

ANTICOAGULATION FORUM

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President's Column

David Garcia, MD

I am pleased to announce that the AC Forum Board of Directors has written a guidelines paper titled **Delivery of Optimized Anticoagulant Therapy: A Consensus Statement from the Anticoagulation Forum** which will be published shortly in *The Annals of Pharmacotherapy*. The manuscript is written for healthcare providers at the "point of delivery" and outlines operational practices designed to optimize anticoagulation therapy. We have covered topics such as the principles of patient selection, provider education and training, interruption of treatment for invasive procedures, and follow-up protocols. Whether a patient is managed in a solo practice or a specialized AMS, the AC Forum advocates that a systematic approach to key elements of care will reduce the likelihood of adverse events. We will let you know the publication date as soon as it is announced.

The Board of Directors also met for a strategic planning meeting to create a long-term plan for the Anticoagulation Forum. We used the membership survey as a basis for many of our discussions, and we found your comments very helpful. After the guidelines paper, our next major effort will be a complete renovation of our website. Please contact Elizabeth Goldstein (egoldstein@acforum.org) if you have suggestions about how the website could be more helpful or are interested in helping us add new content. We are looking for help from our membership for this project.

As we have mentioned in our past few newsletters, CMS has expanded its coverage of home PT/INR monitoring. In this newsletter, Paul Radensky, an expert in this field, has written an article that explains in detail what this means for your practice and specifically what is reimbursed by Medicare. We hope that you will find his article helpful as you determine which of your patients might benefit from self-testing.

We are close to finalizing the program agenda for the 10th National Conference on Anticoagulant Therapy. Again, we used the membership survey to understand the issues that are important to you and I believe that we are putting together an excellent program. Please stay tuned and plan to join us May 7-9, 2009 in San Diego, California. ■

Medicare Expands Coverage for Home PT/INR Monitoring

Paul Radensky

McDermott Will & Emery LLP

On March 19, 2008, the Centers for Medicare & Medicaid Services (CMS) announced that it will significantly expand coverage for home monitoring of prothrombin time (PT/INR) for Medicare beneficiaries to include patients with chronic atrial fibrillation and venous thromboembolism. Since 2002, Medicare has covered home PT/INR monitoring solely for patients with mechanical heart valves. The expanded coverage will now include Medicare beneficiaries meeting the following conditions:

- The beneficiary requires chronic oral anticoagulation with warfarin for a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism;
- The beneficiary has been anticoagulated for at least three months prior to use of the home INR device;
- The beneficiary has undergone a face-to-face educational program on anticoagulation management and demonstrated the correct use of the device prior to its use in the home; and
- The beneficiary continues to use the device correctly in the context of the management of the anticoagulation therapy following initiation of home monitoring; and
- Home-testing with the device occurs no more frequently than once a week.

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Anticoagulation
FORUM

*Lori Preston, MBA
NATT Vice President*

NATT is making great strides as a patient advocacy organization whose mission is to advance public health awareness about blood clots and promote better diagnosis and treatment. Our most current “NATT Updates” include:

- The first NATT chapter (NATT-MN) is in place and operational. NATT Minnesota Chapter Director, Cindy Arnold, is planning events in concert with its Board to fund raise with a “Sock Hop” to raise awareness about the risk of clotting. There is also an “Amazing Race” scheduled to highlight conditions that place certain populations at increased risk for blood clots. A NATT Stop the Clot™ Forum is on the horizon in Minneapolis, set for October 4, 2008.
- A 2nd NATT chapter is presently forming in North Carolina. The energy to develop the NATT-NC Chapter came out of the March 1st, 2008, N.C. Stop the Clot™ Forum executed by Dr. Stephan Moll, Chair of the NATT Medical and Scientific Advisory Board (MASAB). Phil Davis, Chapel Hill, is taking the lead “on the ground” to help define the direction of the North Carolina group. Board member selection is slated to take place on June 12th.
- A Stop the Clot™ Forum is scheduled for Baltimore, Maryland on October 18th, 2008. NATT’s Board members Lori Preston and Stephanie Davis are the coordinators.
- NATT’s MASAB will meet June 19th, 2008, for a whole day of discussions of future MASAB activities, ranging from the creation of “How We Treat...” documents to “VTE risk assessment tools.” Dr. Jack Ansell will take over the leadership of the MASAB in September, 2008. Dr. Moll will assume a new role as NATT’s Medical Director.
- NATT has a new web address – www.stoptheclot.org. The previous web address – www.nattinfo.org – also remains operational.
- NATT upgraded its website in March, 2008, to include search engine optimization enhancement. Further upgrades are in the makings. There are plans to hire a Web Copywriter to give a “voice” to the website and to reinforce NATT’s primary Stop the Clot™ message.
- NATT continues to advocate for facilitation and expansion of INR self-testing, since there is now a firmer platform to promote self-management, given the recent change in CMS guidelines. While this is an important step in the right direction, many obstacles need to be surmounted, including suitable health care provider service reimbursement for patient oversight.
- NATT advocated actively in support of Congressional passage of the Genetic Information Nondiscrimination Act (GINA), with direct involvement by Randy Fenninger, NATT President.

For more information about NATT, visit www.stoptheclot.org ■

Successful Anticoagulation Clinics

In our recent membership survey, we received many comments that people are looking for help with reimbursement issues, staffing models, and understanding how to set up an anticoagulation clinic. To address these questions, board member Lynn Oertel has asked a few clinics with successful business models to describe their model of care.

We will highlight a different clinic in each of the next few newsletters and we would love to highlight the wonderful things you are doing at your clinic! If you would like to submit a short write-up describing your clinic’s successes, please email it to egoldstein@acforum.org.

University of Massachusetts Memorial Hospital, Massachusetts

Pam Burgwinkle, NP

The UMass Memorial Hospital Anticoagulation Center (ACC) was established over twenty years ago. It has undergone tremendous growth and development since that time. Today it is a dynamic outpatient hospital clinic, located off site from the main campus, where anticoagulation therapy for approximately 1550 patients in central Massachusetts is managed. Our services include warfarin management, patient/family education, peri-procedural/operative bridging therapy, thrombophilia evaluation, patient/family education, and an expanding home monitoring program.

The model of service delivery is nurse-led under the direction of a cardiologist. The medical director is not on site, but is available for consults. There is one full time nurse practitioner, four full time equivalent (FTE) registered nurses, three FTE patient care assistants (PCA), and one full time office manager. The ACC works closely with the inpatient anticoagulation consult service which is pharmacist-led under the direction of the same cardiologist. The pharmacists, who are PharmD students, are available for consults and assist in the initial warfarin education of some of our patients. All patients referred to the ACC meet initially with the nurse practitioner for a history and physical, medication reconciliation, verification of anticoagulation indication, target range and length of treatment. This visit is billed using the appropriate evaluation and management code. The initial visit with the RN reviews clinic operation, warfarin specific information (nutrition, alcohol, medication interaction, safety, etc.) and allows the opportunity to sign a contract which specifies patient and ACC responsibilities. The discharge policy is also reviewed at this time.

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Case Vignette

Managing Warfarin Resistance

Lynn Oertel, RN, CACP

Ann Wittkowsky, PharmD, CACP, FASHP, FCCP

The Call

The Anticoagulation Management Service has been asked to recommend a treatment strategy for a patient who appears to have failed warfarin and is allergic to enoxaparin.

The Case

A 55 year old man with metastatic Stage IV non-small cell lung carcinoma presents with recurrent VTE while on warfarin. He has been treated with various chemotherapeutic protocols for the past 1½ years. Approximately six months ago, he developed DVT and PE, and was initially treated with enoxaparin, but developed an allergic reaction after two weeks of therapy (shortness of breath and hives, with no evidence of thrombocytopenia). Since then, he has been treated with warfarin, and has had therapeutic INRs between 2.0 and 3.0, and excellent compliance. He is an active man working full

time; married with 3 children and denies a family history of thrombosis or known cancers.

The Problem

How should this patient be treated both acutely and chronically?

The Resolution

This patient has failed warfarin therapy. He needs an alternative for acute management of DVT, and for long-term prevention. Given his allergic reaction to enoxaparin, he is likely to also be allergic to heparin, and may not tolerate another LMWH.

Fondaparinux may be a reasonable option for both acute and chronic management. Given its synthetic derivation, allergic cross-reactivity is unlikely, although he should be educated and monitored for allergic response. Dosing is based on body weight (5mg SQ qd for < 50k; 7.5mg SQ qd for 50-100k; 10mg SQ qd for > 100k), and platelet count does not need to be monitored as fondaparinux is not associated with heparin-induced thrombocytopenia. ■

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Medicare Expands Coverage

The expansion in coverage was based upon Medicare's review of clinical studies published since 2000 showing that, in patients requiring chronic warfarin therapy for indications other than mechanical heart valves, home PT/INR monitoring can improve time in therapeutic range, reduce thromboembolic events and reduce bleeding events. The studies reviewed by CMS included 8 randomized controlled trials, one prospective cohort study and one retrospective case series. Three studies involved patient self-testing; 7 studies involved patient self-management. Based upon its review of these studies, CMS concluded: (1) time in therapeutic range with home PT/INR monitoring is at least equivalent to testing by the laboratory or in physician office setting and (2) 2 studies showed a reduction in event rates with home PT/INR monitoring.

In expanding coverage to include patients with chronic atrial fibrillation and venous thromboembolism, CMS is continuing the direction it took in 2002 in limiting coverage for home PT/INR monitoring based upon the underlying indication for chronic warfarin therapy. Although many stakeholders commented that CMS should expand coverage to include appropriate patients on chronic warfarin therapy without regard for the underlying indication for

warfarin, CMS declined to do so. CMS concluded: "While there are other indications for long-term anticoagulation and the potential to use home monitoring for these indications, the body of evidence to support home PT/INR testing for these indications is not currently as robust as that for mechanical heart valve, atrial fibrillation and venous thromboembolism." Unlike the 2002 coverage policy where home monitoring remained not covered for patients without mechanical heart valves, with the expansion in coverage to include chronic atrial fibrillation and venous thromboembolism, CMS is leaving to local carrier discretion the decision to cover patients with other underlying indications for warfarin.

In the new coverage policy, CMS indicates that the demonstration and training service must be performed face-to-face. CMS notes that the studies of self-management included face-to-face training. CMS explains clinical evidence indicates that face-to-face training can improve clinical outcomes. CMS will leave to the discretion of local contractors to determine what documentation will be required to support coverage as well as making determinations on a case-by-case basis as to when caregivers may assist beneficiaries performing home PT/INR monitoring.

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Medicare Expands Coverage

CMS has not yet issued revised instructions on the expanded coverage policy. Implementation of the new policy is expected to begin either in July or October of this year. I anticipate that coverage for the expanded indications will be available for patients meeting the requirements for home PT/INR monitoring as of the date of the Final Decision Memorandum that announced CMS's decision to expand coverage—i.e., March 19, 2008, but the implementation instructions will establish the effective date for coverage.

The expanded coverage policy will not change the payment policy for home PT/INR monitoring. When CMS implemented coverage for home PT/INR monitoring in 2002, CMS decided to cover this benefit as a diagnostic service rather than as durable medical equipment. The testing service is billed and paid under the following 3 codes:

Code	Descriptor
G0248	Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient ability to perform testing.
G0249	Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.
G0250	Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service)

I assume that the descriptors of these codes will change to reflect the expansion in coverage to patients with chronic atrial fibrillation and venous thromboembolism, but I shall need to see the implementing instruction to know for certain how the descriptors will change.

The payment rates for these codes should not be affected by the expansion in coverage. The 2008 national, unadjusted payment rates for these codes under the Medicare Physician Fee Schedule are:

Code	2008 Payment
G0248	\$191.20
G0249	\$140.54
G0250	\$9.08

Anticoagulation clinics that bill Medicare as physician offices may furnish and bill all of these services. In addition, home PT/INR monitoring may also be furnished by hospital outpatient clinics. The 2008 national, unadjusted payment rates under the Hospital Outpatient Prospective Payment System is \$105.76 for both the

demonstration and training service (G0248) and the ongoing monitoring service (G0249). In the hospital outpatient setting, only the physician may bill for the review, interpretation and management service (G0250).

Conclusion. The expansion in Medicare coverage for home PT/INR monitoring will provide access to this diagnostic service to nearly all patients on chronic warfarin therapy who wish to monitor themselves at home. It should be easier for anticoagulation clinics who may have considered this service to begin offering it now that a larger proportion of the clinic population will fit under Medicare's coverage policy.

Disclosure: Paul Radensky is counsel to the Prothrombin-time Self-Testing Coalition comprising HemoSense Inc. (an Inverness Medical Innovations Company), International Technidyne Corporation (a wholly-owned subsidiary of Thoratec Corporation), and Roche Diagnostics Corporation, manufacturers of devices used for home PT/INR monitoring. ■

NCBAP Update

The first Certified Anticoagulation Care Provider (CACP) exam of 2008 was held April 19, 2008 in Albuquerque, NM. Twenty healthcare providers from fourteen different states sat for the exam. The results of the exam will be available soon, and new CACPs will be announced in the next AC Forum newsletter.

Three additional exams have been scheduled for 2008. The next exam will be July 26, 2008 in Evansville, IN. Additional 2008 exam dates include Oct. 10, 2008 in Franklin, TN in conjunction with the SECAPS meeting; and December, 2008 in Orlando, FL in conjunction with the ASHP Mid-Year Meeting. Of course, we will also offer an exam at the AC Forum conference on May 7, 2009 in San Diego, CA. Please note that you are not required to attend these meetings in order to sit for the CACP exam. Applications, instructions, and additional details are available on the NCBAP website at www.ncbap.org.

If you were certified between January 1, 2003 and December 31, 2003, your CACP credential expires this year. You should make arrangements to recertify prior to December 31, 2008 either online or at one of the physical exam locations. Online exam dates and additional details are available on the NCBAP website (www.ncbap.org). If you were certified on or before December 31, 2002 and have not renewed your certification, you are now past due and should contact Marie Walker at info@ncbap.org to make arrangements for recertification. ■

Save the Date!

The 10th National Conference on Anticoagulant Therapy will be held May 7-9, 2009 in San Diego, California. Our conference will feature world renowned expert speakers, small group discussions, original research poster session, exhibitors, opportunities to network with colleagues, and much more. Please save the date and plan to join us in sunny California next year.

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National Quality Forum Endorses VTE Hospital Performance Measures (5/15/2008)

1. VTE prophylaxis
2. Intensive Care Unit (ICU) VTE Prophylaxis
3. VTE Patients with Anticoagulation Overlap Therapy
4. VTE Patients Unfractionated Heparin (UFH) Dosages/
Platelet Count Monitoring by Protocol (or Nomogram)
5. VTE Discharge Instructions
6. Incidence of Potentially Preventable VTE

NQF is a voluntary consensus standard-setting organization. For more information on these measures and areas related to hospital care, please access the NQF website:

<http://www.qualityforum.org/news/releases/051508-endorsed-measures.asp>

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Oversulfated Chondroitin Sulfate is a Contaminant in Heparin Associated Adverse Clinical Events

Marco Guerrini, Daniela Beccati, Zachary Shriver, Annamaria Naggi, Karthik Viswanathan, Antonella Bisio, Ishan Capila, Jonathan C Lansing, Sara Guglieri, Blair Fraser, Ali Al-Hakim, Nur Sibel Gunay, Zhenqing Zhang, Luke Robinson, Lucinda Buhse, Mobebe Nasr, Janet Woodcock, Robert Langer, Ganesh Venkataraman, Robert J Linhardt, Benito Casu, Giangiacomo Torri & Ram Sasisekharan

Warnings issued by the United States Food and Drug Administration (FDA) and similar governmental agencies in Europe concerning heparin-associated adverse events, including death, prompted in-depth analyses of contaminated lots using orthogonal high-resolution techniques. The contaminant was found to

contain a disaccharide repeat unit of glucuronic acid linked to acetylgalactosamine. In addition, the disaccharide contained an unusual sulfation pattern preventing its detection by traditional screening methods.

Nature Biotechnology 2008; published online 23 April 2008

Bypass Grafting and Risk of Death

Sebastian Schneeweiss, M.D., Sc.D., John D. Seeger, Pharm.D., Dr.P.H., Joan Landon, M.P.H., and Alexander M. Walker, M.D., Dr.P.H.

Fibrinolytic inhibitors have been widely used in patients undergoing elective coronary artery interventions. Two forms of such therapy generally exist; pharmacological inhibitors (typified by amino-caproic acid [EACA] and tranexamic acid) and animal-derived inhibitors (aprotinin). Over the last year significant concerns have arisen over the safety of aprotinin; as a result, widespread use of the product was curtailed and it is no longer marketed in the United States.

In this study which used data from a large administrative database, patients who received aprotinin were significantly more likely to die than patients who received EACA (4.5% vs 2.5%, adjusted relative risk 1.78). This effect persisted in several models which adjusted for potential confounders.

Data derived from administrative databases should be regarded with caution as there is the possibility that unmeasured biases accounted for the difference in death rates observed in this study. Such biases can only be overcome by a randomized trial with blinded allocation; however, it is unlikely that a randomized study with sufficient power will be performed. As a result, this study (and related systematic reviews) will provide our "best" evidence as to the risk of death in matched patients who receive aprotinin or EACA; its results suggest that aprotinin should be avoided in such patients given the observation of an increased risk of death.

NEJM 2008;358(8):771-783

Clinical Practice Algorithms: Medication Management to Reduce Fall Risk in the Elderly-Anticoagulants, Anticonvulsants, Anticholinergics/Bladder Relaxants, and Antipsychotics.

Bulat T, Castle S, Rutledge M, Quigley P.

This article is the last of a 4-part series of medication algorithms constructed with the intent to optimize patient care. A clinical practice algorithm designed to assess and reduce fall risk among patients who take anticoagulants is presented. The authors acknowledge that there is limited clinical evidence related to fall risk including lack of a standardized definition. Data on falls were primarily drawn from atrial fibrillation studies. The authors

suggest “greater than weekly falls” as a marker for patients whose risk of bleeding may potentially outweigh the benefit of anticoagulant treatment. Additional risk is conveyed if the patient also uses NSAIDs or ETOH, has a history of GI bleeding or is non-compliant. More research on safety assessment and interventions to reduce risk are needed. ■

J Amer Acad of NPs 2008; 20(4):181:190.

Early Risk of Stroke after Transient Ischemic Attack: A Systematic Review and Meta-analysis

Caren M. Wu, MD, MS; Kevin McLaughlin, MB, ChB, PhD; Diane L. Lorenzetti, MLS; Michael D. Hill, MD, MS; Braden J. Manns, MD, MS; William A. Ghali, MD, MPH

This meta-analysis confirms that TIA is a significant risk factor for subsequent stroke. Among studies that evaluated subsequent stroke using face-to-face patient encounters with medical or nursing staff 3 months after TIA, the early risk of stroke was 9.9%, 13.4%, and 17.3% at 2, 30, and 90 days, respectively.

Anticoagulation practitioners should provide thorough and con-

tinuous education about the signs and symptoms of TIA to patients with atrial fibrillation, and should reassess these symptoms at all clinic visits, whether by phone or in person and regardless of INR result. Patients should receive prompt medical attention if TIA symptoms occur, and may need triage from anticoagulation practitioners. ■

Arch Intern Med. 2007;167(22):2417-2422.

Comparison of idraparinux with vitamin K antagonists for prevention of thromboembolism in patients with atrial fibrillation: a randomized, open-label, non-inferiority trial.

The Amadeus Investigators.

The Amadeus trial was a multicenter, open-label, noninferiority trial that randomized 4,576 patients with atrial fibrillation to either idraparinux, a synthetic pentasaccharide Factor Xa inhibitor, or a vitamin K antagonist (warfarin or acenocoumarol). The long half-life of idraparinux allowed for once weekly subcutaneous injection. The trial was stopped early due to excessive bleeding in the idraparinux arm. Elderly individuals and those with renal impairment were at highest risk.

Major bleeding:	3.9 vs 1.4 (idraparinux vs VKA)
Intracranial hemorrhage:	1.1 vs 0.4 (idraparinux vs VKA)
Stroke/systemic embolus:	0.9 vs 1.3 (idraparinux vs VKA)
Venous thromboembolism:	0.1 vs 0.2 (idraparinux vs VKA)

Because of the demonstrated efficacy compared to VKA, a biotinylated form of idraparinux with reduced hemorrhagic risk is in development. ■

Lancet p2008; 371: 315-21

SPECIAL NOTE

As reported by the New York Times News Service on Friday, June 06, 2008 by Jeremy Pearce-Noted hematologist Dr. Oscar Ratnoff of Case Western Reserve University died at age 91. He is credited, along with colleague Earl W. Davie, with discovery of the complex series of steps involved in the coagulation pathway. Please refer to the article written by Jeremy Pearce for more information.

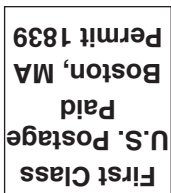
Successful Anticoagulation Clinics

Each subsequent visit to the ACC is with the RN who after receiving the point-of-care (POC) INR from the PCA, assesses the patient and the results and determines the warfarin dose and return visit date based upon a protocol. The nurse practitioner is on site for orders required off protocol or vitamin K administration. We have an electronic medical record and use DoseResponse™ software to track our patients which allows us to see four to five patients every fifteen minutes. Each RN visit (including the initial teaching) is billed using the 99211 code. This code is to be used for outpatient visits that may not require the physical presence of the physician. Typically the visit takes a minimum of five minutes to complete and this includes the POC testing. There is an electronic assessment page completed with each clinic visit which provides guidance to the nursing decision as well as documentation of the decision process.

One of the fastest growing areas is our Home Monitoring Program. Currently, we have 100 patients participating in patient self testing

(PST). Since 2002, Medicare has provided coverage for patients with mechanical heart valves. This is the majority of our patients in the program. However, Massachusetts based insurers Tufts and Harvard Pilgrim will cover (PST) for any anticoagulation indication. Once this was announced, our program began to include other diagnosis. Our patients obtain the monitor from a service company once we submit an application and insurance approves the coverage. We bill G0248 for the initial teaching and demonstration by the patient on how to operate the home monitor. The G0248 is a one time billable fee. We also bill G0250 for the monthly interpretation fee of four results.

Clinic success is measured by the Press Ganey patient satisfaction scores which have been consistently above 90% and time in therapeutic range which was 83.3% for all indications in 2007. Time in therapeutic range was calculated with INR's 0.2 above and below target range. ■



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