Implementation of an Interdisciplinary Anticoagulation Clinic within a Primary Care Center
How to Get Started & Be Successful

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Disclosure

• The presenters of this presentation have nothing to disclose.

Objectives

• Identify the key components of a successful anticoagulation clinic
  - Business plan
  - An interdisciplinary practice model
  - A collaborative practice agreement
  - Documentation
• Discuss the advantages and disadvantages of using point-of-care testing.
• Discuss how to bill for clinical services.
• Discuss the role of new anticoagulants.
• Identify resources that may be utilized in the development of an anticoagulation clinic.
Why Develop A Clinic...

- Associated with better safety, efficacy and therapeutic outcomes
  - Pharmacist-managed anticoagulation clinics associated with...
    - Lower rates of significant bleeding (8.1% vs. 35%)
    - Greater time in therapeutic range (64% vs. 51%)
- Reduced healthcare cost
  - Pharmacist-managed anticoagulation clinics associated with...
    - A cost savings of $162,058 per 100 patients annually
    - Cost savings attributed to a reduction in hospitalization (5% vs. 19%) and ER visit (6% vs. 16.8%)


Why Develop A Clinic...

- Coordinated care of anticoagulation management is endorsed by...
  - National Quality Forum
  - Agency of Healthcare Research and Quality
  - Anticoagulation Forum & American College of Chest Physicians
- Only 30-40% of patients receiving warfarin have access to such services


Background

Yale New Haven Hospital is a 966 bed teaching hospital located in New Haven, Connecticut

- Adult Primary Care Center
  - Primary teaching clinic for Yale Internal Medicine Residents
  - Interdisciplinary team approach
  - Provides care to the underserved patient population
  - Patients referred to our clinic post hospital discharge for ER follow-up or self referral
- Anticoagulation clinic
  - Founded in 1996 out of need to follow and manage patients on anticoagulation effectively
  - ~ 160 patients
How does your institution manage patients on anticoagulation therapy?

What do you think are the key components of a successful anticoagulation clinic?

Elements of a Successful clinic

- Knowledgeable provider / MD Supervision
- Coordinated and organized care
  - Business plan
  - Collaborative practice agreement (CPA)
  - Integrative Collaborative Practice Model
- Systematic monitoring and follow-up
- Rapid and reliable INR monitoring
- Patient Education
- Effective Communication
- Documentation and billing

Business Plan

- **Purpose**
  - To determine the need and impact of the anticoagulation clinic
  - To describe the purpose, function and staffing of the program

- **Key components**
  - Develop an appropriate time-line
  - Establish program goals and objectives
  - Address administrative and organizational elements of the clinic
  - Establish a financial plan
  - Establish a plan for analyzing quality improvement measures, patient outcomes, cost-effectiveness and cost-benefit of the program
Relevance and Needs Assessment

Questions to Answer...
- Who would use the service?
- How many patients would be managed by the clinic?
- Expected growth over the years?
- Patient eligibility and provider referrals
- Determination of staffing and accessibility

Benefits to Think About...
- Decreased healthcare cost
- Better patient outcomes
- Reduced length of stays (LOS)
- Standardization of care
- Decreased risk to the institution

Relevance and Needs Assessment

Quality Improvement Initiatives
- Medicare will pay more to institutions who score well on patient care quality measures and less to those that don’t hit the benchmarks
  - Agency for Health Research and Quality (AHRQ) Patient Safety Indicators (PSI) 12: Postoperative DVT and PE
- Anticoagulation programs provide cost-saving to the third party payers and provide modest improvements in control

http://www.jointcommission.org

Relevance and Needs Assessment

Joint Commission Accreditation
- 2012 Ambulatory Care National Patient Safety Goals
  - 3.05.01: Reduce the likelihood of patient harm associated with the use of anticoagulation therapy
    - Requires primary care providers to use approved protocols to initiate and manage anticoagulation therapy as well as provided patient education

http://www.jointcommission.org
Goals of Our Anticoagulation Clinic

- Provide organized, comprehensive and systematic management of all our adult primary care patients’ anticoagulation therapy through...
  - Patient education regarding their disease state and therapeutic management
  - Point-of-Care testing and dosage modifications of vitamin K antagonist (VKA) therapy
  - Peri- and post-procedural management of anticoagulation
  - Transitional care from warfarin to LMWH or novel anticoagulants with continued therapeutic management

Integrative Collaborative Practice Model

- Supervising Pharmacist
- Clinical Pharmacist(s)
- Pharmacy Residents
- Supervising Physician
- Medical Attendings
- Internal Medicine Residents
- Administrative Staff
- Dietitian
- Clinical support, triage and phone follow-up

Qualification of Personal

- Should be licensed in both a patient-oriented medical field (medicine, nursing or pharmacy) and anticoagulation therapy

- National Certification - Certified Anticoagulation Care Provider (CACP)
  - Offered by the National Certification Board for Anticoagulation Providers (NCBAP)
  - Must have 750 active patient hours 18 months prior to sitting for the national examination
  - Must hold a professional license of two years prior to sitting for the national examination
Qualification of Personal

• Several Training Programs
  – American College of Clinical Pharmacy (ACCP) Anticoagulation Training Program
  – University of Southern Indiana Anticoagulation Management Program
  – American Society of Health System Pharmacists (ASHP) Foundation Antithrombotic Pharmacotherapy Traineeship

Current U.S. Models

• Face-to-Face
  – Point-of-care testing, medication review and dosage adjustments are all done during a clinical visit
  – Duration of Appointments:
    • 30 to 45 minute initial visit for all new patients
    • 10 to 15 minute for follow up
  – Patient Educational Handout
  – Schedule Follow-up:
    • 1 to 4 weeks depending on INR

• Telemedicine
  – Lab Blood Draw Model:
    • Weekly blood draw
    • Results sent directly to provider
    • Provider calls patient with results and dosing adjustments
  – Patient Self Testing (PST) Model:
    • Point-of-care testing done at home by the patient
    • Results called into the clinic by the patient
    • Provider reviews results and makes dosage adjustments
### Financial Plan

<table>
<thead>
<tr>
<th>Cost of Daily Operations</th>
<th>Recoup or Off-set Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Clinical space</td>
<td>• Reimbursement from insurances</td>
</tr>
<tr>
<td>• Staffing</td>
<td>– Practice Model</td>
</tr>
<tr>
<td>• Point-of-Care testing</td>
<td>– Type of Health Insurance</td>
</tr>
<tr>
<td>– Administer the test</td>
<td>– E.g.: Medicare, Medicaid, private third party payers</td>
</tr>
<tr>
<td>– State-mandated Clinical Laboratory Improvement Amendments (CLIA) Certificate</td>
<td>• Overall reduction in institutional cost</td>
</tr>
<tr>
<td>• Documentation and Patient Education</td>
<td>– E.g.: Reduced LOS</td>
</tr>
<tr>
<td>– Cost of software</td>
<td></td>
</tr>
</tbody>
</table>

### Clinical Analysis

- Determine parameters to be reviewed...
  - Quality improvement measures & patient outcomes...
    - Time in therapeutic range INR (gold standard)
      - We use... % therapeutic = \( \frac{\text{# of therapeutic INRs}}{\text{total # of INR readings}} \times 100 \)
    - Adverse events and hospitalizations associated with anticoagulation (bleeding, DVT, PE, etc.)
  - Patient volume
  - Patient satisfaction
- Cost-effectiveness...
- Cost-benefit...

### Brainstorming

Fill in the sections of the Anticoagulation Clinic Business Plan ...
Developing a Collaborative Practice

- State specific legal documentation that grants pharmacist or nurses the right to administer, modify, implement or discontinue anticoagulation therapy

- Required components of a CPA are state specific and highly dependent on state pharmacy laws
  - Pharmacy laws found on any state Board of Pharmacy’s website

- In general...
  - Detailed description of what pharmacist can and cannot do
  - A therapeutic management protocol

Collaborative Practice Agreement

- Components:
  - Introduction
  - Background
  - Patient Population
  - Qualification of Personal
  - Services Provided
  - Procedures and Protocols
  - Signatures of all members of the medical team

Introduction

- The following collaborative practice agreement, between ______ and the anticoagulation medical director, describes the clinical privileges granted to ______ in compliance with ______ state law.

- Specifically, the document outlines the collaborative process and procedures necessary for outpatient anticoagulation management.

- In accordance with state law, the document is reviewed on a(n) ______ basis.
Procedures & Protocols

• All procedures and processes including roles and responsibilities of each collaborative practice team member is outlined in this section
• Services provided by clinical pharmacist:
  – Initial patient assessment and medication review
  – Confirmation or establishment of patient specific INR goals and duration of therapy
  – Patient education
  – Point of care testing / Lab Order for venous puncture INR and renal function
  – Administration, modification, initiation, and/or discontinuation of anticoagulation therapy
  – INR monitoring and follow-up

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Our Anticoagulation Protocol

<table>
<thead>
<tr>
<th>INR (Goal 2-3)</th>
<th>Current Protocol</th>
<th>Suggest updates based on 2012 CHEST Guidelines</th>
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</thead>
<tbody>
<tr>
<td>1.3 – 1.4</td>
<td>Increase weekly dose by 15%</td>
<td>If patient has a history of therapeutic INRs on current dosage, a change in dosage for one abnormal INR reading above or below target INR by 0.5 is not recommended. Instead, recheck INR in one week</td>
</tr>
<tr>
<td></td>
<td>Recheck INR in 1 week</td>
<td></td>
</tr>
<tr>
<td>1.5 – 1.7</td>
<td>Increase weekly dose by 10%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recheck INR in 1 week</td>
<td></td>
</tr>
<tr>
<td>2.0 – 3.0</td>
<td>No change</td>
<td></td>
</tr>
<tr>
<td>3.1 – 3.3</td>
<td>No adjustment, repeat INR in 2 weeks</td>
<td></td>
</tr>
<tr>
<td>3.4 – 4.9</td>
<td>Confirm INR with venipuncture if greater than 4</td>
<td>For an INR of 3.1-3.5 in a patient with a history of therapeutic INRs on current dosage, a change in dosage for one abnormal INR reading above or below target INR by 0.5 is not recommended. Instead, recheck INR in one week</td>
</tr>
<tr>
<td></td>
<td>Hold one dose and decrease weekly dose by 10%</td>
<td></td>
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<td>Confirm INR with venipuncture</td>
<td>Does not recommend the use of vitamin K in patients with an INR of 5-10 and not actively bleeding</td>
</tr>
<tr>
<td></td>
<td>Assess for bleeding</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hold 3 doses</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recheck INR in 2 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• INR &gt; 5 hold dose until INR is therapeutic, decrease by 20%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• INR 3.4 – 4.9 hold x 1 and decrease by 25%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• INR ≤ 3.3 decrease by 15%</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Repeat INR in 1 week</td>
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<td></td>
<td>Assess for bleeding</td>
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</tr>
<tr>
<td></td>
<td>Consider vitamin K 2.5mg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hold 1 dose</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Recheck INR in 1 day</td>
<td></td>
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<tr>
<td></td>
<td>• See above</td>
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Patient Case: Warfarin Dose Management

- The following patients come to the Anticoagulation Clinic for follow-up. Using the dose adjustment protocol, suggest a warfarin dose management plan:

- **Case 1A:** D.M. is a 67 y/o male on warfarin for atrial fibrillation
  - Current Dose: 5mg per day except on Sunday he takes 7.5mg
  - Tablet Strength: 5mg
  - Goal INR: 2-3
  - His INR today is 1.7 and two weeks ago, his INR was 1.6. He denies missing any doses and states that there has been no recent change to his medications and/or diet.

**Case 1A: Answer**

- According to the dosing protocol we should increase the dosage by 10% of the weekly dosage (which is 2.5 mg) and recheck the INR in one week.
  
  \[ 5 \times 6 = 30 + 7.5 \text{ mg} = 37.5 \]
  
  10% of 37.5 = 3.75 or 2.5 for ease of dosing

- According to the 2012 CHEST guidelines, a dose adjustment should not be made if the patient has one abnormal INR reading within 0.5 above or below target INR and a history of therapeutic INRs. Instead, they recommend rechecking the INR in one week.

Patient Case: Warfarin Dose Management

- **Case 1B:** T.M. is a 45 y/o male on warfarin for recurrent left lower extremity DVT
  - Usual dose: 10mg per day
  - Tablet Strength: 5mg
  - Goal INR 2-3
  - Patient has a history of noncompliance and was recently admitted for recurrent DVT. Since hospital discharge (12 days ago) he has been taking warfarin 5mg per day with an enoxaparin bridge, which was completed 5 days ago. His INR today at follow up is 1.3.
Case 1B: Answer

- According to the dosing protocol we should increase the dosage by 15% of the weekly dosage (which is 5 mg) and recheck the INR in one week.
  \[ 5 \times 7 = 35 \text{ mg} \]
  \[ 15\% \text{ of } 35 = 5.25 \text{ or } 5 \text{ mg for ease of dosing} \]
- A 15% increase in dosage is not likely to place this patient into therapeutic range, given is historical dose of 10 mg per day. However one must take into consideration the patient long-standing history of noncompliance and its likelihood of contributing to higher dosages in the past.
- Based on clinical experience the best strategy for T.M. is to resume his “historical” dose of 10 mg

Patient Case: Warfarin Dose Management

- **Case 1C:** G.R. is a 33 y/o female on warfarin for new DVT in the setting of an ICU stay
  - Tablet Strength: 5mg
  - Goal INR: 2-3
  - She is s/p gastric bypass. During her hospital stay, she received warfarin 5mg per day for 4 doses with an INR of 3.76. Due to the elevated INR, warfarin was held upon discharge. She reports limited PO intake and is taking Augmentin.
  - Her INR in the clinic today is 2.9 (which is three day post discharge).

Case 1 C: Answer

- Our dosing protocol does not address dosing adjustment in the presence of drug-drug interactions.
  - Augmentin will likely to increase her INR secondary to reduced GI flora (i.e. vitamin K).
  - In general the rule of thumb is to decrease the dosage by 50% in the presence of an antibiotic known to potentiate the effects of warfarin.
- However this case is further complicated by the supratherapeutic INR 7 days ago on warfarin 5mg daily and current reduced PO intake.
- It is reasonable to air on the side of caution and further reduces the dosage by recommending 2.5 mg daily for the duration of the antibiotic usage and limited PO intake.
Clinic visits, Documentation & Billing

- **Clinic Visit:**
  - Face-to-Face vs. Telemedicine

- **Documentation:**
  - Paper charting/records
  - Add a template to current electronic medical record (EMR)
  - Use separate software to accompany current documentation system
    - CoaguTrak® - Anticoagulation Management Software
      - Web-based anticoagulation software that allows you to both chart and bill for patient encounters

- **Billing:**
  - Can bill for pharmacy ran anticoagulation services under the Medication Therapy Management Service (MTMS) codes:
    - 99605 = Initial face-to-face encounter provided by a pharmacist that included an assessment and intervention (15 minutes in length)
    - 99606 = Subsequent encounter or follow-up encounter
    - 99607 = Each additional 15 minutes needed at any encounter

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Clinic visits, Documentation & Billing

- **Billing:**
  - Can bill for pharmacy ran anticoagulation services under the Medication Therapy Management Service (MTMS) codes:
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Clinic visits, Documentation & Billing

- **Medicare Part B vs. Medicare Part D**
  - Part B must use “E status” – which is used to denote services excluded from physician fee schedules by regulation

- **Indirect vs. Direct billing to Third-Party Payers**
  - **Indirect** – billing for services on behalf of the physician
    - Can only use in states that allow collaborative practice agreements (44 states)
    - “Incident to” billing which allows you to bill for technical/facility fees
  - **Direct** – pharmacist bills insurance directly
    - Limited to specified MTMS services covered by third-party payer (plan dependent)

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http://www.ashp.org/DocLibrary/MemberCenter/Webinars/Webinar20080814.aspx

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Clinic visits, Documentation & Billing

• Outpatient Prospective Payment System
  – Can be used by hospital-based ambulatory care clinics
  – Two component billing system
    • Professional fees
    • Technical/facility fees
  – Allows you to utilize ambulatory patient classification (APC) codes to create a “super bill”
    • Hospital defines code criteria based on time and complexity of service provided
  • CPT codes mapped to the appropriate APC codes:
    – 99211 and 99212 to APC 0600
    – 99213 to APC 0601
    – 99214 to and 99215 to APC 06012

http://www.ashp.org/DocLibrary/MemberCenter/Webinars/Webinar20080814.aspx

Role of Self Monitoring (PST)

• Pros:
  – Empowers the patient
  – Allows for more frequent testing and patient self-management (PSM)
    • PSM = patient self-adjust warfarin dosage based on patient-friendly protocol
  – Allows for online management of warfarin through provider-patient interface
  – Increases patient convenience
  – Lowers thromboembolic events and mortality with no increase in major bleeding

• Cons:
  – Cost of device and test strips in uninsured patients
    • $1500-$2000 per device and $7-12 per test strip


Self Monitoring & Billing

• National Coverage Determination (NCD) for Home Prothrombin Time INR Monitoring for Anticoagulation Management (190.11)
  – Medicare reimburses hospitals for the initial patient training on the point-of-care device, the device itself, test strips and provider oversight for 4 tests per month.

• “G codes”
  – G0248 = training
  – G0249 = device and test strips (4 tests per month)
  – G0250 = provider oversight

http://www.cms.gov/national-coverage-database
• Which of the following patients would be considered a reasonable candidate for home point-of-care monitoring?

**Case 2A:** W.W. is a 75 y/o male on warfarin for AF since 2003. Past medical history includes Parkinson’s disease, colorectal cancer, hypertension and diabetes. He is reliable with follow-up and his primary insurance is Medicare.

**Answer:** While Medicare will cover the cost associated with self-monitoring, W.W.’s Parkinson disease is likely going to affect his dexterity and fine motor skills. These devastating consequences are likely to decrease his ability to effectively perform self-monitoring.

**Case 2B:** D.Y. is a 73 y/o female on warfarin for AF since 2010. Past medical history includes hypertension, hyperlipidemia and GERD. She is reliable with follow-up and her primary insurance is Medicare.

**Answer:** D.Y. would be an excellent candidate for self-monitoring; and has done so successfully for several years.

**Case 2C:** D.S. is a 51 y/o female on warfarin for 1 month for a PE s/p TKR. Past medical history includes asthma, hypertension, GERD, anxiety and alcohol abuse. She is reliable with follow-up and her primary insurance is Medicaid.

**Answer:** D.S.’s pulmonary embolism is secondary to her total knee replacement. The treatment duration for a DVT or PE with a known cause is 6 months to a year. Furthermore she has only been taking her warfarin for a month, so her INR has not likely stabilized. This combined with the lack of need for long term monitoring would likely prevent this patient from receiving reimbursement for self-monitoring and she therefore is not a good candidate.
Role of Novel Anticoagulants

• Dabigatran Etexilate (Pradaxa®)
  – Prodrug that competitively inhibits thrombin
  – Non-inferior to warfarin (RE-LY trial) for VTE prevention in patients with Afib
  – Dose: 150 mg PO BID
    • Requires an acid environment for absorption
    • PPIs will likely reduced absorption
    • Food increases absorption
  – Peak concentrations are seen 2 hrs post ingestion
  – Hepatically metabolized (CYP3A4) and renally eliminated
    • T1/2 = 12-17 hrs
    • Potential drug-drug interactions with CYP3A4 inhibitors/inducers
    • Dosing adjustments need for renal dysfunction


Role of Novel Anticoagulants

• Rivaroxaban (Xarelto®)
  – Selective competitive inhibitor of Factor Xa without antiplatelet effects
  – Non-inferior to warfarin for the prevention of stroke and non-CNS emboli in patients with Afib (ROCKET AF)
    • Also approved for post operative VTE prophylaxis in hip and knee replacements
  – Dose-dependent bioavailability = indication specific dosing
    • 20 mg PO with evening meal for Afib
    • 10 mg PO with or without meals for VTE prophylaxis
  – Hepatically metabolized and eliminated (2/3); remaining 1/3 is eliminated renally unchanged
    • Non-linear pharmacokinetics
    • Dose adjustment required for renal dysfunction
    • Low potential for drug-drug interactions


Role of Novel Anticoagulants

• Apixaban (Eliquis)
  – Direct selective competitive inhibitor of factor Xa
  – Currently under FDA review for prevention of stroke and systemic embolism in patients with Afib (ARISTOLE)
    • Found not only to be non-inferior to warfarin (primary outcome) but superior (secondary outcome)
      • Dose: 5mg PO BID
  – Approved in Europe for VTE prophylaxis secondary to hip and knee replacements
    • Dose: 2.5 mg PO BID
      • Anticoagulant effects are dose dependent
    • Low potential for drug interactions
    • T 1/2 = 12 hrs

Role of Novel Anticoagulants

**Pros:**
- May allow for a more holistic and personalized appropriate
  - Providers would be responsible for converting patients to/from warfarin
  - Less time spent on dosing adjustments = more time to focus on other modifiable CV risk factors (e.g. smoking cessation)

**Cons:**
- Limited data on treatment of acute VTE with or without initial LMWH bridge
- No antidote
- Concerns regarding usage in the elderly and in patients with renal dysfunction
  - Both place the patient at greater risk for bleeding


Patient Cases: Role of Novel Agents

**Case 3A:** M.S. is a 85 y/o female on warfarin for AF. Past medical history includes hypertension, breast cancer and stage IV CKD (Cr 1.9). She is compliant and requires once monthly INR checks.

**Answer:** The use of both Dabigatran and Rivaroxaban is contraindicated in patients with severe renal function (CrCl < 15 mL/min). Based on M.S. current renal function the usage of either agent would not be recommended.

Patient Cases: Role of Novel Agents

**Case 3B:** M.V. is a 77 y/o male on warfarin for AVR. Past medical history includes CVA, prostate cancer, diabetes and CAD. He is usually compliant, but has frequent fluctuations in his INR values. He comes to the clinic weekly for INR checks.

**Answer:** Dabigatran is only FDA approved for the stroke prophylaxis in patients with AF; and is currently used in Europe for DVT/PE prophylaxis after orthopedic surgery. Rivaroxaban is FDA approved for VTE prophylaxis after hip/knee replacements and anticoagulation in AF.
  - This patient is receiving anticoagulation after an aortic valve replacement and therefore would not qualify based on his indication.
Patient Cases: Role of Novel Agents

Case 3D: M.L. is a 64 y/o female on warfarin for AF. Past medical history includes COPD, GERD, hyperlipidemia and CVA. She is mostly compliant, but sometimes forgets to take her medications (often misses visits in the clinic, needs frequent reminders).

Answer: Some would argue that either agent might likely provided better anticoagulation secondary to missed doses, lack of follow up for dosing adjustments and the need to be frequently reminded about her therapy. Others would likely argue that for these same reasons the patient would not be a good candidate and likely benefit from closer follow up.

In Summary: Elements of a Successful Clinic

• A Business Plan
  – MD Supervision
  – Care Management and Coordination of Care
    • Integrative Collaborative Practice Model
    • Recruitment of Qualified Personnel
• Collaborative Practice Agreement (CPA)
  – Protocol for assessment, therapeutic management, and follow-up of anticoagulation therapy
  – Patient Education
  – Effective Communication
• Documentation & Billing

Resources To Get You Started

• Websites:
  – National Certification Board for Anticoagulation Providers <http://www.ncbap.org/>
  – Clotcare <http://www.clotcare.org>
**Resources To Get You Started**

- **Training Programs:**
  - American Society of Health Systems Pharmacists
    <http://www.ashp.org/>
  - American College of Clinical Pharmacist <http://www.accp.org/>
  - Anticoagulation Therapy Management Certification Program from University of Southern Indiana
    <http://health.usi.edu/certificate/anticoagulationtherapy.asp>
  - ASHP’s Antithrombotic Pharmacotherapy Traineeship
    <http://www.ashpfoundation.org/MainMenuCategories/Education/Traineeships/PharmacotherapyTraineeship.aspx>

- **Books:**

- **Articles:**
Resources To Get You Started

- Guidelines:

Questions?
Establishment of need:

Purpose of the Anticoagulation Service:

Goals of the Service:

Administrative, staff and organizational elements necessary to carry out your service:

Qualifications of personal to carry out the service:

Program Model:
Clinical Cases Worksheet 1

Patient Case Set # 1: Warfarin Dose Management

Utilizing the protocol provided to you, construct a management plan for the following patients:

• D.M is a 67 y/o male on warfarin for atrial fibrillation (AF).
  • Current Dose: 5mg per day except on Sunday he takes 7.5mg
  • Tablet Strength: 5mg
  • Goal INR: 2-3
  • His INR today is 1.7 and 2 weeks ago, his INR was 1.6. He denies missing any doses and states that there has been no recent change to his medications and/or diet.

• T.M. is a 45 y/o male on warfarin for recurrent left lower extremity (LLE) DVT.
  • Usual dose: 10mg per day
  • Tablet Strength: 5mg
  • Goal INR 2-3
  • Patient has a history of noncompliance and was recently admitted for recurrent DVT. Since hospital discharge (12 days ago) he has been taking warfarin 5mg per day with an enoxaparin bridge, which was completed 5 days ago. His INR today at follow up is 1.3.

• G.R. is a 33 y/o female on warfarin for new DVT in the setting of an ICU stay.
  • Tablet Strength: 5mg
  • Goal INR: 2-3
  • She is s/p gastric bypass. During her hospital stay, she received warfarin 5mg per day for 4 doses with an INR of 3.76. Due to the elevated INR, warfarin was held upon discharge. She reports limited PO intake and is taking Augmentin.
  • Her INR in the clinic today is 2.9 (which is three day post discharge).
• B.M. is a 55 y/o male on warfarin for a DVT which occurred 4 months ago.
  • Current Dose: 11.25 mg per day
  • Tablet Strength: 7.5 mg
  • Goal INR: 2-3
  • His INR today is 5.1
  • His INR has been therapeutic for the past 8 weeks on current dose. He denies any changes to his medications or diet and reports having 2 self-limited nosebleeds this week.

• T.M is a 44 y/o female on warfarin for recurrent DVT.
  • Current Dose: 7.5mg per day except on Tuesday she takes 11.25mg.
  • Tablet Strength: 7.5mg
  • Goal INR: 2-3
  • Her INR today is 1.7 and 2 weeks ago her INR was 2.4. Patient reports missing one dose last week and ate vegetable pizza yesterday and today.
Clinical Cases Worksheet 1 (Answers)

Patient Case Set # 1: Warfarin Dose Management

Utilizing the protocol provided to you, construct a management plan for the following patients:

- D.M is a 67 y/o male on warfarin for atrial fibrillation (AF).
  - Current Dose: 5mg per day except on Sunday he takes 7.5mg
  - Tablet Strength: 5mg
  - Goal INR: 2-3
  - His INR today is 1.7 and 2 weeks ago, his INR was 1.6. He denies missing any doses and states that there has been no recent change to his medications and/or diet.

**Answer:**

According to the dosing protocol we should increase the dosage by 10% of the weekly dosage (which is 2.5 mg) and recheck the INR in one week.

\[
5 \times 6 = 30 + 7.5 \text{ mg} = 37.5 \quad \text{10% of } 37.5 = 3.75 \text{ or 2.5 for ease of dosing}
\]

According to the 2012 CHEST guidelines, a dose adjustment should not be made if the patient has one abnormal INR reading within 0.5 above or below target INR and a history of therapeutic INRs. Instead, they recommend rechecking the INR in one week.

- T.M. is a 45 y/o male on warfarin for recurrent left lower extremity (LLE) DVT.
  - Usual dose: 10mg per day
  - Tablet Strength: 5mg
  - Goal INR 2-3
  - Patient has a history of noncompliance and was recently admitted for recurrent DVT. Since hospital discharge (12 days ago) he has been taking warfarin 5mg per day with an enoxaparin bridge, which was completed 5 days ago. His INR today at follow up is 1.3.

**Answer:**

According to the dosing protocol we should increase the dosage by 15% of the weekly dosage (which is 5 mg) and recheck the INR in one week.

\[
5 \times 7 = 35 \text{ mg} \quad \text{15% of } 35 = 5.25 \text{ or 5 mg for ease of dosing}
\]

A 15% increase in dosage is not likely to place this patient into therapeutic range, given is historical dose of 10 mg per day. However one must take into consideration the patient long-standing history of noncompliance and its likelihood of contributing to higher dosages in the past.

Based on clinical experience the best strategy for T.M. is to resume his “historical” dose of 10mg plus the LMWH bridge and recheck his INR in 3 days. Once therapeutic the patient can stop the LMWH bridge and POC INR readings can be used to appropriately titrate the patients warfarin.
This case brings up an important concept that must be considered with creating a protocol-based collaborative practice: **What steps should occur if deviations from the protocol are necessary to ensure appropriate patient care?**

- **G.R.** is a 33 y/o female on warfarin for new DVT in the setting of an ICU stay.
  - Tablet Strength: 5mg
  - Goal INR: 2-3
  - She is s/p gastric bypass. During her hospital stay, she received warfarin 5mg per day for 4 doses with an INR of 3.76. Due to the elevated INR, warfarin was held upon discharge. She reports limited PO intake and is taking Augmentin.
  - Her INR in the clinic today is 2.9 (which is three day post discharge).

**Answer:** Our dosing protocol does not address dosing adjustment in the presence of drug-drug interactions. This patient is one Augmentin, which is likely to increase her INR secondary to reduced GI flora (i.e. vitamin K). In general the rule of thumb is to decrease the dosage by 50% in the presence of an antibiotic known to potentiate the effects of warfarin. However this case is further complicated by the supratherapeutic INR 7 days ago on warfarin 5mg daily and current reduced PO intake. In this case, it is reasonable to air on the side of caution and further reduces the dosage by recommending 2.5 mg daily for the duration of the antibiotic usage and limited PO intake.

Again this case highlights the fact that not all patient cases will “fit” within a protocol. Interestingly enough the 2012 CHEST guidelines state that protocol based dosing adjustments result in better patient outcomes when healthcare providers with limited knowledge are preforming the adjustments. Patient outcomes among providers with extensive knowledge were the same regardless of protocol guidance.

**Food for thought:** How do you allow for “professional judgment” in a protocol based collaborative practice?

- **B.M.** is a 55 y/o male on warfarin for a DVT which occurred 4 months ago.
  - Current Dose: 11.25 mg per day
  - Tablet Strength: 7.5 mg
  - Goal INR: 2-3
  - His INR today is 5.1
  - His INR has been therapeutic for the past 8 weeks on current dose. He denies any changes to his medications or diet and reports having 2 self-limited nosebleeds this week.

**Answer:** According to the dosing protocol the POC INR should be confirmed by venous puncture. If the INR is elevated per the venipuncture, you should hold 2 doses and rechecked the
INR in 2 days. According to the 2012 CHEST guidelines, it takes 2.5 days for an INR of 6-10 to decrease below 4.

- T.M is a 44 y/o female on warfarin for recurrent DVT.
  - Current Dose: 7.5mg per day except on Tuesday she takes 11.25mg.
  - Tablet Strength: 7.5mg
  - Goal INR: 2-3
  - Her INR today is 1.7 and 2 weeks ago her INR was 2.4. Patient reports missing one dose last week and ate vegetable pizza yesterday and today.

**Answer:** According to the dosing protocol we should increase the dosage by 10% of the weekly dosage (which is 5 mg) and recheck the INR in one week.

\[(7.5 \times 6) + 11.25 \text{ mg} = 56.25 \text{ mg} \quad 10\% \times 56.25 = 5.6 \text{ mg or 5 mg for ease of dosing}\]

However the patient missed a dosage and had dietary excursions which are likely the cause of her subtherapeutic INR. Also recall that the 2012 CHEST guidelines, state that the dose should not be adjusted if the patient has one abnormal INR reading within 0.5 above or below target INR and a history of therapeutic INRs. Instead, this patient should be counseled on the importance of medication adherence and consistent vitamin K intake. Recommend rechecking the INR in one week.
Clinical Cases Worksheet 2

Patient Case Set # 2: Self-Monitoring

Which of these patients would be considered a reasonable candidate for use of a home point-of-care (POC) monitor?

- **Case 2A**
  
  W.W. is a 75 y/o male on warfarin for AF since 2003. Past medical history includes Parkinson disease, colorectal cancer, hypertension and diabetes. He is reliable with follow-up and his primary insurance is Medicare.

- **Case 2B**
  
  D.Y. is a 73 y/o female on warfarin for AF since 2010. Past medical history includes hypertension, hyperlipidemia and GERD. She is reliable with follow-up and her primary insurance is Medicare.

- **Case 2C**
  
  D.S. is a 51 y/o female on warfarin for 1 month for a PE s/p TKR. Past medical history includes asthma, hypertension, GERD, anxiety and alcohol abuse. She is reliable with follow-up and her primary insurance is Medicaid.

- **Case 2D**
  
  G.M is a 60 y/o male on warfarin for recurrent PE since 2007. Past medical history includes cardiomyopathy, hypertension, hepatitis C and alcohol abuse. He is currently homeless with no phone. He is unreliable with follow-up and his primary insurance is Medicaid.

- **Case 2E**
  
  A.B. is a 57 y/o male on warfarin for 6 weeks after a recent stroke. Past medical history includes hypertension. He is reliable with follow-up and is self-pay.
Clinical Cases Worksheet 2 (Answer)

Patient Case Set # 2: Self-Monitoring

Which of these patients would be considered a reasonable candidate for use of a home point-of-care (POC) monitor?

- **Case 2A**
  - W.W. is a 75 y/o male on warfarin for AF since 2003. Past medical history includes Parkinson disease, colorectal cancer, hypertension and diabetes. He is reliable with follow-up and his primary insurance is Medicare.

  **Answer:** While Medicare will cover the cost associated with self-monitoring, W.W.’s Parkinson disease is likely going to affect his dexterity and fine motor skills. These devastating consequences are likely to decrease his ability to effectively perform self-monitoring.

- **Case 2B**
  - D.Y. is a 73 y/o female on warfarin for AF since 2010. Past medical history includes hypertension, hyperlipidemia and GERD. She is reliable with follow-up and her primary insurance is Medicare.

  **Answer:** D.Y. would be an excellent candidate for self-monitoring; and has done so successfully for several years.

- **Case 2C**
  - D.S. is a 51 y/o female on warfarin for 1 month for a PE s/p TKR. Past medical history includes asthma, hypertension, GERD, anxiety and alcohol abuse. She is reliable with follow-up and her primary insurance is Medicaid.

  **Answer:** D.S.’ pulmonary embolism is secondary to her total knee replacement. The treatment duration for a DVT or PE with a known cause is 6 months to a year. Furthermore she has only been taking her warfarin for a month, so her INR has not likely stabilized. This combined with the lack of need for long term monitoring would likely prevent this patient from receiving reimbursement for self-monitoring and she therefore is not a good candidate.
Case 2D

- G.M is a 60 y/o male on warfarin for recurrent PE since 2007. Past medical history includes cardiomyopathy, hypertension, hepatitis C and alcohol abuse. He is currently homeless with no phone. He is unreliable with follow-up and his primary insurance is Medicaid.

  Answer: G.M. is homeless so proper storage of the device and testing supplies would be of concern. He also has a long standing history of noncompliance and is often lost to f/u. All of these factors make G.M. a poor candidate for self-monitoring.

Case 2E

- A.B. is a 57 y/o male on warfarin for 6 weeks after a recent stroke. Past medical history includes hypertension. He is reliable with follow-up and is self-pay.

  Answer: Recurrent stroke implies life-long therapy; however A.B. has only been on warfarin for 6 weeks and is therefore not likely to have a stable INR. In this patient, you would need to weigh the risk vs. benefit regarding the patient's ability to self-monitor on a weekly basis, report INR readings and appropriately adjust warfarin dosage per clinical provider’s instructions. Lastly this patient is self-pay so the cost of self-monitoring would also need to be considered.
Clinical Cases Worksheet 3

Patient Case Set #3: Role of Novel Agents

Which of these patients would be suitable for some of the newer anticoagulants and what services should you provide regarding this new agents?

- **Case 3A**
  
  M.S. is a 85 y/o female on warfarin for AF. Past medical history includes hypertension, breast cancer and stage IV CKD (Cr 1.9). She is compliant and requires once monthly INR checks.

- **Case 3B**
  
  M.V a 77 y/o male on warfarin for AVR. Past medical history includes CVA, prostate cancer, diabetes and CAD. He is usually compliant, but has frequent fluctuations in his INR values. He comes to the clinic weekly for INR checks.

- **Case 3C**
  
  N.G. is a 50 y/o female on warfarin for AF. Past medical history includes cardiomyopathy/MI, hypertension, hyperlipidemia and renal insufficiency (CrCl 13.5 ml/min). She is compliant and requires once monthly INR checks.

- **Case 3D**
  
  M.L is a 64 y/o female on warfarin for AF. Past medical history includes COPD, GERD, hyperlipidemia and CVA. She is mostly compliant, but sometimes forgets to take her medications (often misses visits in the clinic, needs frequent reminders).
Case 3E

- A.S. is a 69 y/o male on warfarin for AF. Past medical history includes CAD(s/p drug eluting stents), hypertension, hyperlipidemia and a recent GI bleed. He is compliant and his INR is usually stable.

Case 3F

- D.M is a 62 y/o male on warfarin for AF. Past medical history includes diabetes, hypertension and hyperlipidemia. He is compliant and requires once monthly INR checks.
Clinical Cases Worksheet 3 (Answers)

Patient Case Set #3: Role of Novel Agents

Which of these patients would be suitable for some of the newer anticoagulants and what services should you provide regarding this new agents?

Case 3A

- M.S. is a 85 y/o female on warfarin for AF. Past medical history includes hypertension, breast cancer and stage IV CKD (Cr 1.9). She is compliant and requires once monthly INR checks.

Answer: The use of both Dabigatran and Rivaroxaban is contraindicated in patients with severe renal function (CrCl < 15 mL/min). Based on M.S. current renal function the usage of either agent would not be recommended.

Case 3B

- M.V a 77 y/o male on warfarin for AVR. Past medical history includes CVA, prostate cancer, diabetes and CAD. He is usually compliant, but has frequent fluctuations in his INR values. He comes to the clinic weekly for INR checks

Answer: Dabigatran is only FDA approved for the stroke prophylaxis in patients with AF; and is currently used in Europe for DVT/PE prophylaxis after orthopedic surgery. Rivaroxaban is FDA approved for VTE prophylaxis after hip/knee replacements and anticoagulation in AF.

This patient is receiving anticoagulation after an aortic valve replacement and therefore would not qualify based on his indication.

Case 3C

- N.G. is a 50 y/o female on warfarin for AF. Past medical history includes cardiomyopathy/MI, hypertension, hyperlipidemia and renal insufficiency (CrCl 13.5 ml/min). She is compliant and requires once monthly INR checks.

Answer: The use of both Dabigatran and Rivaroxaban is contraindicated in patients with severe renal function (CrCl < 15 mL/min). Based on N.G. current renal function the usage of either agent would not be recommended.

Case 3D

- M.L is a 64 y/o female on warfarin for AF. Past medical history includes COPD, GERD, hyperlipidemia and CVA. She is mostly compliant, but sometimes forgets to take her medications (often misses visits in the clinic, needs frequent reminders).

Answer: Some would argue that either agent might likely provided better anticoagulation secondary to missed doses, lack of follow up for dosing adjustments and the need to be frequently reminded about her therapy. Others would likely argue that for these same reasons the patient would not be a good candidate and likely benefit from closer follow up.
Case 3E

- A.S. is a 69 y/o male on warfarin for AF. Past medical history includes CAD (s/p drug eluting stents), hypertension, hyperlipidemia and a recent GI bleed. He is compliant and his INR is usually stable.

Answer: A.S. has a drug eluting stent and might be still on Clopidrogel (Plavix). Dabigatran has antiplatelet activity and would likely increase the patient’s risk for bleeding when paired with Plavix. Rivaroxaban does not have antiplatelet effects and would be a better choice than Dabigatran. However, given the patient’s recent GI bleed, usage of either agent may not be preferred in this patient.

Case 3F

- D.M is a 62 y/o male on warfarin for AF. Past medical history includes diabetes, hypertension and hyperlipidemia. He is compliant and requires once monthly INR checks.

Answer: D.M. would also be a good candidate for either agent. Dabigatran is formulary, so would therefore be the preferred agent in our institution. To convert him to Dabigatran per our protocol warfarin would be stopped and Dabigatran would be started once this patient’s INR falls below 2.
Resources to Get You Started

Website:
- National Anticoagulation Forum [http://www.acforum.org/]
- National Certification Board for Anticoagulation Providers [http://www.ncbap.org/]
- Clotcare [http://www.clotcare.org]

Training Programs:
- American Society of Health Systems Pharmacists [http://www.ashp.org/]
- American College of Clinical Pharmacist [http://www.accp.org/]
- Anticoagulation Therapy Management Certification Program from University of Southern Indiana [http://health.usi.edu/certificate/anticoagulationtherapy.asp]
- ASHP’s Antithrombotic Pharmacotherapy Traineeship [http://www.ashpfoundation.org/MainMenuCategories/Education/Traineeships/PharmacotherapyTraineeship.aspx]

Books:

Articles:
Resources to Get You Started


Guidelines: