ISMP **Guidelines for Safe Medication Use in Perioperative and Procedural Settings**

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

www.ismp.org

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DEDICATION

These best practice guidelines are dedicated to the memory of Ronald Litman, DO, ML, ISMP's medical director, from 2015-2021. We knew Ron best as our medical director, but he was also a practicing pediatric anesthesiologist at Children's Hospital of Philadelphia (CHOP), and Professor of Anesthesiology and Pediatrics at the Perelman School of Medicine at the University of Pennsylvania. Ron dedicated his life's work to enhancing the patient experience and educating the next generation of providers regarding safe clinical practice, with an eye towards improving the safety of the medication use process. Ron selflessly gave his own time for work on this grant and was an unparalleled champion of this project from the very beginning.

Introduction and Background

Harmful medication errors are a significant public health problem, causing at least 1 death every day and injuring 1.3 million people annually.[1] In the perioperative setting, medication errors occur frequently in all phases of perioperative care and are a common cause of morbidity and mortality.[2-4]

The frequency of medication errors reported in perioperative settings varies widely depending on detection and measurement strategies. Studies report frequencies ranging from 1 medication error in half of all surgical procedures when using observational techniques and record reviews to detect and identify the errors,[5] to as few as 1 error in every 1,285 procedures when relying on self-reported medication errors.[6] A study in one of the few large hospitals that uses **BARCODE SCANNING** and audio/visual feedback to verify the drug prior to administration in the **OPERATING ROOM (OR)** found as many as 1 error in every 20 medication administrations.[5] More than one-third of the errors led to patient harm, and the remaining two-thirds had the potential to cause harm.

Overall, medication errors are estimated to occur in *at least* 1 in every 133 doses administered during anesthesia, alone.[7,8] Given 51.4 million inpatient and 53.3 million outpatient surgical procedures in the US per year, at least 787,218 perioperative medication errors are estimated to occur annually. These errors can cost healthcare organizations up to $5.6 million every year.[9,10]

Although surgery is often considered a single event, a patient moves through the entire perioperative care system during the surgical process, consisting of several different departments, teams, and medication processes.[11] When medication errors occur, they are often the result of the complexity of care combined with the fast-paced and fragmented nature of perioperative service delivery.[5,12,13]

Commonalities and differences can be seen in the types of errors, medications, and contributing factors associated with medication errors occurring in different perioperative and procedural locations. In *preoperative* locations, antibiotics are the most frequent medications involved in errors, along with patient nonadherence to medication instructions prior to arrival for the procedure.[2,14,15] Knowledge deficits, unclear or misunderstood preoperative medication instructions, and errors in transcription of home medications are the most common contributing factors.[15,16]

In *intraoperative* locations such as the **OR**, analgesics, antibiotics, muscle relaxants, and vasopressors are most often involved in errors.[4,5,14,17,18] In particular, Nanji et al[5] noted fenta**NYL**, propofol, and phenylephrine to have the greatest incidence of error. Wrong drug errors due to substitution or syringe swaps, incorrect doses, omissions, and wrong route errors account for up to 70% of all medication error types that occur in intraoperative locations.[3] The medications most often involved in syringe swaps are muscle relaxants and reversal agents[18,19]; differences in anesthesia color-coded syringe labels have not significantly reduced the risk of these errors.[19] Haste; distractions; unlabeled syringes; look-alike appearance of vials, ampules, and labels; knowledge deficits; and communication problems are the most frequently cited causes of intraoperative errors.[2,4,6,8,18,20] Errors in the **OR** are more prevalent later in the day[21,22] and during procedures lasting longer than 6 hours[5] due in part to fatigue.[14,17]

In *postoperative* locations, antibiotics and anticoagulants are commonly associated with errors[20]; antiemetics and anticholinergics are less frequently involved.[8,18] The most prevalent contributing factors are knowledge deficits, known patient allergies, fragmentation of care, and communication problems that result during transfers of care and changes in healthcare providers.[2,4,6,8,18,20-22] Decreased awareness by both patients and physicians of the need to restart medications after surgery has also led to medication errors.[15,16]

Approach to Guideline Development

Recognizing some of the unique medication-related challenges associated with perioperative and procedural locations, ISMP conducted an FDA-funded study in 2019–2022 to identify and quantify the current state of perioperative medication safety systems and practices in US hospitals and ambulatory surgery centers (ASCs), and to test whether differences in organizational demographics significantly influence the level of medication safety. The scope of this assessment project, the *ISMP Medication Safety Self Assessment® for Perioperative Settings* (and subsequent guideline tool development), included perioperative and procedural processes, staff, equipment, environment of care, and medications associated with medical and/or surgical procedures that require **MODERATE SEDATION, DEEP SEDATION, MONITORED ANESTHESIA CARE (MAC), REGIONAL ANESTHESIA** and/or **GENERAL ANESTHESIA**, including diagnostic and **INVASIVE PROCEDURES** that meet this definition. Excluded were procedures that require only minimal sedation, or the care of patients after they are discharged from the facility or transferred out of the perioperative setting to an inpatient bed. Over 385 US facilities (326 hospitals and 60 ASCs) provided data on their current practices as part of this assessment process.

This national assessment was an essential first step toward understanding a baseline of practices and improving medication safety in the perioperative setting.[23] It can itself be used to provide knowledge to healthcare providers about best practices. More importantly, it enables organizations and practitioners to proactively recognize and prioritize gaps in their medication systems and practices not currently recognized through voluntary medication error reporting and analysis.[24] Organizations are encouraged to proactively understand their current state and develop necessary action plans based on best practices.[25] Nationally, some of the lowest-scoring Key Elements and Core Characteristics in the assessment identified the lack of redundancies to detect and correct errors before they reach patients; limits on the complement of qualified and well-rested practitioners to match the clinical workload; the challenges with procurement, standardization, and safe use of medication-related devices; and limited abilities to collect and use essential drug information to make informed decisions.[26]

Consensus Building National Summit

With early assessment results as a backdrop, ISMP held a two-day national invitational perioperative summit in November 2021 to discuss priority medication safety-related topics with clinical experts, representatives from professional organizations, and industry leaders. The goals for the summit entitled ***The Future of Perioperative Medication Safety: Charting our Path Forward*** were to:

- Examine and gain consensus on the most common modifiable medication use risks in inpatient and ambulatory perioperative settings.
- Identify and remove barriers to the adoption of proven technologies that support the safe use of medications in perioperative care settings.
- Develop and communicate best practices associated with the labeling of medications across all phases of perioperative care (including labeling of outsourced compounded injectables).

Expert faculty provided background for participant dialogue on three priority topics, including labeling practices, workflow issues that limit the adoption of known safety technologies including **SMART INFUSION PUMPS**, and the ability to use **BARCODE SCANNING** for real-time drug identification and electronic health record documentation. Upon completion of the summit, participants were asked to provide input on 33 best practice statements, which were then used as a foundation for the final set of guidelines.

How to Use the Guideline Statements

Based on the national results from the ***ISMP Medication Safety Self Assessment® for Perioperative Settings***, literature review, analysis of events reported to the ***ISMP National Medication Errors Reporting Program*** (ISMP MERP), onsite clinical observations by ISMP consultants, and consensus feedback from a national perioperative summit, ISMP has prioritized 71 best practice statements that lend themselves to the biggest opportunity for safety improvement. Public comments were solicited for these statements during a 3 week period where practitioners and organizations were invited to comment, and necessary revisions were completed.

This set of guidelines is made available to hospitals, ambulatory surgery centers, and other procedural locations to address identified national gaps in perioperative and procedural medication safety, providing a steppingstone and support for further implementation of organization-specific action plans to reduce harmful patient events. Each organization should regularly evaluate their practices in perioperative and procedural settings. This includes an ongoing internal process to evaluate safety signals such as reported events, close calls, and hazardous conditions that threaten the safety of the perioperative process.[24] In addition, organizations are encouraged to seek out and use information about medication safety risks and errors that have occurred in other organizations and act to prevent similar errors.[25,27]

Recommendations contained within these guidelines were developed to be used in concert with other relevant resources, including guidelines and recommendations from Anesthesia Patient Safety Foundation (APSF), American Society of Health-System Pharmacists (ASHP), the Association of periOperative Registered Nurses (AORN), and other professional sources, after careful review of applicable regulatory standards.

Bolded terms in **SMALL CAPITAL FONT** are described in the Definitions section of the document.

Ambulatory Surgery Center Opportunities for Safety Enhancements

These guidelines were established with the knowledge that ASCs and other ambulatory procedural locations are a growing and vital segment of healthcare delivery in the United States. In recent years, acuity and demand in ASC settings has been increasing, and at times, without evidence of corresponding growth in dedicated medication error prevention efforts. Many ASC practitioners who participated in the self assessment and/or reviewed the draft guidelines reported less staffing and technology resources than practitioners in inpatient perioperative and procedural care. Due to this disparity, ASC respondents questioned the applicability of certain statements within these guidelines for their practice.

It is ISMP's belief that ambulatory sites, including ASCs, performing similar procedures with similar risk merit the same level of attention to medication safety practices and standards as acute care facilities. We hope that ASCs and other ambulatory procedural settings will view these guideline statements as a roadmap and take the opportunity to align themselves with proven technologies and safety practices identified to limit risk and keep all patients safe during the medication use process, regardless of practice location.

How to Cite the Guidelines:

Institute for Safe Medication Practices (ISMP.) *ISMP Guidelines for Safe Medication Use in Perioperative and Procedural Settings.* ISMP; 2022.

Guideline Statements

KEY ELEMENT I: PATIENT INFORMATION

Essential patient information is obtained, readily available in useful form, and considered when prescribing, dispensing, and administering perioperative medications, and when monitoring the effects of these medications.

Statements

1.1 Reconcile medications taken at home by the patient (or administered in the facility) before the medical and/or surgical procedure with the list of medications prescribed in the perioperative or procedural setting:

- Before arrival (or no later than the time of admission/encounter)
- Upon transfer within the facility (e.g., from the **POST-ANESTHESIA CARE UNIT [PACU]** to an inpatient unit)
- At discharge after surgery or a procedure

Any identified discrepancies (e.g., omissions, duplications, contraindications, unclear information) are resolved as soon as possible.

1.2 On the day of the medical and/or surgical procedure, obtain patient weights measured only in metric units (e.g., grams or kilograms). Avoid the use of a stated, estimated, or historical weight.[28]

Exception: *Excludes life-threatening situations where the delay involved in weighing the patient could lead to serious harm (e.g., major trauma).*

1.3 Employ a standard organizational process to determine if an adult or pediatric patient is **OPIOID-NAÏVE** or **OPIOID-TOLERANT**, and at high risk for respiratory depression. Document findings in a designated, shared electronic health record (EHR) location to automate clinical decision support.[29-32]

1.4 Use continuous electronic monitoring of both oxygenation (e.g., pulse oximetry) and adequacy of ventilation (e.g., **END-TIDAL CARBON DIOXIDE [ETCO$_2$] MONITORING [CAPNOGRAPHY]**) for patients in perioperative and procedural settings receiving one or more of the following:

a) **MODERATE SEDATION**, **DEEP SEDATION**, **MONITORED ANESTHESIA CARE (MAC)**, and/or **GENERAL ANESTHESIA** until facility-defined parameters for recovery have been reached

b) Continuous or intermittent intravenous (IV) or neuraxial opioids (including patient-controlled analgesia [PCA] or patient-controlled **EPIDURAL** analgesia [PCEA])

c) **REGIONAL ANESTHESIA** (e.g., interscalene block) with **both** a local anesthetic and an opioid

KEY ELEMENT II: DRUG INFORMATION

Essential drug information is readily available in useful form and considered when prescribing, preparing, dispensing, and administering perioperative medications, and when monitoring the effects of these medications.

Statements

2.1 Establish and implement safe dosage ranges, taking into consideration patient-related factors such as age, opioid status, and organ function (e.g., renal impairment, liver impairment), for:

- a) Perioperative IV push doses and/or infusions of high-alert medications (e.g., opioids, midazolam, heparin, insulin, vasopressors, and neuromuscular blocking agents [NMBs])
- b) Local anesthetics for peripheral nerve blocks
- c) **NEURAXIAL ANESTHESIA** and/or **EPIDURAL** injections/infusions
- d) Antibiotics

2.2 Create and implement a process to assess for and hold a patient's current medications (i.e., **ANTITHROMBOTIC MEDICATIONS**, **INSULIN**), if necessary, prior to a surgical or diagnostic procedure. Additionally, ensure the process includes a review to restart, retime, or discontinue these same medications following the procedure.

2.3 Enter **pre**operative/**pre**procedural and **post**operative/**post**procedural orders for medications (including solutions for hydration) into an EHR with clinical decision support. Have pharmacist(s) (remotely or onsite) verify these medications orders (including solutions for hydration) before medications are administered.

Exception: *This statement excludes medications administered by* ***ANESTHESIA PROVIDERS*** *as part of their anesthetic management of the patient.*

Note: *For scheduled procedures, the purpose of electronic order entry* ***and*** *verification is to screen against the patient's current medications and medical profile to identify potential allergies, contraindications, interactions, duplicate therapy, and the accuracy and appropriateness of doses before medications are administered.*

2.4 Utilize standard electronic formats, associated with the EHR, for practitioner-and/or procedure-specific preference cards which are updated and/or approved annually by an interprofessional committee. Physical and/or handwritten preference cards are avoided.

Note: *Preference cards may be used as standing orders if approved as such by the organization. Patient care orders, including those from preference cards, must be documented in the patient's medical record*.[33]

2.5 Establish and implement standard policies, protocols, guidelines, and/or order sets to identify, treat, and monitor postprocedural and/or postoperative patients for signs of hyponatremia, water intoxication, and/or syndrome of inappropriate antidiuretic hormone (SIADH).

2.6 Establish a protocol and maintain appropriate quantities of drugs required for treating malignant hyperthermia, based on current reference material from the Malignant Hyperthermia Association of the United States (MHAUS). This protocol and MHAUS resources, including the hotline phone number, should be available in all areas of the organization where **GENERAL ANESTHESIA** is administered (e.g., labor and delivery, ambulatory surgery centers). Provide regular *in situ* simulation training for this form of rescue.[34]

KEY ELEMENT III: COMMUNICATION OF DRUG ORDERS AND OTHER DRUG INFORMATION

Methods of communicating drug orders and other drug information in the perioperative setting are streamlined, standardized, and automated to minimize the risk of error.

Statements

3.1 Only accept face-to-face verbal orders from prescribers who are onsite in the facility during emergencies or during sterile procedures where ungloving would be impractical and jeopardize patient care.

Note: *When receiving verbal orders during emergencies or sterile procedures, repeat back medication orders to the prescriber to confirm the order before administration. Verbal medication orders should include the following: full medication name, doses digit-by-digit (e.g., "one-five" instead of "15"), unit of measure (e.g., mg, mcg), and route of administration. Directly enter all verbal orders into the EHR as soon as possible.*

3.2 Establish and utilize standard protocols, guidelines, and/or order sets for the management of patients who receive an IV or neuraxial opioid postoperatively for pain management, which include dosing guidelines that differentiate between the management of **OPIOID-NAÏVE**, **OPIOID-TOLERANT**, and/or **HIGH-RISK PATIENTS**, as well as conditions that require dose adjustments.

KEY ELEMENT IV: DRUG LABELING, PACKAGING, AND NOMENCLATURE

Strategies are undertaken to minimize the possibility of perioperative errors with manufacturer-prepared, pharmacy-prepared, or commercially prepared (e.g., from a compounding pharmacy or outsourcing facility) drug products that have similar or confusing labeling/packaging and/or drug names that look and/or sound alike.

Statements

4.1 Strive to configure medication vial storage in medication trays, kits, carts, and/or automated dispensing cabinets (ADCs) to allow practitioners to immediately view the vial label (i.e., label is facing up) while selecting medications, instead of a "cap up" storage configuration in which only the top of the vial is facing up.

4.2 Clearly label storage bins and/or ADC pockets, drawers, kits, and/or trays containing NMBs 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"). In addition to the manufacturer's warning on the caps and ferrules, an auxiliary label may be affixed directly on each vial.[35,36]

Readable labels that clearly identify drugs are on all drug containers in the perioperative setting, and drugs remain labeled up to the point of actual drug administration.

Statements

4.3 Eliminate the use of handwritten labels in perioperative/procedural areas by 2025.

Exception: *This excludes medication labels used on the **STERILE FIELD**. Use sterile, pre-printed medication labels on the **STERILE FIELD**, whenever possible.*

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KEY ELEMENT IV continued from page 10

4.4 Include a machine-readable code (e.g., barcode, radiofrequency identification [RFID]) on all syringe and infusion labels, including those that are **PRACTITIONER-PREPARED**, by 2025.

Exception: *This excludes medication labels used on the* ***STERILE FIELD****. Use sterile, pre-printed medication labels on the* ***STERILE FIELD****, whenever possible.*

4.5 Label **PRACTITIONER-PREPARED** syringes of medications with, at a minimum, the full name, concentration/dose of the drug, name or initials of the preparing practitioner, as well as an expiration date (when not used in 24 hours) and time (if expiration occurs in less than 24 hours). Application of an anesthesia color-coded drug class label alone is not sufficient.

Exception: *When allowed by an organizational policy or procedure, syringe labeling is not required if it is prepared immediately before drug administration, never leaves the hand of the preparer before administration, and the entire dose in the syringe is immediately administered, or the remaining volume is immediately wasted or discarded before the syringe leaves the preparer's hand. A beyond-use date and time are not necessary for short procedures, as defined by the facility.*[37,38]

4.6 Require labeling, even if only one medication/solution is on the **STERILE FIELD.**[38]

4.7 Label containers (e.g., syringes, bowls, cups, basins) with medications and solutions (e.g., lidocaine, contrast, methylene blue, thrombin) on the **STERILE FIELD** immediately after filling.[38]

4.8 Never label an empty syringe, basin, cup, or other container in anticipation of use.[37,38]

4.9 Verbally and visually confirm all medications delivered to the **STERILE FIELD**, including medication name, strength, dosage, and expiration date. This verification is completed by the circulating registered nurse and surgical technician, or with the licensed professional performing the procedure, if no surgical technician is available.[38]

4.10 Immediately discard any unattended, unlabeled medication or solution.[38,39]

KEY ELEMENT V: DRUG STANDARDIZATION, STORAGE, AND DISTRIBUTION

IV and REGIONAL ANESTHESIA solutions, drug concentrations, doses, and administration times are standardized whenever possible.

Statements

5.1 For each patient population (adult, pediatric, and neonatal), establish a limited number of standard drug and solution concentrations in the perioperative setting for the following:

- **a)** IV medication infusions (e.g., high-alert medications such as opioids, heparin, insulin, vasopressors, oxytocin, and NMBs)
- **b)** IV hydration infusions
- **c)** **REGIONAL ANESTHESIA** excluding **BOLUS DOSES**
- **d)** **NEURAXIAL ANESTHESIA**
- **e)** Peripheral nerve blocks
- **f)** Parenteral medications used during ophthalmic procedures
- **g)** Irrigations and flush solutions (e.g., heparinized saline)
- **h)** Medications and solutions administered by an **ELASTOMERIC PUMP**
- **i)** Cardioplegic solutions

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KEY ELEMENT V continued from page 11

5.2 Maximize the use of manufacturer-prepared, pharmacy-prepared, or commercially prepared (e.g., from a compounding pharmacy or outsourcing facility) syringes in the perioperative setting for adult, pediatric, and neonatal medication doses.

5.3 When no compounding technology is available, or when no pharmacy or pharmacist is available (e.g., ambulatory settings), the following recommendations should be considered to safely use compounded sterile preparations:

- Maximize the use of manufacturer-prepared products
- Purchase products in patient-specific doses that are ready to administer
- If manufacturer-prepared products are not available, investigate the use of commercially prepared products (e.g., from a compounding pharmacy or outsourcing facility).[40,41]

Medications are provided to and stocked in perioperative settings in a safe and secure manner and are available for administration within a timeframe that meets essential patient needs.

Statements

5.4 Segregate, sequester, and differentiate all NMBs from other medications, wherever they are stored in the organization.

- Eliminate the storage of NMBs in areas of the facility where they are not routinely needed.
- Place NMBs—preferably in a rapid sequence intubation (RSI) kit, in locked-lidded ADC pockets/drawers, or in a sealed box—in patient care areas where they are needed (e.g., perioperative and facility-defined procedural locations, labor and delivery units, ambulatory surgery centers).[36]

5.5 Select, segregate, and secure medications and solutions for injection or irrigation one patient case at a time, immediately prior to the medical and/or surgical procedure. Medications and solutions for multiple patient cases are not removed from storage or prepared at the same time.

5.6 Provide benzocaine oral topical anesthetic spray (to suppress the gag reflex) in a metered dose formulation to limit the duration of each spray and the amount of medication applied, thus lessening the risk of methemoglobinemia.

Note: *Ensure antidotes, reversal agents, and rescue agents are available to be administered if needed. Ensure coupled order sets and protocols are in place for reference.*[42-44]

5.7 Use vials, or a 2- or 3-liter bag, of sterile water for injection, for the preparation of dantrolene formulations. Store sterile water vials or bags used in the reconstitution of dantrolene separately from other IV bag products in the malignant hyperthermia kit or cart.

Note: *Avoid the use of 1,000 mL bags of sterile water for injection, irrigation, or inhalation. Accidental infusion of sterile water may be fatal.*[34,45]

Access to perioperative medications is restricted and controlled.

Statements

5.8 To prevent accidental intravascular injection, whenever possible, delay the placement of clearly labeled topical thrombin on the **STERILE FIELD** until after all parenteral products have been administered. If a delay is not possible, topical thrombin must be sequestered or separated from any parenteral products that are open or immediately available for use on the **STERILE FIELD**.

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KEY ELEMENT V continued from page 12

5.9 Prioritize the use of **PROFILED ADCs** in **pre**operative/**pre**procedural and **post**operative/**post**procedural settings to allow for medication selection after orders have been reviewed and verified by a pharmacist.

Note: *Removal of medications via the* ***OVERRIDE*** *function should be reserved for urgent or lifesaving situations in which a delay would harm the patient.*

Note: *Anesthesia workstations located in* ***intra****operative or facility-defined procedural areas are commonly* ***NOT*** **PROFILED** *and are excluded from* ***OVERRIDE*** *functionality.*[35,46]

5.10 Require a medication order (e.g., electronic, verbal/telephone) or have an approved protocol in effect prior to removing any medication from storage or from ADCs (if available), even if they are removed using the **OVERRIDE** function.

Exception: *This statement excludes medications administered by* ***ANESTHESIA PROVIDERS*** *as part of their anesthetic management of the patient.*[33,46,47]

5.11 If irrigation solutions are not available as manufacturer-prepared or commercially prepared products (e.g., from a compounding pharmacy or outsourcing facility), ideally have pharmacy prepare, label, and supply these solutions, for perioperative and procedural settings.

HAZARDOUS DRUGS, chemicals, and potentially flammable products used in the perioperative setting are safely prepared, dispensed, stored, and administered.

Statements

5.12 Establish and use a protocol to address the safe preparation, handling, transport, storage, administration, disposal, and management of spills for **HAZARDOUS DRUGS** used in the perioperative setting.[48]

5.13 Implement a process for monitoring perioperative and procedural staff who are exposed to **HAZARDOUS DRUGS** based on their job duties. A confidential medical surveillance program should be employed that assesses and documents symptom complaints, physical findings, and appropriate laboratory values.

5.14 Take steps to reduce flammability risks associated with topical skin preparations:

- **a)** Consider the flammability risk when selecting products.
- **b)** Select single-use, properly sized, prefilled applicators of alcohol-based surgical skin prep solutions for the designated surgical site to prevent pooling and the need for disposal of excess skin prep.
- **c)** Ensure that pooling, spilling, or wicking of a flammable surgical skin prep does not occur during or after application.
- **d)** Allow adequate drying time of the skin prep before application of drapes or surgical barriers, or before beginning the procedure (e.g., at least 3 minutes for most alcohol-based skin preps, unless applied to hairy skin or in body folds, which may take up to 1 hour to dry).
- **e)** Consider including drying times on a **SURGICAL SAFETY CHECKLIST** to facilitate communication with the surgical team.
- **f)** Assess the risk of a surgical fire and develop a plan to mitigate. Add a "Surgical Fire Risk Assessment Score" to the preoperative time-out process that requires the surgical team to identify if flammable materials (including skin preps and ointments), oxidizers (e.g., supplemental oxygen), and potential ignition sources will be used during the procedure.[49-51]

5.15 Use prepackaged phenol applicators that contain a small amount of phenol for use during procedures.

Note: *Bulk liquid phenol should be avoided due to increased flammability risk, hazardous material handling requirements, and potential for confusion with other clear liquids.*

KEY ELEMENT VI: MEDICATION DELIVERY DEVICE ACQUISITION, USE, AND MONITORING

The potential for HUMAN ERROR is mitigated through careful procurement, maintenance, use, and standardization of devices used to prepare and administer medications in the perioperative setting.

Statements

6.1 **SMART INFUSION PUMP TECHNOLOGY** with an engaged **DOSE ERROR-REDUCTION SYSTEM (DERS)** is implemented and used in all perioperative and procedural settings, including intraoperatively by **ANESTHESIA PROVIDERS** and other practitioners, for the following:

- a) Continuous medication infusions
- b) Intermittent and secondary infusions
- c) **REGIONAL ANESTHESIA** infusions
- d) Patient-controlled analgesia

6.2 Use **SMART INFUSION PUMP TECHNOLOGY** with an engaged **DERS** for IV hydrating solutions administered in perioperative/procedural settings to limit the risk of complications from fluid over-and under-delivery, especially to volume-sensitive populations (e.g., pediatric or geriatric patient populations).

Exception: *Gravity infusions may be used for IV hydrating solutions if they are only used as a flush solution (***CARRIER FLUID***) by* ***ANESTHESIA PROVIDERS*** *as part of their anesthetic management of the patient or for emergent fluid resuscitation.*

6.3 Establish organizational expectations for the use of **DERS** with the goal of maximizing practitioner compliance to 95% or greater for the administration of all infusions via **SMART INFUSION PUMPS** (including **EPIDURAL** and nerve block infusions).

6.4 Develop and maintain a separate care area in **SMART INFUSION PUMP** libraries for anesthesia administration of medication and fluid infusions with tailored dose error-reduction limits.

6.5 Establish and use upper and lower hard limits, that are tailored for specific patient populations (adult, pediatric, and neonatal) for medication doses, concentrations, infusion rates, **LOADING DOSES**, and **BOLUS DOSES** in **SMART INFUSION PUMPS** used in the preoperative/preprocedural, intraoperative/intraprocedural, and postoperative/postprocedural settings.[52]

6.6 Take steps toward the implementation of bidirectional (i.e., auto-programming and auto-documentation) **SMART INFUSION PUMP** interoperability with the EHR in all preoperative/preprocedural, intraoperative/intraprocedural, and postoperative/postprocedural settings.[53]

6.7 Establish guidelines to promote the use of activated, audible clinical alarms in perioperative settings that optimize alarm limits and reduce clinically nonactionable alerts based on data review.[54]

6.8 **LOADING DOSES** and/or **BOLUS DOSES** are never administered via a continuous infusion by simply increasing the rate of infusion and/or using the basic infusion mode. Use a **SMART INFUSION PUMP** that allows programming of the **BOLUS DOSE** infusion (or **LOADING DOSE** infusion) and continuous infusion with separate hard limits for each.[55]

6.9 Use an interdisciplinary team (e.g., pharmacy, nursing, anesthesia) to transition to the new design standards (ISO 80369-6) for small neuraxial NRFit connectors used on medical device tubing, reducing the risk of misconnections.[56]

6.10 Ensure patient safety is the primary factor considered among others (e.g., effectiveness, usability, reliability, heuristics, design) when selecting and utilizing specific **MEDICATION DELIVERY DEVICES** used in the perioperative and procedural settings. Involve perioperative practitioners in these decisions.

KEY ELEMENT VII: ENVIRONMENTAL FACTORS, WORKFLOW, AND STAFFING PATTERNS

Medications are prescribed, transcribed, prepared, dispensed, and administered in the perioperative setting within an efficient and safe workflow and in a physical environment that offers adequate space and lighting, and allows practitioners to remain focused on the MEDICATION USE PROCESS without distractions.

Statements

7.1 Proactively assess the perioperative/procedural environment to identify hazardous conditions (e.g., interruptions, excess noise, variable temperatures, inadequate lighting, clutter, limited storage space, inappropriate emphasis on production over safe patient care and procedures) that may contribute to medication errors. Review the findings to assist with development of effective risk-reduction strategies to mitigate or prevent hazardous conditions and distractions that might negatively impact safe medication use.

7.2 Ensure oversight of the **MEDICATION USE PROCESS**, by a dedicated pharmacist, in perioperative/ procedural settings.

a) For facilities **with** a daily onsite pharmacist(s): At least one pharmacist works in the perioperative area(s) performing clinical activities such as reviewing patient records and drug orders, supporting the selection, preparation, and administration of drugs; overseeing safe medication storage, managing controlled substance accountability; and providing perioperative staff and patient education.

b) For facilities **without** a daily onsite pharmacist(s): A pharmacist regularly conducts medication safety rounds in perioperative settings, overseeing safe medication selection, storage; preparation, and administration; managing controlled substance accountability; and providing perioperative staff education.

The complement of qualified, well-rested practitioners in the perioperative setting matches the clinical workload without compromising patient safety.

Statement

7.3 Design and follow a fatigue reduction plan for on-call perioperative practitioners and/or those who have worked overtime that provides adequate recovery time for staff between shifts. This plan provides an appropriate response when a practitioner feels, or the organization determines, it would be unsafe to provide care during an immediately subsequent shift due to practitioner fatigue.

KEY ELEMENT VIII: STAFF COMPETENCY AND EDUCATION

Perioperative practitioners receive sufficient orientation to the perioperative MEDICATION USE PROCESS and undergo baseline and annual competency evaluations of knowledge and skills related to safe medication practices.

Statement

8.1 Use examples of perioperative/procedural error-prone conditions (e.g., syringe and infusion bag swaps, unlabeled syringes, problematic medication packages and labels) and adverse events (e.g., emergencies, oversedation, methemoglobinemia, malignant hyperthermia) as topics for orientation and ongoing education for perioperative/procedural staff about medication and patient safety.

Practitioners involved in the perioperative MEDICATION USE PROCESS are provided with ongoing education about perioperative medication error prevention and the safe use of drugs that have the greatest potential to cause harm if misused.

Statements

8.2 At least quarterly, provide perioperative and procedural staff with information about medication risks and errors that could impact their practice, including those that have been reported by external organizations, and provide strategies to minimize these risks and potential for errors.[27,57]

8.3 Educate perioperative/procedural staff about new drugs added to the formulary and alternative products due to drug shortages that are specific to perioperative and procedural care. This education includes risks and hazards that could lead to errors and adverse events, as well as associated risk-reduction strategies.

KEY ELEMENT IX: PATIENT EDUCATION

Patients are included as active partners in their perioperative care and are educated about their medications and ways to avert errors.

Statement

9.1 Provide **pre**operative and ongoing education to patients, caregivers, and visitors about the dangers of any individual other than the patient activating the patient-controlled analgesia (PCA) or patient-controlled **EPIDURAL** analgesia (PCEA) button to deliver a medication dose (i.e., PCA by proxy). Ensure a warning label, "For Patient Use Only," is visible on the cord or activation button for PCA or PCEA.

KEY ELEMENT X: QUALITY PROCESSES AND RISK MANAGEMENT

A safety-supportive culture (e.g., JUST CULTURE) and model of shared accountability for safe SYSTEM DESIGN/REDESIGN and safe behavioral choices are in place and supported by perioperative leaders, managers, and the associated Board of Trustees/Directors.

Statements

10.1 Adopt a safety culture of learning and shared accountability (e.g., **JUST CULTURE**) in perioperative and procedural settings that is in alignment with organizational culture to effectively manage **SYSTEM DESIGN/REDESIGN** and support safe behavioral choices.

10.2 Define and implement a clear process to resolve conflicts when there is concern or disagreement about the safety of a medication order or practice that may place a patient at risk. Ensure all perioperative and procedural practitioners are aware of this process and feel comfortable and empowered to voice a concern.[58]

10.3 Actively engage perioperative leaders and managers in regular dialogue about the untoward consequences of intimidation and promote interdisciplinary respect and cooperation.

Practitioners are motivated to detect and report perioperative adverse events, errors (including close calls), hazards, and observed AT-RISK BEHAVIORS. Interdisciplinary teams regularly analyze these reports, as well as reports of perioperative errors that have occurred in other organizations, to mitigate future risks.

Statements

10.4 Perioperative and procedural practitioners actively participate in organization-wide quality and safety committees and teams to advance perioperative and procedural medication safety efforts.

10.5 Analyze the perioperative **MEDICATION USE PROCESS** at least every two years (e.g., using a proactive risk assessment tool [e.g., www.ismp.org/node/18027]) to identify potential risk factors for medication errors.

10.6 Proactively investigate known medication risks, hazardous conditions, and close calls to assist in the development of effective risk-reduction strategies for high-alert medications used routinely in the perioperative and procedural setting.

10.7 Use multiple sources of information (e.g., data from technology, triggers, drug use evaluations, chart reviews, safety rounds or observations), in addition to voluntary event reporting sources, to proactively evaluate the effectiveness of safety strategies and make any necessary adjustments to action plans to demonstrate sustained improvement over time.

10.8 Employ an interdisciplinary team, including perioperative and procedural practitioners, to analyze data from **SMART INFUSION PUMP TECHNOLOGY** (e.g., compliance rate, percent of overridden alerts, percent of alerts resulting in reprogramming) at least every quarter.[52,59]

10.9 Track the use of rescue agents, reversal agents, and antidotes (e.g., naloxone, lipid emulsion, NMB reversal agents) in perioperative and procedural settings to identify risks or errors with specific medications. Review the data and implement risk-reduction strategies to create sustained improvement.[42]

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Redundancies that support a system of INDEPENDENT DOUBLE CHECKS or automated verification processes are used for vulnerable parts of the perioperative MEDICATION USE PROCESS to detect and correct serious errors before they reach patients.

Statements

10.10 Technology vendors should partner with **ANESTHESIA PROVIDERS** to identify and incorporate perioperative and procedural workflow in future development of integrated machine-readable coding (e.g., **BARCODE SCANNING**, RFID) and documentation systems for use in perioperative and procedural settings.

10.11 Use machine-readable coding (e.g., **BARCODE SCANNING**, RFID) in **pre**operative/**pre**procedural and **post**operative/**post**procedural settings to verify patients **and** medications/solutions prior to administration.

10.12 Take steps to implement machine-readable coding (e.g., **BARCODE SCANNING**, RFID) in **intra**operative/**intra**procedural workflows to confirm medication/solution selection prior to administration.

10.13 Take steps to implement and integrate machine-readable coding (e.g., **BARCODE SCANNING**, RFID) to support real-time EHR documentation of medication doses and fluid administration in all preoperative/preprocedural, intraoperative/intraprocedural, and postoperative/postprocedural settings.[59]

Proven infection prevention practices are followed in perioperative settings when storing, preparing, and administering medications.

Statements

10.14 Do not administer medications from a single syringe to multiple patients, even if the needle or cannula on the syringe is changed.[61]

10.15 Do not administer medications from single-dose vials or ampules to multiple patients or combine leftover contents for later use.[61]

10.16 In all perioperative clinical care areas, NEVER use IV solutions intended for infusion, including minibag solutions, as common source containers to prepare IV flush syringes or to dilute or reconstitute medications for one or more patients.[62]

10.17 Employ organizational practices for compounding sterile preparations in all perioperative and procedural settings that follow USP standards and applicable regulations and guidelines.[40]

Looking Toward the Future of Perioperative Medication Safety

There were several areas of identified risk for which consensus could not be reached during the summit or subsequent discussions, but merit attention for future medication safety work including the following:

Lack of consensus/agreement on the content and sequencing of drug information displayed on labels used in perioperative settings

ISMP supports the use of USP General Chapter <7> *Labeling* standards recommending for "injectable drug products greater than 1 mL, whether packaged in single- or multiple-dose containers, the quantity per total volume should be the primary and prominent expression on the principal display panel of the label, followed in close proximity by quantity per milliliter enclosed by parentheses (quantity/mL)."[63] The American Society of Anesthesiologists (ASA) syringe labeling standards suggest "the drug's generic name and concentration (in units per mL) should be the most prominent items displayed on the label of each syringe." ASA vial and ampule labeling standards suggest "medication containers intended for use in the practice of anesthesiology display the generic name and concentration (as the total amount of medication in the container divided by the total volume) most prominently. Preferably, the concentration in units per mL is also displayed."[64]

Variability in dose expression on medication labels has historically led to error. When the label prominently displays the dose/mL, practitioners have inadvertently administered the entire vial or syringe, believing that was the entire content, and at times resulting in serious harm. Having two different labeling practices in healthcare facilities adds to risk, especially when practitioners must read labels with two different formats. It is also unreasonable to expect that there would be two separate inventories of products—one for anesthesia use—and one for all other practitioners.[64]

Limited adoption of medication-related technology and safety resources

Intraoperative settings

Due to their documented medication safety benefits, **BARCODE SCANNING** for medication selection, administration, and documentation and **SMART INFUSION PUMP TECHNOLOGY** have become standard practice in the majority of US healthcare facilities, yet **ANESTHESIA PROVIDERS** are underrepresented in their use. This limited adoption of medication safety-related technologies, most notably in intraoperative settings, is best illustrated by demographic results from the *ISMP Medication Safety Self Assessment® for Perioperative Settings*.[26] Many providers believe that the differences in anesthesia workflow merit a different solution. In some cases, industry has not been known to identify these differences or include **ANESTHESIA PROVIDERS** in innovations that support this unique workflow. We encourage continued study and innovation regarding the use of medication safety-related technologies (e.g., **SMART INFUSION PUMPS**, **BARCODE SCANNING**) involving **ANESTHESIA PROVIDERS** to support medication safety advancement in the perioperative space.

ASCs and ambulatory settings

As acuity and patient volumes continue to increase in outpatient settings, medication safety principles and medication safety-related technologies need to be incorporated at an equal rate. Opportunities exist to apply the knowledge and experience gained from medication safety practices in inpatient perioperative care as organizations seek to extend their services to ambulatory care settings. Additional resources will likely be required to fully adopt and maintain equivalent medication safety technology standards that apply to all perioperative and procedural care areas. ISMP encourages the implementation of an EHR, **SMART INFUSION PUMP TECHNOLOGY**, and **BARCODE SCANNING** in all perioperative and procedural settings to support reliable care regardless of location.

Definitions

ANESTHESIA PROVIDER(S): A licensed practitioner (e.g., anesthesiologist, certified registered nurse anesthetist [CRNA], certified anesthesiologist assistant) who is trained, qualified, and authorized within the organization to plan and administer **MAC, DEEP SEDATION, GENERAL ANESTHESIA**, and/or **REGIONAL ANESTHESIA**; monitor sedated and/or anesthetized patients during procedures; support patients' vital functions inclusive of hemodynamic stability and airway management during procedures; and diagnose and treat pathologic changes and other clinical problems that might occur during the perioperative period.

ANTITHROMBOTIC MEDICATION(S): Includes anticoagulants (e.g., vitamin K antagonists [warfarin], heparin(s) [unfractionated heparin, low molecular weight heparin]); factor Xa inhibitors (e.g., apixaban, betrixaban, edoxaban, fondaparinux, rivaroxaban); direct thrombin inhibitors (e.g., argatroban, bivalirudin, dabigatran); thrombolytics (e.g., alteplase, tenecteplase); and antiplatelet medications (e.g., aspirin, clopidogrel, dipyridamole, prasugrel, ticagrelor, cangrelor, ticlopidine).

AT-RISK BEHAVIOR(S): Behavioral drift that occurs over time in all humans after successful violations (no adverse outcomes) of a rule; a behavioral choice that increases risk where the risk is not recognized or mistakenly believed to be insignificant or justified. **AT-RISK BEHAVIORS** often occur when individuals knowingly violate policies, procedures, or generally accepted practices in order to work around unexpected problems and system failures to accomplish their work in the moment. Examples include bypassing a duplicate therapy alert during order entry without consideration; technology workarounds; removing more than one patient's medications from an ADC prior to administration; and written orders or documentation that include error-prone abbreviations. The just response to **AT-RISK BEHAVIOR** is to investigate the source and scope of the behavior; remove any barriers to the desired safer choice; and coach (not discipline) individuals to see the significant risk associated with their behavior and to choose more appropriate, safer alternatives.

BARCODE SCANNING: 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 and/or local anesthetic to provide a constant level of analgesia, which may also be administered as **BOLUS DOSES**, PCA, or PCEA.

BOLUS DOSE(S): A discrete dose of medication or fluid given in a set volume at the desired infusion rate or for a specified duration prior to (see **LOADING DOSE**) or during a continuous infusion.

CARRIER FLUID (also called a "medication line"): A small bag of sterile, nonpyrogenic crystalloid fluid used to help deliver and flush the administration set used to administer small volume IV medications or an IV medication titrated to effect. The **CARRIER FLUID** may be administered simultaneously with medication infusions or used before and/or after infusions to ensure any residual incompatible solution has been cleared from the administration set or any residual medication left in the tubing has been administered to the patient.

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 SYSTEM(S) (DERS): Refers to the integral computer software in **SMART INFUSION PUMPS** intended to aid in the prevention of infusion programming-related errors and warn users of potential over- or under-delivery of a medication or fluid by checking programmed doses/rates against facility-configurable preset limits specific to a medication/fluid, and to a clinical application (e.g., **EPIDURAL** administration) and/or location (e.g., neonatal intensive care unit, medical/surgical unit).

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DEFINITIONS continued from page 20

ELASTOMERIC PUMP(S): A device (e.g., Ambu® ACTion™ Fuser Pain Pump, ON-Q* Pump) used after certain procedures to intermittently or continually infuse medications, typically local anesthetics, at a specific rate into the tissues around an incision. The medication is held in a stretchable balloon reservoir (medication reservoir ball), and pressure from the elastic walls of the balloon drives the medication delivery, rather than gravity.

END-TIDAL CARBON DIOXIDE ($ETCO_2$) MONITORING (CAPNOGRAPHY): Breath-by-breath measurement of the amount of carbon dioxide (CO_2) in exhaled air, which assesses ventilation and provides an early warning about a worsening trend in a patient's condition caused by hypoventilation, hyperventilation, increased metabolic activity, decreased cardiac output, and/or poor pulmonary perfusion.

EPIDURAL OR EPIDURAL ANESTHESIA: A technique of managing pain in the thoracic, lumbar, or sacral areas without the loss of consciousness, in which an opioid and/or anesthetic is injected or infused into the peridural space through an indwelling catheter. Administration may be a single injection, a continuous **BASAL INFUSION**, or self-administered (patient-controlled) within programmed limits.

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.

HAZARDOUS DRUG(S): According to the National Institute for Occupational Safety and Health (NIOSH) List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, drugs are considered hazardous if it exhibits one or more of the following characteristics in humans or animals: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing **HAZARDOUS DRUGS**. Examples of **HAZARDOUS DRUGS** used in the perioperative setting include antineoplastic drugs such as fluorouracil, gemcitabine, methotrexate, and mito**MY**cin; non-antineoplastic drugs that meet other NIOSH criteria, such as aza**THIO**prine, car**BAM**azepine, estrogen creams, fosphenytoin, progesterone, and zidovudine; and drugs with reproductive hazards, such as dronedarone, fluconazole, and oxytocin. USP General Chapter <800> provides standards for safe handling of **HAZARDOUS DRUGS** to minimize the risk of exposure to healthcare personnel, patients, and the environment. These standards describe the responsibilities of personnel handling **HAZARDOUS DRUGS**; facility and engineering controls; procedures for deactivating, decontaminating, and cleaning; spill control; and documentation.[48]

HIGH-RISK PATIENT(S) (for respiratory depression): A pediatric or adult patient receiving a central nervous system depressant (e.g., general anesthetic, sedative, opioid) who has risk factors that increase the likelihood of respiratory depression and associated adverse outcomes:

- Age less than 6 months or greater than 55 years
- Obesity
- Hepatic or renal impairment
- 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
- Congenital central hypoventilation syndrome (pediatrics)
- Myasthenia gravis
- Ultra-rapid drug metabolism (genetic polymorphism)
- Smoker
- Concomitant administration of sedating agents
- High opioid dose requirements
- History of naloxone administration

HUMAN ERROR(S): Inadvertently doing something other than what should have been done; a mental slip, lapse, or mistake, such as miscalculating a dose, forgetting to dilute a medication, or transposing the doses of two antibiotics while prescribing the medications. **HUMAN ERRORS** are unintentional acts, not behavioral choices; thus, the just response to **HUMAN ERROR** is to console the individual and to investigate system redesign to prevent/reduce recurrence.

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INDEPENDENT DOUBLE CHECK(S)/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.

INVASIVE PROCEDURE(S): A procedure that penetrates the protective surfaces of a patient's body, generally requiring entry into a body cavity and/or insertion of an indwelling foreign body; is performed in an aseptic surgical field; and requires **MODERATE SEDATION, DEEP SEDATION, MAC, REGIONAL ANESTHESIA**, and/or **GENERAL ANESTHESIA** of the patient to perform. Procedures that do not require sedation or anesthesia as listed above are not included in this definition.

JUST 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 their errors and system vulnerabilities.

LOADING DOSE(S): The initial dose of a medication given by infusion or syringe that is intended to rapidly achieve a therapeutic level prior to initiating the continuous infusion or scheduled maintenance dose infusion.

MEDICATION DELIVERY DEVICE(S): An instrument/equipment used to administer medications and solutions, including programmable large volume and syringe infusion pumps, PCA pumps, **EPIDURAL** infusion pumps, implantable pumps, **ELASTOMERIC PUMPS**, drug-eluting stents, pen devices that contain medication (e.g., **EPINEPH**rine, insulin), oral or ENFit syringes, parenteral syringes, needles, and dosing cups.

MEDICATION USE PROCESS: A series of clinical tasks and sub-tasks for managing the information, environment, and human resources associated with all phases of medication use, including medication procurement, prescribing, preparation, dispensing, administration, and patient monitoring. The **MEDICATION USE PROCESS** consists of ISMP's *Key Elements of the Medication Use System*™ (https://www.ismp.org/key-elements-medication-use) that form a framework for managing medication use safely.

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. **MODERATE SEDATION** should be performed by a qualified individual, separate from the proceduralist, so that vital functions can be continuously monitored and supported.

MONITORED ANESTHESIA CARE (MAC): A specific anesthesia service used for medical and/or surgical procedures in which a qualified **ANESTHESIA PROVIDER** continually monitors and supports the patient's vital functions; diagnoses and treats clinical problems that occur; administers sedative, anxiolytic, or analgesic medications to achieve varying levels of sedation, awareness, and analgesia; and converts to **GENERAL ANESTHESIA** if required.

NEURAXIAL ANESTHESIA: A type of **REGIONAL ANESTHESIA** (excluding peripheral nerve blocks) that involves injection of one or more opioids and/or anesthetic medications by the **EPIDURAL** or intrathecal (spinal) routes of administration to manage pain in the thoracic, lumbar, or sacral region, without loss of consciousness. **NEURAXIAL ANESTHESIA** includes **EPIDURAL ANESTHESIA** and spinal anesthesia.

OPERATING ROOM(S): A specially equipped room that meets the requirements of a restricted area and is designated and equipped for performing medical and/or surgical procedures that require an aseptic field. Any form of anesthesia may be administered in an **OPERATING ROOM** as long as appropriate anesthesia gas administration devices and exhaust systems are provided. A hybrid **OPERATING ROOM** is included in this definition (an **OPERATING ROOM** that has permanently installed equipment [not portable imaging technology] to enable diagnostic imaging before, during, and after medical and/or surgical procedures).

OPIOID-NAÏVE (adult patient): Patients who do NOT meet the definition of **OPIOID-TOLERANT**, and thus have NOT been receiving, for 1 week or longer, at least: 60 mg oral morphine/day; 25 mcg transdermal fenta**NYL**/hour; 30 mg oral oxy**CODONE**/day; 8 mg oral **HYDRO**morphone/day; 25 mg oral oxy**MOR**phone/day; 60 mg oral **HYDRO**codone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.[29-32]

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OPIOID-TOLERANT/OPIOID TOLERANCE (adult 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 fenta**NYL**/hour; 30 mg oral oxy**CODONE**/day; 8 mg oral **HYDRO**morphone/day; 25 mg oral oxy**MOR**phone/day; 60 mg oral **HYDRO**codone/day; or an equianalgesic dose of another opioid, including heroin and/or non-prescribed opioids.[29-32]

OVERRIDE: A process of bypassing the pharmacist's review of a medication order to obtain a medication from a **PROFILED ADC** when assessment of the patient indicates that a delay in therapy would harm the patient.

POST-ANESTHESIA CARE UNIT(S) (PACU): A unit (sometimes called the recovery room or area) that provides a safe environment where immediate care of patients who have undergone a medical and/or surgical procedure can be closely monitored by specially trained practitioners for the return of protective airway reflexes and early recognition and treatment of anesthesia and/or procedural side effects and instability, including airway compromise, respiratory depression, bleeding and other hemodynamic instability, nausea, vomiting, delirium, and pain control.

PRACTITIONER-PREPARED: Refers to medications and/or solutions prepared (e.g., drawn into a syringe, poured into cups or basins) by **ANESTHESIA PROVIDERS**, surgeons, nurses, or other practitioners in the perioperative setting, outside of the pharmacy and/or outside of a biological safety cabinet/laminar flow hood.

PROFILED ADC(S): Functionality that allows an ADC to be interfaced with the pharmacy computer system and EHR, thereby restricting the removal of a medication from the ADC until after a pharmacist has verified the safety of the order. Once pharmacy verification has occurred, a practitioner can select the medication from a patient-specific list on the ADC screen and remove the medication from the ADC.

REGIONAL ANESTHESIA: Refers to peripheral nerve blocks as well as all **NEURAXIAL ANESTHESIA**, including **EPIDURAL ANESTHESIA** and spinal anesthesia.

SMART INFUSION PUMP(S)/SMART INFUSION PUMP TECHNOLOGY: An infusion pump with integral computer software (see **DOSE ERROR-REDUCTION SYSTEMS**) 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- or under-delivery 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 (hard limit).

STERILE FIELD: The area surrounding the site of the incision or perforation into tissue, or the site of introduction of an instrument into a body orifice that has been prepared for an **INVASIVE PROCEDURE**. The area includes all working areas, furniture, and equipment covered with sterile drapes and drape accessories and all personnel in sterile attire.[65]

SURGICAL SAFETY CHECKLIST: A tool similar to that created by the World Health Organization (WHO) (www.ismp.org/ext/655), designed to improve the safety of medical and/or surgical procedures by bringing together the whole procedural team (surgeons, **ANESTHESIA PROVIDERS**, anesthesia personnel, and nurses) to perform key safety checks during vital phases of perioperative care: prior to the induction of anesthesia ("sign in"), prior to skin incision ("time-out"), and before the team leaves the **OPERATING ROOM**.

SYSTEM DESIGN/REDESIGN: Refers to the design/redesign of processes, procedures, equipment, interfaces, overall structure, and the environment or conditions under which staff work, for the purpose of satisfying specific requirements, such as patient safety. The design of a system dictates how reliable it is in terms of satisfying specific requirements.

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About the Institute for Safe Medication Practices

The Institute for Safe Medication Practices (ISMP) is the nation's first 501c (3) nonprofit organization devoted entirely to preventing medication errors. ISMP is known and respected for its medication safety information. For more than 25 years, it has also served as a vital force for progress. ISMP's advocacy work alone has resulted in numerous necessary changes in clinical practice, public policy, and drug labeling and packaging. Among its many initiatives, ISMP runs the only national voluntary practitioner medication error reporting program, publishes newsletters with real-time error information read and trusted throughout the global healthcare community, and offers a wide range of unique educational programs, tools, and guidelines. In 2020, ISMP formally affiliated with ECRI to create one of the largest healthcare quality and safety entities in the world, and ***ECRI and the ISMP Patient Safety Organization*** (PSO) is a federally certified patient safety organization by the US Department of Health and Human Services. As an independent watchdog organization, ISMP receives no advertising revenue and depends entirely on charitable donations, educational grants, newsletter subscriptions, and volunteer efforts to pursue its life-saving work. Visit www.ismp.org and follow @ismp_org to learn more.

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