

Developing an Anticoagulation Clinic

By: Dr. Anuja Rizal Pharm. D., RPh., CACP
Clinical Coordinator
UConn Health Anticoagulation Clinic

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Faculty Disclosure

- Dr. Rizal has no financial relationships with any ineligible companies

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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

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Why do we need an Anticoagulation Clinic?

- Anticoagulation clinics evolving
 - Manage direct oral anticoagulants (DOACs), heparin, LMWH, fondaparinux as well as warfarin
 - Select appropriate anticoagulation agent based on patient specific parameters
 - Determine which patients are appropriate for transitioning between anticoagulants and assist with the transition
 - Act as an anticoagulation information resource for interdisciplinary team
- Patients on anticoagulation therapies require:
 - Patient/family education
 - Periodic assessment of
 - ADRs including thromboembolic and bleeding events
 - Adherence (refill history, pill count)
 - Appropriateness and duration of anticoagulation therapy
 - Baseline and routine monitoring of renal and hepatic function, CBC
 - Agent specific monitoring
 - Warfarin- INR, drug-drug, drug-food interactions, changes in activity/health
 - DOACs- baseline and periodic renal and hepatic function, weight
 - Injectable anticoagulants- anti Xa and aPTT levels

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Advantages of Anticoagulation Clinic

Advantages to pt.	Advantages to institution
Finger-stick INR less invasive	Staff specialized in anticoagulation management often with additional education and training
Formalized patient education improved understanding of disease state. Improved adherence to medication. Pts educated about thromboembolic and bleeding risks and instructed on signs and symptoms thus decreased adverse events.	Staff focused on anticoagulation management thus improved communication and patient follow up
Patient handout decreases potential for dosing errors	Staff follow approved protocols resulting in consistent dosing and monitoring
Clinic visits afford pt's face to face contact with health care provider who can bridge patients health care concerns to appropriate provider which results in decreased need for hospital services eg. ER visits	Track effectiveness of treatment and modify as needed resulting in improved TTR thus better clinical outcomes
Anticoagulation clinic staff can coordinate other health care providers to provide optimal patient care	Cost effective approach <ul style="list-style-type: none"> • Generate revenue for institution • Improved efficiency in the use of resources eg. Doctor/RN time • Decreased overall health care costs by minimizing complications and maximizing effectiveness
Improved clinical outcomes and patient Satisfaction	

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How to Get Started

1. Establish Need for Service and get institution backing
2. Financial considerations
3. Select medical director
4. Clearly define
 - Purpose
 - Goals
 - Scope of services
 - Target patient population
5. Determine staffing needs
6. Establish roles and responsibilities of staff
7. Establish training and qualification requirements for staff
8. Establish supervision
9. Written policies and procedures
10. Quality control
11. Other considerations
 - Clinic Hours
 - Health and Safety
 - Collaborative Practice

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Establish Need for Service and Get Institution Backing

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

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Financial Considerations

- Operating budget
 - Set up considerations and costs
 - Dedicated office space and any renovations needed
 - Supplies
 - Office furniture
 - Refrigerator for cartridges
 - Point of care analyzer
 - Computer
 - Printer
 - Fax
 - Scanner
 - 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

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Select Medical Director

- Extensive anticoagulation clinical knowledge
 - Cardiologist, Hematologist
- Strong advocate for clinic
 - Educate and garnish 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

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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.

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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 ER visits associated with anticoagulation use
- Secondary Goals
 - Efficiency
 - Cost-effectiveness of care
 - Patient Satisfaction
 - Improve quality of life

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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

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Define Target Patient Population

- Consider reimbursement issues for each:
 - Telephone Managed Patients
 - Nursing home/INR/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 result
 - Communication issues
 - Limited information available
 - 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

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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

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Staff Advantages/Disadvantages

Staff	Advantages	Disadvantages
MD	<ul style="list-style-type: none"> • Prescriptive authority • Autonomy in both dosing and billing • Extensive knowledge of anticoagulation medication pharmacokinetic and pharmacodynamic properties 	<ul style="list-style-type: none"> • SSSSS • Care is not focused on anticoagulation • Time spent on anticoagulation management could be better utilized elsewhere
APRN/PA	<ul style="list-style-type: none"> • Prescriptive authority • Autonomy in both dosing and billing* 	<ul style="list-style-type: none"> • SSSS • Would require extensive training to ensure clinical competency • Cannot work under collaborative practice agreement with pharmacist
RN	<ul style="list-style-type: none"> • \$\$\$ • Able to draw venous samples and assess vital signs • Work under established policies and protocols 	<ul style="list-style-type: none"> • No prescriptive authority • Would require extensive training to ensure clinical competency • Cannot work under collaborative practice agreement • Incident to billing
RPh/Pharm D.	<ul style="list-style-type: none"> • Extensive knowledge of anticoagulation medication pharmacokinetic and pharmacodynamic properties • Work autonomously under collaborative practice agreement with MD 	<ul style="list-style-type: none"> • SSSS • No prescriptive authority • Incident to billing • Collaborative practice agreement requires yearly renewal and monthly therapeutic summaries to providers
Pharmacy Technician	<ul style="list-style-type: none"> • \$\$ • Can work under direct supervision of pharmacist • Can cross train to cover various areas as determined by clinic needs 	<ul style="list-style-type: none"> • Can only work under direct supervision of pharmacist
Receptionist	<ul style="list-style-type: none"> • \$\$ • Cost effective 	<ul style="list-style-type: none"> • Unable to cross train thus limited usefulness

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Determine Staffing Needs

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

Clinic Workload Estimate

This chart assumes 15 minute appointments and clinic running on 40 weeks/year

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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 yearly renewal of anticoagulation clinic referral and collaborative practice agreement
 - Ensure appropriateness of billing practices under incident to
 - Provide formalized patient education
 - Facilitate continuity of care for patients during brief interruptions to therapy including developing bridging plan as required
 - Retrieve INR results either from an outside laboratory, venipuncture or fingerstick tests within the clinic
 - Interpret INR results by assessing patient specific factors and adjust warfarin dose as needed
 - Inform patients or designated family members of INR results, warfarin dosing and follow up INR date
 - Identify past due INR patients and address as per policies and procedures
 - Triage telephone calls to appropriate personnel

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Staffing Considerations continued

- Clinic Tasks
 - Bill for services rendered
 - Process refills
 - Consult with physicians as required as determined by clinic specific policies and procedures
 - Order supplies
 - Staff supervision
 - Staff development and training
 - Serve as a resource for patients and providers
 - Perform quality control analysis
 - Monthly liquid quality control of cartridges with each new shipment/lot #
 - Daily electronic simulator test
 - Periodic proficiency testing
 - % Therapeutic
 - Identify non-therapeutic patients and reassess periodically to determine appropriateness of treatment

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Match clinic task to appropriate anticoagulation clinic staff member

Formalized patient education	Receptionist
Bill for services	
Develop bridging plan	Pharmacy Technician
Order supplies	
Make reminder calls for past due INR patients	Pharmacist
Staff supervision	
Interpret and address INR results	

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Match clinic task to appropriate anticoagulation clinic staff member

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Qualification of Personnel

- ACC providers should meet minimum competencies and hold a license in a patient-oriented health-related field (eg. 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

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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

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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 thru 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

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Sample roles and responsibilities

Responsibilities

- The Anti-coagulation Patient will:
 - Follow Anti-coagulation Service instructions regarding anti-coagulation dosing and monitoring.
 - Contact the Anti-coagulation Service with any alteration to the dosing and monitoring plan.
 - Notify the Anti-coagulation Service with any changes to medications (including OTC or herbal products), diet, or medical conditions.
 - Notify the Anti-coagulation specialist with any planned medical testing or intervention so temporary cessation of their anti-coagulation therapy can be considered.
 - Have clinic visit and Anti-coagulation assessment with UConn Health referring provider or UConn Health PCP at least annually.
 - Schedule visits at the Anti-coagulation Clinic at least quarterly.
- The Anti-coagulation Technician or Support Staff will:
 - Arrive, schedule, re-schedule patients in IDX Live.
 - Assist with coordinating patient care with home health agencies, skilled nursing facilities, and laboratories.
 - 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.
 - Assist the Anti-coagulation specialist in notifying patients of INR results (or laboratory parameter specific to the anti-coagulation therapy) with or phone calls.
 - Manage the clinic correspondence with patients and providers.
 - Initiate or renew PT/INR and other lab orders for clinic patients using the appropriate anticoagulation diagnosis under the supervision of the Anti-coagulation specialist.
 - Document any contact or attempted contact with the patient or any agent thereof except for upcoming appointment reminder calls.
 - Contact/attempt to contact and follow-up with patients who do not attend scheduled clinic visits, as per clinic guidelines.

Note: In the absence of Anti-coagulation technicians or support staff, the Anti-coagulation specialist will assume the above responsibilities.

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Responsibilities **Sample roles and responsibilities continued**

3. The Anti-coagulation Specialist will:

- Follow all aspects of the patient's anti-coagulation therapies in collaboration with the patient's referring physician and as necessary the patient's primary care provider or the service medical director.
- Initiate, adjust, or renew orders appropriate for the patient's anti-coagulation therapies, which include anti-coagulation medications, Vitamin K, PT/INR, CBC, urinalysis, basic metabolic panel (BMP), and other related laboratory tests, per established guidelines.
- Continue to monitor the patient's anti-coagulant therapy until the patient's physician discontinues anticoagulant therapy or until the patient is discharged from the clinic by other means.

Assess the status of the particular medical problem necessitating anticoagulation therapy.

- Perform thromboembolic and hemorrhagic risk assessments (refer to attachments 6a/6b) and document in an electronic database.
- Assess patient understanding of disease and treatment and willingness to comply with treatment and clinic visits.
- Educate the patient (using verbal and/or written communication) on the safe and appropriate use of anti-coagulation medication.
- Address each patient's PT/INR (or other anti-coagulation related laboratory result), assess the efficacy of treatment, and determine if therapeutic goals have been achieved. Specifically:
 - Identify patient-related variables that affect therapy and evaluate the stability of each individual result.
 - Make appropriate changes to anti-coagulation therapy when the therapeutic goals of treatment are not being met.
 - Dosing adjustments may deviate from the given guidelines based on referring LIPs or PCP clinical experience and patient's individual case factors. However, these patients will not be treated under the protocols listed here, but rather each such referral will be accompanied by an individualized patient specific protocol for all therapies that would require INRs outside of the ranges of 2-3, or 2.5-3.5.
 - Educate the patient/caregiver on therapeutic results, any dose changes, and any anti-coagulation issues as determined per anti-coagulation specialist.
- Assign a date for follow-up monitoring (if applicable).
- Follow patient's whose INR is unstable (not yet at steady state) at least once to twice weekly as needed.
- Increase the monitoring interval at one week increments, as the INR becomes more stable.
- Follow patients who have a stable INR every 4-12 weeks (see Frequency of Monitoring Anticoagulant Therapy-Attachment 5).
- Refer to the Warfarin Dosing Strategy (Attachment 2), Warfarin Dosing Nomogram for Maintenance Therapy (Attachments 3a and 3b) and Frequency of Monitoring Anticoagulant Therapy (Attachment 5) for dosing and monitoring recommendations. Refer to the Guidelines for Excessively Prolonged INR (Attachment 4) and seek physician consultation for INRs greatly out of range as outlined in section on physician consultation. Assess all drug-related problems and communicate findings to referring physician or primary care as outlined in section on physician consultation.
- Manage any clinically significant drug interactions and contact the physician as needed.
- Educate the patient (using verbal and/or written communication) on the safe and appropriate use of anti-coagulation medication.
- Document all activities performed appropriately in the medical record.

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Question

Establishing roles and responsibilities for the patient will ensure:

- Adherence to prescribed anticoagulation dosing regimen
- Improved communication
- Compliance with regulatory and policy requirements
- All of the above
- None of the above

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Question

Establishing roles and responsibilities for the patient will ensure:

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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's 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 a convenient location
- Update periodically to keep up with changes within the clinic

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Anticoagulation Provider Training

Should Include:

- Basic theory of anticoagulation
 - Normal physiology of coagulation and fibrinolysis
 - Antithrombotic therapy, and thrombogenesis
 - Pharmacokinetic and pharmacodynamic properties of warfarin and other anticoagulants used in the outpatient setting
 - Understanding impact of changes in medications, health, diet and lifestyle to anticoagulation therapy management
 - Signs and symptoms of thromboembolism and knowledge of when to refer to a physician
 - Skills to identify, triage, or manage other medical problems through the appropriate health care provider
 - Understanding the effects of socioeconomic, behavioral, psychological, and environmental factors on patient adherence
 - Understanding of PT, INR, ISI and the relationships between these values, their limitations, and reasons for variability
- Clinical aspects of warfarin: side effects, contraindications, interactions, dosing schemes
 - Ability to interpret INR and related laboratory values and adjust warfarin dose accordingly
 - Determination of optimal intensity and duration of antithrombotic therapy for individual patients
 - Determination of appropriate options for interrupting and/or reversing anticoagulation
- Detailed training on the use of the point of care monitoring device in use at the practice
- Detailed training on the use of any anticoagulation management software in use.
- Practice-based protocol used in the clinic
- Health and safety procedures eg. Bloodborne pathogen training
- Quality control procedures
- Proper documentation

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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:
 - Anticoagulation Monitoring
 - Extended Anticoagulation Prophylaxis post-hospitalization
 - New Oral Anticoagulants
 - Vitamin K Antagonist Pharmacology, Pharmacotherapy and Pharmacogenomics
 - Heparin/Low Molecular Weight Heparin and Fondaparinux Pharmacology and Pharmacotherapy
 - Direct Thrombin Inhibitor Pharmacology and Pharmacotherapy
 - Pharmacist Reimbursement 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 device.
- All Anti-coagulation specialists must show proficiency by successfully passing the anti-coagulation clinic credentialing and i-STAT competency tests with a score of 870%.

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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

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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

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Question

- Which of the following is useful when supervising challenging personnel?
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 - D. All of the above
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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 educational session content and method of delivery
 - Initial laboratory monitoring
 - Warfarin initial and maintenance dose adjustment guidelines
 - Frequency of monitoring INR guidelines
 - Thromboembolic/Hemorrhagic risk assessments

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Develop Written Policies and Procedures continued

- Include:
 - Guidelines for assessing therapy
 - Documentation method and requirement
 - Billing criteria and process
 - Perioperative management of patients on anticoagulation
 - Process for managing and discharging non-compliant patients
 - Method for processing refills
 - Forms used by the clinic and/or sent to the patient following written policies and procedures
 - Communication procedures for patient and referring practitioners
 - Optimal therapeutic range and duration of anticoagulation therapy
 - Quality assurance
 - Identification of high risk patients and management method

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Develop Written Policies and Procedures continued

- 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.uhc.edu/services/anticoagulation/pdfs/agreement_collaborative_practice.pdf

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Determine Clinic Hours

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

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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

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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

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Anticoagulation Software Selection Considerations

- Fields to enter goal INR range, indication for therapy, therapy start/stop dates, medication list, referring md information, patient contact information, thromboembolic/hemorrhagic risk, lab location, pharmacy information, patient status, patient specific notes which all providers need to be aware of, one-time exception dosing, alternate dosing, tablet strength, bridge therapy, issues that need future follow up
- Generate patient handouts, reminder and discharge letters
- Ability to trend data for individual patient
- 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
- Ability to run reports eg.
 - Patients who are past due for INR
 - % Therapeutic or TTR for individual or all clinic patients
 - % non-Therapeutic or TTR for individual or all clinic patients
 - Customizable reports eg. list of patients by indication, referring md etc...
 - Identify non-therapeutic patients
 - Identify high risk patients
 - Adverse events report
 - Issues report

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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

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