



**The Challenge of Assessing Patient Safety
in America's Hospitals**

Appendix

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January 15, 2002

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Medication Safety: Computerized Physician Order Entry (CPOE)

Computerized Physician Order Entry (CPOE) is a practice that has been advocated for reducing medication errors. Such a system is used in conjunction with a pharmacy software program designed to detect potential contraindications, dosing errors or inappropriate routes of administration. The ultimate goal is the reduction of adverse drug events (ADEs) related to preventable causes.

Application of Criteria to CPOE

1. There is sufficient evidence for effectiveness

There is evidence to support that CPOE systems reduce medication errors¹. The AHRQ assessed CPOE with clinical decision support systems (CDSS) as a safety practice with "medium" strength of evidence regarding its impact and effectiveness and placed it on its list of practices for which further research would be highly beneficial.² The AHRQ found no published study that documented a significant reduction in ADEs through the use of CPOE, acknowledging the statistical challenges of the relatively infrequent occurrence of serious adverse drug events (ADEs).² The most frequently cited study of CPOE is from the Brigham and Women's Hospital. In their study, CPOE reported a 55% decrease in serious medication errors, but the decline in preventable ADEs was only 17% and not statistically significant.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

While CPOE with decision support should decrease medication error rates, other interventions have also demonstrated good outcomes (see below). Clinical information systems with pharmacy modules are able to proactively detect many errors, including therapy duplication, dosing errors, allergies, drug-drug interactions, and contraindicated route of administration. Examples of non-CPOE, system-driven initiatives that have demonstrated decreased adverse drug events include:

Albany Medical Center published a description of their 14-year process to reduce medication errors³. This institution is a 631-bed tertiary care center with 26,000 admissions a year. By 1999, their Prescribing Error Program was detecting 2,500 prescribing errors per year. These results were achieved without CPOE, using a refined system that included a central drug distribution process with a pharmacy computer software system and a McKesson Automated Health RxRobot.

Good Samaritan Regional Medical Center (GSRMC) in Phoenix, AZ reported the outcomes from their intervention to reduce ADEs using a computer alert system⁴. The system incorporated integrated patient-specific data including pharmacy orders, patient allergies, demographics, radiology orders and laboratory results. GSRMC reported the ADE alert system detected opportunities to reduce preventable ADE injuries at a rate of 64/1000 patient admissions.

3. There is freedom from known implementation issues

The limited outcomes data related to CPOE likely reflect the infancy of this promising practice and the challenges of implementing this intervention in a resource-constrained environment. The estimated development and implementation cost of CPOE at the Brigham and Women's Hospital was \$1.9 million, with \$500,000 maintenance costs per year. The AHRQ assessed that the cost of purchasing and implementing large, commercial systems varied substantially, but could be on the order of tens of millions of dollars.

4. There is evidence of successful transfer from research to non-research settings

CPOE has been implemented in relatively few hospitals in a non-research, non-beta-test site capacity. Implementation experience and outcomes from these hospitals have not been published in peer-reviewed journals. The AHRQ located published evidence of the effectiveness of CPOE with CDSS for only two hospitals, both of which were teaching hospitals. A separate evaluation of medication error-reducing technologies conducted in 2001 also located few sites with sufficient experience to report outcomes.⁵

Summary: It is clear that CPOE with computerized decision support holds much promise as an initiative that will improve patient safety, but the evidence is insufficient at this time to establish CPOE as a standard of care. CPOE should be considered as one of many practices that a hospital could consider for reducing its ADEs.

Medication Safety – Clinical Pharmacists

One practice to decrease adverse drug events (ADEs) is the use of clinical pharmacists as part of patient care teams (i.e., clinical pharmacists make “rounds” with the patient care team and are available for consultation regarding patients).

Application of Criteria to Clinical Pharmacists

1. There is sufficient evidence for effectiveness

There are numerous reports documenting the effectiveness of pharmacists in detecting and preventing ADEs, but few published reports specifically evaluating the use of clinical pharmacists consultation services/participation in rounds. One of the most frequently cited reports is that of Leape et al, who reported that pharmacist participation in physician rounds in the ICU decreased medication ordering errors significantly (66%). The AHRQ rated clinical pharmacist consultation services as a patient safety practice with medium strength of evidence regarding impact and effectiveness.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

There is no evidence that clinical pharmacist consultation services are superior to other practices in reducing ADEs.

3. There is freedom from known implementation issues

AHRQ rated the cost of implementing clinical pharmacist consultation services as high. This is most likely due to the increase in costs due to salaries and benefits. However, studies examining resource utilization and cost savings in the inpatient setting indicate overall cost savings due to clinical pharmacist activities. Currently, there is a pharmacist shortage in some areas of the U.S.

4. There is evidence of successful transfer from research to non-research settings

Clinical pharmacist consultation services have been used across hospital types (academic, community, public).

Summary: There is evidence that clinical pharmacist consultation decreases preventable ADEs. While the use of clinical pharmacists as part of patient care teams is relatively widely implemented, the activities of the clinical pharmacists vary from hospital to hospital (e.g., consultation for pharmacokinetic services, attendance at rounds), which may yield different outcomes of this practice. Clinical pharmacist participation on patient care teams should be considered one of many practices that a hospital can implement to reduce ADEs.

Medication Safety – Unit Dose Medication Distribution Systems

A practice that is intended to reduce Adverse Drug Events (ADEs) is the use of Unit Dose (UD) distribution systems. A UD distribution system is the dispensing of medications in a package that is ready to administer to the patient. Each package is labeled with the drug name, strength, and expiration date. There are a variety of ways in which the UD medication reaches the patient in a hospital. The UD medication may be placed in patient-specific medication cassettes, stocked in automated dispensing devices, or provided to nursing stations as “ward stock” medications.

Application of Criteria to Unit Dose Distribution Systems

1. There is sufficient evidence for effectiveness

The published literature regarding the effectiveness of unit dose distribution systems is of relatively poor quality. Unit dose systems are effective in reducing medication errors compared to floor stock systems with bulk containers of medications. Based upon its evaluation of published literature, AHRQ rated unit dose distribution systems as a safety practice with lower impact and/or strength of evidence.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

Older published studies demonstrated that UD distribution systems are superior to bulk bottle ward stock systems. However, given that unit dose distribution systems are a JCAHO standard, there are few alternatives to these systems. The evidence is insufficient to determine the superior method for distribution of the unit dose medications (e.g., dispensed in patient cassettes, dispensed in automated dispensing devices, etc.)

3. There is freedom from known implementation issues

Unit dose distribution systems are widely accepted and implemented in hospitals throughout the U.S. As such, the cost of implementation and complexities associated with implementation is low.

4. There is evidence of successful transfer from research to non-research settings

Unit dose distribution systems are widely used. In a 1994 survey conducted by the American Society of Health-system Pharmacists (ASHP), 92% of hospitals practiced unit dose dispensing.⁶

Summary: The use of unit dose medication distribution systems illustrates a commonly used practice that has evolved into a standard over the past two decades, but which would not meet today’s evidence requirements for a practice that should be elevated to a standard. There are numerous studies that demonstrate decreased dispensing-related medication errors with unit dose systems and decreased costs/drug wastage compared to nursing floor-stock systems. However, the methodology described within those published studies does not meet today’s requirements of rigor in health care studies, as performed by the AHRQ evaluation. The relatively modest AHRQ rating regarding the effectiveness of Unit Dose Distribution systems in decreasing ADEs is largely due to the lack of well-designed studies that measured and reported outcomes. The use of unit dose systems is widespread through America’s hospitals, has additional benefits for hospitals (help reduce wastage and increase nursing productivity), and currently has few

alternatives, so it is unlikely that more rigorous studies will be performed in the near future. Other specific practices related to unit dose distribution systems, such as the newer technology of automated devices, complicate the measurement of the effectiveness of unit dose distribution systems as a “stand alone” practice. Thus, unit dose distribution systems represent an example of a practice that does not have reasonable alternatives against which a comparison can be made for greater effectiveness, but does not appear to introduce any additional “harm” into the medication distribution system and has additional benefits that are not directly related to an objective of reduced ADEs.

Infection Control – Prophylactic Antibiotics to Prevent Surgical Site Infections

Surgical infections are a common complication of care, occurring in 2% to 5% of “clean” extra-abdominal surgeries and up to 20% of intra-abdominal surgeries. One safe practice for preventing surgical-related infections is the administration of prophylactic antibiotics. Proponents of this safe practice advocate a brief course of an antimicrobial agent just before an operation in order to reduce intraoperative microbial contamination. Administration is timed to achieve a bactericidal concentration in the serum and tissues at the time of the incision.

Application of Criteria to Prophylactic Antibiotics to Prevent Surgical Site Infections

1. There is sufficient evidence for effectiveness

There is sufficient evidence to conclude that prophylactic antibiotics should be administered to prevent surgical site infections. The AHRQ assessed the practice of prophylactic antibiotics to prevent surgical site infections as a safety practice with "high" strength of evidence regarding its impact and effectiveness. The AHRQ rates the appropriate use of antibiotic prophylaxis among the 11 safe practices with the greatest strength of evidence regarding their impact and effectiveness.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

The evidence established the practice of antibiotic prophylaxis in surgical patients as a practice whose effectiveness is unmatched by other practices.

3. There is freedom from known implementation issues

Antimicrobial prophylaxis is widely accepted and implemented in hospitals throughout the U.S. As such, the cost of implementation and complexities associated with implementation is low.

4. There is evidence of successful transfer from research to non-research settings

The evidence regarding the outcomes of appropriate prophylactic antibiotic use is extensive across different settings.^{7,8} Antimicrobial prophylaxis has been implemented at hospitals throughout the country.

Summary: There is strong evidence that prophylactic antibiotics to prevent surgical infections are beneficial and effective. The superiority of this practice over other practices has been clearly documented. The use of prophylactic antibiotics to prevent surgical infections should be considered a potential standard of care.

Infection Control – Use of Silver Alloy Urinary Catheters

It is estimated that urinary tract infections account for 30% to 40% of nosocomial infections resulting in morbidity, mortality and increased healthcare costs.⁹ It has been proposed that the use of silver alloy urinary catheters will decrease urinary catheter-related infections.

Application of Criteria to Use of Silver Alloy Urinary Catheters

1. There is sufficient evidence for effectiveness

There is sufficient evidence showing a reduction in the development of catheter-associated bacteriuria associated with silver-coated catheters. The AHRQ assessed the use of silver alloy urinary catheters as a safety practice with “high” strength of evidence regarding its safety and effectiveness and placed it on a list of practices for which further research would be highly beneficial.¹³

AHRQ evaluated a meta-analysis that included 4 randomized clinical trials that compared silver catheters with non-coated catheters. All studies showed a reduction in catheter-associated bacteriuria.¹⁶ Since the AHRQ initial review, new clinical studies have been published with conflicting results regarding the efficacy of silver-coated catheters in reducing catheter-associated bacteriuria.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

Other practices that have been employed to decrease urinary catheter-related infections include handwashing, inserting catheter using aseptic technique, maintaining a closed sterile drainage, obtaining urine samples aseptically and maintaining unobstructed urine flow.¹⁰

AHRQ found that the evidence supporting the use of silver alloy urinary catheters to reduce urinary catheter-related bacteriuria was “reasonably strong.” However, it is unknown whether silver-alloy urinary catheters will also result in a decrease in catheter-related bacteremia. Until more studies are conducted evaluating outcomes, there is not sufficient evidence to support the use of silver alloy urinary catheters as superior to other practices.

3. There is freedom from known implementation issues

AHRQ estimated that the cost of a silver alloy urinary catheter tray is \$5.30 more than a non-coated urinary catheter tray. However, it is estimated that despite the increased cost of the silver alloy catheter and its components, the costs are offset by the decrease in nosocomial UTIs.

4. There is evidence of successful transfer from research to non-research settings

Most of the published studies have been conducted at large teaching hospitals/academic medical centers.

Summary: The use of silver alloy urinary catheters is a good practice; however, there are other practices that can be used to prevent nosocomial urinary tract infections. Until more data are available, the practice should be considered one of a number of practices that will enable a hospital to reduce hospital-acquired urinary tract infections.

Infection Control – Continuous Aspiration of Subglottic Secretions

Patients on ventilators may aspirate oropharyngeal secretions, which may contain pathogenic organisms. This aspiration may result in ventilator-associated pneumonia (VAP), a leading cause of morbidity and mortality in ICUs. One practice to decrease the development of ventilator-associated pneumonia is the use of continuous aspiration of subglottic secretions (CASS) using specially designed endotracheal tubes.

Application of Criteria to Volume Standards for CASS

1. There is sufficient evidence for effectiveness

The scientific data regarding this practice are limited, but demonstrate the value of CASS. One study found a statistically significant decrease in VAP for patients while another found a strong trend toward decreased VAP. CASS also has been demonstrated to significantly increase the time to develop VAP. The AHRQ rated CASS as a safety practice with the greatest strength of evidence regarding its impact and effectiveness.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

There are no data comparing CASS to other alternatives, including semi-recumbent positioning and selective decontamination of the digestive tract.

3. There is freedom from known implementation issues

AHRQ estimated the cost of implementing CASS as low; but evaluated the practice as having high technical complexity.

4. There is evidence of successful transfer from research to non-research settings

This practice should be transferred to non-research settings, but there are no reports of outcomes in a non-research setting.

Summary: There is strong evidence that continuous aspiration of subglottic secretions is beneficial and reduces ventilator-associated pneumonia. The superiority of this practice over other practices is unknown and the AHRQ identified technical complexity as a potential implementation consideration. Thus, CASS should be considered one of many practices that a hospital can utilize to reduce ventilator-associated pneumonia.

Management of High-Risk Populations – ICUs Managed by Intensivists

Although ICU beds comprise approximately 10% of hospital beds in the U.S., they consume a disproportionate share of hospital resources. It has been proposed that mortality rates for this high-risk population could be reduced if all ICUs were managed by specialists in critical care medicine (intensivists); i.e., a physician with training in internal medicine, family practice, or pediatrics with additional training in critical care medicine.

Application of Criteria to Intensivist-Managed ICUs

1. There is sufficient evidence for effectiveness

While the evidence for the effectiveness of intensivists is not exhaustive, it is compelling. Several well-designed studies, most involving teaching institutions, have demonstrated improved mortality rates with ICUs staffed by intensivists.^{11,12} Effectiveness has been demonstrated for different models for the role of intensivists (i.e., daily ICU rounds by an intensivist, presence of a full-time intensivist, co-management by an intensivist, mandatory consultation by an intensivist, and only intensivist management).

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

AHRQ found that clinical outcomes in studies of the effectiveness of intensivists were difficult to interpret since they involve different ICU organizational structures with differing roles of the intensivists (closed, vs. co-managed vs. mixed), but rated the effectiveness of this practice as high across the various models of care involving the intensivist.¹³ One study showed an improvement in efficiency (reflected by length-of-stay), but no difference in mortality.¹⁴

There are few studies, however, of alternative practices to improve the outcomes of ICU patients. For example, the impact of the relatively new movement toward “hospitalists” has not been specifically evaluated for ICU patients. Data regarding the impact of intensivists in specialty ICUs (e.g., post-op open-heart surgery or burn units) is not available.

3. There is freedom from known implementation issues

AHRQ estimates the cost of management by an intensivist as medium and the complexities are high. In addition, the AHRQ notes the current shortage of intensivists.

4. There is evidence of successful transfer from research to non-research settings

The “intensivist model” has been implemented in a minority of hospitals, and primarily at large teaching hospitals/academic medical centers. There is little information regarding the implementation and impact of intensivists in other types of hospitals. Greater implementation in non-research settings may be limited by the current shortage of intensivists.

Summary: The use of intensivists for the management of critically ill patients is a practice that should enhance the quality and safety of care for ICU patients. The most effective implementation model (e.g., intensivist-only management, comanagement, mandatory consultation) has not yet been defined by the scientific evidence. The use of intensivists for the management of ICU patients is a promising practice, but cannot be considered a potential standard until the implementation issues, such as the lack of available intensivists, are addressed.

Management of High-Risk Populations - Prevention of Venous Thromboembolism

Thromboembolism prophylaxis is a practice that is advocated to prevent venous thromboembolism in hospitalized patients with risk factors. Patients who are immobile or are in a hypercoagulable state are at higher risk for developing thromboembolism that manifests as a deep venous thrombosis (DVT) or pulmonary embolism (PE). The use of mechanical and pharmacologic interventions have been evaluated for preventing venous thromboembolism.

Application of Criteria for Prevention of Venous Thromboembolism

1. There is sufficient evidence for effectiveness

There is an abundance of evidence supporting thromboembolism prophylaxis to reduce venous thromboembolism in hospitalized patients.¹⁵ The AHRQ assessed prevention of venous thromboembolism as a safety practice with "high" strength of evidence regarding its impact and effectiveness. The AHRQ rated the appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk among the 11 safe practices with the greatest strength of evidence.¹⁶

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

In the AHRQ review, it is documented that there are a significant number of randomized control trials and meta-analyses examining the efficacy of venous thromboembolism prophylaxis. Depending on the population at risk (e.g., general surgery, orthopedic patients, etc.), one prophylaxis strategy may be more effective than another; however, the practice of venous thromboembolism prophylaxis is well documented. The American College of Chest Physicians (ACCP) recommends the "routine use of thromboprophylaxis" for patients at high risk for venous thromboembolism.¹⁵

3. There is freedom from known implementation issues

AHRQ estimated that the cost and complexity of implementing thromboembolism prophylaxis is low.

4. There is evidence of successful transfer from research to non-research setting

The evidence documenting improved outcomes in patients receiving thromboembolism prophylaxis is extensive across different settings. Prophylaxis has been implemented at hospitals throughout the country. A survey of fellows of the American College of Surgeons revealed that in 1997, 96% of the participants stated that they used thromboprophylaxis.¹⁵

Summary: Prevention of venous thromboembolism is a practice that should be considered a potential standard of care.

Management of High-Risk Populations – Volume Standards for High-Risk Surgical Procedures

Volume standards drive the practice of directing patients to facilities that have demonstrated experience in certain high-risk surgical procedures. The rationale for this practice is based upon observational studies that found better outcomes (morbidity, mortality) for hospitals with a high volume of surgeries compared to low volumes. Examples of surgeries or procedures that are often cited as having a correlation between volume and mortality include organ transplants, coronary artery bypass graft (CABG), abdominal aortic aneurysm repair and esophageal cancer resection.

Application of Criteria to Volume Standards for High-Risk Surgical Procedures

1. There is sufficient evidence for effectiveness

There is compelling evidence in the medical literature that there is an association between the volume of procedures performed and mortality rates for a select number of high-risk surgical procedures. Statistical analysis of mortality data for high-risk procedures is challenging, however. AHRQ noted that volume indicators are a proxy--a "noisy" correlate of quality. The heterogeneous nature of the published studies precludes a meta-analysis. The derivation of volume thresholds is an imprecise method and in some instances, is arbitrary. For example, of seven published studies that demonstrated a significant correlation between the volume of CABGs performed and clinical outcomes, each of the studies defined low volume and high volume institutions in a different manner.¹⁷ Thus, the establishment of the threshold between high-volume and low-volume facilities is difficult to determine on an "evidence-based" basis.

2. There is sufficient evidence for greater effectiveness of the practice than alternatives

There is no evidence that volume alone can achieve desired outcomes. Volume statistics for high-risk procedures are more useful when used in conjunction with other outcome statistics such as risk-adjusted mortality and utilization.

3. There is freedom from known implementation issues

The major implementation issue is consensus regarding the appropriate thresholds and consensus regarding this practice from key stakeholders. There appear to be no hospital system barriers to implementation.

4. There is evidence of successful transfer from research to non-research settings

Outcomes related to the "real-life" implementation of this standard have not been published. Estimates of reduced mortality that may result from the use of volume thresholds to direct patient care are based on assumptions and projections that attempt to account for emergency procedures in unstable patients.

Summary: There is compelling evidence in the medical literature that for a select number of high-risk surgical procedures, there is a correlation between volume and favorable outcomes. Interpretation of the medical literature related to volume and outcomes is complex. The methodology used to establish volume-based standards is complex from a statistical and case-mix adjustment perspective. There is disagreement regarding which high-risk procedures should be included and there is variation in the thresholds that have been recommended to differentiate low volume from high volume

institutions. Most importantly, volume indicators are an imprecise proxy for quality. Ideally, these numbers should be used in conjunction with clinical quality measures (e.g., post-surgical complication rate/morbidity rate and mortality). The use of surgical volume measures is one indicator for quality, but does not fulfill the criteria.

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