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June 23, 2009

Maureen Carr
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The Joint Commission
One Renaissance Boulevard
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Dear Ms. Carr,

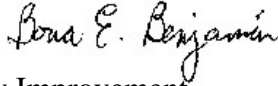
The American Society of Health-System Pharmacists (ASHP) is pleased to offer comments on proposed revisions to the 2009 National Patient Safety Goals (NPSGs).

ASHP is a 35,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems.

ASHP commends The Joint Commission (TJC) for its efforts to remove redundancies and clarify the language of the NPSGs. We believe that this approach, which includes broad engagement of TJC staff, the Professional and Technical Advisory Committees (PTACs) and the field, will result in goals that better balance improved patient safety with achievability and decreased compliance burden.

Our comments address only those goals that are applicable to our members practicing in Hospital/Critical Access Hospitals or that relate to medication use safety and effectiveness. They are provided in the same sequence as presented in the field review document.

Thank you for the opportunity to offer these comments on behalf of ASHP. If you need clarification or more information, please don't hesitate to contact me.

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**ASHP Comments to the Joint in Response to Field Review of the
2009 National Patient Safety Goals
June 2009**

NPSG.03.04.01 The [organization] labels all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.

EP 3: In perioperative and other procedural settings both on and off the sterile field, medication or solution labels include the medication name, strength, amount (if not apparent from the container), preparation date and diluent, expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours.

Comment

ASHP recommends changing “.....medication or solution labels include the medication name, strength, amount (if not apparent from the container)” to

“...medication or solution labels include the medication name, strength and quantity; diluent and volume (if not apparent from the container.)”

The volume of diluent is required for determining final concentration of an infusion or injection.

EP 6: Any medications or solutions found unlabeled are immediately discarded.
EP 8: All labeled containers on the sterile field are removed and their contents discarded at the conclusion of the procedure.

Comment

ASHP recommends referencing EC.02.02.01 (“The hospital manages risks related to hazardous materials and waste”) to ensure appropriate disposal of hazardous medications.

NPSG.03.05.01 Reduce the likelihood of [patient] harm associated with the use of anticoagulant therapy.

EP 1: The hospital implements a defined anticoagulation management program to individualize the care provided to each patient receiving anticoagulant therapy (EP recommended for deletion)

Comment

ASHP strongly urges TJC to retain this EP. Requiring a programmatic approach to anticoagulation has resulted in effective and safe systems for managing therapy with these agents.

ASHP policy supports pharmacists in a leadership role for anticoagulation management services. Pharmacists working collaboratively with medical staff

have developed programs characterized by a comprehensive infrastructure that includes evidence-based protocols; safety procedures; careful monitoring and follow-up; education and training of staff; engagement of patients in their own care; and assigned accountability for therapeutic outcomes. These programs have resulted in improved care and greatly reduced adverse events associated with misuse of anticoagulants, which are highly likely to cause harm if errors occur.

ASHP believes that these significant gains in safety are at risk without a requirement for a systematic approach to managing anticoagulation services. ASHP recommends enhancing the requirement by using the Infection Control standards as a model, i.e. anticoagulation should be the responsibility of a trained professional who is accountable for the quality of care and to whom leadership provides the necessary resources.

This perspective is shared by the authors of the 8th edition of [“Antithrombotic and Thrombolytic Therapy: American College of Chest Physicians \(ACCP\) Evidence-Based Clinical Practice Guidelines”](#) for optimal management of vitamin K antagonist (VKA) therapy which state:

“For health-care providers who manage oral anticoagulation therapy, we recommend that they do so in a systematic and coordinated fashion, incorporating patient education, systematic INR testing, tracking, follow-up, and good patient communication of results and dosing decisions as occurs in an anticoagulation management service (Grade 1B). “

EP 3: Use written approved protocols for the initiation and maintenance of anticoagulant therapy.

Comment

ASHP recommends a note specifying whether the expectation for protocol approval is by an organizational policy committee or by endorsement as a national guideline.

EP 4: Before initiating warfarin therapy, a baseline International Normalized Ratio (INR) is available. While a patient receives warfarin therapy, a current INR is used to monitor and adjust therapy. The baseline and current INR are documented in the medical record.

Comment

ASHP supports TJC’s requirement for a baseline INR, however we note that this requirement is not included in the [ACCP guidelines](#) previously mentioned. Specifically the guideline states:

“In patients beginning VKA therapy, we recommend the initiation of oral anticoagulation with doses between 5 and 10 mg for the first 1 or 2 days for most

individuals, with subsequent dosing based on the international normalized ratio (INR) response (Grade 1B).”

ASHP member experts practicing in anticoagulation services continue to support the requirement to obtain a baseline INR, but have indicated that the time frame around “baseline” and “current” could be broadened. Given these disparate views regarding tight timing between INR and warfarin dosing, ASHP recommends that TJC continue to study this requirement and modify it if indicated.

EP 5: Use accepted guidelines to manage food and drug interactions for patients receiving warfarin.

Comment

ASHP recommends changing the term “accepted guidelines” to “authoritative resources” for this requirement. Food and drug interaction data are frequently revised as research results and new drug safety data become available, therefore there is no accepted guideline for management.

EP 6: When heparin is administered intravenously and continuously, use programmable infusion pumps in order to provide consistent and accurate dosing.

Comment

ASHP recommends clarifying the term “programmable.” We have had queries from members interpreting the intent of this element as a requirement for a pump with software that alerts users when pre-established upper and lower dose limits are exceeded, i.e. an “intelligent” infusion device.

EP 8: Provide education regarding anticoagulant therapy to prescribers, staff, patients, and families. Patient/family education includes:

- The importance of follow-up monitoring
- Compliance issues
- Dietary restrictions
- The potential for adverse drug reactions and interactions

Comment

ASHP recommends changing the wording of “Dietary restrictions” in the third element above to “The importance of stable dietary Vitamin K intake.” Current recommendations for warfarin therapy focus on helping patients understand that adverse events are more likely when their dietary intake of Vitamin K fluctuates, rather than advising them to restrict their intake.

NPSG.07.01.01 Comply with either current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or World Health Organization (WHO) hand hygiene guidelines.

EP 2: Improve compliance with hand hygiene guidelines.

Comment

While this goal is aimed primarily at direct care providers, it has implications for pharmacists, if functioning in that role. ASHP recommends that training, education, and quality improvement activities regarding hand hygiene include these individuals.

Our members with executive responsibilities in hospitals and health-systems have commented on the challenges of implementing this goal and emphasize the essential role of leaders for success as well as the need for intensive education and highly visible promotion of meticulous hand hygiene to all staff.

NPSG.07.03.01 Implement evidence-based practices to prevent health care–associated infections due to multidrug-resistant organisms in hospitals.

Note 1: This requirement applies to, but is not limited to, epidemiologically important organisms such as methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* (CDI), vancomycin-resistant Enterococci (VRE), and multiple drug resistant gram negative bacteria.

Note 2: Surveillance may be targeted, and not organization-wide.

Comment

The importance of antibiotic selection, route of administration, dosing, and duration of therapy is noticeably absent from this goal. ASHP encourages The Joint Commission to consider development of an element of performance (EP) that emphasizes the importance of antibiotic stewardship programs, including the central role of pharmacists, in preventing healthcare-associated infections from multi-drug resistant organisms (MDRO) through appropriate antibiotic utilization, including use of patient care area-specific antibiograms to assess resistance patterns and strategies to prevent collateral damage. This approach is supported by numerous practice guidelines, including the Guidelines for Developing an Institutional Program to Enhance Antimicrobial Stewardship (Available at: www.journals.uchicago.edu/doi/full/10.1086/510393). Drug-specific guidelines, such as Therapeutic monitoring of vancomycin in adult patients: A consensus review of the American Society of Health-System Pharmacists, the Infectious Diseases Society of America, and the Society of Infectious Diseases Pharmacists (Available at www.ajhp.org/cgi/reprint/66/1/82?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&author1=rybak&fulltext=consensus&searchid=1&FIRSTINDEX=0&sortspec=relevance&resourcetype=HWCIT) should be recommended as tools to support these efforts.

In addition, while ASHP commends the overall intent of this goal, the Society encourages The Joint Commission to consider revising the wording from “prevent” to “reduce.” This change recognizes that not all infections are

preventable. For example, some patients, including those who are immunocompromised, may be more vulnerable to health-care associated infections. Another example is *Clostridium difficile* infection, a documented adverse effect of commonly prescribed antibiotics, which may not be preventable in every patient. Most importantly, the suggested language results in a goal that is measurable and supports facilities' efforts to reduce the incidence and type of health care-associated infections.

EP 10: Provide multidrug-resistant organism process and outcome data to key stakeholders, including leaders, licensed independent practitioners, nursing staff, and other clinicians.

Comment

ASHP recommends changing “leaders, licensed independent practitioners, nursing staff, and other clinicians” to “leaders, licensed independent prescribers, and other clinicians involved in patient care” in this EP as well as EP 9 for NPSG 07.04.01. Pharmacists require these data to inform and support decisions on formulary antimicrobials and their appropriate use.

NPSG.07.04.01 Implement best practices or evidence-based guidelines to prevent central line–associated bloodstream infections.

Note: This requirement covers short- and long-term central venous catheters and peripherally inserted central catheter (PICC) lines.

Comment

ASHP supports the intent and proposed revisions to this goal to prevent central line associated infections—a significant cause of patient morbidity and mortality. As noted in our comments on the 2009 draft goal, ASHP encourages The Joint Commission to consider ventilator-associated pneumonia and catheter-associated urinary tract infections for the focus of future goals.

NPSG.07.05.01 Implement best practices for preventing surgical site infections.

EP 8: The hospital does the following:

- Conducts periodic risk assessments for surgical site infections at least annually and whenever changes occur
- Selects surgical site infection measures using best practices or evidence-based guidelines
- Monitors compliance with best practices or evidence-based guidelines
- Evaluates the effectiveness of prevention efforts

Note: This surveillance may be targeted to certain procedures based on the hospital's risk assessment.

Comment

In EP 8, the addition of “at least annually” to define the frequency for risk assessment improves the clarity of this EP. However, ASHP suggests deleting the

phrase “whenever changes occur” based on its ambiguity. If the phrase is retained, additional guidance or an FAQ is needed to define what changes (e.g., changes in infection rates, organisms identified) should prompt an assessment. The Society encourages The Joint Commission to allow facilities flexibility in determining the need for additional risk assessments, which are labor- and resource-intensive.

NPSG.09.02.01 The [organization] reduces the risk of falls.

Goal and all EPs moved to standards

Comment

Medications are a significant factor in falls. ASHP believes that routine medication evaluation is essential for preventing harm from falls in at-risk populations and strongly encourages including a note to that effect in the standard. Lists of medications that may affect equilibrium or coordination to be used in assessment are available, but may not be all-inclusive or applicable to organization-specific patient populations. For this reason, ASHP recommends including pharmacists in the development of fall reduction programs and assessment individual patients at heightened risk for falls.

NPSG.15.01.01 Identify patients at risk for suicide.

Note: This requirement applies only to psychiatric hospitals and patients being treated for emotional or behavioral disorders in general hospitals.

Comment

ASHP recommends reconsideration of the limitations in this note and that, at minimum, some form of suicide prevention screening should be performed for all hospitalized patients. We note that suicide is the second most frequently reported sentinel event, that reports have steadily increased since 2005, and that more suicides were reported in [2008 Sentinel Event Statistics](#) than any other year. Although sentinel event statistics do not include detail on whether these cases occurred in psychiatric treatment settings, suicide is known to be a significant cause of death in the general population (see [CDC Facts on Suicide](#).) Non-psychiatric patients at risk in general hospitals include the chronically or terminally ill, chronic pain sufferers, and patients requiring surgery or treatment of physical disorders who have an undisclosed or undiagnosed emotional disorder, such as post-traumatic shock disorder, depression, or substance abuse.

In addition, recent drug safety data indicate that medications commonly used in non-psychiatric patients increase the risk for suicide. Examples include sedative use in the elderly; antidepressants, particularly in pediatric patients; amantidine; interferon-beta; levetiracetam, gabapentin, and other anticonvulsants; efavirenz; sumatriptan; and smoking cessation medications varenicline and bupropion.