RISK MANAGEMENT IN ANTICOAGULATION

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Faculty Disclosures

Youssef Bessada, PharmD, BCPS, BCCP has no actual or potential conflict of interest associated with this presentation

Previous iteration developed by:
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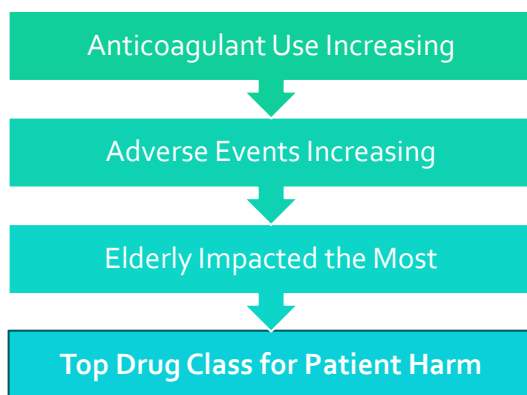- Information reviewed, updated and built upon for new iteration

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Learning Objectives

1. Discuss the education and training needs of pharmacists who participate in anticoagulation services.

2. Discuss the documentation needs of a pharmacists-run anticoagulation service or clinic.

3. Identify corporate infrastructure needs to support anticoagulation services or clinics.

4. Explain the necessary implementation strategies for establishing, strengthening and sustaining an anticoagulation stewardship program

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Risk Management in Anticoagulation

Anticoagulant Use Increasing

⬇

Adverse Events Increasing

⬇

Elderly Impacted the Most

⬇

Top Drug Class for Patient Harm

Burnett AE & Barnes GD. Res Pract Thromb Haemost. 2022 Jul 17;6(5):e12757.
Budnitz DS, et al. JAMA, 2021;326(13), 1299–1309.

eFigure. US Emergency Department (ED) Visits for Adverse Drug Events (ADEs) from Commonly Implicated Drug Classes by Patient Age, 2013-2014*

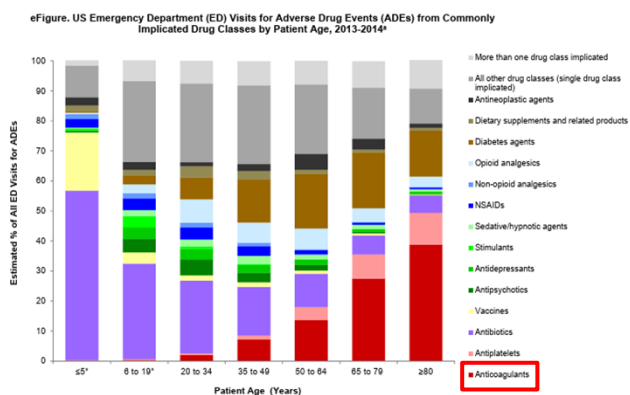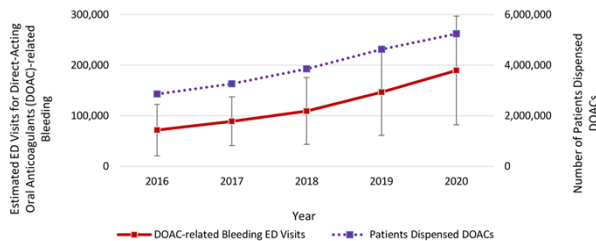*Image from: Shehab N et al. JAMA. 2016 Nov 22;316(20):2115-2125.*

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Risk and the Rise of Anticoagulation Stewardship

DOAC-related ED visits	
2011	2.3%
2017	**37.9%**

Daily Pharmacy Practice Requires Risk Mitigation Strategies:

- Involvement of pharmacy personnel & anticoagulation clinics is proven to improve AC-outcomes

- However, with rise in DOAC use- there is also a rise in DOAC-related adverse events

- Pharmacists are taking on risk when they manage anticoagulation therapy (warfarin, DOACs, LMWH etc.)

Geller AI, et al. Thrombosis Research. 2023; 225, 110–115.
Burnett A, et al. Thrombosis Update. 2022;9:100125

Image from: Geller AI, et al. Thrombosis Research. 2023; 225, 110–115

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Risk Management in Anticoagulation

- **Risk Management-** *Supports implementation of strategies to minimize organizational risk by minimizing the number of avoidable adverse outcomes*

- *Involves protecting:*
  - *Yourself*
  - *Coworkers*
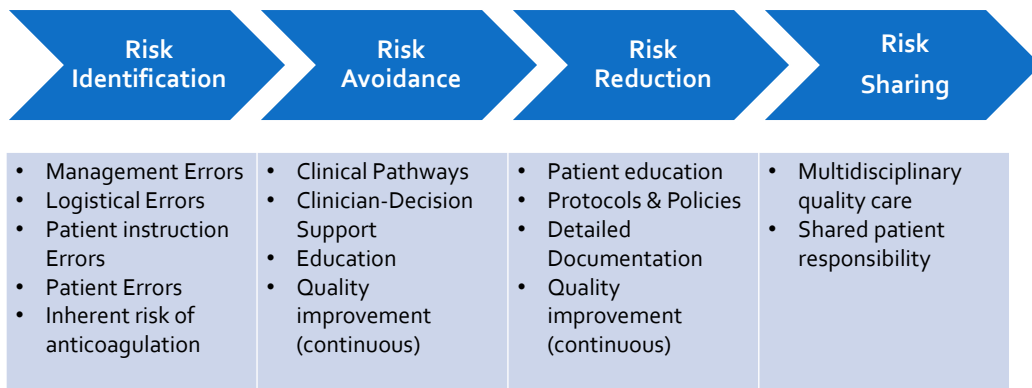 - *Institution*
  - *Patients*

- **Anticoagulation Stewardship -** *A coordinated, efficient, and sustainable system-level initiative designed to achieve optimal anticoagulant-related health outcomes and minimize avoidable adverse drug events (ADEs)*

System-wide Anticoagulation stewardship efforts are the key to risk management in anticoagulation

Core Elements of Anticoagulation Stewardship Program. AC Forum. Accessed 03-24-2025
Burnett AE & Barnes GD. Res Pract Thromb Haemost. 2022 Jul 17;6(5):e12757.
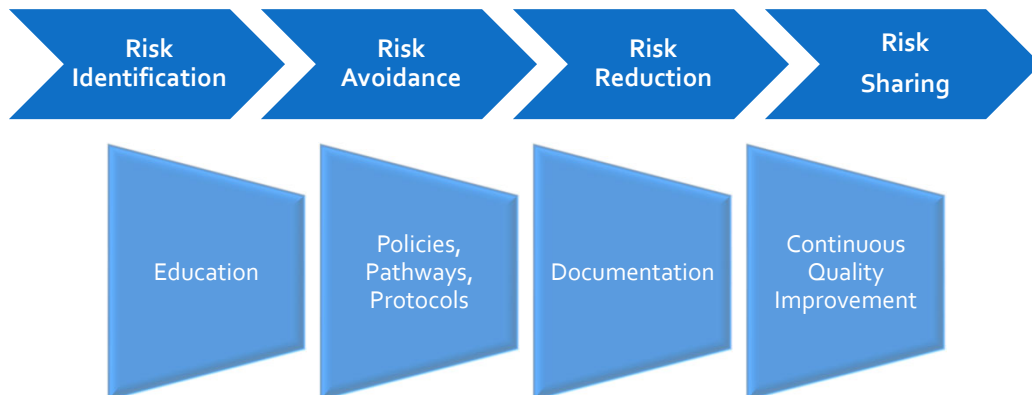
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Risk Management Process

Risk Identification	Risk Avoidance	Risk Reduction	Risk Sharing
• Management Errors • Logistical Errors • Patient instruction Errors • Patient Errors • Inherent risk of anticoagulation	• Clinical Pathways • Clinician-Decision Support • Education • Quality improvement (continuous)	• Patient education • Protocols & Policies • Detailed Documentation • Quality improvement (continuous)	• Multidisciplinary quality care • Shared patient responsibility

Core Elements of Anticoagulation Stewardship Program. AC Forum. Accessed 03-24-2025
National Quality Forum & Anticoagulation Forum. Advancing Anticoagulation Stewardship: A Playbook. Accessed 2025 03 28

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Risk Management Process

Risk Identification	Risk Avoidance	Risk Reduction	Risk Sharing
Education	Policies, Pathways, Protocols	Documentation	Continuous Quality Improvement

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Comprehension Question

Anticoagulation stewardship, as a key to risk management, is most effective when implemented at which level of anticoagulation practice management?

A. Individual-level

B. Clinic-level

C. System-level

Anticoagulation Stewardship - *A coordinated, efficient, and sustainable **system-level initiative** designed to achieve optimal anticoagulant-related health outcomes and minimize avoidable adverse drug events (ADEs)*

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Burnett AE & Barnes GD. Res Pract Thromb Haemost. 2022 Jul 17;6(5):e12757.

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Education

Provider Education	Patient Education
• Core of successfully mitigating risk in anticoagulation programs & stewardship • Should review disease states, medications, and management • Strengthened with competencies, practice and assessment • Provider 1st –strategy, to have successful patient education	• Dependent on provider education • Necessary for "shared-decision making" • Involves patient in responsibility for management & follow-up • Key during transitions of care particularly

Core Elements of Anticoagulation Stewardship Program. AC Forum. Accessed 03-24-2025
National Quality Forum & Anticoagulation Forum. Advancing Anticoagulation Stewardship: A Playbook. Accessed 2025 03 28

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Provider Education

Goal-Oriented, Evidence-Based & Comprehensive

- Proficient knowledge of:
  - Disease states
  - Medications
  - Anticoagulation management

- Depth attained through various levels of Bloom's Taxonomy

- Set **growth** mindset to encourage culture of lifelong learning

- Competency assessed and documented using a standardized method
  - System-specific with own policies (knowledge/case assessment, direct observation etc.) +/or
  - National standard (e.g. National Certification Board for Anticoagulation Providers)
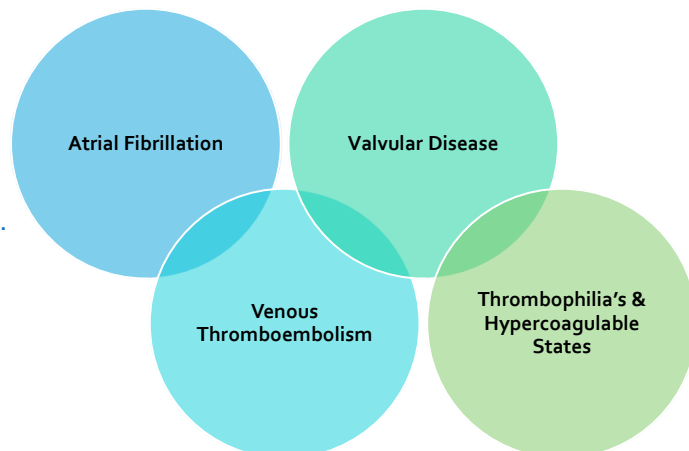
- Resources:

Bloom's Taxonomy

- Knowledge (reading, lectures)
- Comprehension (discussions)
- Application, Analysis, Synthesis (Case presentations, practice-based teaching)

Core guidelines → Situational guidelines → High evidence primary literature → Expert consensus → Large scale Real-world data → Management Review Articles & Resources

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Provider Education: Disease States

- Epidemiology
- Pathophysiology
- Diagnosis
- Evidence-based therapeutic approaches (pharmacologic vs. non-pharmacologic)
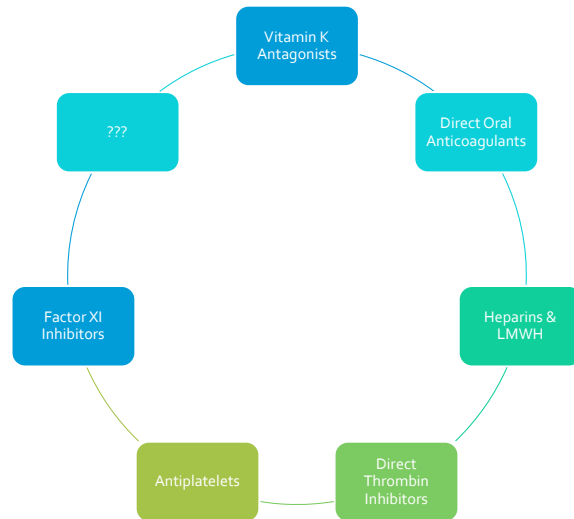- Monitoring
- Follow-up & Progression

Constantly Updated!

Atrial Fibrillation

Valvular Disease

Venous Thromboembolism

Thrombophilia's & Hypercoagulable States
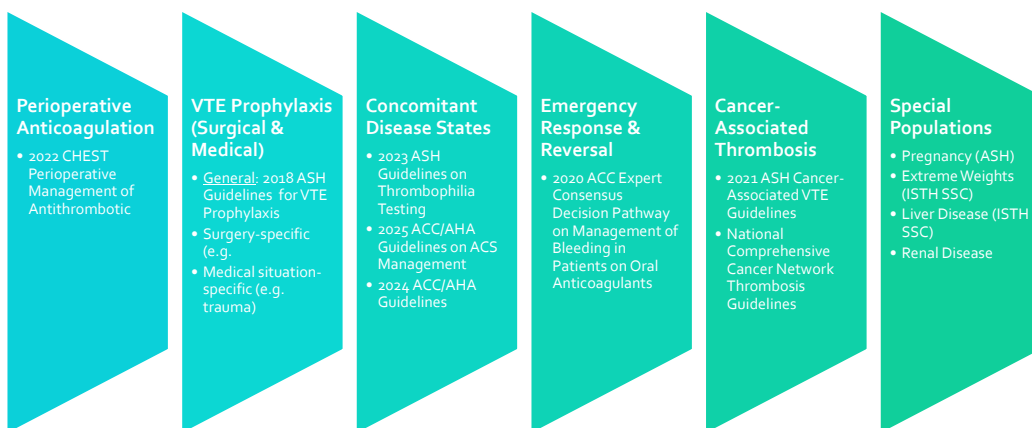
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Provider Education: Medications

- Pharmacology
- Pharmacokinetics /-dynamics
  - Changes in special populations (renal/liver disease, pregnancy, surgery (gastric), extreme body weights, acute illness)
- Therapeutic Efficacy (thrombosis prevention)
- Safety (bleed risk!)
- Interactions (diet & medication)
- Monitoring

Constantly Updated!

- Vitamin K Antagonists
- Direct Oral Anticoagulants
- Heparins & LMWH
- Direct Thrombin Inhibitors
- Antiplatelets
- Factor XI Inhibitors
- ???

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Provider Education: Management

Perioperative Anticoagulation
- 2022 CHEST Perioperative Management of Antithrombotic

VTE Prophylaxis (Surgical & Medical)
- General: 2018 ASH Guidelines for VTE Prophylaxis
- Surgery-specific (e.g.
- Medical situation-specific (e.g. trauma)

Concomitant Disease States
- 2023 ASH Guidelines on Thrombophilia Testing
- 2025 ACC/AHA Guidelines on ACS Management
- 2024 ACC/AHA Guidelines

Emergency Response & Reversal
- 2020 ACC Expert Consensus Decision Pathway on Management of Bleeding in Patients on Oral Anticoagulants

Cancer-Associated Thrombosis
- 2021 ASH Cancer-Associated VTE Guidelines
- National Comprehensive Cancer Network Thrombosis Guidelines

Special Populations
- Pregnancy (ASH)
- Extreme Weights (ISTH SSC)
- Liver Disease (ISTH SSC)
- Renal Disease

Constantly Updated!

Best described through active learning & case-based approaches with resources above

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Patient Education

Pharmacist's Role in Education:

- Serve as expert source of guidance for medication/ lifestyle guidance
- Use patient-friendly terms
- Vital for management in **transitions of care**
- Maximize time in therapeutic range through collaboration (VKA) & minimize avoidable bleed/thrombosis
- **Resources:**
  - Anticoagulation Forum: Patient & Family Education Apps
  - Michigan Anticoagulation Quality Improvement (MAQI) Patient Education Toolkits
  - American Heart Association Guide to Warfarin Toolkit

Image adapted from AC Forum Patient & Family Education Site. Available from: https://acforum.org/web/resource-center-details.php?selectTopic=1

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Comprehension Question

Which of the following is NOT an effective method of standardizing and disseminating provider education as part of a risk management strategy?

A. Assessing comprehension via system-specific or standardized assessments

B. Highlighting patient errors from past risk management strategies

C. Utilizing various levels of Bloom's taxonomy to provide education

Set **growth** mindset to encourage culture of lifelong learning

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Policies, Protocols & Pathways

Policies	Protocols	Pathways
• Define roles, responsibilities and limitations (based on license) • Define education process/standard (providers & patients) • Define prescription actions • Define patient enrollment, discharge and referral (e.g. non-compliance)	• Outline actions associated with various roles • In collaborative practice: define dose-adjustment principles, follow-up and critical values for reporting (and actions) • Provide standardized management steps & processes	• Simplified, proactively agreed upon protocols, in acute management situations • Outline the exact steps & processes each discipline follows in a specific situation • Centered around patient • Require multidisciplinary buy-in

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Policies, Protocols & Pathways

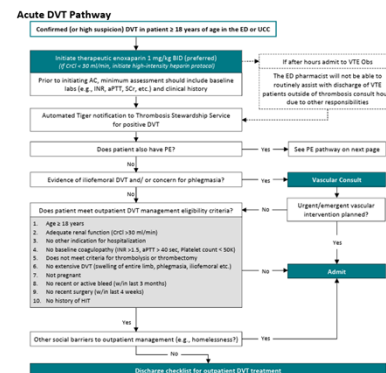| Policy	Protocol	Pathway
Ambulatory or Inpatient Care Pharmacist-Driven Warfarin Management Policy OR AC Perioperative Management Policy	DOAC Renal-Dose Adjustment Protocol OR Nurse-Driven Heparin Dosing Protocol	

UNMH P&T Committee, Thrombosis & Hemostasis Steering Committee Last updated: July 2023. Available from: https://hsc.unm.edu/medicine/departments/emergency-medicine/_docs/clinical_resources/general-policies-and-guidelines/management-of-acute-vte-pathway_7_11_2023_aeb.pdf

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Policies, Protocols & Pathways

- **Necessities**:
  - **Should** ALL be created with multidisciplinary support (Cardiology, Hematology, Pharmacy, Surgery etc.)
  - **Should** be reviewed and approved by leadership regularly
  - **Should** be able to guide new practitioners through key patient scenarios
  - **Should** be clearly documented, if and when, variance from policy occurs

- **Outcome of successful policies, protocols & pathways:**
  - Shifts responsibility and risk from individual practitioners/ care providers
  - Reduces "avoidable" errors and allows root cause analysis for "unavoidable" errors as basis for quality improvement

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Comprehension Question

The goal of a successful policy, protocol or decision pathway is to…

A. Confine decisions to a set of rules that all providers must adhere to

B. Minimize risk by reducing the need for clinical judgement calls

C. Shift risk from individual practitioners/ care providers on to system
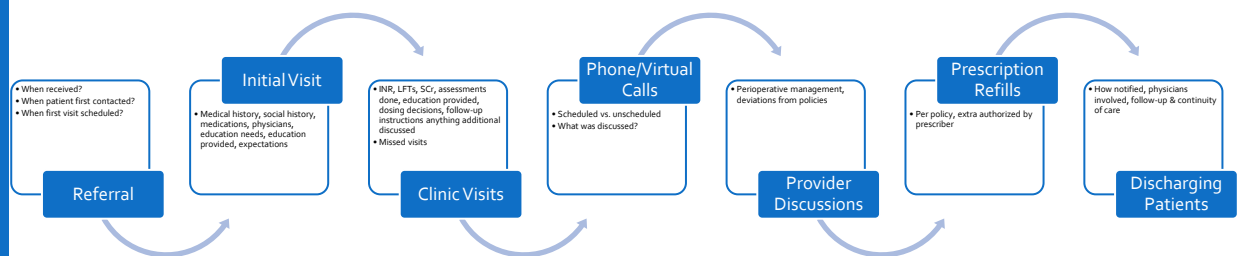
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Documentation

- One of most important "risk management" tools
- Vital to document every happening in a high-risk clinical environment (small and big)
- **Should cover:**
  - Outpatient, inpatient, transitions of care management
  - Education, training, and competency assessment process for providers included in clinical environment
  - **ALL interactions with patients**
  - Quality assurance/improvement

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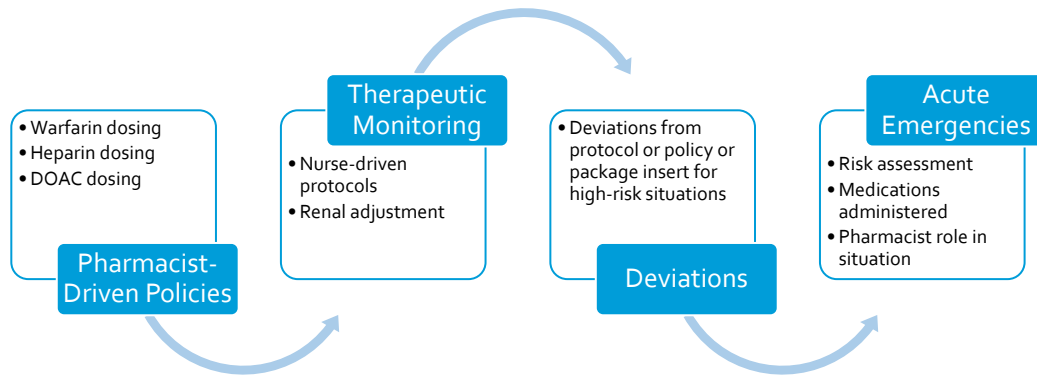
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Documentation: Outpatient Examples

Referral
- When received?
- When patient first contacted?
- When first visit scheduled?

Initial Visit
- Medical history, social history, medications, physicians, education needs, education provided, expectations

Clinic Visits
- INR, LFTs, SCr, assessments done, education provided, dosing decisions, follow-up instructions anything additional discussed
- Missed visits

Phone/Virtual Calls
- Scheduled vs. unscheduled
- What was discussed?

Provider Discussions
- Perioperative management, deviations from policies

Prescription Refills
- Per policy, extra authorized by prescriber

Discharging Patients
- How notified, physicians involved, follow-up & continuity of care

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Documentation: Inpatient Examples

Pharmacist-Driven Policies
- Warfarin dosing
- Heparin dosing
- DOAC dosing

Therapeutic Monitoring
- Nurse-driven protocols
- Renal adjustment

Deviations
- Deviations from protocol or policy or package insert for high-risk situations

Acute Emergencies
- Risk assessment
- Medications administered
- Pharmacist role in situation

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Documentation: Transitions of Care Examples

Education
- Patient education disseminated
- Technique

Monitoring
- Warfarin – next INR check
- DOACs – LFTs, SCr
- Heparins – SCr, injection-site

Follow-Up
- Primary anticoagulation management team
- Communication for unique situations or deviations from policy
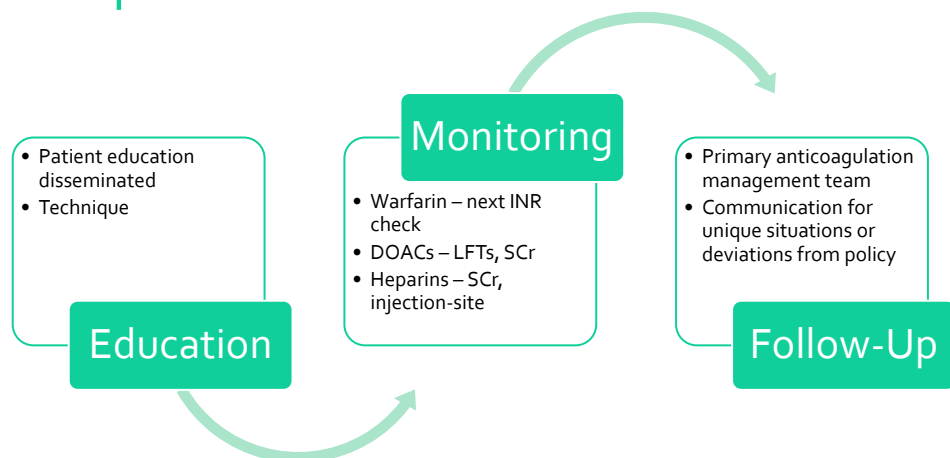
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Documentation

Documentation Logistics

- Paper-charts are prone to error/loss and are out of favor
- Computer-based documentation specific to health system (many available)
  - Commercial
  - Health-system specific
- Key part of infrastructure in risk management strategy

Keys to Effective Documentation Software

- Single database allows for more congruent data collection & dissemination, and minimizes avoidable errors
- Maintains patient privacy
- Utilizes technology to minimize risk, if available (population health reporting, clinician-decision support tools, best practice alerts, effective provider communication etc.)
- Allows for quick & effective access to quality improvement data desired by system (e.g. TTR, % in therapeutic range, missed appointments, incorrect DOAC dosing etc.)
- No perfect system, just perfect practice on existing systems

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Continuous Quality Improvement

- Vital to include on a **regular** basis
- Allows for enhancement of risk management strategy with time and clinical updates
- Should have anticoagulation stewardship champion or committee to lead this
- Prioritize by areas of highest risk
- Allows for enhancement of infrastructure:
  - Clinic staffing (providers & support)
  - Allows safe assessment of care ratios
  - Cost-savings/benefit
  - Patient education
  - New software / clinical tools
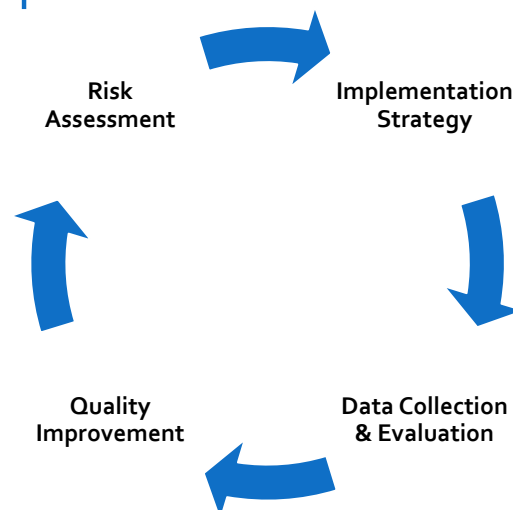
Risk Assessment → Implementation Strategy → Data Collection & Evaluation → Quality Improvement

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Comprehension Question

A key tenant to risk management strategy in anticoagulation management is continuous quality improvement, which can best be implemented into **daily** workflow by:

A. Constantly updating to the best software to review metrics

B. Standardizing documentation to allow for easy retrieval of key metrics

C. Minimizing the number of clinic visits per day to allow for metric review

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Summary

- **Reduce risk by...**
  - Providing high quality anticoagulation stewardship in all phases of care (inpatient, outpatient, TOC)
  - Educating knowledgeable practitioners (who in turn educate patients)
  - Strong and complete policies, protocols & pathways
  - Robust documentation system
  - Continuous quality improvement

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THANK YOU

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