Anticoagulation Management
Clinical Approach

June 2017

Presbyterian provides anticoagulation therapy for the treatment and prevention of thromboembolism (blood clots) using evidence-based practices that are coordinated by multidisciplinary care teams.

**Essentials**

- In hospital, the treatment and prevention of blood clots is managed by the attending physician or the proceduralist, guided by evidence-based protocols. Physicians can and often do delegate the anticoagulation management to pharmacists.
- Outpatient anticoagulation therapy is managed by care teams, in which Pharmacist Clinicians have prescriptive authority and Nurse Care Managers conduct patient testing and monitoring.
- Anticoagulation therapy with warfarin is complex; it requires frequent blood testing and dosage adjustments.
- DOACs are new oral anticoagulants that offer more therapy options to patients with specific clinical indications.

**PHS Success and Impact**

In January 2017, more than 4,000 Presbyterian patients received anticoagulation services.

Presbyterian has been designated as an “Anticoagulation Center of Excellence” by the Anticoagulation FORUM since December 2014. PHS was the first organization to be designated for a combined inpatient/outpatient program. This designation was renewed in December, 2016.

**What we know about Anticoagulation Therapy**

Thromboembolism is a potentially deadly medical condition. Deep vein thrombosis (DVT) — the formation of a blood clot in a deep vein — and pulmonary embolism (PE) — a blood clot that travels to the lungs — together are known as venous thromboembolism (VTE). VTE claims more than 100,000 lives a year in the United States. Up to 60 percent of VTE cases occur during or after hospitalization; hospital associated VTE is a serious patient safety issue. Guidelines for using anticoagulants for treatment and prophylaxis of thromboembolism are well developed.

Individuals who may need anticoagulation services are patients who:

- present with a blood clot and require acute treatment;
- are diagnosed with atrial fibrillation (AF) and require long-term anticoagulant therapy;
- are hospitalized and run a higher than normal risk of blood clot, requiring venous thromboembolism (VTE) prophylaxis;
• have genetic deficiencies in clotting and have need for permanent or long term anticoagulation; or
• have unique or specific conditions that require anticoagulation.

Anticoagulants
Anticoagulants are widely used to potentially prevent, and to treat VTE. They are administered via intravenous infusion (e.g., heparin, bivalirudin), injection (heparin, enoxaparin, etc.), or orally (warfarin, apixaban, etc.). Most of these medications involve complex dosing, monitoring, and require excellent patient adherence in outpatient settings.

Warfarin
Millions of patients in the United States use warfarin (Coumadin®) to potentially prevent strokes or to potentially prevent or treat VTE. Warfarin, a vitamin K antagonist (VKA), is highly effective, and has been in clinical use for over 50 years. However, warfarin is difficult to manage because it has many possible interactions with diet, other drugs, and comorbid conditions that may destabilize anticoagulation control. Control is maintained by performing frequent blood tests to monitor the effect of warfarin and adjusting the dosage accordingly. A patient may require blood testing as much as once per day until an anticoagulation level within therapeutic range is achieved. An ideal level of anticoagulation maximizes benefit (i.e., to protect the patient from blood clots) while minimizing risk (i.e., bleeding, attributable to excessive anticoagulation).

Anticoagulation Clinics
Health care facilities have established outpatient anticoagulation clinics to:

• Monitor patients taking warfarin through INR testing
• Adjust warfarin dosage as needed, so that INR stays within target range
• Monitor patients taking direct oral anticoagulants (DOACs)
• Provide blood tests, dose adjustments, prescriptions, and consults in one location, during one appointment
• Develop protocols that provide evidence-based guidelines for the long-term management of anticoagulation therapy and define the roles and duties of the team of clinicians who manage anticoagulation therapy
• Develop and maintain anti-coagulation resources for patient education

DOACs
Since 2010, a new class of drugs, the direct oral anticoagulants (DOAC), has come to the U.S. market. These are dabigatran, rivaroxaban, apixaban, and edoxaban. One or more of the DOACs has been approved for three main indications:

• Prevention of stroke and systemic embolism in patients with non-valvular AF
• Acute and extended treatment of VTE
• Prevention of VTE after total knee or hip replacement surgery
There are some very important pharmacologic differences between DOACs and warfarin. Since DOACs rely, to varying degrees, on elimination by the kidneys, a patient’s renal function may be a contraindication to treatment or mandate a dose adjustment. Although the DOACs can interact with other medications, the number of potentially clinically significant interactions is small compared to the corresponding number with warfarin. There are no significant dietary interactions for the DOACs. Thus, DOACs do not require monitoring as stringent as that of warfarin. Unlike warfarin, the DOACs have both a rapid onset of action (2 to 3 hours) and a relatively short half-life (24 to 48 hours after the last dose). The DOACs serve as four oral alternatives to warfarin and other VKAs. Many patients for whom these medications are indicated (and for whom cost is not a barrier) may choose them over warfarin because of their advantages as stated above. The cost of DOACs can be prohibitively expensive, especially for our Pres Senior (Medicare) patients.

**Mechanical Prophylaxis**
Special mechanical strategies can also help prevent clots. During a hospital stay, a patient may be given sequential compression devices (SCDs) which squeeze the legs or feet gently, helping with blood flow and preventing clots. Likewise, a Provider may order compression stockings or thrombo embolic deterrent (TED) hose, to help the patient with blood flow.

**PHS’ Approach to Anticoagulation Therapy**
When a patient is diagnosed with VTE, they are treated at the location of their diagnosis (hospital, ED, urgent care, primary care).

When a patient is at an increased risk for thromboembolism or is discharged after VTE diagnosis and treatment, ongoing anticoagulation care is offered at the anticoagulation clinics (Coumadin clinics), which are integrated into Presbyterian Medical Group (PMG) ambulatory clinics, the patient-centered medical home (PCMH). Likewise, anticoagulation care is offered at Presbyterian’s Infusion Center for patients with insurance/access issues or to consult on complex anticoagulation cases.

**Treatment and Prophylaxis for Inpatients**
For the treatment of blood clots, the attending physician will consider risk factors and contraindications to develop the orders for a patient’s anticoagulation therapy or thrombolysis. Often times the physician will order the pharmacist to dose warfarin. This service is available enterprise-wide. Nurses administer the medication according to the orders.

VTE prophylaxis for surgical procedures (i.e., general surgery, total hip or knee replacement, valve replacement) are administered according to procedure-specific evidence-based protocols. These protocols may include both medication (anticoagulant) and mechanical interventions. Prophylaxis may begin pre-procedurally and/or continue post-procedurally in the outpatient anticoagulation clinic. Medical patients may require VTE prophylaxis and are treated with similar, evidence-based protocols.

**Inpatient Care Coordination**
Care coordination for the patient requiring long-term anticoagulation therapy is managed by the Case Manager (RNCM) and/or Social Worker. Discharge planning begins immediately after admission, according to defined care...
The Case Manager or Social Worker identifies the plan for anticoagulation therapy, including the patient’s Primary Care Provider, INR testing site, and any need for medication assistance. Prior to discharge, the Case Manager or Social Worker identifies any Home Health needs, verifies prescription and follow-up appointment, hands off the anticoagulation therapy plan to the Primary Care Provider, and educates the patient about their anticoagulation plan.

**Anticoagulation Clinics**

Most outpatient anticoagulation management services are provided at the PMG anticoagulation clinics. There are 18 ambulatory anticoagulation clinics in Albuquerque, Rio Rancho, Bernalillo, Santa Fe, Espanola, Los Lunas, and Belen, offering Anticoagulation Services. These include three Presbyterian Heart Group (PHG) Coumadin clinics.

Individualized monitoring, dosage adjustments, and education are provided by a care team comprised of a Pharmacist Clinician (PhC), a nurse care manager (RNCM; an RN with advanced training in anticoagulation), and the primary care provider (PCP), according to evidence-based, enterprise-wide protocols. The Anticoagulation Clinic Protocol outlines roles and responsibilities of the care team including prescriptive authority, formulary, administration methods, and procedures for intake, assessment, laboratory testing, dose adjustment, documentation, and communication.

In the State of New Mexico, Pharmacist Clinicians have prescriptive authority; they can independently prescribe any medication used in the scope of a primary care visit, as well as manage a spectrum of common chronic disease states, including anticoagulant therapy. Based on the Provider’s diagnosis, the PhC initiates orders for anticoagulant medication, authorizes refills, adjusts dosages, and discontinues therapy, as clinically indicated.

In each anticoagulation clinic, the PhC is co-located with the RNCM, allowing for immediate communication. The RNCM or the PhC manages patient intake, evaluation (including INR testing), and education. The RNCM can make recommendations regarding dose adjustments or queue-up medication refills, as clinically indicated. The RNCM provides first-hand monitoring during each of the patient’s anticoagulation clinic visits.

The patient’s Primary Care Provider (PCP), Cardiologist, or Specialist makes the diagnosis and initial referral for anticoagulation services and provides oversight to the PhC and RNCM. The referring Provider becomes actively involved in the clinical decision making in specific situations — when anticoagulation therapy may seem more of a risk than a benefit; when INR values are significantly outside the therapeutic range; when the therapy is at its conclusion; or when a patient is being consistently non-compliant. Otherwise, the day-to-day maintenance of anticoagulation therapy is the responsibility of the RNCM and the PhC. More than 95% of the patients receiving warfarin therapy in the CDS have their medicine managed by the clinical pharmacist.

Patients who have had a cardiovascular-related surgery or a vascular consult may receive anticoagulation services from PMG’s Heart Group (PHG). While PHG follows anticoagulation therapy protocols similar to the rest of PMG, a cardiology provider may manage the anticoagulation therapy directly, instead of a Pharmacist Clinician; referrals are made to the RNCMs as needed (see Anticoagulation Clinic Protocol (PMG Heart Group)). Working in both the hospital and outpatient clinic, the PHG RNCMs may do the ordering and education and then

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1 Access to this link requires PHS login.
transition the patient to the PCP for long-term management. They do follow up calls to cardiac patients who have been discharged with anticoagulation therapy plans. Furthermore, the Heart Group RNCMs can manage specific protocols (i.e., bridging with Lovenox or monitoring a patient prior to a scheduled cardioversion).

**Infusion Center**

The Infusion Center, located in the Presbyterian Hospital Physician Office Building and in the PMG clinic on High Resort (Rio Rancho), manages the anticoagulation therapy of patients who require service gap coverage or who do not have a PMG Primary Care Physician on a short-term basis. The Infusion Center follows anticoagulation therapy protocols similar to the rest of PMG; the Infusion Center’s Pathologists manage first-hand the more clinically challenging patients.

**Home Health**

Presbyterian Home Healthcare provides anticoagulation (INR) testing, performed in-home by Registered Nurses and Physical Therapists who have been certified through training. They receive orders from the Provider who will be managing the patient’s dosage adjustment. Depending on the orders, the in-home clinician communicates with the attending physician (who can be the patient’s PCP, a home care physician, or another physician) or the anticoagulation clinic’s PhC or RNCM. The INR results and any orders are entered into the patient’s Homecare chart (Remote client) and sent to the attending physician for signature. If the INR result is greater than the threshold value specified in protocol, the in-home testing clinician notifies the attending physician who then makes treatment decisions.

<table>
<thead>
<tr>
<th>Care Setting</th>
<th>Number of Patients Seen in Jan 2017</th>
<th>Encounters in Jan 2017</th>
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</thead>
<tbody>
<tr>
<td>Inpatient: includes all of CDS and the regional Hospitals</td>
<td>111</td>
<td>923</td>
</tr>
<tr>
<td>Outpatient: PMG anticoagulation clinics, including Heart Group</td>
<td>3,965</td>
<td>6,004</td>
</tr>
<tr>
<td>Outpatient: Infusion Center</td>
<td>75</td>
<td>32</td>
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The figure below compares the patient volume at the PMG Coumadin clinics for January 2017. Three newer clinics (Paradise, Espanola, and Bernalillo/528) show lower volumes of patients.
Key Tools

**DAWN AC** Anticoagulation Software is used by all PHS clinics to record treatment plans, track INR data, and obtain clinical guidance regarding medication dosage adjustments. Patient data must be manually transcribed into Epic.

Clinician Training

- New RNCMs are oriented through a 4-week onboarding process in which they train by working at several anticoagulation clinic sites.
- Professional development training for anticoagulation clinic RNCMs is ongoing at monthly meetings, led by the Pharmacy Anticoagulation Specialist and an Epic Clinical Trainer; special trainings to learn new procedures are convened as needed, led by the Pharmacy Anticoagulation Specialist and the Manager of Pharmacist Clinicians and Anticoagulation Clinic Services.
- RNCMs must pass Point of Care competencies (intake, evaluation, testing, dose adjustment, and education) annually. Likewise, PhCs have annual competencies about medication management for an array of disease states including anticoagulation.
Patient Education and Shared Decision Making

For each patient, the PhC or RNCM offers one-to-one education specific to the patient’s anticoagulation therapy plan at each visit, as needed.

**Patient Education Tools:**
- Blood Clots: A Serious but Preventable Medical Condition (CDC)
- Lovenox®: How to Self-inject Guide
- Lovenox® Patient Administration Video
- Pastillas que diluyen la sangre: Guía para su uso seguro (AHRQ)
- Staying Active and Healthy: Blood Thinners (Healthcare 411 AHRQ)
- Manténgase activo y saludable con los diluyentes de la sangre (Healthcare 411 AHRQ)
- Directory of Anticoagulation Clinic RN Care Managers
- Directory of Anticoagulation Clinic Pharmacist Clinicians

Other tools, specific to the patient’s therapy plan, may be used.

**Shared Decisions**
Although shared decision making does not play a significant role in anticoagulation therapy management, patients do drive some decisions:
- Patients attend the anticoagulation clinic of their choosing.
- Patients’ values are considered in the decisions to begin or end anticoagulation therapy.
- When alternatives to warfarin are available, the PhC or referring Provider discusses these therapy options (benefits and risks) with the patient.

**Leadership**

<table>
<thead>
<tr>
<th>Process Owner</th>
<th>Robert Rangel, PharmD, PhC, BCPS - Director Pharmacist Clinician and Anticoagulation Clinic Services, PMG</th>
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</table>
| Clinical Champions | Deb Thompson, MD, MSPH, FACPM - Medical Director of Patient Safety  
Arand Pierce, MD - Medical Director, Presbyterian Infusion Center  
Linda R. Kelly, PharmD, PhC, CACP - Pharmacy Anticoagulation Specialist, Presbyterian Hospital  
Kathleen T. Wade, Pharm D, PhC, CDE - Manager Pharmacist Clinician and Anticoagulation Clinic Services, PMG  
Ranee Runnebaum, PharmD, MHI - Director of Medication Safety  
Dawn Hansen, RN - Lead Care Manager, PMG Heart Group  
Jennifer Ellis - Director, Presbyterian Infusion Center |
| Governance Bodies | Anticoagulation Subcommittee of the CDS P&T Committee |
Anticoagulation Subcommittee, of the CDS Pharmacy and Therapeutics (P&T) Committee

Membership

- **Co-Chairs:**
  - Linda R. Kelly, PharmD
  - Randle J. Adair, DO

- **Members:**
  - Debby Caraballo, PharmD
  - Josh Davis, PharmD
  - Kate English, PharmD
  - Joan Hagen, RD
  - Tuesday Horner, PharmD
  - Nancy Jordan, Pharm D
  - Andrew Kalishman, MD
  - Jennifer Kirkman, RN
  - Kurt Mahan, PharmD
  - Anne Marie Morosin, MD
  - Catherine Nicholson, RN
  - Ashley Rockymore, RN
  - Jeremy Parsons, MD
  - Arand Pierce, MD
  - Darren Shafer, MD
  - Deborah Thompson, MD
  - Kelly Townsend, MT(ASCP)SH
  - Jay Tseng, MD
  - Richard Vestal, MD
  - Benjamin Wagenman, MD

Activities

- Meets every other month, beginning in February
- Writes and approves anticoagulation policies, procedures, and guidelines
- Makes PHS formulary recommendations to the P&T Committee for approval
- Develops and/or participates in anticoagulation education/training designed for physicians, advance practice clinicians, nurses, pharmacist clinicians, pharmacists, pharmacist technicians, and dieticians
- Reviews:
  - Various drug utilization reviews and other analyses regarding anticoagulation
  - Information regarding adverse drug reactions and medication errors involving anticoagulants; reported quarterly to the subcommittee

Measures of Success

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measure</th>
<th>Aligns with Aim</th>
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<tbody>
<tr>
<td>Therapeutic INR Achieved</td>
<td>Time in Therapeutic Range (% TTR)</td>
<td>Better Health</td>
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<tr>
<td></td>
<td>o measured as a 90-day rolling average</td>
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<tr>
<td></td>
<td>o reported for each clinic site as well as across all clinics</td>
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<td></td>
<td>o goal is &gt;70%</td>
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<tr>
<td>Appointment Attended</td>
<td>Number of Patients who Did Not Attend (% DNA)</td>
<td>Better Health</td>
</tr>
<tr>
<td></td>
<td>o These patients are greater than 4 weeks late for an appointment; since they did not attend, they are non-compliant with their therapy plans</td>
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<tr>
<td></td>
<td>o Reported as an average across all clinics</td>
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<tr>
<td></td>
<td>o Goal is &lt;2.5%</td>
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Data compiled in DAWN show that patients attending PMG anticoagulation clinics consistently achieve therapeutic INRs, and they demonstrate high attendance (low non-compliance). For example, across all PMG anticoagulation clinics for January 2016, Time in Therapeutic Range (TTR) was 71.90% and the Did Not Attend (DNA) rate was only 1.4%.
Both TTR and DNA are reported monthly to anticoagulation clinicians and to the PMG physician and pharmacy scorecards.

**Future Work**

PHS will continue its work as a center of excellence by expand anticoagulation services, refining protocols based on best practices, and identifying the best software tools for collecting and analyzing data.

**Expanded Services**

- Develop a warfarin clinic for orthopedic patients, to provide short-term clot prevention associated with knee and hip replacement surgery.
  - Resulting in streamlined transitions of care for warfarin-treated post-operative orthopedic patients to avoid adverse drug reactions
  - Contact: Patrick Mulkey
- Establish an enterprise-wide guidance for the use of DOACs.
  - Resulting in a widened scope of DOAC use (beyond that of warfarin failure) to promote safe and effective use of anticoagulant medication options; increased access to a wider variety of anticoagulants for members (increased formulary)
  - Contacts: Linda Kelly, Charles Mahan, Randle Adair, Louanne Cunico or Chad Valdez
- Develop an anticoagulated patient registry and update referrals in EPIC.
  - Resulting in improved communication of the patient’s anticoagulant plan among providers; improved transition of care and follow up; fewer anticoagulant complications (bleeding and re-thrombosis) related to noncompliance with anticoagulant regimen
  - Contacts: Amanda Aragon (outpatient), Catherine Nicholson (inpatient)

**Refined Protocols**

- Refine protocols and standardize work flows around transitions of care to accommodate the special needs of anticoagulation patients. This is an EBCD initiative.
  - Resulting in fewer complications with anticoagulation attributed to transitions of care
  - Contacts: Linda Kelly, Catherine Nicholson, Juanita Venable
- Revise protocol(s) for the anticoagulation clinics.
  - Resulting in one document that defines the roles/responsibilities of the care team members across all anticoagulation clinics, including nursing protocols for new patient visits and bridging with enoxaparin
  - Contacts: Kathleen Wade, Robert Rangel, Dawn Hansen
- Revise protocols for anticoagulation bridging.
  - Resulting in alignment with new evidence based guidelines, including both direct acting oral anticoagulants (DOACs) as well as warfarin; Communication procedures for Presbyterian proceduralists (via Epic) and non-Presbyterian proceduralists (via fax/email)
  - Contacts: Kathleen Wade, Linda Kelly
**Glossary**

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
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<tr>
<td><strong>Atrial fibrillation</strong> (AFib or AF)</td>
<td>AFib is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications. About 15–20 percent of people who have strokes have this heart arrhythmia. An estimated 2.7 million Americans are living with AF.</td>
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<tr>
<td><strong>Bridging</strong></td>
<td>Bridging anticoagulation refers to the administering of a short-acting anticoagulant, like enoxaparin (Lovenox®), during a period when warfarin (Coumadin®) therapy is initiated or interrupted (and its anticoagulant effect is outside a therapeutic range). Bridging is an option when a patient requires warfarin to be stopped because of an upcoming surgery/procedure. Bridging aims to reduce the patient’s risk for developing blood clots, such as stroke, but may also increase the patient’s risk for developing potentially serious bleeding complications after surgery. Bridging involves care by the PMG anticoagulation clinic before the procedure, care by the proceduralist peri-procedurally, and then care by the anticoagulation clinic post procedure.</td>
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<tr>
<td><strong>Direct oral anticoagulants</strong> (DOACs)</td>
<td>DOACs are oral medications that inhibit a specific enzyme in the coagulation cascade. DOACs are associated with a low overall risk of major bleeding. However, as with any anticoagulant, life-threatening bleeding can occur. Bleeding is especially concerning with the DOACs because antidotes or specific reversal agents for some of the DOACs are lacking. Additionally, routine coagulation tests cannot be used to determine the degree of anticoagulation, making it more challenging to determine when the anticoagulant effect has resolved.</td>
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<tr>
<td><strong>International normalized ratio</strong> (INR)</td>
<td>This laboratory test is used to determine the degree to which the patient's coagulation has been successfully suppressed by the vitamin K antagonist (VKA). For most patients, the goal is to keep the INR between 2 and 3.</td>
</tr>
<tr>
<td><strong>Percent time in therapeutic INR range</strong> (TTR)</td>
<td>TTR is a way of summarizing INR control over time; the mean therapeutic INR range. It is a widely cited measure of the quality of warfarin therapy.</td>
</tr>
<tr>
<td><strong>Thromboembolism</strong></td>
<td>Formation in a blood vessel of a clot (thrombus) that breaks loose and is carried by the blood stream to obstruct another vessel. The clot may plug a vessel in the lungs (pulmonary embolism), brain (stroke), gastrointestinal tract, kidneys, or leg. Thromboembolism is a significant cause of morbidity and mortality, especially in adults. Treatment may involve anticoagulants, aspirin, or thrombolytics.</td>
</tr>
<tr>
<td><strong>Venous thromboembolism</strong> (VTE)</td>
<td>VTE is the formation of blood clots in the vein. When a clot forms in a deep vein, usually in the leg, it is called a deep vein thrombosis or DVT. If that clot breaks loose and travels to the lungs, it is called a pulmonary embolism or PE. Together, DVT and PE are known as VTE.</td>
</tr>
</tbody>
</table>

**References**

**Clinical Care Model**
- [Patient-Centered Medical Home (PCMH)]
- [Evidence-Based Care Design (EBCD)]
- Transition of Care for VTE Patients ([CPM under construction])
Resources: PHS login required
- Presbyterian Anticoagulation Services (on PresNet)
- Clinical Guidelines: Anticoagulation Clinic Protocol (PMG Heart Group)
- Clinical Guidelines: Anticoagulation Clinic Protocol (PMG)
- Clinical Guidelines: Anticoagulation Discharge Pathway
- Clinical Guidelines: Bridging Order Set, Post-procedure
- Clinical Guidelines: Bridging Order Set, Pre-procedure
- Clinical Guidelines: Definition for Baseline and Current INR
- Policy: Adverse Drug Reaction Monitoring and Medication Error Management PC.PDS.196
- Policy: Adult Clinical Procedure for Discontinuation of Parenteral Anticoagulant Overlap Orders
- Policy: Point of Care: Anticoagulation Testing (Home Health) PHH.EC 5-60
- Training: DOACs: Bridging, Switching, and Transitioning

Additional Resources
- acforum.org
- CHEST Antithrombotic Guidelines
- Presbyterian Anticoagulation Services
- Presbyterian Infusion Center