Practical Issues with Transitioning to DOAC Clinic

Anticoagulation Forum Conference
Ft. Lauderdale, FL - April 12, 2019
Disclosures

Pfizer
Portola
Roche
(1) Have you incorporated DOAC patients into your anticoagulation service?

A. Yes
B. No
C. Not interested
D. Interested, but don’t know how to start
(2) If yes to previous question, how many DOAC patients are enrolled?

A. <50
B. 51-100
C. 101-200
D. 201-300
E. >300
Practical issues

- Gain consensus among local stakeholders that this is the ‘right thing’ to do
- Develop a clinic/institution protocol
- Create a ‘management plan’ to address the needs of DOAC patients
- Identify knowledge gaps and plan staff education
- Develop patient and family education materials
- Address technical challenges within clinic and institution
- Lack of quality examples for ‘how to do’ this
### Challenges

<table>
<thead>
<tr>
<th>MISCONCEPTIONS</th>
<th>IN ACTUALITY . . . . .</th>
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</thead>
<tbody>
<tr>
<td>“DOACs are easy”</td>
<td>Dose adjustments not well understood and often not done.</td>
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<tr>
<td>“No monitoring is needed”</td>
<td>Transitions are complicated.</td>
</tr>
<tr>
<td>“No drug or food interactions”</td>
<td>Renal (and liver) function require monitoring.</td>
</tr>
<tr>
<td>“It’s easy for patients”</td>
<td>There are a few, but important, drug/food interactions.</td>
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<tr>
<td></td>
<td>Many patients are challenged with financial costs, insurance coverage and multiple transitions.</td>
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NPSG.03.05.01  Take extra care with patients who take medicines to thin their blood

Use of approved protocols and evidence-based practice guidelines for the initiation and maintenance of anticoagulation therapy

Use of approved protocols and evidence-based practice guidelines for reversal of anticoagulation and management of bleeding events

Use of approved protocols and evidence-based practice guidelines for perioperative management of all patients on oral anticoagulants

Has a written policy addressing the need for baseline and ongoing laboratory tests to monitor and adjust anticoagulant therapy

Addresses anticoagulation safety practices through:
- Establishing a process to identify, respond to and report adverse drug events
- Evaluating anticoagulation safety practices

Provide education to patients and families including:
- Adherence to medication dose and schedule
- Importance of follow-up appointments and laboratory testing
- Potential drug-drug and drug-food interactions
- Potential for adverse drug reactions

Use only oral unit-dose products, prefilled syringes, or premixed infusion bags when these types of products are available

https://www.jointcommission.org/
DOAC Management Plan
12/28/2018

INITIAL ASSESSMENT + BASELINE LABS + EDUCATIONAL VISIT
(baseline labs: CBC, platelets, Cr, eGFR (CrCl calculated as needed)

1 MONTH
(RN assess need for additional contact for new VTE lead-in dose change)

3 MONTH
(LAB if renal risk)

Based on risk stratification, continue follow-up (F/U) plan as below:

HIGH RISK
- Age ≥ 75 yrs
- Renal Risks
  - eGFR <51 mL/min/1.73 m²
  - 3 Monthly Lab Order or frequency stipulated by provider
- Thrombocytopenia (Plat <50)
- HD

LOW RISK
- 3 Mo F/U, LABS q 6 Mo
- 3 Mo F/U with LABS or as stipulated
- 3 Mo F/U
- 3 Mo F/U with LABS or as stipulated
- 12 mo F/U with LABS

EPISODIC RISKS

NON-ADHERENCE by 20%
- 1 Mo F/U

Hct ↓ 6 pts
- 1 Mo F/U and Hct LAB, if needed

CLINICAL EVENT
- 1 Mo F/U if Moderate or Major Event and LABS, if needed

Resolve when appropriate

Resolves automatically in 45 days

Key: VTE=Venous thromboembolism, F/U=Follow-up phone call

3 Mo F/U, LABS q 6 Mo

3 Mo F/U with LABS or as stipulated

3 Mo F/U with LABS

3 Mo F/U with LABS or as stipulated

3 Mo F/U with LABS
Patient Follow-up: periodic phone assessments, based on risk class, includes assessment of adherence and medication changes

Follow-up (F/U) Assessment documented in Epic Tel Encounter
- Hospitalized/ED visit for what reason and when
- Interruption in DOAC therapy (and details) that AMS unaware of?
- Seen by MD other than ‘well’ visits
- Any side effects? (assess if bruising increased on DOAC when compared with warfarin experience)
- Verification of change in dose as expected (applies to new VTE type indications only: apix on Day 8 of Trt and riva on Day 22 of Trt)
- Check on refills provided with initial Rx – how many refills?
- Issues with drug procurement/financial concerns about getting refills as needed?

DawnAC® Follow-Up Questionnaires (QNRs):
- Adherence* (added risk if less than 80% rule)
- Medication surveillance for potentially interacting meds* that may require dose adjustment or avoid use

DawnAC® Lab QNR*:
- eGFR, Creatinine and Hct obtained per Standard F/U plan

Adverse events – documented in Events Tab, includes documentation of Interruption in Therapy Plan

* This information (along with next scheduled F/U date) displayed in AMS icon via Outbound Interface message from DawnAC®
How do I assess DOAC adherence?
Adherence definition

Considered adherent if “take medication as prescribed more than 80% of the time”

(WHO, 2003)

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<th>Dose regimen</th>
<th># missed doses/time period to qualify for 20% (mark as non-adherent)</th>
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<tbody>
<tr>
<td>Daily</td>
<td>1 out of 7 days&lt;br&gt;3 out of 2 weeks&lt;br&gt;6 out of 4 weeks&lt;br&gt;12 out of 8 weeks</td>
</tr>
<tr>
<td>Twice daily</td>
<td>3 out of 7 days&lt;br&gt;6 out of 2 weeks&lt;br&gt;12 out of 4 weeks&lt;br&gt;24 out of 8 weeks</td>
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## Transitions among oral anticoagulants

### FROM WARFARIN TO DOAC

<table>
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<tr>
<th>Anticoagulant</th>
<th>Manufacturer recommended start when INR</th>
<th>Institutional recommended start when INR</th>
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<tr>
<td>dabigatran</td>
<td>2</td>
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<tr>
<td>rivaroxaban</td>
<td>3</td>
<td>2</td>
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<tr>
<td>apixaban</td>
<td>2</td>
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<tr>
<td>edoxaban</td>
<td>2.5</td>
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### FROM DOAC TO WARFARIN

<table>
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<th>Risk Level</th>
<th>Action</th>
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<tr>
<td>LOW risk</td>
<td>Continue DOAC AND begin warfarin for 3 days (days 1, 2, 3)</td>
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<tr>
<td>HIGH risk</td>
<td>Stop DOAC and begin parenteral anticoagulant AND warfarin at the time of the next scheduled DOAC dose</td>
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<tr>
<td></td>
<td>Stop DOAC and continue warfarin (days 4, 5)</td>
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<td></td>
<td>Continue bridge with parenteral anticoagulant and warfarin</td>
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<tr>
<td></td>
<td>Obtain INR on Day 6 and adjust warfarin accordingly</td>
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<tr>
<td></td>
<td>Obtain INR on Day 3 of bridge and adjust warfarin accordingly</td>
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<td>Assess patient-specific risks and renal function. Collaborate, clarify and document plan with provider.</td>
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Suggested perioperative management approach *(assumes normal renal function)*

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<th>LOW Bleed Risk Surgery Hold:</th>
<th>HIGH Bleed Risk Surgery Hold:</th>
<th>Resume therapy LOW Bleed risk</th>
<th>Resume HIGH Bleed Risk</th>
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<tr>
<td>Dabigatran</td>
<td>2 doses</td>
<td>4 doses</td>
<td>24 h after surgery</td>
<td>2-3 days after surgery</td>
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<tr>
<td>Rivaroxaban</td>
<td>1 dose</td>
<td>2 doses</td>
<td>24 h after surgery</td>
<td>2-3 days after surgery</td>
</tr>
<tr>
<td>Apixaban</td>
<td>2 doses</td>
<td>4 doses</td>
<td>24 h after surgery</td>
<td>2-3 days after surgery</td>
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<tr>
<td>Edoxaban</td>
<td>1 dose</td>
<td>2 doses</td>
<td>After adequate hemostasis is established</td>
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<tr>
<td>warfarin</td>
<td>When INR &lt; 1.5, omit 2-3 days</td>
<td>When INR &lt;1.2, omit 3-5 days</td>
<td>Usually day of or following surgery, provided adequate hemostasis is established</td>
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Develop an education plan to identify and address knowledge gaps

Pre and Post knowledge assessments (AMS staff required to achieve 100% on post test)
- 23 multiple-choice items

Post-assessment “open book”

Pre-assessment results
GOAL
Example of initial clinical staff education curriculum (plan for ongoing education needs)

Blended learning experience

Credit hours awarded (5.66 CHs from institution professional development office plus 1 from online program)

Ruff CT et al. The American Journal of Medicine (2016) 129, S1-S29

Develop easy reference guides – DOACs At-a-Glance Reference Tool

### Edoxaban
- **Indication:** DOAC Accelerated Hypercoagulability
- **Dose:** 60 mg once daily
- **Reversal:** Prothrombin Complex Concentrate

### Apixaban
- **Indication:** DOAC Accelerated Hypercoagulability
- **Dose:** 5 mg twice daily
- **Reversal:** Prothrombin Complex Concentrate

### Rivaroxaban
- **Indication:** DOAC Accelerated Hypercoagulability
- **Dose:** 20 mg daily
- **Reversal:** Prothrombin Complex Concentrate

### Dabigatran
- **Indication:** DOAC Accelerated Hypercoagulability
- **Dose:** 7.5 mg twice daily
- **Reversal:** Prothrombin Complex Concentrate

Accessible on institution intranet and internet
## DOACs and potential drug interactions

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<tr>
<th>Drug Name</th>
<th>Cardarone, Xestorak, Pacerone</th>
<th>Spironolactone</th>
<th>PFE Inhibitor</th>
<th>R/B INDUCER</th>
<th>CYP3A4 INDUCER</th>
<th>Source: Product Insert</th>
<th>MicroMedex</th>
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</table>

- **Amiodarone**: Cardarone, Xestorak, Pacerone
- **Azithromycin**: Spironolactone
- **Carbamazepine**: PFE Inhibitor
- **Carvedilol**: R/B INDUCER
- **Clarithromycin**: CYP3A4 INDUCER
- **Cyclosporine**: PFE Inhibitor
- **Dronedaron**: Spironolactone
- **Erythromycin**: CYP3A4 INDUCER
- **Flucloxacillin**: PFE Inhibitor
- **Indinavir**: CYP3A4 INDUCER
- **Itraconazole**: Spironolactone
- **Ketoconazole**: CYP3A4 INDUCER
- **Lapatinib**: PFE Inhibitor
- **Lopinavir**: CYP3A4 INDUCER
- **Phosphatidylserine**: PFE Inhibitor
- **Rifampin**: Spironolactone
- **Ritonavir**: CYP3A4 INDUCER
- **Saquinavir**: CYP3A4 INDUCER
- **St. John’s wort**: PFE Inhibitor
- **Tacrofusum**: CYP3A4 INDUCER
- **Telaprevir**: CYP3A4 INDUCER
- **Ticemuravir**: PFE Inhibitor
- **Verapamil**: CYP3A4 INDUCER

### Abbreviations
- **Dab**: dabigatran
- **Riv**: rivaroxaban
- **Api**: apixaban
- **D**: dabigatran
- **B**: rivaroxaban
- **A**: apixaban
- **Maj**: major interaction
- **D**: dabigatran
- **B**: rivaroxaban
- **A**: apixaban

### Notes
- Accessible on institution intranet and internet.
## DOACs and potential drug interactions

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<td>VTE: ↓ dose to 30mg</td>
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</table>

See next page for more details. See next page for key.
Develop Patient and Family Education Curriculum

**Phone Education Appointment**
- Existing AMS patients transitioning to a DOAC
- Written materials mailed in advance
- Average time on phone: 20 minutes

**Office Education Appointment**
- New patient to AMS
- Average time: 30-60 minutes

**What does Apixaban (Eliquis®) do?**
- “blood thinner”
- Prevents or treats blood clots

**When to call 911 —Danger Signs—**
- Chest pain, discomfort in arms, back, neck, or jaw
- Trouble breathing
- Severe headache, confusion or numbness
- Sudden vision changes
- Stroke signs:
  - Fall or injury to your head
  - Throwing up blood (might be bright red or looks like coffee grounds)
  - Bleeding you cannot stop

**Anticoagulation Management Service**
**Patient and Family Education**

**What is your pill color and milligram (mg) strength?**
- Take 20mg and 15mg pills with food
- Can crush tablets and place in water or applesauce (use within 4 hours)

**Accessible on institution intranet and internet**
Develop DOAC Medication Guides – Spanish translations available (Betrixaban added)

Dabigatran (Pradaxa®)

Dabigatran (Pradaxa®) is used to prevent blood clots from forming in your body. It is sometimes called a blood thinner. It is used to:
- reduce risk of stroke and blood clots in atrial fibrillation;
- treat blood clots in the veins of legs (deep vein thrombosis) or lungs (pulmonary embolism) and reduce risk of them happening again;
- help prevent blood clots following hip replacement surgery

Apixaban (Eliquis®)

Apixaban (Eliquis®) is used to prevent blood clots from forming in your body. It is sometimes called a blood thinner. It is used to:
- reduce risk of stroke and blood clots in atrial fibrillation;
- treat blood clots in the veins of legs (deep vein thrombosis) or lungs (pulmonary embolism) and reduce risk of them happening again;
- help prevent blood clots following hip or knee replacement surgery

Edoxaban (Savaysa®)

Edoxaban (Savaysa®) is used to prevent blood clots from forming in your body. It is sometimes called a blood thinner. It is used to:
- reduce risk of stroke and blood clots in atrial fibrillation;
- treat blood clots in the veins of legs (deep vein thrombosis) or lungs (pulmonary embolism)

Do NOT STOP TAKING this medicine without talking to the doctor who prescribes it. This drug is NOT for use in people with mechanical heart valves or moderate to severe mitral stenosis.

This drug is NOT for use in people whose kidneys work really well and have atrial fibrillation.

If you have questions about or if you are experiencing side effects of edoxaban (Savaysa®), call your doctor.
Your doctor: ___________________ Telephone #: ___________________

Accessible on institution intranet, internet and Epic
Revised existing Patient Agreement to incorporate DOACs

Anticoagulation therapy (using oral blood thinning drugs such as warfarin (Coumadin®), apixaban (Eliquis®), dabigatran (Pradaxa®), or rivaroxaban (Xarelto®)) has certain risks. Being involved with your medical care, obtaining educational information, following instructions and asking questions are ways to help you be successful when taking blood thinning drugs. Safe management will help lower the risks of bleeding or clotting.

The choice of which blood thinning drug is best for you is a decision made by your doctor and you. There are important differences with each blood thinner. The Anticoagulation Management Service (AMS) can help you by providing education and monitoring progress.

As a patient in AMS, you are responsible to:

- Take your blood thinning drug exactly as instructed at the same time each day. If you are not absolutely certain of the dosage to take, call your nurse for clarification. DO NOT stop taking without talking to your doctor or AMS first.
- Notify the clinic as soon as possible if you forget to take your blood thinning drug. DO NOT take another tablet to “catch up”. If you miss only 1 day, resume your regular dose the next day and inform AMS.
- Maintain good communication with AMS. This includes having a working phone number for the AMS to reach you. I give permission for the AMS staff to leave pertinent information on an answering machine if necessary.
- Notify the AMS if you are seen in an urgent care center or emergency room. Tell any health care provider that is treating you that you are taking a blood thinner.
- Renew your blood thinning drug prescription with your doctor. Do this 2 weeks before your supply runs out or expires. Be sure your pill size does NOT change unless arranged by your AMS nurse.
- To prevent possible drug interactions, always tell health care providers who order new or change medications that you take a blood thinning drug. Start your newly prescribed medication AND notify the AMS.
- Report prolonged or unusual bleeding or bruising, pain swelling or discomfort to your AMS nurse. For serious symptoms, call 911 or report to an emergency room.
- If you consume alcohol, do so in moderation (no more than 1-2 drinks per day), if allowed by your doctor.
- Report travel plans and any changes in contact information (phone numbers, address changes) to your nurse.

If your doctor prescribed warfarin (Coumadin®), this drug requires periodic INR blood testing and follow-up by your warfarin (Coumadin®) manager in AMS.

- Have your INR blood tests as scheduled.
- Dose is based on pill size and color; confirm pill size is the same with all new warfarin (Coumadin®) prescriptions.
- Report changes in eating habits (including nutrition supplements), especially foods high in vitamin K. Your vitamin K intake must remain consistent.
- Report changes in activity level including new exercise programs.

I have read this document and understand the information. I agree to this contract agreement and will
Technical Challenges

- Mechanism or process to manage DOAC population
  - Purchase and install DOAC modules for DawnAC®
  - Staff training

- Create DOAC referral and renewal order with EHR
  - Staff and hospital staff training

- Interfaces with hospital systems
  - Outbound message from DawnAC® to populate AMS Icon for DOAC patients

- Develop strategy to measure and validate work
  - Patient risk stratification to guide follow-up and measure workload
  - Identify value to institution (safety and quality)
Develop a Referral specific to DOACs

Cascading options presented according to:
- Indication
- Drug/dose options
- Transitioning, if applicable
- Acknowledge renal/liver assessment
- Off label use statement

RNs complete worksheet to confirm eligibility
What we’re learning from “the first 100” DOAC patients

DOAC recruitment started May 30, 2017
Total active (as of 2/25/2019) = 252
(3) How would you characterize clinician time to care for these patients?

A. It’s the same
B. Warfarin takes more
C. DOAC takes more
D. I don’t know
A look at DOAC vs WARFARIN patient workload  
(7/22-8/25/2018, excludes education visits, 60 minutes either therapy)

<table>
<thead>
<tr>
<th>DOAC</th>
<th>Volume</th>
<th>Time in Minutes</th>
<th>Total Time in Minutes</th>
<th>Warfarin</th>
<th>Volume</th>
<th>Time in Minutes</th>
<th>Total Time in Minutes</th>
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<tbody>
<tr>
<td>Candidate QNR</td>
<td>18</td>
<td>30</td>
<td>540</td>
<td>Authorized INRs</td>
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<td>Induction</td>
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<td>Low Risk</td>
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<td>15</td>
<td>330</td>
<td>Low</td>
<td>91</td>
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<tr>
<td>High Risk</td>
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<td>17</td>
<td>680</td>
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<td>79</td>
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<tr>
<td>Manual/Bridging</td>
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<td>Total Minutes/month</td>
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<td>Total Active Warfarin Patients</td>
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<td>Minutes Per Patient/month</td>
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<td>Minutes Per Patient/month</td>
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What will your clinic monitor?

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<tr>
<th>Quality &amp; Safety Issues</th>
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<td>Identified dose adjustment needed</td>
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<td>Non-adherence</td>
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<td>Off-label use</td>
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<td>Use in HD</td>
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<td>Concomitant food/drug interactions</td>
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<tr>
<td>Transitions among anticoagulant agents and care settings</td>
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<tr>
<td>VTE dose reduction after 6 months standard treatment</td>
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<td>Clinical Events</td>
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Disseminate information

Google: mgh eed
http://www.mghpcs.org/eed_portal/
Guidelines state “periodic monitoring is needed”, however no definitive plan recommended. Therefore develop a plan and:

- Evaluate ongoing practices, incorporate updates and modify accordingly
- Communication is essential
- Address educational needs for clinical providers and patients/families