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Are You IN or OUT? Outpatient Management of Low-Risk Pulmonary Embolism (LRPE) Patients

webinar

Are You IN or OUT? Outpatient Management of Low-Risk Pulmonary Embolism (LRPE) Patients*

**Atrium Health, Indiana University Health,
Massachusetts General Hospital**

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Using established protocols for discharging low-risk pulmonary embolism (LRPE) patients from emergency rooms/ departments (ERs/EDs) to outpatient treatment at specialty clinics, rather than keeping them in the hospital, has been shown to be safe and effective. Key to these programs is establishing protocols for decision making and facilitating the necessary coordination between ERs/EDs, pharmacy departments, primary care providers (PCPs), and the specialty clinics.

Dr. Rachel P. Rosovsky, director of Thrombosis Research in the Department of Hematology at Massachusetts General Hospital and assistant professor of medicine at Harvard University; Dr. Daren M. Beam, co-director of the PE Response Team at Indiana University Health and assistant professor of emergency medicine at IU School of Medicine; and Dr. Daniel R. Troha, co-founder of the Code PE Program at Atrium Health's Department of Emergency Medicine, provided a detailed look at the protocols they use to assess LRPE patients in the ER, the logistics involved in establishing the specialty clinics to which patients are discharged, and other processes needed for successful implementation of these programs.

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“Outpatient treatment is now feasible, the safety has already been demonstrated, patient satisfaction has increased, and we have shown through our study that the costs are lower to the patient.”

— **Daren M. Beam, M.D., M.S.**, Co-director, PE Response Team Indiana University Health; Assistant Professor of Emergency Medicine, Indiana University School of Medicine

Implementing LRPE Discharge Protocols and Specialty Clinics

Dr. Rosovsky began the presentation noting that venous thromboembolism (VTE) and pulmonary embolism (PE) are a major cause of morbidity and mortality worldwide. There are approximately 900,000 VTE events in the United States every year, she reported, and “the incidence and death rates for PE are on the rise.” PE has an annual economic burden “of greater than \$8.5 billion.” Part of that cost is hospitalization of PE patients who appear at emergency rooms. The question is: Can some of those patients be discharged to outpatient care? Indeed, they can, and Dr. Rosovsky showed how her team is doing just that.

She provided a case study. The patient, a 20-year-old African-American college junior, had presented to the college health service with two days of progressive right calf pain, “so severe,” noted Dr. Rosovsky, that “it was hard for her to walk.” She was told it was a pulled muscle, advised to use heat and ibuprofen, and make a follow-up appointment for three days later. The following evening, however, the patient became acutely short of breath. A call to health services just advised her to attend the previously planned follow-up appointment. “Fortunately,” said Dr. Rosovsky, “she called her mother, who advised her to immediately go to her local emergency room.”

The patient had started oral contraceptives two months prior to this event and also had a fairly extensive family history of blood clots. When she presented to the ER, her C.T. scan showed pulmonary emboli. Application of established LRPE protocols allowed her to be discharged with a month-long supply of anticoagulant, and the patient is currently doing well.

How and why were these protocols established? Dr. Rosovsky indicated, “When we looked at our own data, we noticed that the majority of patients with DVT and PE were actually being admitted.” When ER doctors were asked about all these admissions, the “major reason was concern for litigation and lack of follow-up.” The

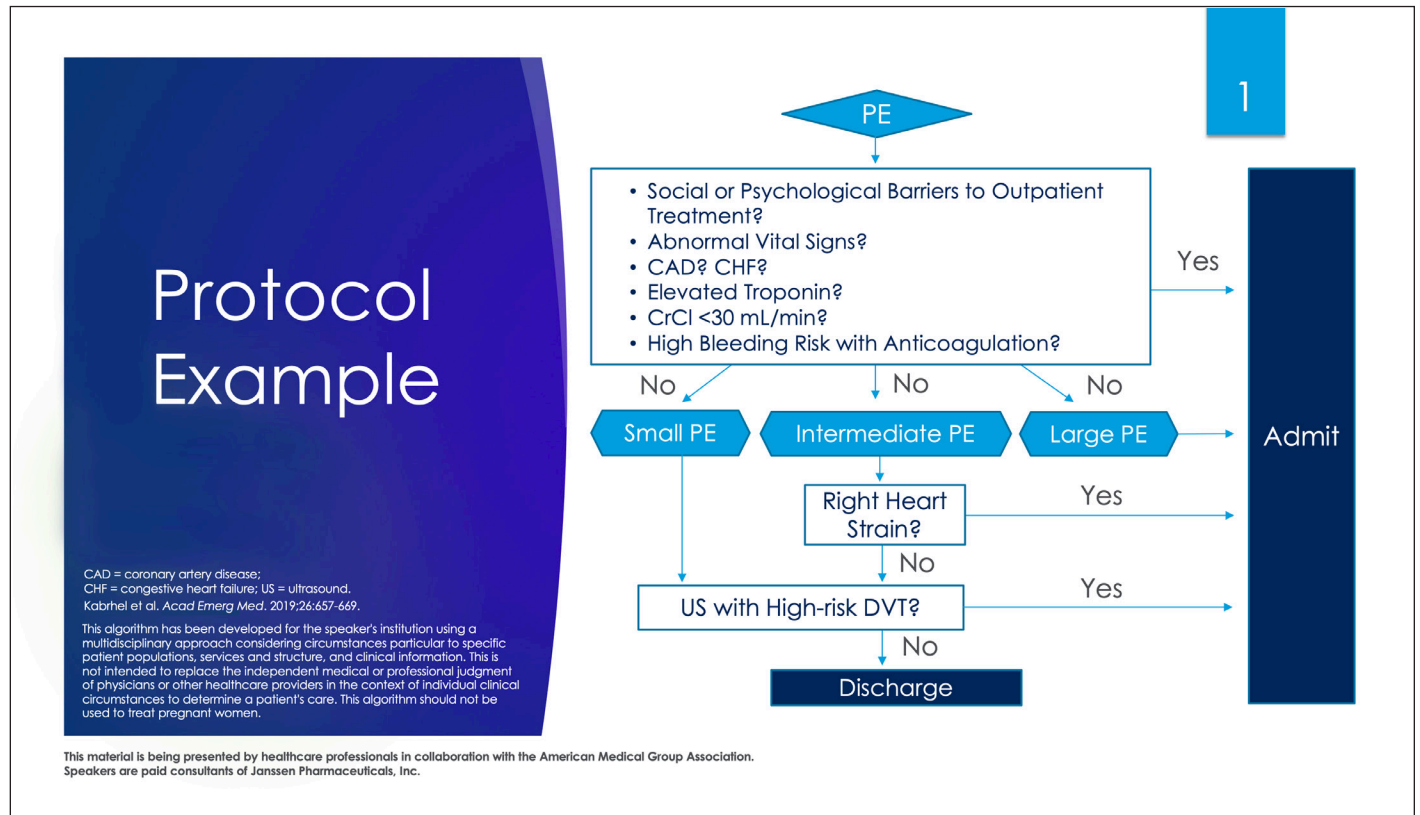
outpatient DVT/PE protocol was established to address these concerns. “The most important aspect of this protocol,” Dr Rosovsky stated, is that “every single patient” gets timely follow-up, “meaning within seven to 10 days,” after discharge from the ER. Also key is to involve the patient’s PCP and offer the choice for follow-up to be by the PCP or “our dedicated outpatient DVT/PE clinic.” As it turned out, “most of the PCPs elected to have patients follow up in our clinic.”

The LRPE protocol at Massachusetts General was based on CHEST (the American College of Chest Physicians) guidelines. Dr. Rosovsky explained: “Patients need to be clinically stable, which means they have to have normal vital signs. They can have no contraindications to anticoagulation. They have to be expected to be compliant with their therapy. They have to feel well enough to be treated at home and have enough support systems at home for that to happen. And they have to have no presence of injury in their heart, which is right ventricular dysfunction, often manifesting as increased biomarkers.” These criteria were expanded to create a system of yes/no questions ease decision-making by ER physicians.

The decision to admit or discharge a PE patient under this protocol begins with a series of six questions, shown in Figure 1. If the answer to any question is “yes” the patient is admitted. According to Dr. Rosovsky, “Did the patient have any social or psychological barriers to outpatient therapy? And if they did, they were admitted. Did they have abnormal vital signs; were they hypotensive, tachycardic, hypoxic, requiring oxygen? If so, they were admitted. Did they have active or a history of extensive cardiac disease or heart failure? If yes, they were admitted.” Any “yes” answer required admission.

If the answer to all six questions is “no,” however, then the type of PE dictated further inquiry. All large PE patients are admitted. Small PE patients undergo an ultrasound to make sure they don’t have a high-risk DVT.

Figure 1: Protocol Example



“If they did,” said Dr. Rosovsky, “they were admitted, because often those patients might need more advanced therapy. If they did not have high-risk DVT, they were eligible for discharge.” Key for intermediate PE patients was making sure they didn’t have right heart strain. “So, in addition to the troponin, they had an echocardiogram to see if there was any evidence of right heart strain.” If so, they were admitted. If not, they, like small PE patients, had an ultrasound to confirm they didn’t have any high-risk DVT.

Dr. Rosovsky’s team included several important considerations in developing their LRPE discharge process. First, everybody had to have follow-up within seven to 10 days. Second, they had to be discharged on the appropriate medication. Dr. Rosovsky noted that, based on current research, “DOACs [direct oral anticoagulants] are now first-line therapy for the majority of patients,” although there are some specific populations (e.g., pregnant women) that require other medications. Finally, it’s important to provide

patient education prior to discharge. Patients need to understand how to take the prescribed medication; to return to the emergency room if they have bleeding, chest pain, pressure, shortness of breath, or other concerning symptoms; and how to reduce bleeding and bruising (e.g., using a soft toothbrush, avoiding contact sports, avoiding NSAIDs [nonsteroidal anti-inflammatory medications]).

“Most importantly,” said Dr. Rosovsky, “patients were discharged with either medication in hand or with the knowledge that it could be obtained in the outpatient setting within that day with the help of the case manager. And we wanted to make sure that they were discharged with a 30-day supply.” After discharge, patients get letters and a call to provide a reminder of the follow-up appointment and any follow-up testing.

To test how well the protocol worked, Dr. Rosovsky and her team looked at ER discharges to outpatient care before and after implementation of the protocol,

a combined group of 2,212 patients. Overall, they saw an increase in the number of patients discharged. For patients with PE, with or without DVT, there was an increase in the number of patients who were discharged as outpatients instead of being admitted. There was also an increase in patients discharged to outpatient care for DVTs overall. “Importantly,” noted Rosovsky, “mortality, bleeding, and return to the emergency room were rare and did not increase after the protocol.”

Of course, it is not just implementation of the protocol in the ER, but the follow-up care at the specialty clinic that led to this success. Dr. Rosovsky described their follow-up clinic process.

“The first thing,” she said, “is we just ask them to tell their story. These people have had a trauma, and most people just want to tell you what happened. But in doing that, you can often identify the underlying etiology of why they got a PE if one exists. We want to make sure patients are up-to-date with age-appropriate cancer screening. And it’s important to follow up any abnormal lab when they were in the emergency room.”

Then, address treatment. “The majority of this follow-up visit is addressing anticoagulation,” advised Rosovsky. “You want to confirm with the patient the type of medication and dose, whether the patient can afford the medication, and whether they’ve adhered to medication instructions and not missed doses. If they are missing doses, delve into what the barriers are and why that’s happening.”

It’s also important to reiterate prior instructions about avoiding nonsteroidals, supplements, or other things that could increase the risk of bleeding and to stress the importance of patients advising providers of anticoagulant use if they’re going to have any procedures. Also, assess whether original symptoms have improved or whether there are any new symptoms. Review signs and symptoms that warrant a call to the patient’s PCP or return to the ER.

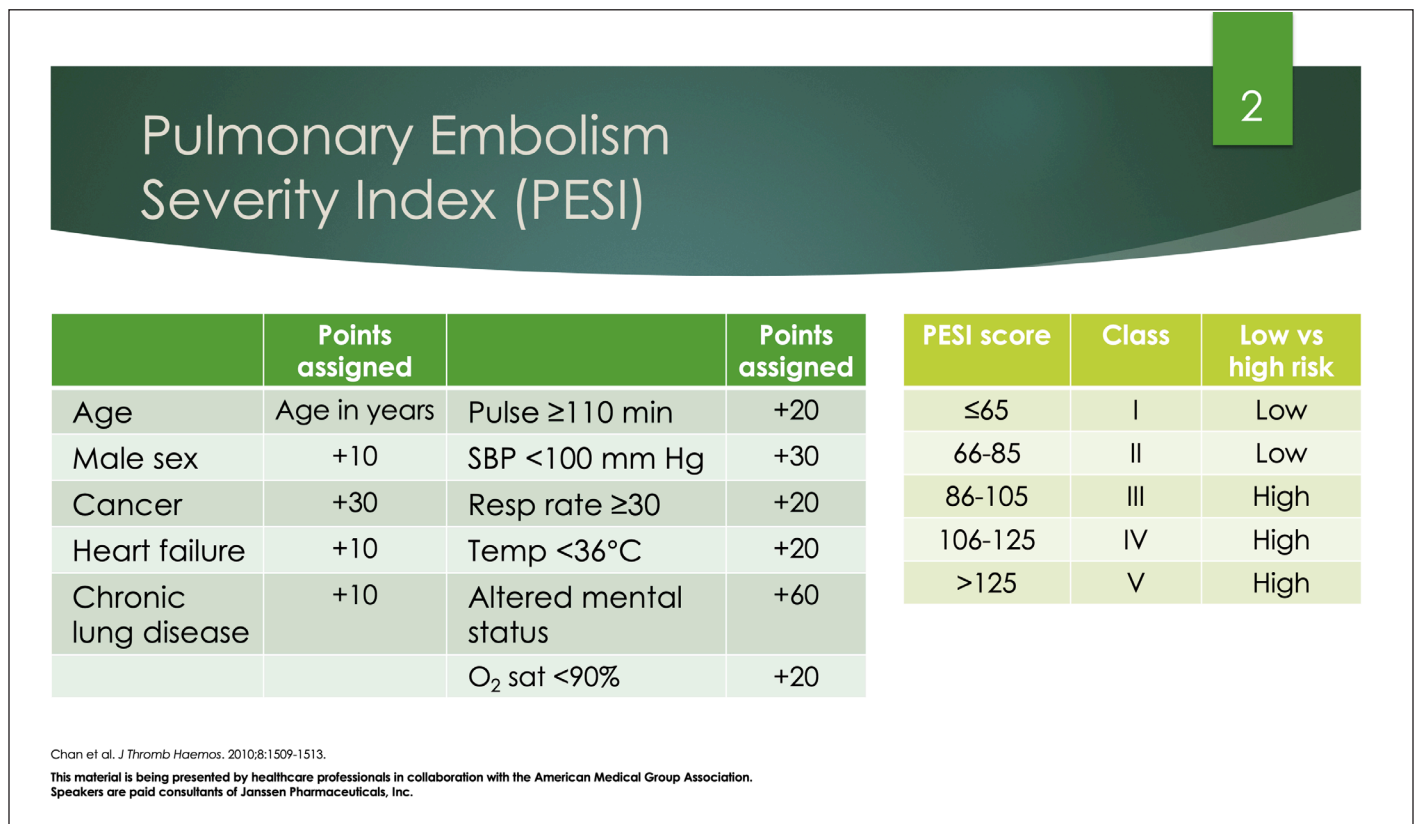
Another key, and often overlooked component, said Rosovsky, is “to assess for any psychological strain or stress.” She noted that most of her patients have some form of this. She also highlighted “post-thrombotic panic disorder, which is relatively new and not studied much,” and stressed the importance of addressing it with patients, “to let them know what is actually normal” and allow for an assessment of whether the patient needs additional assistance in this regard. “Most importantly,” she said, “they should listen to their bodies and trust themselves because they, more than anybody else, know themselves the best.”

Discharge to and treatment by the specialty clinic has been very successful. She shared several lessons learned during the implementation process. “Number one was scheduling a follow-up clinic visit *before* they get discharged from the emergency room,” and include related information with discharge papers because “oftentimes people are so overwhelmed when they’re in the emergency room, they don’t remember anything.” When her team first started their program, they had not considered that the patients needed to leave the ER “with medication in hand. And we quickly realized that that was a problem.” They incorporated a case manager to make sure every discharged PE patient had a 30-day supply of medication in hand or the pharmacy had it waiting for them when they left the ER. The case manager also checks insurance to address coverage for medication as well as the clinic follow-up visit.

Risk Stratification Tools for Use in the ER

Dr. Beam took participants on a deep dive through several risk-stratification tools ERs can use to guide decision making related to discharging PE or VTE patients. The most validated system, Beam advised, is the Pulmonary Embolism Severity Index (PESI) score. Developed in 2005, PESI (see Figure 2) uses a series of clinical characteristics to place patients into different “classes that have different scores, which then are

Figure 2: Pulmonary Embolism Severity Index (PESI)



associated with different risks of mortality or adverse outcomes.” Initial validation of PESI showed the chance of adverse outcome or mortality was very low for class one (mortality rate being zero to 1.6%) and also low in class two (1.7% - 3.5%). Later external validation studies showed the risk was 0% in the very low-risk (class one) category and 1.7% in the low-risk (class two) category.

Dr. Beam noted that the PESI scoring system is “complex” and can become cumbersome in a busy ER. Thus, a simplified version, sPESI, uses six criteria:

- Age > 80 years
- History of cancer
- History of heart failure or chronic lung disease
- Pulse > 110 beats/min
- SBP < 100 mm Hg
- O₂ sat < 90%

Like the protocol described by Dr. Rosovsky, sPESI is “an all-or-none protocol.” The patient must be negative for everything on this scoring system to warrant discharge.

He noted, in particular, that the cancer and oxygen saturation categories limit “the amount of patients that can be used for this, because most patients have had some, or a large percentage of patients have a history of cancer in the remote past,” and “most physicians prior to COVID were uncomfortable sending patients home with an oxygen saturation under 95%.”

The third risk stratification method is the Hestia score, which has been shown to have “a 0% mortality rate and 2% recurrence of VTE.” Similar to the sPESI score, Hestia is an all-or-none protocol. The main difference between Hestia and PESI is that Hestia considers social factors (i.e., is there a medical or social reason for the treatment in hospital for greater than 24 hours?). Dr. Beam provided the example of homeless patients, who “are hard to discharge because of their lack of access to medical care.”

With this research in hand, Dr. Beam’s team developed a two-step protocol. To be considered for discharge,

patients must first meet three criteria: a positive CT pulmonary angiogram (CTPA) showing a pulmonary embolism that is normotensive, no right heart strain, and no abnormal biomarkers. If they meet these criteria, they are then risk stratified using either Hestia, PESI, or sPESI and, if defined as low risk, may be discharged for follow-up to their PCP (especially if the patient needs lifelong anticoagulation) or one of two IU Health embolism clinics.

In developing their approach, the IU Health team took a poll of their ER faculty physicians and found that, similar to Dr. Rosovsky's research, 42% were concerned about follow-up and a quarter were concerned with medical/legal liability. As well, 40% had either never discharged a patient with PE/VTE or were unfamiliar with protocols, 33% believed having necessary drugs on hand was too expensive, and 21% found it easier to admit than to discharge and also felt that patients were more comfortable if they were hospitalized. Since implementing the new protocol, about 25% to 30% of PE patients are discharged from the participating ERs. The embolism clinics have seen more than 700 patients, about a quarter of which experienced PEs. Dr. Beam's key takeaway: "What we've shown through our research is that outpatient treatment is now feasible, the safety has already been demonstrated, patient satisfaction has increased, and we have shown through our study that the costs are lower to the patient."

Building Multidisciplinary Teams and Automating Processes

Dr. Troha focused on the multidisciplinary aspect of the team at Atrium Health, which he said was part of the plan from the outset, in 2015. "This really was vital to the successful creation and implementation of our protocol because we did draw on the expertise of hematology and pharmacy, and our internal medicine colleagues as well, especially to help with our transition or our outpatient clinic." The protocol, he said, was "driven by emergency medicine because it is an ED discharge protocol, but that multidisciplinary collaboration really was key to the

successful implementation of our program." Dr. Troha walked webinar participants through the process a sample patient "L.M." as the guide.

L.M. is a 57-year-old male presenting to one of 17 participating EDs within the hospital system with chest pain and shortness of breath. His vital signs were normal with blood pressure of 125 over 82, heart rate of 95, normal respiratory rate, and normal oxygen saturation. L.M.'s labs were normal, as well, with no elevation of cardiac biomarkers. Serum creatinine, LFTs, and platelet count were all normal. A CT angiogram of the chest was positive for PE, but there were no signs of right heart strain.

L.M. met Atrium's criteria for outpatient treatment, so his emergency provider activated a computerized order set or what Troha called their "power plan." The power plan contains "pertinent labs and orders for the initial anticoagulants" but also sends a message to the hospital pharmacy "to generate a 30-day prescription and a free trial card for the patient," and sends a message to the transition clinic (Atrium's follow-up clinic) indicating that the patient "has been included in the protocol and needs to be contacted by phone for that follow-up appointment, which we do within a week of their ED visit." Finally, the power plan provides custom discharge instructions that help the patient understand the medication they're prescribed, as well as information about the transition clinic, how that works, and when the patient will be contacted. Automating processes has been a key element of success. As Dr. Troha noted, "the power plan activation does a lot of that behind the scenes work and doesn't rely on the emergency provider completing all the steps," which is helpful during a busy shift.

Dr. Troha described the medication delivery element as "crucial." The 17 participating EDs are quite varied. "Some are larger and have a multitude of onsite resources like social workers and onsite pharmacies, but others are smaller and more rural or even a freestanding ED and have less of these resources." It was important to create

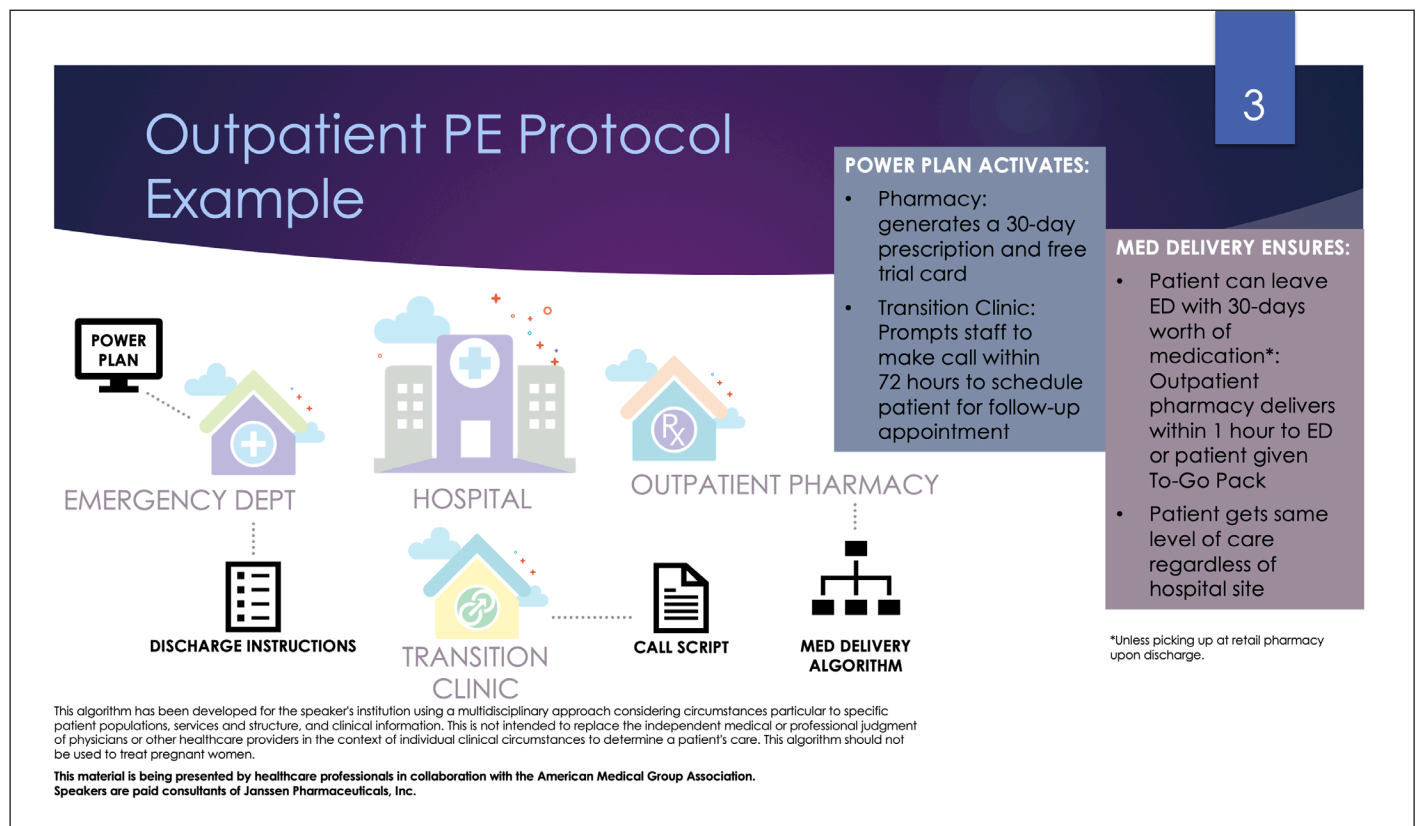
a program that took these difference into account while ensuring every patient has “the option to leave the ED with 30-days’ worth of anticoagulant medication in hand, regardless of which of our 17 EDs they present to.” Thus, if L.M. presented to the large main hospital in Charlotte, the custom algorithm would trigger the outpatient pharmacy to fill the medication and deliver it to the ED while L.M. was waiting to be discharged. If L.M. presented to one of the freestanding EDs in a more rural area (which has no outpatient pharmacy on site), he would still receive 30-days’ worth of medication, in the form of a “to go pack” that is prepared in advance and comes directly from the ED Omnicell.

Within 72 hours of his ER visit, L.M. would be contacted by the transition clinic. This first contact, via phone, uses a specific call script that prompts the transition clinic nurse to ensure that the patient is taking their medication as prescribed and is not experiencing any new symptoms or worsening symptoms, and can also determine if the patient needs transportation assistance

for the clinic visit. For patients that live more remotely and cannot physically come into the clinic in Charlotte, Dr. Troha’s team provides an option for virtual visits, which, he noted “we’ve actually been utilizing for years, even prior to COVID-19 pandemic. And we’ve had a lot of success with that as well.” He noted, clinic staff is “highly tuned in with the latest literature and guidelines and know who needs follow-up imaging, who needs follow-up labs, who needs hypercoagulable work-up and who needs the hematology referral if necessary. So, having at least one visit with the specialty clinic was really beneficial,” especially since the specialty clinic can ensure patients are seen within a week of their ER discharge, which is not always the case with PCPs.

Since the program began, Atrium’s participating EDs have treated and discharged over 1,000 patients with acute DVT and PE. Their latest data poll (approx. 947 patients), shows 0.9% experienced recurrent VTE and only 1.2% experienced bleeding that required hospitalization. Says Troha, “All in all, we’ve been very

Figure 3: Outpatient PE Protocol Example



happy with the safety of our approach and patient satisfaction has been quite high as well.”

Starting an LRPE ER Protocol and Specialty Clinic

Dr. Rosovsky identified several considerations for those wanting to implement discharge protocols and specialty clinics for LRPE patients.

“First,” she said, “what works for you will depend on the needs of your institution as well as your resources.” Consider whether the follow-up clinic will be added to an existing clinic or be a new one. Will it be staffed by one specialty or by numerous specialties (e.g., hematology, vascular, pulmonary, internal medicine)? Next is logistics. “There’s just a lot of moving parts and there’s a lot of people involved ... you’ve got to get all the emergency room people, the pharmacists, the case managers, the nurses, you even have to create the follow-up staff.” Consider structure: “How often are you going to have it? Well, that’s going to depend on the volume of your emergency room. Are you discharging 20 patients a week? One patient a week? Where are you

going to have it? Specifically the location?” You may need funding. “Most importantly,” said Rosovsky, “you want to set up goals of the clinic and meet regularly to address those.”

As well, she said, “there needs to be a leader of the follow-up clinic, someone that’s going to be the person responsible for making sure that this operates.” Dr. Beam concurred, “You have to have a champion of some sort to be able to do this.” Initially, his team found PCPs “were very scared and hesitant to even see these patients as an outpatient because of the way that pulmonary embolism is taught in medical school and medical literature.” Now, with the success of the program, PCPs are “much more comfortable taking care of these patients as outpatients. So you just need that one champion, who can show others that this is safe, reliable, and effective. “It does not have to be a hematologist,” Rosovsky agreed. “As long as you have a leader that’s taking interest in this and knows all the literature and the right kind of follow-up criteria and questions and just having that all in place. So I don’t think it has to be a specific one group or another.”



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