American Board of Emergency Medicine

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May 18, 2011

National Quality Forum
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RE: Appeal Response to the National Quality Forum

To Whom It May Concern:

On behalf of the American Board of Emergency Medicine (ABEM), I have the attached a critical review of measures IEP-005-10: Pulmonary CT Imaging for Pulmonary Embolism, and IEP-007-10: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury.

The mission of ABEM is *"to protect the public by promoting and sustaining the integrity, quality, and standards of training in and practice of Emergency Medicine."* ABEM is a member of the American Board of Medical Specialties and with approximately 27,500 diplomates, the largest certifying organization for emergency physicians. ABEM is the gold standard for certification in emergency medicine. ABEM embraces evidence-based standards, especially those that have been prospectively validated and shown to improve patient safety and quality care. However, upon the review and consideration of measures IEP-005-10 and IEP-007-10, ABEM has concerns about the potentially negative impact that these measures might have on the clinical practice of emergency medicine and patient safety.

I would be pleased to provide any additional information upon your request.

Respectfully submitted,

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Executive Director

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American Board of Emergency Medicine

Appeal Response to the National Quality Forum

Proposed Measures IEP-005-10: Pulmonary CT Imaging for Pulmonary Embolism and IEP-007-10: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury

The American Board of Emergency Medicine (ABEM) appreciates the opportunity to comment on the National Quality Forum (NQF) measures IEP-005-10 (Pulmonary CT Imaging for Pulmonary Embolism) and IEP-007-10 (Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury) during the appeal period.

The mission of ABEM is *"to protect the public by promoting and sustaining the integrity, quality, and standards of training in and practice of Emergency Medicine."* To that end, ABEM is keenly interested in the development and promotion of quality measures that enhance the delivery of emergency care and improve patient safety.

ABEM is the largest certifying organization in emergency medicine with approximately 27,500 diplomates. ABEM is a member of the American Board of Medical Specialties (ABMS), and is the gold standard for certification in emergency medicine. ABEM's commitment to protecting the public and improving emergency care is further shown by requiring a recertification examination (the ConCert exam) and an aggressive maintenance of certification program. ABEM is a not-for-profit organization and is neither an advocacy nor a membership organization.

Lest the ABEM response be construed as contrary to the development of quality measures, ABEM embraces evidence-based standards, especially those that have been prospectively validated and shown to improve patient safety and quality care. To that end, upon the review and consideration of measures IEP-005-10 and IEP-007-10, ABEM has concerns about the potentially negative impact that these measures might have on the clinical practice of emergency medicine and patient safety.

Commentary on NQF Measures IEP-005-10: Pulmonary CT Imaging for Pulmonary Embolism and IEP-007-10: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury

Introduction

Pursuant to NQF processes, ABEM offers the following commentary and concerns regarding measures IEP-005-10 and IEP-007-10. ABEM understands that the period of public comments concludes May 18, 2011.

Although ABEM might not share all of the opinions of the NQF, ABEM believes that ABEM and the NQF share several elements of interest. These include:

- The provision of quality clinical care to the acutely ill and injured patient
- The development of quality measures that enhance the quality of emergency care
- The development of quality measures that enhance patient safety
- The development of quality measures that do not decrease utilization at the expense of quality and safety

ABEM is concerned that measures IEP-005-10 and IEP-007-10 may actually diminish quality care and decrease patient safety. There remain doubts that the totality of the risks and benefits of the imaging measures have been adequately considered. NQF measures should meet a significant scientific threshold. Unfortunately, the original proposal uses selected references, ignores important contrary study results, and cites conjecture (e.g., Goldhaber SZ. *Pol Arch Med Wewn*. 2009). Moreover, caution must be applied to measures that potentially limit obtaining diagnostic studies that identify disease of considerable medical consequence. References should be evidence-based and support the development of the quality measure. Only primary source articles should be used in the citation of specific or quantitative statements. Finally, IEP-005-10 (CT for PE) is seriously flawed; for example, if a physician orders a CT pulmonary angiogram (CTPA) despite a normal D-dimer and a low probability, yet the CTPA shows a central pulmonary embolism (PE), the test is still deemed to be inefficient. Thus, following a utilization rule will trump an accurate and potentially life-saving diagnosis.

Recommended Actions

Based on the following commentary, ABEM respectfully requests that the NQF undertake the following actions:

- Withdrawal of IEP-005-10: Pulmonary CT Imaging for Pulmonary Embolism
- Withdrawal of IEP-007-10: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury

Reference

Goldhaber SZ. European society of cardiology practice guidelines on acute pulmonary embolism: an American's commentary and personal perspectives. Pol Arch Med Wewn. 2009;119:6-7.
PMID: 19341171

Commentary on IEP-005-10: Pulmonary CT Imaging for Patients at Low Risk for Pulmonary Embolism

General Concerns

The measure is calculated as the ratio (percent) of patients who have a documented indication consistent with guidelines prior to imaging divided by the total number of patients undergoing CT pulmonary angiography (CTPA). Those guidelines define the numerator to only include patients with a low clinical probability of PE and a negative D-dimer; a low clinical probability of PE and no D-dimer performed; and no documentation of a pre-test probability. These numerator criteria transform this measure into a utilization measure. Notably, if the physician does not follow the numerator criteria, yet discovers a PE, that case is regarded as inefficient or "unnecessary."

If simply *documenting* the assignment of pre-test probability (including "low" probability), meets the numerator threshold, then this utilization measure is reduced to an artificial exercise in documentation. ABEM does acknowledge the need to capture all physician activity in this situation, and believes that there is some value to defining a pre-test probability (e.g., calculating a Wells Score). However, the absence of doing so in a low-probability situation should not constitute an NQF measure. One runs the risk that physicians who feel that a CT for PE is indicated will simply document an intermediate probability based on implicit judgment, resulting in considerably less meaningful activity.

As ABEM understands this quality measure, any documentation of any pre-test probability satisfies the quality criteria. Further, value cut-offs for D-dimer results will be determined by each emergency department (ED) or institution a priori, and thus will not have universally fixed reference standards for D-dimer result interpretations. Specific commercial methodologies require variable level cut-offs, but for the same assay, a uniform standard could be set. In the absence of this standard-setting, the measure creates uncertainty in interpreting the subsequent data.

Another concern is that despite the suggestion that this measure has broad scientific support, the actual application of this measure occurred at a solitary institution using a fairly specific computerized physician order entry system with an integrated decision. The ability to implement this rule in a general fashion is unproved – many EDs do not share this capability. Recall that 31% of all EDs see fewer than 10,000 visits (Muelleman RL. *Acad Emerg Med.* 2010).

This utilization measure relies heavily on the recommendations published in the *European Heart Journal* (Torbicki. *Eur Heart J.* 2008;29:2276-315). These guidelines use only the Wells Score (both dichotimzed and trichotimized scales) and the revised Geneva score. Two key risk factors for PE are absent from these scales: age (absent from the Wells Criteria) has been shown to be related to the incidence of PE, as has pregnancy. Pregnancy does not appear on either the Wells or the revised Geneva scores. Such a narrow definition of pre-test risk factors could errantly bias physicians away from performing studies in patients with a greater risk of thromboembolic disease.

The Goldhaber reference (Goldhaber SZ. *Pol Arch Med Wewn.* 2009;119:6-7) used to support the original development of the measure is a reflection essay. Interestingly, Dr. Goldhaber's direct observations seem to undercut the use of revised Geneva and Wells scores in European hospitals. In his commentary, Dr. Goldhaber makes the remark that, "When rounding in European hospitals, I have not found routine use of any standardized clinical predication rule for PE."

In reference to the use of D-dimer assays, the Di Nisio paper from Italy is a meta-analysis that shows the tremendous variability among D-dimer assays (Di Nisio M. *J Thromb Haemost.* 2007). Moreover, it confirms the notion that highly sensitive D-dimer assays (essential to exclude disease) could increase the amount of diagnostic imaging. Thus, the suggestion that the use of D-dimer assays will decrease the rate of imaging is refuted. Additional remarks from the article include:

- "Compared to other D-dimer assays, the ELFA, microplate ELISA and latex quantitative assays have higher sensitivity but lower specificity, resulting in a more confident exclusion of the disease at the expense of more additional imaging testing."
- ". . . we found a trade-off between sensitivity and specificity between the various models . . ."
- "In general, systematic reviews of diagnostic accuracy studies are challenged by the variability in design characteristics of the primary studies and by poor quality of reporting. Our results confirm the findings of previous evaluations, which showed that the type of reference standard and age significantly affect the estimated accuracy."
- "As the exclusion of venous thromboembolism is the main goal of the D-dimer test, high sensitivity of the assay is required. However, the specificity of the test determines the number of further imaging procedures required. Our analysis showed the typical inverse relationship between sensitivity and specificity[:] D-dimer methods with a high true-positive fraction also have a higher false-positive fraction. *As a consequence, a larger number of patients with a positive result will be referred to additional imaging tests if D-dimer methods with high sensitivity, such as the D-dimer ELFA, are used*" [emphasis added].

When highly sensitive D-dimer assays are used (and highly sensitive studies must be used to assure patient safety), there is likely to be an increase in the amount of imaging if the results of the D-dimer assays are strictly integrated into decision making.

ABEM is concerned that this measure could dissuade physicians from ordering a diagnostic study when clinical uncertainty exists. Moreover, the measure relies on the hospital to have a highly sensitive D-dimer in order to exclude PE. The authors provide little assurance that D-dimer cut-offs will be standardized and that all cut-off levels will have a sufficiently high NPV. Since the emergency physician (EP) must make an absolute decision with limited and sometimes contradictory information in a time-compressed environment regarding a potentially fatal condition, a high NPV is of paramount importance. This proposed measurement lacks the support and proof of this requisite patient safety element.

This measure is predicated on the assumption that CTPA is being used unnecessarily in patients with very low likelihood of PE. There is little evidence offered that CT pulmonary angiograms (CTPAs) are ordered too often or unnecessarily. Regional variation does not by itself suggest overuse. This could be a reflection of widespread underuse of imaging. Given the high rate of missed PE as demonstrated by autopsy, CTPA may well be *under-ordered.* Physicians do not order CTPAs on every patient with "cardinal signs or symptoms" of PE such as dyspnea or CP; over ten million people present to the ED with PE-like symptoms each year.

Additional Concerns

PE remains a frequent cause of sudden death. Based on autopsy results, the incidence of PE is significantly underestimated. Despite the lethality of this condition, diagnosing PE can be difficult due to vexing protean and vague presentations. The proposed imaging measure seems to have the goal of restricting imaging use. There appears to be a potential default to a simple exercise in documentation. And importantly, the measure does not appear to balance concerns of ionizing radiation exposure against all-cause mortality.

The approach outlined in IEP-005-10 is already familiar to EPs, the majority of whom integrate D-dimer testing into their clinical decision making (Kabrhel. *Acad Emerg Med.* 2009). This measure should not be endorsed by the NQF because there must be a liberal (not restrictive) approach to diagnostic imaging for PE. The solution to more frequently diagnosing this elusive and potentially fatal condition is not to restrict the use of the primary diagnostic tool. Ironically, despite the intention of this utilization rule to reduce the number of CTPAs, as highly sensitive D-dimer use is stressed, the inversely high false-positive rate may increase the number of CTPAs performed.

The rule as proposed (especially as outlined in the European guidelines) has not been sufficiently and prospectively validated in a U.S. trial. Though many peer-review references are provided in the original measure development, the results are inconclusive and conflicting.

Measure IEP-005-10 should be repealed by the NQF for reasons that include:

- The risk of limiting the diagnostic approach for a high-mortality condition.
- The significant under-diagnosis of PE based on autopsy results.
- The significant under-appreciation for the frequency of PE based on the detection of incidental PE. Moreover, incidental PEs are frequently missed on the initial reading of a study. This is not cited to be critical of radiology, it simply helps to better characterize the challenge of diagnosing PE.
- Concern about the discordant interpretation rate. Again, this is not cited to be critical of radiology, but to characterize the challenge in accurately diagnosing PE.
- The fact that computer-assisted detection can aid in detecting PEs that are missed on initial review.
- D-dimer assays are variable based on the methodology used. Moreover, different cut-off levels result in varying sensitivities and specificities.
- Well's Criteria has an insufficient inter-rater estimation, especially when applying this to the trichotomized pre-test ranking.

General Discussion

Despite the high mortality (Goldhaber. *Lancet.* 1999), PE remains a frequently missed diagnosis due to the often nonspecific clinical signs and symptoms (Michota. *Clin Cornerstone.* 2005). Despite the premise of the proposed quality measure, EPs are already selective about the patients they send for CTPA. If every patient who had a "cardinal" sign or symptom of PE (e.g., chest pain, tachypnea, dyspnea, tachycardia, shock, or anxiety) were imaged, the number of CTPAs would increase dramatically. The lethality of PE is considerable. Though mortality statistics vary, in one study of 320 patients who developed PE, 121 (38%) died prior to discharge (Proctor. *Cardiovasc Surg.* 1997).

The diagnosis of PE is so enigmatic that the diagnostic opportunities should not be limited. In a survey of 583 physician-reported errors, PE (tied with drug reaction or overdose) was the most commonly missed or delayed diagnosis (Schiff. *Arch Intern Med.* 2009). The most common source of the error was the failure to order the proper test (also an errant report and errant follow-up of lab reports). Thus, CTPA might be *under-ordered*, contributing to the number of missed PEs.

Autopsy Data

Several autopsy-based series demonstrate an underestimation of PE, and further prove that PE is a commonly missed diagnosis (Thurnheer. *Eur J Intern Med.* 2009; Steiner. *Cardiovasc Pathol.* 2007; Shojania. *Qual Saf Health Care.* 2005; Rao. *Am J Clin Pathol.* 1990; Stevanovic. *Hum Pathol.* 1986; Perkins. *Crit Care.* 2003; Bedell. *Arch Intern Med.* 1986; Walden. *Int Angiol.* 1985; Mercer. *Postgrad Med J.* 1985; Kotoviczl. *Clinics* (Sao Paulo). 2008). Specifically, in Rao's work over half of autopsies (97 of 188) revealed unexpected diagnoses, the most common of which was missed PE (Rao. *Am J Clin Pathol.* 1990). Another study showed a 29% discrepancy rate between clinical and autopsy diagnosis. In discrepant cases, PE was unrecognized in 84% (Stevanovic. *Hum Pathol.* 1986). Even among critically ill patients, the postmortem findings were in complete agreement with pre-death diagnoses in 45% of cases. Again, PE was among the most frequently missed diagnoses (Perkins. *Crit Care.* 2003). PE accounts for a large number of fatalities post-cardiac arrest in which there is a major missed diagnosis (Bedell. *Arch Intern Med.* 1986). This evidence is the source of our conclusions about the incidence of PE being considerably underestimated in the absence of comprehensive necropsy data. In summary, the autopsy data suggest that PE is under-diagnosed, epidemiologically under-estimated, and clinically elusive.

Occult Pulmonary Emboli

A further challenge to detecting pulmonary emboli is the degree to which the disease is occult. An incidental finding in an asymptomatic patient might seem benign, but it could, however, be a harbinger of potentially fatal disease. When otherwise occult PEs are detected, anticoagulation is typically recommended. One prospective evaluation of 487 patients receiving contrast-enhanced MDCT of the chest found that 6% of patients had an "incidental" PE (Ritchie. *Thorax.* 2007). To illustrate the challenge of interpreting the CT studies, the Ritchie study shows that of the 28 patients with PE, nine cases (32%) were missed on initial review by the radiologist. Somewhat similar results were found in oncology patients, for whom the rate of unsuspected incidental PE was 4% (Gladish. *Radiology.* 2006). Of note, 75% of the PEs were not reported by the radiologists on the initial interpretation. In another study of patients from a cancer center, 91 PE cases were analyzed (Engelke. *Clin Radiol.* 2006). Of these, 35 were suspected of having PE and 56 were not. Over half of patients (48 of 91) had true-positive diagnoses, and 47% (43 of 91) had an initial false-negative radiological diagnosis. The challenge of undetected occult PE means that a sufficiently high NVP is difficult to achieve.

Discordant Interpretation

To effectively promulgate patient safety, accurate diagnoses are essential. This is particularly applicable for avoiding missed diagnoses of potentially fatal conditions. Inter-rater agreement should be extremely high for conditions that have grave consequences. Few studies examining inter-observer agreement for CTPA have been published. One study showed a kappa of 0.83 for proximal emboli, which seems good. However, none of the radiologists in the study accurately identified all of the proximal PEs. In fact, for individual radiologists, the kappa values ranged from 0.54 to 0.89 for identifying *proximal* disease. Notably, the kappa was only 0.61 for segmental emboli and 0.38 for subsegmental emboli (Ghanima. *Acta Radiol.* 2007). When a panel of general radiologists was evaluated, the radiologists detected only 157 of 212 emboli, thus missing 26% of PEs (Buhmann S. *Acad Radiol.* 2007). More specifically, 2 of 65 (3%)

central emboli were missed, and 44 of 147 (30%) of peripheral emboli were missed. There were nine false-positive results by the general radiologists. The challenge with accurate interpretation further accents the challenge of providing a sufficient NVP that is high enough to safely discharge patients from the ED.

Computer-assisted Diagnosis
Considering missed interpretation rates, as well as the total number of CTPAs performed daily in the U.S., a considerable number of PEs will be missed. Computer-assisted detection (CAD) is an opportunity to prevent patient harm from missed diagnoses. In one series of 292 consecutive CTPAs, there were originally 67 positive studies for PE. CAD discovered an additional seven cases of PE that were originally missed (Wittenberg. *Eur Radiol.* 2010). Thus, over 9% of all PEs were originally missed. CAD can also yield a high rate of false-positive results, but it has a high NPV (Maizlin. *J Thorac Imaging.* 2007). Moreover, additional lung lesions are detected using CAD. One report reviewed 100 chest CTs that were interpreted as "normal" at clinical double reading. In 33 patients, CAD reported 53 lesions that had been missed (Peldschus. *Chest.* 2005). Of these, 9% were of "high significance," 40% were of "intermediate significance," and 51% were of "low significance." The authors concluded that "significant lung lesions are frequently missed at routine clinical interpretation of chest CT studies but may be detected if CAD is used as an additional reader."

D-dimer
D-dimer assays contribute to the clinical determination of which patients should undergo CT. Given the NPV in low-probability patients, D-dimer levels can be integrated as a guide, but not an absolute rule for the clinician. The high false-positive rates have led to CT imaging in some low-probability patients, when CTPA would otherwise not have occurred. One caution related to relying too heavily on D-dimer assays is that the sensitivity of the assay is dependent on the embolus location (De Monyé. *Am J Respir Crit Care Med.* 2002). Though the sensitivity was 93% for segmental or larger emboli, it was only 50% for subsegmental emboli. The authors conclude that, "*D-dimer concentration and the accuracy of D-dimer assays are clearly dependent on embolus location and smaller, subsegmental emboli may be missed when D-dimer assays are used as a sole test to exclude pulmonary embolism.*" This is extremely problematic, since subsegmental PEs may additionally have a more cryptic clinical presentation. Therefore, the D-dimer, though a good test, should not be proscriptive in the clinical decision to obtain imaging. Even when "optimal" cut-offs are determined, PE will be missed (Vermeer. *Thromb Res.* 2005).

Given the hospital-to-hospital variability of D-dimer assay types and cut-off values for normal/elevated levels, there is too much uncertainty for the widespread use of a decision tool that employs D-dimer testing as an absolute measure for quality. Establishing lower cut-off levels to increase the NPV will paradoxically *increase* the number of chest CTs ordered for the exclusion of PE.

Inter-rater Reliability and the Wells Criteria
The Wells Criteria for determining pre-test probability is suggested as part of this measure. Both Wells and the revised Geneva scores are reasonable criteria to guide, but not determine medical decision making. One of the challenges to using the Wells Score is that certain high-risk factors such as age and hypoxia are not included. Moreover, when prospectively examined, the inter-rater agreement was only moderate for trichotomized scoring (kappa=0.54), which is probably an insufficient agreement upon which to base a key factor in a quality measure (Wolf SJ. *Emerg Med.* 2004).

The Elderly and PE

A concerning omission to this measure is the failure to adequately consider the increased risk of PE in the elderly. One summary article states that, "[d]iagnostic algorithms able to rule out PE and validated in young adult patients may have reduced applicability in elderly patients" (Masotti. *Vasc Health Risk Manag.* 2008).

The Potentially Errant Assumption of Overuse

One of the consequences of maintaining this measure could be that the number of CTPAs might increase. Paradoxically, when some protocols, similar to this measure, have been used, the rate of imaging increases. If D-dimer levels are used in such a way as to have a high NVP and thus include patients for imaging, an increase in the number of CTPAs might likely occur. This possibility is raised in one of the references used to develop the measure (Di Nisio. *J Thromb Haemost.* 2007). This increase actually occurred when applied in clinical practice. In the investigation led by Kline et al. (Kline. *Ann Emerg Med.* 2004), the use of a protocol including a D-dimer for determining the appropriateness of imaging nearly doubled the frequency with which CTPAs were ordered: 0.74% versus 1.42% of all patients. Interestingly, EPs were more likely to *not* image a patient with an elevated D-dimer, in contrast to those physicians who still ordered a CTPA despite a normal D-dimer.

> Clinicians failed to order protocol-specific pulmonary vascular imaging in 109 (19%) of 578 patients, and clinicians overrode a negative protocol to order pulmonary vascular imaging in 63 (8%) of 752 patients. These data suggest that clinicians were more likely to disregard the results of positive testing rather than negative testing.

Therefore, there is limited proof offered that there is a problematic over-ordering of CTPAs. To the contrary, there is proof that decision algorithms can increase the use of CTPA.

Summary

When accepting a measure such as this, all-cause mortality must be considered. Despite the assumption (which is poorly supported by the references) that there are too many unnecessary CTPAs, the reality might well be that there are too few CTPAs. Restricting diagnostic inquiry in a potentially fatal condition that is under-diagnosed is unwise.

Recommendation

ABEM requests that the NQF reconsider and withdraw this measure.

References

Bedell SE, Fulton EJ. Unexpected findings and complications at autopsy after cardiopulmonary resuscitation (CPR). *Arch Intern Med.* 1986;146:1725-8.
PMID: 3753112

Buhmann S, Herzog P, Liang J, Wolf M, Salganicoff M, Kirchhoff C, Reiser M, Becker CH. Clinical evaluation of a computer-aided diagnosis (CAD) prototype for the detection of pulmonary embolism. *Acad Radiol.* 2007;14:651-8.
PMID: 17502254

De Monyé W, Sanson BJ, Mac Gillavry MR, et al.; ANTELOPE-Study Group. Embolus location affects the sensitivity of a rapid quantitative D-dimer assay in the diagnosis of pulmonary embolism. *Am J Respir Crit Care Med.* 2002;165:345-8.
PMID:11818319

Di Nisio M, Squizzato A, Rutjes AW, Büller HR, Zwinderman AH, Bossuyt PM. Diagnostic accuracy of D-dimer test for exclusion of venous thromboembolism: a systematic review. *J Thromb Haemost.* 2007;5:296-304.
PMID: 17155963

Engelke C, Manstein P, Rummeny EJ, Marten K. Suspected and incidental pulmonary embolism on multidetector-row CT: analysis of technical and morphological factors influencing the diagnosis in a cross-sectional cancer centre patient cohort. *Clin Radiol.* 2006;61:71-80.
PMID: 16356819

Ghanima W, Nielssen BE, Holmen LO, Witwit A, Al-Ashtari A, Sandset PM. Multidetector computed tomography (MDCT) in the diagnosis of pulmonary embolism: interobserver agreement among radiologists with varied levels of experience. *Acta Radiol.* 2007;48:165-70.
PMID: 17354136

Gladish GW, Choe DH, Marom EM, Sabloff BS, Broemeling LD, Munden RF. Incidental pulmonary emboli in oncology patients: prevalence, CT evaluation, and natural history. *Radiology.* 2006;240:246-55.
PMID: 16684921

Goldhaber SZ. European society of cardiology practice guidelines on acute pulmonary embolism: an American's commentary and personal perspectives. *Pol Arch Med Wewn.* 2009;119:6-7.
PMID: 19341171

Goldhaber SZ, Visani L, De Rosa M. Acute pulmonary embolism: clinical outcomes in the International Cooperative Pulmonary Embolism Registry (ICOPER). *Lancet.* 1999;353:1386-9.
PMID: 10227218

Hoffman JR, Mower WR, Wolfson AB, Todd KH, Zucker MI. Validity of a set of clinical criteria to rule out injury to the cervical spine in patients with blunt trauma. National Emergency X-Radiography Utilization Study Group. *N Engl J Med.* 2000;343:94-9.
PMID: 10891516

Kabrhel C, Mark Courtney D, Camargo CA Jr, Moore CL, Richman PB, Plewa MC, Nordenholtz KE, Smithline HA, Beam DM, Brown MD, Kline JA. Potential impact of adjusting the threshold of the quantitative D-dimer based on pretest probability of acute pulmonary embolism. *Acad Emerg Med.* 2009;16:325-32.
PMID: 19298619

Kline JA, Webb WB, Jones AE, Hernandez-Nino J. Impact of a rapid rule-out protocol for pulmonary embolism on the rate of screening, missed cases, and pulmonary vascular imaging in an urban US emergency department. *Ann Emerg Med.* 2004;44:490-502.
PMID: 15520709

Kotovicz F, Mauad T, Saldiva PH. Clinico-pathological discrepancies in a general university hospital in São Paulo, Brazil. *Clinics (Sao Paulo).* 2008;63:581-8.
PMID: 18925315

Maizlin ZV, Vos PM, Godoy MC, Cooperberg PL. Computer-aided detection of pulmonary embolism on CT angiography: initial experience. *J Thorac Imaging.* 2007;22:324-9.
PMID: 18043386

Masotti L, Ray P, Righini M, Le Gal G, Antonelli F, Landini G, Cappelli R, Prisco D, Rottoli P. Pulmonary embolism in the elderly: a review on clinical, instrumental and laboratory presentation. *Vasc Health Risk Manag.* 2008;4:629-36.
PMID: 18827912

Mercer J, Talbot IC. Clinical diagnosis: a post-mortem assessment of accuracy in the 1980s. *Postgrad Med J.* 1985;61:713-6.
PMID: 4034461

Michota F. Venous thromboembolism: epidemiology, characteristics, and consequences. *Clin Cornerstone.* 2005;7:8-15.
PMID: 16758647

Muelleman RL, Sullivan AF, Espinola JA, Ginde AA, Wadman MC, Camargo CA Jr. Distribution of emergency departments according to annual visit volume and urban-rural status: implications for access and staffing. *Acad Emerg Med.* 2010;17:1390-7.
PMID: 21122024

Peldschus K, Herzog P, Wood SA, Cheema JI, Costello P, Schoepf UJ. Computer-aided diagnosis as a second reader: spectrum of findings in CT studies of the chest interpreted as normal. *Chest.* 2005;128:1517-23.
PMID: 16162752
Perkins GD, McAuley DF, Davies S, Gao F. Discrepancies between clinical and postmortem diagnoses in critically ill patients: an observational study. *Crit Care.* 2003;7:R129-32.
PMID: 14624686

Proctor MC, Greenfield LJ. Pulmonary embolism: diagnosis, incidence and implications. *Cardiovasc Surg.* 1997;5:77-81.
PMID: 9158127

Rao MG, Rangwala AF. Diagnostic yield from 231 autopsies in a community hospital. *Am J Clin Pathol.* 1990;93:486-90.
PMID: 2321580

Ritchie G, McGurk S, McCreath C, Graham C, Murchison JT. Prospective evaluation of unsuspected pulmonary embolism on contrast enhanced multidetector CT (MDCT) scanning. Thorax. 2007;62:536-40.
PMID: 17158631
PMCID: PMC2117210

Schiff GD, Hasan O, Kim S, Abrams R, Cosby K, Lambert BL, Elstein AS, Hasler S, Kabongo ML, Krosnjar N, Odwazny R, Wisniewski MF, McNutt RA. Diagnostic error in medicine: analysis of 583 physician-reported errors. *Arch Intern Med.* 2009;169:1881-7.
PMID: 19901140

Shojania KG, Burton EC, McDonald KM, Goldman L. Overestimation of clinical diagnostic performance caused by low necropsy rates. *Qual Saf Health Care.* 2005;14:408-13.
PMID: 16326784

Steiner I. Pulmonary embolism—temporal changes. *Cardiovasc Pathol.* 2007;16:248-51.
PMID: 17637434

Stevanovic G, Tucakovic G, Dotlic R, Kanjuh V. Correlation of clinical diagnoses with autopsy findings: a retrospective study of 2,145 consecutive autopsies. *Hum Pathol.* 1986;17:1225-30.
PMID: 3793085

Thurnheer R, Hoess C, Doenecke C, Moll C, Muntwyler J, Krause M. Diagnostic performance in a primary referral hospital assessed by autopsy: evolution over a ten-year period. *Eur J Intern Med.* 2009;20:784-7.
PMID: 19892309

Torbicki A, Perrier A, Konstantinides S, Agnelli G, Galiè N, Pruszczyk P, Bengel F, Brady AJ, Ferreira D, Janssens U, Klepetko W, Mayer E, Remy-Jardin M, Bassand JP; ESC Committee for Practice Guidelines (CPG).Guidelines on the diagnosis and management of acute pulmonary embolism: the Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC*). Eur Heart J.* 2008;29:2276-315.
PMID: 18757870

Vermeer HJ, Ypma P, van Strijen MJ, Muradin AA, Hudig F, Jansen RW, Wijermans PW, Gerrits WB. Exclusion of venous thromboembolism: evaluation of D-Dimer PLUS for the quantitative determination of D-dimer. *Thromb Res.* 2005;115:381-6.
PMID: 15733971

Walden R, Bass A, Modan R, Adar R. Pulmonary embolism in post-mortem material with clinical correlations in 425 cases. *Int Angiol.* 1985;4:469-73.
PMID: 3834011

Wittenberg R, Peters JF, Sonnemans JJ, Prokop M, Schaefer-Prokop CM. Computer-assisted detection of pulmonary embolism: evaluation of pulmonary CT angiograms performed in an on-call setting. *Eur Radiol.* 2010;20:801-6.
PMID: 19862534

Wolf SJ, McCubbin TR, Feldhaus KM, Faragher JP, Adcock DM. Prospective validation of Wells Criteria in the evaluation of patients with suspected pulmonary embolism. *Ann Emerg Med.* 2004;44:503-10.
PMID: 15520710

Commentary on IEP-007-10: Appropriate Head CT Imaging in Adults with Mild Traumatic Brain Injury

Percent of all adults who presented within 24 hours of a non-penetrating head injury with a Glascow Coma Scale (GCS) >13 and underwent head CT for trauma in the Emergency Department (ED) who have a documented indication consistent with guidelines prior to imaging.

ABEM is concerned about this measure and its description. The "guidelines" considered under this rule are the American College of Emergency Physicians (ACEP) 2008 guidelines by Jagoda AS, et al. (Jagoda. *Ann Emerg Med.* 2008).

General Concerns

Numerator Statement

The numerator statement, though mirroring the ACEP 2008 guidelines, is too exclusive to have a sufficient negative predictive value (NPV). The EP must not only identify trauma-related surgical conditions, he or she must also determine the disposition – is this patient safe to send home? Such determination requires broader numerator inclusion criteria for this calculation. For example, any patient with a post-concussive seizure should have a head CT. Likewise, the age threshold of 60 or 65 years (depending on loss of consciousness) should arguably be lower. Finally, patients with alcohol intoxication with minor head trauma should be considered for CT evaluation irrespective of any loss of consciousness.

A number approaching 1.0 appears to reflect favorable performance for this measure, whereas a number approaching 0.0 is unfavorable.

Finally, the numerator statement does not explicitly state that the only numerator patients are those who receive a CT. As written, any patient who meets the criteria (even without undergoing CT scan) is included in the numerator. Thus, the resulting measure can exceed 1.0.

Denominator Statement

The denominator statement includes patients only with a GCS of 14. This is confusing, and should also include patients with a GCS of 15. Beyond that, ABEM is concerned about coupling GCS 14 and GCS 15 patients into the same risk group. Patients with GCS 14 are at greater risk for abnormal CT findings.

Denominator Exceptions

ABEM suggests that a GCS of 14 also be included as a denominator exception.

Supporting Guideline and Other References

ABEM finds the guideline support to be extremely modest. The primary support for this recommendation is the ACEP 2008 mild traumatic brain injury (mTBI) guidelines, which are largely an amalgam of the Canadian and New Orleans criteria. Four other mTBI decision rules are noticeably absent. These include the guidelines from the following groups:

- Neurotraumatology Committee of the World Federation of Neurosurgical Societies
- National Emergency X-Radiography Utilization Study II (NEXUS-II)
- National Institute of Clinical Excellence (NICE)
- Scandinavian Neurotrauma Committee

Further Commentary

Understanding Low-Risk versus Mild Traumatic Brain Injury (mTBI)

When approaching the clinical decision making surrounding CT imaging of the brain for the evaluation of trauma, it is extremely important (albeit often overlooked) to establish clear definitions of minor brain trauma and risk strata. "Mild head injury" or "mild traumatic brain injury" (often defined as GCS 13-15 or GCS 14-15) is not equivalent to "low risk" (see discussion in Schwartz DT. *Emergency Radiology*. 2000, pgs. 385-6).

The Neurotraumatology Committee of the World Federation of Neurosurgical Societies considers low risk mTBI to be a Glasgow Coma Score (GCS) of 15 and without a history of loss of consciousness, amnesia, vomiting, or diffuse headache (Servadei. *J Neurotrauma*. 2001). Medium-risk mTBI patients have a GCS of 15 and one or more of the following symptoms: loss of consciousness, amnesia, vomiting, or diffuse headache. They recommend that a head CT be obtained in these patients. According to this risk stratification scheme, high-risk mTBI patients have a GCS of 14 or 15, with a skull fracture and/or neurological deficits. The high-risk group also includes patients with any of the following: coagulopathy, drug or alcohol consumption, previous neurosurgical procedures, pretrauma epilepsy, or age older than 60 years. Truly low-risk patients do not require imaging. High-risk patients receive scanning. The greatest challenge is determining which clinical factors should direct imaging in the medium-risk group. The difficulty with the designation of mTBI is that it does not provide adequate discrimination for precise clinical decision making. Fortunately, the measure authors exclude patients with a GCS of 13. Still, the denominator statement insists upon including GCS 14 patients. The ED patient with a GCS score of 14 is not "low risk" for intracranial injury. "Trauma patients in the ED with GCS scores of 13 or 14 should all undergo emergency CT scanning" (Schwartz. *Emergency Radiology.* 2000. pg. 386). As many as 21% of patients with mTBI will have a CT abnormality (Jacobs. *J Neurotrauma.* 2010).

A GCS of 15 does not exclusively determine low risk. In a large meta-analysis of over 24,249 patients with an mTBI and a GCS of 15, the frequency of pathologic CT findings was about 8% (af Geijerstam. *Acta Neurochir* (Wien). 2003). Another study showed that over 7% of patients with mTBI and a GCS of 15 will have an abnormal CT (Mikhail. *Am J Emerg Med.* 1992). Of additional note, the Mikhail study shows that age was a risk factor for intracranial injury for patients older than 40 years. Moreover, any loss of consciousness (LOC) or posttraumatic amnesia, by themselves, appear to warrant imaging. In the proposed measure, the LOC *must be accompanied* by other signs or symptoms. Stein et al. found intracranial lesions in nearly 12% of patients with a GCS of 15 and *any* LOC or posttraumatic amnesia (Stein. *Neurosurgery.* 1990). In this same series, similar patients with a GCS of 14 had an incidence of over 18% intracranial lesions. This demonstrates the higher incidence of intracranial lesions among patients with a GCS of 14 compared to patients with a GCS of 15. Admittedly, heterogeneity has not been demonstrated in all series examining mTBI (Tellier. *Brain Inj.* 2009). Finally, for purposes of defining low risk, the GCS must be narrowly defined. A GCS of 15 should not be applied to patients who have any resultant impairment in mental status (Schwartz. *Emergency Radiology*. 2000. pg. 387). This is consistent with the NEXUS–II criterion that any abnormal level of alertness or altered behavior requires CT imaging (Mower. *Ann Emerg Med.* 2002). The need for imaging with even mild cognitive impairment was also shown to be an independent risk factor for intracranial hemorrhage resulting from trauma (Dunham. *J Trauma*. 1996).

Physicians Already Select

EPs currently order CT scans based on clinical presentation and risk variables. Physicians are more likely to order a CT of the head in mTBI when the patient is older, has documented loss of consciousness (LOC) and/or post-traumatic amnesia, is nauseous or vomiting, or arrived by

ambulance, particularly to an urban hospital (Ryu. *Can J Neurol Sci.* 2009). Still, if there is to be an effort to mitigate the presumptions of over-triage (Tellier. *Brain Inj.* 2009), it should not be done using the proposed measures based on the ACEP 2008 guidelines.

Criteria Selection Is Incomplete
Attempts to prospectively develop reliable clinical guidelines for imaging in head trauma have been extremely difficult, especially when trying to achieve a very high sensitivity and a high NPV (Ibañez. *J Neurosurg.* 2004). This is true even when independent risk factors can be determined. Ibañez concludes that, "[a]voiding systematic CT scan indication implies a rate of misdiagnosis that should be known and assumed when planning treatment in these patients by using guidelines based on clinical parameters."

The criteria for CT evaluation that are found in the ACEP 2008 guidelines are derived largely from the Canadian Rules and the New Orleans Rules (Stiell. *Ann Emerg Med.* 2001, and Haydel. *N Engl J Med.* 2000). Unfortunately, in a recent prospective comparison of 7,955 patients by Stein et al., these two decision rules did not perform as well as others (Stein. *Ann Emerg Med.* 2009). The six decision rules that Stein compared were the Canadian CT Head Rule; the Neurotraumatology Committee of the World Federation of Neurosurgical Societies; the New Orleans; the National Emergency X-Radiography Utilization Study II (NEXUS-II); the National Institute of Clinical Excellence (NICE) guidelines; and the Scandinavian Neurotrauma Committee guidelines. This analysis showed that the NEXUS-II and the Scandinavian Neurotrauma Committee clinical decision rules had the best combination of sensitivity and specificity. As ongoing prospective validation for NEXUS-II is taking place, it is premature to adopt clinical guidelines that will probably soon be replaced by superior decision rules. Because core measures tend to be followed for long periods of time, it is prudent to avoid the hasty adoption of a sub-par performance metric.

Loss of Consciousness and Post-traumatic Amnesia
Under the ACEP 2008 Guidelines, LOC and post-traumatic amnesia (by themselves) are insufficient criteria to justify CT scanning. Countering this, Stein has shown that LOC and post-traumatic amnesia are sufficient, by themselves, to warrant obtaining a head CT (Stein. *Brain Inj.* 1993). This report further concludes that "a normal or near-normal mental status examination in a head-injured patient on arrival at the ED is inadequate to exclude a potentially serious intracranial lesion."

The proposed rule suggests that even with LOC, there must be an accompanying symptom. This is a potentially dangerous strategy. Inamasu et al. recommend that any patient who sustains LOC should receive a CT scan, which is in stark contrast to the ACEP 2008 guidelines (Inamasu. *Am J Emerg Med.* 2000).

The Intoxicated Patient
The ACEP 2008 guidelines are further incomplete in that they do not include CT imaging in intoxicated patients who sustain cranial trauma under all circumstances. According to the proposed quality measure, if the intoxicated patient sustains mTBI, yet does not have LOC, the patient should not receive a head CT. This is extremely problematic given the variable histories and confounded examinations that are manifest in intoxicated patients.

Post-traumatic Seizure
The proposed measure does not adequately consider post-traumatic seizure (PTS) as an indication for CT imaging in mTBI. Four of the six most widely accepted decision guidelines for mTBI use post-traumatic seizure (by itself) as an indication for head CT in mTBI. These four guidelines are the Neurotraumatology Committee of the World Federation of Neurosurgical

Societies, the New Orleans, the National Institute of Clinical Excellence (NICE) guidelines, and the Scandinavian Neurotrauma Committee guidelines. Under the ACEP 2008 guidelines, PTS is only an indication for CT if LOC occurred. According to the proposed quality measure, if there has been no LOC, then PTS is not an indication for CT. This is concerning. Independent risk factors for early PTS include subdural hematoma and brain contusion (Wiedemayer. *Brain Inj.* 2002).

Cost Effectiveness
Stein et al. found that head CT for mTBI was cost effective as a general practice and offered better outcomes when compared to alternative diagnostic strategies (Stein. *J Trauma.* 2006; Stein. *Ann Emerg Med.* 1991). Others have also found CT to be a cost-effective monitoring strategy (af Geijerstam. *Emerg Med J.* 2004).

Acceptable Risk
What is not explicitly stated in IEP-007-10 is the acceptable risk for missing significant intracranial lesions in the mTBI patient. Absolute risk in the mTBI, low-risk patient has not been defined. The asymptomatic patient remains a concern. The inclusion of all patients ≥ 65 years of age, and some patients ≥ 60 years in the proposed measure partially mitigates this concern. The risk of CT-detected occult injury (including epidural and subdural) has been studied in the elderly (≥ 65 years). Occult injury occurs in 2.2% of the elderly. Occult injury also occurs in the younger patient, and are also found in 0.8% of younger patients (Rathlev. *Acad Emerg Med.* 2006).

Recommendation

ABEM requests that the NQF reconsider and withdraw this measure.

References

af Geijerstam JL, Britton M. Mild head injury - mortality and complication rate: meta-analysis of findings in a systematic literature review. *Acta Neurochir* (Wien). 2003;145:843-50.
PMID: 14577005

af Geijerstam JL, Britton M, Marké LA. Mild head injury: observation or computed tomography? Economic aspects by literature review and decision analysis. *Emerg Med J.* 2004;21:54-8.
PMID: 14734377

Dunham CM, Coates S, Cooper C. Compelling evidence for discretionary brain computed tomographic imaging in those patients with mild cognitive impairment after blunt trauma. *J Trauma.* 1996;41:679-86.
PMID: 8858028

Haydel MJ, Preston CA, Mills TJ, Luber S, Blaudeau E, DeBlieux PM. Indications for computed tomography in patients with minor head injury. *N Engl J Med.* 2000;343:100-5.
PMID: 10891517

Huddle DC, Glazer M, Chaney DB. Emergency imaging of the brain. *In* Schwartz DT and Reisdorff EJ. *Emergency Radiology.* New York, McGraw-Hill, 2000, pgs. 385-6.

Huddle DC, Glazer M, Chaney DB. Emergency imaging of the brain. *In* Schwartz DT and Reisdorff EJ. *Emergency Radiology.* New York, McGraw-Hill, 2000, pg. 386.

Huddle DC, Glazer M, Chaney DB. Emergency imaging of the brain. *In* Schwartz DT and Reisdorff EJ. *Emergency Radiology.* New York, McGraw-Hill, 2000, pg. 387.

Ibañez J, Arikan F, Pedraza S, Sánchez E, Poca MA, Rodriguez D, Rubio E. Reliability of clinical guidelines in the detection of patients at risk following mild head injury: results of a prospective study. J *Neurosurg.* 2004;100:825-34.
PMID: 15137601

Inamasu J, Hori S, Aoki K, Suga S, Kawase T, Aikawa N. CT scans essential after posttraumatic loss of consciousness. *Am J Emerg Med.* 2000;18:810-1.
PMID: 11103734

Jacobs B, Beems T, Stulemeijer M, et al. Outcome prediction in mild traumatic brain injury: age and clinical variables are stronger predictors than CT abnormalities. *J Neurotrauma.* 2010;27:655-68.
PMID: 20035619

Jagoda AS. Mild traumatic brain injury: key decisions in acute management. *Psychiatr Clin North Am.* 2010;33:797-806.
PMID: 21093679

Jagoda AS, Bazarian JJ, Bruns JJ Jr, et al.; American College of Emergency Physicians; Centers for Disease Control and Prevention. Clinical policy: neuroimaging and decisionmaking in adult mild traumatic brain injury in the acute setting. *Ann Emerg Med.* 2008;52:714-48.
PMID: 19027497

Mikhail MG, Levitt MA, Christopher TA, Sutton MC. Intracranial injury following minor head trauma. *Am J Emerg Med.* 1992;10:24-6.
PMID: 1736908

Mower WR, Hoffman JR, Herbert M, Wolfson AB, Pollack CV Jr, Zucker MI; NEXUS II Investigators. National Emergency X-Radiography Utilization Study. Developing a clinical decision instrument to rule out intracranial injuries in patients with minor head trauma: methodology of the NEXUS II investigation. *Ann Emerg Med.* 2002;40:505-14.
PMID: 12399794

Rathlev NK, Medzon R, Lowery D, Pollack C, Bracken M, Barest G, Wolfson AB, Hoffman JR, Mower WR.et al. Intracranial pathology in elders with blunt head trauma. *Acad Emerg Med.* 2006;13:302-7.
PMID: 16514123

Ryu WH, Feinstein A, Colantonio A, Streiner DL, Dawson D. Regional variability in the use of CT for patients with suspected mild traumatic brain injury. *Can J Neurol Sci.* 2009;36:42-6.
PMID: 19294887

Servadei F, Teasdale G, Merry G. Neurotraumatology Committee of the World Federation of Neurosurgical Societies. Defining acute mild head injury in adults: a proposal based on prognostic factors, diagnosis, and management. *J Neurotrauma.* 2001;18:657-64.
PMID: 11497092

Stein SC, Burnett MG, Glick HA. Indications for CT scanning in mild traumatic brain injury: A cost-effectiveness study. *J Trauma.* 2006;61:558-66.
PMID: 16966987

Stein SC, Fabbri A, Servadei F, Glick HA. A critical comparison of clinical decision instruments for computed tomographic scanning in mild closed traumatic brain injury in adolescents and adults. *Ann Emerg Med.* 2009;53:180-8.
PMID: 18339447

Stein SC, Ross SE. The value of computed tomographic scans in patients with low-risk head injuries. *Neurosurgery.* 1990;26:638-40.
PMID: 2330085

Stein SC, Spettell C, Young G, Ross SE. Limitations of neurological assessment in mild head injury. *Brain Inj.* 1993;7:425-30.
PMID:8401484

Stiell IG, Lesiuk H, Wells GA, Coyle D, McKnight RD, Brison R, Clement C, Eisenhauer MA, Greenberg GH, Macphail I, Reardon M, Worthington J, Verbeek R, Rowe B, Cass D, Dreyer J, Holroyd B, Morrison L, Schull M, Laupacis A; Canadian CT Head and C-Spine Study Group. Canadian CT head rule study for patients with minor head injury: methodology for phase II (validation and economic analysis). *Ann Emerg Med.* 2001;38:317-22.
PMID: 11524653

Tellier A, Marshall SC, Wilson KG, Smith A, Perugini M, Stiell IG.The heterogeneity of mild traumatic brain injury: where do we stand? *Brain Inj.* 2009;23:879-87.
PMID: 20100124

Wiedemayer H, Triesch K, Schäfer H, Stolke D. Early seizures following non-penetrating traumatic brain injury in adults: risk factors and clinical significance. *Brain Inj.* 2002;16:323-30.
PMID: 11953003