Critical Review Form
Therapy

Effectiveness and Acceptability of a Computerized Decision Support System Using Modified Wells Criteria for Evaluation of Suspected Pulmonary Embolism, *Ann Emerg Med* 2011; 57:613-621

Objective: **"To measure the association of introduction of an electronic evidence-based computerized decision support system (CDSS) for the evaluation of pulmonary embolism in an emergency department (ED) with change in CT angiography positivity rates for pulmonary embolism, as well as to determine the computerized decision support system's acceptability to emergency physicians." (p. 614)**

Methods: **Before/after interventional study at a single university affiliated ED with any EM residents. In the pre-intervention period all patient records for those with CT angiography ordered for chest pain, shortness of breath, dyspnea or rule out pulmonary embolism were identified through the electronic radiology ordering system over a 4-month period. The ED faculty then agreed by consensus to use a validated algorithm using a modified dichotomized Well's score as a forced function whenever an order was placed for CT angiography or D-dimer (intervention phase March-June 2008). ED's could opt out if the CT was not being obtained for PE or in pregnant/unstable patients . For all others, however, calculation of the Well's score was mandatory via check box approach (see below).**

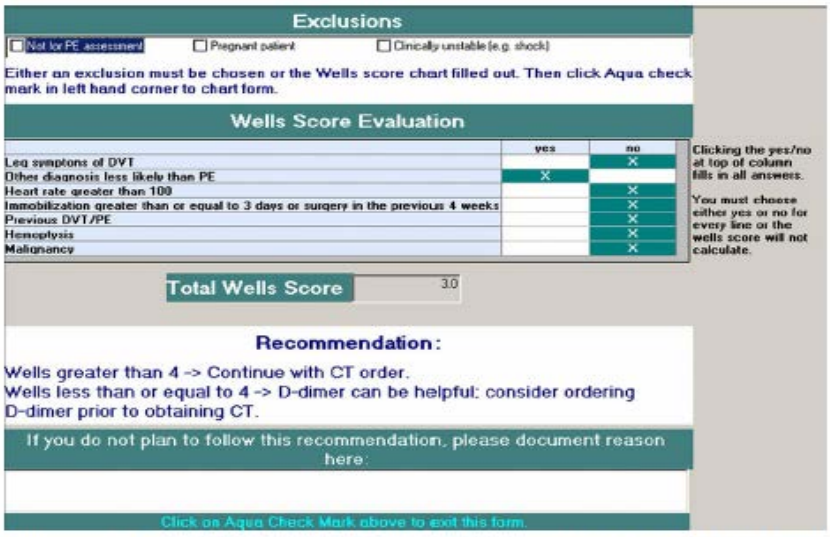

Figure 1. Computerized interface for entering Wells criteria after placing an order for CT angiography.

If a D-dimer had already been ordered, the result pre-populated the screen. Recommendations were provided for further PE-testing, but the final decision rested with the ordering emergency physician.

The primary outcome measure was the CT angiography positivity rate defined as the number of positive pulmonary CT angiograms (PTCA) divided by the total number of PTCA's ordered for evaluation of PE. CT's were obtained on a 64-slice multi detector CT (Light Speed VCT) with 1.25 mm slices and no lower extremity venous scans. All CT's were interpreted by board-certified radiologists within the institution. Outcomes were assessed in both groups by chart review, although the Well's score and alternative testing results were only available for the post-intervention group. The hospital used the HemosIL D-dimer HS and a cut-off of >300 ng/mL as "abnormal". The study had 80% power with 5% significance for 10% difference in PE protocol CT positivity rates if 200 patients were in each group.

Guide		Comments
I.	**Are the results valid?**	
A.	**Did experimental and control groups begin the study with a similar prognosis (answer the questions posed below)?**	
1.	Were patients randomized?	No. This was a before/after investigation without any randomization.
2.	Was randomization concealed (blinded)?	No not randomized.
3.	Were patients analyzed in the groups to which they were randomized?	Not randomized so not relevant. However, "the intention to treat principle was applied for comparison between pre and post intervention data." (p. 615)
4.	Were patients in the treatment and control groups similar with respect to known prognostic factors?	Uncertain. The authors provide no patient demographics by which to risk-stratify pre and post intervention populations (age, PE risk factors, etc.). Therefore, "the study methodology precluded collection of additional patient characteristics which may have reasonably and justifiably influenced the emergency physicians' decision whether to adhere to the computerized decision support system." (p. 619)

B.	**Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1.	Were patients aware of group allocation?	Unclear whether patients were aware of the study protocol or involved in the diagnostic decision making at all.
2.	Were clinicians aware of group allocation?	Yes, clinicians were not blinded to the pre- or post-intervention phase of the study. In fact, they were actively engaged in the decision to turn on (and then turn off) the CDSS. This leaves open the potential for a Hawthorne effect.
3.	Were outcome assessors aware of group allocation?	Yes and there is no reason why chart abstractors could not have been blinded to the study objectives and/or group assignment for individual patients. Blinding of data abstractors is recommended in chart review studies to minimize various forms of bias (Gilbert 1996, Worster 2004).
4.	Was follow-up complete?	No loss to follow up was reported (Fig. 2 p. 616)
II.	**What are the results (answer the questions posed below)?**	
1.	How large was the treatment effect?	• During the intervention phase 495 ED visits that triggered the CDSS but 89 were excluded (trauma = 51, aortic dissection = 13, malignancy = 6, other reason = 11) lowering 404 eligible cases and clinicians opted out of 11 cases leaving 393 for analysis. • 58% of 393 underwent CTPA either with our without D-dimer testing. • EP's did not complete the algorithm or adhere to its recommendation in 26.7% of cases and none provided an explanation in the space provided. 15 underwent CT

		despite low-risk score and negative D-dimer (no PE's identified) and 44 had high pretest probability but did not have CTPA. • The CTPA order rate decreased in the post intervention period from 14 of 1000 ED visits to 12.8 of 1000 ED visits, while the CT-positive rate increased from 8.3% (95% CI 4.9-12.9%) to 12.7% (95% CI 8.6%-17.7%) and the proportion of CTPA preceded by a D-dimer decreased from 70% to 63% (7% difference, 95% CI-2%-15.8%). • In the subset of EP's compliant with the CDSS algorithm, 168 CTPA were ordered for high-risk Well's patients or low-risk Well's with D-dimer >300 and 16.7% (95% CI 11.4-23.2) had a PE identified. • The CDSS algorithm had 100% sensitivity and 9.7% specificity. • Overall non-compliance ranged from 4.8% to 31% among physicians who evaluated ten or more potential PE patients. Reasons provided for non-adherence included, time constraints and lack of confidence in the algorithm. • No patients had a PE on repeat CTPA after an initial negative CT. • At the EP's request the CDSS was removed from the CPOE at the study's conclusion.
	How precise was the estimate of the treatment effect?	See 95% CI above.

III.	How can I apply the results to patient care (answer the questions posed below)?	
1.	Were the study patients similar to my patient?	Uncertain. No patient demographics are provided. Equally important is that no resident EM physicians were involved. Therefore, the external validity of these results in academic settings is uncertain.
2.	Were all clinically important outcomes considered?	False-negative CT rates (as judged by 3-month chart review) were assessed, although the chart review methods are not described. In addition, patient satisfaction was not assessed.
3.	Are the likely treatment benefits worth the potential harm and costs?	It depends. What is an acceptable CT positive rate for PE? How do EP's balance the ease and diagnostic certainty of PE protocol CT with the ever-increasing order rates (testing very low risk patients), highly variable diagnostic practice patterns across and within departments, test-risk (dye-nephropathy, allergic reaction, radiation risk, incidental findings)? And malpractice risk when deviating from the norm?

Limitations

1) **No chart review methods.**
2) **Outcome assessors not blinded.**
3) **No patient or physician demographics provided limiting external validity.**
4) **No acknowledgement of potential Hawthorne effect.**
5) **No description of how the D-dimer threshold was established.**

Bottom Line

A computer decision support systems forcing function using validated algorithms to standardize CTPA test ordering in ED patients with suspected PE can safely reduce CTPA utilization rates without increasing the prevalence of undiagnosed PE. However, despite up-front buy-in from EP's and a 1-2 minute

maximum work-delay to input the Well's Criteria and consider the algorithm recommendations EP's rejected this intervention. Future PE-CDSS should be designed before implementation with the following considerations: speed, real-time delivery, workflow impediments, usability, physician objections, altering rather than stopping behavior, simplicity, minimization of information requested, result assessment and feedback, and maintaining up-to-date, evidence-based CDSS. (Bates 2003)