Implementing a monitoring program for patients on direct oral anticoagulants

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Service

- Backus Hospital Medication Management Clinic located in Norwich, CT provides a newly implemented Direct Oral Anticoagulant (DOAC) management service.
- **Patient population**: patients with non-valvular atrial fibrillation or venous thromboembolism
- **Role of clinical pharmacist:**
  - Initiation of DOAC therapy
  - Monitors for the efficacy and safety of DOAC therapy
  - Provides education on the benefits and risks of DOAC therapy
- **Pharmacist Evaluation:**
  - Lifestyle (diet and exercise)
  - Renal function
  - Drug-drug interactions and other medications use
- Clinical pharmacist communicates to the referring physicians on any significant concerns or recommendations with DOAC therapy.
- The referred patients will be discharged from the clinic when they have been on DOAC for an extended duration (typically >6 months).
- Prior to discharge, the patients will be assessed to ensure that they are well-educated on signs and symptoms of adverse events to DOAC agents and what actions to take if these events were to arise.

Justification

- Many providers choose a DOAC for anticoagulation because of the ease of administration and fewer drug and food interactions.
- A number of providers, however, forego any follow-up with patients on DOAC agents believing it is unwarranted.
- On the contrary, a growing body of evidence and expert opinion supports the importance of follow-up monitoring for these patients.
- **Pharmacist interventions:**
  - Patients' adherence
  - Monitoring for adverse events
  - Improve health outcomes

Adaptability

- DOAC management service can be implemented in pharmacist-driven anticoagulation clinics.
- Many anticoagulation clinics are already staffed with healthcare professionals, who are well trained at evaluating and educating patients for the signs and symptoms of thrombosis and bleeding.
- The same concept along with renal function monitoring is applied in this DOAC management program.

Significance

- The role of a clinical pharmacist is expanding rapidly in the healthcare world in which the pharmacist is gaining more responsibilities as a valuable member of a healthcare team. Since the use of DOACs is on the rise, DOAC management program driven by pharmacist will enhance patient care and safety along with expanding the pharmacist's role in anticoagulation care.

Referral System

1. Diagnosis
   a. Non-valvular atrial fibrillation (NVAF)
   b. Venous thromboembolism (VTE)
2. Direct Oral Anticoagulant of Choice

	Pradaxa® (dabigatran)	Xarelto® (rivaroxaban)	Eliquis® (apixaban)	Savaysa® (edoxaban)
Class	Direct thrombin (IIa) inhibitor	Direct Factor Xa inhibitor	Direct Factor Xa inhibitor	Direct Factor Xa inhibitor
Dosing	NVAF: 150 mg BID DVT/PE: 150 mg BID after 5 to 10 days of parenteral anticoagulation	NVAF: 20 mg daily DVT/PE: 15 mg BID x 21 days, then 20 mg daily	NVAF: 5 mg BID DVT/PE: 10 mg BID x 7 days, then 5 mg BID	NVAF: 60 mg daily DVT/PE: 60 mg daily after 5 to 10 days of parenteral anticoagulation

3. Duration of Anticoagulation Therapy
   a. Indefinite, 3 months, 6 months, or 1 year
4. Other Anticoagulation Status
   a. Current use of oral anticoagulant or LMWH
5. Relevant Past Medical History

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DOAC Monitoring Checklists

The "ABCDEF" of direct oral anticoagulant management

Xarelto (rivaroxaban) Follow-up Checklist

Indication: _____ DATE: _____

Adherence
- # of missed doses in an average week? _____
- Using pillbox? Yes or No
- Pill counting – last pill count: _____ today's pill count: _____

Bleeding Risk
- Lab – H/H (date): _____ PLT (date): _____
  - ○ Decreasing hemoglobin or new anemia? Yes or No
- Circle any episodes or symptoms
  Epistaxis Hemoptysis Excessive hematomas Hematemesis Melena Hematuria
  Fall EtOH overuse Syncope (presyncope) Seizure Uncontrolled HTN

CrCl/Drug Interactions
- HT: _____ WT: _____ SCr (date): _____ eCrCl: _____

CrCl (mL/min)	>50	30-50	15-30
No DDI	15 mg BID x 21 days, then 20 mg daily (VTE) 20 mg daily (NVAF)	No adjustment (VTE) 15 mg daily (NVAF)	Avoid (VTE) 15 mg daily (NVAF)

- ***Avoid concomitant use with P-gp inducers, P-gp and strong CYP 3A4 inducers, and P-gp and strong CYP3A4 inhibitor (diltiazem, verapamil, dronedarone, erythromycin)
- Antiplatelet therapy: Yes or No IF Yes, Name: _____
- Other significant drug interactions: _____

Education
- ☐ Benefit and rationale for continued use of Xarelto (rivaroxaban)
- ☐ Review signs and symptoms of bleeding and actions to take when occurs
- ☐ Review signs and symptoms of thrombosis and actions to take when occurs
- ☐ Dosing instruction, importance of adherence, and handling of a missed dose
- ☐ Avoid OTC ASA & NSAIDs & minimizing EtOH to reduce bleeding risks
- ☐ Other:
  - ○ Take it with evening meal (or foods) if 15mg or 20mg once daily dosing
  - ○ Lactose intolerance – rivaroxaban may contain lactose or galactose

Final Assessment and Plan/Follow-up
- ☐ VTE patient on Day 21 – change dosing from 15mg BID to 20 mg daily
- Patient appears to be stable on Xarelto (rivaroxaban)? Yes or No
- Continue Xarelto (rivaroxaban) at same dose? Yes or No
  - ○ If No, dose adjusted? Specify: _____

Pradaxa (dabigatran) Follow-up Checklist

Indication: _____ DATE: _____

Adherence
- # of missed doses in an average week? _____
- Using pillbox? Yes or No
- Pill counting – last pill count: _____ today's pill count: _____

Bleeding Risk
- Lab – H/H (date): _____ PLT (date): _____
  - ○ Decreasing hemoglobin or new anemia? Yes or No
- Circle any episodes or symptoms
  Epistaxis Hemoptysis Excessive hematomas Hematemesis Melena Hematuria
  Fall EtOH overuse Syncope (presyncope) Seizure Uncontrolled HTN

CrCl/Drug Interactions
- HT: _____ WT: _____ SCr (date): _____ eCrCl: _____

CrCl (mL/min)	>50	30-50	15-30
No DDI	150 mg BID	150 mg BID	75 mg BID (NVAF) Avoid (VTE)
P-gp inducer	Avoid	Avoid	Avoid
P-gp inhibitor	150 mg BID	75 mg BID (NVAF) Avoid (VTE)	Avoid

- Antiplatelet therapy: Yes or No IF Yes, Name: _____
- Other significant drug interactions: _____

Education
- ☐ Benefit and rationale for continued use of Pradaxa (dabigatran)
- ☐ Review signs and symptoms of bleeding and actions to take when occurs
- ☐ Review signs and symptoms of thrombosis and actions to take when occurs
- ☐ Dosing instruction, importance of adherence, and handling of a missed dose
- ☐ Avoid OTC ASA & NSAIDs & minimizing EtOH to reduce bleeding risks
- ☐ Other:
  - ○ Take with a full glass of water without regard to meals to prevent dyspepsia
  - ○ Store tablets in original package to protect from moisture
  - ○ Do no break, chew, or open capsules – increases absorption by 75%

Final Assessment and Plan/Follow-up
- Patient appears to be stable on Pradaxa (dabigatran)? Yes or No
- Continue Pradaxa (dabigatran) at same dose? Yes or No
  - ○ If No, dose adjusted? Specify: _____

Eliquis (apixaban) Follow-up Checklist

Indication: _____ DATE: _____

Adherence
- # of missed doses in an average week? _____
- Using pillbox? Yes or No
- Pill counting – last pill count: _____ today's pill count: _____

Bleeding Risk
- Lab – H/H (date): _____ PLT (date): _____
  - ○ Decreasing hemoglobin or new anemia? Yes or No
- Circle any episodes or symptoms
  Epistaxis Hemoptysis Excessive hematomas Hematemesis Melena Hematuria
  Fall EtOH overuse Syncope (presyncope) Seizure Uncontrolled HTN

CrCl/Drug Interactions
- HT: _____ WT: _____ SCr (date): _____ eCrCl: _____

# of characteristics: Age ≥ 80 yrs, weight ≤60 kg, SCr ≥1.5 mg/dL	0-1 (VTE)	2-3
No DDI	10 mg BID x 7 days, then 5 mg BID (5 mg BID for NVAF)	2.5 mg BID
P-gp inducer or Strong CYP3A4 inducer	Avoid	Avoid
Dual strong P-gp and CYP3A4 inhibitor	2.5 mg BID	Avoid

- ***VTE indication – no dose adjustment needed for above patient characteristics.
- Avoid if CrCl <25 mL/min or SCR >2.5 mg/dL
- Antiplatelet therapy: Yes or No IF Yes, Name: _____
- Other significant drug interactions: _____

Education
- ☐ Benefit and rationale for continued use of Eliquis (apixaban)
- ☐ Review signs and symptoms of bleeding and actions to take when occurs
- ☐ Review signs and symptoms of thrombosis and actions to take when occurs
- ☐ Dosing instruction, importance of adherence, and handling of a missed dose
- ☐ Avoid OTC ASA & NSAIDs & minimizing EtOH to reduce bleeding risks

Final Assessment and Plan/Follow-up
- ☐ VTE patient on Day 8 – change dosing from 10mg BID to 5 mg BID
- Patient appears to be stable on Eliquis (apixaban)? Yes or No
- Continue Eliquis (apixaban) at same dose? Yes or No
  - ○ If No, dose adjusted? Specify: _____

Savaysa (edoxaban) Follow-up Checklist

Indication: _____ DATE: _____

Adherence
- # of missed doses in an average week? _____
- Using pillbox? Yes or No
- Pill counting – last pill count: _____ today's pill count: _____

Bleeding Risk
- Lab – H/H (date): _____ PLT (date): _____
  - ○ Decreasing hemoglobin or new anemia? Yes or No
- Circle any episodes or symptoms
  Epistaxis Hemoptysis Excessive hematomas Hematemesis Melena Hematuria
  Fall EtOH overuse Syncope (presyncope) Seizure Uncontrolled HTN

CrCl/Drug Interactions
- HT: _____ WT: _____ SCr (date): _____ eCrCl: _____

CrCl (mL/min)	>95*	50-95	15-50
No DDI	Avoid (NVAF)* 60 mg daily (VTE)	60 mg daily	30 mg daily
P-gp inducer	Avoid	Avoid	Avoid
P-gp inhibitor	Avoid (NVAF)* 30 mg daily (VTE)	60 mg daily (NVAF) 30 mg daily (VTE)	30 mg daily

- ***VTE indication – 30 mg daily if weight ≤60 kg.
- Avoid if CrCl <15 mL/min
- Antiplatelet therapy: Yes or No IF Yes, Name: _____
- Other significant drug interactions: _____

Education
- ☐ Benefit and rationale for continued use of Savaysa (edoxaban)
- ☐ Review signs and symptoms of bleeding and actions to take when occurs
- ☐ Review signs and symptoms of thrombosis and actions to take when occurs
- ☐ Dosing instruction, importance of adherence, and handling of a missed dose
- ☐ Avoid OTC ASA & NSAIDs & minimizing EtOH to reduce bleeding risks

Final Assessment and Plan/Follow-up
- Patient appears to be stable on Savaysa (edoxaban)? Yes or No
- Continue Savaysa (edoxaban) at same dose? Yes or No
  - ○ If No, dose adjusted? Specify: _____

Reference: Gladstone DJ, Geerts WH, Douketis J, et al. How to monitor patients receiving direct oral anticoagulants for stroke prevention in atrial fibrillation: a practice tool endorsed by Thrombosis Canada, the Canadian Stroke Consortium, the Canadian Cardiovascular Pharmacists Network, and the Canadian Cardiovascular Society. *Ann Intern Med* 2015;163:382-5.