ISMP Medication Safety Self Assessment® for High-Alert Medications

Frequently Asked Questions (FAQs)

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

General Questions

1. What are the benefits of conducting the assessment and submitting the results to the Institute for Safe Medication Practices (ISMP)?

Completion of the assessment allows organizations to assess current practices and systems associated with prescribing, dispensing, and administering high-alert medications, and to identify specific challenges, prioritize opportunities for improvement, and track their experiences over time. Use of the assessment will also help healthcare providers meet or gauge their compliance with managing high-alert medications as required by various state and federal regulatory agencies, such as The Joint Commission and the Centers for Medicare & Medicaid Services.

The assessment suggests best practices and safety system enhancements associated with the safe use of 11 different categories of high-alert medications and a general category encompassing most high-alert medications. Organizations can assess their practices for **one or all** of the categories of high-alert medications, based on preferences and patterns of use. The findings for each high-alert medication category can be submitted separately. Only facilities that submit results to ISMP will be able to obtain weighted scores associated with their assessment results for each item based on its effectiveness in reducing the risk of errors, and have access to aggregate data on a national level for comparison to demographically similar healthcare facilities.

Also, from a national perspective, the following benefits can only be achieved if ISMP can collect and analyze an adequate sample of aggregate assessment responses submitted by healthcare facilities:

- Aggregate results from a large pool of respondents will provide US healthcare providers with important information about the current status of safeguarding high-alert medications, which will create a baseline of provider efforts to enhance medication safety. Such data will be useful in advising healthcare providers about ongoing high-alert medication system improvements.
- Aggregate results will be of significant assistance to healthcare providers who seek top leadership support for improvements in critical areas associated with high-alert medication use.
- ISMP and others will be able to focus additional educational efforts and design useful programs to help healthcare providers implement high-leverage strategies that can positively impact patient safety.

2. Can we complete the assessment and submit the results to the Institute for Safe Medication Practices (ISMP) for just certain high-alert medications that we use in our facility or that are an area of focus for our organization?

Each facility can choose one or more categories of high-alert medications upon which to focus its assessment. Not all the targeted high-alert medications may be used in every facility; thus, each facility may choose which high-alert medications to assess. However, we strongly encourage all facilities to complete the assessment for every category of high-alert medications used in their facility. Some high-alert medications have fewer self-assessment items than other high-alert medication categories, so the total number of assessment items for each participating facility will vary based on which categories are chosen for assessment.

For facilities that submit their responses to the Institute for Safe Medication Practices (ISMP), the demographic questions and the general high-alert medications section must be completed and submitted. After that, any of the 11 categories of high-alert medications can be selected for assessment and data submission.

3. What if a specific self-assessment item does not apply to the services provided in my facility?

Some of the self-assessment items offer the option of a "Not Applicable" response. For these items, "Not Applicable" should only be selected if your facility meets the qualifications in the "Not Applicable" scoring guideline associated with that item.

continued on page 3

continued from page 2

4. Our health system consists of multiple facilities, which share many of the same corporate functions (e.g., PHARMACY AND THERAPEUTICS COMMITTEE, risk management/patient safety, MEDICATION SAFETY OFFICER, information technology, policies and procedures). Should we complete just one assessment for all facilities in our health system?

It is important for each facility in a health system to complete the assessment individually and submit its information separately. The items in the assessment evaluate practices more often than policies and procedures, and although standardization across a health system is desirable, practices often differ. For an accurate assessment, the tool requires information that can only be provided by practitioners who work in the facility. Each facility will truly benefit from completing the assessment individually and obtaining its own individual set of scores to focus on vulnerabilities that may vary from facility to facility. Corporate-level assessment invalidates the tool's effectiveness and usefulness.

5. Should the assessment of each item be based on current policies or actual practices?

The assessment of each item should be based on what actually occurs, not what can be found in current policies or what ought to occur. While some assessment items ask facilities to evaluate whether certain protocols, procedures, and/or policies exist, they also suggest evaluating whether these are actually followed. While it may be easier to identify the existence of certain protocols, procedures, and/or policies alone, assessment of actual compliance with these structural guidelines is vital to understanding where vulnerabilities and improvement opportunities exist. Involving frontline workers in the assessment, who can describe what actually occurs at the "sharp end" of care, can promote accurate assessment, especially if they feel safe describing what normally happens, even if practices differ from protocols, procedures, and/or policies. Focusing on a systems-based approach to identifying deficiencies, rather than blaming individuals for not following a protocol, procedure, or policy, provides an opportunity for leaders to demonstrate that they understand and practice the principles of a **SAFETY CULTURE**.

6. My facility is part of a large health system or collaborative that plans to aggregate the results of its members. How do I obtain the code for the health system or collaborative, which must be entered when setting up my account prior to data submission?

If you are part of a participating health system or collaborative that plans to analyze its aggregate data internally, please enter your assigned health system- or collaborative-specific code when setting up your account. If you do not know your health system- or collaborative-specific code, please contact your health system or collaborative leader before submitting your information. If you are a health system or collaborative leader who would like to obtain a code, please contact: selfassess@ismp.org. If you are not part of a health system or collaborative that will be aggregating its results, please leave this prompt blank.

Demographic Questions

1. Must I answer all of the questions in the demographics sections?

For facilities that submit responses to the Institute for Safe Medication Practices (ISMP), all questions in the general demographics section must be completed. Each facility must complete **either** the Hospitals and Long-Term Care demographic questions, **or** the Outpatient Facilities demographic questions. In addition, all demographic questions (if any) for a high-alert medication category must be completed and submitted before a facility can access the self-assessment items for that high-alert medication category.

Self-Assessment Items

General High-Alert Medications

Item # 3
What is meant by technology-assisted validation? Are GRAVIMETRICS, BARCODE SCANNING TECHNOLOGY, and/or

continued on page 4

continued from page 3

technology that takes pictures during production of COMPOUNDED STERILE PREPARATIONS acceptable alternatives to an INDEPENDENT DOUBLE CHECK?

Validation of base solutions and additives may be assisted using various technologies. **GRAVIMETRICS** is one example. Verifying the base solution and/or all additives via **GRAVIMETRICS** is an acceptable alternative to an **INDEPENDENT DOUBLE CHECK** as long as digital images are taken of all additives in syringes prior to mixing, and the pictures are then used by a practitioner to validate the base solution and all additives (including the actual volume). **BARCODE SCANNING TECHNOLOGY** may assist the validation process but will not confirm the volume and thus still requires an **INDEPENDENT DOUBLE CHECK** of the volume by a second practitioner.

Item # 7
Can infusions that are titrated to effect (e.g., vasopressors) per prescribed criteria or protocol be excluded from pump auto-programming, and can these infusion rates be adjusted by a practitioner at the pump?

No, even for frequently changing infusion rates, the initial and adjusted rates/doses should be programmed via closed-loop interoperability, starting with documentation in the EHR and then transferring this data to the **SMART INFUSION PUMP**. The initial and adjusted infusion rates should not be programmed by the practitioner at the pump.

Item # 33
What is the ideal frequency for conducting a SAFETY CULTURE survey?

Conducting a **SAFETY CULTURE** survey too often risks survey fatigue and not having enough time to implement and measure implementation plans created in response to a prior survey. Too much time between surveys risks not being able to detect and influence in a timely manner the issues that are affecting the culture. While the size and pace of an organization (which affects the time it takes to create widespread change) are factors, for most organizations, no less than 12 months and no longer than 24 months between surveys is optimal. However, don't underestimate the benefits of conducting smaller targeted and more frequent surveys focused on specific areas of interest associated with a **SAFETY CULTURE**.

Neuromuscular Blocking Agents

Item # 12
Instead of stocking dantrolene and any required diluent on patient care units, is it acceptable if dantrolene is dispensed from the pharmacy and available within 10 minutes of diagnosing a malignant hyperthermia event?

If pharmacy services are available 24 hours per day, 7 days per week, and dantrolene (diluted or with an appropriate diluent) can be dispensed and available within 10 minutes when needed, even in emergency situations, the drug and diluent do not need to be stored on the patient care unit.

Magnesium Sulfate Injection

Item # 8
What is meant by administration of "high-dose" magnesium sulfate, for which a RESCUE agent should be easily accessible?

"High-dose" magnesium sulfate refers to doses that are typically used to treat eclampsia, severe pre-eclampsia, or severe hypomagnesemia, which usually range from about 1-2 g IV per hour up to a **MAXIMUM DOSE** of 40 g per 24 hours.

continued on page 5 ▶

continued from page 4

Moderate Sedation in Adults and Children, Minimal Sedation in Children

Item # 4
When is repeating back a verbal order to the prescriber an acceptable alternative to reading back the order?

Readback of verbal orders is required if the receiver is physically able to write down/enter the order into the patient's record so it can be read back, rather than repeated back from memory. Repeating back an order, without first transcribing it, is an acceptable but less safe alternative only if the conditions for the recipient do not allow the immediate transcription of an order before it must be carried out. Such conditions may arise during procedural sedation, when the receiver of the verbal order is unable to leave the patient's bedside to transcribe the order before carrying it out. In such cases, the receiver should repeat back the verbal order to the prescriber for verification before implementation.

Item # 12
Can the patient be recovered in the procedural area, or must there be a separate recovery area?

The recovery area may be in the same location that the procedure was performed; however, trained practitioners must stay with the patient during the entire recovery, and the area must be stocked with emergency equipment and medications that might be necessary during the patient's recovery.

Insulin, Subcutaneous and Intravenous

Item # 1(I)
How might patient symptoms be inconsistent with current blood glucose monitoring, and how should the inconsistency be managed?

A patient who is exhibiting symptoms of hypoglycemia may require **POINT-OF-CARE** blood glucose testing. If the test results are within normal limits, or otherwise inconsistent with the patient's symptoms, a protocol should exist to guide a practitioner to investigate further through **POINT-OF-CARE** retesting, laboratory glucose testing, physician notification, or other means. Or, a patient without symptoms may have a routine **POINT-OF-CARE** blood glucose testing result that falls within the facility's definition of clinically significant hypoglycemia. A facility-developed protocol should guide staff regarding the next steps to take given an apparent inconsistency between the patient's symptoms and test results.

Item # 3
Why is listing the concentration right after the insulin name on MAR/eMARs or medication lists error-prone?

ISMP has received numerous reports of errors where the strength of the insulin was mistaken for the dose when listed following the drug name on the MAR/eMAR or other lists where insulin doses are recorded (e.g., medication history and discharge summary lists). For example, an entry for insulin aspart with a concentration of 100 units/mL following the name was mistaken as a dose of 100 units, even though the patient's dose of 6 units was listed on a subsequent line. Prescribers and nurses typically anticipate seeing the drug name and patient's dose side-by-side, while pharmacists may be accustomed to first viewing the available concentration to determine how best to dispense the patient-specific dose. Thus, on MARs/eMARs and medication lists, it is safest to list the drug name, patient-specific dose, route, and frequency on the first line of entries, and the available concentration and any direction regarding how to prepare the dose below it.

An exception is made for regular insulin U-500 (Humu**LIN** R U-500). In this case, the U-500 concentration is part of the insulin name, and such a high concentration (U-500) is unlikely to be confused as the dose (500 units). Exceptions have not been made for U-200 and U-300 insulin. Insulin products in these concentrations are currently available only in pen devices. The U-200 Tresiba FlexTouch (insulin degludec) pen will not deliver more than 160 units per injection, and the U-300 Toujeo SoloStar (insulin glargine) pen will not deliver more than 80 units per injection, making an actual mix-up between the concentration and the dose unlikely with a single injection.

continued on page 6 ▶

continued from page 5

Item # 4
What score should we select if we use TALL MAN LETTERING, but the unique uppercase letters are not bolded?

Uppercase **TALL MAN LETTERING** should be bolded to help differentiate similar drug names known to be confused with one another. If **TALL MAN LETTERING** without bolding is used in your facility for similar drug name pairs known to be confused, and in all the applications listed in the item, do not score above D. If **TALL MAN LETTERING** without bolding is used in some of the applications listed in the item, or for some similar drug name pairs known to be confused, do not score above C.

Item # 40
Why should weight-based, standard concentrations of pediatric IV insulin infusions never differ by a factor of 10?

Mix-ups between drug strengths that differ by a factor of 10 are a common type of dosing error among products available in 10-fold increments. Thus, the standard concentrations for IV insulin infusions for pediatric patients should be in increments that help avoid inadvertent interchange. For example, a 1 unit/mL insulin infusion is more likely to be confused with a 0.1 unit/mL infusion than a 0.2 units/mL infusion. None of the standard concentrations used for pediatric patients should be available in concentrations that differ by a factor of 10 (0.1 unit/mL and 1 unit/mL). A safer choice for standard concentrations includes 0.2 units/mL, 0.5 units/mL, and/or 1 unit/mL.

Methotrexate for Non-Oncologic Use

Item # 1
Can the default to a "weekly" dose allow both a single weekly dose or divided doses over several days each week?

Yes, "weekly" oral methotrexate doses could be prescribed as a single dose or as divided doses every 12 hours for 3 or 4 doses per week. Thus, the weekly default can allow for the entry of divided doses over several days, but it should not allow daily orders.

Chemotherapy, Oral and Parenteral

Item #18
Why must the total volume to be infused be included on the label of chemotherapy solutions, and how should this information appear?

For a single dose chemotherapy drug infusion, the entire dose in the container must be administered. Thus, the product label must be explicit regarding how to deliver the entire dose, which is dependent on the preparation process. For example, if 160 mg of **CARBO**platin (16 mL) has been added directly to a 100 mL IV bag of 0.9% sodium chloride (with an additional 7 mL of manufacturer overfill), without withdrawal of any solution before admixing, the label should read as follows:

CARBOplatin 160 mg
In 100 mL of 0.9% Sodium Chloride
Total volume to be infused: 123 mL
INFUSE ENTIRE CONTENTS FOR FULL DOSE

With this information, the nurse can enter the volume to be infused in the infusion pump to ensure that the full dose is delivered to the patient.

Despite variability in each manufacturer's overfill volumes, vendors can provide customers with a targeted amount and range of overfill in each of their products based on container sizes.

continued on page 7 ▶

continued from page 6

Anticoagulants

Item # 6
Do prescriber orders that request pharmacy dosing of an anticoagulant require the use of an order set?

Initial orders from a prescriber that request pharmacy dosing of an anticoagulant may not require the use of an order set. However, upon such an order, the pharmacy should initiate the appropriate order set, which activates all the supporting orders related to required patient monitoring and safe use of the anticoagulant. Thus, the initial order for pharmacy dosing does not need to be accomplished using an order set as long as pharmacy then activates the proper order set.

Item # 13
What does the term "bridge" mean in this item when referring to the use of alternative agents to "bridge" the patient?

If a specific anticoagulant such as warfarin must be discontinued before an invasive procedure, the patient may require an alternative agent such as heparin or low molecular weight heparin in the interim. The alternative agent is often referred to as a "bridge" until the long-term anticoagulant can be resumed. 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 will be performed.

Neuraxial Opioids and/or Local Anesthetics

Item # 16
What is meant by "specifically configured for epidural medications" in this item when referring to epidural infusion pumps?

Epidural pumps should have a specifically configured drug library that only includes epidural medications/infusions and not medications/infusions intended for other routes of administration. The library should be configured using both **HARD STOPS** and soft stops to intercept possible errors. The pump screen should also clearly display that it is being used for an epidural infusion.

Opioids

Item # 14
Why can't a pain intensity score alone be used to assess pain?

A pain assessment is a systematic, multidimensional evaluation of all aspects of pain, whereas a pain intensity score provides only a subjective evaluation of the patient's perception of pain severity at a given moment in time. Pain intensity, which is often based on a numeric scale or matched facial expressions, is just one aspect of a pain assessment. Other aspects include, but are not limited to, pain chronicity, quality, location and distribution, etiology, contributing/associated/aggravating factors, impact on the activities of daily living, pain control successes, and barriers to pain assessment and control. While pain is often assessed using subjective information from alert and verbal patients, assessment also requires evaluation of physiological changes in the body and behavioral measurements that may signal pain in nonverbal patients (e.g., facial expressions, crying in infants, sleeplessness, movements, changes in vital signs).

Item # 17
Why should IV doses of opioids never be diluted in a commercially labeled, prefilled flush syringe of 0.9% sodium chloride?

This practice frequently results in a mislabeled syringe, as the labeled flush syringe (0.9% sodium chloride) also contains the diluted medication. In many cases, the barrel of the commercially available 0.9% sodium chloride syringe contains a permanently affixed manufacturer's label containing the product name, product code, and barcode. When another medication is added to this syringe, there is no adequate method to

continued on page 8 ▶

continued from page 7

amend the manufacturer's label without covering the current information. Most often, the syringe remains mislabeled as 0.9% sodium chloride, when it also contains the diluted medication. The risk of mistaking the mislabeled syringe as a 0.9% sodium chloride flush is significant.

Also, commercially available prefilled syringes of normal saline are regulated by the US Food and Drug Administration as devices, not as medications. These devices have been approved for the flushing of vascular access devices, but have NOT been approved for the dilution (or reconstitution) and subsequent administration of medications. Such use would be considered "off label" and is not how manufacturers intended these products to be used, nor have these syringes been tested for product safety when used in this manner. Warnings intended to limit the use of prefilled syringes for medication preparation and administration appear on some syringe barrels, clearly stating "IV flush only." Some manufacturers have also limited or removed the gradation markings on the prefilled flush syringes to prevent measurement of a secondary medication in the flush syringe.

Item # 31
What score should we select if we use TALL MAN LETTERING, but the unique uppercase letters are not bolded?

Uppercase **TALL MAN LETTERING** should be bolded to help differentiate similar drug names known to be confused with one another. If **TALL MAN LETTERING** without bolding is used in your facility for similar drug name pairs known to be confused, and in all the applications listed in the item, do not score above D. If **TALL MAN LETTERING** without bolding is used in some of the applications listed in the item, or for some similar drug name pairs known to be confused, do not score above C.