Performance Improvement Strategies
in VTE Risk Assessment and Prophylaxis

Community of Practice Audioconference

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MODERATOR: Welcome to the Community of Practice Audioconference, featuring venous thromboembolism (VTE) prophylaxis experts Dr. Samuel Goldhaber and Dr. Alok Khorana. Today's discussion is co-sponsored by the Duke University School of Medicine and Med-IQ. I'm Olivia Fritz, your moderator for today's discussion. This audioconference is being recorded; however, resale of the content is prohibited. During today's call you will have an opportunity to discuss strategies for improving VTE prevention among your hospitalized oncology and medically ill patients, as well as voice questions or comments for immediate faculty feedback. This interactive discussion has been developed as part of the AMA-standardized PI CME initiative "Performance Improvement Strategies in VTE Risk Assessment and Prophylaxis". Drs. Goldhaber and Khorana have served as faculty experts for this initiative and will provide a brief overview of this educational opportunity at the beginning of today's audioconference.

I am pleased to now introduce to you Dr. Goldhaber and Dr. Khorana. Dr. Goldhaber is a professor of medicine at Harvard Medical School and Director of the VTE Research Group in the Department of Medicine, Cardiovascular Division, at Brigham and Women's Hospital in Boston. Dr. Khorana is Vice Chief of the Division of Hematology/Oncology and associate professor of medicine in oncology at the James P. Wilmot Cancer Center at the University of Rochester in Rochester, New York. Dr. Goldhaber?

SAMUEL Z. GOLDHABER, MD: Thank you very much for that kind introduction. Good evening and welcome to this Community of Practice Audioconference for VTE Risk Assessment and Prophylaxis in Hospitalized Patients. The goal of this audioconference is to bring together clinicians who are interested in the prevention of VTE to discuss the implementation of current guideline recommendations and recent clinical evidence in routine practice with a special focus on processes or systems of care.

Before we open up the call to your questions, we would like to provide an overview of the framework of this performance improvement initiative, and initially discuss why initiatives such as this one are so important for practicing clinicians. Performance improvement, abbreviated as PI (this PI CME), this is an American Medical Association-approved educational format. Clinicians work on improving their individual performance by retrospectively evaluating patient data and developing an improvement plan for their practice. This particular PI activity focuses on three groups of hospitalized patients with an elevated risk of VTE, first the medically ill, second the oncology patients, and third the orthopaedic surgery patients. To our knowledge, this program is the only PI initiative focused solely on the risk assessment and prophylaxis of VTE in these patient populations.

As some of you know, there are three stages to the process. In the first step, or stage A, participants perform a retrospective analysis of 10 patient charts by completing a short patient data form for each chart. Once the chart review has been completed, participants receive a summary of their practice
patterns relative to those of their peers enrolled in the program and applicable national standards.

In the second step, or stage B, participants review their practice summary and design a process-based improvement strategy specific to the needs of their practice. To help develop a care improvement plan, clinicians may read a complimentary, certified CME implementation guide that outlines the current evidence base and treatment guidelines, as well as provides practical tools and resources.

In the final step, or stage C, participants return to review an additional 10 patient charts after they have implemented their improvement strategy in their practices. Once again, a patient data form is completed for each chart. At the conclusion of stage C, participants receive a summary of their current practice patterns relative to their initial performance, as well as to that of their peers and national standards.

Now I'm going to turn this audioconference over to my friend, Dr. Alok Khorana.

ALOK A. KHORANA, MD: Thank you Dr. Goldhaber, and thank you for that overview of the PI CME framework. As you're all well aware, VTE is a significant public health issue that places a heavy burden on the healthcare system. Hospitalization for acute medical illness increases the risk of VTE more than 10-fold. However, VTE risk assessment and thromboprophylaxis in medically ill patients is often overlooked. Clinicians need to understand that patient outcomes can be dramatically improved by implementing a standardized evidence-based approach to evaluating all hospitalized patients for the risk of VTE and initiating appropriate thromboprophylaxis in a timely manner.

Hospitalized oncology patients are also at particularly high risk of adverse events related to VTE. Cancer is associated with a 6-fold increase in the risk of VTE, and VTE is second only to cancer itself as a leading cause of in-hospital death in this group of patients. Although VTE prophylaxis guidelines to help guide management decisions are available from several organizations, including ASCO and NCCN, the evidence suggests that these patients frequently receive suboptimal prophylaxis during hospitalization.

There is a clear and compelling need to improve thromboprophylaxis among at-risk hospitalized patients. Patient safety initiatives from the US Surgeon General's Office, the National Quality Forum, and The Joint Commission have all brought recent attention to the problem of VTE in the hospital setting. The identification of VTE prophylaxis as an institutional priority, the development and implementation of standardized protocols, and the commitment and willingness of various stakeholders involved in the care of hospitalized patients is needed to combat this largely preventable issue and improve healthcare quality.

We would like to now open this forum up to your questions and comments
about the challenges you face in VTE risk assessment and prophylaxis among hospitalized patients. We will begin with the questions received in advance by e-mail, but please feel free to let the operator know if you have a question you would like addressed this evening.

MODERATOR: Thank you doctor. At this time we will begin the question and answer session. To ask a question, please press zero followed by a one on your touchtone phone. Questions will be answered in the order they are received. Again, if you would like to ask a question, please press zero followed by a one now. Please pause to assess whether we received a live question. Thank you.

Med-IQ received several questions in advance for this audioconference. At this time, Dr. Allison Gardner will share a question that was submitted by one of your colleagues.

ALLISON GARDNER, PHD: The first question is, “What is the role of maintenance full dose versus a prophylactic dose of low-molecular-weight heparin (LMWH) after the completion of therapy?” Dr. Goldhaber?

DR. GOLDHABER: Well, this question can be interpreted in several different ways. If we’re talking about the completion of therapy for an established deep vein thrombosis (DVT) or pulmonary embolism (PE), we have to keep in mind that the current guidelines instruct us to continue full-dose anticoagulation until the cancer is no longer evident and the cancer is cured. So, if someone has an acute DVT or an acute PE in the presence of cancer, then anticoagulation should be continued and therapy really doesn't stop. On the other hand, if one is giving prophylactic LMWH, let's say for hospitalization to avoid a DVT or PE occurring in the first place, generally these prophylaxis regimens/guidelines say about 10 days of therapy. Studies published recently in the Annals of Internal Medicine, with Russell Hull as the first author, indicate that there may be some patients, particularly those who are immobile, who will benefit from an extended duration of VTE prophylaxis for about a month after hospital discharge.

DR. GARDNER: Great, we could move on to the next pre-submitted question. And that is, “When should VTE prophylaxis be initiated in patients admitted with congestive heart failure or pulmonary edema? Should this be initiated in every patient with this diagnosis?”

DR. KHORANA: I guess I’ll take a stab at this first. I think the key here, as with any prophylaxis program, is that health systems need to have in place protocols that ensure that patients who are at risk of VTE receive prophylaxis if it is considered appropriate at the time. Now the key here really is the appropriate time because often we have patients we intend to admit to the hospital but who end up in an observation unit or in the emergency room for several hours, sometimes even for 23 to 26 hours before they end up on a regular floor. And because nobody really takes ownership of those patients at that point in time, it is often the case that VTE prophylaxis is not initiated until the
patient arrives on the floor and somebody notices that it wasn’t started when
the patient was waiting for a room. So, it really is key that VTE prophylaxis—
if you make the determination that the patient is at risk of VTE, which many
patients with heart failure and a pulmonary edema would be—then VTE
prophylaxis should be initiated as soon as possible in the hospital setting,
even before the patient actually arrives on the floor.

DR. GOLDHABER: Congestive heart failure, like cancer, places patients at very
high risk of VTE. And so, as Dr. Khorana says, the best approach is to have
systems in place that identify the patient electronically as admitted with
congestive heart failure or admitted with cancer, and those patients should by
default receive VTE prophylaxis.

MODERATOR: Thank you doctor. And at this time we do have a live question in
queue, and that question comes from Norwood, Massachusetts. Please go
ahead.

FEMALE VOICE: Hi, I was wondering what you would do in a situation where you
have, for instance, an otherwise healthy 62-year-old man, but who has a
history of heparin-induced thrombocytopenia (HIT) from a previous
hospitalization, is not on any current anticoagulation, and is coming in for a
knee replacement. What do you do with this patient?

DR. GOLDHABER: That’s a great question, and it’s a tricky question from many
points of view. I guess the first thing diagnostically is to ask how secure are
we in the prior diagnosis of HIT? And had recent antiplatelet or antibody tests
been performed to determine whether the patient has converted back to a
non-HIT status?

FEMALE VOICE: I would have to say the diagnosis was secure at the time of
diagnosis, and honestly that test has not been repeated. But a good idea.

DR. GOLDHABER: But this was HIT, and of course there are two types of HIT;
there’s HIT with thrombosis, which is often deadly, or without thrombosis.
Which type?

FEMALE VOICE: Without.

DR. GOLDHABER: Without? Well that’s good. Well, I’ll be curious to hear what Dr.
Khorana would say, but I would prophylax this patient with fondaparinux 2.5
mg daily.

DR. KHORANA: I agree. I mean, it’s a great question because there are all kinds of
issues here. One is of course the risk assessment of the patient, and
presumably this is somebody who would be at risk of VTE. There are no
contraindications to prophylaxis, and certainly this patient should receive
some form of protection. If the prior diagnosis is either not clear or if it’s clear
that it was truly HIT, I would certainly err on the side of caution and not
reattempt a heparin but move to fondaparinux, as Dr. Goldhaber suggested.

FEMALE VOICE: Is that your drug of choice? It sounds like it is from both of you.
DR. GOLDHABER: Well the thing is, you can't use heparin, you can't use LMWH—
FEMALE VOICE: Right.

DR. GOLDHABER: And to use an intravenous direct thrombin inhibitor, such as argatroban or—
FEMALE VOICE: Right.

DR. GOLDHABER: Desirudin or bivalirudin would be a bit of overkill.
DR. KHRORANA: Right.
FEMALE VOICE: I see.

DR. KHRORANA: Not to mention the cost issues of some of these other drugs.
FEMALE VOICE: Good point. So, you would always measure their platelet factor 4 level?

DR. GOLDHABER: Well most patients revert to normal after 6 months.
FEMALE VOICE: Okay.

DR. GOLDHABER: I think it's something you want to know before going into surgery. You might not do anything differently, but you'd like to know whether the patient converted back.
FEMALE VOICE: Okay. Thank you.

MODERATOR: Thank you for your question. And Dr. Gardner will you please continue with another pre-submitted question?

DR. GARDNER: Sure, Dr. Khorana, the next question is, “What are your thoughts regarding primary prophylaxis in oncology patients?”

DR. KHRORANA: Well, we could spend an hour discussing this, but let me briefly review what the possibilities are. In general, we understand that cancer patients are at risk of VTE, and unlike in other patients, the risk does not diminish when cancer patients are in the outpatient setting. So, they continue to be at high risk of developing clots despite being mobile and being ambulatory outside of the hospital.

The problem is that we are as yet unsuccessful at identifying truly high-risk patients in the outpatient setting who would benefit from prophylaxis. Certainly, giving it to all cancer patients doesn't make sense because the average rate is much higher and the general population is still low. It's on the order of about 2% or so over a couple of months. It's very high compared to the general population, which is less than 0.1% over a year. But it's still pretty low in terms of a public health standpoint. There are clearly some subgroups of cancer patients who would benefit. The most obvious ones are patients with myeloma who are receiving thalidomide or lenalidomide-based chemotherapy regimens, and for those patients, both the ASCO and NCCN
Guidelines recommend outpatient prophylaxis. The recommendation is primarily for LMWH, although adjusted-dose warfarin is sort of accepted, and then practitioners often use aspirin, although there are not much data to support that.

So, according to the guidelines, that's currently the only high-risk population for which prophylaxis is recommended in the outpatient setting. There are ongoing trials of high-risk cancer patients. One is using a risk score that we use a lot, and another is measuring blood levels or tissue factor, and then only prophylaxing those patients with high tissue factor levels. But we have to await the results of those studies before that recommendation can be made.

MODERATOR: Thank you doctor. And again, as a reminder to our participants, to ask a live question please press zero, one on your touchtone phone.

DR. GARDNER: The next question that was pre-submitted by e-mail is, “How imperative is it to send cancer patients home on DVT prophylaxis?”

DR. KHORANA: So, the similar guidelines apply. I think when cancer patients go home from the hospital, they continue to be at high risk of VTE. And many of the patients in the recently published study of extended prophylaxis that Dr. Goldhaber just pointed out, which was published in the Annals, were in fact patients with cancer. At this point we don't know exactly that subgroup of patients who would benefit from outpatient thromboprophylaxis in the post-discharge setting. When we consider prophylaxis for hospitalized medical patients, it's important to remember that when original studies of inpatient prophylaxis were conducted, the typical duration of prophylaxis was 7 to 11 days. Today it is very common to send patients home in 3 to 4 days after hospital admission. It's not that patients are getting better faster, we just happen to send them home faster because of the pressure on the healthcare system and because of increased home services that are now available.

So, patients are home, and they're still at risk of VTE. In a study done in Massachusetts, almost three-fourths of patients who had out-patient DVTs had recently been in the hospital. So, it's important to make sure that if patients had a high risk of VTE in the hospital that they receive the appropriate duration of prophylaxis, which may include a few days of prophylaxis at home after discharge.

MODERATOR: Thank you doctor. And at this time, we do have an additional question in queue, and that question comes from Washington, DC. Please go ahead with your question.

DR. DELU: Hi, Dr. Delu at the Providence Hospital in Washington, DC. This is not really a malignancy-related question, but there’s a 40-year-old African American female who just underwent bariatric surgery, gastric bypass surgery. Then 11 days after the surgery, even though the patient had the prophylactic so-called IVC filter placed the day before surgery, the patient comes in with a rather massive PE with no previous history of a
thromboembolic disorder. Only significant history is her father at age 80 died of metastatic colon cancer, and she is undergoing colonoscopy on a regular basis for surveillance. When we did the various imaging studies, there was a rather large clot, 3 by 5 cm, above the inferior vena cava as well as at the level of inferior vena cava filter, and below the filter; the DVT screening in the lower extremities are negative. I was wondering, what would be your approach in terms of diagnostic and therapeutic? The patient has been placed immediately on heparin and is currently getting the heparin therapy. This was two days ago, and she is feeling better. Several emboli documented by CT angio, pulmonary angio.

DR. GOLDHABER: It sounds like you did everything you could to try to prevent VTE in the first place. But filters do fail. They have about a 4% failure rate. First of all, filters don't stop all PE, but they usually stop the saddle PE that you described. This patient's PE must have occurred because of pre-existing collateral veins that avoided the filter itself. Although I would say maybe the reason that she's alive is that the filter did catch some of the thrombus and that might have meant a difference between life and death. First of all, the filter now should remain in permanently.

DR. DELU: Right.

DR. GOLDHABER: Without being retrieved. Secondly, it would be very important for you to keep her on long-term anticoagulation. Even though we usually stop anticoagulation at 6 months after a post-operative PE, I would say in this situation, the patient remains at very high risk because she is overweight, and I would probably continue indefinite duration anticoagulation as long as she does tolerate it over time. It will be important for her to follow strictly her new diet because as she loses weight, her risk of recurrent PE will decrease.

DR. KHORANA: I agree, and I would add that if she hasn't had a recent malignancy workup—and it's not something we recommend because on a public health basis, the chance of finding something is low—but if she has a sort of strong family history of colon cancer, and with colonoscopy other workup has not been done recently, you might want to do at least a minimal workup at this point.

DR. DELU: She has had two colonoscopies about 2 years apart, and both times they kept seeing these new polyps. They're so far all benign tubular adenoma, just polyps, but she is due for another within the next few months. They're roughly every 2 to 3 years.

DR. KHORANA: Yeah, I would certainly make sure she gets that.

DR. DELU: Yeah, don't have any genetic information other than her father's, the colon cancer history, in detail.

DR. KHORANA: Okay. Yeah, and she would then, this is sort of off topic, but she probably also might want to consider genetic testing because—
DR. DELU: Exactly.
DR. KHIRANA: —she's younger than 50, she already has polyps, her father had—
DR. DELU: Right.

DR. GOLDHABER: Now I'm also curious, do you know what dose of pharmacologic prophylaxis she was receiving peri-operatively in addition to the filter?

DR. KHIRANA: Actually the review of the records showed that just filter and no anticoagulation whatsoever. So that was one of the big surprises to me. I thought that the, just with the morbid obesity with this type of, well whatever procedure, I thought they would automatically be qualified for some form of peri-operative anticoagulation prophylaxis.

DR. GOLDHABER: So this is a big teaching point.

DR. KHIRANA: Right, that's why I was—

DR. GOLDHABER: The group on the audioconference, you need to understand that the filter does not prevent clots from forming.

DR. KHIRANA: Right.

DR. GOLDHABER: For this, you need an anticoagulant, and I guess before I asked, I had just assumed that she was getting pharmacologic prophylaxis; I was going to make the point that often we double the dose. For instance, we might give enoxaparin 40 mg twice a day to bariatric surgery patients or might give dalteparin 5,000 units twice a day. But I thought she was getting some sort of standard pharmacologic prophylaxis, and then for good measure on top of that a filter. So, I'm not entirely surprised now—

DR. DELU: Right.

DR. GOLDHABER: —that she had a saddle PE.

DR. DELU: Right.

DR. GOLDHABER: I think we were just asking the filter to do so much. It's just a piece of metal. It cannot prevent the thrombotic condition.

DR. KHIRANA: Could the filter be the iatrogenic source of this thromboembolic disorder in that locally just above, below, and all around the filter?

DR. GOLDHABER: Excellent question. We know the patients who have filters placed have double the hospitalization rate for DVT in the year following filter placement. So, I think it could have been the source of the additional thrombus, of course, and stuck in the filter. But nevertheless it's unusual. I wouldn't blame the filter for the saddle PE. I would blame her natural biologic state, and I would just say that we should never do bariatric surgery unless we're giving concomitant pharmacologic prophylaxis.

DR. DELU: Absolutely, yeah.
DR. GOLDHABER: In other words, if she were too high risk of bleeding for prophylaxis, pharmacologic prophylaxis, I would contend she's at too high of a risk of bleeding to undergo the bariatric surgery.

DR. KHORANA: Exactly, yeah. This is actually in addition to being a teachable moment for all of us on the call, but it's also a teachable moment for the surgeons and the surgical system where this patient was operated on because this may be a wake-up call for them. I mean they almost lost this patient.

DR. DELU: The surgical recommendation—are these bariatric surgeons are all aware that, even though a patient has a clean history, she does deserve some peri-operative pharmacologic coverage?

DR. GOLDHABER: I think the bariatric surgeons all know that PE is the number one cause of death in their population. And I don't know, Alok who recommended the filter? For all we know it could have been a medical doc, an internal medicine doctor serving as the consultant.

DR. DELU: Right.

DR. KHORANA: Right, but I'm surprised though because of all of the surgical specialties, oncologic surgeons and bariatric surgeons are some of the best in doing prophylaxis. And as Dr. Goldhaber pointed out, if she was at a high risk of bleeding with a prophylactic dose of LMWH, then certainly perhaps she should not even have been operated on.

DR. GOLDHABER: Right.

DR. KHORANA: For an elective procedure.

DR. DELU: I think the take-home message to emphasize is the fact that the just filter alone is not a panacea and that you have to still do the other things like we would normally do.

DR. KHORANA: Right, and it is for some reason, I don't know if it's a surgical mindset or an engineering mindset, but there's often a greater deal of trust placed by surgeons on IVC filters than by medical doctors. And it's important to keep emphasizing that these filters are only really indicated in patients who have contraindications to treatment of DVT.

DR. DELU: Thank you.

MODERATOR: Thank you doctors. Thank you. This concludes today's VTE Prophylaxis Community of Practice Audioconference, co-sponsored by the Duke University School of Medicine and Med-IQ. This activity is supported by educational grants from Ortho-McNeil, a division of Ortho-McNeill-Janssen Pharmaceuticals Incorporated, administered by Ortho-McNeil Janssen Scientific Affairs, LLC, and sanofi-aventis U.S. Four hundred specialists have enrolled in "Performance Improvement Strategies in VTE Risk Assessment and Prophylaxis" to evaluate and improve their processes of care for the
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