Developing an Anticoagulation Clinic

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Faculty Disclosure
• Dr. Rizal has no actual or potential conflict of interest associated with this presentation

Learning Objectives
• At the conclusion of this activity, pharmacists will be able to:
  – Discuss the benefits of establishing an anticoagulation clinic
  – List the steps required to establish and run an anticoagulation clinic
  – Describe the important aspects of operating an anticoagulation clinic
  – Describe the financial considerations of running an anticoagulation clinic

Why do we need an Anticoagulation Clinic?
• Warfarin is still being used
  – High risk medication with a narrow therapeutic index and variable INR results requiring ongoing monitoring
  – Effective communication essential part of management
  – Management of INR requires considerations of pt’s compliance, diet, etoh use, interacting medications, co-morbidities, age, and genetic predisposition
• NOAC not appropriate for all patients
  – Determine which patients are appropriate for transitioning to NOAC
  – Assist with transition to/from NOAC
  • Determine correct dose, frequency
  • Look at pt’s medication profile to ensure no interacting medications
  • Assess compliance

Advantages of Anticoagulation Clinic

<table>
<thead>
<tr>
<th>Advantages to pt.</th>
<th>Advantages to institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finger-stick INR less invasive</td>
<td>Staff specialized in anticoagulation management often with additional education and training</td>
</tr>
<tr>
<td>Formalized patient education (reduced understanding of disease state, improved adherence to medication) Personalized care and education on education. Staff educated about thromboembolic and bleeding risks and associated risk factors.</td>
<td>Staff focused on anticoagulation management if improved communication and patient follow up.</td>
</tr>
<tr>
<td>Patient focused, removes potential for dosing errors</td>
<td>Staff follows approved protocols resulting in consistent dosing and monitoring</td>
</tr>
<tr>
<td>Clinics afford pt’s time to have contact with health care provider and take charge of their health care services by appropriate provider when results are decreased need for hospital services.</td>
<td>Track effectiveness of treatment and monitor. An improved TTR has better clinical outcomes</td>
</tr>
<tr>
<td>Anticoagulation clinic staff can educate other health care providers to provide optimal patient care</td>
<td>Anticoagulation clinic staff can coordinate other health care providers to provide optimal patient care</td>
</tr>
<tr>
<td>Improved clinical outcomes and patient satisfaction</td>
<td></td>
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</tbody>
</table>
Establish Need for Service and Get Institution Backing

- Joint commission 2015 National Patient Safety Goals
  - Defined anticoagulant management program
  - Designed to reduced risk of adverse events associated with use of anticoagulants
  - Specified in writing
  - Individualized anticoagulation therapy for each pt
  - Use standardized practice
  - Patient involvement
- P&T Committee
  - Clinical trial results show benefit of anticoagulation clinic service
  - Adverse events reports
  - Financial benefit to institution

Financial Considerations

- Operating budget
  - Start up Costs
    - Supplies
    - Office furniture
    - Refrigeration for cartridges
    - Point of care analyzer
    - Computer
    - Printer
    - Fax
    - Software
    - Anticoagulation software acquisition cost
    - Telecommunication needs
  - Ongoing Costs
    - Personnel salaries
    - Overhead-rent, utilities etc..
    - Printer and POC analyzer cartridges
    - Anticoagulation software renewal costs
    - Accreditation
    - Supplies

Select Medical Director

- Extensive anticoagulation clinical knowledge
  - Cardiologist, Hematologist
- Strong advocate for clinic
  - Educate and garner support of medical staff
  - Provides clinical and administrative support to anticoagulation clinic staff
  - Help achieve goals that you’ve set for the clinic
- Approachable and available
  - Set up regular meetings to discuss administrative and clinical issues

Define Purpose

- Having a clearly defined purpose helps guide your decision making as you develop your clinic
  Example:
  To provide all UConn Health patients with optimal dosing and monitoring of anti-coagulation therapy in order to prevent new or recurrent thromboembolic events and to avoid adverse drug events in a cost-effective manner

Goals of Anticoagulation Clinic

- Primary Goals
  - Optimal Efficacy
    - Help determine the appropriateness of care
    - Provide systematic and reproducible warfarin dosing, monitoring and patient evaluation
    - Provide patient education
  - Optimal Safety
    - Provide ongoing patient and provider education
    - Communicate with other providers involved in the patient’s care
    - Minimize adverse events, hospitalizations and ED visits associated with anticoagulation use
- Secondary Goals
  - Efficiency
  - Cost-effectiveness of care
  - Patient Satisfaction
  - Improve quality of life

Scope of Service

- Considerations
  - Anticoagulation Clinic providers will often be first point-of-contact for patients with health inquiries
  - Medication reconciliation
  - Monitoring vital signs
  - Dispensing medication
  - Limit scope of service to something that is achievable with staffing limitations
Define Target Patient Population

- Consider reimbursement issues for each:
  - Telephone Managed Patients
  - Nursing home/hospitalized
  - Assisted living facility
  - Patients with limited mobility
  - Patients with VNA services
  - Patients with at home POC self-testing meters

  Challenges:
  - Delay follow up of lab results
  - Communication Issues
  - Limited information available
  - Unreimbursed if hospital based clinic

- Clinic Patients
  - Reimbursed for services
  - Increased cost to patient
  - Travel considerations for the patient

  - INR range
  - Indication
  - Non-compliant patients
  - Unreliable patients
  - Patients with active alcohol or drug abuse
  - Patients with history of bleeding
  - High risk patients

Determine Staffing Model

- Determine Staffing Model
  - MD
  - RN
  - PA
  - APRN
  - RPh or Pharm. D.
  - Pharmacy Technician
  - Receptionist
  - Combination

- Consider
  - Advantages and disadvantages of each
  - Consider financial implications
  - Consider potential staffing shortages due to vacations, sick days

Staff Advantages/Disadvantages

<table>
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<tr>
<th>Staff</th>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
<tbody>
<tr>
<td>MD</td>
<td>• Prescriptive authority</td>
<td>• Care is not focused on anticoagulation</td>
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<tr>
<td></td>
<td>• Autonomy in both dosing and billing</td>
<td>• Time spent on anticoagulation management could be better utilized</td>
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<tr>
<td></td>
<td>• Extensive knowledge of warfarin’s pharmacokinetic and pharmacodynamic</td>
<td>• $$$</td>
</tr>
<tr>
<td></td>
<td>properties</td>
<td>• Care is not focused on anticoagulation</td>
</tr>
<tr>
<td></td>
<td>• Work autonomously under collaborative practice agreement with pharmacist</td>
<td>• $$$</td>
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<td>• Would require extensive training to ensure clinical competency</td>
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<td>APRN/PA</td>
<td>• Prescriptive authority</td>
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<td></td>
<td>• Cost effective</td>
<td>• Therapeutic summaries to providers</td>
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<tr>
<td>RN</td>
<td>• $$$</td>
<td>• Unable to cross train thus limited usefulness</td>
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<tr>
<td></td>
<td>• Able to draw venous samples and assess vital signs</td>
<td>• Unable to cross train thus limited usefulness</td>
</tr>
<tr>
<td></td>
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<td>Pharmacy</td>
<td>• $$$</td>
<td>• Therapeutic summaries to providers</td>
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<tr>
<td>Technician</td>
<td>• Can work under direct supervision of pharmacist</td>
<td>• Therapeutic summaries to providers</td>
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<tr>
<td></td>
<td>• Can cross train to cover various tasks as determined by clinic needs</td>
<td>• Therapeutic summaries to providers</td>
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<td>Receptionist</td>
<td>• $$$</td>
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Determine Staffing Needs

- Anticipate number of patients to be managed
- Determine number of staff needed accordingly
- Reassess staffing periodically

Staffing Considerations

- Clinic Tasks
  - Schedule patient appointments in the clinic for initial visit, follow up INR visits and education visits
  - Ensure compliance with regulatory bodies
  - Send monthly therapeutic summaries to providers if working under collaborative practice agreement
  - Ensure timely renewal of anticoagulation clinic referral and collaborative practice agreement
  - Ensure appropriateness of billing practices under incident to agreement
  - Facilitate continuity of care for patients during brief interruptions to therapy including developing bridging plan as required
  - Perform quality control analysis
  - Monthly liquid quality control of cartridges with each shipment/lot number
  - Daily electronic simulator test
  - Periodic proficiency testing
  - % Therapeutic
  - % Non-therapeutic
  - Identify non-therapeutic patients and reassess periodically to determine appropriateness of treatment
  - Performance quality control analysis
  - Monitor liquid quality control of cartridges with each shipment/lot number
  - Daily electronic simulator test
  - Periodic proficiency testing
  - % Therapeutic
  - % Non-therapeutic
  - Identify non-therapeutic patients and reassess periodically to determine appropriateness of treatment

Staffing Considerations continued

- Staffing Considerations continued
  - Bill for services rendered
  - Process refills
  - Consult with physicians as required by clinic specific policies and procedures
  - Order supplies
  - Staff supervision
  - Staff development and training
  - Serve as a resource for patients and providers
  - Monthly liquid quality control of cartridges with each shipment/lot number
  - Daily electronic simulator test
  - Periodic proficiency testing
  - % Therapeutic
  - % Non-therapeutic
  - Identify non-therapeutic patients and reassess periodically to determine appropriateness of treatment
Match clinic task to appropriate anticoagulation clinic staff member

<table>
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<tr>
<th>Task</th>
<th>Staff Member</th>
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<tr>
<td>Formalized patient education</td>
<td>Receptionist</td>
</tr>
<tr>
<td>Bill for services</td>
<td></td>
</tr>
<tr>
<td>Develop bridging plan</td>
<td></td>
</tr>
<tr>
<td>Order supplies</td>
<td>Pharmacy technician</td>
</tr>
<tr>
<td>Make reminder calls for past due INR patients</td>
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<tr>
<td>Staff supervision</td>
<td>Pharmacist</td>
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<tr>
<td>Interpret and address INR results</td>
<td>Pharmacist</td>
</tr>
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Qualification of Personnel

- ACC providers should meet minimum competencies and hold a license in a patient-oriented health-related field (e.g., Medicine, nursing, pharmacy)
  - Ability to communicate with patients and anticoagulation providers
  - Skills to authorize and coordinate follow-up with patients and other health care providers
- Receptionist
  - Excellent interpersonal communication
  - Computer and data entry skills
- Certified Pharmacy Technician
  - Excellent interpersonal communication
  - Computer and data entry skills
  - Maintain pharmacy technician certification

Writing Job Description

- Write the job description after carefully analyzing the staffing model, clinic tasks, qualifications needed to complete various clinic tasks
- A well-written job description will be useful in managing employees
- Make the job description flexible to allow for changes and growth
- The job description should be practical, clear and accurate to effectively define your needs
- Include
  - Job title
  - Job objective or overall purpose statement
  - Summary of the general nature and level of the job
  - Description of the broad function and scope of the position
  - List of duties or tasks performed critical to success
  - Key functional and relational responsibilities in order of significance
  - Description of the relationships and roles within the company, including supervisory positions, subordinating roles and other working relationships
  - Salary
  - Work with Human Resources on proper language

Establish roles and responsibilities

- Determine once staffing model established
- Consider clinic tasks and delineate responsibilities to most appropriate staff member
- Clearly define roles and responsibilities of patients, staff members and physicians in the policies and procedures
- Include any change in responsibilities that arise due to staffing considerations
- Ensure all patients, physicians and staff are aware of his/her roles and responsibilities through adequate training
- Reinforce roles and responsibilities through proper supervision and periodic staff evaluation
- Continually update policies and procedures and re-train as necessary for any changes in responsibilities that arise due to changes in the clinic

Sample roles and responsibilities

1. The Anticoagulation Patient will
   a. Follow Anticoagulation Service instructions regarding anti-coagulation dosing and monitoring
   b. Notify the Anti-coagulation Service with any changes to medications (including OTC or herbal products), diet, or medical conditions
   c. Notify the Anti-coagulation Service with any planned medical testing or intervention so temporary cessation of Anti-coagulation therapy can be considered
   d. Have clinic visit and anti-coagulation assessment with UConn Health referring provider or UConn Health PCP at least annually
2. The Anticoagulation Technician or Support Staff will
   a. Answer, schedule, reschedule patients in C2S Live
   b. Assist with coordinating patient care with home health agencies, skilled nursing facilities, and laboratories
   c. Examine patient compliance with PT/INR monitoring by generating reports of patient overdue for INRs and contacting these patients in a timely manner by phone and/or letter
   d. Assist the Anti-coagulation specialist with any planned medical testing or intervention so temporary cessation of Anticoagulation therapy can be considered
   e. Manage the clinic correspondence with patients and providers
   f. Manage the clinic correspondence with patients and providers
   g. Manage the clinic correspondence with patients and providers
   h. Document any contacts or attempted contact with the patient or any agent thereof except for upcoming appointment reminder calls
   i. Communicate with patients who do not attend scheduled clinic visits, as per clinic guidelines
   j. Attend the clinic appointment with the Anti-coagulation. The Anti-coagulation specialist will assume the above responsibilities
Question

Establishing roles and responsibilities for the patient will ensure:

a. Adherence to prescribed anticoagulation dosing regimen
b. Improved communication
c. Compliance with regulatory and policy requirements
d. All of the above
e. None of the above

Training

- Used to establish standard of care
- Helps ensure reproducible results irrespective of staff member
- Content and time to complete will vary as determined by staff roles and responsibilities
- May be written, oral, audiovisual or a combination of the all 3
- May need to be modified to suit the learning needs of the trainee
- Should include assessment to ensure adequate understanding and competence
- Should be provided in an appropriate learning environment
- Should involve real world situations
- Gradually increase workload of the trainee until they are fully competent
- Document
  - Type of training provided
  - Date training was provided
  - Indicate who provided and received the training by having each individual sign and date
- Keep records of the training provided and assessments completed by all staff members in an appropriate manner
- Update periodically to keep up with changes within the clinic

Anticoagulation Provider Training Example

The training will consist of a didactic portion and practical experience. For the didactic portion, all Anti-coagulation specialists must complete one of the following educational requirements:

- Complete all of the learning objectives in the “Anticoagulation Clinic Specialist Training”
- Complete available educational activities in the following areas:
  - Anticoagulant Monitoring
  - Extended Anticoagulation Prophylaxis post-hospitalization
  - New Oral Anticoagulants
  - Hematologic Mucocutaneous Weight Heimar and Fondaparinux Pharmacology and Pharmacotherapy
  - Direct Thrombin Inhibitor Pharmacology and Pharmacotherapy
  - Pharmacologic Reversal for Anticoagulation Services
  - Risk Management in Anticoagulation
- Training will be provided to the Anti-coagulation specialists on the appropriate use and maintenance of the point of care testing devices
- All Anti-coagulation specialists must show proficiency by successfully passing the anticoagulation clinic credentialing and STAT competency tests with a score of 90%.
Supervision

• Clearly establish chain of command
• Designated supervisor in the clinic will:
  – Field difficult patient/provider care concerns
  – Address disciplinary issues
  – Performance evaluations of all clinic staff
  – Direct and lead staff to ensure smooth operation of clinic

Question

Which of the following is useful when supervising challenging personnel?
A. Job description
B. Training
C. Roles and responsibilities
D. All of the above
E. None of the above

Develop Written Policies and Procedures

• Include:
  – Purpose and goals
  – Scope of services
  – Roles and responsibilities of patients and clinic staff
  – Training and competency requirements
  – Criteria for physician consultation
  – Process for managing critically high INR’s
  – Referral process—include inclusion/exclusion criteria
  – Patient education session content and method of delivery
  – Initial laboratory monitoring
  – Warfarin initial and maintenance dose adjustment guidelines
  – Thromboembolic/Hemorrhagic risk assessments

• Things to keep in mind:
  – Keep dosing nomograms flexible to allow clinical judgment
  – Limit liability by including appropriate discharge criteria and identification and management of high risk patient
• Sample collaborative practice agreement
  http://pharmacy.uchc.edu/services/anticoagulation/pdfs/agreement_collaborative_practice.pdf
Determine Clinic Hours

- Possible weekend or evening hours to accommodate working patients
- Consider coverage, staffing levels during vacations

Health and Safety Considerations

- Safe finger-stick blood tests
- Glove/eye protection policy
- Sharps disposal
- Needle-stick injury procedure
- Hepatitis vaccination and antibody testing
- Safe use of liquid quality controls

Collaborative Practice Agreement Considerations

- Yearly collaborative practice agreement renewal for each patient with each provider
- Yearly visit with referring provider
- Minimum monthly therapeutic summaries
- Pharmacists may not enter into collaborative practice agreements with APRNs, PAs
- Prescription refills

Anticoagulation Software Selection Considerations

- Fields to enter goal INR range, indication for therapy, monitoring sites, medication list, referring md information, patient contact information, thromboembolic/hemorrhagic risk, lab results, pharmacy information, patient allergies, patient specific notes which all providers need to be aware of, side-effects, intake dosing, eliminate dosing, labeled strength, bridge therapy, those that need future follow-up
- Generate patient handouts, reminder and discharge letters
- Dosing assistance or calculate % change from previous week's regimen
- Data integrity
- Interface with institution EMR
- Web-based anticoagulation specific software vs. homegrown system
- Ensure hardware and internet connectivity adequate for software being selected
- IT support during clinic hours
- Downtime procedures
- Customizable reports eg. list of patients by indication, referring md.
- Adverse events report
- Issues report

Quality Control and Assurance

- Personnel
  - Through effective management and ongoing training and evaluation
- Patients
  - Run reports periodically to determine TTR, identify non-therapeutic and high-risk patients and discuss with providers as needed

References

- Ansell, Jack E et. Al, Managing Oral Anticoagulation Therapy Clinical and Operational Guidelines
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- https://www.sba.gov/content/writing-effective-job-descriptions