

# ASHP Guidelines on Preventing Medication Errors in Hospitals

## Purpose

The goal of medication therapy is the achievement of defined therapeutic outcomes that improve a patient's quality of life while minimizing patient risk.<sup>1</sup> There are inherent risks, both known and unknown, associated with the use of medications (prescription and nonprescription). This document addresses medication errors, defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.<sup>2</sup>

The landmark Institute of Medicine (IOM) report *To Err Is Human: Building a Safer Health System*, published in 1999, increased the national focus on improvements and the prevention of errors in patient safety.<sup>3</sup> This report drew attention to the significant problem of medical errors in the healthcare system, one type of which is medication errors. Other reports published after 1999 have drawn attention to patient safety improvement efforts, including 5-, 10-, and 15-year updates after *To Err Is Human*,<sup>4-6</sup> as well as the 2007 release of IOM's *Preventing Medication Errors: Quality Chasm Series*.<sup>7</sup> While the original IOM report increased awareness of the significant risk of medical errors, the pace of change is slow, and there is more work to be completed.<sup>6</sup>

The outcomes or clinical significance of many medication errors may be minimal, with few or no consequences that adversely affect a patient. In addition, numerous medication errors go unrecognized and are not detected or reported. Tragically, however, some medication errors result in serious patient morbidity or mortality.<sup>8</sup> Thus, medication errors (including close calls) must not be taken lightly, and risk-reduction strategies and systems should be established to prevent or mitigate patient harm from medication errors.

Reason<sup>9</sup> stated that humans are imperfect, and errors should be expected. A system-based approach should be undertaken at institutions to prevent future errors; this approach strives to change worker conditions and build defenses, barriers, and safeguards to prevent errors from occurring or mitigate the harm if errors do occur.<sup>9</sup> Blaming healthcare workers involved in errors or passively encouraging them to be more careful will not prevent errors since it does not change the underlying conditions that contributed to the error.

The pharmacist should participate in multidisciplinary committees of the organization and take an active role in the evaluation and monitoring of the medication-use process throughout the hospital or healthcare system to examine and improve systems to ensure that medication processes are safe. Furthermore, health-system pharmacists have the responsibility and expertise to lead collaborative, multidisciplinary efforts to prevent medication-related problems that can result in patient harm.<sup>10</sup>

The purpose of these guidelines is to provide the pharmacists with practical recommendations and best practices for preventing and mitigating patient harm from medication errors in the health-system setting. These guidelines are primarily intended to apply to the acute care setting because of the special collaborative processes established in this setting (i.e., formulary system, pharmacy and therapeutics committee, widespread use of automation and electronic health records [EHRs], and opportunity for increased interaction among healthcare providers). However, many of the ideas and principles in these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Medication errors can occur at any point of the medication-use system.<sup>7</sup> For the purposes of these guidelines, the medication-use system is defined in Figure 1.

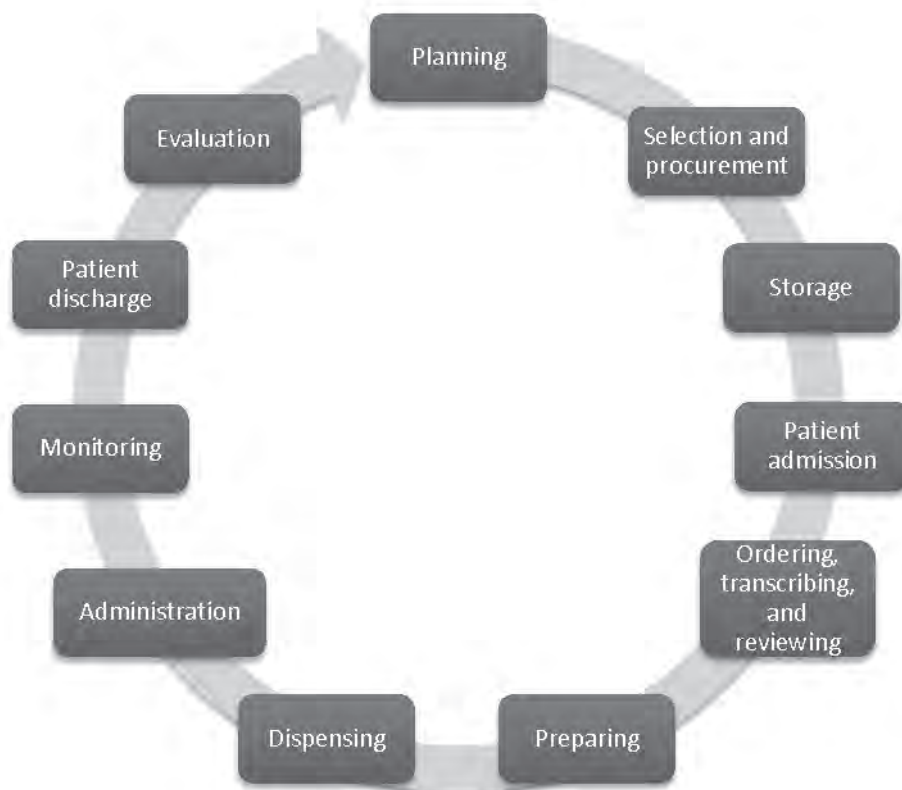
## Planning for Safe Medication Practices

Safe medication practices begin with placing medication safety as an organizational and departmental priority, and implementing a system that will support these practices. The organization must have a comprehensive program that includes a medication safety leader, key elements in place to provide the structure for safe medication practices, and a successful strategic plan.<sup>10</sup> Key supporting elements include a culture of safety built on principles of just culture that is supported at all levels of the organization (from the C-suite to the frontline), an event-reporting system, an interdisciplinary medication safety team, a continuous improvement philosophy regarding evaluation of errors and harm, and strong designs that assess and reduce the risk of errors. If any of these are not well developed, the organization should address them through the planning process in order to meet the continuing goal of ensuring patient safety.

A culture of patient safety, based on the principles of just culture, provides a solid foundation for safe and effective systems and teamwork. In a just culture, safety is valued, reporting of safety risks is encouraged without penalization, and the staff, leadership, and board of trustees are held accountable using a clear and transparent process that evaluates the errors.<sup>8</sup> The evaluation process separates events arising from a flawed system design or inadvertent human error from behavioral choices that compromise safety<sup>11</sup>; there may be consequences when unjustifiable risk is knowingly taken by an individual.<sup>10</sup> A just culture environment should also include a support system for second victims. Second victims are defined as healthcare providers who are involved in an unanticipated adverse patient event, a medical error, or a patient-related injury and become victimized in the sense that the provider is traumatized by the event.<sup>12,13</sup> Programs should be established to support the second victims and to educate healthcare professionals about the second-victim effect.<sup>14</sup>

A system for reporting and reviewing errors is an essential component of a medication safety system; the goal is to enhance patient safety and prevent patient harm. Errors and close calls should be reported and analyzed (e.g., root

**Figure 1.** This diagram is a modification of the Joint Commission’s medication management system, with the addition of 2 steps: patient admission and discharge. These steps were added to appropriately encompass issues that arise during admission and discharge (e.g., medication history and reconciliation errors, patient education barriers).



cause analysis [RCA]) to identify the causes and develop measures to prevent similar occurrences.<sup>5,15,16</sup> Other event detection methods, such as trigger tools, chart review, data from technology, and direct observation, should be considered to complement error-reporting efforts. There are a number of commercially available software systems for online reporting and analysis of medication errors.

A multidisciplinary medication safety team provides a collaborative and systematic approach to addressing medication safety issues and problems as well as proactively assessing risk.<sup>17</sup> In order to ensure overall success, a medication safety leader, preferably a pharmacist, should lead the medication safety efforts throughout the organization. The “ASHP Statement: Role of the Medication Safety Leader” is an important guide.<sup>11</sup> A pharmacist position dedicated to medication safety should be developed to ensure that pharmacists are key safety leaders in the organization.

Lastly, the organization must evaluate and adopt technologies that will help reduce the risk of medication errors and help prevent patient harm.<sup>18,19</sup> Pharmacists must be involved in technology decisions to ensure the safety and effectiveness of technology that impacts the medication-use process.<sup>20</sup> The application of individual technologies will be discussed in subsequent sections.

**Risk Assessment.** The process of completing a medication safety self-assessment will help a health-system organiza-

tion identify medication safety risks within its system so that it can prioritize and plan for improvements. Proactive risk assessment tools, such as assessments available from the Institute for Safe Medication Practices (ISMP) ([www.ismp.org/selfassessments/default.asp](http://www.ismp.org/selfassessments/default.asp)), may be used to identify opportunities for improvement through a gap analysis.<sup>21</sup> ISMP also offers other risk assessment and best-practice tools that focus on specific areas, such as automated dispensing cabinets (ADCs) and anticoagulation.<sup>22</sup> ASHP also publishes policy positions and guidelines that are national best practices ([www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines](http://www.ashp.org/Pharmacy-Practice/Policy-Positions-and-Guidelines)). A failure modes and effects analysis (FMEA) and a gap analysis are other methods that can be used to complete a risk assessment. These proactive tools are used to identify the risk of failure before it occurs so that systems can be designed to minimize risk. Examples of where these tools can be applied include when evaluating high-alert medication processes as well as medication-related equipment (Appendix B).<sup>8,23</sup>

**Reducing the Risk of Errors.** Organizations should prospectively design and implement strategies to reduce certain types of errors in order to prevent patient harm. Areas that must be addressed are high-risk populations, high-risk processes, high-alert medications, and easily confused drug names, also known as “look-alike/sound-alike” (LASA) medications.

Two areas of focus are addressed below. High-alert medications are medications that have an increased risk of causing serious patient harm when used in error. A hospital-specific list of high-alert medications may be developed using the ISMP list of high-alert drugs in conjunction with the hospital's patterns of medication use and harm events.<sup>24</sup> Risk-reduction strategies should be implemented that will (1) prevent errors, (2) make errors visible, and (3) mitigate the harm if an error occurs.<sup>25</sup> Strategies will be successful if they effectively address the underlying cause of error and impact as many steps of the medication-use process as possible; a single risk-reduction strategy should not be depended on in most cases. When developing strategies, the literature should be used to identify risk-reduction strategies that have been proven effective, recommended by experts, or implemented successfully elsewhere (Appendix A).<sup>26</sup>

Examples of safety strategies include but are not limited to

- Using oral syringes that cannot be connected to i.v. tubing ports along with education on the existence of oral syringes and safe use.
- Using epidural tubing without ports.
- Using smart infusion pumps.
- Using electronic prescribing systems with clinical decision support.
- Implementing barcode technology for the preparation, dispensing, and administration of medications.
- Employing evidence-based standard order sets and protocols.
- Standardizing concentrations, diluents, and container sizes.
- Using scales that only weigh patients in kilograms and documenting weight only in kilograms.
- Using commercially available products instead of compounding.
- Dispensing oral and parenteral medications in the most ready-to-administer form.
- Using oral measuring devices only in metric scale.
- Performing independent double checks on dosing, infusion pump programming, and concentrations when appropriate.
- Utilizing auxiliary labels when appropriate.
- Improving readability of labels.

Medications that are commonly confused due to similarities in name, dosage form, or packaging should also be proactively addressed. Medications that are at risk of error can be identified by reviewing local data on errors and the list of confused drug names published by ISMP.<sup>27</sup> Strategies should be implemented that address LASA medication risks. LASA error prevention strategies include differentiation, improved access to information, reminders, limiting access or use, and redundancies.<sup>28</sup>

Strategies for handling LASA medications include

- Using both brand and generic names when appropriate.
- Using tall-man lettering, color, or font to differentiate.<sup>29</sup>
- Including the indication for use on orders.
- Limiting the use of verbal orders.

- Using read-back processes to minimize errors by spelling the medication name and stating the intended purpose.
- Implementing barcode technology and/or radio frequency identification (RFID) for the preparation, dispensing, and administration of medications.
- Avoiding abbreviating drug names if possible.

Product packaging is another source of look-alike drug errors. Strategies to minimize the risk of error include making items look different by purchasing products from different manufacturers, purchasing different-size containers, storing drugs in separate areas, and using alerts on the product and in the storage area.<sup>28</sup>

The practice of performing independent double checks has been widely promoted in healthcare to identify potential errors before they reach patients.<sup>30</sup> However, misuse and improper execution of this practice could jeopardize medication safety. Independent double checks should be selectively applied to certain medications after careful consideration to avoid excessive use and maximize its intent as an independently performed task. An independent double check requires 2 people and must be conducted independently by the second person to reduce bias and increase effectiveness. Avoid using independent double checks as a sole-reliance strategy. Independent double checks should be implemented in combination with other risk-reduction strategies to reduce the frequency of errors.

Pharmacists should be familiar with which medications are managed via a risk evaluation and mitigation strategy (REMS). REMS is a Food and Drug Administration (FDA)-mandated program that seeks to manage the safe use of a medication with known or potential serious risks. The REMS may include a medication guide, patient package insert, communication plan, elements to ensure safe use, and an implementation system. Requirements of REMS programs are not identical among different medications; thus, it is important for pharmacists to understand the unique aspects that may exist.<sup>31</sup>

## Selection and Procurement

Selection and procurement of medications involve appropriately selecting which medications will be stocked in the institution (the formulary) and then safely and effectively obtaining the medications from manufacturers and wholesalers. Best practices for decreasing the risk of errors during selection and procurement can generally be divided into 5 categories: (1) formulary assessment and management, (2) standard concentrations, (3) safety-alert monitoring, (4) safe procurement, and (5) medication shortage management.

**Formulary Assessment and Management.** A well-designed formulary system will guide clinicians to prescribe the safest and most cost-effective agent for treating a particular disease state or medical issue.<sup>32</sup> Formularies limit the selection of medications available so that clinicians become proficient with the dosing, preparation, and administration practices of a selected number of medications. A streamlined formulary can also help to standardize the content of EHRs, pharmacy information systems, and infusion pump settings/medication libraries. Formularies should be designed to enhance the safe use of medications and not simply as a cost-saving measure.

The “ASHP Guidelines on the Pharmacy and Therapeutics Committee and the Formulary System” provide detailed guidance on formularies and medication evaluation documents (i.e., monographs) and should be consulted for more information.<sup>32</sup> In particular, when preparing an evidence-based formulary review document for a medication, a section should be devoted to medication safety assessment and recommendations. In short, the pharmacist should consider whether the medication being reviewed for addition to the formulary has potential safety issues, such as a complicated admixture or administration process, a similarity in sound or appearance to another medication (i.e., LASA medication), dosing or duration limitations, a REMS program, admixture or administration handling precautions, specific requirements on storage or waste, extravasation management, and significant serious adverse effects that should be monitored. This assessment should include a relevant literature search, including published studies and case reports, manufacturer information, and professional organization and agency websites such as those of ISMP, FDA (e.g., MedWatch reports), accreditation agencies (e.g., Joint Commission), Centers for Disease Control and Prevention (i.e., occupational safe handling—National Institute of Occupational Safety’s List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings), and the Environmental Protection Agency (e.g., waste precautions). Health-system pharmacists may choose to develop and use a standard checklist for medication safety review of formulary additions; there are examples on the ASHP Medication-Use Safety Resource Center.<sup>33</sup> If the medication is new and limited information is available, pharmacists need to consider what potential medication safety issues could arise.

When medications with heightened error potential are added to the formulary, strategies to prevent medication errors should be considered. Preferably, these safety enhancements are established and implemented before the initial use of the medication and should be reevaluated as needed.

When planning for formulary additions and changes, the medication’s integration into technology should be carefully coordinated. Dosage forms, concentrations, and ordering options should be limited and standardized.

Questions to ask when integrating new formulary medications into technology include the following:

- Should the routes of administration available for selection be limited?
- Are tall-man letters needed to distinguish from other medications?
- Are there significant medication interaction alerts that should be tested for appropriate firing?
- Are additional alerts or warnings needed for laboratory monitoring requirements, pregnancy contraindications, formulary restrictions, or other issues?
- Can appropriate and important lab results be displayed during order entry or verification?
- Are dose range-checking and smart pump-dosing recommendations integrated into the computer system and pumps? Are they correct?
- Should an order set be created to ease prescribing and monitoring requirements?
- Should the item be stored in ADCs?
- Should the medication be able to be overridden in ADCs?

- Are there additional alerts or warnings needed when withdrawing the medication from the ADC?

**Standard Concentrations.** Hospitals should standardize and limit the number of medication concentrations available; indeed, many regulatory agencies require the use of standardized concentrations. Standardization may help avoid error-prone calculations, reduce waste, streamline inventory, and facilitate the use of premixed i.v. solutions. The “rule of 6” should not be used, as this method for calculating concentrations of continuous infusions led to calculation errors and waste.<sup>34</sup> When more than 1 concentration is needed for medications, the institution should use consistent terminology (e.g., *double strength*, *maximum concentration*) and consider additional labeling to distinguish between concentrations (e.g., label comments, auxiliary labels). Furthermore, all needed concentrations should be available in the pharmacy verification system; conversely, rarely used or nonformulary concentrations should be removed.

National standardized concentrations should be used when they are available and are therapeutically appropriate. Standardize 4 Safety is a national initiative between ASHP and FDA to develop and implement national standardized concentrations for i.v. and oral liquid medications, both adult and pediatric. These standardized concentrations, as developed, will be available on the Standardize 4 Safety website.<sup>35,36</sup>

**Safety-Alert Monitoring.** Medication safety evaluation does not end when a medication is added to the formulary. The pharmacy department should continue to monitor the literature for new medication safety warnings, in addition to the review and analysis of the institution’s medication error reporting data. Analyses and recommendations for handling safety alerts that impact the institution should be managed via the medication safety committee or the pharmacy and therapeutics committee.

Every institution or hospital system should have an ongoing mechanism to react to medication safety updates. ISMP’s website and newsletters are unique resources and provide communication about medication errors and strategies to prevent their reoccurrence.<sup>37</sup> The ISMP website offers much of its content free of charge.

FDA also provides numerous methods to keep up-to-date with medication information. By signing up for the MedWatch E-list (email), clinicians will be notified when MedWatch alerts are released.

The National Alert Network (NAN) should be monitored for urgent advisories about serious errors or information requiring immediate attention. These alerts are distributed via ASHP and ISMP.<sup>38</sup> NAN alerts are incident driven and reach healthcare providers through several national distribution channels.

**Safe Procurement.** The pharmacy department must be responsible for all procurement of medications within the organization, including less-obvious patient care areas (e.g., diagnostic imaging, procedural areas).<sup>39</sup> Medications should not be brought in from outside sources without collaboration with the pharmacy department (e.g., samples, transfers from other institutions). The “ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals” has a section on medication procurement that includes several safety recom-

mentations, including how to handle medication samples and patients' home medication use in the hospital.<sup>39</sup> In short, samples should not be used for inpatient treatment and only used for outpatient treatment with appropriate policies and procedures in place (e.g., maintenance of records, proper storage). Likewise, a patient's own medications should only be used after prescriber order and pharmacist identification.

Pharmacists should be actively involved in the evaluation of all medication device purchasing and replacement decisions (e.g., pumps) and included in discussions related to devices that utilize medications for operational requirements (e.g., dialysis machines). In addition, patients may be admitted to hospitals with indwelling pumps, such as pain management or insulin pumps, and policy and procedures must be established to ensure safety and continuity of care with these unique medication delivery systems.

The pharmacy department should take a lead role in coordination of outsourcing services and should consult the "ASHP Guidelines on Outsourcing Pharmaceutical Services"<sup>40</sup> and the "ASHP Guidelines on Outsourcing Sterile Compounding Services."<sup>41</sup>

**Medication Shortages Management.** Hospitals, via the pharmacy department, should have a process to communicate medication shortages, including alternatives and substitution protocols, to prescribers and other clinical staff. The "ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems" provides detailed guidance.<sup>42</sup> The pharmacy department should take a lead role in developing and managing a contingency plan in close collaboration with affected physicians and health-system committees when faced with severe shortages. Just as when considering the use of a new medication, alternative products should be examined for possible medication safety issues. Oftentimes with shortages, the medication may continue to be available but in a different size, dosage form, or concentration, so medication shortage action plans must examine the implications of these product changes for frontline staff, dispensing system automation, and EHRs. Furthermore, once a shortage is resolved, all system changes that have been made to address the shortage need to be reversed and corrected.

## Storage

Careful arrangement of medication storage in the pharmacy and throughout the hospital can help reduce the risk of medication errors. In the pharmacy, product arrangement should minimize unintended selection of the wrong product or dosage form.<sup>43,44</sup> Steps to minimize selection of the wrong product or dosage form in the pharmacy include the following:

- Use barcode or RFID scanning in the pharmacy to ensure correct products are dispensed.
- Provide adequate space for each medication and strength.
- Ensure labels on bottles face forward.
- Designate separate areas for each dosage form or route of administration.
- Separate frequently confused pairs.
- Segregate high-alert medications and LASA medications.
- Use labeling and alerts when appropriate.

Ambiguous nomenclature should be avoided. The same drug nomenclature should be used in all databases used throughout the entire medication-use process (e.g., EHRs, pharmacy information system, infusion pumps, ADCs), using differentiation and screen alerts for medications that may pose a risk for potential errors, such as LASA medications, medications that should not be crushed, and high-alert medications. Wherever possible, generic names of medications should be used, unless the product is a combination product.

Pharmacy inventory should be managed to reduce the risk of errors associated with drug shortages and expired medications. A system for rotating stock should be established, and all areas should be monitored for expired medications and storage at appropriate temperatures. Because managing expired medications can be challenging, a schedule assigning staff to regularly inspect and remove expired medications should be implemented. A process should also be implemented to ensure medications are not used passed the beyond-use date (i.e., reconstituted bulk bottles).

All medications should be stored securely; access to secured medication areas should be limited to authorized personnel.<sup>44</sup>

Medications that should not be stored outside of the pharmacy include

- Concentrated electrolytes (i.e., potassium chloride, 3% sodium chloride)
- Concentrated oral opioid solutions
- Concentrated insulin U-500
- Sterile water in bags
- Concentrated epinephrine multidose vials
- Neuromuscular blocking agents<sup>28</sup>

The use of ADCs on nursing units can reduce the frequency of certain medication errors.<sup>25,43,45,46</sup> The ISMP guidance document can be consulted for ensuring safe use of an ADC.<sup>25,43,45-47</sup> Medications and the quantity that will be stocked in the ADC should be carefully selected. Medications should be in ready-to-use, unit dose, or unit-of-use containers. Avoid medications that are in bulk supply or those that are multidose vials. Do not stock medications that require extensive dilutions or calculations. Barcoding should be used to assist in stocking and restocking the correct medication. Medications should not be removed from storage until immediately before administration, and any doses that are not administered should be returned to controlled storage promptly. Nurses should not return medications to the ADC, returning them only to the ADC return bin. When configuring storage within the ADC, the use of individual, locked, locked-lidded compartments that open when the product is selected is preferred for all medications, if possible, but at a minimum for high-alert medications, reversal agents, and drugs prone to diversion. If matrix bins are used, each medication and strength must have a separate bin. Steps should be taken to differentiate LASA medications within the ADC. This may include a more-secured configuration of lidded drawers or locked-lidded drawers to separate these medications or make the bins more distinctive. Systematic inventory audits should be performed to identify and remove expired and low-usage products. The ADC functionality allows for medications to be vended from the machine after medication order review and verification by the pharmacist, which is the safest scenario. Functionality of override exists

for emergency situations, which bypasses the pharmacist's review before nurse vending of the medication. The institution must define and approve the specific criteria to allow for medication overrides in emergency situations and specify which specific medication overrides should be allowed.

## Patient Admission

Prescribing errors commonly occur during hospital admission for many reasons, and patients taking numerous medications are at a higher risk for adverse drug events (ADEs), which can include medication errors.<sup>48</sup> The "ASHP Statement on the Pharmacist's Role in Medication Reconciliation" outlines the importance of pharmacists sharing accountability with other hospital and health-system leaders for the ongoing success of the medication reconciliation processes across the continuum of care.<sup>49</sup>

Obtaining a medication history and performing medication reconciliation on admission are crucial, and it is recommended that pharmacy be involved in obtaining an accurate medication history. It is important to standardize this process across the institution in different settings (e.g., outpatient procedures, radiology), have 1 system used for both medication histories and reconciliation, and conduct ongoing education to ensure a safe system for patients.

It is important to have an institutional requirement for the timeframe for completion of medication histories and medication reconciliations. Many institutions require review and reconciliation of the medication list within 24 hours of an inpatient admission. However, high-alert and time-sensitive medications such as anticonvulsants, anticoagulants, antibiotics, and antiparkinsonian agents may need to be reconciled sooner.<sup>50</sup>

## Ordering, Transcribing, and Reviewing

**Ordering.** Ordering errors are failures in the prescribing process that lead to or have the potential to lead to harm to the patient and are committed by credentialed providers, including physicians, nurse practitioners, physician assistants, privileged pharmacists, and others. Common ordering errors include omission, incomplete and unclear orders, wrong drug, wrong time, wrong dose, wrong dosage form, patient allergy, and wrong patient. There are a number of steps that providers must consider when ordering medications: patient assessment, ordering of diagnostic or monitoring tests, diagnoses, patient history, appropriate selection and dose of medication, concomitant therapies, and therapy duration. A single error in any of these steps could result in an ADE. To determine appropriate drug therapy, prescribers should stay abreast of the current state of pharmacotherapy practices and clinical practice guidelines. Prescribers should evaluate the patient's health status and review all existing drug therapy before prescribing new or additional medications. Differentiation between nonpreventable ADEs and medication errors is also a dynamic concept. Growing knowledge about how individual genetic differences result in altered drug metabolism, efficacy, and adverse effects provides a new opportunity to optimize medication use and reduce this category of prescribing errors.

Prescribers should be familiar with the medication-ordering system (e.g., EHR and downtime procedures, written

order process, general medication order policy) and available safety-alert capabilities.<sup>51</sup> The following are recommendations for preventing medication ordering errors:

1. Medication orders must be complete and in compliance with the hospital's medication order policy. They should include patient identifiers (name, date of birth, patient number), patient allergies and weight in metric units, generic drug name, trademarked name (if a specific product is required), route and site of administration, dosage form, dose, strength, quantity, frequency of administration, intended duration of therapy, indication for use for as-needed orders, and prescriber's name. For i.v. medications, a concentration, rate, and time of administration should be specified. Prescribers should review all drug orders for accuracy and clarity immediately after they have prescribed them.
2. Care should be taken to ensure that the intent and indication of medication orders is clear. Prescribers should adhere to the following guidelines:
  - a. Type or write out instructions and avoid using unapproved abbreviations. For example, use "daily" rather than "q.d." (which could be misinterpreted as q.i.d.) or "units" rather than "u" (which could be misinterpreted as a 0).
  - b. Do not use vague or blanket instructions, such as "take as directed" or "resume preop meds," because specific directions can help differentiate among intended medications and clarify instructions for other clinicians.
  - c. Limit the number of as-needed orders for the same therapeutic indication, and provide clear directions regarding the order and symptom hierarchy in which as-needed medications are to be used.
  - d. Avoid range-of-frequency orders. If allowed by the organization, range-of-dose orders should use objective measures to determine the correct dose.
  - e. Specify exact dosage strengths (such as milligrams or milliliters) rather than dosage form units (such as 1 tablet or 1 vial). An exception is for combination drug products, for which the number of dosage form units should be specified, and the combination product name should be identified in the comments field of the medication order.
  - f. When applicable, pediatric prescriptions should be prescribed both in units/weight and total individual dose.<sup>52</sup> For example, if the patient weighs 10 kg, order as acetaminophen 100 mg (10 mg/kg).
  - g. Prescribe by standard nomenclature, using the drug's generic name or trademarked name (if deemed medically necessary). Avoid the following: coined names (e.g., Dr. Doe's syrup or ketofol), chemical names (e.g., 6-mercaptopurine [instead of mercaptopurine] could result in a 6-fold overdose if misinterpreted), abbreviated drug names (e.g., "AZT" could stand for zidovudine, azathioprine, or aztreonam), drug names where numbers are part of the drug name (e.g., Tylenol #3), acronyms, and apothecary or chem-

- ical symbols (unless used as part of specifying a radioactive isotope).
- h. Always use a leading 0 before a decimal expression of <1 (e.g., 0.5 mL). Conversely, a trailing 0 should never be used (e.g., 5.0 mL), since failure to see the decimal could result in a 10-fold overdose. When possible, avoid the use of decimals (e.g., prescribe 500 mg rather than 0.5 g, 25 µg rather than 0.025 mg).
  - i. Use the metric system.
3. Maximize the use of computerized prescriber order entry (CPOE). If CPOE is unavailable, written drug or prescription orders (including signatures) should be legible. Prescribers with poor handwriting should print or type medication or prescription orders. A handwritten order should be completely readable, not merely recognizable through familiarity.
  4. All unclear orders should be regarded as potential errors, as staff should not have to interpret what the physician is ordering. The hospital's patient safety culture should require nursing and pharmacy staff to stop processing the order until clarification is provided by the prescriber.
  5. Verbal or telephonic medication orders should be reserved only for situations in which it is impossible or impractical for the prescriber to write the order or enter it into the computer (e.g., during an emergency situation, if prescriber is involved in a sterile procedure). The prescriber should dictate verbal orders slowly, clearly, and articulately to avoid confusion. The recipient must read back the order to the prescriber slowly, clearly, and articulately to avoid confusion. When read back, the medication name should be spelled out, and the drug dosage (e.g., 15 mg should be repeated as "one-five") and directions must be confirmed. Avoid using abbreviations during the read-back process.
  6. The use of hold orders should be avoided. Instructions with respect to hold orders for medications must be clear. Most often, a hold order is interpreted as an order to discontinue the medication. The hold order must include duration or clearly identified point in time for continuation (e.g., hold until able to tolerate oral diet); otherwise, the medication must be reordered or renewed.
  7. If automatic stop orders are used for therapy discontinuations due to safety reasons, active systems or reminders should be established for the prescriber to be notified that therapy will discontinue, with the opportunity to renew the order, if appropriate.
  8. Automatic dosing protocols, such as therapeutic class substitutions/interchange, i.v.-to-oral switch, renal dosing, dose rounding, and automatic stop orders, should be clearly written or placed into the patient chart or EHR so interdisciplinary care providers know the originally ordered medication and the equivalent approved dose and frequency of the interchanged medication and can reference the approved conversion chart or protocol if needed.
  9. Maximize the use of standard order sets regardless of whether using a paper-based or an EHR. Well-designed order sets integrate and coordinate care by communicating best practices through multiple disciplines, lev-

els of care, and services; promoting evidence-based care; reducing variation and unintentional oversight; enhancing workflow with pertinent instructions that are easily understood and intuitively organized; and reducing unnecessary calls to physicians for clarifications and questions about orders.<sup>53</sup>

10. All new prescribers must have sufficient training and mentoring on medication order entry.

**Transcribing.** Transcribing errors are defined as any deviation during the transfer of information from an order sheet to documentation forms or medication administration records (MARs). Transcribing involves orders that are manually transcribed into written records (e.g., MAR) and those that are electronically transcribed into the EHR. Some of the contributing factors include incomplete or illegible prescriber orders, incomplete or illegible nurse handwriting, use of error-prone abbreviations, inappropriate defaults in the EHR, and lack of familiarity with drug names, doses, or frequencies. Common transcribing errors include wrong drug name, dose, route, frequency, or patient. An environment that is noisy or poorly lit can also contribute to errors. EHRs with CPOE capability increase the speed and accuracy of transcription, which results in fewer medication errors. Reduction of handwritten orders, verbal orders, and standardized order sets also expedite the transcription of orders without CPOE. The following are recommendations for preventing transcribing medication errors<sup>54</sup>:

1. Clarify the order before the prescriber leaves the patient care unit. If the prescriber has left the unit, contact the prescriber before transcribing the order.
2. Do not process incomplete orders. Orders must contain the information required in the hospital's medication order policy.
3. Minimize the use of error-prone abbreviations and avoid the use of unapproved abbreviations on the MAR.
4. Always use a leading zero before a decimal, and never use a trailing zero after the decimal.
5. Complete the transcription process in a quiet, well-lit area, away from distractions.
6. Implement a system to check the MAR document against active orders whether the MAR is manually or computer generated.
7. Implement a second check system for the transcription.

**Reviewing.** Order review errors are normally those that are committed during the process where the pharmacist reviews the prescriber's medication order. However, order review errors may also occur when a proper order review is omitted or when the order review does not occur in a timely manner (e.g., hospital pharmacy is not open 24 hours and does not have telepharmacy services or medication order has been overridden). A fundamental responsibility of a pharmacist is to review the medication order to ensure its appropriateness. Pharmacists must prospectively review all medication orders before the preparation and dispensing of medications, with only a few exceptions (e.g., licensed independent practitioner [LIP] present, urgent situation, LIP in emergency room, screening tool for contrast media in radiology). When medications are dispensed without pharmacist review or

on override, the LIP assumes the role of the pharmacist in checking the order for appropriateness. Common order review errors include but are not limited to wrong drug, wrong dose, wrong patient, wrong route, wrong rate, wrong diluent, wrong dosage form, wrong time, and missed allergy.

## Preparation

Preparation, or admixture, errors are generally considered to occur within the pharmacy department, but they can occur anywhere in the continuum of care when a medication is changed or manipulated from the manufacturer's packaged preparation in any way before being administered to the patient. Common preparation errors include wrong concentration, wrong drug, wrong dose, wrong base solution/diluent, wrong volume, preparations made for the wrong patient, and preparations prepared for administration by the wrong route.

Preparation should occur under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security to ensure medication integrity and personnel safety throughout the hospital.<sup>39</sup>

In most cases, if an item is prepared within the pharmacy and is prepared by a pharmacy technician, an independent double check of the preparation is made by a licensed pharmacist. The same policy may not apply if a pharmacist is preparing the medication or if the item is prepared outside of the pharmacy. Every effort should be made to minimize the compounding of sterile preparations outside of the pharmacy. When compounding does occur outside of the pharmacy, the department of pharmacy should be involved in policies and procedures for items compounded outside the pharmacy and the checking process that is utilized. Ideally, regardless of licensure or job description of the individual who prepares the medication, an independent double check of the preparation should occur. The double check should include verification of the ingredients used, the quantities of the ingredients, and the expiration dates of all components. ISMP recommends performing an independent verification of medications and diluents to ensure the proper ingredients and proper amounts are confirmed before adding them to the final preparation.<sup>55</sup> Doing so eliminates the proxy method of verifying compounded sterile preparations (e.g., utilization of the syringe pullback method as a means to double check the accuracy of prepared medications). Another way to eliminate proxy methods is to use technologies that build barcoding not only into the administration and dispensing phases but also the preparation phase of the medication-use system. In addition to barcoding, pharmacy automation used to improve the safety of the preparation phase includes repackaging equipment, gravimetric verification, compounding technologies, and technology utilized in telepharmacy operations.

Whenever possible, medications should be available for inpatient use in unit-of-use and ready-to-administer packaging without further manipulation by the person administering the medication. Every effort should be made to reduce situations where the person administering the medication has to withdraw doses from containers, reconstitute powdered drug products, split tablets, or perform other similar manipulations. When oral products are not available in unit-of-use packaging, pharmacy staff should repack these preparations. ASHP's "Technical Assistance Bulletin on Repackaging Oral Solids and Liquids in Single Unit and

Unit Dosed Packages" provides detailed guidance on best practices for repackaging.<sup>56</sup> Care should be taken to protect patients and staff if hazardous drugs are being repackaged.<sup>57,58</sup> If barcode technology is integrated into any step of the medication-use process at a hospital, a barcode must be affixed to any repackaged item. The organization should have specific policies and procedures for determining the type of barcode for each repackaged item and how that barcode will be used throughout the medication-use process.

Preparation of medications via feeding tubes is another aspect of preparation, and there are many different types of feeding tubes. Some medications cannot be crushed or chewed, as absorption is disrupted, and some medications cannot be opened for feeding tube use due to biohazard reasons.

Aside from repackaging, compounding is the main mechanism used to prepare medications. Whether nonsterile or sterile compounding is occurring, staff must be adequately trained and facilities must be in compliance with current state and federal standards and regulations to minimize potential for medication errors. Personnel should not only be adequately trained, but must also maintain and document competency on a regular basis for all processes and procedures for which they are responsible. For instance, attention must be paid to calculations, compatibility of preparations, proper storage, and quality-assurance principles. Many compounding errors are due to miscalculations that can result in extreme overdosing or underdosing of a patient, especially in pediatric patients or when high-risk medications like chemotherapy are involved, or can create an incompatibility situation. Incompatibility errors can range from delays in products going into the solution in a timely manner to the combining of 2 drugs creating a dangerous situation for a patient (i.e., calcium and phosphorus binding in parenteral nutrient solutions, creating precipitates). Knowledge of storage requirements, expiration dates of products, and beyond-use dates of preparations is needed to ensure that a properly prepared compound maintains its integrity during the transport and storage phases.

Extemporaneous nonsterile dosage forms include items such as solutions, suspensions, creams, ointments, capsules, suppositories, troches, emulsions, and powders. The medical literature adequately explains the proper processes and procedures that should be followed when preparing these types of products. *United States Pharmacopeia (USP)* chapter 795, among other chapters, outlines many important details about the stability and beyond-use dating of nonsterile compounds.<sup>59</sup> This minimum standard should be followed by individuals preparing nonsterile compounds, but the use of additional quality measures is encouraged. In addition, ASHP's "Technical Assistance Bulletin on Compounding Nonsterile Products in Pharmacies" speaks to best practices in this area.<sup>60</sup> Sterile compounding involves products that need to be sterile when they are administered, such as injections of any type including epidural and intrathecal preparations, irrigations for wounds or body cavities, ophthalmic preparations, and aqueous bronchial and nasal inhalations. *USP* chapter 797 outlines the minimum standards for sterile compounding, regardless of the setting or compounding personnel involved. Additional *USP* chapters apply to sterile compounding and should be evaluated as well. For example, *USP* chapter 85 addresses endotoxin testing, *USP* chapter 71 addresses sterility testing, and *USP* chapter 800



addresses compounding of hazardous preparations.<sup>61</sup> Many state boards of pharmacy have adopted *USP* chapter 797 into the state regulations, at least in part, and inspectors survey against this standard. Very specific guidance is provided for environmental quality, responsibilities of compounding personnel, cleaning and disinfecting the compounding area, and facility design in this chapter. ISMP and ASHP have also promulgated sterile compounding guidelines.<sup>62,63</sup>

All of the published guidelines stress that compounding personnel be competent in preparing compounded sterile preparations and understand the levels of environmental and end-process testing and validation required to ensure the quality and safety of the products. Aseptic technique is required in all sterile compounding situations, and personnel must be adequately trained and regularly audited for competency. Risk levels and subsequent beyond-use dates are to be assigned by compounding personnel and are determined by the complexity of the compounding process and the conditions in which the preparation is made.<sup>59</sup>

Automation is often incorporated into sterile compounding, and the equipment is regularly being updated and new technologies continue to enter the market. Compounders (i.e., those used for parenteral nutrition), repeater pumps, cameras or recording devices for quality documentation, robotic systems, and others are used in sterile compounding. I.V. workflow software and technology must be used for the preparation of sterile admixtures as per the i.v. workflow software and technology instructions for use. Compounding personnel must be competent in using, calibrating, cleaning, and updating existing systems. A solid understanding of all checks and balances built into the organization's sterile compounding processes and the reasons for them must be understood by all compounding personnel to minimize the likelihood of bypassing these systems. Similarly, frontline compounding personnel should be involved in FMEA of new technologies used in compounding or other preparation areas.

*USP* chapter 800 addresses the additional element of protecting the individual preparing the items.<sup>64</sup> In most cases, the preparation of hazardous drugs involves a sterile compounding process, with care taken to avoid exposure of compounding personnel to the hazardous substance. A closed-system transfer device shall be used, as feasible, in the preparation of hazardous drugs. Avoidance of errors in hazardous drug compounding requires similar processes and procedures to those used in nonhazardous drug compounding.

The outsourcing of compounded products is a common practice. Organizations that utilize products made by an outsourced compounding facility should refer to the "ASHP Guidelines on Outsourcing Sterile Compounding Services" and the ASHP Research and Education Foundation's outsourcing sterile products preparation tool.<sup>41,65</sup> These guidance statements provide a mechanism for hospitals to evaluate compounding facilities and determine if practices are aligned with hospital pharmacy leadership decisions to outsource. Similarly, health systems outsourcing radiopharmaceuticals should be familiar with the American Pharmacists Association radiopharmaceutical vendor qualification checklist.<sup>66</sup>

Since neonates, infants, and many young children are unable to swallow solid oral dosages, most medications are needed in a liquid formulation. This requires nonsterile or

sterile compounding with often-complex calculations to provide the proper dilution for the patient.

Since many oral pediatric medications are prepared in oral liquid formulations (dilutions, solutions, and suspensions), the potential for confusing an oral syringe and an i.v. syringe exists. Best practices recommend only using oral syringes for oral preparations and never using i.v. syringes for oral medication administration.<sup>52</sup> Similarly, products intended for other routes (e.g., potentially containing particulates or pyrogens or not sterile) should not be dispensed in an i.v. bag to avoid mistaken administration by the parenteral route.

## Dispensing

All medications in nonemergency situations should be reviewed by a pharmacist (or advanced pharmacy technician qualified and trained to perform "tech-check-tech") before dispensing. The pharmacist should review the original medication order (either the written order or the electronic order). The pharmacist should ensure that all work performed by supportive personnel or through the use of automated devices is checked by manual or technological means. At a minimum, pharmacists should participate in a self-checking process in reading prescriptions, labeling (drug or ingredients and pharmacist-generated labeling), and dosage calculations. For high-alert drug products (e.g., chemotherapy, pediatric medication, total parenteral nutrition), work should be independently checked by a second individual, preferably another pharmacist.<sup>30</sup> Selective use of this strategy can play an important role in medication safety. Pharmacists must make certain that the following are accurate: drug, labeling, packaging, quantity, dose, and instructions. The double check should be done by a second independent practitioner at a different time, not simultaneously with the first pharmacist.

Hospitals with ADCs often experience medication order overrides when a member of the patient care staff withdraws medications from the ADC before pharmacist review of the medication order if a delay would harm the patient or if the patient experiences a sudden change in clinical status.<sup>67</sup> The practice of overrides bypasses the safety net of pharmacy review and should be minimized.<sup>46</sup> The hospital's pharmacy and therapeutics committee and medication safety committee should develop and implement a list of medications with corresponding indications that are authorized for override and include criteria for appropriate override of medications along with the clinical indication for overriding the medication (e.g., aspirin and chest pain), for specific circumstances, and for monitoring compliance to minimize risk. The ADC security functions should be utilized and programmed to maximize medication security and decrease the frequency of overrides. An override monitoring process should be developed, and audits should be performed to ensure appropriate use by nurses and other authorized staff. Available technology, such as barcoding, that complements the ordering, transcribing, and reviewing section of the medication-use process should be used.<sup>46</sup>

Hospitals that do not offer 24-hour pharmacy service should investigate the possibility of telepharmacy or remote review. If these are not possibilities, a qualified healthcare professional (e.g., head nurse, night nurse supervisor) who can conduct the medication order review in the absence of the pharmacist should be identified. The qualified healthcare

professional must be trained on the components of an appropriate medication order.

A pharmacist should conduct a retrospective review of all medication orders generated while the pharmacy was closed (if not conducted by telepharmacy) as soon as a pharmacist is available or the pharmacy opens. A pharmacist verifying orders from another site should have access to drug information and local policies of the non-24-7 site and should have a mechanism to document and communicate problem orders as well as contact the non-24-7 site leadership for orders needing clarification. “ASHP Guidelines on Remote Medication Order Processing” provide clear direction on safe practices.<sup>68</sup>

## Administration

**Administration Errors.** The “5 rights of medication administration”—the right patient, the right drug, the right dose, the right route, and the right time—are often discussed in relation to administration errors.<sup>69,70</sup> The list of “rights” that should be confirmed before administration continues to evolve and is not without controversy since this process still has potential for human error. Common administration errors include wrong patient, wrong route, wrong dosage form, wrong time, wrong dose or rate, and wrong drug.<sup>70</sup> Additional errors in this category may include errors of omission or missed doses. Administration errors that are more specific to i.v. administration include wrong rate or incompatibility at the Y-site of the infusion.

Accidental connections between enteral feeding tubing and epidural and/or i.v. tubing connections can have catastrophic patient effects. Efforts are underway by the Global Enteral Device Supplier Association to design new standards for medical device tubing.<sup>71</sup> The goal of this international working group is to reduce the incidence of tubing misconnections by designing new devices that do not allow connection between unrelated delivery systems. The group is starting with enteral devices.

Practitioners at the bedside are able to prevent a significant number of prescribing and dispensing errors from reaching the patient. When appropriate, independent double checks for high-alert medications should be completed before administration by completing independent calculations and checking the patient’s allergies. Before administering the medication to the patient, 2 patient identifiers should be verified along with communicating the indication for the medication to ensure the patient is knowledgeable about his or her medication’s indications, duration, and potential adverse effects. This communication can identify potential errors. While nurses are most often the practitioners administering medication, other health professionals—including physicians, pharmacists, respiratory therapists, radiology technologists, and rehabilitation staff—also administer medications in the scope of their practice, and the same safe practices apply.

Barcode-assisted medication administration (BCMA) can improve medication safety by verifying that the right drug is being administered to the right patient.<sup>72</sup> Studies have shown that BCMA technology can help reduce medication administration errors.<sup>73,74</sup>

However, if BCMA is not executed appropriately, medication errors can still occur. If a pharmacy-generated label is placed on the wrong medication or covers the infor-

mation on a manufacturer’s label, the BCMA system will not detect this error. When possible, the original manufacturer barcode that appears directly on the product should be scanned instead of the pharmacy label. FDA currently requires barcodes on containers but does not require that unit dose containers be available for all medications. Since not all manufacturers provide barcoded unit-of-use dosage forms and pharmacies routinely prepare half-tablets, automated repackaging equipment is often used. It is essential that a robust verification process is implemented within the pharmacy to ensure proper labeling and dispensing of these medications.

The effectiveness of BCMA is limited by the degree it is used at the bedside. If workarounds are used, errors will still occur. Common examples of workarounds include silencing alerts, using a second preprinted patient label or medication barcode, manually entering the information when the barcode does not scan correctly, and scanning the medications outside of the patient’s room. Evaluating workflow concerns and monitoring BCMA user data on compliance with scanning can assist in combating workarounds.

To ensure BCMA is being used effectively, BCMA reports should be evaluated regularly to assess compliance and identify potential barriers. Direct observation should also be employed to ensure workarounds are not being used. There should also be a process to notify the pharmacy when products are not scanning properly. The pharmacy should dispense patient-specific doses with barcodes whenever possible.

**Administration of I.V. Medications via Smart Infusion Pumps.** Intravenous medication administration errors account for a large number of medication errors.<sup>74</sup> Technology has been focused on decreasing medication errors related to i.v. administration. Infusion devices include gravity administration pumps, pumps that prevent free flow, and smart or intelligent pumps that include built-in medication libraries or guidelines that provide a range for safe administration doses, concentrations, and rates of administration. As with any technology, the devices are only as smart as the information entered into them and are limited by the degree of adoption by the bedside clinician.

Best practices in the area of smart infusion pumps should include a multidisciplinary approach to standardizing concentrations of i.v. medications, evaluation of interoperability options between the pumps and other technology in the organization, setting the lower and upper dosing limits, and careful use of soft and hard limits. Hard limits cannot be bypassed, so they can be a strategic safety step to reduce dangerous use of i.v. medications. If excessive alerts are created, alert fatigue will occur and key safety information alerts will be bypassed. Determination of the medications to be included in the pump, how the medications are listed (i.e., alphabetically by generic name), which areas of the hospital should use them, and how they are operated should not be made without inclusion of pharmacy, nursing, medical staff, and information technology assistance. Many facilities are challenged due to low compliance with the use of smart pumps and the associated drug libraries. If the end user does not select a drug from the drug library and enter the correct information into the pump, the pump safety features are bypassed. Pumps that utilize barcode scanning linked to auto-programming of the pump assist with adherence to these features. Similarly, the pumps cannot prevent line switch errors

on their own. The basic review of tracing the line back from the infusion site to the channel on the pump should occur.

Data that are available from the pumps vary depending on the pump manufacturer and may require wireless or wired downloads of the data to allow for pump optimization. Policies and procedures for how data downloads and pump queries will be completed should be included in the standard operating procedures for infusion pump use. Similarly, policies and procedures should be determined for how and when medication libraries are updated, who is authorized to approve the changes, and how unique situations such as drug shortages should be handled. The pumps also have continuous quality-improvement data programs that can generate reports and trends of medication alerts overridden, bypassed soft alerts, and the use of the free-text or wildcard function for medications not having standardized entries in the pump. The pharmacy should take a leadership role in analyzing these data to keep the drug library settings for alerts, alarms, and advisories as robust as possible while continually improving the settings to reflect current best practices.

**Practitioner Education.** Although nurses are the most common healthcare providers to administer medications, they are not the only practitioners to do so. All practitioners responsible for administering medications should be properly trained on administration procedures. Healthcare systems must establish effective medication administration education programs for practitioners. These programs must include proper patient identification; familiarization with the medication ordering, reviewing, preparing, dispensing, and monitoring system; proper utilization of the 5 rights as a team approach and not just the responsibility of 1 member; medication administration devices; metric equivalents; basic dosage and flow rate calculations; administration of high-alert medications; and effective implementation of independent double checks.<sup>69</sup> Education and training should be documented in the staff competency files and conducted periodically or as needed.

**Patient Education.** Patients and their direct caregivers have the right to know about all aspects of their care, including drug therapy. When patient status allows, healthcare providers should encourage patients to take an active role in their drug therapy by questioning and learning about their treatment regimens in order to act as their advocate and help prevent medication errors. Nurses, pharmacists, or healthcare providers can instruct the patient or direct caregiver on the name and purpose of the prescribed medications, guidelines for safe administration, possible adverse effects, and actions to take if problems occur. Effective communication is imperative and helps ensure better adherence to treatment plans. Basic communication techniques include asking open-ended questions, reflecting patient comments back to them, using the teach-back method, and employing active listening. Patients should be able to explain in their own words how to take their medications and what to expect from the treatment. Clinical staff must be able to recognize a patient's level of health literacy and English language proficiency and take appropriate actions to ensure effective communication.<sup>76</sup> Patients should be instructed to maintain a personal list of all medication therapy including prescribed drugs, nonprescription drugs, home remedies, and medical foods. Patients should also feel free to ask questions about any pro-

cedures and treatments received.<sup>77</sup> Educating patients about the safe and effective use of medication promotes patient involvement in healthcare and can help prevent medication errors. It is very important to involve patients in the administration step as they may be helpful in catching errors as well.

## Monitoring

Monitoring errors may be categorized as follows:

- Failure to monitor medication effects
- Incorrect interpretation of laboratory data used to monitor medication effects
- Incorrect transcription of laboratory test values
- Incorrect timing of monitoring
- Incorrect timing of serum concentration monitoring

Examples of failing to monitor medication effects include not checking a scheduled blood glucose level and checking the level but not reacting to the level. Incorrect interpretation errors might include checking the blood glucose level but giving the wrong amount of corrective or sliding-scale insulin for the value. Incorrect transcription of laboratory test values may include transposed numbers or numbers being transcribed in the wrong place. Incorrect timing errors may occur when a blood glucose level is taken at the wrong time relative to meals or an aminoglycoside level is not taken as a true trough level. Where possible, guidelines for the correct time to obtain blood for serum concentrations and laboratory values should be created collaboratively by pharmacists, nurses, physicians, and laboratory staff. Critical values should be determined with action alerts generated electronically for clinicians, if possible.

**Failure to Monitor.** Failure to monitor medication therapy for efficacy and toxicity may result in treatment failure or unrecognized adverse drug reactions. Hospitals and health systems should train staff to identify common adverse effects encountered by patients and have a pathway in place to react to adverse reactions. If an adverse drug reaction occurs, the patient should be stabilized first and then the reaction (e.g., allergy, contraindication, side effect or intolerance) should be documented in the patient's medical record to allow all practitioners caring for the patient access to the event. If warranted, an allergy to the medication should be placed in the medical record. If criteria are met, the adverse reaction should be reported to MedWatch. Further guidance on how to respond to adverse drug reactions can be found in the "ASHP Guidelines on Adverse Drug Reaction Monitoring and Reporting."<sup>78</sup>

Similarly, practitioners should be adequately trained to monitor for efficacy of medications. Monitoring may come in the form of checking vital signs, monitoring blood glucose, monitoring electrocardiograms, or evaluating other laboratory or test results. When an inadequate response to medication is observed, practitioners need to know how to optimize the patient's therapy and the protocol to do so. For instance, in the case of a high blood glucose result, there should be a protocol in place to automatically increase the rate of an insulin infusion to account for the higher blood glucose. If a protocol does not formally exist, all practitioners need to be aware of how and when to alert prescribers to critical levels. Required monitoring for efficacy and toxicity

should be built into order panels or order sets whenever possible. Pharmacists can take a leadership role in developing such nursing-driven or pharmacist-driven dosing algorithms or order sets. In the hospital, institutional protocols approved by the pharmacy and therapeutics committee can allow pharmacists or nurses to automatically modify dosing, obtain and administer necessary rescue medications (e.g., naloxone, dextrose 50%), and order laboratory tests for patient safety (i.e., point-of-care blood glucose test).

**Incorrect Interpretation.** Root causes of incorrect interpretation errors may include distractions, interruptions, workload, lack of training, confusing protocols, and incorrect documentation. Distractions should be minimized when practitioners are evaluating patient data. Interpreting patient data requires focus, an understanding of the process at hand, and easy access to normal ranges. Clear documentation of the values being monitored must exist to facilitate correct interpretation of data. If a protocol exists, the protocol should be clearly written and readily available such that all practitioners can interpret the protocol in the same way. Practitioners should be adequately trained on interpreting patient data.

**Incorrect Transcription.** Transcribing errors can impact safety when laboratory or point-of-care testing values are recorded incorrectly. These values are critical to patient care decisions and must be documented correctly. Transcription errors include not only transcribing or reporting the wrong laboratory value for a patient but also documenting values for the wrong patient. Contributing factors include lack of technology adoption or utilization, lack of efficient workflow, workload, lack of 2 patient identifiers, and lack of a common place to record data. Many organizations have multiple places where vital signs, pain scores, and bedside blood glucose monitoring are documented. Without a standard place for practitioners to look for this information, the potential for error is present.

**Incorrect Timing.** Timing of laboratory blood draws and other bedside monitoring is critical for accuracy of patient data. Alerts and orders for specific timing of monitoring can be built into decision support software, but care must be taken not to contribute to alert fatigue. Standardization of medication administration times and pertinent monitoring times should be built into the workflow as much as possible. For instance, many organizations have standard times for monitoring International Normalized Ratios (INRs) in relation to warfarin dosing, along with a standard daily administration time for warfarin. For titratable medications (e.g., heparin, vasopressors, insulin), timing of monitoring should be built into order sets. All values should be documented with time and date so that the practitioner reviewing the data has the proper frame of reference for the values.

## Patient Discharge

Pharmacists' involvement in activities before patient discharge provides a valuable opportunity to prevent potential medication errors. Data show that adverse events are a major cause of avoidable hospital readmissions; more postdischarge adverse events are related to medications than other causes.<sup>79</sup> Lack of adherence to medications prescribed at

discharge has also contributed to postdischarge ADEs.<sup>80</sup> Common errors include patients unable to obtain their medications at discharge due to availability, transportation, or insurance coverage; patients not scheduling follow-up appointments and laboratory tests; patients being discharged without all prescribed medications or equipment (e.g., blood glucose monitors); lack of monitoring; and confusion regarding how to take the medications and which prehospitalization medications to discontinue. Pharmacists can contribute to positive outcomes by educating and counseling patients to prepare and motivate them to follow their pharmacotherapeutic regimens and monitoring plans after discharge.<sup>77</sup>

Effective, open-ended questioning and active listening are essential skills for obtaining information from and sharing information with patients. Pharmacists have to adapt messages to fit patients' communication skills and primary languages through the use of teaching aids, interpreters, or cultural guides if necessary. Pharmacists also need to observe and interpret the nonverbal messages (e.g., eye contact, facial expressions, body movements, vocal characteristics) patients give during education and counseling sessions. Education and counseling are most effective when conducted in a room or space that ensures privacy and opportunity to engage in confidential communication. Patient education focused on medications (e.g., drug–food interaction, INR monitoring, and adherence for anticoagulation) and complex pharmacotherapeutic regimens (e.g., glucometer, insulin administration, and multiple medications for diabetes) could prevent medication errors and potential readmission. Proper education empowers patients to participate in their healthcare and provides a safeguard against errors.<sup>81</sup> Caregivers and family members should be involved whenever appropriate.

Pharmacists should participate in multidisciplinary discharge committees and be involved in the medication reconciliation process before discharge. Medication reconciliation requires explaining differences between the medications a patient was taking before admission to the hospital and medications prescribed for the patient during hospitalization. At hospital discharge, an accurate list of medications that a patient is to take after discharge should be provided to the patient.<sup>82</sup> Pharmacists can recognize patients who are at high risk or on complex medication regimens for follow-up by an ambulatory care pharmacist. Pharmacists also can take an active role in discharge medication procurement and explanation of insurance plans and coverage to ensure patients have their medications in-hand before leaving the hospital. If this is not possible, the pharmacist can educate the patient on the newly added medications and prescription plan coverage or prior-authorization processes.

The responsibility for the prevention of medical errors rests not only with healthcare professionals and healthcare systems but also with the patients themselves. By being informed of the names of their medications, the reasons for their use, the times they should be administered, and the correct dose, patients can act as the final check in the system. The practice of carrying an updated list of medications can be invaluable in the event of an emergency or if patients cannot speak for themselves. This reduces the chance of miscommunication or misinformation. When patients take an active and informed role in their healthcare, many errors can be prevented.

## Evaluation

Healthcare organizations should continuously evaluate their systems and processes in order to prevent medication errors. The “ASHP Guidelines: Minimum Standard for Pharmacies in Hospitals” states, “There shall be an ongoing systematic program for quality assessment and improvement of pharmacy services and the medication-use system.”<sup>39</sup> Quality-improvement activities should be routinely performed.

In the planning section, best practices for proactive evaluation of safety by using self-assessments and FMEA are outlined. This section focuses on retrospective evaluation of safety processes:

- RCA
- Medication-use evaluation
- Quality improvement
- Event detection

**RCA.** RCA is a method used to identify system vulnerabilities after an event or close call and to develop an action plan that will prevent the same event from occurring again or at least minimize the possibility of reoccurrence. This method is used after an event occurs, in contrast to FMEA described previously, which is a proactive method for preempting problems. The implementation and effectiveness of the RCA action items should be monitored.<sup>83</sup> Typically, RCAs are used for serious or significant events that the institution wishes to evaluate in closer detail, but the process may be utilized for any event. Each institution must decide who or what determines when an RCA is conducted. In some states, an RCA may be required for sentinel or other serious events.<sup>84</sup> The RCA should be conducted and recommendations implemented within a timely manner. For sentinel events, the Joint Commission requires that hospitals “prepare a thorough and credible comprehensive systematic analysis and action plan within 45 business days of the event or of becoming aware of the event.”<sup>85</sup> An RCA is 1 such comprehensive systemic analysis, but other tools and methodologies may be used.

The health system should identify a standard method and template for performing the RCA and for reporting the results and recommendations. Various RCA resources, experts, and consultants are available. Various templates may be used including the VA National Center for Patient Safety tool and the Joint Commission tool.<sup>86,87</sup> In 2016, the National Patient Safety Foundation released recommendations on conducting an RCA entitled *RCA<sup>2</sup>: Improving Root Cause Analyses and Actions to Prevent Harm*.<sup>88</sup> The institution should consider implementation of these recommendations, which include leadership involvement, timely review, team membership recommendations, and a risk-based prioritization system to identify events requiring RCA review and actions to be taken.

Pharmacy department leadership should provide adequate time for pharmacy staff to attend the RCA meetings, including any needed training.<sup>89</sup> Medication safety officers and pharmacists should be involved in any RCA that is evaluating a medication-related event. Individuals leading RCAs should undergo training.

**Medication-Use Evaluation.** Medication-use evaluation is a performance improvement tool that evaluates specific medication issues or medication-use processes with the

ultimate goal of improving patient care. For further information, consult the “ASHP Guidelines on the Medication-Use Evaluation.”<sup>90</sup> Medication-use evaluation may be used to evaluate and audit a specific high-alert medication, a frequently occurring event, or any other high-alert or error-prone system or medication. Once data collection is completed, data can be evaluated and used to make process improvements, formulary guidelines or restrictions, or decision-support rules to promote best practices.

**Quality Improvement.** The Health Resources and Services Administration defines quality improvement as “systematic and continuous actions that lead to measurable improvement in healthcare services and the health status of targeted patient groups.”<sup>91</sup> Describing the various methods and techniques used in improving healthcare quality is beyond the scope of this guideline. However, pharmacists who participate in medication safety practices should have a working knowledge of the methodologies and tools used in their healthcare system, such as Plan-Do-Study-Act, Lean Production System, Six-Sigma, TeamSTEPPS, and FOCUS-PDCA.<sup>92,93</sup> Changes to processes and systems should follow 1 of these methodologies for optimal planning and success.

**Event Detection.** To reduce preventable medication errors, clinicians must understand what risks are already present in their institutions. Clinicians may learn of events and close calls from various methods including

- Voluntary reporting
- Direct observation method
- Chart review (e.g., trigger medications, such as antidotes and reversal agents)
- Information technology (e.g., computer alerts, data mining, BCMA compliance, data from i.v. infusion pump)
- Pharmacist therapeutic interventions

Voluntary reporting via paper or electronic means is the most basic and common process for event detection, and every institution should have a method to report all events that either reached the patient or did not reach the patient (close calls). The reporting process should be relatively easy and not cumbersome, and reporting should be encouraged and supported by supervisors. For example, some institutions have implemented a “Good Catch” program where clinicians are rewarded with a small prize and acknowledgment. Staff should be educated as to how medication error reports will be used (for safety improvements, not as a success metric).<sup>94</sup> The culture of the organization is key to ensuring staff are comfortable in reporting. Furthermore, when appropriate, individuals who report events should be notified of safety improvements that have occurred as a result; this information may also be shared more collectively at staff meetings (again, as appropriate). However, because voluntary reporting is dependent on many factors, including patient safety culture, type of reporting system, and staff recognition and knowledge, pharmacists should use a combination of the above methods to detect medication errors.<sup>94</sup> Voluntary reporting often collects the most significant events but does not provide a comprehensive look at adverse events or medication errors.

Pharmacists should also share events with external reporting systems for large-scale tracking and trend analysis. For example, events might be shared with the product manufacturer, equipment and technology vendor, FDA, and ISMP.<sup>8</sup> Institutions may also choose to report events through federal patient safety organizations (PSOs). PSOs were developed under the Patient Safety and Quality Improvement Act of 2005 and encourage clinicians and healthcare organizations to voluntarily report and share quality and patient safety information to enhance quality and safety nationally.<sup>95</sup>

Regardless of how medication errors are discovered, the information should be used to prevent future errors. A multidisciplinary group should evaluate error information where feasible to develop risk-reduction strategies. While it is important to focus on errors that have caused harm to the patient, close calls should also be reviewed.

## Conclusion

While medication errors cannot always be prevented, organizations can mitigate and reduce harm through robust system redesign, help employees make safe behavioral choices, and understand why people make the choices they make. If system faults and behavioral choices are understood, risk-reduction strategies can be created. Medication errors can occur at any point of the medication-use system. Health-system pharmacists have the responsibility and expertise to lead and participate in multidisciplinary committees to examine and improve systems currently in place.

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### Appendix A—High-Alert Medication Checklist

Scoring: Each secondary question receives 1 point if you answer “yes” to 50% or greater of any of the questions.

Questions	Question Scoring		Secondary Questions		Secondary Question Scoring		Frequently Asked Questions
	Yes	No	Yes	No	Yes	No	
1. Does this medication exist on the ISMP High Alert Medication list, or does it need to remain on your current list (if already there)?							Definition of ISMP high-alert medications (or drugs): Medications that bear a heightened risk of causing significant patient harm when they are used in error. Although mistakes may or may not be more common with these drugs, the consequences of an error are more devastating to patients.  The current medications on your high alert list should also be reviewed to determine if they need to remain.
2. Have serious errors been reported with this medication internally at your facility? (If it is a medication new to the market, look at other similar medications in the same therapeutic drug class or category), or could the outcome of an error with this medication cause serious patient harm?							Q. How do I evaluate error reports if the medication is new to formulary? A. Evaluate error reports of medications in the same class/category. Serious harm is defined as NCC MERP severity categories F-I.
3. Have errors, reports, alerts, or recommended special restrictions or requirements been reported with this drug by external bodies (e.g., ISMP, FDA)?							Q. Where do I find external sources of error reports for new medications? A. Review reports from ISMP, FDA, Joint Commission, other facilities in your area, listservs and current literature.
4. Does this medication treat a vulnerable patient population? a. Neonates b. Critical Care c. Hematology/Oncology d. Transplant							Q. How should I score this question if my hospital treats patients who are only within these populations (e.g., a children’s hospital or a cancer center)? A. Scoring for this question can be deferred if your patients fall into one of these categories.

**Appendix A—High-Alert Medication Checklist (continued)**

Questions	Question Scoring		Secondary Questions	Secondary Question Scoring		Frequently Asked Questions
	Yes	No		Yes	No	
5. Does this medication require special knowledge or precautions in any of the following medication use phases: prescribing, transcribing, storage, dispensing/preparation, administration, monitoring?			<p>Within the <b>PRESCRIBING</b> phase:</p> <ol style="list-style-type: none"> <li>1. Is this a look-alike, sound-alike drug?</li> <li>2. Should there be limited concentrations available?</li> <li>3. Are there multiple formulations available (e.g., extended-release products, liposomal formulations, multiple dosage forms)?</li> <li>4. Are there standard order sets developed to guide prescribers?</li> <li>5. Should there be maximum dose limits (forcing function)?</li> <li>6. Are weight-based dose limits needed?</li> <li>7. Are there drug information resources?</li> <li>8. Should the medication be considered restricted access to specialized prescribers (e.g., IPA to neurology)?</li> </ol>			
			<p>Within the <b>TRANSCRIBING</b> phase:</p> <ol style="list-style-type: none"> <li>1. Are verbal orders prohibited?</li> </ol>			
			<p>Within the <b>STORAGE</b> phase:</p> <ol style="list-style-type: none"> <li>1. Are there specific medication security requirements?</li> <li>2. Should the medication be placed in a locked location or separated from other medications (concentrated electrolytes, controlled substances, neuromuscular blockers)?</li> <li>3. Should there be limited access (e.g., stored only in the pharmacy, not on a patient care unit)?</li> <li>4. Are auxiliary warning labels required?</li> </ol>			
			<p>Within the <b>DISPENSING/PREPARATION</b> phase:</p> <ol style="list-style-type: none"> <li>1. Should personnel be trained and credentialed?</li> <li>2. Are there special handling/transportation precautions?</li> <li>3. Is the medication available as a unit dose or premade product or does it require compounding?</li> <li>4. Does this medication require limited distribution or access such as storage in a specialized pharmacy location (e.g., satellite pharmacy [pediatrics, oncology, critical care])?</li> <li>5. Is an independent double check recommended?</li> <li>6. Are auxiliary warning labels required?</li> </ol>			

**Appendix A—High-Alert Medication Checklist (continued)**

Questions	Question Scoring		Secondary Questions	Secondary Question Scoring		Frequently Asked Questions
	Yes	No		Yes	No	
			Within the <b>ADMINISTRATION</b> phase: 1. Should there be a limit or maximum infusion rates (forcing functions)? 2. Should the medication be independently double checked prior to administration? 3. Does this medication require special handling? 4. Does the medication require credentialed personnel for administration? 5. Does the medication require special reconstitution or manipulation immediately prior to administration? 6. Is the route of administration considered high risk (e.g., intrathecal, intravenous). 7. Is the medication a vesicant or is there a heightened risk for extravasation? 8. Does the medication match the indication?			
			Within the <b>MONITORING</b> phase: 1. Does the medication have an associated REMS requirement? 2. Is special monitoring required (e.g., labs, vital signs, monitoring equipment)? 3. Is an independent double check required for changes to the infusion rate? 4. Is the medication a vesicant or is there a heightened risk for extravasation? 5. Do the lab results match the patient (correct patient) and were they drawn appropriately (e.g., trough drawn before infusion, not during or after)?			
Total Score for Question Scoring + Secondary Question Scoring						
Final Score						

## Appendix B—Self-Assessment Checklist\*

- A medication safety leader has been designated by the institution.
- A medication safety strategic plan has been developed for the institution.
- A culture of safety has been supported at the highest level of the organization.
- An event reporting system is available for voluntary reporting of patient events.
- A medication safety team/committee has been developed and is multidisciplinary; alternatively, for smaller hospitals, the medication safety "business" can be taken care of at another meeting.
- The institution has a program or support system available for second victims.
- Errors and close calls are analyzed and investigated to develop measures to prevent reoccurrence.
- A clear and transparent process to evaluate errors is used.
- Programs to support second victims and educate healthcare professionals are in place.
- Other methods for event detection are considered, such as direct observation method, trigger medications, and using information technology.
- The institution has a pharmacist position dedicated to medication safety.
- Pharmacists are involved in technology decisions.
- Proactive risk assessment tools are used to identify opportunities for improvement.
- The institution has developed a high-alert medications list. The list is based on the hospital's patterns of medication use and harm events.
- Risk reduction strategies for high alert medications that do not rely upon a single risk-reduction step have been developed based on literature and best practices.
- The institution has developed a look-alike/sound-alike list. The list is based on the hospital's patterns of medication use and harm events.
- Risk reduction strategies for look-alike/sound-alike medications have been developed based on literature and best practices.
- The pharmacy department has a process for handling medications that are managed by REMS.
- The pharmacy department has a well-designed formulary system (see ASHP Guidelines).
- When reviewing a medication for addition to formulary, the formulary review contains a section on medication safety assessment and recommendations; potential safety issues are considered after a relevant literature search.
- A standard checklist is used to review the safety of a new formulary medication.
- Strategies are established to prevent errors with high risk medications prior to addition to formulary.
- When new formulary medications are added to the electronic health record or to pharmacy systems, dosage forms, concentrations and ordering options are limited and standardized.
- Medication concentrations are standardized.
- If multiple concentrations are needed, consistent terminology, auxiliary labels, or label comments are used to distinguish between concentrations.
- The Rule of 6 is not used.
- National standardized concentrations are used when available and therapeutically appropriate (Standardize 4 Safety initiative).
- The medication safety committee monitors and reacts to medication safety alerts and updates from the FDA, ISMP, and other organizations and agencies.
- The pharmacy department is responsible for procurement of all medications within the organization.
- Sample medications are not used for inpatient treatment.
- When hospitalized, patients' own medications should only be used after prescriber order and pharmacist identification.
- Pharmacists are actively involved in the evaluation of all medication device purchasing and replacement decisions (e.g., pumps).
- Policies and procedures are established to ensure safety and continuity of care with patients who come in with indwelling pumps, such as pain management or insulin pumps.
- The pharmacy department takes a lead role in coordination of outsourcing pharmaceutical services.
- The pharmacy has processes in place to communicate medication shortages, including alternatives and substitution protocols, to prescribers and other clinical staff.
- When alternative products are utilized due to a shortage, they should be examined for possible medication safety issues.
- Product arrangement minimizes unintended selection of the wrong product or dosage form.
- The same drug nomenclature used in storage databases is used throughout the entire medication-use process (electronic health records, pharmacy information system, infusion pumps).
- Differentiation and screen alerts are used for medications with risk for potential errors, such as look-alike medications, medications that should not be crushed, and high-alert medications.
- A system for rotating stock has been established. All storage areas are monitored for expired medications and appropriate temperatures.
- A schedule assigning staff to regularly inspect and remove expired medications has been implemented.
- Medications in automated dispensing cabinets (ADCs) are in ready-to-use, unit dose or unit-of-use containers.
- Barcoding is used to assist in stocking and restocking medications. If barcode capability is not available, double checks are used by two staff members to help minimize stocking errors.
- Medications are not removed from storage until immediately prior to administration, and un-administered doses are returned to controlled storage promptly. Nurses do not return medications to ADC stock; only to the ADC return bin.
- If matrix bins are used, each medication and strength has a separate bin.
- Medications with look-alike names or similar packaging are not stored near one another.
- Systematic inventory audits are performed to identify and remove expired and low usage products from ADCs.
- The institution has defined, and the pharmacy and therapeutics and medication safety committees have approved, the specific criteria to allow for medication override emergency situations for ADCs.

**Appendix B—Self-Assessment Checklist\*** (continued)

- Processes for taking a medication history and performing medication reconciliation on admission is standardized across the institution in different settings, (e.g., outpatient procedures, radiology) and ongoing education is conducted to ensure a safer system for patients.
- Institutional requirements for the review and reconciliation of the medication list within a set amount of time of an inpatient admission are outlined. High-risk medications, such as anticonvulsants, anticoagulants, and antibiotics should be reconciled sooner.
- Medication orders include patient identifiers (name, date of birth, patient number), patient allergies, generic drug name, trademarked name (if a specific product is required), route and site of administration, dosage form, dose, strength, quantity, frequency of administration, intended duration of therapy, indication for use, and prescriber's name. For intravenous medications, dilution, rate, and time of administration are specified.
- Vague or blanket instructions, such as "take as directed" or "resume pre-op meds" are not used for medication orders.
- Pediatric prescriptions should be prescribed both in units/weight and total individual dose.
- An independent double check of a preparation occurs regardless of who the preparer is.
- The pull-back method is avoided as a means to check preparations.
- For oral products not available in unit-of-use packaging, the preparations are repackaged by pharmacy staff.
- Frontline compounding personnel are involved in FMEA of new technologies used in compounding or other preparation areas.
- Oral syringes are only used for oral preparations and IV syringes are never used for oral medication administration.
- Products intended for other routes (e.g., potentially containing particulates, pyrogens or not sterile) are not dispensed in an IV bag to avoid mistaken administration by the parenteral route.
- All medications in nonemergency situations are reviewed by a pharmacist before dispensing.
- For high-risk drug products, (e.g., chemotherapy, pediatric medication, PPN), work is independently checked by a second individual, preferably another pharmacist.
- The hospital's pharmacy and therapeutics committee and medication safety committee has developed and implemented a list of medications with corresponding indications that are authorized for override. Criteria for appropriate override of medications are included, along with the clinical indication for overriding the medication (i.e., aspirin and chest pain), for specific circumstances. Compliance is monitored to minimize risk.
- An override monitoring process has been developed and audits are performed to ensure appropriate use by nurses and other authorized staff.
- BCMA reports are evaluated regularly to assess compliance and to identify potential barriers to ensure BCMA is being used effectively.
- A process is in place to notify the pharmacy when products are not scanning properly.
- The pharmacy dispenses patient-specific doses with barcodes whenever possible.
- Policies and procedures have been determined for how and when medication libraries are updated, who needs to approve the changes, and how unique situations such as drug shortages should be handled.
- The continuous quality improvement data analytics programs that are generated as reports and trends of medication alerts (overrides, bypass of soft alerts, and use of the free-text or "wildcard" function for medications not having standardized entries in the pump) are analyzed to keep the drug library settings for alerts, alarms, and advisories as robust as possible. Settings are continually updated and improved to encourage and reflect current best practices.
- All practitioners responsible for administering medications are properly trained on administration procedures.
- Effective medication administration education programs for practitioners have been established, and training is documented in the staff competency files and conducted periodically or as needed.
- Guidelines for the correct time to obtain blood for serum concentrations and laboratory values were created collaboratively by pharmacists, nurses, physicians, and laboratory staff.
- Critical values are determined with action alerts for clinicians and generated electronically.
- Staff is trained to identify common adverse effects encountered by patients. A pathway is in place to react to adverse reactions.
- Required monitoring for efficacy and toxicity is built into order panels or order sets whenever possible.
- Distractions are minimized when practitioners are evaluating patient data.
- Protocols are clearly written and readily available such that all practitioners can interpret each protocol in the same way.
- Institutional protocols approved by the pharmacy and therapeutics committee have been implemented to allow pharmacists or nurses to automatically modify dosing, obtain necessary rescue medications (i.e., naloxone, dextrose 50%, insulin), and order laboratory tests for patient safety.
- A standard place for practitioners to look for vital signs, pain scores, laboratory values, and point-of-care testing values is available.
- Standardization of medication administration times and pertinent monitoring times is built into the workflow and order sets.
- Pharmacists participate in multi-disciplinary discharge committees and are involved in the medication reconciliation process prior to discharge.
- There is an ongoing systematic program for improvement of pharmacy services and the medication-use system utilizing medication use evaluations and quality improvement tools such as Plan-Do-Study-Act (PDSA), Lean Production System, Six-Sigma, TeamSTEPPS<sup>®</sup> and FOCUS-PDCA.
- Root cause analyses (RCAs) (or other comprehensive systemic analyses) are performed for serious or significant medication events but may be used for any event that the institution wishes to evaluate in closer detail.
- Each institution (or pharmaceutical department) has a process for when an RCA is conducted.
- The institution or pharmaceutical department should consider utilizing the RCA2: Improving Root Cause Analyses and Actions to Prevent Harm recommendations.
- Regardless, there is a standard method and template for performing the RCA, as well as for reporting of the results and recommendations.
- Medication safety officers and pharmacists are involved in all RCAs evaluating a medication-related event.

## Appendix B—Self-Assessment Checklist\* (continued)

- Adequate time is set aside for pharmacy staff (and other hospital personnel) to attend the RCA meetings, including any needed training.
- Recommendations from a RCA or systemic analysis are monitored to ensure implementation.
- The institution has a method for voluntary reporting of events.
- Individuals who report events are notified of safety improvements that have occurred as a result; this information is also shared more collectively at staff meetings.
- The pharmaceutical department uses other methods to detect medication events, such as trigger tools or analysis of pharmacist therapeutic interventions.
- Events are shared with external organizations and agencies like the FDA and ISMP.

\*This checklist is included for information purposes only and may not be comprehensive.

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