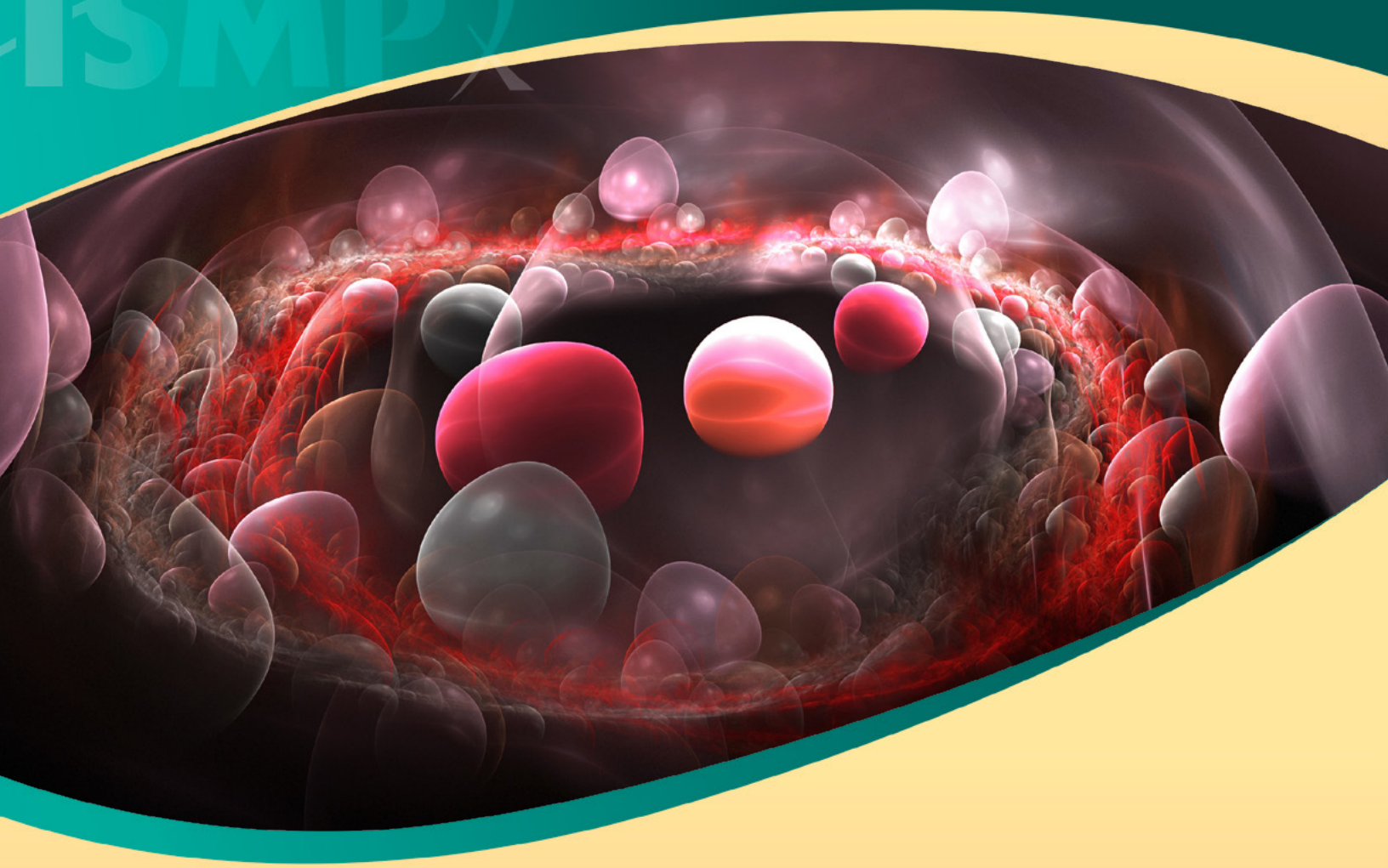

2017

ISMP Medication Safety Self Assessment® for Antithrombotic Therapy

ISMP

INSTITUTE FOR SAFE MEDICATION PRACTICES

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ISMP thanks the following members of our volunteer Advisory Panel who helped review the content of the ISMP Medication Safety Self Assessment® for Antithrombotic Therapy.

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We would also like to acknowledge the ISMP staff and fellows whose tireless efforts supported the completion of this assessment tool.

Dear Healthcare Provider:

The Institute for Safe Medication Practices (ISMP) is pleased to provide the nation's hospitals with the *2017 ISMP Medication Safety Self Assessment® for Antithrombotic Therapy*.

This tool is a revision of the 2005 version of the self assessment to include safety strategies for the newer oral anticoagulants. The self assessment will help you assess the medication safety practices in your institution surrounding the use of antithrombotic therapy and identify opportunities for improvement.

This tool contains items that address the use of antithrombotic drugs, many of which are on the ISMP List of High-Alert Medications. Many of the items included in the tool represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP National Medication Errors Reporting Program (ISMP-MERP) and other reporting programs, problems identified during on-site consultations with hospitals, and guidelines in the medical literature.

Antithrombotic therapy involves practitioners from multiple disciplines and departments. Therefore, we strongly urge you to use the following process to complete this tool:

- Establish a multidisciplinary team (see recommended team members on page 7).
- Assess your organization's use of antithrombotic agents through a consensus vote from all team members after thoroughly investigating the level of implementation for each self-assessment item.
- Document your progress toward improvement by re-assessing your use of antithrombotic agents with this tool on a regular basis.

We believe that you will find this tool to be useful as you assess the safe use of antithrombotic agents in your organization.

Sincerely,

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, Institute for Safe Medication Practices

About the Institute for Safe Medication Practices (ISMP)

The Institute for Safe Medication Practices (ISMP), based in suburban Philadelphia, is the nation's only 501c(3) nonprofit organization devoted entirely to medication error prevention and safe medication use. The organization is known and respected worldwide as the premier resource for impartial, timely, and accurate medication safety information.

ISMP represents more than 40 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. The Institute's medication error prevention efforts began in 1975 with a groundbreaking and continuing column in *Hospital Pharmacy* that increases understanding and educates healthcare professionals and others about medication error prevention.

Today, a continuously expanding core of knowledge in medication safety fuels the Institute's initiatives to improve the medication use process. These initiatives, which are built upon a Just Culture approach and system-based solutions, fall into five key areas: knowledge, analysis, education, cooperation, and communication.

A cornerstone of ISMP's medication error prevention efforts is a voluntary practitioner error-reporting program to learn about errors happening across the nation, understand their causes, and share "lessons learned" with the healthcare community. Each year, the ISMP National Medication Errors Reporting Program (MERP), receives hundreds of error reports from healthcare professionals. In addition, ISMP's wholly owned corporate subsidiary, Med-ERRS (Medical Error Recognition and Revision Strategies), works directly and confidentially with the pharmaceutical industry to prevent errors that stem from confusing or misleading drug names, labels, and packages.

The Institute's other initiatives include publishing five medication safety newsletters for healthcare professionals and consumers that collectively reach more than 3.5 million readers; presenting frequent educational programs, including webinars on current medication use issues; offering posters, videos, patient brochures, books, and other resources; and providing confidential consultation services to healthcare systems to proactively evaluate medication systems or analyze medication-related sentinel events.

ISMP collaborates on a continuing basis with a wide variety of healthcare practitioners, legislative and regulatory bodies, healthcare institutions, healthcare professional organizations, regulatory and accrediting agencies, employer and insurer groups, and the pharmaceutical industry.

As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its lifesaving work. For more information, visit ISMP online at: www.ismp.org.

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES
www.ismp.org

The ISMP Medication Safety Self Assessment® for Antithrombotic Therapy is designed to:

Heighten awareness of items related to the safe use of antithrombotic agents and create a baseline of hospital efforts to enhance safety with these agents and evaluate these efforts over time.

The self assessment is divided into eight key elements that significantly influence safe use of antithrombotic agents. Each key element is defined by one or more core characteristics of a safe medication system. Self-assessment items are provided to help you evaluate your success with achieving each core characteristic.

ISMP is not a standards-setting organization. As such, the self-assessment items in this document are not purported to represent a minimum standard of practice and should not be considered as such. In fact, some of the self-assessment criteria represent innovative practices and system enhancements that are not widely implemented in most hospitals today. However, their value in reducing errors is grounded in scientific research and expert analysis of medication errors and their causes.

Glossary (for purposes of this self assessment)

ANTITHROMBOTIC AGENTS include warfarin, heparin(s), factor Xa inhibitors, direct thrombin inhibitors, thrombolytics, and glycoprotein IIb-IIIa (GPIIb-IIIa) inhibitors.

EXAMPLES

DIRECT THROMBIN INHIBITORS
argatroban
bivalirudin (Angiomax®)
dabigatran (Pradaxa®)

FACTOR Xa INHIBITORS
apixaban (Eliquis®)
edoxaban (Savaysa®)
rivaroxaban (Xarelto®)

GLYCOPROTEIN IIb-IIIa INHIBITORS
abciximab (ReoPro®)
eptifibatide (Integrilin®)
tirofiban (Aggrastat®)

HEPARIN(S)
unfractionated heparin
fondaparinux (Arixtra®)
low molecular weight heparin
- dalteparin (Fragmin®)
- enoxaparin (Lovenox®)

THROMBOLYTICS
alteplase (Activase®)
reteplase (Retavase®)
tenecteplase (TNKase®)

Abbreviations

ADC – automated dispensing cabinet

aPTT – activated partial thromboplastin time

DOAC – direct oral anticoagulant

HIT – heparin-induced thrombocytopenia

INR – international normalized ratio

LMWH – low molecular weight heparin

NSAIDs – nonsteroidal anti-inflammatory drug(s)

PCC – prothrombin complex concentrate

TNK – tenecteplase

TPA – tissue plasminogen activator

UFH – unfractionated heparin

Definitions (for purposes of the self-assessment tool)

Key terms with definitions are designated throughout the text in **BOLD CAPITAL LETTERS**.

CAREGIVER
Family member, friend, or other person assisting or monitoring the patient's adherence to instructions in the outpatient setting.

COMPUTER ORDER ENTRY SYSTEM
Refers to any computer system into which medical orders are entered, including pharmacy computer systems into which pharmacy staff enter or validate medication orders, as well as computerized prescriber order entry (CPOE) systems into which medical staff enter medication orders.

HIGH-ALERT MEDICATIONS (OR DRUGS)
Medications that have a high risk of causing serious injury or death to a patient if they are misused. Errors with these products are not necessarily more common, but their results can be more devastating. Examples of high-alert medications include antithrombotic agents, insulin, chemotherapy, concentrated electrolytes, IV digoxin, opioids, neuromuscular blocking agents, and IV adrenergic agonists. A complete list can be found at: www.ismp.org/Tools/highAlertMedicationLists.asp.

INDEPENDENT DOUBLE CHECK
A procedure in which two individuals, preferably two licensed practitioners, separately check each component of the work process. An example would be one person calculating a medication dose for a specific patient and a second individual independently performing the same calculation (not just verifying the calculation) and matching the results.

INTERFACED
A direct link between two information systems in which information from one system is immediately available to the user of the second system, and integrated in a way that supports clinical decision making (e.g., interfacing the laboratory and pharmacy computer systems would immediately provide corresponding laboratory data to the pharmacist while they are entering a specific medication order). This may or may not include a bi-directional interface of the systems to allow communication in both directions.

PRACTITIONER
A licensed healthcare professional such as a physician, physician assistant, nurse anesthetist, nurse practitioner, nurse, or pharmacist.

SMART INFUSION PUMP
An infusion pump with clinical decision support software that is capable of alerting the user to unsafe dose limits and programming errors if standard concentrations and dose limits have been programmed into the pump's library.

Instructions for Conducting the Self Assessment

1 Establish a multidisciplinary team consisting of or similar to the following:

- representative from administration
- chief medical officer
- representative from nursing management
- representative from pharmacy management
- representative from clinical informatics
- risk management and/or quality improvement professionals
- at least two nurses from different specialty areas who administer antithrombotic drugs
- at least two pharmacists (clinical and distribution) who are involved in antithrombotic therapy
- representative from the clinical laboratory
- at least one active staff physician, preferably a hematologist, internist, or hospitalist
- representative from antithrombotic team and/or clinic (if team or clinic exists).

Your team should be provided with sufficient time to complete the self assessment and be charged with the responsibility to evaluate, accurately and honestly, the current status of antithrombotic therapy in your facility. Because antithrombotic therapy is a complex, interdisciplinary process, the value and accuracy of the self assessment is significantly reduced if it is completed by a single discipline. ISMP estimates that it will take two team meetings to complete the self assessment.

2 Read and review the self assessment in its entirety before beginning the assessment process.

3 Convene the team.

Ensure that each team member can view either a hardcopy or electronic version of the self assessment during the evaluation process. There are two options for completing the assessment.

- **Option 1:** Print a hard copy of the self assessment, fill in your choice (A through C, or Not Applicable) for each self-assessment item, and enter your responses into the online self-assessment form. (See ***Step 5*** for how to access the online form.)

- **Option 2:** Use the online self-assessment form to view at team meetings and enter your choice (A through C, or Not Applicable) for each self-assessment item, while saving your entered information between meetings. (See ***Step 5*** for how to access the online form.)

> **NOTE:** By entering your organization's responses into the online self-assessment form, you will receive a score for each key element and core characteristic and for the entire self assessment.

4 Discuss each core characteristic and evaluate your organization's success with implementing the self-assessment items.

As necessary, investigate and verify the level of implementation with other healthcare practitioners outside your team. When a consensus on the level of implementation for each self-assessment item has been reached, select the appropriate column using the following scoring key:

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

Important Scoring Guidelines

For all self-assessment items: Unless otherwise stated, self-assessment items refer to antithrombotics and related medications prescribed, dispensed, and administered to all inpatients and outpatients typically seen in most hospitals, such as patients admitted to the emergency department and ambulatory surgery/procedure units.

For self-assessment items with multiple components: Full implementation (score C) is evidenced only if all components are present. If only one or some of the components have been partially or fully implemented throughout the organization, self-assessment scores should not exceed level "B."

For self-assessment items with two distinct elements, each separated with the word "OR" and labeled (a) and (b): Answer either part (a) OR part (b), but not both.

For self-assessment items that offer an option of "Not Applicable": Select "Not Applicable" only if the item does not correspond to any services you provide in your hospital, either to inpatients or outpatients.

5 Enter your responses in the online self-assessment form.

This step will be done simultaneously with ***Step 4*** if ***Option 2*** is used by the team to complete the assessment.

If you do NOT enter all of your responses during the same session and need to return to your entered information at a later time: Immediately prior to closing out of your session, save your entered information by clicking the "Save and continue later" link (located on the red bar at the top of each webpage), entering your email address, and pressing "Save." An email (from SurveyGizmo) will then be sent to the provided email address with a link that can be used to return to your saved information. *If you do not receive an email, please check your spam, junk, or clutter email folder or quarantined messages.*

To access the online form, go to: https://surveys.ismp.org/s3/2017-ISMP-Medication-Safety-Self-Assessment-for-Antithrombotic-Therapy.

PLEASE NOTE: ISMP will not be collecting or aggregating data received through the online form.

IMPORTANT! Only save your information once per session. This should be done immediately prior to exiting out of the online assessment. Your entered information is only saved when you are prompted to enter your email address and to press "Save."

If you DO enter all of your hospital's responses during the same session, but want the ability to return to your hospital's results at a later time: Prior to completing Key Element VIII (Quality Processes and Risk Management), click on the "Save and continue later" link (located on the red bar at the top of the webpage), enter your email address, and press "Save." An email (from SurveyGizmo) will then be sent to the provided email address with a link that can be used to view your hospital's results. *If you do not receive an email, please check your spam, junk, or clutter email folder or quarantined messages.*

> **IMPORTANT!** This must occur prior to clicking "Next" on the Key Element VIII webpage.

6 Obtain your hospital's results.

To receive your results, click "Next" on the Key Element VIII webpage if you have finished answering all of the assessment items. You will then be prompted to print two reports. The first report is how your hospital answered each self-assessment item. The second report contains your hospital's score, the maximum score, and your hospital's score as a percentage of the maximum score for each key element and core characteristic and for the entire self assessment.

> **IMPORTANT!** If you did not save your hospital's assessment by providing an email address as described in ***Step 5***, this will be your last opportunity to print these two reports. If you did save your hospital's assessment by providing an email address, you can use the link that was emailed to the provided address at any point to retrieve your hospital's reports.

If you have questions, please visit the Frequently Asked Questions (FAQs) on the ISMP website (http://www.ismp.org/selfassessments/Antithrombotic/2017).

Self-assessment items that have been initially associated with a Frequently Asked Question are highlighted with "FAQ." Other Frequently Asked Questions will be posted to the website as encountered. Contact ISMP at selfassess@ismp.org or call (215) 947-7797 during usual business hours (Eastern Time) if you need additional assistance.

Identifying and Prioritizing Opportunities for Improvement

1 Identify areas of weakness.

Identify the key elements and core characteristics with the greatest opportunities for improvement (those with the lowest scores as a percentage of the maximum score), as well as the individual self-assessment items with a response of A or B.

2 Prioritize your work.

Prioritize the above identified opportunities for improvement.

- Start with items that you know you can achieve without considerable delay. Including these types of items at the top of your prioritized list can help ensure early success and establish momentum for ongoing improvements.
- An item that scored B suggests that the risk-reduction strategy has been implemented in part with some success in the organization. Building upon these early successes is a natural progression of effort.
- Do not hesitate to include a resource-intensive strategy high on your priority list. Items that require extensive time and financial outlays to implement also require extensive planning. Making a resource-intensive strategy a priority helps to ensure that the planning work begins immediately, even if implementation is a year or more away.
- Successful change begins with acquiring staffs' buy-in to the change process. Strategies that incite enthusiasm strengthen the commitment to achieving a shared goal.

3 Develop an action plan.

Develop your medication safety action plan with the goal of obtaining a C (full implementation) for each of your identified priorities.

4 Monitor progress.

Monitor your hospital's progress with implementing the self-assessment items and continue to work toward the goals that your organization outlined in its action plan. Plan to perform the self assessment again at a later date to track your hospital's improvement in medication safety.

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

I. PATIENT INFORMATION

Core Characteristic #1

Essential patient information is obtained and readily available in a useful form when prescribing, dispensing, administering, and monitoring antithrombotic therapy.

		A	B	C
1	The patient's diagnosis, allergies, height, actual body weight (in metric units), and most recent pertinent laboratory data are obtained and readily accessible to healthcare providers who prescribe, dispense, administer, or monitor antithrombotic therapy.			
2	A baseline hemoglobin, hematocrit, platelet count, aPTT, and INR are obtained prior to initiating antithrombotic therapy.			
FAQ 3	A serum creatinine is ordered when initiating therapy with a DOAC or LMWH.			
4	During inpatient antithrombotic therapy of more than 5 days with UFH or a LMWH, a platelet count is repeated every 2-3 days from day 4 to day 14 or until heparin is stopped, whichever comes first.			
5	An INR is obtained prior to initiating warfarin therapy.			
6	On admission, an INR is ordered for all patients who were receiving warfarin therapy before being admitted unless an INR was obtained within the past 48 hours and the result is available.			
7	For hospitalized patients receiving warfarin, the hospital has defined the frequency for obtaining an INR.			
8	After initiating an infusion with UFH, accompanied by the administration of a bolus dose, an aPTT or anti-factor Xa test is obtained *no sooner* than 6 hours after the start of the infusion (unless bleeding occurs sooner) and repeated every 12-24 hours thereafter if stable.			
9	Blood specimens for INRs are drawn at a standard time each day, enabling the results to be available before warfarin doses are prescribed.			
10	The hospital provides stat laboratory test results 24 hours per day and 7 days per week to ensure safe and timely monitoring of antithrombotic therapy.			
11	Prescribers, pharmacists, and nurses can easily and electronically access inpatient laboratory results (e.g., hemoglobin, hematocrit, liver function tests, serum creatinine, creatinine clearance, INR, aPTT, platelet count, anti-factor Xa levels) to guide antithrombotic therapy.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

I. PATIENT INFORMATION (continued)

		A	B	C
12	Prescribers, pharmacists, and nurses can easily and electronically access outpatient laboratory results (e.g., hemoglobin, hematocrit, liver function tests, serum creatinine, creatinine clearance, INR, aPTT, platelet count, anti-factor Xa levels), including results from affiliated clinics, to guide antithrombotic therapy.			
13	Antithrombotic agents cannot be ordered or verified (by pharmacy), until the patient's actual metric weight has been entered into the patient's medical record.			
FAQ 14	All weight-based protocols/guidelines identify which patient weight value (e.g., actual body weight, ideal body weight, or other medical staff-approved dosing weight) is to be used in the calculations.			
15	Prior to initiating antithrombotic therapy, healthcare **PRACTITIONERS** screen the medical record for co-existing diseases or conditions (e.g., hepatic impairment, heart failure, pregnancy, hypercoagulable states, renal impairment, hypoalbuminemia, acute infection/febrile state) that could affect the dose requirements for antithrombotic therapy.			
16	Prior to initiating antithrombotic therapy, healthcare **PRACTITIONERS** question patients about recent trauma, surgery, or bleeding problems experienced while receiving any previous antithrombotic therapy; and if encountered, these conditions are documented in the medical record and are readily accessible to healthcare **PRACTITIONERS** who prescribe, dispense, administer, or monitor antithrombotic therapy.			
FAQ 17	Prior to ordering UFH or LMWH, prescribers specifically ask patients if they have a known history of HIT (or have been told that they are allergic to heparin); and positive responses are documented in a manner that would generate an electronic alert if any form of heparin is ordered.			
FAQ 18	Prior to initiating the use of UFH for catheter flushes, arterial line infusions, or heparin-coated catheters or instruments, patients are specifically asked if they have a known history of HIT and/or allergy to heparin; and positive responses are documented in a manner that would generate an electronic alert if heparin is ordered.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

I. PATIENT INFORMATION (continued)

Core Characteristic #2

Essential patient information is used to monitor and manage the effects of antithrombotic therapy, and to adjust the treatment plan when indicated by evidence-based practices.

		A	B	C
19	The indication and therapeutic goal for antithrombotic therapy is documented and used to manage antithrombotic therapy.			
20	When warfarin is prescribed, all **PRACTITIONERS** monitor INR values to ensure that the INR is maintained at a level consistent with recommendations or protocols for the specific disease or condition for which antithrombotic therapy is prescribed.			
21	When UFH is prescribed for therapeutic anticoagulation, all **PRACTITIONERS** monitor aPTT values or anti-factor Xa levels to ensure the aPTT or anti-factor Xa level is maintained in the appropriate target range consistent with current practice.			
22A	As specified by medical staff-approved protocols/guidelines, pharmacists and/or nurses can automatically modify the dose for specific antithrombotic agents when laboratory values are above or below the target range.			
	OR *(Respond to #22A or #22B only)*			
22B	Pharmacists and/or nurses directly contact the prescriber within a hospital-defined timeframe to discuss laboratory values above or below the target range and potential modifications to antithrombotic therapy.			
23	Protocols/guidelines exist to adjust the dose of LMWHs, direct thrombin inhibitors, and factor Xa inhibitors, as appropriate, for patients with renal impairment, extremes of body weight, pregnancy, and in other special populations such as infants or neonates.			
24	When warfarin therapy is initiated for a patient with active thrombosis, UFH or LMWH therapy is continued until warfarin has been administered for a minimum of 5 days and the INR reaches a therapeutic level and is stable.			
FAQ 25	Patients on warfarin therapy for active thrombosis, who are being discharged with a subtherapeutic INR, are consistently evaluated regarding the need for a parenteral subcutaneous anticoagulant until a therapeutic INR is reached; and when appropriate, patients are maintained or "bridged" with a parenteral subcutaneous anticoagulant until therapeutic INR levels are reached.			
FAQ 26	If a patient's platelet count decreases to less than 100,000/mm^3 or less than 50% of the baseline, a 4T's score (or other risk scoring tool sanctioned by the institution) is calculated to assess if HIT is a possible diagnosis.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

II. DRUG INFORMATION

Core Characteristic #3

Essential drug information is readily available in a useful form and considered when prescribing, dispensing, administering, and monitoring antithrombotic therapy.

		A	B	C
27	All antithrombotics are included in a defined list of **HIGH-ALERT MEDICATIONS**, which has been communicated to all healthcare **PRACTITIONERS** in the organization.			
28	Disease-specific protocols/guidelines and order sets for antithrombotic therapy exist and are used when antithrombotics are prescribed, dispensed, and administered.			
29	All protocols/guidelines and order sets for antithrombotic therapy undergo a formal approval process, which includes review by **PRACTITIONERS** who are primary users of these tools, before use.			
30	All protocols/guidelines, order sets, flow sheets, and/or checklists for antithrombotic therapy are reviewed every 3 years and revised when significant, new information becomes available.			
31	*Disease-specific* protocols/guidelines and order sets (e.g., for atrial fibrillation, deep vein thrombosis, pulmonary embolism) are available electronically and used to guide appropriate and safe use of *oral antithrombotic agents*, and the different protocols are clearly titled to ensure proper identification.			
32	*Disease-specific* protocols/guidelines and order sets (e.g., for stroke, cardiac disease, deep vein thrombosis, atrial fibrillation, venous thromboembolism prevention and treatment) are available and used to guide appropriate and safe use of *UFH or other antithrombotics*, and the different protocols are clearly labeled to ensure proper identification.			
33	When chronic warfarin therapy must be discontinued prior to an invasive procedure, guidelines exist that define when warfarin should be stopped, when bridging with LMWH or UFH should be considered, and when anticoagulants should be started after the procedure.			
34	There is a formal process to screen patients before invasive procedures for antithrombotic agents that could cause patient harm if not discontinued or stopped inappropriately.			
35	If antithrombotic therapy is held for a surgical or other procedure and that procedure is significantly delayed or postponed, a reliable process is in place to remind the prescriber to evaluate the need to resume antithrombotic therapy.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

II. DRUG INFORMATION (continued)

		A	B	C
36	When intravenous UFH is prescribed, a standardized weight-based protocol is used to guide dosing and dose adjustments based on aPTT or anti-factor Xa results.			
37	Protocols/guidelines exist for transition between different antithrombotic agents.			
38	**PRACTITIONERS** are alerted to serious drug interactions that can affect the dose of antithrombotics, and appropriate therapeutic adjustments are made as necessary.			
39	To prevent spinal hematoma, guidelines exist for monitoring and/or discontinuing antithrombotic therapy when inserting or removing epidural catheters for regional anesthesia or other neuraxial procedures.			

Core Characteristic #4

Essential drug information is readily available in a useful form to guide the management of adverse drug reactions that may occur when antithrombotic agents are prescribed.

40	Protocols/guidelines and order sets exist to guide the management of supra-therapeutic INR values associated with warfarin and take into consideration the INR value, the absence or presence of clinically significant bleeding, and other factors that influence the necessity and urgency of reversal.			
FAQ 41	Unless rapid reduction of an INR associated with warfarin is required, protocols/guidelines direct prescribers to order oral phytonadione (vitamin K_1).			
42	If intravenous vitamin K_1 is required (e.g., life-threatening warfarin overdose, life-threatening bleeding, or need for an urgent invasive procedure), admixture procedures require diluting the medication in at least 50 mL of solution and instructions require the administration of the medication over 30-60 minutes.			
43	Protocols/guidelines and order sets exist to guide the reversal of anticoagulation from the administration of direct thrombin inhibitors and factor Xa inhibitors and take into consideration the absence or presence of clinically significant bleeding and other factors that influence the necessity and urgency of reversal. These protocols clearly identify which reversal agent(s) are to be used and how they should be prepared, labeled, dispensed, and administered.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

II. DRUG INFORMATION (continued)

		A	B	C
44	Protocols/guidelines and order sets used for reversing the effects of warfarin with PCC/fresh frozen plasma include orders to ensure that appropriate administration of vitamin K_1 is not omitted.			
45	If HIT is *suspected or diagnosed*, there is a mechanism in place to ensure that all sources of UFH or LMWH (including UFH used for arterial lines or catheter flushes, heparin-coated catheters or instruments) are discontinued.			
46	If HIT is *suspected or diagnosed*, there is a mechanism in place to ensure that a prominent entry is placed in the patient's medical record, to alert staff to avoid the administration of, or exposure to, heparin in any form (including LMWH, UFH used for arterial line infusions or catheter flushes, heparin-coated catheters or instruments).			
47	If HIT is *suspected* (e.g., intermediate or high 4T's score), patient evaluation criteria consistently include laboratory testing for the HIT antibody.			
48	Medical staff-approved protocols/guidelines exist to treat patients with *known* or *suspected* HIT with direct thrombin inhibitors (e.g., argatroban, bivalirudin) if antithrombotic therapy is required.			
49	In patients with HIT, protocols/guidelines permit warfarin therapy *only* if the patient is also receiving a direct thrombin inhibitor and the platelet count is trending upward.			
FAQ 50	When combination therapy with warfarin and a direct thrombin inhibitor is used to treat HIT, protocols permit the discontinuation of the direct thrombin inhibitor *only* after the patient has achieved a therapeutic INR that is determined based on the direct thrombin inhibitor selected.			
FAQ 51	In patients with HIT, protocols/guidelines address how to interpret the INR when a direct thrombin inhibitor and warfarin are used together to maintain anticoagulation.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

Core Characteristic #5

Methods of communicating orders for antithrombotics and other essential drug information are standardized and automated to minimize the risk for error.

		A	B	C
52	Orders for antithrombotics that are governed by an "automatic stop order" policy are not discontinued without the *specific* approval of the prescriber.			
53	The **COMPUTER ORDER ENTRY SYSTEM** is directly **INTERFACED** with the laboratory system and automatically alerts **PRACTITIONERS** to abnormal values indicating a potential need to modify antithrombotic therapy.			
54	The **COMPUTER ORDER ENTRY SYSTEM** alerts healthcare **PRACTITIONERS** when a patient has received an antithrombotic agent prior to admission (e.g., in a referring hospital within the same system, in the emergency department, cardiac catheterization laboratory, interventional radiology) when new orders are entered for antithrombotic agents (to ensure that adequate time has elapsed between doses of the same or different antithrombotics).			
55	The **COMPUTER ORDER ENTRY SYSTEM** alerts healthcare **PRACTITIONERS** to duplicate class orders for antithrombotics (for two or more drugs within the same class).			
56	Heparin dose changes and subsequent bolus doses are consistently documented in the patient's medical record.			
57	An institution-approved protocol/guideline permits and guides the rounding of doses for certain antithrombotic agents (e.g., enoxaparin 83 mg could be rounded to 80 mg, a weight-based heparin bolus dose of 2,485 units could be rounded to 2,500 units).			
FAQ 58	When prothrombin complex concentrate (human) (e.g., Kcentra) is prescribed, and the standard organizational practice is to use nominal dosing to prepare the dose, an approved medical staff policy exists to support the use of nominal dosing.			
59	Protocols/guidelines and order sets identify the specific interventions, treatments, and drugs (e.g., intramuscular injections, certain vascular access procedures) that should be avoided for patients receiving antithrombotics.			
60	Registered dieticians are available to consult with patients about dietary restrictions or other issues as needed.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

IV. DRUG STORAGE, STOCK, STANDARDIZATION, AND DISTRIBUTION

Core Characteristic #6

Antithrombotic concentrations, doses, and administration times are standardized whenever possible.

		A	B	C
61	Concentrations for infusions of antithrombotic agents are standardized to a single concentration that is used in at least 90% of the cases.			
62	The formulary limits the variety of UFH vial concentrations and sizes.			
FAQ 63	If vials of concentrated UFH (10,000 units/mL or greater) are required in the organization, these concentrations are restricted to the pharmacy and segregated from other UFH products.			
64	Only commercially prepared, premixed IV solutions of heparin are used in the facility unless unavailable.			
FAQ 65A	Commercially prepared, premixed IV solutions of GPIIb-IIIa platelet inhibitors and direct thrombin inhibitors are used when available, or the solutions are prepared in the pharmacy if not available commercially. *Scoring guideline: Select NOT APPLICABLE if you do not use GPIIb-IIIa inhibitors or direct thrombin inhibitors.*			
	OR *(Respond to #65A or #65B only)*		**NOT APPLICABLE**	
FAQ 65B	IV infusions of GPIIb-IIIa platelet inhibitors and direct thrombin inhibitors are prepared in patient care units by trained **PRACTITIONERS** only, using a kit containing the drug, supplies needed for preparation, and preparation instructions.			
66A	Pharmacy prepares all thrombolytic bolus doses (except those used for catheter clearance).			
	OR *(Respond to #66A or #66B only)*			
66B	Thrombolytic bolus doses are prepared by trained **PRACTITIONERS** only, using a disease-specific kit (e.g., stroke, acute myocardial infarction) containing the protocol, drug, supplies needed for preparation, and preparation instructions.			
67A	Pharmacy prepares all thrombolytic infusions.			
	OR *(Respond to #67A or #67B only)*			
67B	Thrombolytic infusions are prepared by trained **PRACTITIONERS** only, using a disease-specific kit (e.g., stroke, acute myocardial infarction) containing the protocol, drug, supplies needed for preparation, and preparation instructions.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

IV. DRUG STORAGE, STOCK, STANDARDIZATION, AND DISTRIBUTION (continued)

		A	B	C
68	When alteplase and tenecteplase are both available in patient care areas, measures are taken to prevent mix-ups between these two products (e.g., drug name abbreviations [TPA, TNK] are not used, each product is stored in a separate location, warnings are placed on ADC screens, kits are used for alteplase for strokes). *Scoring guideline: Select NOT APPLICABLE if you do not have both of these drugs in your hospital.*			
		NOT APPLICABLE		
69	All strengths of warfarin tablets dispensed within the facility are purchased from a single manufacturer to promote consistent color differentiation.			
70	Warfarin administration is scheduled for the same time each day, after INR results are available (e.g., afternoon, early evening).			
71	Appropriate reversal agents or antidotes (e.g., protamine, vitamin K_1, idaru**CIZU**mab, PCC) are *readily accessible* for the antithrombotic agents used in the hospital.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

V. MEDICATION DEVICE ACQUISITION, USE, AND MONITORING

Core Characteristic #7

The potential for human error is mitigated through careful procurement, maintenance, use, and standardization of devices used to deliver medications and provide test results.

		A	B	C
72	The laboratory notifies prescribers, pharmacists, and those responsible for protocol development when lot numbers for laboratory reagents that are used to measure the aPTT are changed. When this occurs, all coagulation assays are recalibrated and dosing protocols are modified as needed (e.g., weight-based heparin order sets). Information in the medical record related to heparin therapy is also modified as needed. Nurses are also informed that the therapeutic ranges and corresponding doses have been changed on protocols used to adjust therapy.			
73	When a new lot of reagent is received, point-of-care testing and other devices used to monitor antithrombotic therapy (e.g., activated clotting time, INR) are checked and recalibrated.			
74	Processes exist and staff receive training with activated clotting time point-of-care testing devices to ensure that high response and low response cartridges are segregated and are used as intended in the correct heparin intensity assessment setting. (For example, if low intensity cartridges are being used for extracorporeal membrane oxygenation [ECMO] patients in pediatrics, higher response cartridges are not stocked in pediatrics; if high response cartridges are used in the cardiovascular operating room [OR], low response cartridges are not stocked in the OR.) *Scoring guideline: Select NOT APPLICABLE if you do not use activated clotting time point-of-care testing devices.*			**NOT APPLICABLE**
75	**SMART INFUSION PUMPS** with functionality employed to intercept and prevent wrong dose/wrong infusion rate errors due to misprogramming the pump, miscalculation, or an inaccurately prescribed dose or infusion rate, are used for the IV administration of all antithrombotic infusions (including platelet inhibitors).			
76	When standard institutional concentrations or dosing units are changed for a particular antithrombotic, procedures are in place to ensure that the libraries in all **SMART INFUSION PUMPS** and the electronic medical record system are updated as soon as these changes are in effect.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VI. COMPETENCY AND STAFF EDUCATION

Core Characteristic #8

PRACTITIONERS receive sufficient orientation to organizational protocols and policies for antithrombotic therapy, and undergo a baseline and ongoing competency evaluation of knowledge and skills of related safe medication practices.

		A	B	C
77	All **PRACTITIONERS** who prescribe, dispense, administer, and/or monitor antithrombotic therapy receive initial training and undergo baseline competency evaluation to demonstrate proficiency with their role in antithrombotic therapy, before practicing independently.			
78	**PRACTITIONERS** who prescribe, dispense, administer, and/or monitor antithrombotic therapy are provided with initial and ongoing education necessary for performing these functions.			
79	**PRACTITIONERS** who prescribe, dispense, administer, and/or monitor antithrombotic therapy are educated about any related new drugs added to the formulary and associated protocols/guidelines and restrictions before the drugs are used in the hospital.			
80	**PRACTITIONERS** who prescribe, dispense, and/or administer dabigatran are instructed that the capsules are not to be opened and that the contents must not be mixed with food or tube feeding solutions. *Scoring guideline: Select NOT APPLICABLE if you do not use dabigatran.*			
		NOT APPLICABLE		
81	**PRACTITIONERS** who prescribe, dispense, administer, and/or monitor antithrombotic therapy receive ongoing information about related errors that occur within the organization, error-prone situations, errors occurring in other healthcare facilities, and strategies to prevent such errors.			
82	Staff members who educate patients about the proper use of point-of-care self-testing devices have demonstrated proficiency with the use and maintenance of the instruments.			
83	When antithrombotic protocols/guidelines or order sets are modified, all **PRACTITIONERS** affected by the changes are informed.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VII. PATIENT EDUCATION

Core Characteristic #9

Patients are included as active partners in their antithrombotic therapy through education about their medications and ways to avert errors. There is a transition of care process as part of discharge planning and education.

		A	B	C
84	Patients on warfarin, and/or their **CAREGIVERS**, receive verbal and up-to-date written information (6th grade reading level or lower) about proper dietary measures and their effect on overall therapy goals.			
85	Patients on antithrombotic therapy, and/or their **CAREGIVERS**, receive verbal and up-to-date written information (6th grade reading level or lower) about how their antithrombotic therapy is monitored and the need for medical supervision and adherence to prescribed treatment.			
86	Patients on antithrombotic therapy, and/or their **CAREGIVERS**, receive verbal and up-to-date written information (6th grade reading level or lower) about the signs and symptoms of bleeding or thromboembolic complications and when to seek medical attention.			
87	Patients on antithrombotic therapy, and/or their **CAREGIVERS**, receive verbal and up-to-date written information (6th grade reading level or lower) about drug and herbal interactions, and are provided with examples of over-the-counter drugs, nutritional supplements, and herbal products to avoid.			
88	Patients on antithrombotic therapy are instructed to inform all **PRACTITIONERS** they encounter that they are on antithrombotic therapy.			
89	Patients on warfarin are informed that Coumadin, Jantoven, and warfarin contain the same active ingredient, to avoid the potential for duplicate therapy if the drug is prescribed using both brand and generic names.			
90	Patients on warfarin, and/or their **CAREGIVERS**, are instructed on how to manage dose changes safely once at home when their existing tablet strength differs from a newly prescribed dose.			
91	Patients on warfarin, dabigatran, rivaroxaban, apixaban, or edoxaban, and/or their **CAREGIVERS**, are instructed that their antithrombotic dose may change during the course of treatment based on the results of certain laboratory tests (e.g., INR, renal function values).			
92	Patients on rivaroxaban or apixaban for the treatment of deep vein thrombosis or pulmonary embolism, and/or their **CAREGIVERS**, are instructed that their dose will be reduced after 21 days or 7 days respectively. *Scoring guideline: Select NOT APPLICABLE if you do not use rivaroxaban or apixaban.*			**NOT APPLICABLE**

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VII. PATIENT EDUCATION (continued)

		A	B	C
93	Patients on dabigatran, and/or their **CAREGIVERS**, are instructed on the proper storage and handling of their medication (e.g., once opened, the product is only stable for 4 months). *Scoring guideline: Select NOT APPLICABLE if you do not use dabigatran.*			
		NOT APPLICABLE		
94	Patients on dabigatran, and/or their **CAREGIVERS**, are instructed to drink a full glass of water with their dose and NOT to break, chew, or empty the contents of the capsules as this may result in increased drug exposure. *Scoring guideline: Select NOT APPLICABLE if you do not use dabigatran.*			
		NOT APPLICABLE		
95	Patients and/or their **CAREGIVERS** who will be administering antithrombotic products via the subcutaneous route at home demonstrate proficiency with the techniques and methods of drug administration prior to discharge or leaving the facility.			
96	Patients and/or their **CAREGIVERS** who will be administering subcutaneous antithrombotics at home are provided with the necessary supplies for administration and disposal of used syringes and with educational kits when available.			
97	Patients and/or their **CAREGIVERS** who will use point-of-care testing devices are trained on the operation of the device prior to use and the process for reporting results to the clinic or **PRACTITIONER**.			
98	Facility-approved instructional tools, such as videos, drug information booklets, or brochures (6th grade reading level or lower) are routinely used to complement patient education about antithrombotic therapy.			
99	For inpatients, education about antithrombotics begins when therapy is initiated, and information about post-discharge antithrombotic therapy is provided beginning at least 24 hours prior to discharge.			
100	When patients are discharged on warfarin or DOAC therapy, there is a transition of care process that verifies that the patient has a confirmed, scheduled appointment with the laboratory, physician, or anticoagulant clinic, and the importance of keeping follow-up appointments is emphasized.			
101	Prior to discharge, there is a transition of care process that verifies that the patient has been provided with a prescription for the antithrombotic agent and that the patient will be able to obtain the medication (e.g., insurance coverage is available, including patient ability to afford copays), and if necessary, any required prior authorization has been completed.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VII. PATIENT EDUCATION (continued)

		A	B	C
102	Upon discharge, any changes made to a patient's medication regimen that could affect either the risk of bleeding or thrombosis (e.g., anticoagulants, antiplatelet agents, NSAIDs) are clearly and consistently documented on the discharge summary and communicated to the patient's primary care providers.			
103	Patients diagnosed with HIT are instructed to communicate this information to all physicians and other healthcare providers.			
104	Patients previously taking an antithrombotic agent(s) at home as an outpatient and subsequently discharged on a different antithrombotic agent(s) receive verbal and written instructions identifying which agents they should continue to take and which agents they should discontinue.			
105	Pharmacists are available for consultations to assist with patient education when any healthcare **PRACTITIONER** identifies a patient who is at risk for non-adherence with their prescribed antithrombotic therapy.			
106	All patients discharged on warfarin therapy are referred to an anticoagulation clinic for comprehensive education, monitoring, and adjustments in their antithrombotic therapy.			
FAQ 107	Post-discharge follow-up is provided for patients discharged on DOACs. Follow-up *may* include referral to an anticoagulation clinic, if available, or other interaction with **PRACTITIONERS** via phone or other media. Reassessment at regular intervals either by an anticoagulation clinic or primary provider is advised.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VIII. QUALITY PROCESSES AND RISK MANAGEMENT

Core Characteristic #10

PRACTITIONERS are stimulated to detect and report errors, and interdisciplinary teams regularly analyze errors that have occurred within the organization and in other organizations for the purpose of redesigning systems to best support safe **PRACTITIONER** performance.

		A	B	C
108	In addition to **PRACTITIONER** reporting systems, markers or triggers for selected *drug orders* (e.g., use of reversal agents/antidotes such as vitamin K_1, idaru**CIZU**mab, protamine, fresh frozen plasma, PCC) are used to enhance detection of potential adverse drug events.			
109	In addition to **PRACTITIONER** reporting systems, markers or triggers for selected *laboratory tests* (e.g., aPTT greater than 100 seconds, INR greater than "x" as defined by facility, platelet count less than 100,000/mm^3) are used to enhance detection of potential adverse drug events.			
FAQ 110	On a regular basis, a convened interdisciplinary team retrospectively reviews case summaries where bleeding or thromboembolic events have occurred, and organization-wide process changes are made as needed.			
111	The pharmacy and therapeutics committee, or other appropriate hospital committee, regularly assesses the safe and efficacious use of antithrombotic agents prescribed in the hospital.			
112	The organization performs ongoing review of compliance with established antithrombotic protocols, and a convened interdisciplinary team recommends and facilitates action to improve compliance.			

Core Characteristic #11

Simple redundancies that support a system of **INDEPENDENT DOUBLE CHECKS** are used for vulnerable parts of antithrombotic therapy to detect and correct serious errors before they reach patients.

113	When a pharmacist enters an order for antithrombotic therapy, a second pharmacist or other licensed professional performs and documents an **INDEPENDENT DOUBLE CHECK** of the calculations, preparation, and labeling of pharmacy-prepared parenteral antithrombotic agents, using the original order for verification, prior to dispensing the drugs.			
114	Nurses perform and document an **INDEPENDENT DOUBLE CHECK** of all calculations, preparations, and labeling of antithrombotic agents, using the original order for verification, prior to preparing and administering the drugs, if a pharmacist is not available.			

A	There has been no activity to implement this item
B	This item has been partially implemented
C	This item is fully implemented in the organization

VIII. QUALITY PROCESSES AND RISK MANAGEMENT (continued)

		A	B	C
115	With each new bag/bottle, or change in the rate of infusion for IV antithrombotics (including platelet inhibitors), one **PRACTITIONER** readies the solution for administration and another **PRACTITIONER** independently verifies and documents that the correct patient, drug, drug concentration, rate of infusion, channel selection (for multiple-channel pumps), and line attachments have been selected before starting the infusion.			