ISMP Medication Safety Self Assessment® for Perioperative Settings

Frequently Asked Questions (FAQs)

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

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PRA Burden Statement

According to the Paperwork Reduction Act (PRA) of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information, unless it displays a valid Office of Management and Budget (OMB) control/number. The valid OMB control/number for this information collection is 0910-0847, and the expiration date is 12/31/2022. The time required to determine eligibility to use the assessment is estimated to average 2 minutes per person. The time required for small teams to complete this information collection is estimated to be 8.54 hours for ambulatory surgery centers and 25.67 hours for hospitals.

Security of Information

Security of Participant Information

Your participant information will remain secure to the extent permitted by law, and your personal identifying information will not be included in any reports.

Security of Self-Assessment Findings Submitted to ISMP

All information submitted to ISMP is stored in a secure database maintained solely by ISMP. All information is submitted anonymously, and organizations can expect the usual high standard of confidentiality associated with any information submitted to ISMP.

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. Furthermore, 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.

Key Abbreviations, Key Definitions, and Glossary Terms

Key abbreviations, key definitions, and glossary terms used throughout the assessment and FAQs can be found in the **ISMP Medication Safety Self Assessment® for Perioperative Settings** workbook (www.ismp.org/node/18027). Glossary terms are designated throughout the assessment and FAQs in **BOLD, SMALL CAPITAL LETTERS.** In the online version of the assessment, glossary terms are linked to their definitions when they appear in a demographic question or self-assessment item.

Frequently Asked Questions

General Questions

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

Completion of the assessment allows perioperative teams in hospitals, ambulatory surgery centers, and other surgical sites to pinpoint how currently designed systems, staff practices, and emerging challenges may impact perioperative medication safety. The assessment will allow organizations to identify and prioritize opportunities for improvement; create organization-specific, safety-focused initiatives; compare their experiences with the aggregate experiences of demographically similar organizations; and track their experiences over time. Use of the assessment will also help healthcare providers meet or gauge their compliance with perioperative medication safety requirements from various state and federal regulatory agencies, such as The Joint Commission and the Centers for Medicare & Medicaid Services.

The assessment suggests best practices and safety system enhancements associated with using medications in the perioperative setting. Only facilities that submit results to ISMP will be able to obtain weighted scores associated with their assessment results for each item based on its effectiveness in reducing the risk of errors, and have access to aggregate data on a national level for comparison to demographically similar healthcare facilities.

Also, from a national perspective, benefits can only be achieved if ISMP can collect and analyze an adequate sample of aggregate assessment responses submitted by healthcare facilities. Aggregate results from a large pool of respondents will provide US hospitals, ambulatory surgery centers, and other surgical sites with important information about the current status of perioperative medication safety, which will create a baseline of provider efforts. Such data will be useful in advising healthcare providers about ongoing perioperative medication system improvements. Aggregate results will be of significant assistance to healthcare providers who seek top leadership support for improvements in perioperative medication safety. Also, ISMP and others will be able to design useful programs and tools to help healthcare providers implement **HIGH-LEVERAGE RISK-REDUCTION STRATEGIES** in the perioperative setting that can positively impact medication safety.

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

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

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

The assessment of each item should be based on what actually occurs, not what can be found in current policies or what ought to occur. While some assessment items ask facilities to evaluate whether certain protocols, procedures, and/or policies exist, they also suggest evaluating whether these are actually followed. While it may be easier to identify the existence of certain protocols, procedures, and/or policies alone, assessment of actual compliance with these structural guidelines is vital to understanding where vulnerabilities and improvement opportunities exist.

Involving frontline practitioners in the assessment, who can describe what actually occurs at the "sharp end" of care, can promote accurate assessment, especially if they feel safe describing what normally happens, even if practices differ from protocols, procedures, and/or policies. Focusing on a systems-based approach to identifying deficiencies, rather than

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General Questions continued

blaming individuals for not following a protocol, procedure, or policy, provides an opportunity for leaders to demonstrate that they understand and practice the principles of a **Just Culture.**

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

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

Glossary Terms

What are Patient Safety Leadership WalkRounds and how are they carried out?

Patient Safety Leadership WalkRounds are a process designed to open the lines of communication between perioperative practitioners and senior leaders. The core **Patient Safety Leadership WalkRounds** team should consist of at least one senior-ranking executive (e.g., chief nursing officer, chief operating officer); the manager and/or director of the perioperative setting (e.g., **operating room** manager, medical director, department of surgery chief); a patient safety advocate (e.g., **medication safety officer**, patient safety officer, quality or risk manager); and a scribe to document the conversation. A staff member who perioperative practitioners consider to be an informal leader may also be a regular member of the **Patient Safety Leadership WalkRounds.**

The rounds should be designed to accomplish four primary goals:

1) Obtain information from frontline staff about processes, the culture, and barriers to safety
2) Increase awareness of safety issues among all perioperative practitioners and leaders
3) Demonstrate leadership commitment to safety as a high priority
4) Act, after careful analysis, on the information collected from perioperative practitioners to improve the work environment and the overall delivery of care

The **Patient Safety Leadership WalkRounds** should be conducted in a safe, non-judgmental environment, without risk of embarrassment or retribution to those who speak up. To elicit dialogue about episodes of harm or concerns about risk, scripted questions should be asked, such as:

- In what way does the system fail you?
- What keeps you up at night with worry about your work?
- How was the last patient harmed in any way?
- Can you think of how a patient was prevented from harm as a result of your interaction?

After the rounds, the information collected should be analyzed and used to categorize and prioritize action items, develop an action plan, implement the plan, and measure progress. Structures should be developed to provide communication back to all rounds' participants, senior leaders, appropriate committees, and the Board of Trustees/Directors.

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General Demographics for Hospitals

Question # 8

Should we include students who rotate through a perioperative area, even if the perioperative area is not their primary site for training?

When identifying onsite training in the perioperative setting for professional students/residents/fellows from an accredited program, please include students who have a distinct rotation measuring at least 160 hours (4 weeks) in a perioperative setting as part of their onsite training.

Questions # 13, # 14, and # 15

Why are you asking for the total number of medical and/or surgical procedures, and the types of procedures, during 2019 and not 2020?

For the total number of medical and/or surgical procedures (inpatient and outpatient) performed in your hospital, and for the types of procedures your hospital has conducted, we are asking for data from 2019, before the coronavirus disease 2019 (COVID-19) pandemic, so the numbers and types of procedures will reflect a typical 12-month period.

Questions # 16 and # 17

How do I estimate the percent of ANESTHESIA PROVIDER types that comprise my primary staffing model when the ratio is different based on the types of procedures (e.g., endoscopies vs. cardiac surgery) and/or types of patients (e.g., adult vs. pediatric)?

Please base your estimate on the primary staffing model reflective of the entire hospital, taking all staffing models, including rotating staff, into consideration.

Question # 20

Are you asking about whether the technology is just available to perioperative practitioners or actively used by perioperative practitioners?

When responding to the demographic questions about technology, please provide information regarding just its availability in the perioperative setting, not whether the technology is actively used. The degree of actively employing the various technologies will be evaluated per specific self-assessment items. The demographic questions are simply asking whether the technology is available for use, not the degree of actual use.

General Demographics for Freestanding Ambulatory Facilities

Question # 7

Should we include students who rotate through a perioperative area, even if the perioperative area is not their primary site for training?

When identifying onsite training in the perioperative setting for professional students/residents/fellows from an accredited program, please include students who have a distinct rotation measuring at least 160 hours (4 weeks) in a perioperative setting as part of their onsite training.

Questions # 13 and # 14

Why are you asking for the total number of medical and/or surgical procedures, and the types of procedures, during 2019 and not 2020?

For the total number of medical and/or surgical procedures performed in your facility, and for the types of procedures your facility has conducted, we are asking for data from 2019, before the coronavirus disease 2019 (COVID-19) pandemic, so the numbers and types of procedures will reflect a typical 12-month period.

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General Demographics for Freestanding Ambulatory Facilities continued

Questions # 15 and # 16

How do I estimate the percent of ANESTHESIA PROVIDER types that comprise my primary staffing model when the ratio is different based on the types of procedures (e.g., endoscopies vs. cardiac surgery) and/or types of patients (e.g., adult vs. pediatric)?

Please base your estimate on the primary staffing model reflective of the entire facility, taking all staffing models into consideration.

Question # 19

Are you asking about whether the technology is just available to perioperative practitioners or actively used by perioperative practitioners?

When responding to the demographic questions about technology, please provide information regarding just its availability in the perioperative setting, not whether the technology is actively used. The degree of actively employing the various technologies will be evaluated per specific self-assessment items. The demographic questions are simply asking whether the technology is available for use, not the degree of actual use.

Self-Assessment Items

Key Element I: Patient Information

Core Characteristic # 1

Item # 4

What is required of medication reconciliation in the perioperative setting?

Medication reconciliation in the perioperative setting is a formal process of ensuring accurate and complete medication information transfer at all interfaces of care. After obtaining an accurate history of all medications a perioperative patient takes regularly, this medication list is considered by the entire perioperative team when planning the care of the patient, including the anesthesia plan of care and when prescribing medications before, during, and after the procedure.

During medication reconciliation before the procedure, patients are clearly informed which of their daily medications to hold and/or continue before arriving at the facility for the procedure. Specific instructions for each medication on the list should be provided. Because a patient's medication list may be obtained days (or weeks) prior to the procedure, verification of the medication list, as well as verification of the medications held or continued, should occur right before the medical and/or surgical procedure.

Medication reconciliation after the procedure typically requires review of the patient's medication list to ensure no discrepancies exist between the medications taken prior to the procedure and the medications the patient has received during and after the procedure.

Upon discharge, the patient's medication list is again reviewed, and the patient is informed when to resume or not to resume previous prescription and over-the-counter medications taken before the medical and/or surgical procedure. Specific instructions for each medication, including any changes or discontinuations, should be provided, along with instructions for newly prescribed medications. While it is acceptable to ask the patient to follow up with their primary care provider (PCP) regarding the continued use of chronic medications taken prior to the procedure, all patients must be informed at the time of discharge whether to resume or hold previously taken medications in the interim, until follow-up with their PCP can occur.

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Self-Assessment Items continued

Item # 6

Why does patient allergy information need to be "properly coded" to allow for clinical decision support allergy screening?

To help achieve clinical decision support allergy screening, documentation of drug allergy information must be standardized and mapped to the drug database ("properly coded") to aid in triggering drug allergy alerts based on criticality and necessity.

Item # 9

How might a healthcare provider collect and document the opioid status of perioperative patients?

Healthcare providers have used a variety of methods to gather and document the opioid status of patients after first establishing standard criteria for **OPIOID TOLERANCE**. For example, some providers ask all patients about opioid use (including heroin and/or non-prescribed opioids) during the past 1-2 weeks and make an initial determination of opioid status when creating a home medication list, which is verified upon medication reconciliation and documented on the patient's medication list. Some providers collect this information upon admission (or encounter) and document it within the EHR where prescribers, pharmacists, and nurses can easily view it. Other providers require a determination of opioid status per established criteria with all opioid pain management orders. In these cases, opioid status is determined and documented within the opioid pain management order set, which guides the appropriate selection and doses of opioids.

Item # 11

Can patient weights be obtained before the day of the procedure so any weight-based medications can be prescribed and verified ahead of time?

Measured patient weights may be needed prior to the day of the procedure to calculate doses and prescribe certain weight-based medications (e.g., preprocedure antibiotics) ahead of time. Organizations may have policies in place regarding the currency of these measured patient weights (e.g., 1 week, 30 days) used for this purpose. However, on the day of the procedure, every patient should be weighed on a scale using metric measurements. Except in emergencies, the patient's stated weight, a healthcare provider's estimated weight, or a previously documented weight (even from a preprocedure assessment encounter) should not be relied upon. Significant differences in a patient's weight during a preprocedure assessment and the day of the procedure should be communicated to the medical and/or surgical procedure team and the pharmacy.

Item # 15

Why should blood glucose measurements be obtained so frequently for patients undergoing a medical and/or surgical procedure who have type 1 or type 2 diabetes?

Hypoglycemia and hyperglycemia have been linked to significant perioperative complications (Wallace J, Jiwani S, Gyasi-Antwi P, Meal A, Adams GG. Management of diabetes patients across the perioperative pathway: a systematic review. *Endocrinol Diabetes Metab J*. 2020;4[1]:1-16). Hypoglycemia has been identified as a risk factor for mortality (Duncan AE. Hyperglycemia and perioperative glucose management. *Curr Pharm Des*. 2012;18[38]:6195-203), and hyperglycemia has been identified as a risk factor for both mortality and morbidities, including: nonhealing of an incision, increased length of stay, and poor patient outcomes (e.g., wound infections and dehiscence, deep vein thrombosis, pneumonia and upper respiratory infection, urinary tract infections, septicemia, vascular complications, stroke and heart attack, atrial fibrillation).

Best practices to reduce the risk of these complications include measuring the blood glucose of patients with type 1 and type 2 diabetes mellitus 4 hours preoperatively, every 2 hours intraoperatively, and at least once within 2 hours postoperatively (Hommel I, van Gurp PJ, Tack CJ, Wollersheim H, Hulscher ME. Perioperative diabetes care: development and validation of quality indicators throughout the entire hospital care pathway. *BMJ Qual Saf*. 2016;25[7]:525–34), and acting appropriately on that information. For example, elective procedures may be canceled until a high blood glucose measurement is brought under control, or medications may be prescribed (e.g., insulin), adjusted (e.g., dose reductions), or avoided (e.g., dextrose as a **CARRIER FLUID**, dexamethasone for nausea) during the perioperative period to avoid complications.

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Self-Assessment Items continued

Item # 18

How long is continuous electronic monitoring of both oxygenation and ventilation adequacy required for perioperative patients who are receiving continuous or intermittent IV or neuraxial opioids?

Continuous electronic monitoring of oxygenation and ventilation adequacy is required for all patients during the entire time while they are receiving continuous or intermittent IV or neuraxial opioids. This includes after patients have been transferred from the perioperative setting to an inpatient setting when continued hospitalization is required. However, the scope of this assessment only includes the perioperative setting: the preoperative, intraoperative, and postoperative phases of a medical and/or surgical procedure, extending from the time a patient is prepared for a procedure until they are discharged home after the procedure or transferred out of the perioperative setting, usually to an inpatient bed. Thus, this assessment item only addresses continuous electronic monitoring of oxygenation and ventilation adequacy during the perioperative period or until discharge.

While facilities do not need to assess whether patients continue to be monitored after being transferred out of the perioperative setting, it is expected that such monitoring will continue as long as the patient is receiving continuous or intermittent IV or neuraxial opioids.

Key Element III: Communication of Drug Orders and Other Drug Information

Core Characteristic # 3

Item # 51

How do standard order sets for pre- and postoperative care improve safety? How can their use allow for individualized, patient-specific care?

Standard order sets that reflect evidence-based best practices can improve compliance with recommended processes of care. They can:

- Standardize, integrate, and coordinate care by communicating best practices
- Prevent gaps in care due to forgetting to order a particular medication, monitoring criteria, or other therapy
- Modify practice through evidence-based care
- Reduce variation and unintentional oversight of important treatment modalities
- Decrease the potential for medication errors through integrated safety alerts and reminders
- Improve patient outcomes

Most pre- and postoperative standard order sets are based on service lines, with a set of orders for each general type of medical or surgical procedure performed. Their development requires a thorough and ongoing review of evidence-based best practices and consensus among service line prescribers.

Although standard order sets are often a critical component for implementing best practices, they can also be flexible and allow customization of certain orders to individualize patient care. For example, dosing of medications is often customized to the patient within safe dosing ranges included in the order set. Additionally, while a standard order set may be fully applicable to most patients, a small percentage of patients may require customization of certain orders, such as opting out of an order or changing the order with justification.

Item # 53a

Why is this item limited to only adults and older pediatric patients? When is it appropriate to use PCA or PCEA for pediatric patients?

Infants and young children are not appropriate candidates for PCA or PCEA. Any patient using PCA or PCEA must have the mental alertness and cognitive, physical, and psychological ability to manage their own pain and self-administer each dose. One

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Self-Assessment Items continued

of the key safety features of PCA or PCEA is that a sedated patient will not press the button to deliver more opioid. Thus, only older pediatric patients who can manage their own pain and administer each dose are appropriate candidates for PCA or PCEA.

The benefits of PCA or PCEA have led some healthcare practitioners to unsafely extend its use to infants and young children, who cannot deliver each dose themselves, facilitating the dangerous practice of PCA (or PCEA) by proxy. PCA or PCEA use in infants and young children has also spurred ethical debates about the potential for undertreatment caused by the poorly coordinated efforts of family members (who are not at the bedside continuously) and clinicians, and the inability of these patients to clearly communicate their pain level. Also, while pediatric patients of any age may be a **HIGH-RISK PATIENT** for respiratory depression, the opioid (**NAÏVE**, **TOLERANT**) status of infants and young pediatric patients is often difficult to determine, adding to the risk of opioid toxicity.

Key Element IV: Drug Labeling, Packaging, and Nomenclature

Core Characteristic # 4

Item # 65

How can an examination of medication labeling and packaging for error potential be accomplished before use when product availability is quickly changing?

Product availability limitations and wholesaler contractual choices may mean that practitioners in perioperative settings often receive variable **COMMERCIALLY MANUFACTURED** and/or **COMMERCIALLY PREPARED** products. Although the medications may be the same as used previously, the labeling and packaging may be different, as well as the concentration, total amount in the container, and/or formulation. These are challenges practitioners may face daily—what they get today may be different tomorrow.

Nonetheless, a small group of interdisciplinary perioperative practitioners, or even a standing committee (e.g., pharmacy and therapeutics) or subcommittee at larger facilities, should take the time to examine the labeling and packaging of medications that are new or different than what was used previously, to identify error potential related to, for example:

- Look-alike or confusing drug name presentations, labeling, or packaging
- Possible confusion about the dose per mL (or per tablet) and the total dose in the container
- Lack of a single barcode that scans properly for each dose
- Cluttered labeling, small font size, not enough background contrast to read the label
- Unclear instructions for preparation
- Inadequate prominence of reminders and warnings
- Overemphasis of company logos and trade dress

If labeling and packaging error potential is identified, error-reduction strategies (e.g., auxiliary labels, interactive technology warnings, purchase from another manufacturer) should be implemented before using the product.

Item # 74

Why should the label of COMMERCIALLY PREPARED products prominently list the total amount of drug per total volume as the primary display of strength, followed by the per mL amount in parentheses?

Based on standards set by USP (USP General Chapter <7>) and enforced by the US Food and Drug Administration (FDA), all **COMMERCIALLY MANUFACTURED** products must prominently list the total amount of drug per total volume as the primary display of strength on the label, followed by the per mL amount in parentheses. Thus, most practitioners have become familiar with this presentation of strength and expect the first line of dosing information on a label to be the total amount of drug in the container.

In contrast, 503B outsourcers are not required to follow USP General Chapter <7> labeling requirements, and thus, **COMMERCIALLY PREPARED** products sometimes prominently display the per mL amount on the label, which may be requested

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Self-Assessment Items continued

by a facility. Having a combination of products with the per mL strength prominently displayed on the label and products with the per container amount prominently displayed on the label has led to errors in which the per mL amount was mistakenly believed to be the full amount of drug in a container.

A single, standard display of the strength is required to reduce the risk of errors. Thus, organizations should request the per container amount to be the prominent display on the label of all **COMMERCIALLY PREPARED** products. The per mL amount will also be listed below the per container amount, but the larger per container amount will alert practitioners to the total amount of drug in the container. The per mL amount, listed right below the per container amount, can be used by practitioners for dose calculations.

Key Element V: Drug Standardization, Storage, and Distribution

Core Characteristic # 6

Item # 92

For pharmacy-prepared IV medication infusions, REGIONAL ANESTHESIA infusions, irrigation and flush solutions, and cardioplegic solutions: Is it acceptable for perioperative practitioners to prepare and administer/use a temporary infusion/solution until the pharmacy can prepare and dispense a replacement infusion/solution?

No. The safety goal of this best practice is to avoid **PRACTITIONER-PREPARED** admixture or compounding in the immediate perioperative setting and to instead use **COMMERCIALLY MANUFACTURED**, **COMMERCIALLY PREPARED**, and/or pharmacy-prepared solutions, which have typically undergone a rigorous quality control check to verify the infusion/solution contents. If a **COMMERCIALLY MANUFACTURED**, **COMMERCIALLY PREPARED**, or pharmacy-prepared infusion/solution is not readily available in the perioperative setting and workflow issues cause a delay in dispensing an infusion/solution, patient needs will dictate whether perioperative practitioners will be required to mix or compound a temporary infusion/solution. However, even temporary **PRACTITIONER-PREPARED** infusions/solutions do not meet the intent of this best practice except in emergencies.

Items # 93 and # 94

Do these best practices mean that prefilled syringes are used for at least 80% of all medication doses administered from a syringe in the perioperative setting, or that prefilled syringes are used for at least 80% of all the different medications administered from a syringe in the perioperative setting?

This best practice recommends using prefilled syringes for at least 80% of the total number of medication doses administered via syringe in the perioperative setting, not at least 80% of all the different medications administered via syringe in the perioperative setting. In most perioperative settings, the common medications administered via a syringe are lidocaine, propofol, fenta**NYL** or another opioid, a neuromuscular blocking agent, and vasoactive medications. These medications likely represent more than 80% of the total number of medication doses administered via syringe in the perioperative setting, which should be provided in prefilled syringes. This best practice does not mean that at least 80% of all the different medications that might be administered via syringe are available in prefilled syringes, which may not be practical.

Core Characteristic # 7

Item # 105

Why must a full dose of dantrolene/Ryanodex be available for use within 10 minutes of diagnosing a malignant hyperthermia event?

The Malignant Hyperthermia Association of the United States (MHAUS) recommends that a full dose of dantrolene/Ryanodex be readily available for use within 10 minutes of recognizing a malignant hyperthermia crisis. The likelihood of serious complications from malignant hyperthermia increases with every 10-minute delay in treatment, reaching complication rates of 100% with a 50-minute delay (Joshi GP, Desai MS, Gayer S, Vila H. Succinylcholine for emergency airway rescue in class B ambulatory facilities: The Society for Ambulatory Anesthesia position statement. *Anesth Analg.* 2017;124[5]:1447–9). Thus, treatment with dantrolene/Ryanodex should be initiated within 10 minutes of diagnosis.

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Self-Assessment Items continued

Core Characteristic # 8

Item # 115
What are interactive alerts and why are they important?

The most noticeable and effective alerts are placed in such a way that the task is temporarily interrupted, and the recipient must physically interact with it in some way to continue. Interactive alerts are not easily overridden and may involve answering questions or entering or confirming critical information. In contrast, passive alerts do not require any special actions from recipients and are more easily overridden and less effective for alerting recipients to hazards and encouraging compliance with the desired safe behaviors. While interactive alerts are desirable, they are intrusive to the process and should be reserved for the most critical alerts.

Key Element VI: Medication Delivery Device Acquisition, Use, and Monitoring

Core Characteristic # 10

Item # 149
What is NRFit?

Medical device connectors for neuraxial applications are changing from Luer connectors to ISO 80369-6-compliant connectors, which are incompatible with the Luer system, thus preventing misconnections. NRFit is the name selected for these ISO-compliant neuraxial connectors. The NRFit connector diameter is smaller than the Luer connector diameter, with a smaller collar and tip, making it unlikely that a medical device intended for neuraxial applications will fit together with medical device connectors used for other clinical applications, such as respiratory, enteral, urological, limb cuff, or IV routes of administration. There appears to be an industry trend to use yellow for NRFit devices and to include a NRFit logo on compliant devices.

NRFit connectors were developed because of numerous wrong-route errors, some with catastrophic outcomes, occurring around the world. Neuraxial administration of IV medications and vice versa have been particularly concerning. Implementation of the NRFit connector provides a way to reduce the risk of neuraxial misconnections. NRFit must be introduced in a healthcare organization in a planned and coordinated manner. For details on how to implement NRFit, visit: www.ismp.org/node/18860.

Key Element VII: Environmental Factors, Workflow, and Staffing Patterns

Core Characteristic # 11

Item # 150
What are foot-candles?

A foot-candle (fc) is a unit of illumination or brightness equivalent to that produced by one candle at a distance of 1 foot (USP General Chapter <1066> *Physical Environments That Promote Safe Medication Use*. October 1, 2010. www.ismp.org/ext/525). Each foot-candle is equal to 1 lumen per square foot. Foot-candles are commonly measured by a light meter (photometer) with an illuminance/brightness sensor in foot-candles (or lux). In some standards, the term candela has replaced foot-candle as the measure of illumination, which is also equal to 1 lumen per square foot (or 10.764 lux). A light meter can be used to ensure that perioperative areas where medications are stored, prepared, checked, and administered are properly lit with lighting levels between 90 to 150 foot-candles.

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Self-Assessment Items continued

Core Characteristic # 12

Item # 157

What are the main components of a fatigue reduction plan?

Perioperative leaders and practitioners should collaborate to permanently shift the pervasive cultural expectation that staff must (or can) work when fatigued. This should start with a preemptive fatigue reduction plan that includes fatigue prevention strategies, confidential fatigue assessment and reporting, and fatigue management steps when such conditions are identified (Battié RN, Rall H, Khorsand L, Hill J. Addressing perioperative staff member fatigue. *AORN J*. 2017;105[3]:285-91).

Prevention strategies may include establishing non-fatiguing perioperative staffing patterns, such as avoidance of overtime on routine shifts, clear guidance on the use of overtime during on-call assignments, shift time limitations (8 hours vs. 12 hours), breaks during each shift, napping if allowed, sufficient downtime between shifts, and limitations on the number of shifts worked in a row before a day off. Prevention of fatigue may also require examining the perioperative schedule each day to anticipate fatigue-inducing case loads and, after mutual agreement, offering shift adjustments to affected practitioners.

Perioperative practitioners should also feel safe participating in a daily fatigue assessment and reporting conditions when they feel it might be unsafe for them to perform a task. The American Society of PeriAnesthesia Nurses (ASPAN) offers an online fatigue evaluation checklist and self assessment (www.ismp.org/ext/537, members-only access).

If practitioner alertness is questionable, and/or a practitioner states that they feel fatigued, conversation between the practitioner and perioperative leader regarding accommodations due to fatigue is required. Leaders should be prepared for the possibility of:

- Overnight on-call personnel not working their regularly scheduled shifts
- Delaying procedures until adequate staffing is found
- Reassigning essential tasks
- Encouraging ridesharing and napping for fatigued staff who cannot safely drive home

Importantly, an adjusted case load, delay in procedures, or planned late arrival of a perioperative practitioner due to fatigue from working on call and/or overtime should not result in **DISCIPLINARY SANCTION** or other punitive action.

Key Element X: Quality Processes and Risk Management

Core Characteristic # 16

Item # 185

How can the severity of the outcome of an adverse event influence a leader's or manager's response towards individuals involved in an event and/or the need for SYSTEM REDESIGN?

A severity or outcome bias exists when healthcare leaders and managers make decisions about individuals and systems based on the outcome of an event—the more severe the outcome, the more severe the response. The problem with allowing a severity or outcome bias to drive our response to an event is two-fold. First, when we base our decisions on the outcome, we may punish individuals who do not deserve to be punished, simply because there was an adverse outcome, rather than fairly and justly evaluating the quality of their behavioral choices. Second, a severity or outcome bias promotes a "no harm, no foul" culture that underreacts to events and potentially fatal **SYSTEM DESIGN** flaws that have not yet caused patient harm. Leaders and managers may wait until harm happens before responding to the risk. In a **JUST CULTURE**, the severity or outcome bias must be removed from the assessment of the system and the quality of the behavioral choices of involved individuals. Leaders and managers must respond to the risk by redesigning systems and reducing risky behavioral choices, regardless of whether harm has occurred.

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Self-Assessment Items continued

Item # 187

Should DISCIPLINARY SANCTIONS be taken against a practitioner making frequent errors or for violating a policy or procedure?

Not necessarily. Most policy violations are **AT-RISK BEHAVIORS** that require **SYSTEM REDESIGN** and practitioner **COACHING**, not **DISCIPLINARY SANCTION**. It is human nature to drift away from strict procedural compliance and to develop unsafe habits for which we fail to see the risk. Human behavior runs counter to safety because the rewards for risk taking (e.g., saved time) are often immediate and positive, while possible adverse outcomes are often delayed and remote. As a result, even the most educated and careful individuals will learn to master dangerous shortcuts, particularly when faced with an unanticipated system problem (e.g., technology glitches, time urgency). Over time, the risk associated with these behaviors fades. Individuals are not choosing to put patients in harm's way; instead, they feel they are still acting safely. To effectively manage policy violations, removing the barriers to safe behavioral choices, removing the rewards for successful policy violations, and **COACHING** individuals to see the risk associated with their choices is recommended.

Likewise, leaders and managers should not mete out **DISCIPLINARY SANCTION** for repetitive **HUMAN ERRORS**, which are not behavioral choices. Human fallibility is inevitable, and for every task there is a natural rate of error, so we are all destined to make repetitive **HUMAN ERRORS**. **HUMAN ERROR** is inadvertent, so **DISCIPLINARY SANCTIONS** are both unfair and ineffective. If a leader or manager is concerned about a series of **HUMAN ERRORS** an individual has made, further investigation should focus on making sure the erroneous task is being carried out as designed, determining if behavioral choices are setting the individual up to make **HUMAN ERRORS**, and identifying and correcting any system-based causes of the repetitive **HUMAN ERRORS**.

DISCIPLINARY SANCTION is warranted for **RECKLESS BEHAVIOR**—a conscious disregard of a known substantial and unjustifiable risk. More on these topics can be found at: www.ismp.org/node/18547.

Core Characteristic # 17

Item # 190

What are PATIENT SAFETY LEADERSHIP WALKROUNDS and how are they carried out?

PATIENT SAFETY LEADERSHIP WALKROUNDS are a process designed to open the lines of communication between perioperative practitioners and senior leaders. The core **PATIENT SAFETY LEADERSHIP WALKROUNDS** team should consist of at least one senior-ranking executive (e.g., chief nursing officer, chief operating officer); the manager and/or director of the perioperative setting (e.g., **OPERATING ROOM** manager, medical director, department of surgery chief); a patient safety advocate (e.g., **MEDICATION SAFETY OFFICER**, patient safety officer, quality or risk manager); and a scribe to document the conversation. A staff member who perioperative practitioners consider to be an informal leader may also be a regular member of the **PATIENT SAFETY LEADERSHIP WALKROUNDS**.

The rounds should be designed to accomplish four primary goals:

1) Obtain information from frontline staff about processes, the culture, and barriers to safety
2) Increase awareness of safety issues among all perioperative practitioners and leaders
3) Demonstrate leadership commitment to safety as a high priority
4) Act, after careful analysis, on the information collected from perioperative practitioners to improve the work environment and the overall delivery of care

The **PATIENT SAFETY LEADERSHIP WALKROUNDS** should be conducted in a safe, non-judgmental environment, without risk of embarrassment or retribution to those who speak up. To elicit dialogue about episodes of harm or concerns about risk, scripted questions should be asked, such as:

- In what way does the system fail you?
- What keeps you up at night with worry about your work?
- How was the last patient harmed in any way?
- Can you think of how a patient was prevented from harm as a result of your interaction?

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Self-Assessment Items continued

After the rounds, the information collected should be analyzed and used to categorize and prioritize action items, develop an action plan, implement the plan, and measure progress. Structures should be developed to provide communication back to all rounds' participants, senior leaders, appropriate committees, and the Board of Trustees/Directors.

Core Characteristic # 19

Item # 214

Should PN be discontinued or continued during a medical and/or surgical procedure?

The American Society for Parenteral and Enteral Nutrition (ASPEN) has not issued an official recommendation regarding PN and surgery. This issue was considered in 2014 during the development of ASPEN PN consensus recommendations (Ayers P, Adams S, Boullata J, et al. A.S.P.E.N. parenteral nutrition safety consensus recommendations. *JPEN J Parenter Enteral Nutr.* 2014;38[3]:296-33). However, there was little scientific evidence to support one specific recommendation. Evaluation of the optimal approach for managing PN during surgery is a topic requiring further research due to variability in the complexity and length of each procedure and the patient's condition. For example, there is a vast difference between a simple surgical wound debridement in a young, healthy patient and a long and complicated pancreaticoduodenectomy in an elderly patient with comorbid conditions.

As with other areas of PN administration, ASPEN recommends that providers develop policies regarding PN infusions and appropriate metabolic monitoring during surgery. When the PN infusion is continued during surgery, the prescribed infusion rate should be maintained, with close monitoring of blood glucose levels and insulin administration as needed to maintain glycemic control. The use of PN infusions for fluid resuscitation should be avoided. When PN infusions are discontinued during surgery, consideration should be given to avoiding unnecessary manipulations of the catheter hub and close monitoring of blood glucose levels.

Items # 217 and # 218

Why should medications from COMMERCIALLY MANUFACTURED, cartridge-type syringes never be withdrawn into another syringe for administration?

Cartridge-type syringes (e.g., Carpuject) were introduced to the marketplace to save time, avoid delays in administration, and reduce the risk of errors. Over the years, practitioners have adopted an unsafe practice of using the prefilled syringe cartridges as single-dose or multiple-dose vials by withdrawing the medication from the cartridges. Using the cartridges as vials can lead to contamination, given that the cartridges were not intended to be used in this manner. This unsafe practice can also lead to dosing errors, drug mix-ups, and other types of medication errors, particularly because the prepared syringes are often unlabeled.

Item # 219

Why is it an unsafe practice to dilute or reconstitute an IV push medication by drawing up the contents into a COMMERCIALLY MANUFACTURED prefilled flush syringe of 0.9% sodium chloride?

COMMERCIALLY MANUFACTURED prefilled syringes of 0.9% sodium chloride (and heparin) are regulated by the US Food and Drug Administration (FDA) as devices and approved only for the flushing of vascular access devices. They have not been approved or tested for the reconstitution, dilution, and/or subsequent administration of IV push medications, and manufacturers clearly warn on the syringe barrel that the solution should be used for "IV flush only."

Also, the mislabeling that occurs when medications are added to a prefilled syringe and a secondary label is not applied creates significant risk for errors. In many cases, the manufacturer's label is permanently affixed to the syringe barrel and contains product codes and a barcode, as well as specific information about the fluid and its volume. When another medication is added to this syringe, there is no adequate method to amend the manufacturer's label, without covering the current information. Thus, the syringe frequently remains labeled as 0.9% sodium chloride, when it also contains the diluted or reconstituted medication.