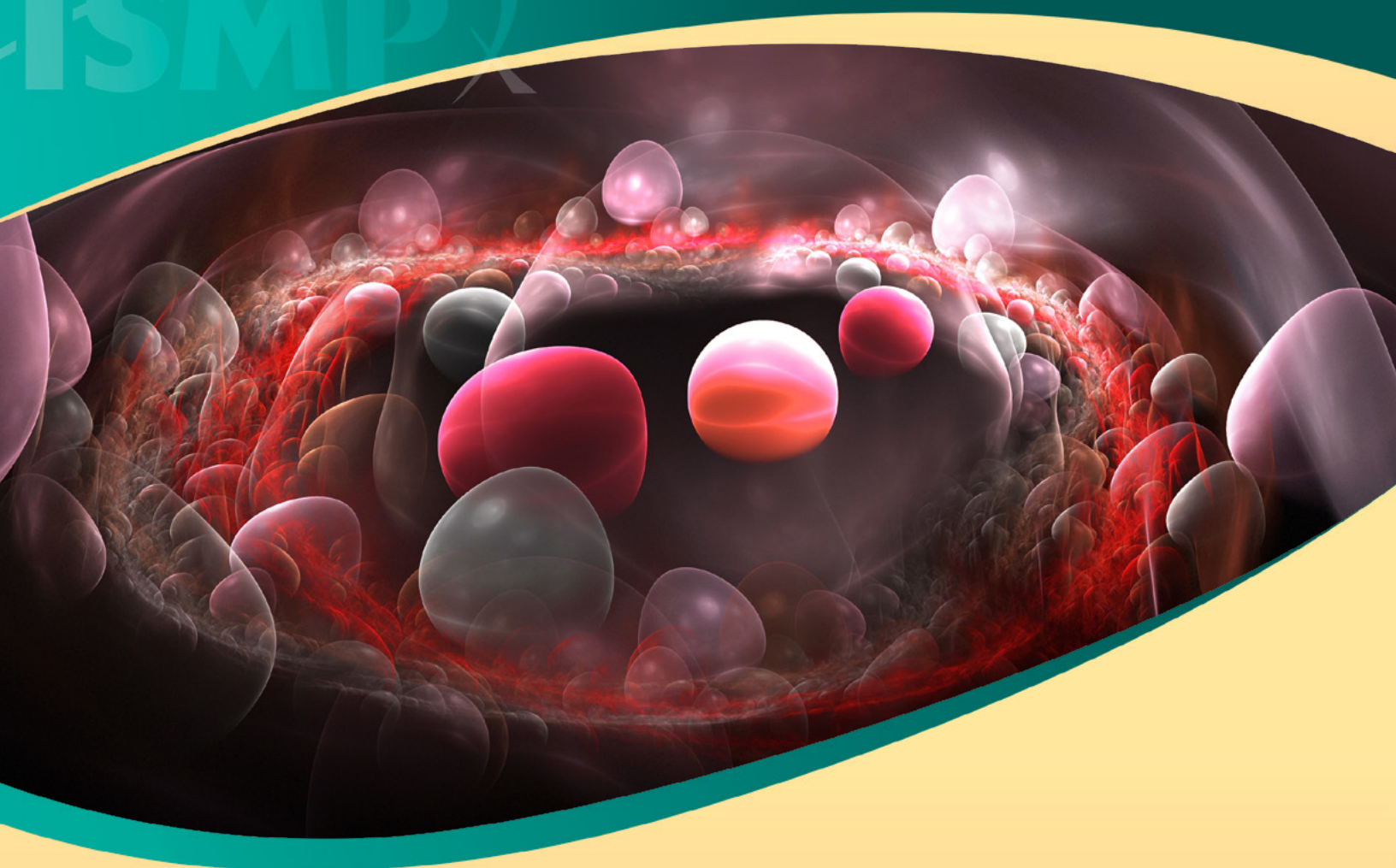


ISMP



2017

**ISMP Medication Safety
Self Assessment[®] for
Antithrombotic Therapy**

Frequently Asked Questions (FAQs)

I. PATIENT INFORMATION

Core Characteristic #1

Item #3.

Why do you use the term DOAC for direct oral anticoagulants?

The International Society on Thrombosis and Haemostasis has suggested that the term DOAC (Direct Oral AntiCoagulant) be used to describe the new class of oral anticoagulants versus other terms that have appeared in the literature. In particular, the term NOAC is not recommended as there have been reports where the use of NOAC (used to indicate New or Novel Oral AntiCoagulant) was interpreted to mean “No anticoagulation” which could unintentionally result in the failure to order or administer a needed anticoagulant.

Item #14.

What is meant by “dosing weight”?

For certain patients, ideal body weight or actual weight cannot be used to safely calculate the appropriate dose for an antithrombotic agent. The organization should have a medical staff-approved formula that identifies these patients (e.g., patients whose ideal or actual body weight falls outside of an established range) and provides a calculation for an adjusted weight that is to be used to provide the appropriate dose for the patient.

Why are both of the terms “protocols” and “guidelines” used in many of the statements? How are they different?

Protocols are generally more prescriptive than guidelines. For some diseases, treatment protocols may be appropriate while at other times, guidelines may be more appropriate to follow for some situations, in that they generally allow more flexibility than protocols. An explanation of the difference between protocols and guidelines for antithrombotic therapy can be found in the following reference.

Wittkowsky AK, Spinler SA, Dager W, Gulseth MP, Nutescu EA. Dosing guidelines, not protocols, for managing warfarin therapy. *Am J Health Syst Pharm.* 2010;67(18):1554-6.

Items #17. and #18.

My hospital is concerned about documenting that a patient is allergic to heparin after an episode of HIT because the allergy will remain in the medical record forever.

Although patients who have experienced HIT are often able to receive heparin at a future time, after HIT antibodies have cleared, there is a concern that a patient could be inadvertently re-exposed to heparin without retesting for the antibody; therefore, many decide to prevent such a re-exposure by adding heparin as an allergy, thus prompting an allergy alert if heparin is ordered. **PRACTITIONERS** need to consider a patient’s past history of HIT and the need for testing for the HIT antibody if they wish to prescribe heparin for that patient at a future point in time.

I. PATIENT INFORMATION

Core Characteristic #2

Item #25.

What does the term “bridged” mean in this item?

When some patients are discharged on warfarin but have not yet achieved a therapeutic INR, physicians will prescribe LMWH to be administered to the patient at home along with their warfarin therapy to provide adequate anticoagulation until their INR reaches a therapeutic level. The anticoagulation provided by the LMWH is often referred

to as a “bridge” to the long-term anticoagulation that will be provided by warfarin. The organization should develop protocols that define when bridge therapy will be prescribed. Often the decision is based on the patient’s diagnosis or type of surgical procedure that has been performed (e.g., total joint replacement).

Item #26.

What is a 4T’s score and how is it used in the diagnosis of heparin-induced thrombocytopenia?

The following table, used with permission from the journal, *Blood*, describes the 4T’s used to assist in the diagnosis of heparin-induced thrombocytopenia.

The 4Ts scoring system

4Ts category	2 points	1 point	0 points
Thrombocytopenia	Platelet count fall > 50% and platelet nadir ≥ 20	Platelet count 30%-50% or platelet nadir 10-19	Platelet count fall < 30% or platelet nadir < 10
Timing of platelet count fall	Clear onset days 5-10 or platelet fall ≤ 1 day (prior heparin exposure within 30 days)	Consistent with days 5-10 fall, but not clear (eg, missing platelet counts); onset after day 10; or fall ≤ 1 day (prior heparin exposure 30-100 days ago)	Platelet count ≤ 4 days without recent exposure
Thrombosis or other sequelae	New thrombosis (confirmed); skin necrosis; acute systemic reaction postintravenous unfractionated heparin bolus	Progressive or recurrent thrombosis; non-necrotizing (erythematous) skin lesions; suspected thrombosis (not proven)	None
Other causes of thrombocytopenia	None apparent	Possible	Definite

- The 4Ts score is the sum of the values for each of the 4 categories. Scores of 1-3, 4-5, and 6-8 are considered to correspond to a low, intermediate, and high probability of HIT, respectively.

Cuker A, Gimotty PA, Crowther MA, Warkentin TE. Predictive value of the 4Ts scoring system for heparin-induced thrombocytopenia: a systematic review and meta-analysis. *Blood*. 2012;120(20):4160-7.

II. DRUG INFORMATION
Core Characteristic #4

Item #41.

How can oral phytonadione be used considering that the tablets only exist in a 5 mg dosage form?

The injectable form of phytonadione can be diluted and used to administer a low dose of the drug. While this is an off-label use for the injection, it has been done in this manner in studies.

Items #50. and #51.**Why can't I rely on the INR value obtained while a patient is on a direct thrombin inhibitor to monitor the level of anticoagulation?**

Direct thrombin inhibitors (DTIs) elevate the INR value by interfering with the assay used to determine the INR. In the absence of warfarin, this elevation should not be interpreted as an elevated level of anticoagulation which could cause **PRACTITIONERS** to prematurely discontinue therapy. Argatroban may result in a larger INR elevation than bivalirudin. When a patient is on therapeutic doses of argatroban, the INR is often greater than 2 before warfarin is administered. If a patient is on a DTI and an INR is available, a therapeutic approach may be to initiate warfarin and identify an increase in the INR of 1.5 – 2 as a desirable INR value for discontinuing therapy with the DTI. As an alternative, identify a pre-selected INR value (usually greater than 4 when using argatroban) that when reached will enable the discontinuation of therapy with the DTI.

Dager WE, Gulseth MP, Nutescu EA, eds. Anticoagulation therapy: a point-of-care guide. Bethesda, MD: American Society of Health-System Pharmacists; 2011.

III. COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION**Core Characteristic #5****Item #58.****If a vial of Kcentra is labeled 500 units but there is a range of 400-620 units of Factor IX in the vial, shouldn't we prepare a dose based on the actual content of the vial versus considering it to contain 500 units?**

In clinical studies involving prothrombin complex concentrate (human) (Kcentra), the 500 unit vials and 1,000 unit vials were considered to contain 500 units and 1,000 units of Factor IX respectively, regardless of the actual labeled content of Factor IX in each vial (*referred to as nominal dosing*).

It is recommended to use this dosing method, that is, the **PRACTITIONER** should prepare the dose with the consideration that a vial contains 500 units or 1,000 units and disregard the actual labeled content for Factor IX. Therefore, if a dose of 1,250 units is prescribed, *2.5 vials of the 500 unit vial* should be used or as an alternative, *a 1,000 unit vial and half of a 500 unit vial* can be used to prepare the dose.

IV. DRUG STORAGE, STOCK, STANDARDIZATION, AND DISTRIBUTION**Core Characteristic #6****Item #63.****My hospital stocks heparin 10,000 units per mL vials on patient care units for bolus doses of heparin for patients on heparin infusions. Why do you recommend limiting storage of this concentration to the pharmacy only?**

Vials containing 10,000 units/mL have been confused with vials containing 10 units/mL (the concentration frequently used for heparin flush) and administered in error. Two widely published errors occurred in 2006 and 2007, where this confusion led to the death of 3 premature infants in one case and in another instance, resulted in bleeding in two other infants. Thus, ISMP has recommended limiting storage of vials containing 10,000 units/mL or greater to the pharmacy department.

Items #65a and #65b.

Pharmacy supplies the majority of the GPIIb-IIIa solutions, as either premixed products or pharmacy-prepared, but we also prepare medications in the patient care area when pharmacy services are not available. Should I answer part (a) or part (b) of this item?

If you use manufacturer-prepared, premixed GPIIb-IIIa platelet inhibitors and/or pharmacy-prepared GPIIb-IIIa platelet inhibitors, then you should answer part (a). If you also prepare these products in the patient care area, then you should select B (partially implemented) for part (a) of this item.

Answer part (b) if the pharmacy does not dispense the manufacturer-prepared, premixed product and/or the pharmacy does NOT prepare the product.

VII. PATIENT EDUCATION

Core Characteristic #9

Item #107.

I thought the advantage of DOACs was that they did not require follow-up monitoring of INRs, so why should we refer patients discharged on DOACs to an anticoagulation clinic?

Recent publications and guidelines and the recently published AC Forum (Anticoagulation Forum) Guidance Statement for the practical management of the DOACs in VTE treatment (<http://link.springer.com/article/10.1007/s11239-015-1310-7>) have discussed this topic. The AC Forum guidance states: *"We suggest that hospitals implement systematic DOAC management and documentation processes that address appropriate patient selection, dose initiation, perioperative management, switches between anticoagulants and transitions between care settings. Whenever possible, implementation of a specialized inpatient and outpatient anticoagulation services is strongly encouraged. We also strongly recommend that clinicians utilize a DOAC discharge checklist to ensure all key aspects of patient care and DOAC therapy are addressed."*

VIII. QUALITY PROCESSES AND RISK MANAGEMENT

Core Characteristic #10

Item #110.

We have an interdisciplinary team that shares error experiences but we do not routinely convene in person. Should we answer partially implemented for this item?

In our experience, organizations that have set a routine time to meet for the purpose of sharing and analyzing external and internal errors are more successful than those organizations that seldom meet or only meet when a sentinel event occurs. If you do not have routine face-to-face meetings, your answer should not exceed partially implemented.