



ISMP Medication Safety Self Assessment® for High-Alert Medications

General High-Alert Medications
Neuromuscular Blocking Agents
Concentrated Electrolytes Injection
Magnesium Sulfate Injection
**Moderate Sedation in Adults and Children,
Minimal Sedation in Children**
Insulin, Subcutaneous and Intravenous
**Lipid-Based Medications and Conventional
Counterparts**
Methotrexate for Non-Oncologic Use
Chemotherapy, Oral and Parenteral
Anticoagulants
Neuraxial Opioids and/or Local Anesthetics
Opioids

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Organizations That Have Endorsed the
ISMP Medication Safety Self Assessment® for High-Alert Medications

- American Association of Colleges of Nursing
- American Hospital Association
- American Nurses Association
- American Society for Healthcare Risk Management
- American Society for Parenteral and Enteral Nutrition
- American Society of Health-System Pharmacists
- Anesthesia Patient Safety Foundation
- Association for the Advancement of Medical Instrumentation Foundation
- Association of periOperative Registered Nurses
- ECRI Institute
- Health Care Improvement Foundation
- Infusion Nurses Society
- Institute for Healthcare Improvement
- National Committee for Quality Assurance
- National Patient Safety Foundation
- Pediatric Pharmacy Advocacy Group
- Society of Critical Care Medicine
- The Joint Commission
- USP

Invitation to Participate

Dear Healthcare Provider:

The Institute for Safe Medication Practices (ISMP) is pleased to provide our nation's healthcare providers with the **ISMP Medication Safety Self Assessment® for High-Alert Medications**. This tool, funded by the US Food and Drug Administration (FDA), offers hospitals, long-term care facilities, and certain outpatient facilities, such as ambulatory surgery centers, emergency/urgent care facilities, oncology clinics, treatment centers, dental surgery centers, endoscopy centers, and diagnostic testing centers, a unique opportunity to assess the safety of systems and practices associated with up to 11 categories of high-alert medications. ISMP defines high-alert medications as those bearing a heightened risk of causing significant patient harm when used in error.

The assessment items were assembled by ISMP working with an expert Advisory Group to ensure that the systems and practices most critical to patient safety were included and achievable in many healthcare facilities. As with our past **ISMP Medication Safety Self Assessment®** tools, many key organizations have endorsed or supported the **ISMP Medication Safety Self Assessment® for High-Alert Medications** and offered their ongoing support of this important endeavor. Our endorsers' names appear on the previous page, and their logos appear on the back cover and on our website.

Healthcare facilities that complete the assessment for any or all of the targeted high-alert medications will be able to identify specific challenges and opportunities for improvement as well as track their experiences over time. Use of the self assessment will also help 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. Healthcare facilities that submit their assessment findings to ISMP anonymously via a secure internet portal by **February 28, 2018**, will also be able to obtain weighted scores for each item based on their effectiveness in reducing the risk of errors, as well as access aggregate data to compare their individual experiences to the aggregate experiences of demographically similar healthcare providers.

In addition to the usual high standard of confidentiality associated with any information submitted to ISMP, we are also a federally certified patient safety organization (PSO). If self-assessment information is collected within the health system's patient safety evaluation system and submitted to ISMP as patient safety work product, the information is granted protection from discovery in connection with a federal, state, or local civil, administrative, or disciplinary proceeding. No contract with ISMP is required for this legal protection.

As with the data submitted by thousands of healthcare providers in response to our prior **ISMP Medication Safety Self Assessment®** tools, we will use the aggregate findings to develop tools and plan curricula and other means of support to assist you in enhancing safety when using high-alert medications. Additionally, an analysis of the aggregate results will be submitted for publication in a professional journal to detail our nation's baseline efforts to prevent patient harm from errors associated with high-alert medications.

ISMP, FDA, and the endorsing organizations encourage you to participate in this very important endeavor by completing the self assessment as directed in the instructions and by submitting your findings anonymously to ISMP. We welcome the opportunity to work with you as you assess the safe use of high-alert medications in your organization!

Warm regards,



Michael R. Cohen, RPh, MS, ScD (hon), DPS (hon), FASHP

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Purpose

The **ISMP Medication Safety Self Assessment® for High-Alert Medications** is designed to:

- Heighten healthcare providers' awareness of critical safe medication systems and practices associated with high-alert medications
- Assist healthcare providers with identifying and prioritizing opportunities for reducing patient harm when prescribing, preparing, dispensing, and administering high-alert medications
- Create a baseline of national efforts to enhance safety when prescribing, preparing, dispensing, and administering high-alert medications
- Determine the challenges healthcare providers face in keeping patients safe during high-alert medication use

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 items represent innovative practices and system enhancements that are not widely implemented in healthcare facilities today. However, their value in reducing errors is grounded in scientific research and/or expert analysis of errors with high-alert medications and their causes.

The **ISMP Medication Safety Self Assessment® for High-Alert Medications** and its components are copyrighted by ISMP and may not be used in whole or in part for any other purpose or by any other entity except for self assessment of medication systems by healthcare facilities as part of their ongoing quality improvement activities. The aggregate results of this assessment will be used for research and educational purposes only.

Targeted High-Alert Medications

The **ISMP Medication Safety Self Assessment® for High-Alert Medications** offers hospitals, long-term care facilities, and certain outpatient facilities, such as ambulatory surgery centers, emergency/urgent care facilities, oncology clinics, treatment centers, dental surgery centers, endoscopy centers, and diagnostic testing centers, a unique opportunity to assess the safety of systems and practices with up to 11 categories of high-alert medications:

- **Neuromuscular Blocking Agents** (1 demographic question, 15 self-assessment items)
- **Concentrated Electrolytes Injection** (26 self-assessment items)
- **Magnesium Sulfate Injection** (2 demographic questions, 22 self-assessment items)
- **Moderate Sedation in Adults and Children, Minimal Sedation in Children** (40 self-assessment items)
- **Insulin, Subcutaneous and Intravenous** (5 demographic questions, 45 self-assessment items)
- **Lipid-Based Medications and Conventional Counterparts** (9 self-assessment items)
- **Methotrexate for Non-Oncologic Use** (7 self-assessment items)
- **Chemotherapy, Oral and Parenteral** (5 demographic questions, 48 self-assessment items)
- **Anticoagulants** (1 demographic question, 43 self-assessment items)
- **Neuraxial Opioids and/or Local Anesthetics** (32 self-assessment items)
- **Opioids** (60 self-assessment items)

The assessment also includes a set of general assessment items (33 in total) that are applicable to all or most high-alert medications.

Not all the targeted high-alert medications may be used in every inpatient or outpatient facility; thus, **each facility can choose one or more of these high-alert medications upon which to focus its assessment**. However, we strongly encourage all facilities to complete

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the assessment for every high-alert medication category used in their facility. All facilities using the assessment to evaluate systems and practices associated with one or more high-alert medication categories should also complete the general assessment items.

Some high-alert medications have fewer self-assessment items than other larger categories of high-alert medications, so the total number of assessment items will vary based on which categories are chosen for analysis.

The assessment includes general demographic questions. A few of the high-alert medication categories also have one or more drug-specific demographic questions. The demographic data will only be used to analyze the aggregate findings from the self assessment and allow demographically similar organizations to compare themselves to others. The demographic questions do not ask for any contextually identifiable information.

All facilities submitting data to ISMP must complete the demographic questions and general high-alert medications section of the assessment.

Detailed instructions for completing the assessment can be found starting on page 10.

Key Definitions (for purposes of this self assessment)

Caregiver

A family member, friend, or other person not providing patient care on behalf of the healthcare facility, who is assisting the patient with medication administration, particularly in the outpatient setting, or monitoring the patient's adherence to instructions.

Computer order entry system

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 systems into which authorized prescribers enter medical orders.

Guideline

Recommendations that provide acceptable practices and options, including drug therapy, for managing a particular procedure or treatment for a specific diagnosis or condition, which can be used to assist in clinical decision making and adapted to the patient's specific needs.

High-alert medications (or drugs)

Medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are more devastating to patients. Examples of high-alert medications include insulin, opioids, neuromuscular blocking agents, anticoagulants, and many others. Complete lists of high-alert medications used in the acute care setting, community and ambulatory healthcare setting, and long-term care setting can be found at: www.ismp.org/Tools/highAlertMedicationLists.asp.

Implemented

Accomplished or achieved in practice, not just in policy.

Medication (or drug)

Medication includes: prescription medications; sample medications; herbal remedies; vitamins; nutraceuticals; over-the-counter drugs; vaccines; diagnostic and contrast agents used on or administered to persons to diagnose, treat, or prevent disease or other abnormal conditions; radioactive medications; respiratory therapy treatments; parenteral nutrition; blood derivatives; intravenous solutions (plain, with electrolytes and/or drugs); and any product designated by the US Food and Drug Administration (FDA) as a drug. The definition of medication does not include enteral nutrition solutions (which are considered food products), oxygen, and other medical gases unless explicitly stated.

Minimal sedation

A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and physical coordination may be impaired, airway reflexes and ventilatory and cardiovascular functions are unaffected.

Moderate sedation

A drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

Neonate (or neonatal)

A newborn infant less than 1 month old.

Neuraxial

Medications or solutions administered by the epidural or intrathecal (spinal) routes of administration.

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Order set

Standardized list or template of logically grouped medical orders used to treat specific clinical situations (e.g., a specific diagnosis, a specific drug therapy), which follow pre-established clinical guidelines based on evidence-based best practices. The use of order sets can decrease variation in care; enhance compliance with recommended treatment guidelines; promote complete, unambiguous, and accurate orders; reduce the risk of prescribing errors; and improve patient outcomes.

Pediatric

An infant older than 1 month, toddler, child, or adolescent (age limit typically up to 18-21 years).

Practitioner

A licensed healthcare professional who is authorized within the institution to prescribe, dispense, or administer medications, such as a physician, physician assistant, nurse anesthetist, nurse practitioner, nurse, pharmacist, or respiratory therapist.

Protocol

A defined, standard regimen intended to be followed for managing a particular procedure, drug therapy, or treatment for a specific diagnosis or condition, which often includes medication precautions and dosing instructions, supportive treatments, and patient monitoring.

Unit stock

Medications that are not labeled or stored for a specific patient and that are available outside the pharmacy. This would include medications stored in medication rooms, refrigerators, storage cabinets, and ADCs, for potential administration to various patients.

ADDITIONAL GLOSSARY TERMS

Additional defined terms can be found in the **Glossary (page 89)** and are designated throughout the text in **BOLD, SMALL CAPITAL LETTERS**. In the online version of the assessment, these additional terms are linked to their definitions when they appear in a self-assessment item, or the definitions can be found on the left side of the webpage when they appear in a demographic question.

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Key Abbreviations

ACLS

Advanced cardiovascular life support

BSA

BODY SURFACE AREA

FAQ

Frequently asked question

PALS

Pediatric advanced life support

ADC

Automated dispensing cabinet

ECG

Electrocardiogram

IM

Intramuscular(ly)

PCA

Patient-controlled analgesia

AUC

AREA UNDER THE CURVE

EHR

Electronic health record

IV

Intravenous(ly)

PN

Parenteral nutrition

eMAR

Electronic medication administration record

MAR

Medication administration record

Instructions for Conducting the Self Assessment

It is important that each facility within a multifacility system complete the self assessment individually.

1. Establish a team

Establish a core interdisciplinary team consisting of, or similar to, the following:

- Senior facility leader
- Chief medical leader
- Chief nurse leader
- At least one (outpatient) or two (inpatient) nurses
- At least one (outpatient) or two (inpatient) staff physicians

If applicable to the healthcare setting, the core team should also include:

- Pharmacy director
- At least two staff pharmacists
- Clinical information technology specialist
- Medication safety or patient safety officer/manager
- Risk management and quality improvement professionals

Choose a team leader from among the core team. The team leader and core team should participate in the assessment of the general high-alert assessment items as well as all high-alert medications chosen for analysis.

Once the core team has selected which of the 11 high-alert medications to evaluate as a part of the self-assessment process (please see Step 5 on **page 11**), additional practitioners who prescribe, dispense, and administer these medications should also be added to the core team to help inform the evaluation. Because the assessment should be based on what actually occurs, not what is in current policies or what ought to occur, the team should include frontline staff who use the medications. For example, if assessing moderate and minimal sedation, you will need to include nurses, pharmacists, anesthesia providers, and other physicians with experience using these medications for that purpose on the assessment team. Focusing on a systems-based approach to identifying deficiencies, rather than blaming individuals for not following a policy, provides an opportunity for leaders to demonstrate that they understand and practice the principles of a **SAFETY CULTURE**.

During each team meeting, team members should be provided with sufficient time to complete the demographic questions and self-assessment items and be charged with the responsibility to evaluate, accurately and honestly, the status of high-alert medication systems and practices in your facility. **Because medication use is a complex, interdisciplinary process, the value and accuracy of the self assessment is significantly reduced if it is completed by a single discipline.**

2. Read the directions and provide assessment items, definitions, and FAQs to team members

Read and review the self-assessment directions, demographic questions, and assessment items before beginning the assessment process. The team leader may want to provide each core team member with either a hardcopy or electronic version of the self assessment for review before the first team meeting. Based on the high-alert medication(s) selected for evaluation, the team leader may also want to provide ancillary practitioners whose expertise is in the use of those medications with the self-assessment items that are applicable to their area(s) of practice.

All team members can also be provided with either a hardcopy or electronic version of the list of key definitions and abbreviations, the glossary, and the FAQs for the applicable section(s), to review before each meeting. These can be accessed at: www.ismp.org/selfassessments/saham.

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3. Choose an option for completing the assessment

There are two options for completing the assessment.

- **Option 1:** Print hardcopies of the applicable section(s) of the self assessment to share with team members, and manually fill in your choice (A through E, or Not Applicable) for each self-assessment item. Submission of your information to ISMP, however, must be completed using the online self-assessment form.

- **Option 2:** Use the online self-assessment form to view the applicable section(s) at team meetings, and select your choice (A through E, or Not Applicable) for each self-assessment item, while saving your entered information between meetings. (Please see Step 1 on **page 13** for information regarding accessing the online self-assessment form and creating an account with a username and password.) **Please note:** If Option 2 is used to complete the assessment, the demographic questions and general assessment items will need to be answered and submitted to ISMP in order to gain access to all sections of the assessment.

4. Verify demographic information

Before the first team meeting, the team leader may need to gather and verify some of the responses to the demographic questions.

5. Convene the first team meeting to complete the general demographics and general high-alert medications assessment, and select the high-alert medications for analysis

For the first team meeting, convene the core members to complete the general demographic questions (if submitting the findings of the assessment to ISMP or using Option 2 to complete the assessment), complete the general high-alert medications assessment items, and select one or more of the high-alert medications for analysis. We anticipate that it will take one team meeting of approximately 2 hours to complete the general demographic questions, evaluate the general assessment items, choose the high-alert medications for analysis, and develop a timeline for conducting each analysis.

To conduct the assessment for general high-alert medications, discuss each item and evaluate your facility's success with implementing the item. 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 choice (A through E, or Not Applicable), using the following scoring key and guidelines:

Scoring Key

- A. There has been no activity to implement this item.
- B. This item has been formally discussed and considered, but it has not been implemented.
- C. This item has been partially implemented for some or all patients, orders, drugs, or staff.
- D. This item is fully implemented for some patients, orders, drugs, or staff.
- E. This item is fully implemented for all patients, orders, drugs, or staff.

Important Choice Selection Guidelines

For all self-assessment items: An explanation of the **Scope** precedes each section of the assessment to describe the high-alert medications to which the assessment items refer, unless otherwise stated in each individual assessment item.

For self-assessment items with multiple components in a single item: Full implementation (choice of D or E) is evidenced **only if all components** are present for some or all patients, orders, drugs, or staff. If only one or some of the components have been partially or fully implemented for some or all patients, orders, drugs, or staff, self-assessment choices should not exceed level C.

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For self-assessment items with multiple subparts labeled in lowercase, sequential letters (a, b, c, and so on): Select a choice (A through E, or Not Applicable) for each of the items separately.

For self-assessment items with two distinct components, each separated with the word “OR,” and labeled a and b: Choose the one component within the item that is most relevant to your facility, and select your choice (A through E, or Not Applicable) for only that one element.

For self-assessment items with an option of “Not Applicable”: Select “Not Applicable” only if your facility meets the “Not Applicable” scoring guideline for that item.

If you have questions, refer to the FAQs available on our website: www.ismp.org/selfassessments/saham. The online self-assessment form has certain items directly linked to FAQ responses. If you need additional assistance, contact ISMP at selfassess@ismp.org, or submit a question using either the “Contact Us” link on the ISMP website or the “Need help?” link found on the online self-assessment form.

Facilities may want to consider assigning an individual to record any discussion generated around each self-assessment item and the rationale behind the selected choice. This information, meant for internal use only, can assist the team when reviewing scores for individual items or reassessing your organization at a later date. This will provide insight into why the choice selected for each self-assessment item had been chosen at that point in time.

6. Conduct the assessment for each selected high-alert medication category

For each high-alert medication selected for analysis, convene the appropriate team members to complete the associated demographics (if any) and conduct the assessment using the scoring key and guidelines described in Step 5 on **page 11**. The number of meetings needed to complete each high-alert medication category will vary depending on the number of medications selected for analysis and the number of associated demographic questions and self-assessment items for each high-alert medication.

7. Submit your information to ISMP

To submit your information to ISMP or to use Option 2 to complete the assessment, go to: https://ismpassessments.org/high_alert/, which can also be accessed through the ISMP website at: www.ismp.org/selfassessments/saham. See **page 13** for further information about creating a username and password, entering your information, submitting your completed assessment to ISMP, and accessing your results.

Submit your self-assessment findings to ISMP by February 28, 2018.

Instructions for Entering and Submitting Information to ISMP

1. Create a new user account for the online self-assessment form

To enter and view your assessment results, and to submit your findings to ISMP, one individual from your facility's core team will need to create a free account. To create a new account, go to: https://ismpassessments.org/high_alert/, which can also be accessed through the ISMP website at: www.ismp.org/selfassessments/saham, and click on the "Create new account" link. The team member creating the account for your organization will be prompted to create a username and password, as well as to select the one category that best describes your facility (see **page 17** for the category options). There will also be an option to provide an email address that can be used if necessary to reset your password. If your facility is 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 (or codes if participating in more than one) in the provided field(s) under your facility's account.

Please note: An email address is not required when setting up an account; however, because ISMP does not ask for any information that could be used to identify a specific facility's assessment, a user's account and assessment results can only be retrieved with an email address that is linked to the account (in the event of a forgotten username and/or password), or with the account username (in the event of a forgotten password if no email address was provided).

At any point following the creation of the account, you can access your organization's account by going to: https://ismpassessments.org/high_alert/ and entering your facility's username and password. If you have forgotten your password, and an email address was entered when creating the account, click on the "Lost my password" link. For retrieval of your username (if an email address was provided) or your password (if an email address was not provided, but you have your user name), please contact ISMP. To exit the online form at any point, click on the "Log out" button found in the top right-hand corner of the webpage.

Your organization's account will allow you to:

- Enter your information into the online self-assessment form
- Save your entered information and return to the online form at a later time
- Submit information to ISMP
- View a report of how your organization answered each general demographic question and any demographic questions in each of the selected high-alert medication categories
- View a report of how your organization answered the self-assessment items in the general high-alert medications section and in each of the evaluated high-alert medication categories, along with your facility's weighted score for each item and total score for each completed section/category
- View the Preliminary Aggregate Results workbook for the general high-alert medications section and applicable high-alert medications after the final submission date and once the results have been tabulated in the second quarter of 2018

2. Complete and submit the general demographic questions

Once a new user account has been created, access the secure online form by clicking on the "Start Assessment" button. Based on the facility category selected when creating your account, you will be directed to the general demographic questions that are applicable to your practice setting. Complete the general demographic questions and save your entered information by clicking on the "Save" button found at the bottom of the demographics section.

If you have completed all of the demographic questions and are ready to submit, click on the "Preview before submitting" button found at the bottom of the demographics section, which will allow you to review your responses before submitting to ISMP. If you have not completed all of the questions, the system will alert you to those that have not yet been completed. All general demographic questions are required and must be answered to submit your information and move to the next section of the assessment.

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Please note: You will not be able to access the general high-alert medications assessment items or the assessment items for each of the high-alert medication categories until you have submitted your general demographic information. Once you submit your demographic information, you will not be able to change any of your selected answers.

3. Complete the general high-alert medications self-assessment items

Once your organization has submitted its answers for the general demographic questions, you will be directed to complete the general self-assessment items that are applicable to more than one high-alert medication category. Follow the directions below to navigate through the online assessment and submit your responses to ISMP.

Navigation and Data Submission

To begin, click on the "Start/Resume Assessment" button. To save your organization's answer for an assessment item and to advance to the next item, click on the "Save and continue" button found below each self-assessment item. If you need to end a session and resume completing the assessment at a later time, you will still need to click on the "Save and continue" button in order to save the last item that has been answered.

Once you have answered the last item in this section of the assessment, click on the "Save and continue button." If you are ready to submit this section of the assessment, click on the "Save and continue button." You will then be queried to verify that you do want to submit. Close the pop-up window and click on the "Save and continue" button again to continue with your submission. If you are not ready to submit, you can either use the "Back" button to make any changes or you can log out. If you are working on one of the 11 high-alert medication categories, you also have the option of clicking on another high-alert medication tab to begin working on a different section of the assessment.

Please note: All general high-alert medications self-assessment items are required and must be answered to submit your information and move to the demographics (if any) and self-assessment sections of the 11 high-alert medication categories. Once you submit the section containing the general high-alert medications self-assessment items, you will not be able to change any of your selected answers.

4. Complete the demographic questions (if any) and self-assessment items for one or more of the high-alert medication categories

Healthcare facilities are encouraged to submit their completed self assessment for each evaluated high-alert medication anonymously to ISMP. Each high-alert medication can be submitted separately at different times within the reporting period and will be linked to your general demographics and general high-alert assessment items. To complete and submit a high-alert medication category, select the corresponding tab.

If the high-alert medication category includes a demographics section, answer the questions and submit your findings to ISMP following the directions in Step 2 ([page 13](#)). All demographic questions must be answered and submitted before you can access the self-assessment section of that high-alert medication category.

Once your organization has submitted its answers to the demographic questions (if any), complete the self-assessment items for that high-alert medication category and submit your findings to ISMP following the **Navigation and Data Submission** directions in Step 3. All self-assessment items must be answered to submit your information for that high-alert medication category.

Please note: Once you submit the demographics and/or self-assessment items for a specific high-alert medication category, you will not be able to change any of your selected answers.

5. Generate and view your reports with weighted scores

After submitting a section of the assessment, you will automatically be directed to a report containing how your organization answered each assessment item in that section, your organization's numerical score and the maximum weighted score for each assessment item in that section,

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and your organization's total score and the maximum possible score for that entire section. At any point, once a self-assessment section has been submitted to ISMP, you can access your facility's demographic answers and assessment results by clicking on "My account" in the top right-hand corner of the webpage.

Weighted scores are not visible on the online self-assessment form while entering your information. Organizations can obtain their weighted scores only after they submit their completed self assessment to ISMP for the general high-alert medications section and for each completed high-alert medication category. Without weighted scores, facilities will be unable to compare their experiences to other demographically similar facilities that are participating in this study.

Explanation of Weighted Scores

To determine a weight for each self-assessment item, ISMP staff used a standard process to independently evaluate each item to determine its impact on patient safety and its ability to sustain improvement.

Therefore, the self-assessment items with the highest weight are those that:

- Target system design/redesign
- Do not rely heavily upon human memory, performance, and vigilance
- Demonstrate through scientific evidence that they are effective in reducing serious medication errors
- Solve several medication-error related problems at the same time
- Safeguard high-risk patient populations
- Prevent errors that have the greatest potential to cause patient harm
- Simplify, standardize, or centralize complex, error-prone processes
- Create high-level system design barriers (e.g., forcing functions, failsafes) to prevent errors
- Create high-level system redundancies to capture errors before they reach patients
- Reduce practitioner tolerance of risk and increase incentives for making safe behavioral choices
- Make it hard for healthcare practitioners to do their job wrong, and easy for them to do it right
- Develop and sustain a **SAFETY CULTURE**

Most of the self-assessment items are weighted in a way that results in no numerical score (zero value) unless there is partial or full implementation (choice of C, D, or E) of the item. However, a few of the items that require extensive planning have been assigned a weighted score for formally discussing the item (choice of B). Some of the self-assessment items are weighted in a way that results in no numerical score unless there is full implementation of the item throughout the organization.

Weighted scores have also been assigned to "Not Applicable" choices based on the degree of risk associated with not implementing the suggested error-reduction strategy (e.g., **SMART PUMP TECHNOLOGY**) or the degree of risk avoided by not treating a specific population (e.g., pediatrics).

Access to Comparative Reports

ISMP will prepare and publish a Preliminary Aggregate Results workbook for the general high-alert medications section and each of the targeted high-alert medications, which will contain comparative reports of the safety practices in US facilities based on the data submitted. Once the data collection period has ended in 2018, facilities that have submitted information to ISMP will be able to access these aggregate comparative reports by accessing their account that was used to enter and submit their self-assessment information at: https://ismpassessments.org/high_alert/. This

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workbook should be available in the second quarter of 2018. In addition, further analysis of the data will be completed, and the results will be submitted for publication in a peer-reviewed journal.

Security and Protection of Self-Assessment Information Submitted to ISMP

All information submitted to ISMP is stored in a secure database maintained solely by ISMP. All information is submitted anonymously.

Although demographic information is collected as part of the assessment process, ISMP will NOT be able to identify individual facilities that have entered and/or submitted information. Further, the database does not allow viewing of demographic information associated with individual assessment information. All information is contextually de-identified, and the demographics are used only for aggregate data reports. Usernames and passwords required for submitting information to ISMP are created by the facilities and can be as non-descriptive as desired by the organizations.

In addition to the usual high standard of confidentiality associated with any information submitted to ISMP, we would also like to remind participants that ISMP is a federally certified patient safety organization (PSO). If self-assessment information is collected within the facility's patient safety evaluation system and submitted to ISMP as patient safety work product, the information is granted protection from discovery in connection with a federal, state, or local civil, administrative, or disciplinary proceeding. No contract with ISMP is required for this legal protection. Further guidelines regarding submitting information to ISMP as a PSO can be found on our website at: www.ismp.org/docs/PSOguidelines.pdf. Please contact ISMP by email (ismpinfo@ismp.org) if you have any questions.

General Demographics

All questions in the demographics section must be completed.

Please select the one category that best describes the facility completing this assessment.

- Hospital
- Long-term care
- Ambulatory surgery center
- Emergency care/urgent care facility
- Dental surgery center
- Endoscopy center
- Diagnostic testing center
- Outpatient clinic or treatment center
- Other outpatient facility: (please specify) _____

For **hospital or long-term care** participants, please complete the **General Demographics for Hospitals and Long-Term Care**. For all other participants, please complete the **General Demographics for Outpatient Facilities** (beginning on the bottom of page 22).

► General Demographics: Hospitals and Long-Term Care

General

- 1) Please select the one category that best describes the number of inpatient beds currently staffed for use in your facility, based on average inpatient census.
 - Up to 25 beds
 - └ Is your facility a critical access hospital (CAH)? Please see the following for criteria that must be met in order for a hospital to be designated a CAH: www.ismp.org/sc?id=2816.
 - Yes
 - No
 - 26 to 99 beds
 - 100 to 299 beds
 - 300 to 499 beds
 - 500 beds and over
- 2) Please select the one category that best describes the location of your facility.
 - Urban
 - Rural

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3) Please select the one category that best describes the type of organization that is responsible for establishing policy for the overall operation of your facility.

- Non-government, not-for-profit
- Investor-owned, for-profit
- Government, non-federal

└ **Type?**

- State
- County
- City
- Other

- Government, federal

└ **Type?**

- Military
- Public Health Service
- Veterans Affairs
- Other

4) Please select the one category that best describes the type of service that your facility provides to the majority of its admissions.

- Long-term care
- Acute long-term care
- General medical and surgical
- Specialty: Pediatrics and/or neonatal
- Specialty: Rehabilitation
- Specialty: Behavioral health
- Specialty: Oncology
- Specialty: Women and children
- Other: (please specify) _____

5) Does your facility provide any of the following services? (select all that apply)

- Trauma services (select for any level of service)
- Labor and delivery services
- General pediatric services (inpatient)
- Pediatric intensive care services
- Neonatal intensive care services (select for any level of service)
- Oncology services (select even if chemotherapy is administered infrequently)
- Transplant services
- Cardiac catheterization
- Hemodialysis
- Behavioral health services
- Long-term care services
- We do NOT provide any of the services listed

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6) Is your facility part of a larger healthcare system with common ownership and/or governance?

Yes

 └ **How many facilities comprise your health system?**

- 2-5
- 6-10
- 11-30
- 31 or more

No

7) Please select if your facility is located in the US/US territory, at a US military foreign site, or in a non-US country.

US/US territory

 └ **Please specify the US state or US territory in which your facility is located.**

-
- US military foreign site
 - Non-US country

 └ **Please specify the non-US country in which your facility is located.**

Training Programs

19

8) Does your facility have a physician residency-training program that has been approved by the American Osteopathic Association (AOA) and/or the Accreditation Council for Graduate Medical Education (ACGME)?

Yes

 └ **Setting?**

- Community teaching hospital
- Academic medical center
- Other: (please specify) _____

No

9) Does your facility have a pharmacy residency-training program that has been accredited, or is pending accreditation, by the American Society of Health-System Pharmacists (ASHP)?

Yes

No

10) Does your facility serve as a clinical site to train students from an accredited program?

Yes

 └ **Select all that apply**

- Medical students
- Registered nursing students
- Licensed practical nursing students
- Advanced practice nursing students (master's or doctorate degree)
- Radiology technician students
- Respiratory therapy technician students
- Pharmacy students
- Other: (please specify) _____

No

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Pharmacy Services

11) How are pharmacy services managed in your facility?

- Internally
- Externally

12) Is a pharmacist physically present onsite in the facility 24 hours a day, 7 days per week, to review orders and dispense medications?

- Yes
- No

└ During hours when the pharmacy is not open and/or a pharmacist is not onsite, is remote pharmacist order entry and order review/verification a service that is provided?

- Yes, during all hours that the pharmacy is not open and/or a pharmacist is not onsite
- Yes, during some hours that the pharmacy is not open and/or a pharmacist is not onsite
- No

13) Beyond the central pharmacy, are there satellite pharmacies located and operated in the facility?

- Yes

└ Locations? (select all that apply)

- Emergency department
- Surgical suites
- Oncology unit
- Pediatric unit
- Intensive care, adult
- Intensive care, pediatrics
- Intensive care, neonatal
- Long-term care
- Other: (please specify) _____

- No

Specialty Staff

14) Does your organization employ one or more full-time or part-time MEDICATION SAFETY OFFICERS (i.e., an individual dedicated to medication safety)?

- Yes

└ Employment?

- At least one person full time
- One person part time
- More than one person part time

└ Profession? (select all that apply)

- Physician
- Pharmacist
- Nurse
- Other: (please specify) _____

- No

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15) Does your facility employ or contract with HOSPITALISTS/INTENSIVISTS, physician assistants, or advanced practice nurses who work in-house following patients in the organization and prescribing medications?

Yes

 └ **Coverage?** (select all that apply)

- Part-time coverage: Specialty unit(s)
- Part-time coverage: General unit(s)
- Part-time coverage: Facility-wide
- Full-time coverage (24/7): Specialty unit(s)
- Full-time coverage (24/7): General unit(s)
- Full-time coverage (24/7): Facility-wide

No

Available Technology

16) Has your facility implemented EHRs?

- Yes, EHRs have been implemented facility-wide (inpatient and outpatient)
- Yes, EHRs have been implemented, but only in some locations

 └ **Scope of implementation?** (select all that apply)

- EHRs are used for patients/residents admitted to inpatient units
- EHRs are used for emergency department patients
- EHRs are used for patients/residents in some outpatient units/clinics
- EHRs are used for patients/residents in all outpatient units/clinics
- Other: (please specify) _____

No

17) Does your facility use SMART INFUSION PUMPS with DOSE ERROR-REDUCTION SOFTWARE (DERS) that is capable of alerting the user to unsafe doses or infusion rates?

Yes

 └ **Uses?** (select all that apply)

- General purpose
- PCA
- Epidural administration
- Small volume infusions via a syringe
- Chemotherapy
- Operating room/anesthesia use
- Other specialty uses: (please specify) _____

 └ **Interoperability? Are the SMART INFUSION PUMPS interoperable with the facility's EHR (i.e., BARCODE SCANNING TECHNOLOGY is used to transmit prescriber-ordered, pharmacist-reviewed infusion parameters to prepopulate the infusion pump, and IV infusion data is sent back to the EHR)?**

- Yes
- No

No

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18) Does your facility use a COMPUTERIZED PRESCRIBER ORDER ENTRY system?

Yes

 └ **Scope of implementation?** (select all that apply)

- Used in all inpatient (or long-term care resident) areas
- Used in all inpatient areas except for chemotherapy and/or PN orders
- Used only in some inpatient (or long-term care resident) areas
- Used in the emergency department
- Used in the operating room
- Used in the post-anesthesia care unit
- Used in all outpatient areas (e.g., ambulatory surgical and medical procedure units, oncology clinics, dialysis units)
(Exclude the emergency department, which is listed separately)
- Used only in some outpatient areas *(Exclude the emergency department, which is listed separately)*
- Other: (please specify) _____

No

19) Does your facility provide stat centralized (within the facility setting) laboratory services and test results (excluding POINT-OF-CARE bedside testing) 24 hours a day, 7 days per week, to ensure safe and timely monitoring of medication therapy?

Yes

No

► General Demographics: Outpatient Facilities

General

1) Please select the one category that best describes the average number of patient visits per month to your facility.

- Less than 100
- 100 to 499
- 500 to 1,499
- 1,500 to 2,499
- 2,500 to 3,999
- 4,000 to 4,999
- 5,000 and over

2) Please select the one category that best describes the location of your facility.

- Urban
- Rural

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3) Please select the one category that best describes the type of organization that is responsible for establishing policy for the overall operation of your facility.

- Non-government, not-for-profit
- Investor-owned, for-profit
- Government, non-federal

└ **Type?**

- State
 - County
 - City
 - Other
- Government, federal

└ **Type?**

- Military
- Public Health Service
- Veterans Affairs
- Other

4) Please select the one category that best describes the type of service that your facility provides to the majority of its patients.

- General medical
- Specialty: Emergency or urgent care
- Specialty: Ambulatory surgery
- Specialty: Endoscopy
- Specialty: Oncology/infusion
- Specialty: Hemodialysis
- Specialty: Anticoagulation
- Specialty: Pain management
- Other: (please specify) _____

23

5) Please select if your facility is located in the US/US territory, at a US military foreign site, or in a non-US country.

- US/US territory

└ **Please specify the US state or US territory in which your facility is located.**

-
- US military foreign site
 - Non-US country

└ **Please specify the non-US country in which your facility is located.**

Training Programs

6) Does your facility serve as a clinical site to train healthcare students/residents from an accredited program?

- Yes

└ **Select all that apply**

- Medical residents from a program approved by the American Osteopathic Association (AOA) and/or the Accreditation Council for Graduate Medical Education (ACGME)?
- Medical students
- Pharmacy residents from a program accredited by the American Society of Health-System Pharmacists (ASHP)

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- Pharmacy students
- Registered nursing students
- Licensed practical nursing students
- Advanced practice nursing students (master's or doctorate degree)
- Radiology technician students
- Respiratory therapy technician students
- Other: (please specify) _____

No

Pharmacy Services

7) How are pharmacy services provided for medications administered in your facility? (select all that apply)

- Facility has an onsite pharmacy
- Facility receives pharmaceuticals from an affiliated hospital or health system
- Facility receives pharmaceuticals from an outsourced provider not affiliated (other than by contract) with the facility
- Facility has no pharmacy services since medications are not administered in the facility
- Other: (please specify) _____

8) Is a pharmacist physically present onsite during all hours of operation to review orders and dispense medications to be administered to patients onsite?

- Yes
- No

└ During hours when a pharmacist is not onsite, is remote pharmacist order entry and order review/verification a service that is provided?

- Yes, during all hours that a pharmacist is not onsite
- Yes, during some hours that a pharmacist is not onsite
- No

9) Is a pharmacy onsite to dispense medications to patients for administration at home?

- Yes
- No

Specialty Staff

10) Does your facility employ one or more full-time or part-time MEDICATION SAFETY OFFICERS (i.e., an individual dedicated to medication safety)?

- Yes

└ Employment?

- At least one person full time
- One person part time
- More than one person part time

└ Profession? (select all that apply)

- Physician
- Pharmacist
- Nurse
- Other: (please specify) _____

No

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Available Technology

11) Has your facility implemented EHRs?

- Yes
- No

12) Does your facility use a COMPUTERIZED PRESCRIBER ORDER ENTRY system?

- Yes
- No

13) Does your facility use SMART INFUSION PUMPS with DOSE ERROR-REDUCTION SOFTWARE (DERS) that is capable of alerting the user to unsafe doses or infusion rates?

- Yes

↳ Uses? (select all that apply)

- General purpose
- PCA
- Epidural administration
- Small volume infusions via a syringe
- Chemotherapy
- Operating room/anesthesia use
- Other specialty uses: (please specify) _____

↳ Interoperability? Are the SMART INFUSION PUMPS interoperable with the facility's EHR (i.e., BARCODE SCANNING TECHNOLOGY is used to transmit prescriber-ordered, pharmacist-reviewed infusion parameters to prepopulate the infusion pump, and IV infusion data is sent back to the EHR)?

- Yes
- No

No

General High-Alert Medications

Scope: Unless otherwise stated, these items pertain to the high-alert medications included in this assessment (if used in the facility) and those on the facility's list of high-alert medications.

► Self-Assessment Items

| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|-------------------|---|---|---|---|---|----------------|
| Technology | | | | | | |
| 1 | COMPUTERIZED PRESCRIBER ORDER ENTRY systems are used to transmit nonemergent orders for high-alert medications in all settings in the facility (e.g., emergency departments, post-anesthesia care units, clinics, inpatient units). | | | | | |
| 2 | MACHINE-READABLE CODING is used to verify all base solutions and additives (including verification prior to attachment to automated compounders) when preparing COMPOUNDED STERILE PREPARATIONS of high-alert medications. Scoring guideline: Choose Not Applicable <u>only if</u> COMPOUNDED STERILE PREPARATIONS of high-alert medications are never prepared in your facility. | | | | | |
| | | | | | | NOT APPLICABLE |
| FAQ 3 | For COMPOUNDED STERILE PREPARATIONS containing high-alert medications, the base solution and all additives (including the actual volume in syringes) are INDEPENDENTLY DOUBLE CHECKED by a practitioner (even if initially prepared by a pharmacist) <u>prior</u> to mixing when no technology-assisted validation is in place to confirm the correct products <u>and</u> volumes. (The SYRINGE PULLBACK METHOD is not used as part of the verification process.) Scoring guideline: Choose Not Applicable <u>only if</u> COMPOUNDED STERILE PREPARATIONS of high-alert medications are never prepared in your facility. | | | | | |
| | | | | | | NOT APPLICABLE |
| 4 | MACHINE-READABLE CODING is used in the following locations and/or for the following tasks: (score each item individually) | | | | | |
| a | In the pharmacy for selection of high-alert medications <u>prior</u> to dispensing or leaving the pharmacy | | | | | |
| b | When filling ADCs with high-alert medications, scanning each medication or solution individually before stocking it Scoring guideline: Choose Not Applicable <u>only if</u> ADCs are never used in your facility. | | | | | |
| | | | | | | NOT APPLICABLE |
| c | When removing high-alert medications from ADCs via override or from open/multiple-dose matrix drawers Scoring guideline: Choose Not Applicable <u>only if</u> ADCs are never used in your facility. | | | | | |
| | | | | | | NOT APPLICABLE |
| d | At the patient's bedside <u>prior</u> to administration to identify both the patient and the medication/dose | | | | | |
| 5 | eMARs are accessible at the patient's bedside and used for reference during the drug administration process. | | | | | |

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| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--------------------------|---|---|---|---|---|---|
| 6 | SMART INFUSION PUMPS with activated DOSE ERROR-REDUCTION SOFTWARE (DERS) are used to administer IV and/or epidural high-alert medications. Exception: IV push medications administered by a practitioner, and small volume vesicant infusions which, when administered via the peripheral IV route, should only be infused by gravity and not by an infusion/syringe pump. Scoring guideline: Choose Not Applicable <u>only if</u> high-alert medication infusions are never administered in your facility. | | | | | |
| FAQ 7 | SMART INFUSION PUMPS are integrated with the computer order entry systems and EHR; and auto-programming of high-alert medication infusions occurs through this closed-loop technology directly via the medication order. Scoring guideline: Choose Not Applicable <u>only if</u> SMART INFUSION PUMPS are never used and/or high-alert medication infusions are never administered in your facility. | | | | | |
| 8 | Prescribers, pharmacists, and nurses can easily and electronically access the most current inpatient and outpatient laboratory values while working in their respective clinical locations. | | | | | |
| Technology Alerts | | | | | | |
| 9 | All inpatient and/or outpatient orders are entered into a computer order entry system and screened electronically against the patient's current medications and medical profile to identify potential contraindications, interactions, and duplicate therapy <u>before</u> high-alert medications are administered, unless a delay in administration could result in patient harm. | | | | | |
| 10 | The following technology systems used in the facility are tested at least annually to ensure that MAXIMUM DOSE alerts are functional for high-alert medications; and alerts are created for those that are not present: (score each item individually) | | | | | |
| a | Computer order entry systems (prescriber and pharmacy) | | | | | |
| b | Automated compounding devices Scoring guideline: Choose Not Applicable <u>only if</u> automated compounding devices are never used and/or PARENTERAL products are never compounded in your facility. | | | | | |
| c | SMART INFUSION PUMPS Scoring guideline: Choose Not Applicable <u>only if</u> SMART INFUSION PUMPS are never used and/or high-alert medication infusions are never administered in your facility. | | | | | |
| 11 | The EHR and/or computer order entry system alerts the user if the patient's documented weight or height exceeds a threshold that suggests the possibility of an error (e.g., entering weight in pounds instead of kg, switching height and weight entries, entering a weight that exceeds a facility-defined percent gained or lost). | | | | | |
| 12 | Computer order entry systems are directly INTERFACED or integrated with the laboratory system and <u>automatically</u> alert practitioners who are placing and/or verifying orders to abnormal values, indicating a potential need to modify therapy with high-alert medications. | | | | | |
| 13 | An active computer surveillance system (e.g., DATA MONITORING SOFTWARE) is used to monitor available data sources to optimize therapy and identify patients at risk of harm from high-alert medications (e.g., decreased platelet count in a patient receiving heparin), <u>and</u> to notify an authorized practitioner of intervention opportunities in real time. | | | | | |

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| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|----------------------------------|---|---|---|---|---|----------------|
| Dispensing | | | | | | |
| 14 | Orders for weight-based high-alert medications cannot be verified, dispensed, or administered until the patient's recent, actual weight (not stated, estimated, or historical weight) in metric units has been entered in the pharmacy computer order entry system (i.e., orders cannot be verified until the weight field has been populated). Exception: Emergent orders for which a delay in administration could cause patient harm. | | | | | |
| 15 | Pharmacists work onsite in patient care areas at least 8 hours each day performing clinical activities (e.g., reviewing medication orders, verifying medications, attending interdisciplinary rounds, providing input into the selection and administration of medications, educating patients) where high-alert medications are ordered and administered. | | | | | |
| Device Management | | | | | | |
| 16 | Before purchasing a new administration device to deliver a high-alert medication (e.g., insulin pen, SMART INFUSION PUMP , elastomeric pump, intrathecal pump) the facility conducts a PROACTIVE RISK ASSESSMENT using a sample device and implements strategies to minimize the risk of errors. | | | | | |
| Administration | | | | | | |
| 17 | When infusions of high-alert medications are started, reconnected, or changed (new bag or syringe), or the rate is adjusted, the tubing is traced by hand from the solution container, to the pump, and then to the patient for verification of the proper pump/channel and route of administration. Scoring guideline: Choose Not Applicable <u>only if high-alert medication infusions are never administered in your facility.</u> | | | | | NOT APPLICABLE |
| INDEPENDENT DOUBLE CHECKS | | | | | | |
| 18 | When starting or restarting an IV or epidural high-alert medication infusion, and with each new bag/bottle/syringe or change in the infusion rate, one practitioner readies the solution and a second practitioner, using the EHR/order/MAR/eMAR and available technology (e.g., integrated SMART INFUSION PUMPS, BARCODE SCANNING TECHNOLOGY), independently verifies the following before starting the infusion: patient; drug/solution; drug concentration; rate of infusion; line and pump attachment; and channel selection (for multiple-channel pumps). (The latter two elements require verification by a practitioner even if technology is employed to verify the other elements.) Exception: Frequent rate changes to titrate a medication (e.g., vasopressors) to effect. Scoring guideline: Choose Not Applicable <u>only if IV or epidural high-alert medication infusions are never administered in your facility.</u> | | | | | NOT APPLICABLE |
| 19 | For IV or epidural high-alert medication infusions, an INDEPENDENT DOUBLE CHECK between the oncoming and outgoing nurse at shift change is required to verify the patient, drug/solution, drug concentration, rate of infusion, line and pump attachment, and channel selection (for multiple-channel pumps). Scoring guideline: Choose Not Applicable <u>only if IV or epidural high-alert medication infusions are never administered in your facility and/or there is no transition between staff caring for patients or shift changes.</u> | | | | | NOT APPLICABLE |
| Expression of Drug Doses | | | | | | |
| 20 | The abbreviation "U" or "u" is never used for units when expressing medication (e.g., heparin, insulin) doses in any paper, label, or electronic format used to communicate medications in the facility. | | | | | |

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| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--|---|---|---|---|---|----------------|
| 21 | Trailing zeros are not used when expressing medication doses (e.g., 5 mg, never 5.0 mg), and leading zeros are used when expressing doses less than 1 measurement unit (e.g., .03 mg, never .3 mg) in any paper, label, or electronic format used to communicate medications in the facility. | | | | | |
| 22 | Orders for weight-based high-alert medications for neonatal and younger pediatric patients below a facility-specified weight (e.g., 40 kg) include the basis for the dose (e.g., mg/kg or mcg/kg) along with the total calculated patient-specific dose (e.g., morphine 0.1 mg/kg x 15 kg = 1.5 mg IV every 4 hours PRN severe pain). Scoring guideline: Choose Not Applicable only if your facility never administers high-alert medications to neonates or younger pediatric patients. | | | | | NOT APPLICABLE |
| 23 | Standard protocols, order sets, and orders express IV and neuraxial high-alert medication infusions/ doses in a manner (e.g., mg, mmol, mEq, mg/kg, mcg/kg/min) and sequence that matches the entries on MARs/eMARs, pharmacy labels and/or AUTOMATED SYSTEM LABELS, infusion pumps, and automated compounders (if utilized). Scoring guideline: Choose Not Applicable only if IV and/or neuraxial high-alert medications are never administered in your facility. | | | | | NOT APPLICABLE |
| Product Differentiation | | | | | | |
| 24 | When more than one standard concentration is needed for high-alert medication infusions (for adult, pediatric, or neonatal patients), the facility uses consistent terminology and visual cues to distinguish between the concentrations on labels, MARs/eMARs, and electronic (e.g., computer order entry systems, ADCs, SMART INFUSION PUMPS) screens. Scoring guideline: Choose Not Applicable only if high-alert medication infusions are never administered in your facility. | | | | | NOT APPLICABLE |
| 25 | To minimize errors with high-alert medications that have similar or confusing labels, packaging, and/or drug names, process strategies (e.g., BARCODE SCANNING TECHNOLOGY, TALL MAN LETTERING) and environmental strategies (e.g., segregated storage, lidded compartments in ADCs) are in place. | | | | | |
| Rapid Response Team | | | | | | |
| 26 | A rapid response team is available 24 hours a day, 7 days a week (or whenever the facility is open), and consistently responds to patient, family, and staff concerns about increasing instability and/or clinical deterioration of the patient. | | | | | |
| Staff Competency and Education | | | | | | |
| 27 | Practical, hands-on techniques such as SIMULATION TRAINING are used at least annually with practitioners and teams (e.g., rapid response teams) to promote initial and continuing competence with high-alert medications and emergency responses to adverse drug events; and known error-prone conditions are embedded in the training to help staff avoid them, detect them, and/or manage their effects. | | | | | |
| 28 | Practitioners who prescribe, dispense, and administer high-alert medications receive ongoing information about associated risks and errors that have occurred in the organization and have been reported by external organizations, and about strategies to minimize these risks and errors. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 29 | Criteria have been established to trigger an automatic consultation with a pharmacist or other patient educator for patients who take or will be taking facility-defined high-alert medications at home. | | | | | |

continued on page 30 ►

ISMP Medication Safety Self Assessment®
for High-Alert Medications

| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|-------------------------|--|---|---|---|---|---|
| 30 | Patients prescribed therapy with high-alert medications are provided with information about the common types of errors known to be problematic with these drugs (e.g., methotrexate inadvertently prescribed daily for arthritis, wrong dose errors due to frequently changing warfarin orders, mix-ups between rapid-acting and BASAL INSULINS), <u>and</u> how to prevent and detect these errors. | | | | | |
| Learning Culture | | | | | | |
| 31 | The organization routinely reviews the following data and reports; <u>and</u> a convened interdisciplinary team investigates identified problems, learns their causes, and recommends/facilitates action for improvement: (score each item individually) | | | | | |
| a | Staff compliance with protocols, guidelines, and order sets related to high-alert medications | | | | | |
| b | Staff compliance with technology (e.g., BARCODE SCANNING TECHNOLOGY rates, activation of SMART INFUSION PUMP DOSE ERROR-REDUCTION SOFTWARE [DERS] , ADC overrides) | | | | | |
| c | Technology alerts (e.g., MAXIMUM DOSES , serious drug interaction, allergies) associated with high-alert medications to determine whether practitioners are responding to them appropriately | | | | | |
| d | Internal reports of risk, errors, and adverse events related to high-alert medications | | | | | |
| e | External reports of risk, errors, and adverse events related to high-alert medications | | | | | |
| 32 | The following investigative resources are used to identify risks or errors with high-alert medications and to demonstrate sustained improvement after implementation of risk-reduction strategies: (score each item individually) | | | | | |
| a | Medication event reports | | | | | |
| b | Adverse drug reaction reports | | | | | |
| c | Pharmacy interventions (e.g., pharmacist suggestion of a therapeutic change to improve the safety of a medication order) | | | | | |
| d | Rapid response team calls | | | | | |
| e | Use of reversal agents or antidotes (e.g., flumazenil, naloxone, sugammadex, vitamin K ₁ , fresh frozen plasma, prothrombin complex concentrates, dantrolene) | | | | | |
| f | Certain laboratory or monitoring results (e.g., aPTT or INR greater than "x," heparin-induced thrombocytopenia [HIT] antibody; hypoglycemia and hyperglycemia) | | | | | |
| g | Other clinical TRIGGERS (e.g., airway interventions, unplanned or prolonged hospitalization, inability to complete a procedure [sedation failures], opioid-induced respiratory depression or unintended advancing sedation) | | | | | |
| FAQ 33 | Staff are anonymously surveyed every 1 to 2 years to assess the organization's SAFETY CULTURE ; <u>and</u> the findings are used to advance the organization's SAFETY CULTURE . | | | | | |

Neuromuscular Blocking Agents

Scope: Unless otherwise stated, these items pertain to all neuromuscular blocking agents used in any inpatient and outpatient locations associated with the facility.

► Demographic Question

1) What percent of neuromuscular blocking agents used by anesthesia staff are dispensed by the pharmacy in either pre-filled syringes or prepared infusions?

- Less than 10%
- 11% to 25%
- 26% to 50%
- 51% to 75%
- 76% to 90%
- Greater than 90%

► Self-Assessment Items

| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--------------------|---|---|---|---|---|---|
| Prescribing | | | | | | |
| 1 | Outside the operating room (OR) and post-anesthesia care unit (PACU), neuromuscular blocking agents used for maintenance of paralysis in patients on a ventilator are prescribed via a protocol or order set. Scoring guideline: Choose <i>Not Applicable</i> <u>only</u> if neuromuscular blocking agents are never used outside the OR or PACU for patients on a ventilator. | | | | | |
| 2 | Organizational policies do not allow orders for neuromuscular blocking agents with directions to "use as needed for agitation." | | | | | |
| Dispensing | | | | | | |
| 3 | If a neuromuscular blocking agent (e.g., continuous infusion) is ordered for a patient located in a care environment that does not typically support mechanical ventilation, pharmacy staff are required to verify that the patient is (or will be) supported by mechanical ventilation before dispensing the product. | | | | | |
| Storage | | | | | | |
| 4 | Neuromuscular blocking agents are <u>only</u> available in rapid sequence intubation kits, surgical suites, post-anesthesia care unit/anesthesia stock, the emergency department, and/or critical care units, where patients can be ventilated and monitored by practitioners with demonstrated competencies. | | | | | |

ISMP Medication Safety Self Assessment®
for High-Alert Medications

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|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| 5 | Refrigerated and nonrefrigerated neuromuscular blocking agents are segregated from other medications or sequestered in a rapid sequence intubation kit or lidded box/drawer wherever they are stored in the facility (including ADCs, pharmacy, anesthesia supplies). | | | | | |
| 6 | Storage bins and/or ADC pockets or drawers containing neuromuscular blocking agents include an auxiliary label to clearly communicate that respiratory paralysis will occur and ventilation is required (e.g., WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST; WARNING: CAUSES RESPIRATORY PARALYSIS—PATIENT MUST BE VENTILATED). <i>Scoring guideline: Compliance can also be achieved by affixing an auxiliary warning label (in addition to the manufacturers' warning on the cap and ferrule) directly on all vials and/or other containers stocked in the storage locations, or by displaying a warning on an ADC screen, which must be acknowledged prior to removal of a neuromuscular blocking agent—score accordingly.</i> | | | | | |
| Product Labeling | | | | | | |
| 7 | Final containers (e.g., pharmacy-prepared syringes, IV bags, pharmacy-repackaged vials) of pharmacy-prepared and dispensed neuromuscular blocking agents include a clearly visible warning (e.g., WARNING: PARALYZING AGENT—CAUSES RESPIRATORY ARREST; WARNING: CAUSES RESPIRATORY PARALYSIS—PATIENT MUST BE VENTILATED) that does not obscure important label information to communicate that respiratory paralysis will occur and ventilation is required. | | | | | |
| 8 | Syringes of neuromuscular blocking agents prepared by anesthesia staff are labeled with the name and concentration/dose of the drug, and the expiration date and time. (An anesthesia color-coded drug class label alone is not sufficient.) <i>Exception: Labeling is not required if the syringe is prepared immediately before drug administration, never leaves the hand of the preparer before administration, and the entire dose in the syringe is administered or the remaining volume is immediately wasted or discarded before the syringe leaves the hand. Expiration date and time are not required for short procedures, as defined by the facility.</i> | | | | | |
| Drug Preparation | | | | | | |
| 9 | Anesthesia staff are provided with <u>and</u> use labeled, prefilled syringes of neuromuscular blocking agents that are available from an outsourcer or prepared by pharmacy, rather than using self-prepared syringes. | | | | | |
| 10 | Only the pharmacy prepares and dispenses continuous infusions of neuromuscular blocking agents to patient care units outside the surgical suites. | | | | | |
| 11 | A single, standardized concentration of a neuromuscular blocking agent is used for continuous infusions. | | | | | |
| Malignant Hyperthermia Management | | | | | | |
| FAQ 12 | Dantrolene and any required diluent is readily available (within 10 minutes of diagnosing a malignant hyperthermia event) in all patient care areas where succinylcholine is stocked (even if succinylcholine is only available in emergency intubation supplies). | | | | | |

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for High-Alert Medications

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|---|---|
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| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|-------------------------------|--|---|---|---|---|---|
| <i>Discontinuation</i> | | | | | | |
| 13 | Before extubating a patient who was receiving a neuromuscular blocking agent, the IV administration set is flushed (or the set is changed) within an appropriate period of time before attempting extubation (based on the drug's duration of action) to prevent an inadvertent bolus after extubation of any residual drug remaining in the IV tubing. | | | | | |
| 14 | All continuous infusions of neuromuscular blocking agents are immediately discarded after discontinuation (and not left to hang on an IV pole or at the bedside). | | | | | |
| 15 | Vials, syringes, or unused infusion bags containing neuromuscular blocking agents dispensed from the pharmacy or removed from unit stock are not transferred with the patient to a receiving unit, even if the patient still requires their use. The agents must be returned to the pharmacy immediately and dispensed to the new unit only in response to new orders post-transfer. | | | | | |

Concentrated Electrolytes Injection

Scope: Unless otherwise stated, these items pertain to the following injectable concentrated electrolytes: potassium chloride; hypertonic sodium chloride for injection (greater than 0.9% concentration); potassium phosphate; sodium phosphate; and potassium acetate.

► Self-Assessment Items

| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--|---|---|---|---|---|---|
| General Electrolyte Replacement Therapy | | | | | | |
| Protocols and Order Sets | | | | | | |
| 1 | Standard protocols exist and are followed for adult, pediatric, and/or neonatal electrolyte replacement therapy to treat hypokalemia, hyponatremia, and hypophosphatemia. | | | | | |
| 2 | Standard protocols for adult, pediatric, and/or neonatal electrolyte replacement therapy include the following: (score each item individually) | | | | | |
| a | Maximum concentration and infusion rate of IV solutions, and the concentration at which administration through a central IV access line is required | | | | | |
| b | Type and frequency of patient monitoring required (e.g., continuous ECG monitoring, patient assessment, serum electrolyte level and other laboratory monitoring) during IV administration and following therapy to evaluate the patient's response | | | | | |
| 3 | Standard order sets exist and are used to prescribe adult, pediatric, and/or neonatal electrolyte replacement therapy <u>and</u> include required patient monitoring. | | | | | |
| Products and Storage | | | | | | |
| 4 | Commercially available premixed solutions or outsourced admixtures are used for electrolyte replacement therapy when they are available; otherwise, the pharmacy prepares and dispenses all IV infusions for electrolyte replacement therapy. | | | | | |
| 5 | In the pharmacy, containers of concentrated electrolytes are stored in a separate area designated for IV compounding and admixture supplies, and are physically separated from other medications and each other. | | | | | |
| 6 | Vials of concentrated forms of electrolytes that require dilution before IV administration are not available as unit stock (including in ADCs) on any patient care units (including in operating room/anesthesia stock), and are not dispensed to patient care units for individual patients. Exception: Vials in a cardiac surgery kit or a cardiac surgery locked storage area (see item # 15). | | | | | |

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|---|---|
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
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| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E | | | | | |
|--|--|----------------|---|---|---|---|--|--|--|--|--|
| Product Labeling | | | | | | | | | | | |
| 7 | Product labels and associated work labels used by pharmacy staff to compound electrolyte solutions include the actual strength of the base solution and strength and dose of each additive, not just the volume amounts needed to prepare the products. | | | | | | | | | | |
| Expression of Drug Doses | | | | | | | | | | | |
| 8 | Small volume single or intermittent IV infusions of potassium chloride, potassium phosphate, sodium phosphate, or sodium chloride in concentrations greater than 0.9%, are never referred to as "bolus" doses in computer order entry systems, order sets, protocols, pharmacy labels and/or AUTOMATED SYSTEM LABELS , MARs/eMARs, ADC screens, and/or infusion pump screens. ("Bolus" doses might be misinterpreted as direct, undiluted, and/or rapid IV administration.) Exception: 23.4% sodium chloride administered IV push to treat elevated intracranial pressure. See items # 18-22 in the section on Hypertonic Sodium Chloride for Injection (Greater Than 0.9%). | | | | | | | | | | |
| IV to Oral Supplements | | | | | | | | | | | |
| 9 | A pharmacy-managed or automated system is in place to proactively convert IV to oral electrolyte replacement therapy if the patient can tolerate it and his or her medical needs can be met. | | | | | | | | | | |
| Electrolytes in Parenteral Nutrition (PN) | | | | | | | | | | | |
| Scoring guideline for this section: Choose Not Applicable <u>only</u> if PN is never prescribed in your facility. | | | | | | | | | | | |
| Prescribing | | | | | | | | | | | |
| 10 | Standard order sets for PN list electrolyte additives in the same sequence, dosing units (e.g., mg, mEq), and concentrations (e.g., mg/mL, mg/L) as in the pharmacy computer order entry system and automated compounder (if utilized). | | | | | | | | | | |
| | | NOT APPLICABLE | | | | | | | | | |
| 11 | PN electrolyte additives are prescribed for adults as a total dose per day, and for neonates or pediatric patients as a metric weight-based dose per day (e.g., mg/kg/day) or total dose per day. Additional scoring guideline: If you provide care to only adults, neonates, or pediatric patients, score this item as it relates to the patient population you serve. | | | | | | | | | | |
| | | NOT APPLICABLE | | | | | | | | | |
| Potassium Chloride for Injection Concentrate | | | | | | | | | | | |
| Products Used | | | | | | | | | | | |
| 12 | For adult maintenance IV infusions that require potassium chloride, only commercially available, pre-mixed IV solutions containing the electrolyte are used (i.e., pharmacy does not prepare maintenance solutions containing potassium chloride). Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | | | | | | |
| | | NOT APPLICABLE | | | | | | | | | |
| 13 | For single or intermittent small volume infusions to treat hypokalemia in adults, only commercially available premixed IV solutions labeled as "highly concentrated" potassium chloride are used. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | | | | | | |
| | | NOT APPLICABLE | | | | | | | | | |

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|---|---|
| A | There has been no activity to implement this item. |
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|---|---|---|---|---|---|---|
| 14 | Commercially available premixed IV solutions, outsourced solutions, or pharmacy-prepared solutions containing potassium chloride are used for single or intermittent small volume infusions to treat hypokalemia in pediatric and/or neonatal patients. Scoring guideline: Choose Not Applicable <i>only if your facility does not provide care to neonates or pediatric patients.</i> | | | | | |
| Storage | | | | | | |
| 15 | In surgical areas, vials of concentrated potassium chloride or high-dose potassium cardioplegic solutions are sequestered in sealed kits or locked storage areas and obtained immediately before use; and once the procedure has been completed, there is an effective process in place to return unused products to their secure locations or dispose of the partially empty vials or bags. Scoring guideline: Choose Not Applicable <i>only if your facility does not perform cardiac surgery that requires stopping the heart, or if your facility uses an alternative to potassium chloride to stop the heart during surgery (e.g., adenosine, lidocaine, and magnesium solutions).</i> | | | | | |
| Hypertonic Sodium Chloride for Injection (Greater Than 0.9%) | | | | | | |
| Products Used | | | | | | |
| 16 | Base solutions requiring concentrations of sodium chloride that are available in commercially pre-mixed solutions (e.g., 0.45%, 0.9%, 3%) are not compounded manually using a concentrated sodium chloride solution (e.g., 23.4%); instead, the commercially available premixed solutions of sodium chloride are utilized. | | | | | |
| 17 | To prevent mix-ups with 5% dextrose solutions, IV containers of 5% sodium chloride are not procured, ordered, or stocked in the facility. | | | | | |
| Protocols and Order Sets | | | | | | |
| 18 | Standard protocols and order sets exist and are followed for each indication for which IV hypertonic sodium chloride is used (e.g., hyponatremia, elevated intracranial pressure, other off-label use). | | | | | |
| 19 | Protocols for IV hypertonic sodium chloride include directions for administration (e.g., maximum concentration, rate of administration, the concentration at which administration through a central IV access line is required) and the type and frequency of patient monitoring required during IV administration (e.g., patient assessment parameters, laboratory monitoring). | | | | | |
| Storage and Product Labeling | | | | | | |
| 20 | Containers of 3% sodium chloride are restricted to the pharmacy and/or approved critical care or emergency/urgent care units, stocked in limited quantities, labeled with appropriate warnings (e.g., CONCENTRATED sodium chloride, administer via central line only), and segregated from other medications. Scoring guideline: Select a score of E if containers of 3% sodium chloride are never procured, present, or used in the facility. | | | | | |
| 21 | Vials containing 23.4% sodium chloride are not stocked outside the pharmacy or dispensed to patient care units. | | | | | |

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| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|----|--|---|---|---|---|---|
| 22 | Any IV push doses of 23.4% sodium chloride used in critical care or emergency/urgent care units are prepared and dispensed from the pharmacy, labeled with appropriate warnings (e.g., CONCENTRATED sodium chloride 23.4%, administer via central line only), and hand-delivered to the healthcare professional who will be administering the drug. Scoring guideline: Choose Not Applicable <u>only</u> if IV push doses of 23.4% sodium chloride are never prescribed, dispensed, or administered in your facility. | | | | | |

Potassium Phosphate and Sodium Phosphate

Dosing

| | | | | | | |
|----|--|--|--|--|--|--|
| 23 | Practitioners use a standard, facility-defined dosing unit of measure (e.g., mmol vs. mEq) to prescribe, label, dispense, administer, and document doses of potassium phosphate for all adult, pediatric, and neonatal patients. Exception: The dosing unit of measure used for a potassium phosphate additive to PN may differ from other prescribed doses of potassium phosphate, as long as the dosing unit used for the PN additive matches the prescriber and pharmacy computer order entry systems and automated compounding (if utilized). | | | | | |
|----|--|--|--|--|--|--|

Concomitant Potassium

| | | | | | | |
|----|--|--|--|--|--|--|
| 24 | When IV potassium phosphate is prescribed, there is an automated or manual process in place to calculate the concomitant amount of potassium the patient will receive with each dose and verify that it is appropriate considering the patient's potassium level and all other sources of this electrolyte (e.g., maintenance fluids, PN, single electrolyte replacement doses). | | | | | |
|----|--|--|--|--|--|--|

Products Used

| | | | | | | |
|----|--|--|--|--|--|--|
| 25 | Whenever possible, sodium phosphate injection is used to treat hypophosphatemia rather than potassium phosphate injection. | | | | | |
|----|--|--|--|--|--|--|

Organ Preservation Solutions

Storage

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|----|---|--|--|--|--|--|
| 26 | Organ preservation solutions used during organ harvesting are brought into the facility and/or stored in sealed kits or locked storage areas, labeled with an appropriate warning (e.g., "Organ Harvest Use Only"), and obtained from storage immediately before use; and once the procedure has been completed, there is an effective process to return any unused products to their secure locations or to dispose of partially empty bags. Scoring guideline: Choose Not Applicable <u>only</u> if organ harvesting never occurs in your facility. | | | | | |
|----|---|--|--|--|--|--|

Magnesium Sulfate Injection

Scope: Unless otherwise stated, these items pertain to magnesium sulfate injection administered via the **PARENTERAL** (i.e., IV, IM) route of administration **ONLY**. Oral or topical forms of the drug are excluded.

► Demographic Questions

- 1) In your facility, for which indications do you use PARENTERAL magnesium sulfate? (select all that apply)
 Eclampsia/pre-eclampsia and/or neuroprotection of the fetus (labor and delivery and/or emergency department administration)
 Treatment or prevention of hypomagnesemia or nutritional depletion
 Cardiac indications (e.g., Torsades de pointes)
 Other: (please specify) _____

- 2) Commercially available, premixed IV solutions of magnesium sulfate stocked in the pharmacy include those with the following total amounts of drug in the containers: (select all that apply)
 None—we don't stock commercially available, premixed solutions of magnesium sulfate
 1 g
 2 g
 4 g
 20 g
 40 g
 Other: (please specify) _____

► Self-Assessment Items

| | |
|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|---------------------------------|--|---|---|---|---|---|
| General Items | | | | | | |
| Protocols and Order Sets | | | | | | |
| 1 | Separate protocols and order sets have been established and are used for each indication for which PARENTERAL magnesium sulfate is used. | | | | | |
| 2 | PARENTERAL magnesium sulfate protocols and order sets require periodic monitoring of magnesium blood levels, serum creatinine, and clinical patient assessments at defined intervals to determine the effectiveness of treatment and detect signs of toxicity. | | | | | |

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|---|---|
| A | There has been no activity to implement this item. |
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|---------------------------------|---|---|---|---|---|---|
| Expression of Drug Name | | | | | | |
| 3 | Magnesium sulfate is never abbreviated (e.g., MS, MgSO ₄ , Mag) in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, pharmacy labels and/or AUTOMATED SYSTEM LABELS , and any other format used to communicate medications in the facility. | | | | | |
| Expression of Drug Doses | | | | | | |
| 4 | Practitioners use a standard, facility-defined dosing unit of measure (e.g., g vs. mEq) to prescribe, label, dispense, administer, and document magnesium sulfate doses for all <u>adult</u> patients and <u>older pediatric</u> patients above a specified weight. Exception: The dosing unit of measure used for a magnesium sulfate additive to PN may differ from other prescribed doses of magnesium sulfate, as long as the dosing unit used for the PN additive matches the prescriber and pharmacy computer order entry systems and automated compounding (if utilized). Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults or older pediatric patients. | | | | | |
| 5 | Practitioners use a standard, facility-defined dosing unit of measure (e.g., mg or mg/kg vs. mEq or mEq/kg) to prescribe, label, dispense, administer, and document magnesium sulfate doses for <u>neonates</u> and <u>younger pediatric</u> patients below a specified weight. Exception: The dosing unit of measure used for a magnesium sulfate additive to PN may differ from other prescribed doses of magnesium sulfate, as long as the dosing unit used for the PN additive matches the prescriber and pharmacy computer order entry systems and automated compounding (if utilized). Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates or younger pediatric patients. | | | | | |
| Dosing | | | | | | |
| 6 | Information technology is available and used to assist any clinician who needs to convert the dosing units listed on a manufacturer's label of PARENTERAL magnesium sulfate to the standard unit of measure used to prescribe, dispense, administer, and document magnesium sulfate doses (e.g., g to mEq). | | | | | |
| Storage | | | | | | |
| 7 | Vials of magnesium sulfate are not stocked outside the pharmacy in patient care units. Exception: Vials of magnesium sulfate may be stored in secured resuscitation carts. | | | | | |
| Emergency Preparedness | | | | | | |
| FAQ 8 | To respond to emergencies caused by magnesium sulfate overdoses, a standard protocol has been established that guides the administration of a RESCUE agent (i.e., calcium gluconate) after prescriber notification; and the RESCUE agent is easily accessible, along with directions for use, in all clinical areas where high-dose magnesium sulfate is administered. | | | | | |

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|---|---|
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
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| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| Prevent or Treat Hypomagnesemia | | | | | | |
| Protocols and Order Sets | | | | | | |
| 9 | Magnesium sulfate electrolyte replacement protocols have been established and are used to prevent and treat hypomagnesemia. | | | | | |
| 10 | Standard order sets have been established and are used to prescribe magnesium sulfate to treat hypomagnesemia. | | | | | |
| Patient Monitoring | | | | | | |
| 11 | During administration of intermittent doses of IV magnesium sulfate, the patient is assessed for signs of toxicity (e.g., hypotension; respiratory depression; signs of pulmonary edema; bradycardia; cardiac arrhythmia; loss of deep tendon reflexes; progressive muscle weakness; decreased urine output; headache; clonus) at defined intervals (e.g., every 15 minutes for the first hour, every 30 minutes for the second hour, then hourly). | | | | | |
| Pre-eclampsia and Eclampsia, Fetal Neuroprotection | | | | | | |
| Scoring guideline for this section: Choose Not Applicable for these items <i>only</i> if your facility never treats pregnant patients with pre-eclampsia or eclampsia using IV magnesium sulfate in any unit or setting, including during an emergency. | | | | | | |
| Protocols and Order Sets | | | | | | |
| 12 | Specific magnesium sulfate dosing and administration protocols that address the unique needs of pregnant patients have been established and are accessible and used to prevent and treat severe pre-eclampsia or eclampsia and/or to provide fetal neuroprotection. | | | | | |
| 13 | Magnesium sulfate standard order sets for pregnant patients have been established and are used to prescribe magnesium sulfate for severe pre-eclampsia and eclampsia and/or to provide fetal neuroprotection. | | | | | |
| Loading Doses | | | | | | |
| 14a | For all loading doses, either commercially available, premixed minibags of magnesium sulfate solution or pharmacy-prepared minibags are used. (Nurses do not prepare magnesium sulfate doses in syringes or minibags on patient care units except during resuscitation.) | | | | | |
| OR | | | | | | |
| 14b | Loading doses of magnesium sulfate are administered by trained staff from a maintenance infusion bag, using <i>only</i> a SMART INFUSION PUMP with DOSE ERROR-REDUCTION SOFTWARE and a “loading dose” (sometimes called a “bolus dose”) feature that automatically starts/resumes the maintenance infusion at the prescribed rate of infusion once the loading dose has infused. Loading doses are never administered via a basic infusion mode. | | | | | |
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|---|---|
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| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|------------------------------------|--|----------------|---|---|---|---|
| Products Used | | | | | | |
| 15 | Commercially available, premixed bags of magnesium sulfate solution are used for all maintenance infusions. | | | | | |
| | | NOT APPLICABLE | | | | |
| 16 | Only 20 g/500 mL bags (<u>not</u> 40 g/1,000 mL bags) of magnesium sulfate are used for maintenance solutions to limit the amount of drug the patient could receive if an error occurs and to differentiate magnesium sulfate from other infusions in 1,000 mL bags (e.g., oxytocin, Lactated Ringer's). | | | | | |
| | | NOT APPLICABLE | | | | |
| Patient Monitoring | | | | | | |
| 17 | During IV magnesium sulfate administration, the patient undergoes continuous cardiac monitoring, is assessed for signs of toxicity (e.g., hypotension; respiratory depression; signs of pulmonary edema; bradycardia; cardiac arrhythmia; loss of deep tendon reflexes; progressive muscle weakness; decreased urine output; headache; clonus) at defined intervals; and fetal heart rates and maternal uterine activity are monitored. | | | | | |
| | | NOT APPLICABLE | | | | |
| 18 | One-to-one nursing care at the bedside is provided during the first hour of IV administration (including the loading dose), with patient assessment intervals at least every 15 minutes. | | | | | |
| | | NOT APPLICABLE | | | | |
| 19 | During the second hour of IV administration, patient assessments are conducted at least every 30 minutes. | | | | | |
| | | NOT APPLICABLE | | | | |
| 20 | After the first 2 hours of IV administration, patients (even if stable) continue to be assessed at least every hour. | | | | | |
| | | NOT APPLICABLE | | | | |
| Discontinuation or Stoppage | | | | | | |
| 21 | Upon discontinuation of a magnesium sulfate infusion, the solution is immediately disconnected from the patient; and the container is removed from the IV pole and discarded to prevent accidental administration at a later time. | | | | | |
| | | NOT APPLICABLE | | | | |
| 22 | Upon temporary stoppage of magnesium sulfate infusions, the solution is immediately disconnected from the patient. Exception: Short stoppages caused by conditions such as changing a gown. | | | | | |
| | | NOT APPLICABLE | | | | |

Moderate Sedation in Adults and Children, Minimal Sedation in Children

Scope for Moderate Sedation: Unless otherwise stated, these items pertain to all moderate sedation agents (e.g., ketamine, propofol, midazolam, dexmedetomidine, etomidate, fentanyl in combination with another agent(s) [e.g., midazolam, propofol], nitrous oxide in oxygen) administered to adults, neonates, and pediatric patients undergoing a procedure in any setting (e.g., hospital, surgery center, freestanding imaging facility, dental facility, private office).

Scope for Minimal Sedation: Unless otherwise stated, these items pertain to all minimal sedation agents (e.g., midazolam, diazepam, ketamine [using injection solution], compounded pentobarbital, compounded chloral hydrate, nitrous oxide in oxygen) administered only to neonates or pediatric patients undergoing a procedure in any setting (e.g., hospital, surgery center, freestanding imaging facility, dental facility, private office).

Exclusions: Sedation of patients undergoing mechanical ventilation in a critical care environment, or sedation used to provide analgesia to patients postoperatively or to patients with chronic painful conditions or receiving hospice/end-of-life care.

► Self-Assessment Items

| | | | | | |
|---|---|--|--|--|--|
| A | There has been no activity to implement this item. | | | | |
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. | | | | |
| D | This item is fully implemented for some patients, orders, drugs, or staff. | | | | |
| E | This item is fully implemented for all patients, orders, drugs, or staff. | | | | |

| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| General Items for Moderate and Minimal Sedation | | | | | | |
| TIME-OUT Process | | | | | | |
| 1 | Prior to sedation and the procedure, a standardized TIME-OUT is performed by the immediate members of the team that includes verification of the patient's name; the procedure; and the sedation, monitoring, and RESCUE plan. | | | | | |
| Sedation and RESCUE Plan | | | | | | |
| 2 | The physician planning sedation conducts a pre-procedure assessment of the patient that includes, at a minimum: (score each item individually) | | | | | |
| a | Vital signs | | | | | |
| b | Airway risk assessment (e.g., identification of anatomical variants, potential difficulties with intubation) | | | | | |
| c | Health assessment and medical history to uncover problems that could impact ventilation (e.g., asthma, allergies, sleep-disordered breathing) and cardiac stability (e.g., significant cardiovascular disease, dysrhythmias) during sedation | | | | | |
| d | Patient's medication history, drug allergies, and previous sedation reactions | | | | | |
| e | Identification of potential contraindications and/or drug interactions related to possible sedation agents | | | | | |
| 3 | The patient is re-evaluated by the physician immediately before sedation to verify the appropriateness of the sedation plan of care. | | | | | |

continued on page 43 ►

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|---|---|
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| | | A | B | C | D | E |
|-------------------------------|---|---|---|---|---|----------------|
| Verbal Orders | | | | | | |
| FAQ 4 | During a procedure, drug names and doses communicated verbally by the prescriber are read back (or repeated back, if conditions do not allow immediate transcription of the verbal order) to the prescriber for verification before administration. | | | | | |
| Emergency Preparedness | | | | | | |
| 5 | During sedation and patient recovery, supplemental oxygen and age-/size-appropriate equipment and medications that may be needed to RESCUE or resuscitate a sedated patient are readily accessible, regardless of the location of the procedure or recovery. | | | | | |
| 6 | In nonhospital facilities, a protocol for the immediate activation of emergency medical services (EMS) for life-threatening complications has been established, with clear understanding that this does not replace the practitioner's responsibility to provide initial RESCUE . Scoring guideline: Choose Not Applicable <u>only if your facility is a hospital</u> . | | | | | NOT APPLICABLE |
| 7 | For neonates and/or pediatric patients, at least one practitioner skilled in obtaining vascular access in children is available during the procedure and the recovery period. Scoring guideline: Choose Not Applicable <u>only if your facility never administers moderate or minimal sedation to neonates or pediatric patients</u> . | | | | | NOT APPLICABLE |
| Reversal Agents | | | | | | |
| 8 | Protocols and order sets exist and are used to RESCUE a patient who has entered a higher level of sedation than intended, taking into consideration factors that influence the necessity and urgency of reversal. | | | | | |
| 9 | Appropriate reversal agents (e.g., flumazenil, naloxone) are readily accessible <u>and</u> accompanied by a clear indication for when they should be used, their order of use, directions for administration near the point of use, and a protocol or coupled order set that permits emergency administration. | | | | | |
| 10 | Reversal agents are not administered electively to solely decrease patient recovery time. | | | | | |
| 11 | Patients who receive a reversal agent are monitored for signs of resedation for at least 90 minutes after administration of the reversal agent. | | | | | |
| Patient Monitoring | | | | | | |
| FAQ 12 | After the procedure, patients are monitored in a recovery area staffed with practitioners who are trained to monitor and recover sedated patients. | | | | | |
| 13 | Predefined criteria for adults (e.g., Aldrete Scoring System, Post-Anesthetic Discharge Scoring System), and for neonates and/or pediatric patients if applicable (e.g., ability to remain awake for at least 20 minutes in a quiet environment), exist to determine when a patient has approached a pre-sedation state and can be discharged from the facility or no longer requires post-procedure recovery monitoring. | | | | | |

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| | | A | B | C | D | E |
|--|---|---|---|---|---|----------------|
| 14 | A longer period of monitoring beyond meeting predefined criteria (see item # 13) is required for patients who have received a long-acting sedative and/or have an anatomical airway problem or underlying medical condition that might compromise blood pressure or ventilation (e.g., sleep-disordered breathing), or if the ability of the responsible adult to observe the patient after discharge is limited. | | | | | |
| Accompanied by a Responsible Adult | | | | | | |
| 15 | Patients who are discharged post-procedure are accompanied by a responsible adult who agrees to drive the patient home; and staff reasonably confirm that a responsible adult will be available to observe the patient for the remainder of the day. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 16 | Patients and/or the responsible adult staying with the patient are instructed to observe for signs of rebound sedation, and when and how to seek immediate medical attention. | | | | | |
| 17 | Special instructions are given to the adult responsible for neonates and/or younger pediatric patients who will be transported home in a car safety seat regarding the need to carefully observe the child's head position to avoid airway obstruction. Scoring guideline: Choose Not Applicable only if your facility never administers moderate or minimal sedation to neonates or younger pediatric patients. | | | | | NOT APPLICABLE |
| Staff Competency and Education | | | | | | |
| 18 | Practitioners involved in minimal or moderate sedation participate in at least annual reviews, SIMULATION TRAINING of rare emergencies, and practice drills of the facility's emergency protocols to ensure proper functioning of the equipment and coordination of staff roles in such emergencies. | | | | | |
| Moderate Sedation | | | | | | |
| Anesthesia Oversight | | | | | | |
| 19 | The anesthesia department is involved in developing and approving all protocols, guidelines, and/or order sets associated with moderate sedation that specify the agents or combination of agents used; the training, supervision, and privileging of practitioners who sedate or monitor patients; patient assessment and monitoring before, during, and after sedation; locations where sedation is allowed; and required emergency equipment, medications, and oxygen. | | | | | |
| 20 | The medications, routes, and dosage ranges used for moderate sedation have been selected based on known drug properties that impact their onset, duration, synergistic effects, and adverse effects; and they have been reviewed by an anesthesiologist and a pharmacist (or the PHARMACY AND THERAPEUTICS COMMITTEE or similar medical staff committee) to ensure they are supported by current literature, expert opinion, and/or national guidelines. | | | | | |

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| | | A | B | C | D | E |
|---------------------------------------|---|---|---|---|---|---|
| Locations | | | | | | |
| 21 | The organization has conducted a thorough assessment to identify all locations where moderate sedation of patients occurs (including outpatient locations, if applicable) to standardize the care, monitor these practice sites, and provide oversight to promote safety. | | | | | |
| Staff Competency and Education | | | | | | |
| 22 | All healthcare practitioners who administer moderate sedation have current certification in advanced airway assessment and management appropriate for the patient population (e.g., PALS; ACLS; advanced trauma life support [ATLS]; medical board certification/board eligible in emergency medicine, critical care, pulmonary medicine, anesthesia). | | | | | |
| 23 | If a registered nurse, advanced practice nurse, or physician assistant is allowed to administer certain facility-defined moderate sedation agents, such administration occurs only within the scope of their professional practice <u>and</u> under the direct supervision of a physician, dentist, or podiatrist qualified by education, training, and credentialing to administer moderate sedation. | | | | | |
| 24 | Only a physician, dentist, podiatrist, or other credentialed professional (e.g., nurse anesthetist) who is trained in the use of drugs causing DEEP SEDATION , qualified to RESCUE patients from GENERAL ANESTHESIA or severe respiratory depression, and not simultaneously involved in a procedure, are permitted to administer medications that could lead to DEEP SEDATION of non-ventilated patients (e.g., propofol, ketamine, etomidate), <u>even if moderate sedation is intended</u> . (PALS or ACLS certification alone is not sufficient.) | | | | | |
| 25 | Practitioners who titrate moderate sedation agents to effect have received training about each drug's onset, peak, and duration; how to determine whether a previous dose has taken full effect before administering another dose; and to consider other drugs administered that might increase the risk of hypotension or sedation, to prevent overdoses caused by DOSE STACKING . | | | | | |
| Protocols and Guidelines | | | | | | |
| 26 | A standard protocol for moderate sedation of <u>adults</u> exists, which includes uniform monitoring requirements; <u>and</u> the protocol is employed regardless of the setting in which the sedation and procedure occur. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | |
| 27 | A standard protocol for moderate sedation of <u>neonates</u> and/or <u>pediatric</u> patients exists, which includes uniform monitoring requirements; <u>and</u> the protocol is employed regardless of the setting in which the sedation and procedure occur. Scoring guideline: Choose Not Applicable <u>only</u> if your facility never administers moderate sedation to neonates or pediatric patients. | | | | | |
| 28 | Protocols or guidelines have been established to assist practitioners with titrating drugs used for moderate sedation to effect; <u>and</u> the protocols or guidelines include the recommended incremental doses; intervals between doses; the onset, peak, and duration of the drugs; and any special considerations. | | | | | |

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|---|---|
| A | There has been no activity to implement this item. |
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
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| | | A | B | C | D | E |
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| Products Used | | | | | | |
| 29 | Only a 1 mg/mL strength of midazolam injection is provided to procedural areas to prevent dosing confusion and facilitate slow titration of the drug. Scoring guideline: Choose Not Applicable <u>only if</u> your facility never stocks midazolam injection in procedural areas. | | | | | NOT APPLICABLE |
| 30 | If the 100 mg/mL strength of ketamine is dispensed to and/or stocked in procedural areas (e.g., for intranasal or IM injection), an auxiliary label warns that the drug should not be administered IV without dilution. Scoring guideline: Choose Not Applicable <u>only if</u> your facility never stocks ketamine 100 mg/mL in procedural areas, or never dispenses the product to procedural areas. | | | | | NOT APPLICABLE |
| 31 | If a combination of ketamine and propofol is used for moderate sedation, the drugs are not mixed together in the same syringe or infusion bag; and the combination is never referred to as "ketofol" or another coined name. Scoring guideline: Choose Not Applicable <u>only if</u> your facility never uses a combination of ketamine and propofol for moderate sedation. | | | | | NOT APPLICABLE |
| Patient Monitoring | | | | | | |
| 32 | In addition to the practitioner performing the procedure, a second ACLS- and/or PALS-trained practitioner with knowledge of the emergency cart inventory and/or emergency response is responsible for monitoring the patient during the entire procedure without competing responsibilities, and for assisting in any supportive or resuscitation measures, if required. | | | | | |
| 33 | During moderate sedation, the adequacy of ventilation and other patient parameters are evaluated by continual observation of clinical signs, pulse rate, blood pressure, counted respiratory rate or minute ventilation, depth and quality of respirations, and pulse oximetry and/or capnography. | | | | | |
| 34 | After the procedure, patients who received moderate sedation are monitored for signs of respiratory depression at facility-defined frequencies (e.g., every 10-15 minutes) by evaluating the patient's level of sedation; vital signs (including rate, depth, and quality of respirations); and pulse oximetry and/or capnography results until the patient has approached a pre-sedation state and no longer requires post-procedure recovery monitoring per the facility's predefined criteria (see item # 13). | | | | | |
| Minimal Sedation in Children | | | | | | |
| Scoring guideline: Choose Not Applicable for these items <u>only if</u> your facility never prescribes, dispenses, or administers minimal sedation to children. | | | | | | |
| Protocols and Order Sets | | | | | | |
| 35 | A standard protocol exists and is followed for minimal sedation of neonates and/or pediatric patients by a NONANESTHESIOLOGIST SEDATION PRACTITIONER outside the operating room, which includes uniform, specialty-independent monitoring requirements. | | | | | NOT APPLICABLE |

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|---|---|
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| | | A | B | C | D | E |
|---------------------------|--|---|---|---|---|---|
| Order Verification | | | | | | |
| 36 | A pharmacist reviews and verifies all orders for minimal sedation of a child prior to administration. | | | | | |
| NOT APPLICABLE | | | | | | |
| Administration | | | | | | |
| 37 | Only trained healthcare workers (not parents or other care providers) administer oral sedatives (e.g., midazolam) to neonates and/or pediatric patients in preparation for a procedure, after the child has arrived at the facility to ensure proper supervision, cardiorespiratory/neurologic monitoring, and immediate access to resuscitation equipment and medications in the event of respiratory depression. | | | | | |
| NOT APPLICABLE | | | | | | |
| 38 | Pharmacy dispenses all prescribed doses of oral liquid medications for minimal sedation in unit-dose cups that contain the exact prescribed amount, or in patient-specific oral syringes that display the volume using the metric scale; and these doses include a bar-coded label listing the drug name, concentration, patient's dose, and expiration date. | | | | | |
| NOT APPLICABLE | | | | | | |
| 39 | Oral liquid medications used for minimal sedation are administered via a dosing cup or oral syringe marked "Oral Use Only" (never from a PARENTERAL syringe). | | | | | |
| NOT APPLICABLE | | | | | | |
| Monitoring | | | | | | |
| 40 | Prior to the procedure but after minimal sedation has been administered, neonates and/or pediatric patients are monitored in an area that is staffed with practitioners trained to monitor sedated children and stocked with appropriate emergency equipment and medications. | | | | | |
| NOT APPLICABLE | | | | | | |

Insulin, Subcutaneous and Intravenous

Scope: Unless otherwise stated, these items pertain to all concentrations of insulin prescribed, prepared, dispensed, and/or administered by the subcutaneous, IM (rare), and/or IV routes of administration using a vial and syringe, pen, continuous subcutaneous insulin infusion device (insulin pump), and/or infusion.

► Demographic Questions

- 1) If a patient admitted to the facility takes insulin at home in a higher concentration than 100 units/mL (U-100), how are these insulin doses typically provided during hospitalization, long-term care admission, or outpatient encounter?
(select all that apply)
 - Insulin doses of the same form and concentration are available and dispensed for the patient
 - The patient is converted to U-100 insulin doses
 - The patient is started on an insulin infusion
 - The patient is asked to supply his or her own insulin from home for administration in the facility
 - We never administer insulin in our facility
 - Other: (please specify) _____
- 2) Where is general (non-patient specific) unit stock of insulin pens and vials stored in patient care units/treatment areas?

Insulin pens? (select all that apply)

- L ADC in a matrix drawer containing multiple insulin types
- ADC in matrix drawers containing a single insulin type
- ADC in a single drug access drawer
- ADC refrigerator
- General medication refrigerator
- General stock at room temperature
- Non-patient specific insulin pens are not stocked in patient care units/treatment areas
- We don't stock insulin pens anywhere in our facility
- Other: (please specify) _____

Insulin vials? (select all that apply)

- L ADC in a matrix drawer containing multiple insulin types
- ADC in matrix drawers containing a single insulin type
- ADC in a single drug access drawer
- ADC refrigerator
- General medication refrigerator
- General stock at room temperature
- Non-patient specific insulin vials are not stocked in patient care units/treatment areas
- We don't stock insulin vials anywhere in our facility
- Other: (please specify) _____

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continued from page 48

3) How are bedside POINT-OF-CARE blood glucose values documented at your facility? (select all that apply)

- Manually documented on a paper form (e.g., diabetic flow sheet, MAR/eMAR, notes)
- Manually documented on a paper form (e.g., diabetic flow sheet, MAR/eMAR, notes), which is later entered into the patient's EHR
- Manually documented directly into the EHR
- Electronically imported into the EHR via a blood glucose monitor that is docked with a computer
- Electronically imported into the EHR from a blood glucose monitor via wireless technology
- Other: (please specify) _____

4) Does your facility employ or contract with a certified diabetes educator/coordinator?

- Yes

└ Coverage?

- 1 full-time equivalent (FTE)
- More than 1 FTE
- Less than 1 FTE

- No

5) Is there an endocrinologist or other physician diabetes specialist on staff and/or employed at your facility?

- Yes

└ Coverage?

- Routinely and automatically consulted for all patients with diabetes admitted to the facility
- Routinely and automatically consulted for patients with diabetes admitted to the facility with complex problems related to diabetes

└ Including? (select all that apply)

- Patients who use a form of **CONCENTRATED INSULIN** prior to or during admission
- Patients who use an insulin pump
- Pediatric patients
- Patients with clinical conditions that significantly impact insulin needs beyond the typical stress of hospitalization or illness (e.g., acute renal failure, transplants, open heart surgery, sepsis, or other critical illness)
- Patients with uncontrolled hyperglycemia or hypoglycemia
- Patients newly diagnosed with type 1 diabetes
- Other: (please specify) _____

- Voluntarily consulted as requested by admitting physicians

└ Frequency?

- 75% or more of all patients with diabetes
- 50% to 74% of all patients with diabetes
- 25% to 49% of all patients with diabetes
- Fewer than 25% of all patients with diabetes

- No

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► Self-Assessment Items

| | |
|---|---|
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| | | A | B | C | D | E |
|--|---|---|---|---|---|---|
| General Items | | | | | | |
| Protocols and Order Sets | | | | | | |
| 1 | Standard insulin protocols and/or order sets exist and are used to guide care when: (score each item individually) | | | | | |
| a | Converting from oral agents to insulin | | | | | |
| b | Managing insulin during planned and unplanned interruptions of oral and enteral nutrition | | | | | |
| c | Circumstances when a clinician other than the prescriber may adjust or hold an insulin dose | | | | | |
| d | Using CONCENTRATED INSULINS | | | | | |
| e | Managing pregnant and postpartum patients with pre-existing diabetes | | | | | |
| f | Managing patients receiving glucocorticoid therapy | | | | | |
| g | Treating hyperkalemia | | | | | |
| h | Treating calcium-channel blocker overdoses using high-dose insulin | | | | | |
| i | Treating clinically significant hyperglycemia and hyperosmolar hyperglycemic state | | | | | |
| j | Treating clinically significant hypoglycemia | | | | | |
| k | Monitoring patients via defined laboratory testing and bedside POINT-OF-CARE glucose monitoring, and communicating critical blood glucose values | | | | | |
| FAQ 1 | Managing patients when their symptoms are inconsistent with a current blood glucose value | | | | | |
| Prescribing | | | | | | |
| 2 | An IV insulin infusion or scheduled subcutaneous insulin with BASAL, NUTRITIONAL, and CORRECTION-AL INSULIN doses is used to manage blood glucose levels in patients with diabetes; and patient blood glucose levels are <u>not</u> managed solely using sliding scale insulin. | | | | | |
| Expression of Drug Names, Concentrations, and Doses | | | | | | |
| FAQ 3 | The insulin concentration (e.g., U-100, U-200, U-300) does not follow the name of the insulin on the MAR/eMAR or other medication lists, with the exception of regular insulin U-500 (HumuLIN R U-500). | | | | | |
| FAQ 4 | TALL MAN LETTERING with bolded text for the unique letter characters of look-alike insulin names (e.g., Huma LOG and Humu LIN ; Novo LOG and Novo LIN) is used when displaying the names in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, and pharmacy labels and/or AUTOMATED SYSTEM LABELS . | | | | | |

continued on page 51 ►

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| | | A | B | C | D | E |
|------------------------|---|----------------|---|---|---|---|
| 5 | Generic names for insulin products are included in computer order entry systems, order sets, protocols, MARs/eMARs, ADC screens, infusion pump screens, pharmacy labels and/or AUTOMATED SYSTEM LABELS , and any other format used to communicate the drug in the facility. | | | | | |
| 6 | Combination insulins are expressed using the complete name and dose expression on the same line (e.g., NovoLOG Mix 70/30, not just NovoLOG Mix) in computer order entry systems, order sets, protocols, MARs/eMARs, ADC screens, infusion pump screens, pharmacy labels and/or AUTOMATED SYSTEM LABELS , and any other format used to communicate the drug in the facility. | | | | | |
| Dispensing | | | | | | |
| 7 | Pharmacists confirm that the patient has an appropriate indication before verifying initial insulin orders. | | | | | |
| 8 | The pharmacy prepares and dispenses patient-specific, prefilled syringes of BASAL INSULIN doses (if stability permits), with patient-specific, bar-coded labels, for patients who are not using an insulin pen device or pump to deliver BASAL INSULIN doses. Scoring guideline: Choose Not Applicable <u>only if your facility does not provide care to inpatients or if your facility only uses pens and/or pumps to deliver BASAL INSULIN doses.</u> | | | | | |
| | | NOT APPLICABLE | | | | |
| Administration | | | | | | |
| 9 | If bedside BARCODE SCANNING TECHNOLOGY is utilized <u>and</u> insulin vials are dispensed (unit stock or patient-specific) and stored in patient care areas, a process has been developed to enable the application of a patient-specific and drug-specific bar-coded label on clinician-prepared syringes to facilitate the scanning process. Scoring guideline: Choose Not Applicable <u>only if your facility does not utilize BARCODE SCANNING TECHNOLOGY and/or insulin vials.</u> | | | | | |
| | | NOT APPLICABLE | | | | |
| 10 | Prior to the administration of insulin, practitioners perform a patient assessment of the following: (score each item individually) | | | | | |
| a | An appropriate diagnosis or indication for insulin use | | | | | |
| b | Most current blood glucose value either from the laboratory or POINT-OF-CARE testing | | | | | |
| c | Symptoms of hypoglycemia or hyperglycemia | | | | | |
| d | Nutritional status (e.g., NPO, receiving enteral nutrition or PN, last oral intake) | | | | | |
| e | Changes in the patient's condition (e.g., infection) | | | | | |
| 11 | Insulin doses, including NUTRITIONAL and BASAL doses, are <u>only</u> held or modified with a prescriber's order or via explicit directions in an existing protocol or order set. | | | | | |
| Insulin Storage | | | | | | |
| 12 | U-100 insulin vials are not dispensed or stored as unit stock in neonatal intensive care units (NICUs). Scoring guideline: Choose Not Applicable <u>only if your facility does not have a NICU.</u> | | | | | |
| | | NOT APPLICABLE | | | | |

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| | |
|---|---|
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| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
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| | | A | B | C | D | E |
|---|--|---|---|---|---|----------------|
| 13 | Vials or syringes of insulin are removed from under the pharmacy laminar airflow workbench(es) (hood[s]) immediately after use and never kept under the hood for future use. | | | | | |
| Monitoring | | | | | | |
| 14 | All patient-specific, diabetes care-related information, including blood glucose values and significant changes in carbohydrate intake (e.g., NPO status, changes in enteral nutrition or PN), is communicated in one designated place in the patient's health record (e.g., an electronic dashboard) and accessible to all clinicians. | | | | | |
| 15 | There is a coordinated process to promote timely blood glucose checks and administration of NUTRITIONAL INSULIN doses in conjunction with meal delivery. Scoring guideline: Choose Not Applicable <i>only if your facility never provides full meals to patients.</i> | | | | | NOT APPLICABLE |
| 16 | In inpatient settings, a standardized process has been established to communicate to an authorized prescriber on the patient's care team any significant changes in a patient's carbohydrate intake (e.g., changes in enteral nutrition or PN, NPO status), which may require an adjustment of the insulin. Scoring guideline: Choose Not Applicable <i>only if your facility does not provide care to inpatients.</i> | | | | | NOT APPLICABLE |
| 17 | The prescriber identifies the patient's pre-meal and random target glucose ranges in the patient's health record. | | | | | |
| Management of Hypoglycemia and Hyperglycemia | | | | | | |
| 18 | Organizations have defined clinically important hypoglycemia in terms of symptoms and blood glucose concentrations at which physicians should be notified and when emergency treatment with a RESCUE agent should be administered by a qualified practitioner per protocol. | | | | | |
| 19 | An endocrinologist or practitioner trained in insulin management (e.g., physician, nurse practitioner, physician assistant, or pharmacist) as determined by the organization is consulted for patients with uncontrolled hyperglycemia or hypoglycemia. | | | | | |
| 20 | During an insulin-dependent patient's hospitalization or treatment, a single blood glucose value below a facility-established minimum prompts the insulin prescriber to conduct a patient, nutrition, and drug therapy reassessment to determine if modification of diet and/or glucose-lowering treatment is necessary. | | | | | |
| 21 | During an insulin-dependent patient's hospitalization or treatment, a pattern of blood glucose values below a facility-established minimum (e.g., two episodes that require intervention) prompts a team of prescribers, nurses, pharmacists, and dieticians to conduct a patient, nutrition, and drug therapy reassessment to determine if modification of diet and/or glucose-lowering treatment is necessary. | | | | | |
| 22 | For all patients on insulin, a risk assessment is conducted upon hospital or facility admission and periodically thereafter to identify those who are at high risk for developing hypoglycemia (e.g., low body weight, BASAL INSULIN doses greater than 0.25 units/kg, BASAL -only dosing, concomitant oral diabetic therapy) or hyperglycemia (e.g., infection, pancreatitis, trauma, alcohol abuse); and these patients are specifically targeted for preventive interventions. | | | | | |

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| | | A | B | C | D | E |
|--|---|---|---|---|---|---|
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 23 | For patients being discharged on insulin, criteria have been established to trigger an <u>automatic</u> consultation with a certified diabetes educator or other diabetes management specialist for patient education. | | | | | |
| 24 Prior to hospital discharge or leaving a treatment facility, patients on insulin therapy are assessed for their understanding of the following: (score each item individually) | | | | | | |
| a | Type of insulin they will use and their dose(s) in units | | | | | |
| b | Proper dose measurement and self-administration technique assessed by patient demonstration using the same administration device that will be used at home (e.g., vial and syringe, pen, pump) | | | | | |
| c | Proper use and disposal of needles, syringes, lancets, and pumps | | | | | |
| d | Knowledge of their blood glucose targets and when glucose testing should be accomplished | | | | | |
| e | Ability to use a blood glucose meter to test blood glucose, keep a record of the values, and self-monitor | | | | | |
| f | The signs and symptoms of hypoglycemia and hyperglycemia, and how to prevent these effects or respond if these symptoms occur | | | | | |
| g | Nutritional management of diabetes | | | | | |
| 25 | Prior to hospital discharge or leaving a treatment facility, patients receive verbal <u>and</u> up-to-date written instructions at an appropriate reading level and in their preferred language about each prescribed insulin, dose, frequency, route, timing with meals and glucose testing, and special precautions. | | | | | |
| 26 | Prior to hospital discharge or leaving a treatment facility, a process is in place to ensure that patients have or will obtain the medications or prescriptions, equipment, and supplies needed at home to manage their insulin therapy (e.g., insulin, syringes or pen needles, blood glucose meter and strips, lancets and lancing device, glucagon emergency kit). | | | | | |

Insulin Pens

Scoring guideline for this section: Choose Not Applicable for these items only if your facility never dispenses or administers insulin via pen devices.

| 27a | Insulin pens are dispensed from the pharmacy for individual patients as ordered with a patient-specific and drug-specific bar-coded label and <u>not</u> stored in patient care units as non-patient specific unit stock. | | | | |
|------------|--|--|--|--|----------------|
| OR | OR | | | | NOT APPLICABLE |
| 27b | Insulin pens are removed from a profiled ADC only after the pharmacy has verified a corresponding order; and a process has been developed to enable the application of a patient-specific and drug-specific bar-coded label on the pen body immediately upon removal. Additional scoring guideline: Do not select a score above B if pens are stocked in an unprofiled ADC or in another location outside an ADC, or if a patient-specific and drug-specific bar-coded label is not available for immediate application upon removal of the pen from unit stock. | | | | |
| | | | | | NOT APPLICABLE |

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| | | A | B | C | D | E |
|---------------------------------------|--|---|---|---|---|---|
| 28 | All pharmacy labels, AUTOMATED SYSTEM LABELS , and practitioner labels are applied on the body of the insulin pen (not on the removable cap) using a flag or tadpole method (a self-supporting tag label extending to the side of the pen and secured along a narrow strip of the pen barrel), without obscuring important information on the manufacturer's label or the dose counter/dose window. | | | | | |
| Administration | | | | | | |
| 29 | All insulin pens are labeled with a distinct patient-specific and drug-specific barcode(s) that is/are scanned before administration to verify the correct insulin type and correct patient. | | | | | |
| Staff Competency and Education | | | | | | |
| 30 | During initial orientation and annually thereafter, all nurses and other health professionals who may administer insulin are educated about the proper use of insulin pens for a single patient and the dangers of sharing pens with other patients, even after changing the needle. | | | | | |
| Learning Culture | | | | | | |
| 31 | The facility encourages immediate reporting of actual or potential instances when an insulin pen has been used or was almost used for more than one patient, or when an insulin pen cartridge has been used as a vial, with doses withdrawn from the cartridge with a syringe. | | | | | |
| CONCENTRATED INSULIN | | | | | | |
| Medication History | | | | | | |
| 32 | When obtaining a medication history upon admission or reviewing the patient's home medication list, CONCENTRATED INSULIN regimens are verified and include the actual dose in units and the type of syringe or pen device used by the patient (e.g., actual dose of U-500 insulin is the same when using a pen or U-500 insulin syringe; 0.4 mL on a tuberculin syringe = 200 units of U-500 insulin; the dose set with the dial of U-200 and U-300 insulin pens is the actual dose delivered). | | | | | |
| Dispensing | | | | | | |
| 33 | In inpatient settings, for U-500 insulin, the pharmacy dispenses either pens or prefilled syringes for individual patients as ordered with a patient-specific and drug-specific bar-coded label; and U-500 insulin vials and empty U-500 insulin syringes are not distributed to patient care areas or stored in patient-specific bins. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to inpatients, or if you never dispense or administer U-500 insulin. | | | | | |
| Administration | | | | | | |
| 34 | Either U-500 insulin pens or U-500 insulin syringes and vials are used to administer U-500 insulin to patients during hospitalization or treatment (never a U-100 insulin syringe or a tuberculin syringe). Scoring guideline: Choose Not Applicable <u>only</u> if you never administer U-500 insulin in your facility. | | | | | |

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| | | A | B | C | D | E |
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| Product Differentiation | | | | | | |
| 35 | CONCENTRATED INSULIN products are clearly identified in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, pharmacy labels and/or AUTOMATED SYSTEM LABELS , and any other format used to communicate the products in the facility. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 36 | Patients who are taking U-500 insulin at home receive verbal <u>and</u> up-to-date written instructions at an appropriate reading level and in their preferred language regarding the actual dose in units and the importance of using U-500 insulin syringes or a pen (not U-100 insulin syringes or tuberculin syringes) to measure and administer each dose. | | | | | |
| 37 | Patients who are taking a CONCENTRATED INSULIN via pen receive verbal <u>and</u> up-to-date written instructions at an appropriate reading level and in their preferred language regarding how to dial and administer the actual insulin dose (no dose conversion is necessary). | | | | | |
| IV Insulin | | | | | | |
| Scoring guideline for this section: Choose Not Applicable for these items only if you never prescribe, dispense, and/or administer IV insulin in your facility. | | | | | | |
| Drug Preparation and Dispensing | | | | | | |
| 38 | A single, standard concentration (e.g., 1 unit/mL) is used for continuous IV insulin infusions for adults. Additional scoring guideline: Choose Not Applicable <u>only</u> if you never administer continuous IV insulin infusions to adults in your facility. | | | | | |
| 39 | A single, standard concentration (e.g., 0.1 unit/mL) is used for continuous IV insulin infusions for at least 80% of neonates, and no more than one additional concentration is used for the remaining neonates. Additional scoring guideline: Choose Not Applicable <u>only</u> if you never administer continuous IV insulin infusions to neonates in your facility. | | | | | |
| FAQ 40 | Based on patient weight, no more than three standard concentrations (e.g., 0.2 units/mL, 0.5 units/mL, 1 unit/mL) are used for continuous IV insulin infusions in <u>pediatric</u> patients, with the highest concentration equal to the single standard concentration used in adult patients (e.g., 1 unit/mL); <u>and</u> the standard concentrations do NOT differ by a factor of 10 (e.g., 0.1 unit/mL and 1 unit/mL), which is prone to mix-ups. Additional scoring guideline: Choose Not Applicable <u>only</u> if you never administer continuous IV insulin infusions to pediatric patients in your facility. | | | | | |
| 41a | Pharmacy prepares all continuous IV insulin infusions for patients receiving care in the facility, including the emergency department, surgical suites (including infusions administered by anesthesia staff), and other procedural areas. | | | | | |
| OR 41b | OR If the pharmacy does not provide 24-hour services: A night cabinet is stocked with an appropriate container of base solution and a vial of regular insulin along with clear directions to prepare an infusion in the facility's standard concentration(s). | | | | | |

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| | | A | B | C | D | E |
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| Diluted Insulin | | | | | | |
| 42a | Syringes of diluted insulin for neonates are prepared <u>only</u> in the pharmacy and dispensed for individual patients with a patient-specific label that includes the total amount/total volume, the diluted concentration, and a warning to clearly distinguish them from U-100 insulin. Additional scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates. | | | | | |
| OR | | NOT APPLICABLE | | | | |
| 42b | Vials of diluted insulin for neonates are prepared <u>only</u> in the pharmacy, dispensed for individual patients, and include patient-specific labels with warnings to clearly distinguish them from U-100 insulin vials; and guidelines on how to measure an insulin dose using a standard syringe (not an insulin syringe) are available to practitioners. Additional scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates. | | | | | |
| Treatment of Hyperkalemia | | | | | | |
| 43a | Pharmacy prepares, clearly labels, and dispenses patient-specific doses of insulin in a minibag or syringe that allows IV administration when insulin is needed to treat hyperkalemia. | | | | | |
| OR | | NOT APPLICABLE | | | | |
| 43b | The pharmacy dispenses a hyperkalemia kit to patient care units containing a 3 mL vial of a short- or rapid-acting insulin; alcohol swabs; 50% dextrose injection; an insulin syringe that allows IV administration; directions for preparation, administration, and patient monitoring requirements; and a label for the syringe (to apply after preparation but before administration). | | | | | |
| Continuous Subcutaneous Insulin Infusion Devices (Insulin Pumps) | | | | | | |
| Scoring guideline for this section: Choose Not Applicable for the items in this section <u>only</u> if your facility is not a hospital. | | | | | | |
| Protocols and Guidelines | | | | | | |
| 44 | Organizational policies, protocols, and/or guidelines are in place to guide the care of patients with a continuous subcutaneous insulin infusion device (insulin pump) who are hospitalized, which include: (score each item individually) | | | | | |
| a | Criteria to determine which patients are appropriate to manage their own pumps upon hospital admission, and to determine ongoing competence for continual management of their own pumps during hospitalization | | | | | |
| b | Conditions that would necessitate removal of the insulin pump during hospitalization, even if the patient is deemed competent to manage his or her own pump (e.g., alarms, sensor alerts, or error alerts that cannot be cleared or are repetitive; pump malfunction; battery depletion; unexplained fluctuations in blood glucose levels; inconsistencies with patient symptoms and expected insulin delivery by the pump) | | | | | |
| c | A process to transition patients from the pump to an alternative means of insulin delivery during hospitalization if the pump is removed | | | | | |

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|-----------|---|----------------|---|---|---|---|
| 45 | If the pump is managed by the patient while in the hospital, the policies, protocols, or guidelines include: (score each item individually) | | | | | |
| a | The means for obtaining patient consent after reviewing the risks and patient responsibilities | | | | | |
| | | NOT APPLICABLE | | | | |
| b | A process for prescribing the insulin to be given via the patient's pump, which requires specification of the insulin infusion rates based on time of day, meal coverage doses, and CORRECTIONAL INSULIN doses | | | | | |
| | | NOT APPLICABLE | | | | |
| c | Criteria for when an endocrinologist, diabetes educator, or other diabetes management specialist with knowledge of the pump must be contacted for consultation and/or to provide orders | | | | | |
| | | NOT APPLICABLE | | | | |
| d | A mechanism to communicate and document patient-initiated pump setting changes, doses, glucose monitoring results, site changes, and rate changes | | | | | |
| | | NOT APPLICABLE | | | | |
| e | A requirement for the patient to access the pump history and review all pump insulin delivery, pump alarms, and glucose monitoring values with a nurse or other practitioner at least daily | | | | | |
| | | NOT APPLICABLE | | | | |
| f | A process to measure and track the patient's blood glucose level | | | | | |
| | | NOT APPLICABLE | | | | |
| g | Evaluation prior to surgical procedures to determine the appropriateness of continuing insulin delivery via the pump during the procedure | | | | | |
| | | NOT APPLICABLE | | | | |
| h | A procedure to avoid exposure of the pump to ionizing radiation or magnetic fields during imaging procedures | | | | | |
| | | NOT APPLICABLE | | | | |
| i | A requirement for pharmacy to dispense all insulin used to refill the insulin pump | | | | | |
| | | NOT APPLICABLE | | | | |
| j | A procedure to manage the pump when the patient is not able to do so (e.g., medical emergency, surgery) | | | | | |
| | | NOT APPLICABLE | | | | |

Lipid-Based Medications and Conventional Counterparts

Scope: Unless otherwise stated, these items pertain only to drugs available in both lipid-based and conventional formulations, including amphotericin B, bupivacaine, cytarabine, DOXOrubicin, irinotecan, and vinCRISTine.

► Self-Assessment Items

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| | | A | B | C | D | E |
|--------------------------|---|---|---|---|---|---|
| Products Used | | | | | | |
| 1 | Whenever possible, only the lipid-based or the conventional formulation of a drug (not both) is available on formulary or used (e.g., only the lipid-based formulation of amphotericin B is on formulary or used) to reduce the risk of confusion between these products. | | | | | |
| Storage | | | | | | |
| 2 | Drugs available in both lipid-based and conventional formulations are stocked only in the pharmacy and dispensed for specific patients as prescribed. Exception: Bupivacaine (including Exparel) may be part of anesthesia stock outside the pharmacy. | | | | | |
| 3 | Lipid-based and conventional formulations of the same drug are stored in different bins that are physically separated. | | | | | |
| 4 | Lipid-based formulations of different drugs are not stored together or next to each other. | | | | | |
| Product Labeling | | | | | | |
| 5 | Clearly visible cautionary labels are affixed to lipid-based product containers to differentiate them from conventional forms of drugs. | | | | | |
| Technology Alerts | | | | | | |
| 6 | The computer order entry system performs dose range checks when entering all lipid-based drugs or their conventional counterparts to warn practitioners if the wrong formulation or dose has been prescribed or selected. | | | | | |
| 7 | When a dosing deviation has been detected by a computer order entry system, the system requires a HARD STOP verification that the correct formulation of the drug has been selected. | | | | | |

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| | | A | B | C | D | E |
|---------------------------------------|--|---|---|---|---|---|
| Product Differentiation | | | | | | |
| 8 | Lipid-based drugs and their conventional counterparts are communicated using brand names (if available) and generic names, or just brand names if space is limited, to differentiate them in the following applications: (score each item individually) | | | | | |
| a | Protocols, guidelines, and order sets | | | | | |
| b | Drug fields in prescriber computer order entry systems | | | | | |
| c | Drug fields in pharmacy computer order entry systems | | | | | |
| d | Pharmacy labels and/or AUTOMATED SYSTEM LABELS | | | | | |
| e | Storage bin/shelf labels | | | | | |
| f | ADC screens | | | | | |
| g | MARs/eMARs | | | | | |
| h | Drug fields on SMART INFUSION PUMP screens | | | | | |
| Staff Competency and Education | | | | | | |
| 9 | Practitioners who may prescribe, dispense, or administer lipid-based drugs and/or conventional counterparts have been educated about the differences between these formulations and the risk of patient harm if these products are confused with each other. | | | | | |

Methotrexate for Non-Oncologic Use

Scope: Unless otherwise stated, these items pertain to methotrexate administered by any route (i.e., oral, IM, subcutaneous, or IV) and used **ONLY** to treat non-oncologic conditions, such as rheumatoid arthritis, psoriasis, certain connective tissue or muscle inflammatory diseases, Crohn's disease, and multiple sclerosis. Methotrexate used for an oncologic indication is **EXCLUDED**.

► Self-Assessment Items

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| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| Computer Decision Support and Warnings | | | | | | |
| FAQ 1 | Computer order entry systems have been programmed to default to a weekly rather than daily dosage regimen for subcutaneous, IM, and oral methotrexate. | | | | | |
| 2a | Computer order entry systems require a HARD STOP verification and mandatory entry or selection from a drop-down menu of an appropriate oncologic indication for subcutaneous, IM, and oral methotrexate in order to override the weekly dosage regimen and select a daily schedule for a defined number of doses or days. | | | | | |
| OR | | | | | | |
| 2b | For manual systems and computer order entry systems that do not allow a HARD STOP , pharmacists clarify daily orders for subcutaneous, IM, and oral methotrexate if the patient does not have a documented oncologic diagnosis, to ensure the frequency and duration is appropriate and safe for the patient. | | | | | |
| Folate Supplement | | | | | | |
| 3 | If folate has not been prescribed with methotrexate, pharmacists follow up with the prescriber to determine if initiation of this supplement is desired. | | | | | |
| 30-Day Supply | | | | | | |
| 4 | Prescriptions for non-oncologic use of methotrexate provided to patients upon discharge only include the number of tablets or other dosage forms needed for weekly dosing, not to exceed a 4-week (30-day) supply. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 5 | Patients who are discharged on methotrexate receive clear verbal and up-to-date written instructions at an appropriate reading level and in their preferred language that specify the weekly dosing schedule, emphasize the danger with taking extra doses, and warn patients to avoid taking extra doses for symptom control. | | | | | |
| 6 | Patients who are discharged on methotrexate are asked to repeat back the instructions to validate understanding of the weekly dosing schedule and toxicities of the medication if taken more frequently than prescribed. | | | | | |
| 7 | A healthcare professional verifies all printed medication lists and discharge instructions to ensure they indicate the correct dosage regimen for methotrexate prior to providing them to the patient. | | | | | |

Chemotherapy, Oral and Parenteral

Scope: Unless otherwise stated, these items pertain to cytotoxic, antineoplastic agents administered by any route (i.e., oral, IM, subcutaneous, IV, intrathecal, intraventricular, intraperitoneal, intra-arterial, intravesicular, intrapleural, implantable) and used to treat an oncologic diagnosis. Chemotherapy agents prescribed for a non-oncologic indication are **EXCLUDED** (although the same safety strategies described in these assessment items are fully applicable to all cytotoxic, antineoplastic agents regardless of the indication).

► Demographic Questions

- 1) Is your facility a National Cancer Institute (NCI)-designated or Commission on Cancer (CoC)-accredited cancer center?
 Yes
 No
- 2) What is the average number of chemotherapy doses administered per month at your facility?
 Less than 50 251 to 1,000
 50 to 100 1,001 to 3,000
 101 to 250 More than 3,000
- 3) Does your facility participate in CLINICAL TRIALS involving chemotherapy in which INVESTIGATIONAL DRUGS are used?
 Yes
 No
- 4) Who is permitted to prescribe chemotherapy for patients in your facility without final verification by another prescriber? (select all that apply)
 Board certified oncologists
 Board certified hematologists
 Oncology fellows
 Oncology residents
 Urologists (regional treatment of urinary tract cancers)
 Interventional radiologists (intra-arterial chemotherapy)
 Surgical oncologists
 Advanced practice oncology nurse(s)
 Oncology physician assistant(s)
 Other: (please specify) _____
- 5) Who prepares (i.e., compounds or mixes) chemotherapy for patients in your facility? (select all that apply)
 Pharmacists
 Pharmacy technicians
 Physicians
 Registered nurses
 Advanced practice nurses
 Outsourced through compounding pharmacy
 Other: (please specify) _____

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► **Self-Assessment Items**

| | | | | | |
|---|---|--|--|--|--|
| A | There has been no activity to implement this item. | | | | |
| B | This item has been formally discussed and considered, but it has not been implemented. | | | | |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. | | | | |
| D | This item is fully implemented for some patients, orders, drugs, or staff. | | | | |
| E | This item is fully implemented for all patients, orders, drugs, or staff. | | | | |

| | | A | B | C | D | E |
|--|---|---|---|---|---|---|
| General Items | | | | | | |
| Protocols, Guidelines, and Order Sets | | | | | | |
| 1 | Standard order sets have been established for at least 90% of all chemotherapy protocols that are used in the facility; and these standard order sets are used to prescribe the chemotherapy. | | | | | |
| 2 | The type of metric weight used for dosing chemotherapy (i.e., actual weight, ideal weight, or adjusted weight) is predefined in the order set or identified by the prescriber. | | | | | |
| 3 | A literature/compendia reference and patient-specific monitoring plan are provided when prescribing chemotherapy that is outside of generally established guidelines. | | | | | |
| Prescribing | | | | | | |
| 4 | All chemotherapy (e.g., initial CYCLE , subsequent CYCLES , changes/modifications) used to treat an oncologic diagnosis is ordered (or verified prior to initiating the order) by an attending-level prescriber who has been granted privileges to order the specific chemotherapy. | | | | | |
| 5 | Prescribers enter inpatient and outpatient chemotherapy (non-INVESTIGATIONAL DRUGS) and other treatment-related medication orders into a COMPUTERIZED PRESCRIBER ORDER ENTRY system that is directly INTERFACED with an EHR, including the pharmacy computer. Scoring guideline: Scoring should be based on all settings—inpatient, outpatient, or both—where chemotherapy (non-INVESTIGATIONAL DRUGS) is prescribed in your facility. | | | | | |
| 6 | Verbal/telephone orders are <u>never</u> accepted for chemotherapy <u>except</u> to hold or discontinue chemotherapy. | | | | | |
| Expression of Drug Names | | | | | | |
| 7 | If an acronym is used to identify the chemotherapy protocol, the acronym is defined in the order, and each medication is prescribed individually, with the dose and schedule designated for each. (For example: CMV for bladder cancer is defined as CIS platin 100 mg/m ² /day on Day 2, methotrexate 30 mg/m ² /day on Day 1 and Day 8, vinBLAS tine 4 mg/m ² /day on Day 1 and Day 8.) | | | | | |
| Expression of Drug Doses | | | | | | |
| 8 | Chemotherapy drugs for specific days are written explicitly (e.g., orders are written as “Day 1, 2, 3,” and never as “Days 1-3,” which can be misunderstood as days 1 and 3; orders are written as “Daily for 21 consecutive days and stop for 7 consecutive days,” and never as “Days 1-21, stop for Days 22-28”). | | | | | |
| 9 | Prescribers include the patient-specific dose and the mg/kg, mg/m ² , units/m ² , AUC , or other dosing method used to calculate the patient-specific dose for all chemotherapy orders (e.g., for a 1.67 m ² patient: 240 mg/m ² ; dose = 400 mg). | | | | | |

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|---|---|
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| | | A | B | C | D | E |
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| 10 | Prescribing the total chemotherapy dose for the entire CYCLE of treatment is prohibited (e.g., order for 400 mg/m ² on day 1, 2, 3, and 4, <u>not</u> 1,600 mg/m ² over 4 days; or fluorouracil 750 mg/m ² continuous infusion on day 1, 2, 3, 4, and 5, <u>not</u> 3,750 mg/m ² continuous infusion over 5 days). | | | | | |
| 11 | A standardized rounding procedure exists and is followed for PARENTERAL chemotherapy doses, unless otherwise required by an INVESTIGATIONAL DRUG protocol (e.g., calculated chemotherapy doses with a decimal point that are less than 10 mg are rounded to the nearest tenth, and doses greater than or equal to 10 mg are rounded to the closest whole number). | | | | | |
| Technology Alerts | | | | | | |
| 12 | The computer order entry system has been programmed to exclude inappropriate routes of administration from selection choices, or it alerts the practitioner if an inappropriate route has been selected and prevents (HARD STOP) the order from being processed (e.g., vinCRISTine can only be ordered IV). | | | | | |
| 13 | The computer order entry system alerts prescribers and pharmacists to excessive or subtherapeutic chemotherapy doses using protocol-specific dosing ranges. | | | | | |
| Dispensing | | | | | | |
| 14 | All chemotherapy is provided to patient care areas in a form that requires no further preparation or manipulation by the practitioner who will be administering it (e.g., the medication is in a syringe, or in an infusion bag with an attached administration set fully primed and a closed system transfer device). | | | | | |
| 15 | GRAVIMETRICS is used to confirm the expected weight and volume of a COMPOUNDED STERILE PREPARATION containing chemotherapy that is prepared in the facility. | | | | | |
| Drug Preparation and Administration | | | | | | |
| 16 | Chemotherapy is prepared, dispensed, and administered only within facility-defined timeframes when adequate resources and trained staff are available to review the order, assess the patient, prepare and check the chemotherapy, and administer the chemotherapy without feeling rushed. | | | | | |
| Products Used | | | | | | |
| 17 | Commercially available standard base solutions (e.g., sodium chloride 0.9%, dextrose 5% in water) are used for chemotherapy preparation and not compounded by the facility. | | | | | |
| Product Labeling | | | | | | |
| FAQ | For COMPOUNDED STERILE PREPARATIONS of chemotherapy solutions, the <u>total</u> volume to be infused is expressed on the pharmacy label, which includes the volume of all additives, the base solution, and any overfill volume that exists in the container (including the manufacturer's overfill in a container of premixed base solution). | | | | | |
| 18 | | | | | | |
| 19 | For chemotherapy infusions in which the dose remaining in the tubing must also be infused to deliver the entire dose, the product label specifies that the tubing should be flushed with a particular diluent and volume. | | | | | |
| 20 | The prescribed rate of infusion is included on the product label of chemotherapy infusions. | | | | | |

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| INDEPENDENT DOUBLE CHECKS | | | | | | |
| 21 | The patient's BSA (unless AUC is used for dosing) and creatinine clearance are calculated before each CYCLE of chemotherapy, using a standard method defined by the facility. | | | | | |
| 22 | Before preparing and dispensing chemotherapy, a pharmacist conducts and documents (e.g., initials or electronically) an INDEPENDENT DOUBLE CHECK of the prescriber's dosing method (e.g., mg/kg, mg/m ² , units/m ² , or AUC) and calculated dose per the protocol or treatment plan, using the patient's BSA , weight, or AUC . | | | | | |
| 23 | Before preparing the chemotherapy, a pharmacist conducts and documents (e.g., with initials or electronically) an INDEPENDENT DOUBLE CHECK of the anticipated diluent, drug, and proper dilution volume for chemotherapy preparations; and the base solution and all additives (including the actual drug amount and volume in syringes) are verified <u>prior</u> to mixing. (The SYRINGE PULLBACK METHOD is not used as part of the verification process.) | | | | | |
| 24 | Before dispensing and administering each dose of chemotherapy, the dispensing pharmacist and nurse administering the chemotherapy independently verify and document the current CYCLE and the day within the CYCLE of chemotherapy (e.g., CYCLE 3 of 6, day 3 of 5) against an established protocol or treatment plan for the patient. | | | | | |
| 25 | Before administering chemotherapy, a nurse conducts and documents (e.g., with initials or electronically) an INDEPENDENT DOUBLE CHECK of the prescriber's dosing method (e.g., mg/kg, mg/m ² , units/m ² , or AUC) and calculated dose per the protocol or treatment plan, using the patient's BSA , weight, or AUC . | | | | | |
| Emergency Preparedness | | | | | | |
| 26 | A protocol(s) exists and is used to direct the emergency treatment of hypersensitivity reactions, overdoses, or life-threatening toxicities related to certain types of chemotherapy (e.g., uridine triacetate for treating overdoses of fluorouracil or capecitabine). | | | | | |
| Patient Monitoring | | | | | | |
| 27 | Current general and treatment- and drug-specific diagnostic and laboratory test results (e.g., Multi Gated Acquisition [MUGA] scan for anthracyclines; renal function tests for CIS platin-based treatments) are evaluated prior to preparation and administration of the first dose of chemotherapy, and before subsequent doses when indicated. | | | | | |
| 28 | A system is in place (electronic or manual) to document, track, and communicate the lifetime cumulative dose of chemotherapy as appropriate (e.g., anthracyclines, bleomycin). | | | | | |
| Staff Competency and Education | | | | | | |
| 29 | Before granting or renewing privileges for prescribing chemotherapy, a thorough vetting of the prescriber's therapy-specific training, scope of practice, certification, experience, and familiarity and compliance with the facility's safety strategies is carried out by the medical staff to confirm and document initial and ongoing competency. | | | | | |

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|---|---|
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| 30 | The facility requires mandatory internal and/or external staff training/certification in chemotherapy and assesses staff competency prior to prescribing, preparing, dispensing, or administering chemotherapy, or monitoring patients who have received chemotherapy. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 31 | Before the first dose of chemotherapy and prior to each subsequent CYCLE, the prescriber or other qualified practitioner provides patients with the treatment protocol (schedule); the brand and generic name of the drug(s); the general purpose of the drug(s); the dose(s) and duration of therapy; immediate and delayed side effects; and when to seek medical help. | | | | | |
| Oral Chemotherapy | | | | | | |
| General | | | | | | |
| 32 | The processes used to ensure the safety of orders for cytotoxic oral (e.g., temozolomide, lomustine) and other NON-PARENTERAL dosage forms of chemotherapy are the same as those in place for PARENTERAL dosage forms. | | | | | |
| Expression of Drug Doses | | | | | | |
| 33 | In treatment plans, prescriptions or orders, and instructions for the patient, oral chemotherapy doses and schedules are described as the amount of medication to be taken <u>per dose</u> , not as a total daily dose that is to be taken in divided doses. | | | | | |
| 34 | Unless otherwise required by an INVESTIGATIONAL DRUG protocol, a standardized procedure exists and is followed throughout the facility for rounding oral chemotherapy doses to the nearest capsule or tablet strength, or otherwise providing the medication in a form that can be taken by the patient in the proper dose. | | | | | |
| Quantity Dispensed | | | | | | |
| 35 | For intermittent treatment with oral chemotherapy, the quantity of drugs prescribed and dispensed for ambulatory patients (e.g., number of tablets/capsules) is the exact quantity required for a single CYCLE of treatment (e.g., capecitabine is available in 500 mg tablets; one CYCLE of treatment is ordered for capecitabine 1,250 mg/m ² [BSA = 1.6 m ²] twice a day for 2 weeks = 2,000 mg twice a day for 2 weeks = 112 tablets). Scoring guideline: If your facility does not dispense oral chemotherapy for patients to self-administer at home, score this item as it relates to prescribing chemotherapy for ambulatory patients <u>only</u> . If your facility dispenses oral chemotherapy for ambulatory patients, score this item as it relates to <u>both</u> prescribing and dispensing the chemotherapy. Choose Not Applicable <u>only</u> if your facility does not prescribe or dispense oral chemotherapy for patients to self-administer at home. | | | | | |
| | | NOT APPLICABLE | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 36 | When providing patients with a prescription for oral chemotherapy, the prescriber or another qualified practitioner reviews the brand and generic name of the drug; the general purpose; amount of each single dose; the duration of therapy; what to do if a dose is missed; safe handling, storage, and disposal of the drug; immediate and delayed side effects; and when and how to seek medical help. | | | | | |

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| | | A | B | C | D | E |
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| Vinca Alkaloids (vinBLAStine, vinCRIStine, vindesine, vinorelbine) and bortezomib | | | | | | |
| Dispensing | | | | | | |
| 37 | VinCRIStine is dispensed in a minibag of a compatible solution (e.g., 25 mL for pediatric patients, 50 mL for adults); and vinCRIStine doses are <u>never</u> dispensed and/or administered in a syringe. | | | | | |
| 38 | Vinca alkaloids and bortezomib are dispensed with a prominent warning label that reads: FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES. | | | | | |
| Administration | | | | | | |
| 39 | The presence of vinca alkaloids and bortezomib is prohibited in areas where intrathecal medications are administered. Scoring guideline: Choose Not Applicable <u>only</u> if you never administer intrathecal medications in your facility. | | | | | |
| 40 | Confirmation that the administration of any prescribed intrathecal medications has been completed is required before dispensing a vinca alkaloid or bortezomib. Scoring guideline: Choose Not Applicable <u>only</u> if you never administer intrathecal medications in your facility. | | | | | |
| INVESTIGATIONAL Chemotherapy | | | | | | |
| Scoring guideline for this section: Choose Not Applicable for these items <u>only</u> if your facility never prescribes, dispenses, or administers INVESTIGATIONAL chemotherapy. | | | | | | |
| Prescribing | | | | | | |
| 41 | Prescribers enter inpatient and outpatient INVESTIGATIONAL chemotherapy and other treatment-related medication orders into a COMPUTERIZED PRESCRIBER ORDER ENTRY system that is directly INTERFACED with an EHR, including the pharmacy computer. Additional scoring guideline: Scoring should be based on all settings—inpatient, outpatient, or both—where INVESTIGATIONAL chemotherapy is prescribed in your facility. | | | | | |
| 42 | Practitioners involved in prescribing, preparing, dispensing, or administering INVESTIGATIONAL chemotherapy drugs have real-time access to current study protocols, investigator's brochures, safety data sheets, and protocol summary sheets. | | | | | |
| 43 | Checklists or study-specific reference sheets applicable to required tasks have been created for pharmacy and nursing staff to ensure consistent processes. | | | | | |
| Protocols, Checklists, and Reference Sheets | | | | | | |
| 44 | INVESTIGATIONAL chemotherapy drugs are stored in a designated, secure area in the pharmacy, and separated by different strengths and by protocol name, number, or other identifier (e.g., Protocol A, Placebo A; Protocol B, Placebo B; Drug A or B (blinded); Drug A + Drug B; Drug A x mg, Drug A 2x mg) in labeled bins or shelves. | | | | | |
| Storage | | | | | | |

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| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| Product Labeling | | | | | | |
| 45 | A pharmacy-prepared label is affixed to individual INVESTIGATIONAL chemotherapy drugs or a bag that holds a supply of vials/containers of the same drug/strength/concentration to provide any information that is poorly visible or missing on the product label (e.g., strength, concentration, lot numbers). | | | | | |
| 46 | A pharmacy-prepared label is affixed to INVESTIGATIONAL chemotherapy drugs dispensed for a specific patient to provide dosing and other important information that is poorly visible or missing on the product label (e.g., strength, concentration). | | | | | |
| Staff Competency and Education | | | | | | |
| 47 | Pharmacists, pharmacy technicians, and nurses who handle, prepare, dispense, administer, or monitor the storage conditions of INVESTIGATIONAL DRUGS have received standardized training on relevant facility policies and procedures; <u>and</u> competency has been verified prior to participation in these processes. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 48 | When dispensing INVESTIGATIONAL chemotherapy drugs to patients, contact information, including both a daytime telephone number and an emergency number for any questions or issues that arise, is provided in writing. Additional scoring guideline: Choose Not Applicable <u>only if your facility does not dispense oral INVESTIGATIONAL chemotherapy to patients to self-administer at home.</u> | | | | | |

Anticoagulants

Scope: Unless otherwise stated, these items pertain only to warfarin, direct oral anticoagulants (e.g., dabigatran, apixaban, rivaroxaban, edoxaban), unfractionated heparin, and low molecular weight heparin.

► Demographic Question

1) Does your organization provide an anticoagulation management service or clinic to assist with dosing, monitoring, and patient education?

Yes

└ **Inpatient?**

- └ **Select the type of healthcare providers who staff the service or clinic** (select one or more that apply)
- Physician
 - Pharmacist
 - Nurse
 - Physician assistant
 - Dietician
 - Laboratory technician
 - Other: (please specify) _____

└ **Outpatient?**

- └ **Select the type of healthcare providers who staff the service or clinic** (select one or more that apply)
- Physician
 - Pharmacist
 - Nurse
 - Physician assistant
 - Dietician
 - Laboratory technician
 - Other: (please specify) _____

No

► Self-Assessment Items

| | |
|---|---|
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| | A | B | C | D | E |
|---------------------------|--|---|---|---|---|
| General Items | | | | | |
| Patient Monitoring | | | | | |
| 1 | A baseline hemoglobin, hematocrit, platelet count, aPTT, and INR are obtained within 48 hours prior to initiating anticoagulation therapy (inpatient or outpatient). | | | | |

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| | | A | B | C | D | E |
|----------|---|---|---|---|---|---|
| 2 | All patient-specific, anticoagulation therapy-related information, including laboratory/ POINT-OF-CARE testing results and doses administered, is communicated in one designated place in the patient's health record (e.g., an electronic dashboard) <u>and</u> accessible to all staff with patient care responsibilities. | | | | | |
| 3 | The most recent laboratory value, with the date and time of testing, is automatically displayed on computer order entry system screens when placing and verifying an order for an anticoagulant that typically requires dose adjustments based on laboratory results. | | | | | |
| 4 | From the order entry screen, when placing or verifying an order for an anticoagulant, healthcare providers can quickly pull up a view of historical laboratory values to determine trends over time. | | | | | |

Protocols, Guidelines, and Order Sets

| | | | | | | |
|--------------|--|--|--|--|--|--|
| 5 | Disease-specific protocols for warfarin, direct oral anticoagulants, unfractionated heparin, and low molecular weight heparin exist, are available electronically, and are used when anticoagulants are prescribed, dispensed, and administered; <u>and</u> the protocols are clearly titled to ensure proper use. | | | | | |
| FAQ 6 | Disease-specific order sets for warfarin, direct oral anticoagulants, unfractionated heparin, and low molecular weight heparin exist and are used when anticoagulants are prescribed; <u>and</u> the order sets include all required patient monitoring. | | | | | |
| 7 | Protocols and order sets identify the specific drugs, interventions, and treatments (e.g., neuraxial procedures, certain vascular access procedures) that should be avoided in patients receiving anticoagulants. | | | | | |
| 8 | Protocols or guidelines exist to facilitate the transition between different anticoagulants. | | | | | |

Dosing

| | | | | | | |
|-----------|---|--|--|--|--|--|
| 9 | The indication and therapeutic goal for anticoagulation is documented in at least one consistent and conspicuous location (e.g., order set, MAR/eMAR) and used to manage the patient's therapy. | | | | | |
| 10 | As specified by medical staff-approved protocols, pharmacists and/or nurses automatically modify the dose of anticoagulants when laboratory values are below or above the target range; <u>and/or</u> pharmacists and/or nurses directly contact the prescriber within a facility-defined timeframe to report these laboratory values and discuss potential dose modifications. | | | | | |
| 11 | All dosing changes, including those directed by medical staff-approved protocols, are documented in the patient's health record so practitioners can determine the patient's current dose at all times and verify each dosing change. | | | | | |
| 12 | A facility-approved protocol permits and guides the rounding of doses for certain anticoagulants (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). | | | | | |

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| | | A | B | C | D | E |
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| Holding or Discontinuing Anticoagulants | | | | | | |
| FAQ 13 | A standard, reliable process is in place for screening patients for recent anticoagulant use before invasive procedures; and if therapy must be discontinued, protocols or guidelines define when anti-coagulants should be stopped and restarted, and when alternative agents to bridge the patient should be considered. | | | | | |
| 14 | The patient's active orders, MAR/eMAR, and/or pertinent laboratory values are checked immediately prior to surgery to verify that any anticoagulants were stopped or administered as prescribed and that the patient has reached the desired level of anticoagulation. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide surgical services. | | | | | NOT APPLICABLE |
| 15 | Orders for anticoagulants that are governed by an AUTOMATIC STOP ORDER policy are not discontinued without the specific approval of the prescriber. Scoring guideline: Choose Not Applicable <u>only if</u> anticoagulants are not governed by an AUTOMATIC STOP ORDER policy in your facility. | | | | | NOT APPLICABLE |
| Duplicate or Repetitive Doses | | | | | | |
| 16 | When orders for antithrombotics are entered, the computer order entry system alerts practitioners if the patient has received an antithrombotic (including anticoagulants), even a one-time dose, within the prior 24 hours in any location in the organization (e.g., emergency department, cardiac catheterization laboratory, interventional radiology), to ensure that adequate time has elapsed between doses of the same or different antithrombotics. | | | | | |
| Reversal Agents | | | | | | |
| 17 | Protocols and order sets exist and are used to direct the reversal of anticoagulation, taking into consideration the absence or presence of clinically significant bleeding, and other factors that influence the necessity and urgency of reversal. | | | | | |
| 18 | Appropriate reversal agents or antidotes for anticoagulants (e.g., protamine, vitamin K ₁ , idarucizumab, prothrombin complex concentrates) are readily accessible and accompanied by a clear indication for when they should be used and directions for administration near the point of use. | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 19 | Patients taking anticoagulants receive verbal and up-to-date written information at an appropriate reading level and in their preferred language about the drug; monitoring and follow-up; potential adverse drug reactions; signs of bleeding/thrombosis; situations that require contacting the prescriber or visiting an emergency department; examples of over-the-counter medications, nutritional supplements, and herbal medications to avoid; and how to operate any POINT-OF-CARE testing devices, if applicable. | | | | | |
| 20 | Patients previously taking an anticoagulant at home and subsequently prescribed a different anticoagulant are specifically told which anticoagulants they should continue to take or discontinue. | | | | | |
| 21 | When patients taking an anticoagulant are discharged or leaving an outpatient facility, a practitioner verifies that the patient has a scheduled appointment for clinician reassessment of anticoagulation and laboratory testing if required. | | | | | |

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A B C D E

Direct Oral Anticoagulants (e.g., dabigatran, apixaban, rivaroxaban, edoxaban)

Patient Monitoring

- 22** A serum creatinine and the patient's measured metric weight are obtained, and an estimated creatinine clearance is calculated, within 48 hours prior to initiating therapy with a direct oral anticoagulant (in addition to laboratory tests outlined in assessment item # 1).

Expression of Drug Names

- 23** The abbreviation NoAC, NOAC, or No-AC (intended to mean novel or new oral anticoagulant, or non-vitamin K₁ oral anticoagulant) is not used when referring to direct oral anticoagulants to avoid misunderstanding as "No anticoagulant."

Staff Competency and Education

- 24** 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.

Patient Education (Includes Caregiver Education When Appropriate)

- 25** Patients taking rivaroxaban or apixaban for the treatment of deep vein thrombosis or pulmonary embolism are instructed that the dose will be reduced after 21 days or 7 days respectively.

- 26** Patients taking dabigatran are educated about the following: (score each item individually)

- a** Proper storage and handling of their medication (e.g., keep in its original container or blister packs; remove only one capsule at the time of use and immediately close the bottle tightly; once the bottle is opened, the product is only stable for 4 months)

- b** Take the medication with a full glass of water and do not break, crush, chew, or empty the contents of the capsules

Unfractionated and Low Molecular Weight Heparin

Patient Monitoring

- 27** After initiating and/or changing the dose of an unfractionated heparin infusion, 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 at least every 24 hours thereafter once it is stable.

- 28** A serum creatinine and the patient's measured metric weight are obtained, and an estimated creatinine clearance is calculated, within 48 hours prior to initiating therapy with low molecular weight heparin (in addition to laboratory tests outlined in assessment item # 1).

Protocol and Order Set

- 29** When IV unfractionated heparin is prescribed, a standardized weight-based protocol and order set are used to prescribe and direct dosing and dose adjustments based on aPTT or anti-factor Xa results.

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| | | A | B | C | D | E |
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| Products and Storage | | | | | | |
| 30 | The variety of different unfractionated heparin vial concentrations and sizes is limited to only those needed in the facility. | | | | | |
| 31 | Only commercially prepared, premixed IV solutions of unfractionated heparin are used in the facility unless unavailable. | | | | | |
| 32 | Therapeutic infusions of unfractionated heparin are standardized to a single concentration for adults and pediatric patients (for neonates, see next item). Scoring guideline: If your facility provides care to only pediatric patients or only adults, score this item as it relates to the patient population your facility treats. | | | | | |
| 33 | Infusions that contain unfractionated heparin are standardized to no more than two concentrations for neonates based on weight (e.g., less than 1 kg and 1 kg and greater). Exception: Infusions used during extracorporeal membrane oxygenation. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates with IV or arterial infusions. | | | | | NOT APPLICABLE |
| 34 | For adults, commercially prepared, unit-dose syringes of heparin flush or lock solutions, or single-use vials of heparin (100 units/mL, volume not greater than 5 mL) are stocked in clinical areas wherever they are needed (when saline flushes will not suffice). Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | NOT APPLICABLE |
| 35 | For neonates, pharmacy prepares and dispenses a single concentration of diluted heparin flush solution (when saline flushes will not suffice) in unit-dose syringes or patient-specific vials, which are clearly labeled as a diluted heparin flush preparation. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates with IV or arterial infusions. | | | | | NOT APPLICABLE |
| Heparin-Induced Thrombocytopenia (HIT) | | | | | | |
| 36 | Prior to ordering unfractionated heparin or low molecular weight heparin, initiating the use of unfractionated heparin for catheter flushes, or using heparin-coated catheters or instruments, a history of heparin-induced thrombocytopenia (HIT) and/or allergy to heparin is determined by reviewing the medical record and by asking the patient; and a positive history is documented in a manner that would generate an electronic alert if any form of heparin is prescribed. | | | | | |
| 37 | If HIT is suspected or diagnosed during current therapy, there is a mechanism in place to ensure the following: (score each item individually) | | | | | |
| a | All sources of unfractionated heparin and low molecular weight heparin (including use for arterial lines or catheter flushes) are discontinued | | | | | |
| b | 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 use for arterial lines or catheter flushes, heparin-coated catheters or instruments) | | | | | |

ISMP Medication Safety Self Assessment®
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|---|---|
| A | There has been no activity to implement this item. |
| B | This item has been formally discussed and considered, but it has not been implemented. |
| C | This item has been partially implemented for some or all patients, orders, drugs, or staff. |
| D | This item is fully implemented for some patients, orders, drugs, or staff. |
| E | This item is fully implemented for all patients, orders, drugs, or staff. |

| | | A | B | C | D | E |
|--|--|----------------|---|---|---|---|
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 38 | Patients who will be administering subcutaneous unfractionated or low molecular weight heparin at home are instructed about the methods of dose measurement and drug administration, including proper disposal of syringes and/or needles; and patients demonstrate proficiency with these techniques prior to discharge or leaving the facility. | | | | | |
| Warfarin | | | | | | |
| Patient Monitoring | | | | | | |
| 39 | An INR is obtained prior to initiating warfarin therapy and upon admission or presentation of patients who have been receiving warfarin previously, unless an INR was obtained within the prior 48 hours and the result is available. | | | | | |
| 40 | A reliable system is in place to manage possible interactions in patients receiving warfarin and enteral feedings (e.g., holding continuous or intermittent feedings for at least 1 hour before and after warfarin doses, specified monitoring of anticoagulation effect after starting and discontinuing enteral feedings). | | | | | |
| Prescribing | | | | | | |
| 41 | For hospitalized patients, new orders for warfarin doses are required every day (or per the prescribed frequency of administration). Scoring guideline: Choose Not Applicable <u>only</u> if your facility is not a hospital. | | | | | |
| | | NOT APPLICABLE | | | | |
| Administration | | | | | | |
| 42 | Warfarin administration for inpatients is scheduled for the same time each day, after INR results are available (e.g., afternoon, early evening). Scoring guideline: Choose Not Applicable <u>only</u> if your facility treats outpatients exclusively. | | | | | |
| | | NOT APPLICABLE | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 43 | Patients taking warfarin are educated about the following: (score each item individually) | | | | | |
| a | Proper dietary measures and their effect on overall therapy goals (e.g., foods high in vitamin K ₁ should be eaten consistently) | | | | | |
| b | How to manage dose changes safely when their existing tablet strength differs from a newly prescribed dose | | | | | |
| c | That Coumadin, Jantoven, and warfarin contain the same active ingredient, and to avoid taking them together if the drug is prescribed using various brand and generic names | | | | | |

Neuraxial Opioids and/or Local Anesthetics

Scope: Unless otherwise stated, these items pertain to single drug and combinations of all opioids and/or local anesthetics administered to adults, neonates, and pediatric patients by the neuraxial route of administration. This includes continuous infusions of epidural analgesia/anesthesia with opioids and/or local anesthetics (including epidural PCA); single injections of epidural or intrathecal opioids and/or local anesthetics; and combination intrathecal injection and epidural continuous infusion. Examples of neuraxial opioids include: morphine, HYDROmorphine, fentaNYL, and SUFentanil. Examples of neuraxial local anesthetics include: bupivacaine, ropivacaine, lidocaine, and chloroprocaine.

► Self-Assessment Items

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|---|---|
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| Protocols, Guidelines, and/or Order sets | | | | | | |
| 1 | Standard protocols, guidelines, and/or order sets exist and are followed for the management of patients who receive neuraxial opioids and/or local anesthetics, which include: (score each item individually) | | | | | |
| a | Detection and management of inadequate analgesia | | | | | |
| b | The type and frequency of monitoring required during administration | | | | | |
| c | Identification and treatment of complications (e.g., accidental catheter disconnection, opioid/local anesthetic toxicity) | | | | | |
| d | Instructions for changing solution bags or syringes and removing catheters | | | | | |
| e | When to discontinue and restart anticoagulants and antiplatelet medications when inserting or removing neuraxial catheters (to prevent spinal hematoma) | | | | | |
| f | A warning that the patient should not receive other pain medications, central nervous system (CNS) depressants, or epidural drugs without the consent of an anesthesia practitioner | | | | | |
| 2 | When used outside of the operating room and post-anesthesia care unit, neuraxial opioids and/or local anesthetics are prescribed via a standard order set(s). | | | | | |
| Anesthesia Oversight | | | | | | |
| 3 | The anesthesia department is involved in developing and approving all protocols, guidelines, and/or order sets associated with neuraxial opioids and/or local anesthetics. | | | | | |
| 4 | Only anesthesia- or pain management-trained practitioners with demonstrated competency are permitted to prescribe, start, adjust, or administer infusions, injections, or bolus doses of neuraxial opioids and/or local anesthetics. | | | | | |

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| | | A | B | C | D | E |
|---------------------------|--|---|---|---|---|---|
| Products Used | | | | | | |
| 5 | The facility has established standard mixtures, concentrations, and safe MAXIMUM DOSES for neuraxial opioids and/or local anesthetics, which are used for 90% of <u>adult</u> patients. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | |
| 6 | The facility has established standard mixtures, concentrations, and safe MAXIMUM DOSES for neuraxial opioids and/or local anesthetics, which are used for 90% of <u>neonatal</u> and <u>pediatric</u> patients. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates or pediatric patients. | | | | | |
| 7 | The anesthesia department, with support from the pharmacy and/or PHARMACY AND THERAPEUTICS COMMITTEE , has conducted a literature search and evaluated the potential for using a neuraxial local anesthetic that is less cardiotoxic than bupivacaine (e.g., ropivacaine) for certain patient populations. | | | | | |
| 8 | Due to the long duration of action, neuraxial morphine or HYDRO mophone is not administered to outpatient surgical patients who plan to be discharged within 24 hours post-procedure. | | | | | |
| Patient Assessment | | | | | | |
| 9 | The practitioner planning the administration of neuraxial opioids and/or local anesthetics conducts and documents a pre-procedure assessment of the patient that includes, at a minimum: (score each item individually) | | | | | |
| a | Vital signs | | | | | |
| b | Medication history (e.g., pre-procedure opioids [including opioid patches], anticoagulants), drug allergies, and previous adverse opioid and/or local anesthetic reactions | | | | | |
| c | Airway assessment (e.g., anatomical variants, potential difficulties with intubation or ventilation, airway classification) | | | | | |
| d | General health assessment to uncover problems that could impact ventilation (e.g., sleep-disordered breathing) and co-existing conditions that may increase the risk of complications (e.g., obesity, impaired coagulation, infection, cardiac instability, compromised immunity) | | | | | |
| e | Examination of the patient's back or other site of injection | | | | | |
| Dispensing | | | | | | |
| 10 | Pharmacy (not anesthesia services) purchases and dispenses all opioids and/or local anesthetics for neuraxial administration. | | | | | |
| 11 | Neuraxial infusions and injections of opioids and/or local anesthetics not commercially available are prepared in the pharmacy and dispensed in the most ready-to-administer form (e.g., labeled syringe, small volume bag). | | | | | |

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| 12 | Neuraxial opioids (with or without local anesthetics) are <u>not</u> dispensed to clinical areas (outside of anesthesia carts) in batches that also contain medications for other routes of administration, are not left in medication rooms or storage areas for clinical staff to put away, <u>and</u> are not delivered via pneumatic tube systems. | | | | | |
| TIME-OUT Process | | | | | | |
| 13 | Prior to administration, a standardized TIME-OUT is performed by the immediate team (e.g., anesthesia provider, physician, and nurse) to verify the patient's name and date of birth; the procedure; the neuraxial medication (including review or BARCODE SCANNING of the product label to confirm the drug[s], concentration[s], and preservative-free status); and the monitoring and RESCUE plan. | | | | | |
| Administration | | | | | | |
| 14 | Neuraxial opioids and/or local anesthetics are obtained by the person who will be administering the drug <u>and</u> only brought to the patient's bedside immediately before they are needed to avoid potential confusion with other medications or solutions prescribed for the patient. | | | | | |
| Preventing Misconnections and Wrong Route Errors | | | | | | |
| 15 | Equipment used for neuraxial opioid and/or local anesthetic insertion and infusion is standardized throughout the facility so that it is familiar to all practitioners administering or supervising neuraxial analgesia. | | | | | |
| FAQ 16 | Infusion pumps (including syringe pumps) used for epidural medications are standardized throughout the facility, specifically configured for epidural medications, visually distinguishable from those used for IV administration, and labeled or visually identified as delivering epidural medication. | | | | | |
| 17 | Dual-channel infusion pumps are not used for simultaneous administration of IV and epidural infusions. | | | | | |
| 18 | Infusion pumps used to administer medications and solutions via different routes of administration (e.g., IV and epidural) are not stacked on the same pole. | | | | | |
| 19 | Epidural infusion lines and central venous access lines are secured on opposite sides of the patient's back or chest. | | | | | |
| 20 | Administration sets with yellow-striped tubing and without injection ports are used for all epidural infusions, and not for any other purpose; <u>and</u> the end of the tubing closest to the patient is clearly labeled "Epidural." | | | | | |
| 21 | All bags and syringes of neuraxial opioids and/or local anesthetics, and their overwraps if applicable, are labeled with a prominent auxiliary warning (e.g., For Epidural Use Only; For Intrathecal Use Only) in a large font size (e.g., greater than 20 point) on both sides of the bag or syringe. | | | | | |

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| 22 | The pharmacy dispenses epidural infusions with an epidural administration set/tubing or connects the epidural tubing to the bag prior to dispensing the infusion. | | | | | |
| Reversal Agents and Treatment of Toxicity | | | | | | |
| 23 | A protocol and/or order set exists and is used to identify and treat local anesthetic toxicity. | | | | | |
| 24 | Resuscitation equipment, supplemental oxygen, and naloxone are readily accessible wherever neuraxial opioids and/or local anesthetics are administered; and the naloxone is accompanied by clear indications for when it should be used, directions for preparation and administration near the point of use, and a protocol or coupled order set that permits emergency administration. | | | | | |
| 25 | Lipid emulsion is readily accessible wherever neuraxial opioids and/or local anesthetics are administered; and the lipid emulsion is accompanied by clear indications for when it should be used, directions for administration near the point of use, and a protocol or coupled order set that permits emergency administration. | | | | | |
| Patient Monitoring | | | | | | |
| 26 | Patients receiving a neuraxial opioid or a local anesthetic/opioid combination are monitored at facility-defined frequencies for the following: level of sedation; pain score; degree of motor or sensory block (if applicable); adequacy of ventilation (e.g., respiratory rate, depth and quality of respirations, capnography); pulse rate; and blood pressure. | | | | | |
| 27 | Patients receiving neuraxial local anesthetics (without an opioid) are monitored at facility-defined frequencies for the following: pain score; degree of motor or sensory block; adequacy of ventilation (e.g., respiratory rate, depth and quality of respirations); pulse rate; and blood pressure. | | | | | |
| 28 | Protocols direct practitioners regarding the type, frequency, and duration of patient monitoring based on: (score each item individually) | | | | | |
| a | The age and medical conditions (including sleep-disordered breathing) of the patient | | | | | |
| b | Changes in infusion rates | | | | | |
| c | The pharmacokinetic effects of the various opioids and/or local anesthetics | | | | | |
| d | If the patient experiences excessive sedation, prolonged or progressive motor block, or cardiovascular/respiratory instability | | | | | |
| e | If the patient is receiving neuraxial opioids concomitantly with PARENTERAL opioids, sedatives, or hypnotics | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 29 | Patients receive verbal and up-to-date written information at an appropriate reading level and in their preferred language about the signs and symptoms of an epidural abscess or post-dural puncture headache and what to do if it occurs since patients may be discharged before the onset of symptoms. | | | | | |

continued on page 78 ►

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|--|--|---|---|---|---|---|
| Neuraxial Analgesia in Children | | | | | | |
| 30 | Dosing regimens for neonates and pediatric patients are adapted for age and weight with MAXIMUM DOSES clearly defined in protocols to minimize the risk of cumulative opioid and local anesthetic toxicity. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates or pediatric patients. | | | | | |
| NOT APPLICABLE | | | | | | |
| Neuraxial Analgesia during Labor and Delivery | | | | | | |
| 31 | Fetal heart rate patterns are monitored at facility-defined frequencies by a qualified practitioner immediately before, during, and after administration of neuraxial analgesia during labor and delivery. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide labor and delivery services. | | | | | |
| NOT APPLICABLE | | | | | | |
| 32 | The plan of care for neuraxial analgesia during labor and delivery is documented in the patient's health record <u>and</u> verbally communicated to the patient's nurse by the obstetrician and/or anesthesia provider. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide labor and delivery services. | | | | | |
| NOT APPLICABLE | | | | | | |

Opioids

Scope: Unless otherwise stated, these items pertain to opioids (including in combination with other analgesics) used for any indication **EXCEPT** moderate sedation, that are administered by any route **EXCEPT** neuraxial, including: oral, IV, IM, subcutaneous, transdermal, sublingual, buccal/transmucosal, and intranasal.

► Self-Assessment Items

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| | | A | B | C | D | E |
|---|---|---|---|---|---|---|
| | General Items | | | | | |
| | Protocols, Guidelines, and Order Sets | | | | | |
| 1 | Standard protocols and/or guidelines for <u>adults</u> exist and are used to guide practitioners when opioids are prescribed, prepared, dispensed, and administered, and when patients are monitored. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to adults. | | | | | |
| 2 | Standard protocols and/or guidelines for <u>neonates</u> and <u>pediatric</u> patients exist and are used to guide practitioners when opioids are prescribed, prepared, dispensed, and administered, and when patients are monitored. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to neonates or pediatric patients. | | | | | |
| 3 | One or more protocols and/or guidelines associated with opioid use contain the following content: (score each item individually) | | | | | |
| a | The use of specific opioids, including dosing guidelines that differentiate between the management of OPioid-naïve , OPioid-tolerant , and HIGH-RISK PATIENTS ; and conditions that require dose adjustments | | | | | |
| b | The management of patients with ABERRANT DRUG-RELATED BEHAVIORS | | | | | |
| c | Administration of adjuvant agents (e.g., nonsteroidal anti-inflammatory agents, gabapentin, clo NID ine, dexmedetomidine) to reduce opioid use | | | | | |
| d | Tapering and discontinuing opioids to avoid withdrawal symptoms | | | | | |
| e | Avoiding concomitant use of other opioids/sedating agents (or adjusting doses if administered concomitantly) | | | | | |
| f | Equianalgesic dose conversion between different opioids and/or routes of administration | | | | | |
| g | Monitoring requirements, including the frequency, intensity, duration, and methods of monitoring based on patients' individual risk factors, response to therapy, and pharmacologic regimen | | | | | |
| h | Management of potentially serious adverse effects such as respiratory depression, inadequate oxygenation/ventilation, unintended advancing sedation, and allergic reaction | | | | | |

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|---------------------------------------|--|---|---|---|---|----------------|
| 4 | Any opioid equianalgesic dosing chart(s) relied upon by the facility has been reviewed and approved by a pain management specialist and/or an appropriate committee (e.g., PHARMACY AND THERAPEUTICS). | | | | | |
| 5 | Inpatient opioid standard order sets for neonates and pediatric patients provide fixed weight-based doses that require only the input of the patient's weight in metric units to determine the dose. <i>Scoring guideline: Choose Not Applicable only if your facility does not provide care to neonates or pediatric patients in an inpatient setting.</i> | | | | | NOT APPLICABLE |
| Patient Assessment | | | | | | |
| 6 | Before prescribing an opioid, a standard process based on established definitions is used to determine if a patient is OPIOID-NAÏVE or OPIOID-TOLERANT , and if the patient is a HIGH-RISK PATIENT or exhibits ABERRANT DRUG-RELATED BEHAVIORS ; and this information is documented in a designated location in the medical record and used to establish a monitoring plan for the patient. | | | | | |
| 7 | The facility uses a validated, standardized sedation scale (e.g., Pasero Opioid-Induced Sedation Scale [POSS]) to guide the assessment and early detection of unintended advancing sedation during opioid therapy. | | | | | |
| 8 | Upon admission or patient encounter, practitioners ask alert and oriented patients with a recent history of pain whether they are wearing an opioid transdermal patch or implanted drug delivery system; or they complete a skin examination of patients who are unresponsive, confused, or exhibiting ABERRANT DRUG-RELATED BEHAVIORS to detect a patch or implanted drug delivery system. | | | | | |
| Products Used | | | | | | |
| 9 | Concentrations of continuous IV opioid infusions for <u>adult</u> patients are standardized per drug to a single usual concentration (e.g., for OPIOID-NAÏVE PATIENTS) and a single high concentration (e.g., for certain OPIOID-TOLERANT PATIENTS). <i>Scoring guideline: Choose Not Applicable only if your facility does not provide care to adults receiving continuous IV infusions.</i> | | | | | |
| 10 | Concentrations of continuous IV opioid infusions for <u>neonates</u> and <u>pediatric</u> patients are standardized per drug to a single usual concentration (e.g., for OPIOID-NAÏVE PATIENTS) and a single high concentration (e.g., for certain OPIOID-TOLERANT PATIENTS). <i>Scoring guideline: Choose Not Applicable only if your facility does not provide care to neonates or pediatric patients receiving continuous IV infusions.</i> | | | | | |
| 11a OR 11b | Opium tincture is not on the formulary and/or is not available in the facility, even in the pharmacy. OR If opium tincture is on the formulary and/or is available anywhere in the facility, paregoric is not available anywhere, even in the pharmacy. | | | | | |
| Prescribing | | | | | | |
| 12 | When initiating orders for opioids, computer order entry systems default to the lowest initial starting dose and frequency, and alert practitioners when a dose adjustment is required due to age, renal or liver impairment, or when patients are prescribed other sedating medications. | | | | | |

continued on page 81 ▶

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|---|---|
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| | | A | B | C | D | E |
|---------------------------|---|---|---|---|---|---|
| Dispensing | | | | | | |
| 13 | Commercially available opioid IV infusions or prefilled syringes/bags/cassettes for IV PCA are used whenever available; and pharmacy prepares and dispenses any IV and PCA opioid infusions that are not commercially available for individual patients as prescribed. Scoring guideline: Choose Not Applicable <i>only if patients in your facility never receive IV or PCA opioid infusions.</i> | | | | | |
| NOT APPLICABLE | | | | | | |
| Administration | | | | | | |
| FAQ 14 | If multiple choices for pain therapy have been prescribed, practitioners are provided with standard guidance (beyond individual judgment) for selecting which medication and dose should be administered and how often, based on the patient's pain assessment and functional status (not pain intensity score alone) to prevent dangerous DOSE STACKING and respiratory depression. | | | | | |
| 15 | For patients receiving IV opioids, nurses communicate the patients' opioid status (OPIOID-NAÏVE or OPIOID-TOLERANT); recent pain assessment, sedation score, and medications administered; and risk factors for unintended advancing sedation and respiratory depression, during change-of-shift report and across all patient transitions in care. Scoring guideline: Choose Not Applicable <i>only if patients in your facility never receive IV opioids or patient care never transitions between shifts, practitioners, or settings.</i> | | | | | |
| 16 | IV push doses of opioids in commercially available or pharmacy-prepared prefilled syringes are <u>not</u> further diluted. Note: Drug references may mention possible dilution to facilitate slow titration of the dose during administration. However, dilution should <u>not</u> occur unless recommended by the manufacturer or supported by evidence in peer-reviewed literature, and approved by the facility. Scoring guideline: Choose Not Applicable <i>only if patients never receive IV push doses of opioids in your facility.</i> | | | | | |
| FAQ 17 | IV push doses of opioids are <u>never</u> diluted by drawing up the contents into a commercially labeled, prefilled flush syringe of 0.9% sodium chloride. Scoring guideline: Choose Not Applicable <i>only if patients never receive IV push doses of opioids in your facility.</i> | | | | | |
| NOT APPLICABLE | | | | | | |
| Patient Monitoring | | | | | | |
| 18 | Continuous pulse oximetry is used to monitor all patients receiving continuous IV opioids (including PCA with or without a BASAL INFUSION) for indications other than palliative/end-of-life care. Scoring guideline: Choose Not Applicable <i>only if patients never receive continuous IV opioids in your facility.</i> | | | | | |
| 19 | A reliable method of measuring the adequacy of ventilation and airflow (e.g., capnography) is used to monitor all patients receiving supplemental oxygen and continuous IV opioids (including PCA with or without a BASAL INFUSION) for indications other than palliative/end-of-life care. Scoring guideline: Choose Not Applicable <i>only if patients never receive continuous IV opioids in your facility.</i> | | | | | |
| 20 | Alarms for pulse oximetry and/or capnography are set to minimize the risk of missing significant respiratory depression as well as minimizing nuisance alarms; and these alarms reach the responsible nurse promptly (e.g., via text message). | | | | | |

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|---|---|
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|---|--|----------------|---|---|---|---|
| 21 | Prior to any opioid administration, a nurse performs an assessment of the patient (e.g., vital signs, pain assessment using the facility's pain assessment scale) and verifies when the last dose of an opioid and/or other sedating agent was taken or administered to ensure the time interval between doses is appropriate. | | | | | |
| 22 | Following the administration of intermittent opioid doses, nurses perform a post-administration assessment within the facility-designated timeframe of respirations (i.e., quality of respirations, respiratory effort, rate, rhythm), circulation (i.e., heart rate, blood pressure), sedation (using the facility's sedation scale), and pain (using the facility's pain assessment scale[s]). | | | | | |
| 23 | During the administration of continuous IV opioids, nurses perform an assessment of the following within the facility-designated timeframe: (score each item individually) Scoring guideline: Choose Not Applicable for items a through e only if patients never receive continuous IV opioids in your facility. | | | | | |
| a | Respiration (i.e., quality of respirations, respiratory effort, rate, rhythm, breath sounds) | | | | | |
| | | NOT APPLICABLE | | | | |
| b | Oxygenation (i.e., pulse oximetry) and/or ventilation (i.e., capnography) | | | | | |
| | | NOT APPLICABLE | | | | |
| c | Circulation (i.e., heart rate, blood pressure) | | | | | |
| | | NOT APPLICABLE | | | | |
| d | Sedation (using the facility's sedation scale) | | | | | |
| | | NOT APPLICABLE | | | | |
| e | Pain (using the facility's pain assessment scale[s]) | | | | | |
| | | NOT APPLICABLE | | | | |
| 24 | Predefined discharge/transfer criteria for adults, neonates, and/or pediatric patients exist to make clear the minimum amount of time that a patient must be monitored after receiving opioids, and the level of alertness and respiratory adequacy required to be discharged from the facility or transferred from the procedural/operative area. | | | | | |
| Storage | | | | | | |
| Scoring guideline for this section: Choose Not Applicable only if the products listed in the items are not available in your facility. | | | | | | |
| 25 | Immediate-release and extended-release formulations of the same opioid are stored separately in the pharmacy (e.g., different bins, drawers, or cabinets that are physically separated) and in patient care areas (e.g., separate locked, lidded compartments in ADCs). | | | | | |
| | | NOT APPLICABLE | | | | |

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| | |
|---|---|
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| | | A | B | C | D | E |
|----|---|---|---|---|---|----------------|
| 26 | Highly concentrated and usual-strength formulations of the same opioid are stored separately in the pharmacy (e.g., different bins, drawers, or cabinets that are physically separated) and in patient care areas (e.g., separate locked, lidded compartments in ADCs). | | | | | NOT APPLICABLE |
| 27 | Highly concentrated oral liquid and PARENTERAL opioids are only stored in the pharmacy and in certain patient care units (in unit doses only) where significant chronic, cancer, or end-of-life pain is treated; these products are not stocked in the emergency department. | | | | | NOT APPLICABLE |
| 28 | Morphine and HYDRO morphine are not stored right next to each other in the pharmacy and/or in patient care areas. | | | | | NOT APPLICABLE |
| 29 | Outside of the pharmacy, morphine and HYDRO morphine are stocked in different strengths (e.g., 1 mg/mL prefilled syringes of HYDRO morphine; 2 mg/mL prefilled syringes of morphine). | | | | | NOT APPLICABLE |

Expression of Drug Names

| | | | | | |
|----|--|--|--|--|--|
| 30 | The abbreviations MSO ₄ for morphine and MgSO ₄ for magnesium sulfate (which could be confused with each other), and DTO for deodorized tincture of opium (which could be mistaken as diluted opium tincture), are never used when expressing the drug names in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, pharmacy labels and/or AUTOMATED SYSTEM LABELS , and any other format used to communicate the drug in the facility. | | | | |
|----|--|--|--|--|--|

Product Differentiation

| | | | | | |
|--------|---|--|--|--|--|
| FAQ 31 | TALL MAN LETTERING with bolded text for the unique letter characters of look-alike opioid drug names (e.g., HYDRO morphine and morphine, oxy CODONE and Oxy CONTIN) is used when displaying the names in computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, infusion pump screens, drug storage bins, and pharmacy labels and/or AUTOMATED SYSTEM LABELS . | | | | |
| 32 | An auxiliary label noting its concentrated strength is affixed to nonstandard or highly concentrated opioid products that are dispensed from the pharmacy. | | | | |

Reversal Agents

| | | | | | |
|----|---|--|--|--|--|
| 33 | Guidelines exist to RESCUE a patient with unintended advancing sedation and/or respiratory depression during opioid therapy, and, if labor and delivery services are provided, for a neonate with severe respiratory depression whose mother received an opioid within hours of delivery. | | | | |
| 34 | Resuscitation equipment, supplemental oxygen, and naloxone are readily accessible wherever opioids are administered; and the naloxone is accompanied by a clear indication for when it should be used, directions for preparation and administration near the point of use, and a protocol or coupled order set that permits emergency administration. | | | | |
| 35 | Patients who receive naloxone are monitored for signs of resedation and respiratory depression for at least 90 minutes after administration of the reversal agent. | | | | |

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| | | A | B | C | D | E |
|--|--|---|---|---|---|---|
| Staff Competency and Education | | | | | | |
| 36 | Educational programs for all practitioners who care for patients receiving opioids are delivered at least every year around the following content: (score each item individually) | | | | | |
| a | Definition and differences in the management of OPIOID-NAÏVE , OPIOID-TOLERANT , and HIGH-RISK PATIENTS | | | | | |
| b | Opioid conversions and how to use any tools provided by the facility | | | | | |
| c | Appropriate starting doses and the danger of rapid dose escalation | | | | | |
| d | Indications for extended-release and long-acting opioids, associated risks, and education on the requirements of the US Food and Drug Administration <i>Extended-Release and Long-Acting (ER/LA) Opioid Analgesics Risk Evaluation and Mitigation Strategy (REMS)</i> | | | | | |
| e | Risk of initiating transdermal fentaNYL patches in OPIOID-NAÏVE PATIENTS | | | | | |
| f | Clinical and technological (e.g., capnography) monitoring requirements | | | | | |
| g | Sedation as the first sign of respiratory depression | | | | | |
| Patient Education (Includes Caregiver Education When Appropriate) | | | | | | |
| 37 | Patients discharged on opioids are provided with verbal and up-to-date written information at an appropriate reading level and in their preferred language about pain management and safe use of opioid medications, including the following: (score each item individually) | | | | | |
| a | The impact of opioid therapy on psychomotor and cognitive function (which may affect ambulation, work, driving) | | | | | |
| b | Effect of taking too much opioid medication and when/who to call for medical attention | | | | | |
| c | Avoidance of other central nervous system depressants (including alcohol and over-the-counter or illicit drugs) | | | | | |
| d | Not sharing opioids with others | | | | | |
| e | Secure storage and disposal, including drug take-back programs available in the community | | | | | |
| f | How to obtain naloxone from a retail pharmacy if the patient has risk factors for opioid overdose | | | | | |
| Specific Opioids or Modes of Delivery | | | | | | |
| Combination Opioids with Acetaminophen | | | | | | |
| 38 | Computer order entry systems alert practitioners if the prescribed medication(s) could exceed the maximum safe daily dose of acetaminophen for adults, neonates, and pediatric patients, considering all possible scheduled and "PRN" doses of acetaminophen-containing medications. | | | | | |

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|---|--|---|---|---|---|---|
| 39 | Patients who are prescribed an opioid with acetaminophen to take at home are educated about the amount of acetaminophen in each tablet; the MAXIMUM (single) DOSE ; how many doses they can take each day; and to avoid taking other prescription and nonprescription acetaminophen/medications that contain acetaminophen. | | | | | |
| Extended-Release, Long-Acting, and High-Dose Opioids | | | | | | |
| 40 | A process is in place (e.g., alert requesting confirmation during order entry) to verify that the patient is OPIOID-TOLERANT with chronic pain before dispensing extended-release and long-acting opioids that are indicated <u>only</u> for these patients (e.g., extended-release oxy CODONE [80 mg or higher doses], extended-release HYDRO morphe, extended-release morphine [100 mg or 200 mg tablets], fenta NYL transdermal patches). | | | | | |
| 41 | A process is in place (e.g., alert requesting confirmation during order entry) to verify that the patient is OPIOID-TOLERANT with chronic pain before dispensing high-dose opioids indicated <u>only</u> for breakthrough pain in OPIOID-TOLERANT PATIENTS (e.g., certain forms of fenta NYL [Actiq, Fentora, Lazanda, Subsys, Abstral]). | | | | | |
| Patient-Controlled Analgesia (PCA) | | | | | | |
| Scoring guideline for this section: Choose Not Applicable <u>only</u> if patients in your facility never receive opioid PCA. | | | | | | |
| 42 | Patient selection criteria have been established and are followed for PCA therapy, which exclude patients who cannot control medication delivery themselves due to their level of consciousness, physiological condition, or limited cognitive ability and comprehension. | | | | | |
| 43 | PCA is initially prescribed using a standard order set. Exception: Excludes dose changes based on the patient's response after implementation of PCA. | | | | | |
| 44 | Order sets for PCA include: recommended initial and MAXIMUM DOSES (bolus and demand) and a lock-out interval based on whether the patient is OPIOID-NAÏVE or OPIOID-TOLERANT , and/or a HIGH-RISK PATIENT ; monitoring guidelines; and an order for naloxone to reverse respiratory depression, including directions for use. | | | | | |
| 45 | PCA BASAL INFUSIONS are not used initially in OPIOID-NAÏVE PATIENTS . | | | | | |
| 46 | Patients, family members, and visitors are educated about the dangers of any individual other than the patient activating the PCA button to deliver a medication dose (i.e., PCA by proxy); and a warning label, " FOR PATIENT USE ONLY ," appears on the cord or activation button for PCA. | | | | | |

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| Opioid Transdermal System (fentaNYL, buprenorphine) | | | | | | |
| 47 | The fentaNYL transdermal patch that delivers 12.5 mcg/hour is expressed as fentaNYL transdermal (or DURAGESIC) "12" and not "12.5" in orders, computer order entry systems, order sets, protocols, guidelines, MARs/eMARs, ADC screens, drug storage bins, and pharmacy labels and/or AUTOMATED SYSTEM LABELS, to prevent confusion with 125 mcg/hour dosing. | | | | | |
| 48 | The date, time, and anatomical location of an opioid transdermal patch applied to a patient by a practitioner is documented on the patient's MAR/eMAR. | | | | | |
| 49 | In inpatient settings, at least once per shift, a practitioner verifies that the opioid patch is still in place on the patient's skin in the same anatomical location where it had been documented. Scoring guideline: Choose Not Applicable <u>only</u> if your facility does not provide care to inpatients. | | | | | NOT APPLICABLE |
| 50 | Practitioners remove any previously applied transdermal opioid patches prior to the application of a new patch and document the patch removal on the patient's MAR/eMAR. | | | | | |
| 51 | An organizational policy on the proper disposal of opioid patches (e.g., narcotic disposal system containers, containers that deactivate residual drug, flushing down the toilet, <u>not</u> thrown in ordinary trash receptacles) exists and is followed. | | | | | |
| 52 | Patients being discharged or leaving the facility with a new prescription for an opioid transdermal patch are provided with verbal and up-to-date written information at an appropriate reading level and in their preferred language about: (score each item individually) | | | | | |
| a | How to apply the patch properly | | | | | |
| b | Avoidance of heat exposure (e.g., hot tubs, sun bathing, heating pad over patch) | | | | | |
| c | Removal of the old patch before application of a new patch | | | | | |
| d | Secure storage and disposal of the patches to avoid unintended access by children, pets, and individuals with ABERRANT DRUG-RELATED BEHAVIORS | | | | | |

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| | | A | B | C | D | E |
|---|---|----------------|---|---|---|---|
| Methadone | | | | | | |
| Scoring guideline for this section: Choose <i>Not Applicable</i> <u>only</u> if methadone is never prescribed for patients in your facility. | | | | | | |
| 53 | Protocols for prescribing methadone to adults and/or children have been established and include the following: (score each item individually) | | | | | |
| a | ECG before treatment and at defined intervals thereafter (based on baseline ECG, high dose, dose changes, drug interactions, other risk factors [e.g., electrolyte abnormalities], patient symptoms) | | | | | |
| | | NOT APPLICABLE | | | | |
| b | Recommended initial MAXIMUM DOSE and dose increases | | | | | |
| | | NOT APPLICABLE | | | | |
| c | Assessment and monitoring requirements | | | | | |
| | | NOT APPLICABLE | | | | |
| d | Guidelines for managing pain in patients taking methadone to treat addiction | | | | | |
| | | NOT APPLICABLE | | | | |
| 54 | Methadone is only prescribed or initiated by practitioners who have substantial experience with its use; are familiar with the drug's risk profile, adverse effects, and pharmacologic properties (e.g., long/variable half-life, interactions, effects on the QTc interval, respiratory depression); <u>and</u> they are prepared to educate and closely monitor their patients. | | | | | |
| | | NOT APPLICABLE | | | | |
| 55 | If an inpatient is being treated for opioid addiction by an approved methadone provider/clinic, the patient's dose is confirmed with the methadone provider and the source is documented prior to the first dose if the drug is continued during hospitalization or long-term care. Additional scoring guideline: Choose <i>Not Applicable</i> <u>only</u> if your facility does not provide care to inpatients. | | | | | |
| | | NOT APPLICABLE | | | | |
| 56 | Mnemonics in computer order entry systems are configured to prevent confusion between methadone and other drugs that start with "met...", especially those with similar strengths (e.g., methylphenidate). | | | | | |
| | | NOT APPLICABLE | | | | |

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| | | A | B | C | D | E |
|-----------|---|----------------|---|---|---|---|
| 57 | Patients who will be, or are, self-administering methadone at home for chronic pain or addiction treatment are educated about the following: (score each item individually) | | | | | |
| a | Importance of taking the drug exactly as prescribed to avoid a potentially fatal build up in the body | | | | | |
| | | NOT APPLICABLE | | | | |
| b | Plans for monitoring therapy and adjusting doses | | | | | |
| | | NOT APPLICABLE | | | | |
| c | Serious side effects to report to the prescriber | | | | | |
| | | NOT APPLICABLE | | | | |
| d | Risks associated with methadone, including the drug's long/variable half-life, risk of respiratory depression, sudden death (from QTc interval prolongation and arrhythmia), and drug-drug interactions | | | | | |
| | | NOT APPLICABLE | | | | |
| e | Importance of disclosing methadone use to other healthcare providers, including retail pharmacists | | | | | |
| | | NOT APPLICABLE | | | | |

Opioid Addiction and Abuse

| | | | | | | |
|-----------|--|--|--|--|--|--|
| 58 | Effective systems are in place to deter and promptly identify drug diversion at any point of opioid use, from procurement to administration and/or wasting of unused drug; and an internal group is available to quickly investigate concerns that arise during drug diversion surveillance. | | | | | |
| 59 | Adequate pain treatment is not withheld from patients with active or previous opioid addiction because of fears of worsening addiction or precipitation of relapse. | | | | | |
| 60 | Prescribers access data from Prescription Drug Monitoring Programs (PDMPs) to identify past and present opioid prescriptions during the assessment of patients who may require outpatient opioids, and if refills are provided, to determine the safety and appropriateness of the opioid prescriptions. | | | | | |

Glossary

Aberrant drug-related behaviors: A set of concerning behaviors in which individuals make a directed and concerted effort to obtain an opioid medication for relief of undertreated pain (pseudoaddiction), satisfy an addiction or abuse disorder, or for drug diversion. Some of these behaviors include reporting an allergy to everything but a certain opioid; obtaining opioids from multiple prescribers, pharmacies, and emergency departments; frequent requests for early refills or replacement of lost/stolen/spilled opioids; providing inconsistent stories about pain; clock watching; or hoarding of analgesics.

Area under the curve (AUC): The amount of drug exposure or total drug concentration in plasma over a period of time. In addition to using the AUC in the setting of clinical research, it can be used to help guide the dosing of drugs such as **CARBOplatin**.

Automatic stop order: Refers to automatic stoppage of certain medications within an organization-defined timeframe, if prescribers do not state the number of doses or days, after which the medications are discontinued and must be reordered if continuation is desired.

Automated system label: Label for patient-specific or unit-dose medications that is created or printed from automated devices such as pharmacy robotics or an ADC.

Barcode scanning technology: The use of optical machine-readable representation of data found in barcodes on medication packages and patient identification bands to verify that the correct patient is receiving the correct medication, the correct solution or ingredient is selected prior to compounding a preparation, or the correct medication is retrieved from or stocked in the correct storage location. The process involves the use of a barcode scanner, an electrical device that can read and output printed barcodes to a computer.

Basal infusion: A continuous infusion of an opioid to provide a constant level of analgesia, which may also be administered with bolus doses or patient-controlled analgesia (PCA).

Basal insulin: Insulin administered on a scheduled basis to maintain constant blood glucose levels during periods of fasting and between meals (e.g., long-acting insulin analogs, such as glargine or detemir).

Body surface area (BSA): The total surface of the human body based on height and weight that is used to calculate many chemotherapy drug doses. It is expressed as meters squared (m^2).

Clinical trial: Defined by the National Institutes of Health (NIH) as a research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Compounded sterile preparation: A preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance. A product produced by reconstituting a conventionally manufactured product for an individual patient strictly in accordance with the directions contained in the approved labeling provided by the product manufacturer is not considered a compounded sterile preparation.

Computerized prescriber order entry: Refers to an inpatient and/or outpatient electronic or computer system into which an authorized prescriber enters medical orders.

Concentrated insulin: Any insulin with a concentration greater than 100 units/mL, including U-200, U-300, and U-500 insulin.

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Correctional insulin: Insulin administered to lower hyperglycemic glucose levels, not to cover nutritional intake (e.g., rapid-acting insulin analogs, such as glulisine, lispro, and aspart). Correctional doses may be combined with nutritional doses and administered simultaneously before a meal. Correctional doses should still be given to treat hyperglycemia when patients are not eating.

Cycle: A dose of chemotherapy that is repeated at regular intervals. Several chemotherapy cycles may make up a total treatment protocol. For example, the CHOP chemotherapy protocol may consist of one cycle given every 3 weeks, resulting in six cycles for the course of therapy.

Data monitoring software: Automated clinical decision support systems that “listen” to a wide variety of information sources (e.g., laboratory, pharmacy, radiology) across the organization, “watch” for specific problems that can be predefined by the organization, “link” this information to patients’ electronic health records, and “notify” clinicians electronically of situations that may represent a risk to their patients *as soon as this information becomes available*.

Deep sedation: A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

Dose error-reduction software (DERS): Refers to the integral computer software in smart infusion pumps intended to warn users of potential over- or underdelivery of a drug, electrolyte, or other fluid by checking programmed doses against preset limits specific to a drug (e.g., morphine) and to a clinical application (e.g., epidural administration) or location (e.g., neonatal intensive care unit, medical/surgical unit).

Dose stacking: The administration of another dose of the same medication or class of medication (e.g., pain medications) before the peak effect of the previous dose/medication has been reached, which could result in an excessive total drug effect over time. For example, peak analgesic effect with morphine may not be achieved for up to 20 minutes following intravenous administration. Dose stacking is possible if more morphine is given before the previous dose reaches its peak effect. However, morphine may be titrated safely in certain settings (e.g., immediate postoperative setting) every 5 minutes if smaller bolus doses are used.

General anesthesia: A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

Gravimetrics: Refers to a measurement technique in which the amounts of each ingredient in a compounded product are determined by weighing the final product. The expected weight of the combined base solution and all additives or other ingredients is based on available information about the specific gravity of each of the intended components. This quality control step provides a quantitative measurement to verify accuracy when preparing compounded sterile products.

Hard stop: A forcing function in the computer system, intravenous infusion device, or other technology that will not allow the practitioner to proceed with the selection or entry.

High-risk patient: Patient with risk factors that increase the likelihood of an adverse outcome. For example, patients who are at high risk for opioid-induced respiratory depression may have the following risk factors:

- Age greater than 55 years
- Obesity
- Hepatic or renal impairment

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- Known or suspected sleep-disordered breathing (e.g., snoring, upper airway resistance syndrome, obstructive sleep apnea-hypopnea syndrome)
- Large neck circumference
- Anatomical maxilla or mandible abnormalities
- Prolonged surgery (greater than 2 hours)
- Thoracic or upper abdominal surgical incisions that may impair adequate ventilation
- Pulmonary or cardiac disease or dysfunction or major organ failure
- Smoker
- Concomitant administration of sedating agents
- High opioid dose requirements
- History of naloxone administration

Hospitalist/intensivist: A physician (not an intern or resident) who assumes responsibility for the observation and treatment of hospitalized patients and returns them to the care of their primary healthcare providers when they are discharged. An intensivist typically works in the intensive care unit.

Independent double check (or independently double checked): 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 such that the information from one system is available to the user of the second system and integrated into the system 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 he/she is entering or verifying a specific medication order). This may or may not include a bi-directional interface of the two systems to allow communication in both directions.

Investigational drug (investigational): Defined by the National Institutes of Health (NIH) as a substance that has been tested in the laboratory and has been approved by the US Food and Drug Administration (FDA) for testing in people. Clinical trials test how well investigational drugs work and whether they are safe to use. An investigational drug may be approved by the FDA for use in one disease or condition but still be considered investigational in other diseases or conditions.

Machine-readable coding: Refers to technology in which a set of signs, letters, or radio waves are used to identify people and/or objects, including medications. Examples include barcode scanning technology (see defined term) or radio frequency identification (RFID), which involves wireless emission of radio waves that are transmitted and received to communicate identity and other information.

Maximum dose: The dose of a medication that represents the upper limit that is normally found in the literature and/or manufacturer recommendations. Maximum doses may vary according to age, weight, or diagnosis.

Medication safety officer: A clinical practitioner designated by an organization to serve as the authoritative leader in safe medication use for the purpose of reducing patient harm related to medication use. Other titles used to describe this role include medication safety leader, medication safety manager, medication safety coordinator, medication safety clinical specialist, medication safety pharmacist or nurse, and director of medication safety.

Nonanesthesiologist sedation practitioner: A licensed physician, dentist, or podiatrist who has not completed postgraduate training in anesthesiology but is specifically trained to personally administer or supervise the administration of moderate sedation.

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Non-parenteral: By the alimentary canal (enteral), topical, or transdermal routes of administration.

Nutritional (prandial) insulin: Insulin administered ideally 0-30 minutes before a meal to prevent the predicted postprandial rise in glucose levels (e.g., rapid-acting insulin analogs, such as glulisine, lispro, and aspart). Nutritional doses should be withheld when patients are NPO.

Opioid-naïve patient: Patients who do not meet the definition of opioid-tolerant.

Opioid-tolerant patient: Opioid tolerance is defined by the following markers: Patients receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fentaNYL/hour; 30 mg oral oxyCODONE/day; 8 mg oral HYDROmorphine/day; 25 mg oral oxyMORphone/day; 60 mg oral HYDROcodone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.

PARENTERAL: By some route of administration other than topical, transdermal, or through the alimentary canal (enteral) (e.g., subcutaneous, intramuscular, intravenous, or neuraxial injection).

Pharmacy and therapeutics committee: An interdisciplinary committee that convenes on a scheduled basis, or when necessary, to review the safety and efficacy, and establish approved uses and required monitoring of medications that will be available for use in the organization. The committee also sets policy and procedures, on behalf of the medical staff and administration, on the safety of the entire medication-use process.

Point-of-care: At or near to where the patient is located and receiving care—that is, at the time and place of patient care.

Proactive risk assessment: The process of identifying and systematically analyzing the risks and hazards embedded in the process and structure of care to prevent adverse events from occurring. Knowing where the risks and hazards are helps to inform the design, planning, and development of appropriate interventions that will eliminate or minimize risks and hazards before patient injuries occur.

Rescue: An intervention (usually provided urgently) used to reverse an adverse drug effect (e.g., to correct adverse physiologic consequences of a deeper-than-intended level of sedation), or to reverse a pathophysiologic condition (e.g., use of a hypertonic saline rescue to treat severe hypovolemia).

Safety culture: Refers to a safety-supportive model of shared accountability where healthcare institutions are accountable for the systems they design; for supporting the safe behavioral choices of patients, visitors, and staff; and for responding to staff behaviors in a fair and just manner. In turn, staff are accountable for the quality of their behavioral choices (human error is not a behavioral choice) and for reporting hazards, errors, and system vulnerabilities.

Simulation training: Hands-on training through virtual, live, or constructive experiences that are provided outside of day-to-day practice to teach various skills associated with a complex or hazardous task. Simulation training involves acting out or mimicking an actual or probable real-life condition, event, or situation to gain or sharpen skills associated with responding to these conditions, events, or situations.

Smart infusion pump/technology: An infusion pump with integral computer software (see dose error-reduction software) that is, at a minimum, capable of: 1) maintaining a drug library of standard drug concentrations, which when enabled, is used to support dose calculations and alert the user to incorrect orders, calculation errors, or programming errors that would result in significant over- and underdelivery of a drug, electrolyte, or other fluid; and 2) capturing administrative infusion data in a systematic, objective manner to support improvement in medication use. If the programmed dose is outside the preset limits, the pump alerts clinicians and can either require confirmation before beginning delivery (soft limit) or not allow delivery at all (hard limit).

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Syringe pullback method: A retrospective verification process used during drug preparation in which: 1) the drug or diluent is drawn into a syringe and injected into an infusion bag/container; 2) the syringe plunger is “drawn back” to demonstrate the volume that was added to the bag/container; and 3) the syringe is placed next to the source container(s) from which the drug or diluent was withdrawn for a second individual to verify the preparation. (This is not a recommended method to verify final drug preparation.)

Tall man lettering: Refers to a method of differentiating the appearance of similar drug names known to be confused with one another by using bolded, uppercase letters to draw attention to a small group of unique letter characters that are different in each of the drug names. A list of look-alike drug names with recommended tall man letters can be found at: www.ismp.org/Tools/tallmanletters.pdf.

Time-out: A formal process of active communication among all team members involved in a procedure by which, immediately prior to the procedure, healthcare providers pause to review a standardized checklist to confirm key aspects of the procedure, such as verification of the patient, the procedure to be performed, laterality, drugs to be administered, and a patient monitoring and rescue plan.

Triggers: Critical indicators (e.g., laboratory values, patient symptoms, use of antidotes for medications administered) that alert practitioners to the need for evaluation of a potential adverse event.

About the Institute for Safe Medication Practices (ISMP)

The Institute for Safe Medication Practices (ISMP) is the nation's only nonprofit, charitable organization devoted entirely to medication error prevention and safe medication use. ISMP is known and respected worldwide as the leading resource for independent and effective medication safety recommendations.

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.

The Institute's recommended strategies for error prevention and risk identification are based on up-to-the minute information gained from analysis of voluntary reports to the ISMP National Medication Errors Reporting Program, the ISMP National Vaccine Errors Reporting Program, and the ISMP National Consumer Medication Errors Reporting Program, along with onsite visits to individual healthcare organizations, and advice from outside experts.

ISMP's initiatives, which are built upon system-based solutions, include: five medication safety newsletters for healthcare professionals and consumers that reach more than 1 million total readers; educational programs, including webinars on medication use issues; confidential consulting services to healthcare systems to proactively evaluate medication systems or analyze medication related sentinel events; advocacy for the adoption of safe medication standards; independent research to identify and describe evidence-based safe medication practices; and a consumer website (www.consumermedsafety.org) that provides patients with access to free medication safety information and alerts.

ISMP works with healthcare practitioners and institutions, regulatory and accrediting agencies, consumers, professional organizations, the pharmaceutical industry, and others to accomplish its mission. It is a federally certified patient safety organization (PSO), providing legal protection and confidentiality for patient safety data and error reports it receives.

As an independent nonprofit 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.

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