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A Letter from the Chair of the Board

Dear Colleague:

This first newsletter of 2012 deals with an important aspect of patient care – the monitoring of patients on anti-coagulation therapy. These medications have inherent risks associated with them and require the diligence of treating Physicians to both assess and mitigate those risks when placing patients on them. As always, communication is a key component of risk management in this area.

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Anti-Coagulation Therapies: A Review of Best Practices for Managing Risk

Consider the following scenario: A male patient presented to the emergency department of a local hospital with a fractured hip as a result of an MVA. An orthopaedic surgeon was called in by the emergency Physician to repair the injury to the patient. Both the emergency Physician and the surgeon failed to review the patient's past medical history of deep vein thrombosis and pulmonary embolism. As a result, the patient was not provided appropriate anti-coagulant therapy in a timely manner. The procedure to fix the fracture was uneventful, but the patient suffered a pulmonary embolism post-operatively and subsequently died. Litigation followed which resulted in allegations of a failure to provide the needed anti-coagulant therapy as warranted by the patient's medical history.

It is a well-established fact that anti-coagulants, such as warfarin, have been around for quite a while and are considered to be life-saving medications. They are also known to be extremely high risk, as even small dosage changes can have severe consequences. Excessive anti-coagulation intake can cause bleeding and insufficient anti-coagulation can lead to thrombosis-related injuries, including deep vein thrombosis (DVT), stroke and pulmonary embolism. Errors associated with

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anti-coagulation therapies are a leading cause of severe harm or death caused by medication errors, which include errors in prescribing, monitoring or patient counseling, as well as errors in dispensing, preparing and/or administering the medication.[i] Venous thromboembolic events affect over two million people in the United States each year and 200,000 people die of pulmonary embolism annually.[ii] Consequently, there are a substantial number of malpractice lawsuits filed each year related to anti-coagulation therapies and thrombotic events.

Every health care provider needs to remain aware of the risks associated with the use of anti-coagulants and take steps to manage those risks. There are three broad categories of patients for whom anti-coagulation risks must be assessed and managed: patients who have been diagnosed with a medical condition that requires anti-coagulation therapy, such as DVT or atrial fibrillation; patients who need short term anti-coagulation therapy as a prophylactic measure to prevent formation of clots, such as patients immobilized by illness, injury or a surgical procedure; and patients on long term anti-coagulation therapy who are undergoing invasive procedures that pose a risk of bleeding.

Guidelines:

Numerous medical professional associations have published guidelines for addressing the use of anti-coagulant therapies within the context of their specialties. These guidelines address both the use of anti-coagulant therapies, as well as the interactions of anti-coagulant therapies with other medical treatments. Many of these guidelines are periodically updated to reflect recent developments in medical literature and state of the art knowledge. They are intended to be an educational device and to inform the Physician of the state of the art. However, they are not definitive and routinely contain disclaimers such as the following: *The recommendations in this guideline are not intended to be a fixed protocol as some patients may require more or less treatment or different means of diagnosis.*

On September 23, 2011, the American Academy of Orthopaedic Surgeons published updated clinical practice guidelines (the AAOS Guidelines). This new publication, which replaced guidelines published in 2007, addresses therapies available to prevent a formation of venous thromboembolic (VTE) disease in patients who have an increased risk due to orthopaedic surgery and/or due to limited mobility while recovering from surgery. These guidelines emphasize the need to evaluate a patient for bleeding risks as well as for risks of developing thromboembolic disease. They also suggest when pharmacologic agents or mechanical compressive devices should be used. For example, patients with a known bleeding risk, such as hemophilia, require mechanical compressive devices for prophylaxis, and pharmacological agents should not be used; patients who are not at elevated risk of thrombosis can use either method, and patients with a prior venous thromboembolism need both. In all cases, the guidelines recommend early mobilization to prevent clot formation, as it is both low cost and poses minimal risk to the patient.[iii]

On November 1, 2011, the American College of Physicians published new clinical guidelines for the prevention of venous thrombosis in non-surgical hospitalized patients. These guidelines recommend assessment of the risk for thromboembolism and bleeding in **all** hospitalized medical patients prior to initiation of prophylaxis; recommend pharmacologic prophylaxis unless the risk for bleeding outweighs the likely benefits, and recommend against the use of graduated compression stockings.[iv]

The National Institute for Health and Clinical Excellence in the United Kingdom has recently published guidelines aimed at preventing venous thrombosis in hospitalized patients, and included detailed pathways for different categories of patients, such as surgical patients, obstetrical patients and critical care patients. The "NICE" guidelines emphasize: assessing a patient's risk for bleeding and for venous thrombosis upon admission and every 24 hours thereafter; keeping patients hydrated and encouraging mobilization; offering prophylactic pharmacological anti-coagulant therapy to all medical patients assessed to be at increased risk for venous thrombosis unless contra-indicated; and starting the prophylaxis as soon as possible after the assessment is complete.[v]

A brief review of available literature indicates that guidelines have also been published that are directed to a variety of specialties. Recommendations for family medicine Physicians and internists include guidelines for treating VTE in both the inpatient and outpatient setting. These guidelines recommend that anti-coagulation be maintained for three to six months for VTE secondary to transient risk factors, and for more than 12 months for recurrent VTE.[vi] Recommendations targeted at gastroenterologists emphasize that the most common site of significant bleeding in patients receiving oral anti-coagulation therapy is in the GI tract, and address balancing the risks of bleeding from endoscopic procedures against the risk of a thromboembolic event from interrupting therapy, and provides recommendations for managing antithrombotic patients undergoing endoscopic procedures, including alternatives to interrupting their anti-coagulation therapy.[vii] The American College of Chest Physician guidelines, which are geared toward a multitude of specialties including pulmonologists, critical care specialists, thoracic surgeons, and related disciplines, emphasize treatment of patients who have been diagnosed with DVT in order to reduce the risk of short term complications such as pulmonary embolism and long term complications such as postphlebitic syndrome.[viii]

Guidelines published by professional associations **do not** establish the standard of care. In fact, guidelines can vary from one practice group to the next and have been known to contradict each other.[ix] In a medical malpractice suit, guidelines published by professional associations cannot be used, in and of themselves, to prove the standard of care. They can, however, be relied upon by a medical expert as a source for determining the standard of care applicable to a practitioner in that field. The existence of published guidelines, and a particular practitioner's adherence or deviation therefrom, carries a great deal of weight with a jury. Every health care provider needs to be familiar with the clinical practice guidelines published by her own professional association and applicable to her field of practice. If a particular patient's unique situation mandates deviation from the published clinical guidelines, those unique traits, and how they are being addressed, should be clearly documented in the patient's medical record.

While the guidelines and associated literature may vary in the details of when and how anti-coagulants should be used in specific patient populations, they **all** agree on certain essential categories of care: assessment, monitoring and communication.

Assessment:

If a patient has recently been diagnosed with a condition that suggests treatment with anti-coagulant therapy, a careful assessment for bleeding risks must be performed, including a review of family history for inherited bleeding disorders, review of current medications, tests for liver disease, and consideration for any co-morbid medical conditions such as uncontrolled systolic hypertension. Such an assessment must also be done for every patient who is experiencing a transient condition that increases risk for VTE, such as reduced mobility for more than three days, surgery that is longer than 60-90 minutes in duration, especially surgery to the lower limbs, active cancer or cancer treatment, or critical care admission. Risk factors for development of VTE should be considered in that assessment, including obesity, age, hormone replacement therapy, known thrombophilias and co-morbid medical conditions such as heart disease or inflammatory conditions.

Patients should be periodically reassessed to determine if any of their risk factors have changed, for example where a surgical site infection has lengthened the duration of the patient's hospital stay or period of immobility. Patients should also be reassessed if the treatment plan changes, such as when a surgery is being rescheduled. The assessment should be documented in the patient chart, indicating that an assessment has been performed, listing any risk factors identified and indicating treatment modalities to be utilized or changed. The results of the assessment, including any recommendations arising therefrom, should be discussed with the patient.

Monitoring:

Careful monitoring of pharmacological anti-coagulation is necessary not only to ensure that a therapeutic effect is achieved and maintained, but to insure against accidental overdoses that can lead to bleeding events, especially gastrointestinal bleeds. A patient's international normalized ratio (INR) levels should be checked before any pharmacological anti-coagulation therapy is initiated. INR levels should be monitored closely until therapeutic levels are achieved and stabilized, and periodically thereafter. Any dosage changes should be closely monitored with repeat labs. If a patient has a complicated dosing schedule, poor compliance with medical directions or inadequate social support, the Physician may want more frequent

follow-up and blood tests to monitor for evidence of medication errors by the patient. Follow-up orders and lab results should be clearly documented in the patient chart. Consider this situation where anti-coagulation was haphazardly monitored:

A female patient was admitted to a local hospital by her family practice Physician for an acute DVT and was treated with heparin anti-coagulation. During the course of her hospitalization, PTT levels **were** ordered but not routinely monitored for a period of two days. In addition, when PTT levels were monitored and determined to be dangerously high, nursing staff failed to recognize and timely report these levels to the attending as authorized under the hospital's own heparin protocol. As a result, the patient suffered a retroperitoneal bleed causing renal failure and compartment syndrome. The ensuing lawsuit alleged a failure on the part of the Physician to discontinue the patient's heparin therapy in response to the elevated PTT levels and to recognize her deteriorating condition.

Patient Communication:

Communications with the patient who is a candidate for, or is receiving, anti-coagulation therapy should extend beyond obtaining informed consent to educating the patient and encouraging the patient to play an active role in his or her own health care. The patient should be instructed not just of the risks of taking the medication as prescribed, but also of the risks associated with not complying with the medical instructions, dosage schedule or dosage amounts, including taking too much or taking too little. If pharmacological anti-coagulants are being used, the patient should be educated that the objective of the medication schedule is to achieve and maintain a therapeutic level of the medication, and that frequent blood tests are needed to monitor those levels to ensure that the risks of both stroke and bleeding events are minimized.

Since pharmacological anti-coagulants such as warfarin often have a specific dosing schedule, with both amounts and times specified, the patient should be given straightforward written instructions for their medication, including, if applicable, when to stop taking the medication. Any changes in the dosage or schedule should be accompanied by a new set of instructions for the patient. Copies of the instructions provided to the patient should be kept in the file. The patient should also be instructed to check her instructions against the medication provided by the pharmacist, to make sure the dosage amounts match.

Provider Communication:

A primary care provider whose patient is receiving anti-coagulant therapy should maintain a heightened level of communication with other health care providers. When referring such a patient for surgery or an interventional procedure, the primary care provider should not assume that the other provider is aware of and/or will address the patient's anti-coagulation needs. Any referral should be accompanied with a letter or note that specifies what anti-coagulation therapy the patient is receiving, the reason for the therapy, and the primary care provider's recommendations for halting the anti-coagulation therapy during the procedure, alternative therapies, or bridge therapies, if applicable. The primary care provider should make sure that it is clearly understood which Physician is making the medication orders, communicating instructions to the patient, and providing monitoring. The primary care provider should also follow-up with the specialist or surgeon after the procedure and reassess the status of the patient's anti-coagulation therapy.

A surgeon or specialist (consulting Physician) who is treating a patient who is known to be receiving anti-coagulation therapy should also take steps to communicate with the patient's referring Physician and/or primary care provider. The patient's medication regimen should be confirmed with the prescribing Physician, and any plans to halt the medication for the procedure or to provide bridge therapy should be discussed. The consulting Physician should clarify with the referring Physician who is taking responsibility for directing the patient on when to stop/start the medication changes and for monitoring the patient. The consulting Physician should provide the referring Physician with copies of the medication instructions given to the patient. Any surgeon who refers a patient for medical clearance before surgery should ensure that the consulting Physician addresses the patient's anti-coagulation regimen. If the consult report is silent on the issue, or

CME Test Questions

Instructions for CME Participation

CME Accreditation Statement – MEDICAL MUTUAL Liability Insurance Society of Maryland, which is affiliated with Professionals Advocate® Insurance Company, is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for Physicians.

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Instructions – to receive credit, please follow these steps:

1. Read the articles contained in the newsletter and then answer the test questions.
2. Mail or fax your completed answers for grading:

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3. One of our goals is to assess the continuing educational needs of our readers so we may enhance the educational effectiveness of the *Doctors RX*. To achieve this goal, we need your help. You must complete the CME evaluation form to receive credit.
4. Completion Deadline: August 31, 2012
5. Upon completion of the test and evaluation form, a certificate of credit will be mailed to you.

1. The standard of care for a health care provider is contained in clinical guidelines published by his or her professional association.

   A. True B. False

2. When should a hospitalized patient be assessed for risk of developing thromboembolic disease?

   A. Upon admission
   B. When an invasive procedure or surgery is cancelled or rescheduled
   C. When the patient's clinical condition changes
   D. At regular intervals throughout the hospital admission
   E. All of the above

3. Which of the following is a risk factor for development of thromboembolic disease?

   A. Mobility significantly reduced for more than three days
   B. Patient is in critical care
   C. Hormone replacement therapy
   D. Patient is obese
   E. All of the above

4. Which of the following is NOT a contra-indication to pharmacological anti-coagulation therapies?

   A. Acute liver failure
   B. Hemophilia
   C. Patient has uncontrolled systolic hypertension
   D. Obesity

5. Patients undergoing elective knee arthroplasty who are not at elevated risk of thrombosis do not need prophylactic anti-coagulation therapy.

   A. True B. False

6. A patient undergoing a screening endoscopic procedure can remain on anti-coagulant therapy in some circumstances.

   A. True B. False

7. How many deaths each year are attributed to pulmonary embolism?

   A. 20,000
   B. 200,000
   C. 2,000,000

8. The American College of Physicians recommends the use of graduated compression stockings to prevent VTE in non-surgical hospitalized patients.

   A. True B. False

9. Patients should be encouraged to mobilize after orthopaedic surgery to decrease the risk of blood clot formation.

   A. True B. False

10. Complications associated with venous thromboembolic disease include deep vein thrombosis, stroke, pulmonary embolism, and postphlebitic syndrome.

    A. True B. False

CME Evaluation Form

Statement of Educational Purpose

Doctors RX is a newsletter sent twice each year to the insured Physicians of MEDICAL MUTUAL/Professionals Advocate.® Its mission and educational purpose is to identify current health care related risk management issues and provide Physicians with educational information that will enable them to reduce their malpractice liability risk.

Readers of the newsletter should be able to obtain the following educational objectives:
1) Gain information on topics of particular importance to them as Physicians,
2) Assess the newsletter's value to them as practicing Physicians, and
3) Assess how this information may influence their own practices.

CME Objectives for "Anti-Coagulation Therapies: A Review of Best Practices for Managing Risk"

Educational Objectives: As a result of participating in this enduring material, participants should be better able to:
1) Implement proper documentation and monitoring of patients receiving anti-coagulation therapy
2) Understand the importance of communication with patients and other health care providers when administering anti-coagulation therapy
3) Identify best practices and the importance of obtaining informed consent when administering or changing these therapies

	Strongly Agree				**Strongly Disagree**
Part 1. Educational Value:	5	4	3	2	1
I learned something new that was important.	❑	❑	❑	❑	❑
I verified some important information.	❑	❑	❑	❑	❑
I plan to seek more information on this topic.	❑	❑	❑	❑	❑
This information is likely to have an impact on my practice.	❑	❑	❑	❑	❑

Part 2. Commitment to Change: What change(s) (if any) do you plan to make in your practice as a result of reading this newsletter?

_____

_____

_____

Part 3. Statement of Completion: I attest to having completed the CME activity.

Signature: _____ Date: _____

Part 4. Identify Information: Please PRINT legibly or type the following:

Name: _____ Telephone Number: _____

Address: _____

_____

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does not provide clear recommendations regarding changes to the anti-coagulation therapy for purposes of the surgical procedure, the surgeon should contact the consulting Physician for clarification.

All of the communications between these various health care providers should be clearly documented in the patient's chart by both the primary care provider/referring Physician and the specialist, surgeon, or consulting Physician. No primary care Physician should assume that the specialist or surgeon is addressing and/or altering the patient's anti-coagulation therapy to accommodate their procedure, and vice versa.

In a Nutshell

As our population ages and the obesity epidemic, with all its attendant medical complications, rages on, the patient population at risk for the development of thromboembolic disease continues to grow. Continued research and frequent reviews of the literature by medical professionals is constantly refining and improving the techniques available for preventing the development of thromboembolic disease and treating it when it does arise. The effectiveness of these techniques, however, continues to depend upon the medical practitioner's diligence in assessing patient risk, employing appropriate techniques to mitigate that risk, and avoiding complications associated with those therapies by consistently monitoring the patient's condition through blood tests, through patient education, and by enlisting the assistance of the patient's other health care providers with consistent communication.

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v. *The National Institute for Health and Clinical Excellence ("NICE"), Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital, CG92.*

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vii. *Management of antithrombotic agents for endoscopic procedures, Gastrointestinal Endoscopy, Sept. 2009, Vol. 70, No. 6, at 1060.*

viii. *Antithrombotic and Thrombolytic Therapy, American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition), Chest, June 2008, Vol. 133, No. 6.*

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A Note on Anti-Coagulant Alternative Medications

There are other drugs on the market that are being utilized as alternative medications to warfarin under certain circumstances. Unlike warfarin and other similar anti-coagulants, **Dabigatran** (Pradaxa®) does not require frequent blood tests for international normalized ratio (INR) monitoring. The downside is that there is no specific way to reverse the anti-coagulant effect in the event of a major bleeding event. In December 2011, the Food and Drug Administration (FDA) published a safety announcement regarding the drug Pradaxa® and is in the process of determining whether the post-marketing reports of serious bleeding in patients taking Pradaxa® are occurring more commonly than would be expected. The FDA believes that for the time being, the benefits of Pradaxa® continue to exceed the potential risks when the drug is used appropriately.

As with all anti-coagulant therapy, the key to avoiding unintended consequences is ***communication*** with the patient and with other treating Physicians.

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