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L. Douglas Pepper, M.D.
Chairman, Peer Review Committee,
Monongahela Valley Hospital
1163 Country Club Road
Monongahela, PA 15063-1095

Dear Dr. Pepper:

Re: Physician/Hospital Quality Issue; confidential, protected by PA Peer Review Act

The evening of [REDACTED] I was working in the Emergency Department at Monongahela Valley Hospital. I saw a patient named [REDACTED]. She was a 55 year old woman who presented with a chief complaint of right leg swelling. She had bilateral calf and ankle swelling two days prior, which went away, leaving residual swelling of the right lateral calf area. She had a strong family history of deep venous thrombosis (DVT): her sister had had multiple DVTs. She was overweight, and smoked. Note that Goldhaber's famous recent study of pulmonary embolism (PE) risk factors in women said: *In multivariate analysis, obesity, cigarette smoking, and hypertension were independent predictors of pulmonary embolism.*¹ She also gave a history of three months of dyspnea on exertion, raising suspicion for pulmonary embolism.

Her physical exam was notable for an area of induration and swelling of the right proximal lateral calf, suggestive of either superficial phlebitis or erythema nodosum; but she also had swelling of the right calf and tenderness of the right calf, popliteal area and distal thigh posteriorly, over the deep calf veins.

In general terms, clinical suspicion for deep venous thrombosis was moderate. Using the Wells criteria, the patient did not have alternative diagnosis as likely as DVT (I thought DVT slightly more likely than erythema nodosum), did have localized tenderness along the course of the deep veins, and did have significant swelling of the leg, which means her clinical suspicion would also be objectively graded as moderate.

I asked the secretary to order a stat venous Doppler ultrasound to confirm or rule out deep venous thrombosis. She told me that, although the hospital did have technicians on call to perform this test, they would not do so unless a D-dimer test was performed first. I obtained a D-dimer test which was negative.

However, with a moderate pretest clinical suspicion, and in accordance with the evidence cited below, I found this insufficient to rule out deep venous thrombosis. Therefore, I asked

for the Doppler ultrasound to be performed anyway. The secretary told to contact Dr. [REDACTED] about this.

I spoke with Dr. [REDACTED] and described the situation. He declined to allow the technician to be called in, and strongly suggested that I admit the patient on heparin.

Given the dangers of anticoagulation described below, I did not feel that starting the patient on heparin was either good medicine or, should the patient develop complications from the heparin, legally defensible.

My understanding is that not performing Doppler ultrasound at night unless a D-dimer is positive is a hospital policy and not related to physician on-call issues.

Please let me review the thinking that led me to transfer this patient, and why I am referring this case for review by both the physician QI process and by Risk Management.

1. D-dimer testing

There is excellent evidence that one of the newer, more-specific D-dimer assays can be appropriately used, *when* combined with a clinical scoring system, to reliably exclude deep venous thrombosis, but only in those with a low pretest probability/clinical suspicion as judged by the clinical scoring system. The literature emphasizes (1) the need to use a clinical scoring system, and (2) the need for imaging in addition to or instead of the d-dimer assay when pretest probability/clinical suspicion is moderate or high. Wells himself, in an important 2006 review article in JAMA, notes that *Diagnostic accuracy for DVT improves when clinical probability is estimated before diagnostic tests. ... In low-probability patients with negative D-dimer results, diagnosis of DVT can be excluded without ultrasound; in patients with high clinical suspicion for DVT, [D-dimer] results should not affect clinical decisions.*³ Wells' criteria are the accepted clinical criteria for determining pretest probability/clinical suspicion for DVT.²

The American College of Emergency Physicians *Clinical Policy: Critical Issues in the Evaluation and Management of Adult Patients Presenting With Suspected Lower-Extremity Deep Venous Thrombosis* states:

Level B recommendations. *In patients with low clinical probability for lower-extremity DVT, the following test results can be used to exclude DVT:*

- 1. A negative quantitative D-dimer assay result (turbidimetric or ELISA) for exclusion of proximal and distal lower-extremity DVT.*
- 2. A negative whole blood D-dimer assay result in conjunction with the Wells et al scoring system for exclusion of proximal and distal DVT.*
- 3. A negative whole blood D-dimer assay result for exclusion of proximal lower-extremity DVT.*

*Patients with a moderate-to-high risk of lower extremity DVT cannot have DVT excluded by a single negative D-dimer test.*⁴

2. Heparin is a dangerous drug

As with any anticoagulant, heparin, or even low molecular weight heparin (LMWH) carry a significant risk of bleeding complications. The overall rate of bleeding complications for those with venous thrombosis treated with heparin is estimated as about 3%.⁵ However, one recent study comparing low-molecular weight (LMWH) vs. unfractionated heparin (UFH) for acute coronary syndromes found that for both, the rate of serious bleeding complications over a 30-day period was around 7% (LMWH 6.5%, UFH 7%).⁶

Over the past decade, both LMWH and UFH have become well-known for causing Heparin-Induced Thrombocytopenia (HIT), an antibody-mediated reaction resulting in irreversible aggregation of platelets.^{7,8} HIT may also progress to venous and arterial thromboses: Heparin-Induced Thrombocytopenia and Thrombosis (HITT), with life-threatening thrombosis being relatively common. And, even a brief exposure to heparin can cause these life-threatening complications.⁹ One landmark study showed an HIT incidence of about 3% in those treated with unfractionated heparin,¹⁰ although a 1% incidence seems more likely for those treated only briefly.¹¹ Nonetheless, if one out of one hundred people gets a life-threatening complication, most would agree that a drug is quite dangerous and should only be used when the benefit clearly outweighs the risk.

HIT now seems to be an subject of great interest to safety advocates and malpractice attorneys. The first page of Google Internet search results shows:

- a Wikipedia web page devoted HIT,
- a law firm's website advertising for patients who have developed HIT and HITT, and
- a website named heparininducedthrombocytopenia.com.

3. "Admit and put on heparin"?

Venous thromboembolism is common. Consider the amount of effort we expend on behalf of those with suspected coronary disease. The incidence of acute coronary syndromes is about 260 per 100,000 per year,¹² but the incidence is venous thromboembolism (DVT and PE) is about 117 per 100,000 per year—almost half as common as coronary ischemia.¹⁴ And compare the amount of money and effort expended on those with suspected coronary ischemia—frequent admissions of those with suspected coronary ischemia to special monitored units, repeated enzyme tests, and stress tests—with what we do for suspected thromboembolism.

As with coronary disease, complications of venous thromboembolism are severe. One study showed that, over a six-month period after diagnosis, *19% had adverse events: 12.5% of patients died, 5.5% had clinically confirmed VTE recurrence, and 9.8% suffered bleeding complications (44% with major bleeding)*.¹³

A common problem for hospitals is how to deal with patients who present in the evening or night with symptoms suggestive of DVT or PE.

The practice of "admit on heparin and do the study in the AM" has been fairly common in the past. But people bleed on heparin. And we now know that some people on heparin get a

DVT or pulmonary embolism from simply being on heparin. Some of these people die. We also know now how to use a sensitive d-dimer assay combined with a clinical scoring system how to determine the right testing strategy for suspected DVT.

When a risky medication such as heparin is given solely for the convenience of not calling people into the hospital in the middle of the night, it might be difficult to defend in court.

For example: the May 1, 2007 Emergency Medicine Journal Club at the University of Pittsburgh discussed the recent literature on DVT and PE. While the prime purpose of this meeting was to discuss the literature, the practice of “admit and put on heparin” was also discussed. In the expert opinion of the university faculty there, the current information on HIT, combined with the availability of clinical scoring systems such as the Wells score, makes this practice outmoded. When the question was asked: “Who would be willing to serve as an expert witness for the plaintiff for someone harmed by the ‘admit and put on heparin’ policy?” all of the faculty raised their hands.

4. Proposed diagnostic strategy

Clinicians inappropriately forgo imaging studies after a negative d-dimer test much more often than inappropriately ordering imaging when, according to the clinical scoring test and d-dimer results, no imaging is needed (90% vs. 10%).¹⁵ Nonetheless, 10% is a figure that can be reduced.

Calling in ultrasound technicians on off hours is expensive. It is expensive in terms of on-call pay, it is expensive in terms of trying to recruit and retain technicians, and it is expensive in terms of the risks when sleep-deprived technicians drive to and from the hospital in the middle of the night, and it is expensive in terms of trying to recruit ultrasound technicians who are willing to take call.

Emergency physicians have a reputation for calling in ultrasound technicians more often than is really needed. Especially in community hospitals, this reputation is likely justified. Many emergency physicians, when faced with a relatively young and healthy patient who may have a fairly common condition that can lead to sudden death, tend to be conservative, to act as patient advocates, and to discount concerns of overuse of hospital resources.

But, over the past decade, the evolution of more specific D-dimer assays, and multiple studies of clinical scoring, suggest the following. Let us use a clinical scoring system, in a manner that is easy to use, quick and reliable. This would determine which ED patients get a venous ultrasound, not only in the off hours, but during the day as well. This would eliminate unneeded venous ultrasounds, ensure that venous ultrasounds are done when truly needed, and eliminate both the risk of the “admit and put on heparin” strategy and transfers for venous ultrasounds.

Based on the literature cited above, and work on similar issues at other hospitals, you will find enclosed a draft DVT worksheet for your consideration. This uses established design principles from the literature (e.g., in Barnett’s *Forms for People*) to provide a quick and easy way to understand the algorithm and a worksheet for figuring both the Wells DVT score and the recommended diagnostic strategy. I hereby reassign rights to this document to

Monongahela Valley Hospital (on a nonexclusive basis—I've developed similar forms for other hospitals) as well as providing the original artwork in Adobe Illustrator format for the hospital to use as it sees fit. I also have a similar document regarding ED workup of suspected pulmonary embolism that may be of interest; it should be done in [REDACTED] and I will forward it to you—it might cut down on the number of chest CT angiograms.

And, as far as the patient in question: I transferred the patient, with her assent, to [REDACTED]. The on-call ultrasound technician there performed a Doppler ultrasound. This was negative, and the patient was discharged from [REDACTED] with a diagnosis of erythema nodosum, without having been placed on heparin.

Thank you for your consideration of this matter.

Yours aye,



Keith Conover, M.D., FACEP

Enclosure: proposed DVT Guidelines: MVH-Forms-ED-DVT.pdf

cc: Dr. Brenda Walther, Chair, Emergency Department
MVH Risk Management, Kristin Pergola

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