Core Elements of Anticoagulation Stewardship Programs

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Contributors

ANTICOAGULATION FORUM STEERING COMMITTEE MEMBERS

Scott Kaatz, DO, MSc, FACP, SFHM
Clinical Professor of Medicine, Wayne State University School of Medicine
Medical Director for Professional Development and Research, Division of Hospital Medicine, Henry Ford Hospital
Anticoagulation Forum President, Chair, Steering Committee

Jack Ansell, MD, MACP
Professor of Medicine, Hofstra Northwell Zucker School of Medicine
Co-Chair, Core Elements Subcommittee

Allison Burnett, PharmD, PhC, CACP
Assistant Clinical Professor, University of New Mexico College of Pharmacy
Inpatient Antithrombosis Stewardship Service, University of New Mexico Hospital
Co-Chair, Core Elements Subcommittee

Steven Deitelzweig, MD, MMM, FACC, SFHM, FACP, RVT
Professor of Medicine, Ochsner Clinical School and University of Queensland
Ochsner Health System
Co-Chair, Gap Analysis Subcommittee

Daniel M. Witt, PharmD, FCCP, BCPS
Professor and Chair Department of Pharmacotherapy, University of Utah College of Pharmacy
Co-Chair, Gap Analysis Subcommittee

David Garcia, MD
Professor of Medicine, Division of Hematology, University of Washington
Assistant Medical Director, Anti-thrombotic Therapy, University of Washington Medical Center

Tracy Minichiello, MD
Professor of Medicine, University of California San Francisco
Chief, Anticoagulation and Thrombosis Services, San Francisco VA Medical Center

Elizabeth Goldstein, MBA
Executive Director, Anticoagulation Forum

Darren Triller, PharmD
WellScriptEd Consulting, Inc.

TECHNICAL EXPERT PANEL MEMBERS

Victoria Agramonte, RN
Senior Director Performance Improvement
The Brooklyn Hospital Center

Andrew Bland, MD, MBA, MSAP, FAAP, FACP
Medical Director, Division of Healthcare Quality Evaluation
The Joint Commission

Brittany Bogan, FACHE, CPPS
Senior Vice President, Safety & Quality and Executive Director
Michigan Health & Hospital Association

Debra Feinberg, JD, BS, RPh, FASHP
Clinical Associate Professor, University of Binghamton School of Pharmacy

Randy Fenninger, JD
Chief Executive Officer
National Blood Clot Alliance

Helen Larios, MBA, MSN, RN
Project Director - Clinical
The Joint Commission

Steven Meisel, PharmD, CPPS
System Director of Medication Safety
Fairview Health Services

Anne Myrka, RPh, MAT
Director, Drug Safety
IPRO

Jesse Roach, MD
Medical Officer
Centers for Medicare and Medicaid Services

Shelly Sahu, MD
Assistant Research Clinician
National Institutes of Health

Nadine Shehab, PharmD, MPH
Division of Healthcare Quality Promotion
Centers for Disease Control

Barbara J. Zarowitz, Pharm.D., FCCP, FCCM, BCPS, BCGP, FASCP
Senior Advisor, Peter Lamy Center on Drug Therapy and Aging
Affiliate Professor, University of Maryland School of Pharmacy

> Acknowledgements

ANTICOAGULATION FORUM BOARD OF DIRECTORS

Arthur Allen, PharmD, CACP
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Jack Ansell, MD, MACP
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University of Pennsylvania

William Dager, PharmD, BCPS, FASHP, FCCP, FCCM, MCCM
University of California Davis Health

Steven Deitelzweig, MD, MMM, FACC, SFHM, FACP, RVT
Ochsner Health System

Stacy Ellsworth, RN, MSN, CCRC
Henry Ford Hospital

David Garcia, MD
University of Washington

Scott Kaatz, DO, MSc, FACP, SFHM
Henry Ford Hospital

Eva Kline-Rogers, MS, NP, AACC
University of Michigan

Renato Lopes, MD, PhD
Duke University

Tracy Minichiello, MD
University of California, San Francisco

Charles Pollack, MD, MA, FACEP
Thomas Jefferson University

Michael Streiff, MD
Johns Hopkins University

Sara Vazquez, PharmD, BCPS, CACP
University of Utah Health

Diane Wirth, ANP, CACP
Grady Memorial Hospital

The Anticoagulation Forum acknowledges and is indebted to the individuals and organizations that have previously developed and disseminated antibiotic stewardship guides and resources.**[1-4]** These successful initiatives have provided an excellent model for the development of the *Core Elements of Anticoagulation Stewardship Programs* guide.

Similarities in structure and terminology between the *Core Elements of Anticoagulation Stewardship Programs* guide and earlier antibiotic stewardship resources are intended to enhance familiarity of concepts among organizational leaders, thereby accelerating uptake of the recommendations.

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Introduction

Anticoagulants are life-saving therapies for individuals with cardiac and vascular disorders.

Anticoagulants reduce stroke in patients with atrial fibrillation by as much as 62%[5], prevent valve thrombosis and embolism in patients with cardiac valve prostheses, and reduce the risk of pulmonary embolism and recurrence in patients with venous thromboembolism (VTE).[6] Approximately 1%–2% of persons living in industrialized societies are prescribed anticoagulants as outpatients, and up to 40% of all medical inpatients may warrant VTE prophylaxis.[7,8] Unfortunately, every anticoagulant agent comes with risks including major and life-threatening bleeding, the frequency of which increases significantly with drug dosage, common patient characteristics (e.g. elderly, kidney disease), and suboptimal clinical management.

"Anticoagulants consistently rank as the class of medications most frequently leading to emergency room visits and hospital admissions for adverse drug events."

In the outpatient setting, anticoagulants have consistently ranked as the class of medications most frequently leading to emergency room visits and hospital admissions for adverse drug events (ADEs), and rates continue to rise.[9-11] According to nationally representative surveillance performed by the Centers for Disease Control and Prevention (CDC), warfarin has been implicated in approximately 32% of emergency visits for ADEs in the elderly, 50% of which result in hospitalization.[11] Although direct oral anticoagulants (DOACs) require less intensive dose management than warfarin and are associated with lower rates of major bleeding,[12] they are not devoid of potential complications. Between 2013 and 2014, rivaroxaban and dabigatran were the 5th and 10th most common drugs, respectively, to cause emergency room visits for ADEs in older adults, reflecting increased use of this drug class and their potential for ADEs.[11] Hospitalization rates for DOAC-related ADEs were similar to that of warfarin.

Anticoagulation therapy has been identified as a leading cause of harm among hospitalized Medicare beneficiaries.[13] Errors involving anticoagulant prescribing and administration in hospitals occur far too frequently and are considered largely preventable.[14] Anticoagulants are also the most frequent cause of serious ADEs in nursing homes [15] that can be reduced or prevented through improved systems of care.[16-18] Patient transitions between care settings complicate anticoagulation management and introduce opportunities for medication errors and preventable ADEs, and improvements in communication and clinical management during transitions have been recommended.[19-21] Finally, anticoagulation-related medical evidence continues to evolve rapidly, and organizational care processes must be frequently evaluated and updated to reflect current best practices.

Improving the systematic management of anticoagulants within and across care settings is therefore a key priority. In the U.S. Department of Health and Human Services (HHS) National Action Plan for Adverse Drug Event Prevention, anticoagulants are one of three top drug classes targeted for enhanced national surveillance and prevention efforts.[22] The Joint Commission (TJC) has recently updated their longstanding national patient safety goal for anticoagulant therapy (NPSG 03.05.01) to include proper management goals for the DOACs.[23] As payment models progress from volume to value, improvements in the systems supporting anticoagulated patients will result not only in greater safety, but also optimized patient outcomes, reduced waste, and fiscal sustainability.

A systematic approach to anticoagulant management using dedicated systems – primarily anticoagulation clinics – is known to improve outcomes by reducing thrombosis and major bleeding and may generate financial benefits as well.[24-25] From the time of their origin in the 1960's, outpatient anticoagulation clinics have been limited in scope, but recent evidence shows the value of expanding the anticoagulation safety mandate through organizational stewardship programs,[26-32] of which anticoagulation clinics are one component. Stewardship principles offer improved outcomes for patients across care settings, regardless of which anticoagulant agent is utilized.

This document presents the *Core Elements of Anticoagulation Stewardship Programs*. It builds upon the long-standing experience of anticoagulation clinics and organized inpatient services, resources from the Anticoagulation Forum,[33-36] guidance of professional societies such as the American College of Chest Physicians,[37] the American Society of Hematology,[38] and the American Society of Health System Pharmacists,[39] as well as the quality goals articulated by TJC and the National Action Plan for Adverse Drug Event Prevention.[22,23] The authors of this document have followed the successful example set by Antibiotic Stewardship frameworks developed by the CDC and other organizations,[1,2,4,40] while developing new core elements and strategies specific to anticoagulant agents.

For the purpose of this guide, the Steering Committee and Anticoagulation Forum Board of Directors define anticoagulation stewardship as:

Coordinated, efficient, and sustainable system-level initiatives designed to achieve optimal anticoagulant-related health outcomes and minimize avoidable adverse drug events through the:

- Application of optimal evidence-based care
- Appropriate prescribing, dispensing, and administration of anticoagulants and related agents
- Provision of appropriate patient monitoring and clinical responsiveness

Summary of Core Elements of Anticoagulation Stewardship Programs

Secure Administrative Leadership Commitment
Dedicating necessary human, financial, and technology resources

Establish Professional Accountability and Expertise
Appointing a single leader responsible for program outcomes, supported by at least one clinician with expertise in anticoagulation management

Engage Multidisciplinary Support
Involving key specialists and disciplines to obtain perspective from all domains of the care delivery system

Perform Data Collection, Tracking, and Analysis
Defining the population, objectively evaluating performance, and guiding decision-making

Implement Systematic Care
Implementing sustainable, efficient, evidence-based action(s) at the system level to assure the safety and quality of anticoagulation management

Facilitate Transitions of Care
Creating systems to optimize communication and ensure safe transitions between care settings

Advance Education, Comprehension, and Competency
Assuring that clinicians, patients, and others have the knowledge and skills necessary to optimize outcomes

Secure administrative leadership commitment: Dedicating necessary human, financial, and technology resources

Executive support is vital to the development, implementation, and sustainability of a successful anticoagulation stewardship program. While large academic medical centers and integrated health systems may be among the first to adopt comprehensive anticoagulation stewardship programs, it is likely that all care settings where patients are treated with anticoagulants stand to benefit from some form of stewardship.

Long-term care facilities, physician practices, ambulatory surgery centers, and other specialty care settings that routinely encounter anticoagulation patients should consider the need for and value of anticoagulation stewardship activities.

Administrative leadership support may take a number of forms, including but not limited to:

- Visible endorsement of stewardship efforts within institutional statements and/or strategic plans
- Provision of budgeted resources (e.g. personnel, technology, etc.) that are scaled to organizational size and identified needs
- Incorporation of anticoagulation-related priorities into broader organizational quality improvement and safety strategies, metrics, and goals
- Promotion of system-wide, multidisciplinary involvement in stewardship activities
- Creation and population of essential anticoagulation stewardship roles and positions with trained and experienced personnel
- Formal inclusion of stewardship responsibilities in individual job descriptions and performance assessments
- Commitment of resources for staff training and patient education
- Regular reassessment of the level and amount of resources needed for sustained success

In addition to improving patient safety, organizational investments in anticoagulation stewardship activities are likely to result in substantial cost savings.[25-27,41,42] Anticoagulation quality is also becoming a focus in accreditation standards and quality measures associated with value-based purchasing programs.[23,43]

Establish professional accountability and expertise: Appointing a single leader responsible for program outcomes, supported by at least one clinician with expertise in anticoagulation management

Successful anticoagulation stewardship programs are typically characterized by the presence of a capable and visible leader (i.e. “champion”) who has access to clinicians with current expertise in anticoagulation management.

The leader may or may not be a clinician (e.g. physician, nurse, or pharmacist), but will require sufficient training, expertise and credentials to develop, implement, and maintain the stewardship program. Regardless of background or discipline, the program leader requires full support from his/her respective department and administration to assure the necessary time and resources to fulfill the role.

Key duties of the leader include:

- Develop stewardship goals and implement a strategy to reach them
- Identify and petition for necessary resources
- Evaluate and report on program performance, including patient outcomes
- Represent and advocate for the stewardship program at administrative meetings

In large organizations, additional clinician experts will likely be required to advance program initiatives and provide support to the program leader. These clinicians should be supported to maintain their level of expertise through ongoing advanced training in anticoagulation management.

In smaller organizations a single clinician with suitable expertise and influence may serve in multiple capacities. When adequate anticoagulation expertise is not available within the organization (e.g. primary care practice, long term care facility, specialty clinic, etc.) efforts should be undertaken to obtain initial and sustainable expertise from outside entities, either through collaboration with other local providers (e.g. hospital) or by engaging consultants or contractors (e.g. consultant pharmacists).

Engage multidisciplinary support:
Involving key specialists and disciplines to obtain perspective from all domains of the care delivery system

Anticoagulation therapy is unique not only because it is so widely utilized in adult patient populations and in important subsets of pediatric patients, but also because it can lead to catastrophic bleeding or thromboembolism if not managed properly. Whether anticoagulation is a primary focus of a patient care encounter or not, any deficiencies in clinical management, communication, drug administration, or patient adherence can contribute to irremediable patient harm.

Effective stewardship programs should proactively consider all internal and external departments, disciplines, and entities that impact the quality of anticoagulation-related care from patient intake to discharge. For outpatient organizations, consideration should be given to other entities that provide concurrent services to their anticoagulated patients (e.g. specialists).

The table on the following page includes a list of multidisciplinary perspectives that are important to stewardship efforts. The medical specialties most relevant to an individual anticoagulation stewardship program will vary based on the care setting and the patient population served. Providers that frequently prescribe anticoagulants (e.g. cardiology, hematology, internal medicine), manage patients with bleeding (e.g. emergency services), and perform invasive procedures should be considered for participation in stewardship program development and maintenance efforts.

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Stewardship Example 1: Tertiary Care Center

Senior executives at a tertiary care hospital recognize the need for an anticoagulation stewardship program and a prominent physician with extensive anticoagulation experience agrees to serve as lead.

Resources are allocated for the leader and clinical pharmacists, nurses, and information technology staff to dedicate time to the program, and a standing multidisciplinary committee is established to obtain input from relevant departments and medical specialties.

Initial data analysis identifies high variability in periprocedural management of anticoagulants, insufficient documentation and communication about anticoagulants at the time of patient admission and discharge, and low VTE prophylaxis rates among medically ill patients as high priorities for action.

Work groups are established to operate in parallel on these priority areas and system-level improvements are implemented and scaled across the organization in conjunction with established staff education efforts. Serial performance measurement demonstrates sustained improvements and the committee moves forward to identify and address other priority areas.

> Engage multidisciplinary support

Successful programs typically establish a multidisciplinary committee that meets regularly (e.g. monthly) to guide and support stewardship activities. For efficiency and sustainability, cross-representation from multidisciplinary perspectives should be engaged.

For internal entities, cross-functional, matrix management models may be more suitable than hierarchical approaches, because the latter can be perceived as assigning sole responsibility for anticoagulation stewardship to a single department or unit.

More creativity and flexibility may be needed to adequately engage entities outside of the program's organization. For example, a home care agency may be external to a hospital but play a pivotal role in the management of high-risk patients after discharge. If the nurses who staff a particular agency are limited in their availability to attend on-site meetings at a hospital, alternative processes to engage them and incorporate their perspectives in the stewardship program should be identified. Similar accommodations may be needed to effectively engage other external care providers (e.g. rehabilitation centers), contracted services (e.g. consultant pharmacists), and vendors (e.g. software, laboratory).

Multidisciplinary Perspectives Important to Anticoagulation Stewardship Efforts

Blood Bank – Provides blood products and clotting factors for emergent bleeding events

Case Management – Supports anticoagulated patients as they navigate the health care system

Clinical Providers – Prescribes and monitors anticoagulants, provides overall care to patients, and manages bleeding and clotting events

Discharge Planning – Facilitates safe and cohesive patient care transitions

Education – Supports staff and patient education and comprehension

Emergency Medical Services – Manages acute bleeding and clotting events

Finance – Evaluates and supports the overall fiscal viability and sustainability of programs

Home Care – Manages high-risk outpatients and provides key services during transitions after surgery and hospitalization

Imaging – Supports the diagnosis of emergent bleeding and clotting events

Information Technology – Supports data analysis and the maximal use of electronic health record features

Laboratory – Performs tests required to diagnose clotting disorders and guide dosing of anticoagulants

Long-Term Care – Cares for patient age group at highest risk of bleeding and clotting events

Nursing – Provides clinical care to patients on anticoagulant therapy, and administers anticoagulants and reversal agents

Nutrition – Supports care of patients on warfarin, which is sensitive to dietary changes

Pharmacy – Acquires, prepares, and dispenses medications (anticoagulants, reversal agents and others) and contributes to policy and procedure development and adherence

Quality Improvement – Evaluates and reports organizational performance

Rehabilitation – Cares for patients during care intervals when high-quality anticoagulation management is vital

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

Perform data collection, tracking, and analysis: Defining the population, objectively evaluating performance, and guiding decision-making

Effective data collection and analysis are essential to identify priorities for action, assess performance, and inform key stakeholders. While care settings will vary in their access to data and availability of technological resources, every effort should be made to develop a sound data collection and analysis process at baseline and to refine and expand it going forward.

Data analysts and information technology experts are essential for the creation of effective data collection tools, application of appropriate analytic methods, interpretation of results, and the development of illustrative reports. Therefore, the program budget must include technology and data analysis resources proportional to the scale of the stewardship program.

Environmental Scan: A pivotal initial step in the creation of an effective stewardship program is the execution of an environmental scan to characterize the full scope of patient population(s) and care providers.

CHARACTERIZE THE PATIENT POPULATION: An evaluation of patients receiving or eligible for anticoagulation in the care setting should be conducted. The process should identify key groups and points in care, such as patients:

- Utilizing anticoagulation
- Undergoing invasive procedures
- Experiencing transitions of care

IDENTIFY KEY CARE PROVIDERS: A broad evaluation of care providers and related entities involved in the care of patients should be carried out, including the names and services provided by specific parties. For example, the analysis may identify:

- Prescribers of anticoagulants
- Interventionalists performing procedures on anticoagulated patients
- Home care agencies, rehabilitation and long-term care facilities receiving or referring anticoagulated patients

Execute the Analytic Process: With the broad patient and provider populations adequately identified, analytic processes should be undertaken to evaluate performance and identify potential priorities for action.

EVALUATE PERFORMANCE: The analytic process should seek to objectively characterize anticoagulation-related care concerns applicable to the organization's patients. The table on the following page lists system deficiencies that frequently contribute to suboptimal patient outcomes and that should be considered for evaluation, depending upon the care setting.

Validated Measures: When possible, validated, endorsed or nationally recognized quality measures should be utilized, characterizing both patient outcomes and care processes applicable to the organization's patient population. Such measures provide the opportunity to benchmark performance against other organizations or facilities and can potentially be leveraged in value-based care relationships with payer organizations.**[44-46]**

Other Metrics: Organizations are encouraged to develop and employ additional setting-specific performance metrics to guide decision making. Examples include, but are not limited to:

- Percentage of anticoagulant prescriptions properly adjusted for indication, patient characteristics (e.g. age, weight, renal function) and concomitant therapies (e.g. drug interactions)
- Adherence rate to anticoagulation management protocols, policies and procedures (e.g. periprocedural, reversal, acute VTE)
- Percentage of care transitions with documentation and communication of essential information
- Incidence of anticoagulant-associated adverse events (e.g. major bleeding, thrombosis, death)
- Proportion of patients receiving formal education about the use of anticoagulants
- Proportion of patients screened for appropriate use of concomitant anticoagulant and antiplatelet therapy

IDENTIFY POTENTIAL PRIORITIES: Results of initial and ongoing analysis will identify areas of known or suspected deficiencies in patient outcomes or system quality. Areas in which data is either unavailable or of poor quality should also receive attention.

Common Anticoagulation-Related System Deficiencies Examples

Underutilization

- At-risk atrial fibrillation patients not proactively identified
- Failure to objectively evaluate or interpret risk vs. benefit using patient-specific factors
- Failure to implement or adhere to VTE prophylaxis risk stratification protocols
- Failure to appropriately resume anticoagulation after interruption or reversal

Overutilization

- Utilization of VTE prophylaxis in low-risk patients
- Excessive duration of VTE treatment (e.g. > 3 months for surgically provoked clot)

Inappropriate prescribing

- Lack of familiarity with available agents
- Utilization of anticoagulants despite contraindications (e.g. DOACs with mechanical heart valves)
- Empiric dose reductions of DOACs
- Lack of dose adjustment(s) for age, weight, organ function
- Wrong dose for indication (e.g. AF dosing in VTE patients)

Suboptimal management

- Lack of identification of anticoagulation patients at intake/admission
- Non-standardized, non-evidence based approaches to common indications (e.g. VTE, AF, stroke, heart valves, ACS) or therapies (use of heparin dosing nomograms)
- Significant drug interactions
- Warfarin with time in therapeutic INR range <65%
- Inappropriate or non-standard approach to periprocedural management
- Lack of appropriate VTE risk assessment and application of prophylaxis among hospitalized patients
- Inappropriate transitions between anticoagulants
- Lack of customization to needs of special populations (e.g., pediatrics, obstetrics, cancer)

Inappropriate use of diagnostic testing and laboratory measurement

- Inherited or acquired thrombophilias
- Heparin-induced thrombocytopenia
- Inappropriate timing of testing

Suboptimal management of anticoagulant-related adverse events

- Lack of familiarity with available reversal agents
- Excessive or inappropriate use of reversal agents
- Lack of streamlined infrastructure to expedite administration of needed reversal agents
- Lack of rapid response to acute thrombotic and bleeding events

Suboptimal care transitions

- Failure to address existing barriers to care and social determinants of health (e.g. insurance coverage, cost of medications, transportation challenges, health literacy issues)
- Inadequate anticoagulant-related information available to clinicians to safely and effectively manage the patient
- Poor coordination of services/communication

Failure to address patient factors

- Patient adherence issues
- High-risk behaviors
- Inadequate education/comprehension
- Lack of established, effective communication channels
- Suboptimal responsiveness to patient needs/inquiries
- Insurance limits and ability to pay for prescriptions

Excessive event rates

- Bleeding
- Thrombosis
- Emergency department visits
- Readmissions

Implement systematic care: Implementing sustainable, efficient, evidence-based action(s) at the system level to assure the safety and quality of anticoagulation management

The safety, quality, and efficacy of anticoagulation management can be optimized with a systematic, evidence-based approach to therapy. The program leader should establish fiscally and operationally efficient protocols and practice guidelines for the initiation and maintenance of anticoagulant therapy relevant to their care setting. Standarized care will improve patient clinical outcomes while reducing the likelihood of anticoagulant-related adverse drug events.

Effective models may employ and include any combination of components, such as:

- Policies and procedures
- Evidence-based protocols
- Standardized order sets
- Clinical decision support features
- Clinical pharmacy programs (e.g. renal dosing, parenteral to oral programs, etc.)
- Collaborative drug therapy management agreements
- Risk assessment tools
- Decision algorithms
- Dosing nomograms
- Formulary restrictions
- Educational programs and materials

The use of "passive" processes (e.g. automated order sets) should be leveraged to maximize program impact and sustainability in the face of limited resources.**[47]**

High-quality stewardship resources from multiple government agencies and professional organizations are available through the Anticoagulation Forum's Centers of Excellence Resource Center (excellence.acforum.org).

Adherence to Key Principles: Optimal anticoagulation management should reflect the following important characteristics:

- Evidence-based: The anticoagulation-related literature base is evolving rapidly, and intervention strategies should reflect available medical evidence and follow recognized best practices.
- Patient-centered: Patient perspectives and priorities should be included in program design, especially in the outpatient setting where appropriate anticoagulant administration and adherence is critical to outcomes.
- Systematic: Interventions should target deficiencies at the system level, improving underlying processes that support and sustain high-quality patient care.
- Integrated: Interventions and improvement efforts should be fully integrated into organizational decision-making and clinical workflows. Clinical decision support tools, order sets, and other resources should become cohesive components of routine patient care processes. Anticoagulation stewardship success and sustainability will be more achievable if efforts align with other ongoing initiatives within the organization.

Continuous Quality Improvement: All interventions and stewardship program components should be re-evaluated for impact; ongoing data collection and analysis should be used to guide continuous improvements. As interventions become stable and fully sustainable, additional stewardship priorities should be identified and addressed.

Stewardship Example 2: Multi-Practice Primary Care Network

Analysis of clinic data identifies inappropriate dosing of DOACs among patients with AF as a priority for action and the leadership appropriates funds to support minor modifications to the electronic medical record.

Protected time is provided to a staff APN to work on the project with a clinical faculty preceptor from a local college of pharmacy. A standard order set with clinical decision support features is configured to guide DOAC dosing based on patient factors (e.g. renal function) and to assure follow-up encounters to support adherence.

Implementation of the order set across all practice locations follows education and discussion at regularly scheduled quarterly meetings to assure provider awareness and support. Monthly reports are generated from the EHR and evaluated by the project champion who, in turn, prompts leadership engagement of providers with prescribing patterns that do not align with the evidence-based order set.

Facilitate transitions of care: Creating systems to optimize communication and ensure safe transitions between care settings

Transitions of care render all patients, but particularly those on anticoagulants, vulnerable to miscommunication and gaps in clinical management that can result in serious and even catastrophic adverse events. Each organization should evaluate the quality of their care transition processes to ensure clear and effective communication about anticoagulant therapy and related patient and provider roles and responsibilities.[21]

For patients being treated with an anticoagulant, relevant care transitions may include any instance where a patient experiences:

- Change in care setting or living environment
- Additional or different medical service provider(s)
- New medical diagnoses or fluctuation in acuity
- Addition, deletion, or modification to drug therapy
- Invasive medical procedure or surgery
- Change in pharmacy benefits/health insurance coverage

Organizations tend to be most cognizant of inpatient facility admissions and discharges, but transitions between inpatient care units, among outpatient service providers, and involving medications (anticoagulants and interacting agents) require attention. Generalized care transition processes should be evaluated for their ability to reliably communicate explicit information specific to anticoagulation management.

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Stewardship Example 3: Independent Long-Term Care Facility

Recognizing the value of an organized anticoagulation stewardship program, the facility ownership identifies the staff advanced practice nurse as the program leader and allocates additional funds for the consultant pharmacist to perform a baseline audit and provide ongoing technical expertise and support pertaining to anticoagulants.

The audit identifies multiple cases of medication administration errors and delays involving anticoagulants, particularly among short-term rehabilitation patients. Revisions to the intake/referral process are implemented to assure the identification of all anticoagulated admissions and the receipt of definitive information regarding anticoagulant dosing, timing, and duration. All staff undergo training about the new processes.

Serial audits document dramatic improvements in the quality of information obtained upon admissions and no medication administration errors or delays are identified.

Core tenets of a successful care transition program include:

- Proactive solicitation and acquisition of key information (e.g. admission policy/procedure, standardized patient interview)
- Organization and effective communication of key information (e.g. consolidated discharge summary)
- Specific instructions about (1) any imminent laboratory testing (e.g. INR measurement or assessment of platelet count) that is clinically indicated, and (2) any recommended action(s), based on the results of such testing
- Structured communication among care providers (e.g. acknowledged roles, responsibilities)
- Anticipation and resolution of barriers to care (e.g. access to medications)
- Consistent, accurate medication reconciliation
- Appropriate referral and timely follow up
- Established channels of patient-provider communication

The elements outlined above should be incorporated into a care transitions checklist to ensure all essential elements have been addressed prior to the patient leaving the current care setting.[48]

Advance education, comprehension, and competency: Assuring that clinicians, patients, and others have the knowledge and skills necessary to optimize outcomes

Effective education of both healthcare personnel and patients, families, and caregivers is an essential component of optimized anticoagulant management, regardless of care setting. Both patient and provider education should be provided regularly, repeated at scheduled intervals, and systematically documented. Because maximal impact is achieved through comprehension, educational approaches should be meaningful and measurable.

Patient education resources should be formatted to be as accessible and effective as possible. Written resources should be concise and visually appealing, being produced in the font size, reading level, and language(s) most appropriate to the population receiving care. Multi-modal resources (e.g. video, audio) can be developed to reach additional patient populations (e.g. visually impaired, low literacy) and leveraged to enhance overall program effectiveness.

Patient comprehension should be routinely assessed in some manner (e.g. “teach back”, formal assessments), systematically documented, and communicated with other providers. **[21,49,50]** Tracking the proportion of patients who receive (and preferably comprehend) educational resources about their anticoagulant medication is a suggested metric for the stewardship program.

All clinical personnel and support staff routinely engaged in the care of anticoagulation patients should be educated on clinical aspects of anticoagulant therapies, as well as policies and procedures of the stewardship program (e.g. reception staff responses to reported bleeding). Clinicians that serve as experts for the stewardship program should demonstrate ongoing comprehension and competency of anticoagulation management.

Education of external healthcare facility administration and staff (e.g. skilled nursing facilities, rehabilitation facilities, etc.) may also be beneficial to promote awareness, standardization and bi-directional efforts in regard to transitions of care.

Additional Considerations

Anticoagulants are not the sole therapeutic modality for the prevention or treatment of thromboembolism. Other drug classes (e.g. antiplatelet drugs), external and internal devices (e.g. pneumatic compression, left atrial appendage closure, IVC filters), and patient activities (e.g. ambulation) all play a role in the care of patients experiencing or those at risk of thrombosis.

The current *Core Elements of Anticoagulation Stewardship Programs* focuses specifically on anticoagulants because of their complexity of use and documented risk of avoidable adverse events. However, depending on the care setting and patient population, successful and impactful stewardship programs will likely involve processes associated with other prevention and treatment modalities as well.

The clinical management of anticoagulant-associated bleeding and optimized use of reversal agents is a rapidly expanding area that is also well-suited for stewardship programs. Product costs and complex logistics involved in timely ordering, preparation, and administration of these agents require organized, evidence-based processes to optimize patient outcomes and minimize waste.

Finally, while not specifically addressed in this guide, specialty testing and diagnosis, such as for heparin-induced thrombocytopenia (HIT) and thrombophilia (e.g. antiphospholipid syndrome), are additional areas where anticoagulation stewardship is warranted, as it can have a impact on resource utilization and optimal patient management.

The *Core Elements of Anticoagulation Stewardship Programs* guide is intended to be applicable to all care settings and all anticoagulation patient populations. By thoroughly evaluating a population's characteristics and implementing effective, evidence-based system improvements to address high-priority concerns, all care settings can optimize the quality and safety of anticoagulant use and overall patient management.

Checklist for Core Elements of Anticoagulation Stewardship Programs

The following checklist supports the *Core Elements of Anticoagulation Stewardship Programs.* This checklist should be used to systematically assess key elements and actions that are integral to successful anticoagulation stewardship efforts and high-quality patient care.

Healthcare organization administrators should work in tandem with healthcare staff knowledgeable in anticoagulation therapy, using this checklist as a guide to determine if essential support, resources, and initiatives are in place for optimal management of patients on anticoagulation medications.

As each healthcare setting is unique, it is recognized that no single anticoagulation stewardship program model will fit all facilities. As such, implementation of checklist elements may need to be customized, based on infrastructure and access to resources.

Scoring: Evaluate your organization's current state and provide a score for each item using the following scale.

0 = Not yet addressed
1 = Partially implemented
2 = Fully implemented
NA = Not applicable to organization

1. Secure administrative leadership commitment	Score
A. Provides visible endorsement of stewardship efforts by incorporating anticoagulation-related priorities into organizational strategic plans or quality improvement action plans, reviews performance annually and holds itself accountable for stewardship goals	☐
B. Budgets resources for development and ongoing support of anticoagulation stewardship activities that are appropriately matched to size, function and needs of the organization (e.g. dedicated positions, training, information technology support, etc.)	☐

2. Establish professional accountability and expertise	Score
A. Identifies a champion to serve as the program leader who is responsible for oversight of anticoagulation stewardship activities and achievement of related goals	☐
B. Identifies one or more clinician(s) with advanced training and expertise in anticoagulation management to support the program leader in development, implementation and evaluation of stewardship activities	☐

Scoring: Evaluate your organization's current state and provide a score for each item using this scale.
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3. Engage multidisciplinary support

Score

A. Identifies representatives from key areas to obtain valuable perspectives from all domains of the care delivery system, such as:

- ☐ **I.** Surgical Provider(s)
- ☐ **II.** Non-Surgical Provider(s)
- ☐ **III.** Nursing
- ☐ **IV.** Pharmacy
- ☐ **V.** Quality Improvement
- ☐ **VI.** Laboratory
- ☐ **VII.** Information Technology
- ☐ **VIII.** Data Analytics
- ☐ **IX.** Case Management
- ☐ **X.** Administrative Leadership
- ☐ **XI.** Other(s) _____

B. Establishes a mechanism (e.g. standing committee) to solicit multidisciplinary input on stewardship program development, implementation and performance improvement ☐

4. Perform data collection, tracking and analysis

Score

A. Allocates information technology and data analytic resources to develop and implement necessary tools and processes for ongoing evaluation of anticoagulation stewardship activities and performance ☐

B. Tracks processes and outcomes (including net clinical benefit) to evaluate the safety, efficacy and cost-effectiveness of anticoagulation-related care, such as:

- ☐ **I.** Adherence to evidence-based clinical guidelines, protocols and/or policies related to anticoagulation
- ☐ **II.** Adequate documentation of key anticoagulation information
- ☐ **III.** Quality of anticoagulation management (e.g. TTR, INR >5, etc.)
- ☐ **IV.** Adverse events (e.g. bleeding, thrombosis, medication errors)
- ☐ **V.** Healthcare staff education on anticoagulant therapies
- ☐ **VI.** Patient/family/caregiver education on anticoagulant therapies
- ☐ **VII.** Safety and effectiveness of care transitions
- ☐ **VIII.** Other(s) _____

C. Evaluates organizational performance of key measures annually to identify opportunities for improvement ☐

D. Implements a mechanism for feedback to administrators, providers and other healthcare staff as to anticoagulation stewardship performance ☐

Scoring: Evaluate your organization's current state and provide a score for each item using this scale.
0 = Not yet addressed **1** = Partially Implemented **2** = Fully Implemented **NA** = Not applicable to organization

5. Implement systematic care

Score

A. Develops and implements an institutional policy that addresses key anticoagulation stewardship aspects, such as structure and function of the program, delineation of roles and responsibilities of those caring for anticoagulation patients and need for baseline and ongoing monitoring ☐

B. Develops and implements evidence-based clinical guidelines, protocols, order sets or pathways that address common anticoagulation drugs, disease states or clinical situations, such as:

- ☐ **I.** Parenteral and oral anticoagulants
- ☐ **II.** Prevention and treatment of venous thromboembolism
- ☐ **III.** Stroke prevention in atrial fibrillation
- ☐ **IV.** Cardiac valves
- ☐ **V.** Management of bleeding, reversal, and resumption of anticoagulants
- ☐ **VI.** Perioperative management of anticoagulants
- ☐ **VIII.** Other(s) _____

C. Implements specific pharmacy-driven interventions, including, but not limited to:

- ☐ **I.** Automatic, evidence-based dose adjustments by pharmacy for age, weight, organ function
- ☐ **II.** Automatic alerts to identify unnecessary therapeutic duplications or inappropriate prescribing (e.g. epidurals, extremes of weight, etc.)
- ☐ **III.** Other(s) _____

6. Facilitate transitions of care

Score

A. Implements standardized processes to proactively identify new or incoming patients receiving anticoagulant therapy and obtain relevant information to assure safe and effective anticoagulation therapy when care begins in the new setting ☐

B. Implements standardized evidence-based processes for periprocedural anticoagulation management ☐

C. Implements standardized processes to proactively identify current anticoagulant users transitioning to other care settings and communicates bi-directionally to assure that relevant information is shared and acknowledged to support safe and effective anticoagulation therapy when care begins in the subsequent setting ☐

Scoring: Evaluate your organization's current state and provide a score for each item using this scale.
0 = Not yet addressed **1** = Partially Implemented **2** = Fully Implemented **NA** = Not applicable to organization

7. Advance education, comprehension, and competency	Score
A. Ensures that clinical expert(s) responsible for anticoagulation stewardship achieve and maintain their level of expertise through advanced training	☐
B. Establishes processes to ensure patients and caregivers receive and comprehend anticoagulation-related education, especially at each care transition, that is culturally appropriate, in the preferred language, and is presented at an appropriate health literacy level	☐

Checklist items scored as "not yet addressed" or "partially implemented" should be priorities for action, while "fully implemented" program elements should undergo periodic re-evaluation. To support areas needing improvement, high-quality resources from multiple organizations are available through the Anticoagulation Forum's Centers of Excellence Resource Center (excellence.acforum.org).

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