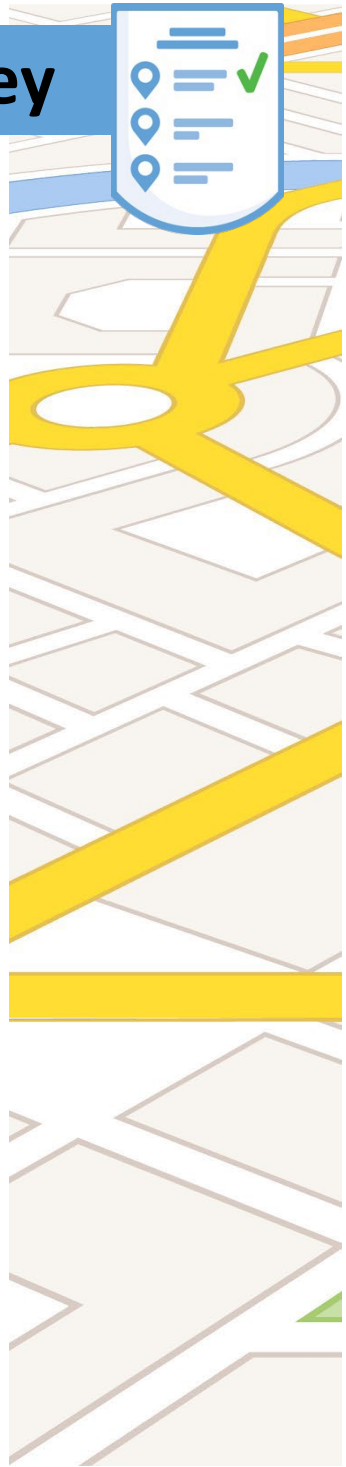
The Roadmap to Success:

Adverse Drug Event (ADE)
Anticoagulant Management

HSAG HQIC

Preparing for Your Journey



Any successful journey begins with planning and preparation. Three key areas should be addressed before beginning any quality improvement or patient safety initiative.

Leadership Commitment

The success of a project can be determined by the level of commitment and support from leadership. It is important for hospital leaders to communicate a consistent, frequent message in support of the project. The executive project champion can establish accountability, dedicate resources, and break through barriers.

Project Champion

It is important to have a person(s) who is a significant influence with frontline staff, physicians, and other key personnel. Frequently, we think of a physician as a champion as they are instrumental in garnering provider buy-in and practice change. However, depending on the project, it can be any key personnel with the authority and skills to influence change, lead by example, and assist in essential messaging of the goals and vision for a project.

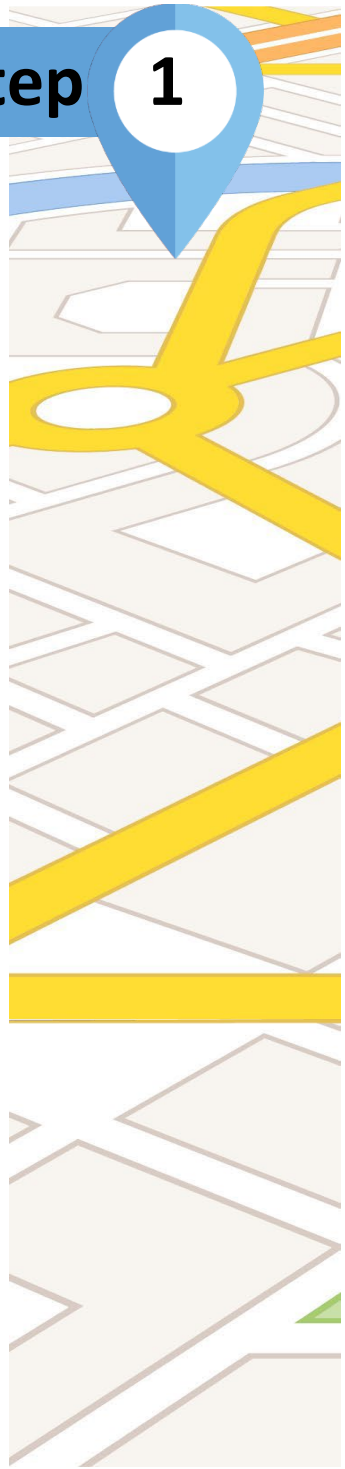
Multidisciplinary Project Team

The project team should consist of representatives from key areas throughout your facility with the skills, knowledge, and experience in their fields of expertise. A team member should possess strong communication skills, have a collaborative mindset, and show a commitment to change. It is vital to **have representation from frontline staff who will be impacted most by the change**. It is also important to keep the size of your team manageable. Remember, a team can have ad hoc members whose role is to provide expertise in a specific area for a short period of time.

For more information on team forming, access the following resource at www.hsag.com/hqic-quality-series:

- Quality and Safety Series Video on Team Forming

Science-Driven Prevention and Treatment—Step 1



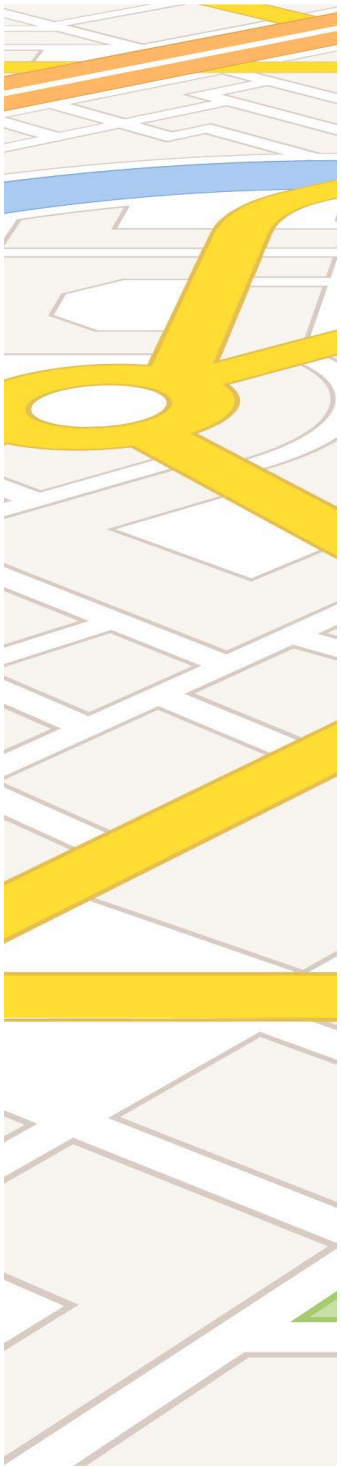
Rationale:

Anticoagulation medications are high-risk medications due to complex dosing, insufficient monitoring, and inconsistent patient compliance. Use of science-based prevention and treatment strategies ensure that the appropriate medication for the indication is selected, as well as the appropriate dose and frequency.

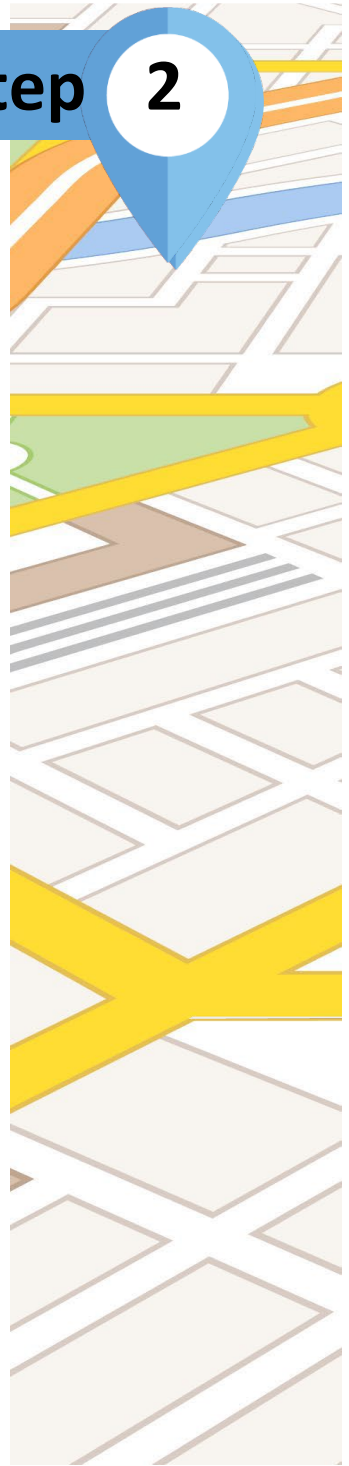
Implementing evidence-based guidelines and protocols is an integral part of anticoagulation therapy management to minimize the risk of adverse drug events (ADEs).

	Strategies to Implement	Tools and Resources
☐	Promote a multidisciplinary, coordinated, and systematic approach to inpatient anticoagulation management. For example: • Anticoagulant rounds • Pharmacist-/nurse-managed anticoagulation services • Anticoagulation stewardship	• Anticoagulation FORUM, Core Elements of Anticoagulation Stewardship Program: https://acforum-excellence.org/Resource-Center/resource_files/-2019-09-18-110254.pdf • Federal Bureau of Prisons (BOP) Anticoagulation Protocol: https://www.bop.gov/resources/health_care_mngmt.jsp • National Library of Medicine. A Rapid Guidance Process for the Development of an Anticoagulation Protocol in the COVID-19 Pandemic: https://pubmed.ncbi.nlm.nih.gov/34048378/ • Michigan Anticoagulation Quality Improvement Initiative—Provider Toolkit: http://anticoagulationtoolkit.org/providers • American Society of Hematology (ASH) Pocket Guides: https://www.hematology.org/education/clinicians/guidelines-and-quality-care/pocket-guides
☐	Address the safe use of anticoagulants commonly used in inpatient settings (e.g., heparin) and novel oral anticoagulants (NOACs) in nationally recognized patient safety measures and clinical guidelines.	
☐	Implement approved protocols and evidence-based practice guidelines to begin and maintain anticoagulation therapy. Factors that should be addressed in the protocols and practice guidelines include: • Bleeding risk evaluation. • Medication selection. • Dosing, including adjustments for age and renal or liver function. • Drug-drug and food-drug interactions. • Other risk factors, as applicable.	
☐	Implement approved protocols and evidence-based practice guidelines for anticoagulation reversal and management of anticoagulant-associated bleeding events for each anticoagulant medication. Factors that should be addressed in the protocols and practice guidelines include: • Which reversal agent should be used based on the anticoagulant medication. • The severity of the patient's bleeding event.	

	Strategies to Implement	Tools and Resources
☐	Implement approved protocols and evidence-based practice guidelines for managing perioperative patients that are on oral anticoagulants. The perioperative anticoagulation management protocol should: • Address when an anticoagulant should be stopped prior to surgery. • Indicate if a bridging medication should be used. • Indicate at what dose the patient's anticoagulant medication should be restarted.	• American College of Chest Physicians—Perioperative Management of Antithrombotic Therapy: https://journal.chestnet.org/article/S0012-3692(12)60127-5/fulltext • The University of Texas MD Anderson Cancer Center—Peri-Procedure Management of Anticoagulants: https://www.mdanderson.org/content/dam/mdanderson/documents/for-physicians/algorithms/clinical-management/clin-management-peri-procedure-anticoagulants-web-algorithm.pdf
☐	Ensure there is a written policy that addresses the need for baseline and ongoing laboratory tests for monitoring and adjusting anticoagulation therapy. • For all patients receiving warfarin therapy, use a current international normalized ratio (INR) to monitor and adjust dosage. • For patients on a direct oral anticoagulant (DOAC), follow evidence-based guidelines regarding the need for laboratory testing.	



Promote Safer Care—Step 2



Rationale:

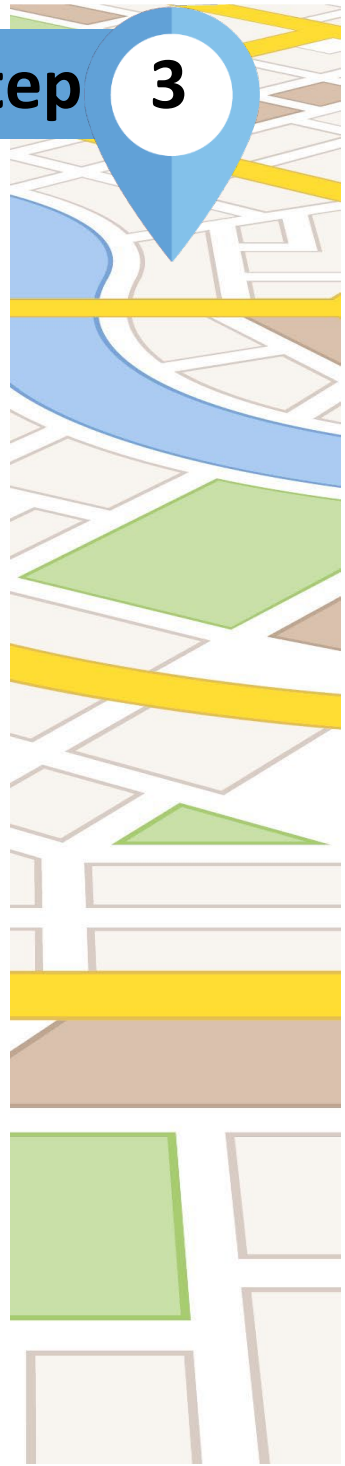
Healthcare providers have a basic responsibility to protect patients from accidental harm. Identifying common, preventable, and measurable healthcare-associated anticoagulant ADEs is a key component of quality improvement efforts to drive prevention, benchmark progress, and promote a culture of anticoagulation safety.

	Strategies to Implement
☐	Improve provider and staff knowledge of high-quality inpatient anticoagulation management through provider education.
☐	Improve dissemination of/increase accessibility to evidence-based, inpatient anticoagulation management strategies/tools.
☐	Address gaps in evidence and provider/physician knowledge regarding NOAC management by developing guidelines/algorithms for safe use (e.g., clinician guidance for laboratory testing).
☐	Evaluate safety practices: • Establish a process to identify, respond to, and report ADEs, (include ADE outcomes). • Take actions to improve safety practices and measure the effectiveness of those actions within a specified timeframe (i.e., perform root cause analysis based on use of reversal agents, transfer to a high level of care, or international normalized ratio [INR] greater than 5).
☐	Implement strategies to minimize medication administration errors (e.g., incorrect preparation, strength, rate, and/or dose). • Use only unit-dosing products, prefilled syringes, or premixed infusion bags, when available. • Use programable pumps when heparin is administered through a continuous IV.
☐	Work toward zero harm. • Use clinical decision support to provide high-INR alerts and aid in dosing and management of warfarin. • Conduct daily safety huddles as a tool for high reliability. • Implement a pharmacist-led anticoagulation management service.

Tools and Resources

- Joint Commission—Critical Access Hospital 2021 National Patient Safety Goals: https://www.jointcommission.org/standards/national-patient-safety-goals/critical-access-hospital-national-patient-safety-goals/
- Joint Commission—Hospital 2021 National Patient Safety Goals: https://www.jointcommission.org/standards/national-patient-safety-goals/hospital-national-patient-safety-goals/
- Anticoagulant FORUM: https://acforum-excellence.org/
- Minnesota Hospital Association—Anti-coagulation Agent Adverse Drug Event Gap Analysis: https://www.mnhospitals.org/Portals/0/Documents/ptsafety/ade/Medication-Safety-Gap-Analysis-Anticoagulation-Agent.pdf
- Anticoagulation FORUM—Administrative Over-sight Gap Analysis: Hospitals and Skilled Nursing Facilities: https://acforum.org/web/downloads/ACF%20Gap%20Analysis%20Report.pdf
- Institute for Healthcare Improvement (IHI) How-to Guide. Prevent Harm from High-Alert Medications: http://www.ihi.org/resources/Pages/Tools/HowtoGuidePreventHarmfromHighAlertMedications.aspx
- IHI Trigger Tool for Measuring ADEs: http://www.ihi.org/resources/Pages/Tools/TriggerToolforMeasuringAdverseDrugEvents.aspx

Effective Communication and Care Coordination—Step 3

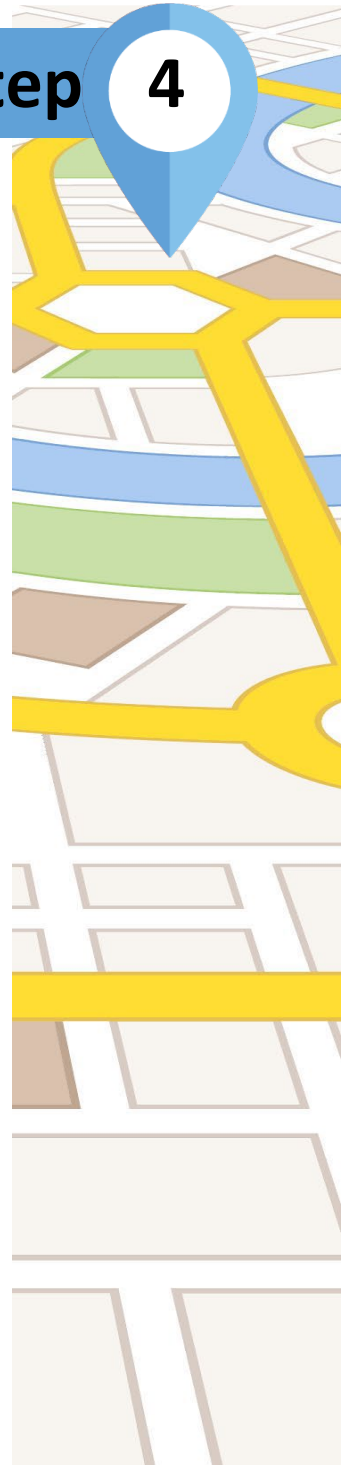


Rationale:

Effective team collaboration and care coordination are essential. When the care team is not communicating effectively, patient safety is at risk for several reasons, including lack of critical information, misinterpretation of information, unclear orders, and overlooked changes in status. Lack of communication creates situations in which ADEs can occur. These ADEs have the potential to cause severe injury or unexpected patient death.

	Strategies to Implement	Tools and Resources
☐	Establish a structured communication process (e.g., Situation, Background, Assessment, Recommendation [SBAR]) for communications related to critical laboratory values and high-risk medication alerts.	• Patient Safety Movement Foundation—Handoff Communications: https://patientsafetymovement.org/wp-content/uploads/2016/02/APSS-6_HOC-7.pdf • Agency for Healthcare Research and Quality (AHRQ)—Re-Engineered Discharge (RED) Toolkit: https://www.ahrq.gov/patient-safety/settings/hospital/red/toolkit/index.html • Society of Hospital Medicine (SHM)—Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS) Toolkit: https://www.hospitalmedicine.org/globalassets/clinical-topics/clinical-pdf/shm_medication_reconciliation_guide.pdf • Pharmacist Drug Adherence Work-up Tool (DRAW©): https://www.colorado.gov/pacific/sites/default/files/DC_CD_Adherence-Screening-DRAW_Million-Hearts.pdf • National Action Plan for ADE Prevention: https://health.gov/sites/default/files/2019-09/ADE-Action-Plan-508c.pdf
☐	Establish an effective medication reconciliation process upon admission and discharge.	
☐	Engage the hospital pharmacist at time of discharge.	
☐	Improve electronic health record (EHR) tools to enable provider access to real-time, integrated pharmacy/laboratory data to facilitate seamless access to pertinent medication and laboratory results. For example: • Develop electronic flowsheets that display trends in daily labs, associated medications, reversal medications, etc., that are specific to and can support optimal anticoagulation management. • Use clinical decision-support tools specific to anticoagulation management.	
☐	Integrate anticoagulation-specific targets into existing care transition models.	

Patient and Family Engagement—Step 4

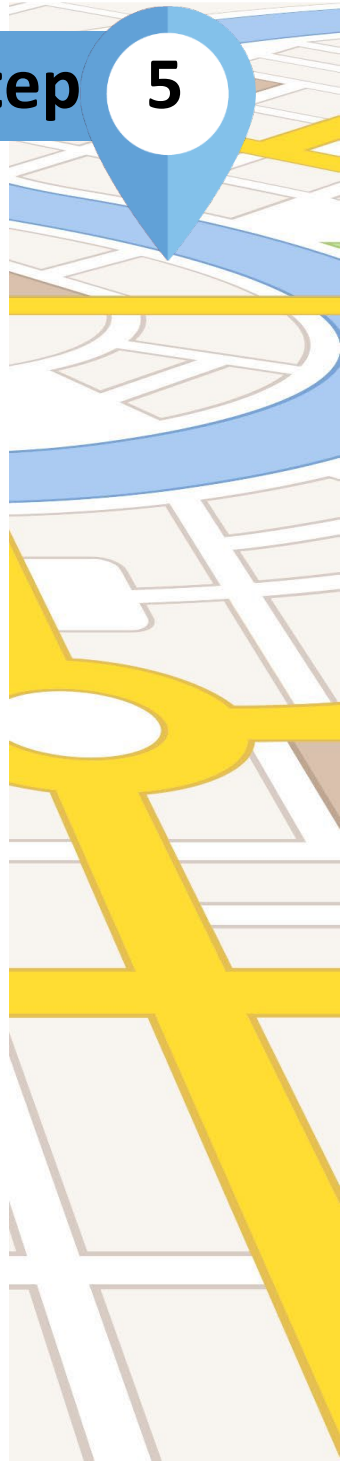


Rationale:

Patients and families are valuable partners to prevent anticoagulant ADEs, such as bleeding and venous thromboembolism. Nonadherence to anticoagulation therapy places patients at risk for bleeding and/or clotting that can lead to severe ADEs or unexpected patient death.

	Strategies to Implement	Tools and Resources
☐	Educate patients and their families using the teach-back method. Key components of anticoagulant medication education include: • Indication for use. • Symptoms for monitoring. • Adherence to medication dose and schedule. • Importance of follow-up appointments and lab testing, if applicable. • Potential drug-drug and drug-food interactions. • The potential for adverse drug reactions. Using teach-back, patients and families should be able to: • Describe the treatment goals and pathophysiology of clot formation. • Identify the signs/symptoms of bleeding and clotting related to anticoagulation therapy. • Describe the risks of missing doses and/or excessive dosing.	• HSAG HQIC Blood Thinner Self-Management Plan and Blood Thinner Safety Zone Tool: https://www.hsag.com/globalassets/hqic/zonetool_bloodthinner_hqic.pdf • Michigan Anticoagulation Quality Improvement Initiative—Patient Toolkit: http://anticoagulationtoolkit.org/patients • UpToDate® Patient education—Warfarin (Beyond the Basics): https://www.uptodate.com/contents/warfarin-beyond-the-basics • American Association of Colleges of Pharmacy. AACP Medication Adherence Educator's Toolkit: https://www.aacp.org/sites/default/files/aacp_ncpa_medication_adherence_educators_toolkit_0.pdf • AHRQ—Communication and Optimal Resolution (CANDOR) Toolkit: https://www.ahrq.gov/patient-safety/capacity/candor/modules.html
☐	Consider using a standardized process to assess individual needs in the event of an urgent or emergent incident (e.g., risk for falls and bleeding).	
☐	Engage patients and families in disclosure communication following anticoagulant ADEs.	

Promote Best Practices Within the Community—Step 5

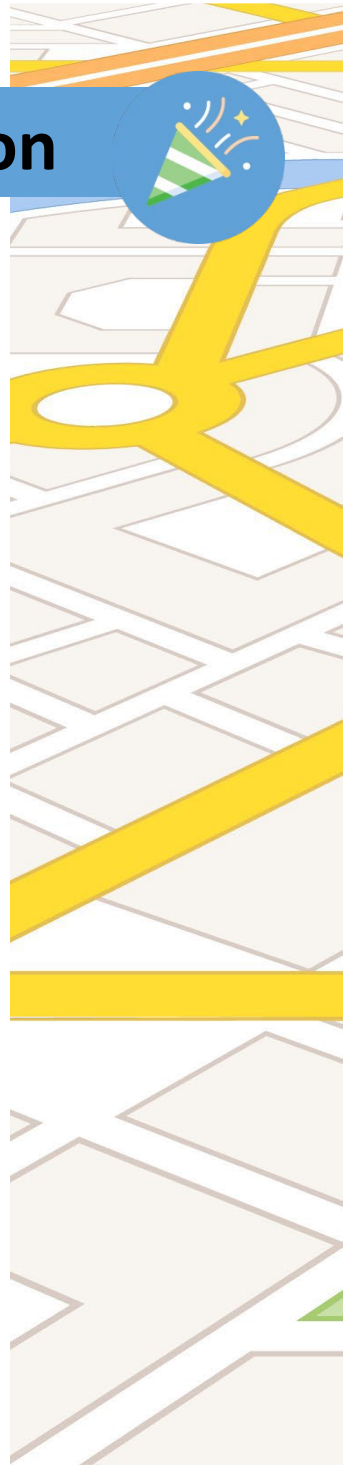


Rationale:

Promotion of best practices within the community, including effective hand-off communication, is vital to ensuring the continuity and safety of the patient's care. It is essential to recognize individualized support needs when transitioning from the hospital to home. Patients who face social disparities such as poverty, limited literacy, or belonging to a racial or ethnic minority group are particularly at risk for experiencing poor transitions of care.

	Strategies to Implement	Tools and Resources
☐	Identify and promote adoption of standards that constitute high-quality anticoagulation management (e.g., "Anticoagulation Center of Excellence").	• Project BOOST (Better Outcomes by Optimizing Safe Transitions: https://www.hospitalmedicine.org/globalassets/professional-development/professional-dev-pdf/boost-guide-second-edition.pdf • America Society of Consultant Pharmacists (ASCP) Foundation—Medication Safety During Transitions of Care: https://www.ascp.com/page/mstoc • Anticoagulation FORUM—Core Elements of Anticoagulation Stewardship Programs: https://acforum.org/web/downloads/ACF%20Anticoagulation%20Stewardship%20Guide.pdf • Centers for Medicare & Medicaid Services (CMS)—Health-Related Social Needs (HRSN) Screening Tool: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf • The Disparities Solution Center—Addressing Disparities in Diagnostic Error & Medication Safety in the Home: https://5536401f-20a1-4e61-a28e-914fb5dcef51.filesusr.com/ugd/888d39_deb78f570d574e29819c44682946f669.pdf • HSAG HQIC Secure Data Portal—Review your facility's demographic data by selecting the "Summary" tab on the Performance Dashboard: https://www.hsag.com/hqic
☐	Provide handoff communication to the next provider of care which includes: • Inpatient dosing history. • Inpatient INR value history. • Date the next INR is due. • Daily dosing schedule to be followed until date of next INR. • A confirmed appointment scheduled for the laboratory, physician, and/or anticoagulation clinic.	
☐	Assure equity in access to and delivery of clinical care through: • Screening for social determinants of health. Key things to consider include: – Access to transportation for routine monitoring of lab values. – Ability to afford prescribed medications. – Readability of discharge patient education materials. • Data collection and analysis of disparities. • Telehealth. • Interpreter/translation services.	

Your Final Destination



Now that you've reached your destination, it is important that your efforts are not futile. One of the most challenging aspects of quality improvement and change is sustaining the gains. These key tactics will help you ensure ongoing success.

Ensuring Your Process Is Stable

Most projects involve monitoring of both process and outcome measures. These data play an important role in identifying when you've achieved change. It is important to review your data to identify and address special cause variation; recognize positive trend changes (six to eight data points at or above goal); and achieve predictable, consistent results.
Remember: *"Every system is perfectly designed to get the results it gets."*—W.E. Deming

For more information on data, variation, and change, access the following resource at www.hsag.com/hqic-quality-series:

- Quality and Safety Series Video on Data Plan

Control Plan/Sustainability Plan

A control or sustainability plan is a method for documenting the key elements of quality control that are necessary to assure that process changes and desired outcomes will be maintained. At a minimum, this plan should include ongoing monitoring of process steps that are critical to quality, frequency of monitoring, sampling methodology, and corrective actions if there is noted variation.

For more information on control and sustainability plans, access the following resource at www.hsag.com/hqic-quality-series:

- Quality and Safety Series Video on Sustainability and Control Plan

Project Hand-Off

Depending on the size of your facility and resources that are available, it may be necessary to hand off your project to a "process owner." A process owner is a person or department responsible for monitoring a process and sustaining the changes according to the control or sustainability plan. The person or department should be the entity that will most significantly experience the gains of the improved process or project.

Tools and Resources

- The Joint Commission—National Patient Safety Goals Effective January 2021 for the Hospital Program. Available at: https://www.jointcommission.org/-
- /media/tjc/documents/standards/national-patient-safety-goals/2021/npsg_chapter_hap_jan2021.pdf. Accessed on June 30, 2021.
- Anticoagulation FORUM. Available at: https://acforum.org/web/. Accessed on June 30, 2021.
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- American Society of Hematology (ASH) Pocket Guide. Available at: https://www.hematology.org/education/clinicians/guidelines-and-quality-care/pocket-guides. Accessed on June 30, 2021.
- AHQR—Medication Errors and Adverse Drug Events. Available at: https://psnet.ahrq.gov/primer/medication-errors-and-adverse-drug-events#. Accessed on June 30, 2021.
- IHI—Reduce Adverse Drug Events Involving Intravenous Medications. Available at: http://www.ihi.org/resources/Pages/Changes/ReduceAdverseDrugEventsInvolvingIntravenousMedications.aspx. Accessed on June 30, 2021.
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- ASCP Foundation—Medication Safety During Transitions of Care. Available at: https://www.ascp.com/page/mstoc. Accessed on June 30, 2021.
- CMS—Health-Related Social Needs (HRSN) Screening Tool. Available at: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf. Accessed on August 16, 2021.
- The Disparities Solution Center. Available at: https://www.mghdisparitiessolutions.org/. Accessed on August 16, 2021.
- Federal Bureau of Prisons (BOP). Available at: https://www.bop.gov/resources/health_care_mngmt.jsp. Accessed on September 1, 2021.

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- Patient Safety Movement Foundation – Actionable Patient Safety Solutions (APSS) #6: Hand-off communications. Available at: https://patientsafetymovement.org/wp-content/uploads/2016/02/APSS-6_HOC-7.pdf. Accessed on September 1, 2021.
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- SHM—Multi-Center Medication Reconciliation Quality Improvement Study (MARQUIS) Toolkit. Available at: https://www.hospitalmedicine.org/globalassets/clinical-topics/clinical-pdf/shm_medication_reconciliation_guide.pdf. Accessed on September 1, 2021.
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