



June 13, 2008

Acting Administrator Kerry N. Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Attention: CMS – 1390-P

Re: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; 73 Fed. Reg., 23528 (April 30, 2008)

Dear Acting Administrator Weems:

Representatives of the American College of Chest Physicians, American Thoracic Society, Society of Critical Care Medicine, the National Association for Medical Direction of Respiratory Care, American Association of Critical Care Nurses, and the American Association for Respiratory Care collaborated to discuss the proposed CMS policy for serious preventable adverse events, in particular Hospital Acquired Conditions (HACs). Our societies are interdisciplinary and multidisciplinary experts in pulmonary, critical care, and sleep medicine, representing over 150,000 practicing clinicians in the United States.

As professional societies representing both our members and the patients that they serve, we believe that the development of performance measures and outcomes reporting for HACs represents an important new era both for CMS and the field of Critical Care. The leadership of our professional societies would like to work in partnership with CMS to ensure that patients receive safe, high-quality care that reduces and eliminates unnecessary risk. We believe it essential that the health care system must be accountable for the quality of care provided to patients, and that performance measures and outcomes reporting be established in a way that will ensure that patients receive the highest quality of care possible, consistent with the published peer-reviewed literature for effective clinical practice. In fact, we feel a responsibility to help develop these measures of accountability and facilitate their adoption by health care institutions and practitioners.

Overall Comments & Observations:

It is clear that not all hospital-acquired conditions/infections are preventable. Congress recognized this important distinction when it established Section 1886(d)(4)(D)(iv)(III) of the Social Security Act to read that “such conditions could reasonably have been prevented through the application of evidence-based guidelines.” Our societies interpret the mandate to CMS to identify conditions that can genuinely be reduced to “never events” through strict adherence to clinical practice guidelines. If conditions and infections cannot reasonably be expected to be eliminated through such clinical practice guidelines, the conditions do not meet the strict legislative mandate or the explanatory report language included in Conference Report 109-362.

We suggest that there are, in fact, three categories of HACs, and that CMS has authority to adjust payment if the HAC applies ONLY to #1, below.

1. 100% Preventable: These are HACs that are always preventable. We agree that for this category the CMS proposal is appropriate as it implements 1886 (d)(4)(D)(iv)(III). Examples of this category are wrong-site surgery, ABO-incompatibility transfusions, and clinically significant medication errors.

2. Reducible but not 100% preventable: These HACs are reducible but they are not entirely preventable even with preventive measures and clinical practice guidelines. For these conditions, adherence to evidence-based guidelines can significantly reduce, but never completely prevent, the condition. Examples of this category are Ventilator Associated Pneumonia (VAP) and DVT/PE described in detail in our comments below. At present, there will always be a case rate for these conditions despite the strictest adherence to evidence-based guidelines. As noted above, we believe that payment adjustments based on the use (or non-use) of good evidence-based guidelines that have been shown to reduce this type of HAC are reasonable, but we do not believe CMS has the authority to adjust payment based only on the presence of this type of HAC.

3. Effect of preventive measures unclear: There are some conditions for which preventive measures have either not been established or not conclusively proven in the peer-reviewed literature. Although these conditions are known to develop in hospitalized patients, an evidence-based set of performance measures would be difficult to develop. Examples of this category are Iatrogenic Pneumothorax and Delirium, which we describe in detail below. We believe that more research should be encouraged in this group before payment adjustment decisions are made.

To determine the category for each condition in the CMS HAC proposal, we suggest that each condition and associated set of performance measures be evaluated in the context of the following four questions:

- Does an evidence-based guideline exist to prevent the condition?
- Based on definitive study and research, how effective is the evidence-based guideline when strictly adhered to?

- If not entirely effective, what is the expected rate of the condition when the evidence-based guideline is followed versus when it is not followed?
- Have unintended consequences from guideline usage and payment adjustment strategies been carefully considered and appropriate risk-benefit analyses been done?

We suggest that by using these principles to guide the process, a coherent set of performance measures and conditions can be identified to ensure that hospitalized patients receive the best possible evidence-based care.

We regard all nine of the proposed conditions listed as worthy of comment. However, we chose four as the focus of this comment letter.

Ventilator Associated Pneumonia (VAP):

We believe that VAP is reducible but not entirely preventable even with preventive measures described in the American Association for Respiratory Care's (AARC) and other clinical practice guidelines.

Evidence-Based Guidelines (EBGs) designed to reduce VAP: The most widely used approach for prevention is to apply a “ventilator bundle”. The bundle that is most commonly used includes 5 elements: daily interruption of sedation, head of the bed elevation, daily attempt to wean from the ventilator, gastrointestinal bleeding prophylaxis, and deep venous thrombosis prophylaxis. These are widely accepted by the medical community as being generally safe and effective.

Effects of EBGs on the rates of VAP: In an early report, the ventilator bundle described above was applied in 35 ICUs and led to a 44.5% reduction in VAP rates to a range of 1.8-5.9/1,000 ventilator days, but not a rate of zero. In that trial, although VAP rates declined, the overall ICU mortality, length of stay, and antibiotic use did not change. To add credibility and validity to a decline in VAP rates, there should be an improvement in these consequences of VAP. To date, these outcomes have not been reported in any EBG related to VAP. Thus, current EBGs must be considered as tools that improve the processes of care, but they have not been clearly shown to reduce the important clinical and financial consequences of VAP.

While preventive interventions such as the EBG bundles are directed at modifiable risks for VAP, many risks are patient-related, including: immunosuppressive therapy, co-morbid illness, the presence of acute lung injury (ARDS), malnutrition or renal failure at the time of admission, history of cigarette smoking, need for major surgery, admission after trauma or burns, need for massive transfusion, coma, and need for prior antibiotic therapy (1). The duration of mechanical ventilation also affects risk, with the risk of VAP being reported in one study as 3%/day of ventilation during the first 5 days, 2%/day on days 6-10, and 1%/day in the third week of ventilation (2).

Therefore, we conclude that VAP can be reduced substantially by the use of EBGs, but because of many risk factors that cannot be controlled or avoided, it is unreasonable to expect reductions in VAP lower than 2-6 events/1,000 ventilator days.

Unintended consequences: We are concerned that inappropriate payment structures will promote inaccurate public reporting. Specifically, because the diagnosis of VAP is imprecise and depends on observer interpretation of clinical signs and data, VAP rates can rise or fall depending upon a number of factors outside the clinical arena (e.g. media reporting, and legislative or regulatory mandates). Monitoring and assessing effectiveness of prevention strategies along with appropriate payments to hospitals can thus be compromised.

Illustrating this concept is the fact that the National Nosocomial Infection Surveillance (NNIS) definition does not always coincide with the definition of VAP that takes quantitative bronchoscopic cultures into account. In one study of trauma patients, the NNIS definition agreed with the quantitative bronchoscopic culture findings in 263 episodes. However, using quantitative cultures as the gold standard, in 32 episodes the diagnosis by NNIS was false positive, and in 30 episodes it was false negative (3).

One other limitation of the diagnostic methods is illustrated by a commitment to observe VAP rates in 71 German ICUs (i.e. focusing on VAP diagnosis). This led to a 24% drop in VAP rates over a 3-year period with no intervention actually being implemented to achieve this (4). These findings highlight the subjective nature of the diagnosis and the ability to reduce rates at will, with no intervention, just by re-defining the illness.

Another consequence of concern would be an inappropriate increase in diagnostic scrutiny for possible pneumonia on admission. Given the uncertainty of the pneumonia definitions noted above, this could lead to overdiagnosis with inappropriate overuse of antibiotics.

Conclusion and Recommendations: We believe that the development of VAP is reducible, but not always preventable. There is no study in the peer-reviewed literature that has demonstrated a zero VAP rate, and there is conclusive evidence that even adherence to published evidence-based clinical practice guidelines does not ensure VAP as a “never event”. On the other hand, the current EBGs for reducing VAP are safe and reasonable to use in virtually all ventilator patients. Financial incentives to encourage their use seem appropriate.

References:

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Additional Reading:

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- Van Nieuwenhoven CA, et al. Feasibility and Effects of The Semirecumbent Position to Prevent Ventilator-Associated Pneumonia: A Randomized Study. *Crit Care Med* 2006; 34:396-402

Iatrogenic Pneumothorax (IP)

We believe that effective preventive measures make IP reducible but not 100% preventable. IP does not meet all criteria for selection as a candidate for a preventable Hospital Acquired Condition because that inclusion presumes that IP is a wholly preventable condition, because we currently do not have the knowledge or technology to eliminate its occurrence.

Evidence-Based Guidelines (EBGs) and their effects on reducing rates of IP: Per statute, selected conditions must be reasonably preventable through the application of evidence-based guidelines. CMS quotes a document found at:

www.ncbi.nlm.nih.gov/pubmed/1485006

This is not an evidence-based guideline for preventing IP. (1) Rather, it is an analysis of prospective data acquired in conjunction with a multicenter Veterans Administration (VA) population study designed primarily to assess recurrence prevention strategies for spontaneous pneumothorax. (2) No evidence-based guideline exists to date for iatrogenic pneumothorax. (3) The *British Thoracic Society Guidelines for the Management of*

Pleural Disease chapter on spontaneous pneumothorax mentions iatrogenic pneumothorax only in passing (page 49) with no recommendations. (4) Neither the most recent review of IP available from PubMed (5), nor a very recent book chapter (6) note available guidelines for diagnosis, prevention, or care of IP. These two publications highlight that the incidence of IP is likely high, as noted by CMS, and appears on the rise due to increasing adoption and evolution of invasive diagnostic and supportive measures.

As with many potential iatrogenic complications, physician experience is inversely proportional to incidence, but no absolute number of procedures can predict physician competence and consequent absence of IP given individual physician procedural competence acquisition rates. Diverse procedures, including those with incompletely predictable but expectedly higher risks for IP, such as transthoracic needle biopsy of lung lesions, further complicate baseline incidence determination. Additionally, such procedures may be chosen to provide the greatest benefit with the least patient risk, even if an IP may occur. Perhaps procedures *expected* to result in a high IP rate (e.g., transthoracic and transbronchial needle biopsy), should be monitored in a separate category if IP is to be considered in the future for an appropriate HAC designation.

With respect to requested comments regarding risk stratification for IP, we believe that IP is a “reducible but not 100% preventable” condition at this time. There is potential to move closer to “100% preventable” for some procedures such as central line placement and otherwise uncomplicated (minimal accompanying pre-existing lung disease) thoracentesis, with adequate data and eventual widespread availability of necessary technology.

Unintended consequences: The most worrisome response to classification of all IP as a HAC is that otherwise-indicated diagnostic or therapeutic procedures may be avoided in order to maintain an acceptably low incidence rate.

Conclusion and Recommendations: Although reduction of IP is a very important goal, current knowledge and evidence about its incidence and prevention are constrained by the diverse etiology of IP. As opposed to VAP, IP is a condition where definition of the entity is clear, but evidence-based guidelines for prevention and recommendations for interventions to improve outcome are presently not available.

Iatrogenic pneumothoraces, particularly those related to central line placement and thoracentesis, likely fall into a “reducible but not 100% preventable” category. Nevertheless, continued data acquisition for common procedures with an apparent higher incidence of IP (including central line and thoracentesis), are required. As such, we support the mandatory reporting of all IP by hospitals within the context of research efforts to establish the necessary incidence data and to identify potential factors that may reveal increased risk and practices that subsequently reduce the incidence of IP. We do not believe that IP can be classified as a preventable condition until these data are gathered and evidence-based guidelines for IP prevention are published.

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Additional Reading:

Rosen AK, et al. Tracking rates of patient safety indicators over time. Lessons from the Veterans Administration. *Med Care* 2006; 44: 850-861

Deep Vein Thrombosis/Pulmonary Embolism (DVT/PE)

CMS proposes to add hospital-acquired deep venous thrombosis (DVT) and pulmonary embolism (PE), to its list of preventable conditions and cites the American College of Chest Physicians (ACCP) antithrombotic guidelines (1). CMS appropriately asks for comments on the degree to which this HAC is “reasonably preventable” through the application of guidelines. Comments have been requested on determining the presence of DVT and PE on admission. CMS has not asked about the risk of patient harm from guideline implementation but this issue needs to be addressed as well.

Guideline-recommended measures make DVT/PE reducible but not completely preventable. Rigorously performed clinical trials have demonstrated that neither DVT nor PE are entirely preventable. General medical patients treated with state-of-the-art prophylactic regimens continue to have an incidence of DVT or PE of about 3-7% per medical admission (2-6). In patients who are critically ill (e.g. heart failure or severe respiratory disease), the incidence is about two-fold higher, even when appropriate prophylaxis is administered. (7, 8). Trauma patients have a very high risk of DVT/PE, and prophylaxis clearly reduces this risk. However, when venography is performed in this population, as many as 31% of patients may develop DVT/PE, in the setting of aggressive prophylaxis (9). In general surgery, anticoagulant prophylaxis reduces the risk of both asymptomatic and symptomatic DVT/PE by at least 60% (1,10), but certainly not to zero. Among 142 patients who underwent a variety of vascular surgical procedures, all of whom received thromboprophylaxis with intraoperative pneumatic compression and perioperative low-dose unfractionated heparin, the respective rates of DVT and proximal

DVT, detected by routine screening with ultrasound on day 7 to 10, were 10% and 6% (1).

In the setting of orthopedic surgery, symptomatic DVT/PE continues to be reported in 1.5%-10% of patients after surgery (1). Asymptomatic DVT/PE, found by screening is present in a higher percentage. In a large North American randomized clinical trial of patients undergoing total hip replacement, all of whom received aggressive anticoagulation prophylaxis regimens, the overall rates of DVT/PE in each group were 6 and 8% (12). In total knee replacement, and hip fracture surgery, the DVT/PE rates are as high or higher, and similarly, cannot be reduced to zero (1). In other surgical and medical patients, DVT/PE risk can be decreased, but never to zero. Thus we must recognize that a proportion of all hospitalized patients will develop this disease.

Because these studies demonstrate that DVT/PE are reducible, but not close to preventable, in most patient populations, these conditions do not meet the legislative criteria of 1886 (d)(4)(D)(iv)(III) which mandates that the condition could reasonably have been prevented through the application of evidence-based guidelines.

It is not possible to recognize all DVT/PE events as being “present on admission”. In its release of March 24, 2006, the National Quality Forum recognizes: “ Symptoms of DVT may include pain, swelling, tenderness, discoloration or redness of the affected area, and skin that is warm to the touch. However, as many as half of all DVT episodes are silent; for thousands of sufferers, the first symptom is a PE that is followed by death.” Unlike patients undergoing elective surgery, the medically ill often have progressive worsening of the underlying risk factor (e.g., pneumonia or heart failure) over the weeks preceding admission. The DVT/PE event may well occur before admission but be diagnosed after admission. Noninvasive studies that could be performed on admission in asymptomatic patients include D-dimer measurement and lower extremity compression ultrasound. D-dimer is nonspecific and a number of entities other than thromboembolism are associated with a positive test. Studies in the mid-1990’s clearly demonstrated that compression ultrasound missed about 50% of asymptomatic DVT (13). More aggressive testing exposes patients to complications from overzealous use of contrast imaging. Because certain patients may require testing other than ultrasound, unnecessary risk due to contrast dye with magnetic resonance imaging, contrast venography, and chest CT angiograms will lead to an increase in renal insufficiency and allergic reactions.

Unintended consequences: CMS has not asked for comments on the risk to patients should DVT prophylaxis with anticoagulants be mandated, but this is an important issue. There will be unintended consequences if anticoagulant prophylaxis for DVT and PE are overutilized. While we wish to reduce the incidence of hospital-acquired DVT, we must recognize that only a small proportion of all hospitalized patients actually acquire this disease. Although we have no way to predict who will develop DVT, patients who would not develop it are at risk of complications of prophylaxis. Even in appropriate circumstances, prophylaxis has been associated with increased risk of major bleeding episodes in about 0.5% - 1.5% of cases (4,3,9). In patients who have high risks for active bleeding or other adverse effects, the danger from prophylactic anticoagulation would

outweigh the potential benefits. Heparin-induced thrombocytopenia is a potentially catastrophic entity, which may occur in 3 to 5% of hospitalized patients (15). An increase in well-intended but possibly inappropriate prophylaxis will increase this problem. Based on generally accepted studies one could say that in a population of 100 hospitalized patients, DVT could be prevented in seven by the use of prophylactic anticoagulation while 93 patients are put at risk of medication-related injury.

Conclusions and Recommendations: While recognizing the potential for patient harm, we believe that DVT prophylaxis should be the “standard of care” in most patient populations. Within the hospital there are sub-populations of patients for whom the benefit of prophylaxis outweighs the risk of drug-related injury. We recommend that CMS focus on those sub-populations and the most effective measures for dealing with them. Further research should be encouraged in patient populations with high risk who do not respond well to current measures. We also encourage further research to improve the accuracy of diagnosis. For all the reasons stated above, we recommend that CMS focus its initial effort, under the Value Based Purchasing Initiative, to support the use of DVT and PE prophylaxis in specific high-risk patient populations.

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Delirium in the Critically Ill

There are no data in the most prevalent realm of delirium (i.e., critically ill patients) that demonstrate that delirium is completely or consistently avoidable. Delirium, or acute brain dysfunction, is a life threatening global disturbance in cognitive function that develops in a majority of critically ill patients. ICU delirium develops in 20% to 50% of hospitalized patients and in 50% to 80% of critically ill ICU patients.

Evidence-based Guidelines Designed to Reduce ICU Delirium in the Critically Ill:

Evidence-based guidelines for the prevention dementia are lacking. The randomized trial by Inouye et al in hospitalized, non-ICU patients reduced delirium rates from 15% to 9%. This study is not applicable to critically ill patients, who are at much greater risk for delirium. Further, studies demonstrating reductions in *duration* or symptom *severity* have not been performed in critically ill patients.

Advanced age and history of dementia are strong risk factors for delirium, and put the elderly at a heightened risk for delirium. A significant number of elderly patients admitted to an ICU have pre-existing dementia, and this group has a 56% or greater risk of delirium if admitted to the ICU. As with other nosocomial complications, delirium is the result of interplay between the disease, the host and processes of care.

Three important factors causally associated with delirium are sepsis, surgery, and administration of sedatives and analgesics. In sepsis, the prevalence of coexistent delirium as an organ dysfunction is nearly universal at admission to the hospital, therefore, our goal in healthcare is reducing its duration rather than primary prevention.

Sedatives and analgesics currently represent the leading modifiable risk factors for transitioning to delirium, in the ICU, and as a result may be the best target for delirium prevention. These very potent drugs are nearly universally used in critically ill patients to reduce work of breathing, alleviate agitation, and prevent dislodgement of support devices. Prior studies have demonstrated reductions in duration of mechanical ventilation and ICU length of stay with protocolized, target-based sedation and daily wake-up trials, and by changing the mode of administration of these drugs (intermittent versus continuous infusion). In the recent ABC Trial, an intervention designed to protocolize sedation and mandate a daily spontaneous awakening trial resulted in a remarkable benefit to the intervention patients, with 4 days less in the ICU and hospital and a 14% absolute risk reduction in death at 1 year. Despite these large benefits from the “wake up and breathe” ABC Trial protocol, there was not a reduction in either the incidence of delirium (>70% in both groups) or the median number of days spent in delirium (2 days in both groups). One recent study comparing sedation with lorazepam to that with dexmedetomidine found that the latter resulted in a >2-fold reduction in days alive without delirium, as well as a nearly 30% reduction in the prevalence of coma, but the majority of patients in the intervention group still developed delirium. Thus, the limited arsenal of evidence-based interventions in this regard consists only of avoidance of benzodiazepines in general, and specifically lorazepam, for maintenance of sedation. While this intervention may successfully reduce the duration of delirium, there is currently no evidence that it can eliminate it altogether.

Unintended Consequences: The unintended consequence of avoidance of medications with the potential to cause delirium in the critically ill (e.g., narcotics) may be undue pain for patients, particularly after surgery, as well the possibility of harm due to dislodgement of lifesaving and monitoring devices in this patient population.

Conclusions and Recommendations: Clinicians must do their best to prevent delirium in the ICU, with particular attention among the elderly, who are already at very high risk to develop delirium because of cognitive changes related to aging. Research in this area is lacking, and we strongly urge funding for trials to prevent of this condition. In particular, future sedation trials need to incorporate delirium as an outcome. The paucity of interventions known to mitigate its development make a mandate for “delirium elimination” little more than a desperate gesture to contain expenditures, rather than a sensible target for improving patient care.

References: (for additional reading see educational website www.icudelirium.org)

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As mentioned above, we firmly believe that by adherence to standards of care and evidence-based clinical practice guidelines, based on rigorous evidence that have been proven to prevent or reduce hospital acquired complications, our patients will be spared unnecessary prolongation of hospital care and other adverse outcomes. We welcome an initiative focused on the reduction or elimination of these complications and look forward to an ongoing partnership with CMS that will facilitate this goal.

Sincerely,



Alvin V. Thomas, Jr., MD, FCCP
President, American College of Chest Physicians



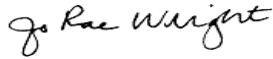
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