clinical guideline, checklist, or "bundle" of multiple types of interventions?
- o Yes
- o No

55. Use textbox to state any important study features or concerns not captured above.

D) Results

56. For unit of treatment allocation (e.g., clinics, providers, patients), were results reported for at least 80% of participants?
- o Yes (state %)
- o No (state %)
- o Not stated
- o Does not apply – SBA or ITS study

57. If unit of analysis differed from unit of treatment allocation (e.g., providers randomized, but patient level outcomes
analyzed), were results reported for at least 80% of participants?
- o Yes (state %)
- o No (state %)
- o Not stated or not clear
- o Not applicable (unit of analysis same as unit of treatment allocation, or study is SBA or ITS)

58. What was the length of the study follow-up period? (describe)

Studies addressing Surgical Site Infections

59. Did the study address Surgical Site Infections?
- o Yes
- o No (go to question 85)

60. Which specific surgeries were targeted by the intervention? (select all that apply)
- o Cardiothoracic surgery (includes coronary artery bypass graft) (specify)
- o Vascular surgery (specify)
- o Orthopedic surgery (includes total knee replacement, total hip replacement) (specify)
- o Gynecologic surgery (includes hysterectomy) (specify)
- o Colorectal surgery (specify)
- o Other type of surgery not listed above (specify)
- o All surgeries performed at a hospital or hospitals
- o Not clear or not specified

61. What were the outcome types? (check all that apply)
- o Surgical site infection rate
- o Compliance with Hand hygiene
- o Compliance with appropriate timing of perioperative antibiotics (enter definition of appropriate timing as specified in study)
- o Compliance with administering perioperative antibiotics for the appropriate duration (enter definition of appropriate duration as defined in the study)
- o Compliance with appropriate selection of perioperative antibiotics (list which antibiotics were recommended and nonrecommended)
- o Compliance with decreasing use of preoperative shaving of the operative site
- o Compliance with improving perioperative glucose control
- o Compliance with perioperative normothermia
- o Compliance with a clinical guideline for preventing surgical site infections (use this if study mandated an explicit guideline or "bundle" incorporating more than one of the interventions described above)
- o Costs associated with intervention
- o Adverse effects of the intervention [specify]
- o Provider satisfaction with QI strategy
- o Not sure or other (describe)

62. If the study reported surgical site infection rates, did the study define infections according to Centers for Disease Control (CDC) or National Nosocomial Infection Surveillance System (NNIS) protocols?
- o Yes
- o No
- o Unclear

63. Which SSI were measured? (check all that apply)
- o Superficial wound infections
- o Deep incisional or organ space infections
- o All surgical site infections
- o Other (describe)
- o No specific definition provided

64. If wound infection was used as an outcome, what was the duration of surveillance?
- o If specified, enter length of post-operative surveillance (text box)

65. For studies reporting data in the form of surgical site infection rate, provide the following data for the CONTROL group. *If data is missing, record "NR"*
- o Exact units of measurement
- o Infection rate prior to intervention (s)
- o Infection rate after intervention(s) (Not applicable to SBA studies)
- o Percentage change in infection rate (Not applicable to SBA studies)
- o Does not apply – simple before-after study

66. For studies reporting data in the form of surgical site infection rate, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*
- o Exact units of measurement
- o Infection rate prior to intervention
- o Infection rate after intervention

67. Enter any data on surgical site infection rates not abstracted above here:
- o Control group before intervention
- o Control group after intervention
- o Intervention group before intervention
- o Intervention group after intervention

68. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the CONTROL group; if data is missing, record “NR”

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

69. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the INTERVENTION group; if data is missing, record “NR”. *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

70. For studies reporting data in the form of adherence to appropriate timing of perioperative antibiotics, provide the following data for the CONTROL group; if data is missing, record “NR”

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

70. For studies reporting data in the form of adherence to administering perioperative antibiotics for the appropriate duration, provide the following data for the CONTROL group; if data is missing, record “NR”

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

70. For studies reporting data in the form of adherence to appropriate selection of perioperative antibiotics, provide the following data for the CONTROL group; if data is missing, record “NR”

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

71. For studies reporting data in the form of adherence to appropriate use of perioperative antibiotics, provide the following data for the INTERVENTION group; if data is missing, record “NR”. *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

72. For studies reporting data in the form of adherence to protocols for perioperative shaving of the surgical site, provide the following data for the CONTROL group; if data is missing, record “NR”

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

73. For studies reporting data in the form of adherence to protocols for perioperative shaving of the surgical site, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

74. For studies reporting data in the form of adherence to protocols for perioperative normothermia, provide the following data for the CONTROL group; if data is missing, record "NR"

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

75. For studies reporting data in the form of adherence to protocols for perioperative normothermia, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

76. For studies reporting data in the form of adherence to protocols for perioperative glucose control, provide the following data for the CONTROL group; if data is missing, record "NR"

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

77. For studies reporting data in the form of adherence to protocols for perioperative glucose control, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

78. Provide the following data for other types of measurements of adherence to preventive interventions not abstracted above:

- o Specific preventive intervention and units of measurement
- o Value in CONTROL group before intervention
- o Value in CONTROL group after intervention
- o Value in INTERVENTION group before intervention
- o Value in INTERVENTION group after intervention

Measures of costs

Note: cost outcomes should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)

79. For studies reporting cost outcomes, what specific measures were used?
- o Total cost of surgical site infection to hospital or health system
- o Total cost of inappropriate antimicrobial prophylaxis averted
- o Total cost of interventions to prevent surgical site infection
- o Other (describe)
- o No measurement of costs

80. For studies reporting the total cost of surgical site infections, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

81. For studies reporting the total cost of inappropriate antimicrobial prophylaxis avoided, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

82. For studies reporting the total cost of interventions to prevent surgical site infections, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

Studies addressing Central Line Infections

83. Did the study address Central Line Infections?
- o Yes
- o No (go to question 104)

84. What were the outcome types? (check all that apply)
- Central line infection rate
- Compliance with Hand hygiene
- Compliance with maximal sterile barrier precautions
- Compliance with appropriate catheter site selection
- Compliance with use of chlorhexidine skin prophylaxis

- Compliance with prompt removal of unnecessary catheters
- Compliance with a clinical guideline for preventing central line infections (use this if study mandated an explicit guideline, checklist or "bundle" incorporating more than one of the interventions described above)
- Costs associated with intervention
- Adverse effects of the intervention [specify]
- Provider satisfaction with QI strategy
- Not sure or other (describe)

85. If the study reported central line infection rates, did the study define infections according to Centers for Disease Control (CDC) or National Nosocomial Infection Surveillance System (NNIS) protocols?
- Yes
- No (enter definition of CLABSI as documented in article)
- Does not apply – did not report infection rates

86. If the study reported central line infection rates, for which specific types of central lines were infections measured?
- o All central lines
- o Only non-tunnelled central lines
- o Not specified
- o Other or unclear (enter relevant information from article)
- o Does not apply – did not report infection rates

87. For studies reporting data in the form of CLABSI rate, provide the following data for the CONTROL group. *If data is missing, record "NR"*
- o Exact units of measurement
- o Infection rate prior to intervention (s)
- o Infection rate after intervention(s) (Not applicable to SBA studies)
- o Percentage change in infection rate (Not applicable to SBA studies)
- o Does not apply – simple before-after study

88. For studies reporting data in the form of CLABSI rate, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*
- o Exact units of measurement
- o Infection rate prior to intervention
- o Infection rate after intervention

89. Enter any data on CLABSI rates not abstracted above here:
- o Control group before intervention
- o Control group after intervention
- o Intervention group before intervention
- o Intervention group after intervention

90. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the CONTROL group; if data is missing, record "NR"
- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

91. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

92. For studies reporting data in the form of adherence to appropriate use of maximal sterile barrier precautions, provide the following data for the CONTROL group; if data is missing, record "NR"

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

93. For studies reporting data in the form of adherence to appropriate catheter site selection, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

94. For studies reporting data in the form of adherence to use of chlorhexidine for skin disinfection, provide the following data for the CONTROL group; if data is missing, record "NR"

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

95. For studies reporting data in the form of adherence to protocols for prompt removal of unnecessary catheters, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

96. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing CLABSI, provide the following data for the CONTROL group; if data is missing, record "NR"

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

97. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing CLABSI, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*

- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

98. Provide the following data for other types of measurements of adherence to preventive interventions not abstracted above:
- o Specific preventive intervention and units of measurement
- o Value in CONTROL group before intervention
- o Value in CONTROL group after intervention
- o Value in INTERVENTION group before intervention
- o Value in INTERVENTION group after intervention

Measures of costs
Note: cost outcomes should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)

99. For studies reporting cost outcomes, what specific measures were used?
- o Total cost of CLABSI to hospital or health system
- o Total cost of interventions to prevent CLABSI
- o Other (describe)
- o No measurement of costs

100. For studies reporting the total cost of CLABSI, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

101. For studies reporting the total cost of interventions to prevent CLABSI, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

Ventilator-Associated Pneumonia

102. Did the study address Ventilator Associated Pneumonia (VAP)?
- o Yes
- o No (go to question 121)

103. What were the outcome types? (check all that apply)
- VAP rate
- Compliance with Hand hygiene
- Compliance with head of bed elevation
- Compliance with protocols to assess readiness for ventilator weaning (includes daily lifting of sedation)

- Compliance with a clinical guideline for preventing VAP (use this if study mandated an explicit guideline, checklist or "bundle" incorporating more than one of the interventions described above)
- Costs associated with intervention
- Adverse effects of the intervention [specify]
- Provider satisfaction with QI strategy
- Not sure or other (describe)

104. If the study reported VAP rates, did the study use invasive methods to establish the diagnosis of VAP? (check all that apply)
- Yes – used bronchoalveolar lavage (BAL)
- Yes – used sampling with protected specimen brush (PSB)
- No – used clinical criteria only (specify criteria, e.g., new infiltrate on chest x-ray, fever, elevated white blood cell count)
- Study used both invasive and clinical criteria to diagnose VAP
- Not clear or not specified
- Does not apply – did not report VAP rates

105. For studies reporting data in the form of VAP rate, provide the following data for the CONTROL group. *If data is missing, record "NR"*
- o Exact units of measurement
- o Infection rate prior to intervention (s)
- o Infection rate after intervention(s) (Not applicable to SBA studies)
- o Percentage change in infection rate (Not applicable to SBA studies)
- o Does not apply – simple before-after study

106. For studies reporting data in the form of VAP rate, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*
- o Exact units of measurement
- o Infection rate prior to intervention
- o Infection rate after intervention

107. Enter any data on VAP rates not abstracted above here:
- o Control group before intervention
- o Control group after intervention
- o Intervention group before intervention
- o Intervention group after intervention

108. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the CONTROL group; if data is missing, record "NR"
- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate before intervention
- o Percentage change in compliance rate
- o Not applicable – simple before-after study

109. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- o Exact units of measurement
- o Adherence rate before intervention
- o Adherence rate after intervention
- o Percentage change in compliance rate

110. For studies reporting data in the form of adherence to head of the bed elevation, provide the following data for the CONTROL group; if data is missing, record "NR"
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate before intervention
- Percentage change in compliance rate
- Not applicable – simple before-after study

111. For studies reporting data in the form of adherence to head of the bed elevation, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate after intervention
- Percentage change in compliance rate

112. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing VAP, provide the following data for the CONTROL group; if data is missing, record "NR"
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate before intervention
- Percentage change in compliance rate
- Not applicable – simple before-after study

113. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing VAP, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate after intervention
- Percentage change in compliance rate

114. Provide the following data for other types of measurements of adherence to preventive interventions not abstracted above:
- Specific preventive intervention and units of measurement
- Value in CONTROL group before intervention
- Value in CONTROL group after intervention
- Value in INTERVENTION group before intervention
- Value in INTERVENTION group after intervention

Measures of costs

Note: cost outcomes should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)

115. For studies reporting cost outcomes, what specific measures were used?
- Total cost of VAP to hospital or health system
- Total cost of interventions to prevent VAP
- Other (describe)
- No measurement of costs

116. For studies reporting the total cost of VAP, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- Exact units of measurement
- Total costs in CONTROL group before intervention
- Total costs in CONTROL group after intervention
- Cost difference before intervention (intervention – control)

- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

117. For studies reporting the total cost of interventions to prevent VAP, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)

- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

Urinary Catheter-associated UTI

118. Did the study address urinary catheter-associated UTI (UTI)?

- o Yes
- o No (go to question xx)

119. What were the outcome types? (check all that apply)

- Rate of symptomatic urinary tract infection
- Rate of asymptomatic bacteriuria
- Rate of use of indwelling urinary catheters
- Compliance with Hand hygiene
- Compliance with prompt removal of unnecessary catheters
- Compliance with aseptic insertion and catheter care
- Compliance with a clinical guideline for preventing UTI (use this if study mandated an explicit guideline, checklist or "bundle" incorporating more than one of the interventions described above)
- Costs associated with intervention
- Adverse effects of the intervention [specify]
- Provider satisfaction with QI strategy
- Not sure or other (describe)

120. If the study reported rates of symptomatic UTI, did the study define infections according to Centers for Disease Control (CDC) or National Nosocomial Infection Surveillance System (NNIS) protocols?

- Yes
- No (enter definition of UTI as documented in article)
- Does not apply – did not report rates of symptomatic UTI

121. If the study reported rates of asymptomatic bacteriuria, how was this defined?

- o Enter definition of asymptomatic bacteriuria[text box]
- o Does not apply – did not report rates of asymptomatic bacteriuria

122. For studies reporting symptomatic UTI rate, provide the following data for the CONTROL group. *If data is missing, record "NR"*

- Exact units of measurement
- Infection rate prior to intervention (s)
- Infection rate after intervention(s) (Not applicable to SBA studies)
- Percentage change in infection rate (Not applicable to SBA studies)
- Does not apply – simple before-after study

123. For studies reporting symptomatic UTI rate, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*

- Exact units of measurement
- Infection rate prior to intervention
- Infection rate after intervention

124. For studies reporting rate of asymptomatic bacteriuria, provide the following data for the CONTROL group. *If data is missing, record "NR"*

- Exact units of measurement
- Infection rate prior to intervention (s)
- Infection rate after intervention(s) (Not applicable to SBA studies)
- Percentage change in infection rate (Not applicable to SBA studies)
- Does not apply – simple before-after study

125. For studies reporting rate of asymptomatic bacteriuria, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*

- Exact units of measurement
- Infection rate prior to intervention
- Infection rate after intervention

126. Enter any data on rate of symptomatic UTI or asymptomatic bacteriuria not abstracted above here:

- Exact units of measurement
- Control group before intervention
- Control group after intervention
- Intervention group before intervention
- Intervention group after intervention

127. For studies reporting rate of use of indwelling urinary catheters, provide the following data for the CONTROL group. *If data is missing, record "NR"*

- Exact units of measurement
- Rate of use of catheters prior to intervention (s)
- Rate of use of catheter after intervention(s) (Not applicable to SBA studies)
- Percentage change in rate of use of catheters (Not applicable to SBA studies)
- Does not apply – simple before-after study

128. For studies reporting rate of use of indwelling urinary catheters, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: for simple before-after studies, enter "before" data in "prior to intervention" box and "after" data in "after intervention" box*

- Exact units of measurement
- Infection rate prior to intervention
- Infection rate after intervention

129. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the CONTROL group; if data is missing, record "NR"

- Exact units of measurement
- Adherence rate before intervention

- Adherence rate before intervention
- Percentage change in compliance rate
- Not applicable – simple before-after study

130. For studies reporting data in the form of adherence to hand hygiene, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate after intervention
- Percentage change in compliance rate

131. For studies reporting data in the form of adherence to aseptic catheter care, provide the following data for the CONTROL group; if data is missing, record "NR"
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate before intervention
- Percentage change in compliance rate
- Not applicable – simple before-after study

132. For studies reporting data in the form of adherence to aseptic catheter care, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate after intervention
- Percentage change in compliance rate

133. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing UTI, provide the following data for the CONTROL group; if data is missing, record "NR"
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate before intervention
- Percentage change in compliance rate
- Not applicable – simple before-after study

134. For studies reporting data in the form of adherence to an explicit clinical guideline for preventing UTI, provide the following data for the INTERVENTION group; if data is missing, record "NR". *Note: enter all data for simple before-after studies here*
- Exact units of measurement
- Adherence rate before intervention
- Adherence rate after intervention
- Percentage change in compliance rate

135. Provide the following data for other types of measurements of adherence to preventive interventions not abstracted above:
- Specific preventive intervention and units of measurement
- Value in CONTROL group before intervention
- Value in CONTROL group after intervention
- Value in INTERVENTION group before intervention
- Value in INTERVENTION group after intervention

Measures of costs
Note: cost outcomes should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)

136. For studies reporting cost outcomes, what specific measures were used?
- o Total cost of UTI to hospital or health system
- o Total cost of interventions to prevent UTI
- o Other (describe)
- o No measurement of costs

137. For studies reporting the total cost of UTI, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

138. For studies reporting the total cost of interventions to prevent UTI, record the following data:
(Note: for simple before-after studies, enter all data in "intervention" boxes)
- o Exact units of measurement
- o Total costs in CONTROL group before intervention
- o Total costs in CONTROL group after intervention
- o Cost difference before intervention (intervention – control)
- o Total costs in INTERVENTION group before intervention
- o Total costs in INTERVENTION group after intervention
- o Cost difference after intervention (intervention – control)
- o Net change in costs attributable to intervention (cost difference after – cost difference before)

For all studies

Provider satisfaction with intervention
Note: provider satisfaction should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)

139. For studies reporting data on PROVIDER satisfaction with the intervention, provide the following data; if data is missing,record "NR"
- o No measure of provider satisfaction
- o Percent satisfaction in CONTROL group after intervention
- o Percent satisfaction in INTERVENTION group after intervention
- o Absolute difference (intervention – control)

Adverse events associated with the intervention

Note: adverse events should be abstracted only if the study also has usable data for one of the primary outcomes (nosocomial infection rate or provider compliance rate)
140. Did the study report data on adverse events associated with the intervention?
- o Yes (specify)
- o No

141. If the study reported data on adverse events associated with the intervention, enter data here: [text box]

142. Use textbox to state any important study results or concerns not documented above. **[text box]**

Appendix C. Listing of Excluded Studies

Abdel-Razek A. Nosocomial infections in ventilated patients. Middle East J Anesthesiol. 1992;11(4):369-79.	Not an evaluation of a QI intervention
Abi-Said D, Raad I, Umphrey J, et al. Infusion therapy team and dressing changes of central venous catheters. Infect Control Hosp Epidemiol. 1999;20(2):101-5.	Not an evaluation of a QI intervention
Adams-Chapman I, Stoll BJ. Prevention of nosocomial infections in the neonatal intensive care unit. Curr Opin Pediatr. 2002;14(2):157-64.	Study design did not meet criteria for RCT, CBA, ITS or SBA
Alcohol for hand hygiene: new comparative studies add to the evidence base. Can Commun Dis Rep. 2003;29(1):4-6.	Not an evaluation of a QI intervention
Al-Hashemy AM, Seleem MI, Khan ZA, et al. Postoperative wound infection in surgical procedures. Saudi Med J. 2004;25(8):1122-3.	Not an evaluation of a QI intervention
Allen SD, Conger KB. Serratia marcescens infection of the urinary tract: a nosocomial infection. J Urol. 1969;101(4):621-3.	Not an evaluation of a QI intervention
Alpert JJ, Heagarty MC, Robertson L, et al. Effective use of comprehensive pediatric care. Utilization of health resources. American Journal of Diseases of Children. 1968;116(5):529.	Excluded topic
Alvarado CJ, Reichelderfer M. APIC guideline for infection prevention and control in flexible endoscopy. Association for Professionals in Infection Control. Am J Infect Control. 2000;28(2):138-55.	Excluded topic
Aly H, Herson V, Duncan A, et al. Is bloodstream infection preventable among premature infants? A tale of two cities. Pediatrics. 2005;115(6):1513-8.	Study design did not meet criteria for RCT, CBA, ITS or SBA
Amer FA, Mohtady HA, el-Behedy IM, et al. Bacteria of nosocomial urinary tract infections at a university hospital in Egypt: identification and associated risk factors. Infect Control Hosp Epidemiol. 2004;25(11):895-7.	Not an evaluation of a QI intervention
Andersen C, Hart J, Vemgal P, et al. Prospective evaluation of a multi-factorial prevention strategy on the impact of nosocomial infection in very-low-birthweight infants. J Hosp Infect 2005; 61:162-7.	Other
Andriole VT. Hospital acquired urinary infections and the indwelling catheter. Urol Clin North Am. 1975;2(3):451-69.	Not an evaluation of a QI intervention
Antimicrobial prophylaxis for surgery. Treat Guidel Med Lett. 2004;2(20):27-32.	Not an evaluation of a QI intervention
APIC position paper: prevention of device-mediated bloodborne infections to health care workers. Association for Professionals in Infection Control and Epidemiology, Inc. Am J Infect Control. 1998;26(6):578-80.	Not an evaluation of a QI intervention
Aronow HU, Bolton LB, Aydin C, et al. Patient focused care: evaluating the dual goals of quality improvement and cost reduction abstract. AHSR & FHSR Annual Meeting Abstract Book. 1994;11:8.	Study design did not meet criteria for RCT, CBA, ITS or SBA
Austin TW, Austin MA, Coleman B, et al. Total knee replacement surgery and surgical site infection: a prospective audit. Can J Surg. 2004;47(2):145.	Not an evaluation of a QI intervention
Avery CM, Jamieson N, Calne RY. Effective administration of heparin and antibiotic prophylaxis. Br J Surg. 1995;82(8):1136-7.	Not an evaluation of a QI intervention
Babcock HM. Surveillance for surgical-site infections: it''s getting better all the time. Infect Control Hosp Epidemiol. 2003;24(10):722-3.	Not an evaluation of a QI intervention

Bagnulo H. Principles and problems in surgical infections. Introduction. Surg Infect (Larchmt). 2001;2 Suppl 1:S1-2.	Not an evaluation of a QI intervention
Bailey DR, Riedel DC. Study evaluates Blue Cross recertification experiment. Modern Hospital. 1968;110(2):106.	Excluded topic
Ball C. Medical devices and their role in the incidence of ventilator-associated pneumonia--challenging some sacred cows! Intensive Crit Care Nurs. 2005;21(3):131-4.	Not an evaluation of a QI intervention
Bard biocath hydrophilic-coated Foley catheters. Health Devices. 1988;17(2):69.	Not an evaluation of a QI intervention
Barson AJ. Fatal Pseudomonas aeruginosa bronchopneumonia in a children"s hospital. Arch Dis Child. 1971;46(245):55-60.	Not an evaluation of a QI intervention
Bartlett RC. Control of hospital-associated infection. Prog Clin Pathol. 1972;4:259-82.	Not an evaluation of a QI intervention
Bates DW, Makary MA, Teich JM, et al. Asking residents about adverse events in a computer dialogue: how accurate are they? Jt Comm J Qual Improv. 1998;24(4):197-202.	Not an evaluation of a QI intervention
Bishop-Kurylo D. The clinical experience of continuous quality improvement in the neonatal intensive care unit. J Perinat Neonatal Nurs. 1998;12(1):51-7.	No eligible outcomes
Blenkharn JJ. Prevention of bacteriuria during urinary catheterization of patients in an intensive care unit: evaluation of the 'Ureofix 500' closed drainage system. J Hosp Infect. 1985;6(2):187-93.	Not an evaluation of a QI intervention
Bleyer AJ, Mason L, Russell G, et al. A randomized, controlled trial of a new vascular catheter flush solution (minocycline-EDTA) in temporary hemodialysis access. Infect Control Hosp Epidemiol. 2005;26(6):520-4.	Not an evaluation of a QI intervention
Bloom B, Craddock A, Delmore P, et al. Reducing acquired infections in the NICU: observing and implementing meaningful differences in process between high and low acquired infection rate centers. Journal of Perinatology. 2003;23(6):489.	No eligible outcomes
Bodiwala GG, George TK. Surgical gloves during wound repair in the accident-and-emergency department. Lancet. 1982;2(8289):91-2.	Not an evaluation of a QI intervention
Boelle PY, Golliot F, Valleron AJ. A framework for benchmarking hospital performance: application to surgical site infection. Stud Health Technol Inform. 2003;95:777-82.	Not an evaluation of a QI intervention
Bond P, Harris C. Best practice in urinary catheterisation and catheter care. Nurs Times. 2005;101(8):54, 6, 8.	Not an evaluation of a QI intervention
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Appendix D. Technical Experts and Peer Reviewers

Technical Expert Panel

Martin Eccles, M.D., Centre for Health Services Research, University of Newcastle upon Tyne, EPOC

Russell Glasgow, Ph.D., Kaiser Permanente, Colorado

Jeremy Grimshaw, M.B.Ch.B., Ph.D., University of Ottawa, Cochrane Collaboration Effective Practice and Organisation of Care Group (EPOC)

Charles Homer, M.D., M.P.H., National Institute for Children's Health Care Quality

Harmon Jordan, Sc.D., previously with New England Medical Center Evidence-based Practice Center, currently at Abt Associates

Val Lawrence, M.D., M.Sc., The University of Texas Health Science Center at San Antonio and South Texas Veterans Health Care System

Andrew Oxman, M.D., M.Sc., Department of Health Services Research, Norwegian Directorate for Health and Social Welfare, EPOC

James Zazzali, Ph.D., RAND

Peer Reviewers

David Atkins, M.D., M.P.H., Chief Medical Officer, Agency for Healthcare Research and Quality, Center for Outcomes and Evidence

Victoria Fraser, M.D., Professor of Medicine, Co-Director Division of Infectious Diseases, Washington University School of Medicine

Stephan Harbarth, M.D., M.S., (For Dr. Didier Pittet), Hôpitaux Universitaires de Genève Service de Prévention et Contrôle de l'Infection

Jukka Korpela, M.D., Ph.D., Medical Bacteriology Program Officer, Bacteriology and Mycology Branch, Division of Microbiology and Infectious Diseases NIAID / NIH / DHHS

Ebbing Lautenbach, M.D., M.P.H., Assistant Professor of Medicine and Epidemiology U. of Pennsylvania

Trish Perl, M.D., M.Sc., Assistant Professor of Medicine, Johns Hopkins University School of Medicine, Division of Infectious Diseases, Joint Appointment, Epidemiology, Johns Hopkins School of Public Health and Hygiene

Peter Pronovost, M.D., Ph.D., Professor, Departments of Anesthesiology and Critical Care, Surgery, and Health Policy, Johns Hopkins University of Medicine

Roger Resar, M.D., Senior Fellow, Institute for Healthcare Improvement (IHI)

Thomas R. Russell, M.D., Executive Director, American College of Surgeons

Sanjay Saint, M.D., M.P.H., Research Investigator, Ann Arbor VA Medical Center Director, VA/UM Patient Safety Enhancement Program Associate Professor of Medicine, University of Michigan Medical School, University of Michigan

Margaret Toth, M.D., Chief Quality Officer, Delmarva Foundation, Ohio KePRO