Medication Safety

What Are the Risk Exposures?

Medication-related errors and liability are cited as the fourth most common root cause of claims, after diagnostic, surgical/procedural, and medical management issues, and ahead of obstetrics-related issues.[1] The Institute of Medicine (IOM) 1999 report, *To Err is Human: Building a Safer Health System*, dramatically increased the need to improve patient safety across the healthcare continuum. This landmark report estimated that medication errors caused 7,000 deaths annually in all healthcare settings.[2] The report cited three reasons for a renewed focus on medication safety: patients suffer great harm from medication errors, the cost of medication errors is high, and the strategies to prevent such errors are well-known.[2] Since the IOM published this report, measures have been implemented to help streamline medication processes. These measures include barcoding, electronic medical records, computerized physician order entry, and automated drug cabinets.

More recent data from the Institute of Safe Medication Practices (ISMP) notes:

> One indicator of the drug risks to the U.S. public is the subtotal of new adverse event reports that are domestic in origin and are fatal, disabling, or serious enough to result in hospitalization or have other severe medical consequences. In 2016, the FDA received 311,790 reports in this category, a decline of 8.4% from the previous year. The annual toll included 45,255 (14.5%) patient deaths, and 110,179 cases (35.3%) requiring hospitalization. For 8.1% of the 2016 cases, a medication error was shown as contributing to the injury reported.[3]

Despite the measures that have been implemented to help streamline medication processes, Coverys closed claims data from the years 2014 to 2018 shows a sharp increase in the frequency of medication-related claims from 2017 (189 claims) to 2018 (281 claims). Monitoring/management, ordering medication, and administration of medication emerged as the top three categories, while the top three medications involved in closed claims were anticoagulants, opioids, and antibiotics.

Medication safety is a challenge that requires broad, rapid, and effective interventions. The causes of medication risk issues are identifiable, successful remedies are available, and in many cases, the cost of implementation is relatively low.

When Is This a Risk Issue?

Medication errors occur for a multitude of reasons. While many medication errors result in no harm to the patient, others may result in injury or death. The section that follows highlights the risk issues that organizations should consider when crafting, implementing, and assessing medication safety policies.

Updated: April 2019

Medication Safety Definitions

Medication Error

The National Coordinating Council for Medication Error and Prevention has approved the following as its working definition of a medication error:

> A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing, order communication, product labeling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use.[4]

Adverse Drug Reaction

An adverse drug reaction (ADR) is "an unwanted, undesirable effect of a medication that occurs during clinical use."[5] The reactions can vary and may range from a nuisance effect, such as a dry mouth, to severe reactions, such as anaphylaxis. Additionally, adverse drug reactions can occur following an error-free administration of the medication.

Adverse Drug Event

An adverse drug event (ADE) is "an injury resulting from medical intervention related to a drug. This includes medication errors, adverse drug reactions, allergic reactions, and overdoses."[6]

Near Miss/Close Call

A near miss/close call refers to "an error that happened but did not reach the patient."[7] The patient is not harmed, but the potential for harm was there. When a near miss or close call occurs, it should be considered a patient safety event.

High-Alert Medications

High-alert medications (HAMs) bear a heightened risk of causing significant patient harm when they are used in error.[8] The consequences of errors with these medications can be devastating to patients. Examples of high-alert medications include heparin, warfarin, insulin, chemotherapy drugs, potassium chloride, opioids, neuromuscular blocking agents, antithrombotic agents, and adrenergic agonists.

The ISMP has published high-alert medication lists for several settings, including acute care, long-term care, and community/ambulatory care settings. These may be accessed on the ISMP website at: https://www.ismp.org/resources?field_resource_type_target_id%5B13%5D=13#resources--resources_list.

Organization Culture

Accountability

There are many potential causes for a medication error. In order to address both educational and disciplinary perspectives, the accountability model includes three categories of error-prone

staff behaviors: human oversight, at-risk-behavior, and recklessness. A patient safety culture that includes an accountability model will differentiate accountability according to the root cause of error.

Just Culture
Implementing a just culture provides a sense of balance between the individual staff member or physician and the organization that bears responsibility for developing and improving workplace systems. Such a culture encourages honest reporting by maintaining employee safety standards while striving to foster a quality learning environment, taking the focus from errors to outcomes.[9]

Error Reporting
Accurately identifying and reporting errors is a major component of a medication safety system. In order to precisely measure, analyze, and decrease medication errors and adverse drug events, as well as capture near misses, the organization must be aware of when, where, and how these events occur. There is no single common method for defining, detecting, and reporting events. Indeed, even errors that cause patient harm may go undetected because a cause-effect relationship is not understood.

Errors may go unreported due to a fear of personal consequences. Error reporting that is too time-consuming or asks for details beyond only the most critical information may also be a barrier. Additionally, error reporting that results in negative consequences may deter providers from reporting. Finally, while some medication errors may necessitate disciplinary action, this phase of systems improvement needs to be separate from educational or remedial action.

Performance Improvement Program
An organizationwide performance improvement program is critical to continuously address medication-related patient safety issues. Performance improvement promotes error reduction and fosters a patient safety culture.

Risk and Loss Identification and Classification
Early notification of actual or potential medication errors and credible information are the best tools an organization can use to identify trends and reduce or eliminate medication-related errors. Medication error identification tools are varied in type; using a combination of tools is recommended in all facility settings.

It is also helpful to capture the frequency of actual or potential errors and to classify them according to their severity. Gathering this information, placing it into a usable format, and then analyzing the data allows organizations to address medication-related events.
The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) has developed a Medication Error Index for categorizing medication errors. Categorizing medication errors helps prioritize them, which can assist with medication safety improvement efforts.

Trigger Tools

When relying on members of the healthcare team to report medication errors, fewer errors may be captured for a variety of reasons. Most notably, there are differing views on what constitutes a reportable error. Using triggers (or clues) is a strategy that may be employed to identify a harmful event before it occurs. "Triggers have become a widely used way to retrospectively analyze medical records in order to identify errors and adverse events, measure the frequency with which such events occur, and track the progress of safety initiatives over time."[10] Additionally, "Triggers alert patient safety personnel to possible adverse events so they can review the medical record to determine if an actual or potential adverse event has occurred."[10] Computerized methods of detecting and reporting trigger screens have proven very efficient and reliable. A great initial investment in electronic record capability is required to implement a trigger-based system, but it can yield significant savings in the time required by professional auditors, such as nurses and pharmacists. Another benefit is the value of concurrent review, which provides opportunities for more rapid action before harm reaches the patient.

The Institute for Healthcare Improvement (IHI) has addressed the use of trigger tools in *IHI Global Trigger Tool for Measuring Adverse Events*, Second Edition.

Compliance Audits

In order to determine compliance with high-risk medication safety procedures, baseline measurements need to be taken. Resulting data points form the foundation of the performance improvement cycle and are followed by periodic audits. The assumption is that as compliance with core processes increases, the number of adverse medication events will decrease.

Equipment that can be cumbersome to operate may give rise to personnel developing short cuts. Examples include automated dispensing cabinets, smart IV pumps, and bedside computerized delivery units. The information on these computers may be downloaded and analyzed for compliance with operating instructions and provide useful information for quality improvement and patient safety.

Technology

Technology has been developed to help facilitate medication ordering and administration. Updated technology can assist with standardization processes and reduce reliance on memory. Additionally, electronic information systems may decrease the number of steps in a process, promoting medication safety.

Barcoding, automated dispensing cabinets (ADCs), and smart pumps may all help with safe medication administration. One study on barcoding reported a 41.4 percent error reduction in non-timing error medication errors and a substantial reduction in order transcription errors.[11] A computer physician order entry (CPOE) system can help facilitate accurate medication ordering and prescription review. Ideally, a CPOE system should be evaluated and pilot tested before it is implemented to reduce the potential of unintended and detrimental effects. CPOE systems have proven to be a very effective for reducing medication errors, in some cases by as much as 48 percent.[12] Additionally, a CPOE system automatically checks for drug allergies and interactions, eliminates "do not use" abbreviations, and decision support can be built into the

order entry system. One disadvantage, however, is that providers may be able to override the system, negating the error reducing effect.

ADCs may improve the efficiency of drug dispensing and may even lead to a reduced need for staff members. However, some studies conducted prior to the software and hardware enhancements that are currently available showed mixed results in medication error reduction. Organizations may consider instituting guidelines if they plan to implement ADCs in their facility. In 2019, the ISMP published *Guidelines for the Safe Use of Automated Dispensing Cabinets*. The introductory note from the ISMP president states:

> We are now far more comfortable with the ability of ADCs to support the safety of the medication distribution system while making required drugs readily accessible in a variety of patient care areas. However, this is not to say that there are not continued improvements to be made or potential pitfalls associated with the use of these devices, particularly if workflow expectations are not well designed or defined. Clearly, if remaining risks to safety are not properly managed, patients can be placed in jeopardy.[13]

Education and Training
Medication systems can be complex, as can a patient's medication therapies. Proper education, training, and competency demonstrations should be standardized to help keep patients safe.

Real-Time Support Tools
Access to reliable drug information can play a significant role in averting serious misjudgments and unfortunate medication errors. Sufficient and reliable information must be promptly available to providers about new drugs, infrequently used drugs, and non-formulary drugs.

Intravenous (IV) Therapies
Given the direct route used, an error made in the administration of an IV medication or electrolyte therapy can result in particularly severe outcomes. Multiple strategies should be implemented to increase the safety of IV therapy. Organizations may consider using *ISMP Safe Practice Guidelines for Adult IV Push Medications* as a resource when developing these strategies. In addition, the ISMP has published *Part I: Survey Results Show Unsafe Practices Persist with IV Push Medications*. Implementing safe practices and remaining aware of unsafe practices associated with IV therapy are key components for decreasing medication errors associated with IV therapies.

Distractions
The potential for omitting a drug or for ordering, preparing, and/or administering an improper dose or wrong drug increases when distractions, such as call bells, ringing phones, or conversations, are not addressed and minimized. Policies should address the need for healthcare workers to deal with medication processes in environments that are as free from distractions as possible.

Small or Rural Hospital Pharmacies

It is not uncommon for pharmacy services to operate under reduced hours in small and rural hospitals. Due to the potential risk of errors and adverse outcomes with less than 24/7 pharmacy coverage, facilities should implement policies for accessing medications when the pharmacy is closed. In this situation, a pharmacist should be on-call to answer questions and respond in person when necessary. Remote medication order processing may be an option; however this would not preclude keeping a pharmacist on-call.

Patient Education

Ensuring that patients know their medications, the reasons why the medications were prescribed, the expected effects of the medications, and the potential side effects is crucial to medication safety. Additionally, a detailed health history which includes current medications, any adverse effects previously experienced, and general clinical status is also necessary to help prevent medication errors and injury.

Communication Between Providers

Patient Hand-Offs

Inaccurate or delayed information can be a root cause of error, as can unclear communication between providers and/or an insufficient opportunity to ask questions. Transitions in patient care occur frequently in healthcare, including transitions from shift to shift, from service to service, from facility to facility, or from facility to home. While necessary, these transitions carry the risk that crucial patient care information will be omitted, misplaced, or miscommunicated. It is therefore important to have a standardized and structured way to relay information.

Problem Resolution

Differences of opinion or the need for clarification of treatment orders can occur during patient care. Clarification of orders is often required, such as when written orders cannot be deciphered or when face-to-face communication is not possible. These should be anticipated and a process to clarify orders should be in place.

Abbreviations

The use of certain abbreviations in healthcare carries significant patient safety implications. A list of prohibited high-risk abbreviations should be readily available to all prescribers and providers. For more sample list, see *ISMP's List of Error-Prone Abbreviations*.

High-Risk Medications

Anticoagulants, opioids, and antibiotics deserve special consideration to ensure patient outcomes and reduce error.

Anticoagulants

As a class of drugs, anticoagulants are one of the top five drug types associated with patient safety events in the United States. According to their annual 2016 report, the ISMP noted that harm from oral anticoagulants ranked as one of the highest priority drug safety problems.[14] The report provides five steps that entities may take to minimize harm caused by anticoagulants. Referencing a 2016 CDC study, the ISMP stated "anticoagulant drugs

accounted for more emergency department (ED) visits for outpatient adverse effects than any other class of drugs in therapeutic use" and further, "anticoagulant events were mostly severe, with 48.8% requiring a hospital stay."[14] The ISMP annual report concluded that:

> From the onset, long-term use of oral anticoagulants exemplified a dangerous balance between a clearly demonstrated benefit in preventing ischemic stroke against the high risk of bleeding and fewer-in-number but substantially increased risk of hemorrhagic strokes. Many healthcare professionals have been willing to risk causing more hemorrhages that can be treated in order to prevent disabling, life-changing ischemic strokes. But, given that few other outpatient drug treatments cause serious injuries to 6% or more patients treated for a year, the need is great to reduce the risks associated with this class of drugs.[14]

According to a Coverys white paper, "Events involving opioids and anticoagulation drugs represent the highest percentage of medication-related claims, followed by antibiotics."[1]

According to the Office of Disease Prevention and Health Promotion:

> Among hospitalized patients (i.e., inpatient settings), significant challenges to optimal anticoagulation management persist despite advancements in health care delivery models and health information technology (health IT) resources (e.g., computerized physician order entry, electronic medication administration records, clinical decision support).[15]

Over time, new anticoagulants have been added, which has created a new set of problems.

Managing new oral anticoagulants was the ninth concern listed in ECRI Institute's *Top 10 Patient Safety Concerns for 2017*. In an article on managing new oral anticoagulants, the ECRI Institute states:

> A query of ECRI Institute PSO's event report database identified 1,226 events associated with the new oral anticoagulants between 2010 and mid-2016. Of the 494 events for which a harm score was provided, almost 34% resulted in patient harm, ranging from temporary injuries to death. Bleeding events were among the most common types of events that reached patients.[16]

A Coverys white paper states:

- The majority of anticoagulation claims allege medication-related issues (49 percent) or lapses in clinical judgment (19 percent).
- More than 40 percent of claims related to anticoagulants involved general medicine prescribers, whereas only a small percentage of claims involved medical subspecialties, surgery, orthopedics, or emergency medicine.

- The issuance and management of anticoagulation drugs accounts for 28 percent of all anticoagulation claims in the office/clinic setting and 43 percent of such claims in the hospital setting.
- With anticoagulation medications, dosing is vital. Among risk management subcategories in anticoagulation claims, computation and prescribing error were involved in the highest number (32 percent) of cases.
- Anticoagulation claims were steady across our five-year review. Nearly all allegations involved the beginning and the end of the episode of care with 44 percent of anticoagulation claims stemming from the initial ordering of the medication and 44 percent of all such claims relating to the monitoring and management of the patient over time.[1]

Opioids
According to the Centers for Disease Control (CDC):

> Opioid pain medication use presents serious risks, including overdose and opioid use disorder. From 1999 to 2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States [i]. In the past decade, while the death rates for the top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid pain medication has increased markedly [ii].[17]

According to a Coverys white paper, "opioids accounted for the highest percentage of medication-related claims—more than 14 percent."[1]

While some clinicians are beginning to address the opioid crisis, much more work needs to be done. Responsible pain management should address patient needs without creating a culture of dependency. The CDC has published an excellent resource, *Guideline for Prescribing Opioids for Chronic Pain – Improving Practice through Recommendations.*

Additionally, facilities should develop and implement policies that address drug diversion.

Antibiotics
Antibiotics have been proven to successfully treat numerous dangerous infections and save lives. Unfortunately, these tremendous benefits are accompanied by serious risks, such as adverse drug effects and the manifestation of serious infections (e.g., Clostridium difficile).[18] Antibiotic misuse has contributed to the growth of antibiotic-resistant organisms, even impacting those who have never taken an antibiotic. This sadly contributes to an estimated 23,000 death each year.[19] "In recognition of the urgent need to improve antibiotic use in hospitals and the benefits of antibiotic stewardship programs, in 2014 CDC recommended that all acute care hospitals implement Antibiotic Stewardship Programs."[19] Implementing an Antibiotic Stewardship Program can help ensure appropriate antibiotic therapy, assist in decreasing adverse events, and help reduce the development of antibiotic resistance.

How Can I Reduce Risk?

Individual practitioners work diligently every day within highly complex medication systems to provide exceptional care to patients. Yet, despite their best efforts, there are times when the human interface with complicated medication systems goes awry and medication errors occur. Safety-minded organizations impacted by diminishing resources, ever-changing technology, complex therapies, and newly marketed pharmaceutical products are challenged to implement high-leverage medication error prevention strategies to reduce the possibility of patient harm.

The ISMP has targeted 14 best practices for medication safety for prescribing practitioners in a publication titled *2018-2019 Targeted Medication Safety Best Practices for Hospitals*.

Address Medication Safety Organizationwide	
Address safety	• Ensure that leaders, physicians, and staff members are included in medication safety efforts. • Adopt a non-punitive policy for reporting potential and actual medication errors. • Provide incentives for reporting medication safety issues. • Establish a multidisciplinary committee, composed of pharmacists, nurses, and prescribing clinicians, which meets regularly to examine medication error trends and suggests process improvements. • Share success stories and improvement opportunities with other departments and disciplines. • Provide multiple methods for staff members to report errors and suggest improvements for using medication safely. • Standardize and simplify procedures and protocols. • Conduct audits to determine which processes are working well and which need to be revised.

Implement culture of safety program	• Conduct a survey of safety culture to evaluate the following:
	  ○ Investment in resources, such as information systems, to reduce medication errors;
	  ○ Safety as an executive priority, with leaders acting on barriers to safe practices;

Address Medication Safety Organizationwide	
	○ Adequate staffing levels and back-up coverage for nurses, pharmacists, and physicians; ○ Unit-based clinical pharmacists as a resource to physicians and nurses; ○ Positive feedback for consistent use of policies, procedures, and clinical protocols; ○ Strength of teamwork; ○ "Stopping the line" empowerment of front-line staff members; ○ A learning culture in which errors and near-misses are seen as opportunities for improvement; and ○ Experiences with reporting errors.
Implement formal error reporting program	• Evaluate the reporting system to determine if it is used as intended. • Educate and support staff members so that the error reporting process is understood, accepted, and implemented consistently. • Consider putting a confidential hotline reporting system and/or employee suggestion program in place. • Balance provider accountability with a visible effort to find and address root causes related to the medication delivery system. • Analyze error reports promptly and give timely feedback to the reporting provider. • Report actual events and near-miss events separately. • Educate new physicians, residents, and other prescribing clinicians (e.g., nurse practitioners, physician assistants) on basic principles of medication safety, prescription writing, and what to include on a prescription or order.

Address Medication Safety Organizationwide	
	• Provide clear expectations to licensed caregivers regarding established procedures and safeguards aimed at medication error prevention. • Establish reasonable workloads and work hours for all caregivers. ○ Ensure that established workloads and work hours are only rarely exceeded, such as during an emergency.
Implement continuous performance improvement program	• Enact full-cycle plan-do-check-act (PDCA) medication error improvement projects. ○ Include executive-level oversight, physician participation, and data-based outcome evaluation. • Use a systems perspective with regard to medication error prevention. • Collaborate across departments and disciplines. • Establish effective, multichannel error reporting procedures with staff support members. • Provide employees and providers with a process to submit suggestions for improvement. • Provide incentives for staff members to commit to error prevention (e.g., data feedback on improvements accomplished). • Consider using root cause analyses in performance improvement activities.

Establish a pharmacy and therapeutics committee	• Establish a committee that focuses on developing medication-related policies.
	• Have the committee be responsible for the following:
	  ○ Evaluation and use of medications within the institution;
	  ○ Developing a formulary;
	  ○ Usage of drug delivery devices;
	  ○ Evaluating medication errors and near-misses; and

Address Medication Safety Organizationwide

- Include a pharmacist, physicians, other prescribing clinicians, nurses, and the risk manager.

Use Medication Error Identification Tools

Consider retrospective claims classification

- Choose the severity level at which events are acted upon.
- Keep in mind that near miss and close call events provide excellent data to improve safety and prevent foreseeable harm.
- Consider the following severity categories recommended by Coverys:
  - Resulted in temporary harm to patient that requires intervention;
  - Resulted in temporary harm to patient that requires initial or prolonged hospitalization;
  - Resulted in permanent harm to patient;
  - Resulted in harm to patient that required intervention to sustain life; and
  - Resulted in harm to patient that led to death.
- Another resource that organizations may consider using to categorize medication errors is *NCCMERP's* Medication Error Index.

Consider medication process classification

- Classify each medication-related event according to when it occurred in the medication process.
- Understand the distinct categories of the medication process and the related elements in order to provide detailed classification:
  - Prescribing:
    - Clinical assessment.
    - Drug choice.
    - Drug schedule.
    - Documentation in medical record.
    - Medication order (written, verbal, electronic).

Use Medication Error Identification Tools

- Patient education.
  - Dispensing:
    - Data entry/screening.
    - Preparation of medication.
    - Pharmacist review.
    - Dispensing to patient.
    - Over-the-counter drugs (patient self-dispenses).
  - Administering:
    - Verifying instructions.
    - Preparing/measuring dose.
    - Verifying patient identity.
    - Administering dose.
    - Over-the-counter drugs (patient self-administers).
  - Monitoring and management:
    - Self-monitoring response.
    - Prescriber monitors for therapeutic/adverse effects.
    - Document in medical record.
    - Adverse event – discontinue medication and call physician/prescribing clinician or visit ED.
  - Controlled substances:
    - Wasting and disposal.
    - Returns to pharmacy.

Use "trigger" tools

- Consider the following when developing trigger tools or when determining which trigger tool to use:
  - For diagnostic-related errors, identify the diagnostic errors to focus on and prioritize them;
  - Determine standardized definitions and criteria to determine inclusion and exclusion criteria;

Use Medication Error Identification Tools

- Identify potential electronic sources to collect and review data; and
- Review current literature related to trigger tools to determine which tools work best with the organization.

- Understand that any trigger tool methodology may not identify all sources of patient harm or the cause of patient harm.

Use an event reporting system to report medication errors

- Please see the ***Risk Identification*** chapter in the Coverys *Healthcare Facility Risk Management Manual*.

Conduct root cause analyses

- Please review the ***Root Cause Analysis*** chapter in the Coverys *Healthcare Facility Risk Management Manual*.

Conduct Compliance Audits Related to Medication Safety Procedures

Take baseline measurements

- Collect data through the following sources:
  - Medical record audits;
  - Manual or electronic documentation audits;
  - Direct observation of staff member actions;
  - Interviews;
  - Self-reports and self-assessments;
  - On-site reviews of medication supplies, labeling, and storage; and
  - Medication reconciliation forms.
- Make sure that the three-step process for medication reconciliation is consistently followed:
  - Verification (i.e., collecting accurate medication histories);
  - Clarification to ensure that medication and medication dosages are correct; and
  - Reconciliation - Reconciling medications to ensure that all medications a patient takes include drug name, dosage, frequency, and

Conduct Compliance Audits Related to Medication Safety Procedures

	route, as well as that any changes in medications that may have been prescribed during a patient's stay are compared against prescribing orders throughout the patients admission, transfer, or discharge continuum.

Determine compliance	• Determine staff member compliance with the following:
	  ○ Validating patient identification before medication administration;
	  ○ Determining if bar code administration follows the organization's policies and procedures;
	  ○ Limiting verbal and telephone orders;
	  ○ Determining whether medication orders contain any error-prone abbreviations;
	  ○ Using a standardized hand-off communication processes;
	  ○ Ensuring pharmacist overview and verification prior to administering first dose of newly prescribed medications;
	  ○ Safeguarding high-risk medication concentrations;
	  ○ Double-checking high-risk medications;
	  ○ Implementing safeguard actions for look-alike, sound-alike medications;
	  ○ Practicing safe medication labeling;
	  ○ Documenting medication reconciliation at transition points; and
	  ○ Including the patient and family members in the medication process.

Use Proactive Interventions for Safe Medication Administration

Consider medication safety experts	• Seek the advice of medication safety industry experts, such as the Institute for Safe Medication Practice (ISMP) and the Institute for Healthcare Improvement (IHI).

Use Proactive Interventions for Safe Medication Administration

- Consider the following recommendations from the NCCMERP:
  - Clarify any order that is incomplete, illegible, or raises questions or concerns through a formal process;
  - Use technology, such as barcoding, computer order entry, and smart pumps;
  - Require the following checks before administering any medication: right dose, right medication, right medication form, right route, right patient, right time, right reason, and right anticipated response;
  - Provide education and training and require demonstration of competency for medication administration devices;
  - Use only electronic infusion devices that prevent free-flow;
  - Monitor and evaluate the safety of medication administration devices;
  - Ensure that those who administer medications have easy access to patient information, such as medical history, drug allergies, weight, diagnoses, current medications, lab results, and plan of care at all times, and especially during transitions in care;
  - Ensure that those who administer medications have easy access to medication information, such as indications, contraindications for use, the expected response, known or suspected adverse drug effects, interactions with other medications or substances, how to respond to adverse drug events, storage, drug preparation, and dosing guidelines;
  - Require that only properly labeled medications are administered and that labels be read when preparing a medication, just prior to administering a medication, and when replacing unused medication into its storage location;

Use Proactive Interventions for Safe Medication Administration

- Require the patient and the patient's caregiver to have a conversation regarding the medication name, reasons for the medication, expected effects, and untoward effects upon first-time administration, and to conduct a review upon subsequent administrations;
- Require monitoring and documentation of the patient's response and any adverse effects; and
- Establish policies for drugs prepared by professionals other than pharmacists.

Enhance Prescribing Clinician Knowledge and Skills

Ensure prescribing clinicians have requisite knowledge

- Be certain prescribers are knowledgeable about the purpose, indications, and expected outcomes of the frequently ordered, dispensed, and administered medications.
- Ensure that attention is paid to the facility-specific patient population.
- Be certain that knowledge includes usual dose range, frequency, and intended route of administration, as well as contraindications and precautions.
- Avert potential adverse reactions through close patient monitoring, especially with respect to high-risk medications.

Provide real-time support

- Ensure that physicians and other clinician prescribers have real-time access to decision support tools.
- Offer clinical pharmacy consultation as a ready resource for all prescribers.
- Make educational information, such as newsletters, drug summary sheets, computer aids, and electronic drug reference materials, readily available.

Implement IV Administration Safeguards

Use safeguards

- Ensure that all IV pump lines are properly labeled.

Implement IV Administration Safeguards

- Test nursing care providers on the correct operation and programming of each type of IV pump used by the facility.
- Use hands-on teaching and direct observation of nurse providers to ensure that they are using correct IV medication administration techniques.

Implement IV standardization

- Standardize all IV solutions, equipment, and supplies:
  - Implement unit doses;
  - Use "smart IV pumps" that can intercept and prevent wrong doses or wrong infusion rates; and
  - Use a central pharmacy IV admixture program 24 hours a day, seven days a week.

Address Look-Alike/Sound-Alike Drugs

Implement prevention measures

- Ensure that the purpose of the medication is included on the prescription or medication order.
- Provide both generic and brand names of drugs on medication orders and labels.
- Prohibit the storing of problem medications alphabetically by name.
  - Store these medications out of order or in alternate locations.
  - Ensure that look-alike/sound-alike drugs are not near each other in the ADC.
- Use high-alert stickers or electronic alerts to make sure that double-checks are executed prior to administration.
- "Segregate, sequester, and differentiate all neuromuscular blocking agents (NMBs) from other medications, wherever they are stored in the organization."[20]
- Use tall man lettering to distinguish between similar drug names.
  - From ISMP:

    Tall man lettering, a term coined by the Institute for Safe Medication Practices

Address Look-Alike/Sound-Alike Drugs

(ISMP), describes a method for differentiating the unique letter characters of similar drug names known to have been confused with one another. Starting with a drug name printed in lowercase letters, tall man lettering highlights the differences between similar drug names by capitalizing dissimilar letters. Accentuating a unique portion of a drug name with uppercase letters along with other means, such as color, bolding, or contrast, can draw attention to the dissimilarities between look-alike drug names as well as alert healthcare providers that the drug name can be confused with another drug name.[21]

Standardize and Limit Number of Drug Concentrations

Regulate drug concentrations

- Standardize and limit the number of drug concentrations to decrease the potential administration of rapidly detrimental, excessive dosages of high-concentration, high-alert drugs.
- Maintain only single concentrations of high-alert drugs in stock (e.g., morphine, heparin, insulin, vasopressors).
- Restrict access to concentrated electrolytes to pharmacy staff members only.
- Perform an independent double-check of high-alert medications.

Use Available Technology and Electronic Information Systems

Consider bar coding systems

- Understand that bar coding involves a system in which the healthcare worker scans a bar-coded label worn by the patient and then scans the medication.
- Understand that the system then confirms that the patient has been prescribed the medication.
- Be aware that if the patient and medication do not match, the system issues a warning.
- Be aware that workloads, especially for nurses administering medications, may increase initially.

Use Available Technology and Electronic Information Systems

- If bar coding is implemented, review scan rates and overrides as an element of the quality assurance process.

Use ADCs

- Understand that ADCs are medication cabinets that electronically dispense medications and track medication use.
- Understand that ADCs allow medications to be stored on nursing units and retrieved quickly and conveniently once the order is entered.
- Be aware that ADCs dispense only to a specific patient and guard against “wrong patient” error.

Minimize Distractions in Medication Ordering, Preparation, and Administration

Reduce distractions

- Establish policies and practices that help minimize distractions, such as posting visible “do not disturb” signs in select high-risk areas.
- Place phones away from areas where healthcare workers are preparing, dispensing, or administering medications.
- Facilitate the use of a pocket checklist for select critical tasks.
- Raise staff member awareness of the effects of distractions and how to avoid them.

Make Good Use of Pharmacists

Involve pharmacists

- Include pharmacists as part of the patient care team.
- Ensure that pharmacists monitor high-alert medications.
- Be sure that pharmacists review lab values for serum drug levels daily (or as often as may be required).
- Be certain that pharmacists monitor drug therapy for all patients in the intensive care setting.
- Involve pharmacists in patient and family member education in the acute care setting and, most importantly, prior to discharge.

Updated: April 2019

Make Good Use of Pharmacists	
Provide guidance for pharmacies with limited hours	• Make a limited set of medications (approved by the organization) available after pharmacy hours. • Store these medications outside of the pharmacy in a secure manner (e.g., locked cabinet). • Ensure that only trained and designated prescribers and nurses may access these medications. • Establish quality control procedures to prevent medication retrieval errors. • Ensure that a qualified pharmacist is available to answer questions or provide medications which are not accessible to non-pharmacy staff members. • Review after-hour access for appropriateness on a regular basis.[22]
Educate and Involve Patients	
Access patient/family member information	• Ensure that the facility has a list of patient's current medications and treatment orders. • Obtain information related to current medical problems, procedures ordered and completed, and any comorbidities. • Obtain information regarding any recent adverse events or complications. • Obtain an accurate height and weight (in kilograms[20]) for each patient. • Obtain patient information regarding any allergies. Obtain information regarding both the allergen and the patient's reaction to it. With regard to claimed medication allergies, confirm whether it is a true allergy or an intolerance. • Ensure that any recent diagnostic results, blood levels, etc., are available. • Obtain the patient's general clinical status prior to medication administration (e.g., observable vital functions, such as respiration, whether patient is alert

Educate and Involve Patients	
	or lethargic, current pain level, any complaints regarding potential medication side effects). • Try to gather details regarding family dynamics and support that may impact the patient's health status.

Educate patients	• Provide patients with formal education regarding prescription medications, including:
	  ○ Reason the drug is prescribed;
	  ○ Any instructions regarding administration;
	  ○ Intended and untoward effects; and
	  ○ Special precautions.
	• Give patients the opportunity to ask questions about medications.
	• Provide education about medication administration policies, such as barcoding and wristband checks.
	• Encourage patients to speak up if they believe they are getting the wrong medication.
	• Develop a process to evaluate current discharge instruction policies and practices for effectiveness.

Establish Policies That Strengthen Provider Communication	
Use structured hand-off communication	• Use standardized, structured communication when transferring information, authority, and responsibility for a patient during a care transition.[23] • Develop guidelines for verbal as well as written hand-offs.
Implement chain of command	• Develop a chain of command policy that includes the means for contacting a decision maker when needed. • Ensure that the policy states under which circumstances to implement the process. • Develop clear documentation guidelines. • Evaluate each event that triggers the chain of command process to determine the type of issues,

Establish Policies That Strengthen Provider Communication	
	patterns with providers, and any recommended actions to follow.
Use a formal repeat- or read-back process	• Implement a repeat-back process to verify verbal orders. • Implement a read-back process to clarify illegible written orders.
Prohibit high-risk abbreviations	• Make a list of prohibited high-risk abbreviations readily available to providers. • Audit patient charts regularly for abbreviation usage.[8]

Educate Prescribers and Healthcare Providers on Anticoagulant Therapy	
Educate regarding anticoagulants	• Develop a program to educate prescribers, nurses, and pharmacists on patient selection and those patients for whom anticoagulants are contraindicated. • Develop guidelines for screening patients to identify their current medications, drug compatibility, and conditions, such as heparin-induced antibodies or heparin-induced thrombocytopenia, or any other factors that may alter dosing or that contraindicate anticoagulants. • Ensure that standard baseline information, such as weight in kilograms and serum creatinine function, is documented on an anticoagulation checklist prior to ordering anticoagulants. • Be sure the age of the patient is considered during ordering. • Ensure that the patient's current calculated creatinine clearance and other labs are available when prescribing electronically. • Provide access during medication ordering to process control charts displaying a patient's trend in INR values. • Ensure that a process addresses anticoagulant hold orders and a reminder to consider reinstating the anticoagulant.

Educate Prescribers and Healthcare Providers on Anticoagulant Therapy

- ***Anticoagulation Overview, Resources, and Self-Assessment - SAMPLE*** tool is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

Educate Prescribers and Healthcare Providers on Opioid Therapy

Educate regarding opioids

- Develop a program to educate prescribers, nurses, and pharmacists on patient selection and those patients for whom opioids are contraindicated.
- Develop guidelines for screening patients to identify their current medications, drug compatibility, and conditions or factors that may alter dosing or that contraindicate prescribing opioids.
- Develop pain management protocols that address the criteria for a pain management consultation and include the following for patients receiving opioids:
  - Time frames for opioid therapy;
  - Anticipated progress;
  - Reasons for discontinuance of opioids; and
  - Requirement to query the state prescription drug monitoring program.
- Ensure that written dosing guidelines for oral and parenteral opioids are available to all prescribers.
- Ensure that pharmacy checks are in place before opioids are dispensed to the unit.
- Develop a hard stop policy for pharmacy personnel to implement when any medication is contraindicated or insufficient information is available to evaluate the order.
- Eliminate the prescribing of fentanyl patches for opioid-naïve patients and/or patients with acute pain.[20]
- Be certain that all clinician prescriber orders for opioids include the following:
  - Name, age, and weight (in kilograms) of patient;

Educate Prescribers and Healthcare Providers on Opioid Therapy

- Date and time;
- Drug name;
- Drug dose;
- Drug frequency;
- Drug route;
- Instructions for use; and
- If applicable, the drug strength, concentration, quantity, and/or duration.

Develop opioid administration and monitoring guidelines

- Address the timing of opioid administration, explaining when opioids are “not eligible” or are “eligible for” scheduled dosing times.
- Develop a system to evaluate opioid administration timing policies.
- Develop opioid pre-administration guidelines that require assessing the patient.
- Ensure that the patient assessment includes:
  - Evaluation of pain level;
  - Respiratory rate;
  - Heart rate;
  - Blood pressure;
  - Last dose of opioids or medications that may alter the effects of opioids; and
  - Laboratory test results, when applicable.
- Generate post-administration guidelines that require patient assessment within a designated time frame of administration and includes:
  - Evaluation of pain level;
  - Respiratory rate;
  - Heart rate;
  - Blood pressure; and
  - Patient’s report of medication’s effects.

Educate Prescribers and Healthcare Providers on Opioid Therapy

- Consider conducting continuous patient monitoring through motion and low perfusion pulse oximetry that has a primary and secondary notification alert.
- Implement post-administration documentation guidelines that require:
  - The time of opioid administration;
  - Dose and route of oral and parenteral opioids;
  - The location of administration; and
  - The removal of transdermal opioids.
- Ensure that smart pumps are used for all PCA-administered opioids.
- Require double, independent checks for each new opioid infusion preparation or syringe or change in the rate of an infusion.
- Ensure that reversal agents and guidelines for use are accessible on all units where opioids are administered.
- Provide education on the untoward effects of opioid medication usage to patients and their family members, when possible and permissible.
- Instruct patients how to alert a nursing staff member.
- Develop a pain management contract for use with patients who are discharged on opioids. Make sure that the contract addresses:
  - Education and agreement on opioid use;
  - The need to use one provider and one pharmacy for prescriptions;
  - Follow-up instructions on provider visits;
  - Proper drug disposal; and
  - Instructions to not use illicit drugs.
- ***Hospital Opioid Self-Assessment Tool and Instructions-SAMPLE*** is available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.

Educate Prescribers and Healthcare Providers on Opioid Therapy	
Prevent drug diversion	• Develop and implement guidelines that require discontinued opioids to be returned to the pharmacy within a certain time frame. • Develop and implement guidelines addressing how to dispose of opioids that were opened but will not be used. • Ensure that the drug disposal program complies with federal and state laws and guidelines.
Sample Tools	• ***Controlled Substance Access and Handling – SAMPLE***; • ***Drug Diversion Investigation Checklist – SAMPLE***; • ***Drug Diversion Prevention, Detection and Response – SAMPLE***; • ***Drug Diversion Program Essential Components – SAMPLE***; • ***Drug Diversion Risk Rounds Checklist – SAMPLE***; • ***Drug Diversion Specialist Job Description – SAMPLE***; • ***Identification, Reporting and Evaluation of Impaired Staff Member – SAMPLE***; and • ***Reasonable Suspicion Testing for Drug Diversion or Impairment in Staff Member with Clinical Duties – SAMPLE*** are available in the Healthcare Facility Tool Chest on the Risk Management Policyholder Resources Portal.
Develop Support for Optimizing Use of Antibiotics	
Optimize antibiotic use	• Ensure that prescribing policies require documentation of certain information for all antibiotic orders and address antibiotic selection treatment guidelines. • Implement interventions to improve antibiotic usage, including: ○ Appropriateness of antibiotic use (e.g., correct antibiotic, correct dose and route of

Develop Support for Optimizing Use of Antibiotics	
	administration, determination if a more targeted antibiotic may be needed based upon culture and sensitivity reports); ○ A required approval process for certain antibiotics; ○ Audits conducted to track compliance; ○ Changes by the pharmacist of antibiotic administration route and dose, when appropriate; ○ Time-sensitive stop orders and automatic alerts are used, when indicated; and ○ Specific antibiotic interventions for community-acquired pneumonia; urinary tract, non-C difficile, some bloodstream, and skin/soft tissue infections; MRSA; and surgical prophylaxis.[19]
Provide education	• Provide facility-specific education regarding antibiotic usage and antibiograms. • Educate clinicians and other staff members on improving antibiotic prescribing.[19]
Obtain support and accountability	• Ensure that a written support statement and a specific budget are in place to help sustain efforts to improve antibiotic use. • Choose a physician leader who is responsible for the antibiotic stewardship program and its outcomes. • Include nurses, clinicians, and quality improvement, microbiology, and IT staff members in stewardship efforts. • Choose a pharmacist leader designated to work on improving antibiotic use.[19]
Implement tracking mechanisms	• Monitor adherence to documentation, facility-specific treatment programs, and any specific interventions. • Monitor rates of C. difficile infection and produce a cumulative antibiotic susceptibility report. • Monitor the use of antibiotics at the unit and facility levels. Monitor antibiotics used, grams used, and purchasing cost of the medications.[19]

References:

1. Hanscom R, Small M, Lambrecht A. A dose of insight: a data-driven review of the state of medication-related errors & liability in American healthcare. Coverys white paper. Available at: https://coverys.com/PDFs/Coverys_White_Paper-A_Dose_of_Insight.aspx
2. Kohn L, Corrigan J, Donaldson M. *To Err is Human: Building a Safer Health System*. Washington DC: National Academy Press; 2000.
3. Institute for Safe Medication Practices. Executive summary. ISMP Quarter Watch. https://www.ismp.org/sites/default/files/attachments/2018-01/2016Q4_1.pdf. July 12, 2017. Accessed March 21, 2019.
4. National Coordinating Council for Medication Error and Prevention. About medication errors. https://www.nccmerp.org/about-medication-errors. Accessed March 21, 2019.
5. Schatz SN, Weber RJ. Adverse drug reactions. PSAP 2015. CNS/Pharmacy Practice. Available at: https://www.accp.com/docs/bookstore/psap/2015B2.SampleChapter.pdf
6. Office of Disease Prevention and Health Promotion, Overview - Adverse drug events. https://health.gov/hcq/ade.asp. Page last updated March 21, 2019. Accessed March 21, 2019.
7. Institute for Safe Medication Practices. ISMP survey helps define near miss and close call. https://www.ismp.org/resources/ismp-survey-helps-define-near-miss-and-close-call. September 24, 2009. Accessed March 21, 2019.
8. Institute for Safe Medication Practices. Frequently asked questions. https://forms.ismp.org/faq.asp. 2019. Accessed March 21, 2019.
9. Boysen PG II. Just culture: a foundation for balanced accountability and patient safety. *The Ochsner Journal*. 2013;13(3):400-406.
10. Agency for Healthcare Research and Quality, Patient Safety Network. Triggers and trigger tools. https://psnet.ahrq.gov/primers/primer/33/Triggers-and-Trigger-Tools. Last updated January 2019, Accessed March 21, 2019.
11. Poon EG, Keohane CA, Yoon CS, et al. Effect of bar-code technology on the safety of medication administration. *JAMA*. 2010;362(18):1698-1707.
12. Radley DC, Wasserman MR, Olsho LE, Shoemaker SJ, Spranca MD, Bradshaw B. Reduction in medication errors in hospitals due to adoption of computerized provider order entry systems. *J Am Med Inform Assoc*. 2013;20(3):470-476.
13. Institute for Safe Medication Practices. *Guidelines for the Safe Use of Automated Dispensing Cabinets*. ISMP. 2019.
14. Institute for Safe Medication Practices. QuarterWatch™ (2016 Annual Report) Part II: Oral anticoagulants—the nation's top risk of acute injury from drugs. https://www.ismp.org/resources/quarterwatchtm-2016-annual-report-part-ii-oral-anticoagulants-nations-top-risk-acute. July 27, 2017. Accessed March 21, 2019.
15. U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion. *National Action Plan for Adverse Drug Event Prevention*. Washington, DC. 2014. Available at: https://health.gov/hcq/pdfs/ADE-Action-Plan-508c.pdf
16. ECRI Institute. Management of new oral anticoagulants. *Healthcare Risk, Quality, &Safety Guidance*. Published March 13, 2017.
17. Dowell D, Haegerich TM, Chou R. CDC guideline for prescribing opioids for chronic pain — United States, 2016. *MMWR*. 2016;65(1):1-49. Citing [i] CDC. Multiple cause of death data on CDC WONDER. Atlanta, GA: US Department of Health and Human Services, CDC; 2016; and [ii] CDC, National Center for Health Statistics. Health, United States, 2014: with special feature on adults aged 55–64. Hyattsville, MD: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2015. Available at: https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
18. Paulozzi L, Jones C, Mack K, Rudd RA; Div of Unintentional Injury Prevention, National Center for Injury Prevention and Control, CDC. Vital signs: overdoses of prescription opioid pain relievers – United States, 1999-2008. *MMWR*. 2011;60(43):1487-1492.

19. Centers for Disease Control and Prevention. Core elements of hospital antibiotic stewardship programs. https://www.cdc.gov/antibiotic-use/healthcare/implementation/core-elements.html, Page last reviewed May 7, 2015. Accessed March 21, 2019.
20. Institute for Safe Medication Practices. *2018-2019 Targeted Medication Safety Best Practices for Hospitals.* Available at: https://www.ismp.org/sites/default/files/attachments/2019-01/TMSBP-for-Hospitalsv2.pdf
21. Institute for Safe Medication Practices. Special Edition: Tall man lettering; ISMP updates its list of drug names with tall man letters. https://www.ismp.org/resources/special-edition-tall-man-lettering-ismp-updates-its-list-drug-names-tall-man-letters, June 2, 2016, Accessed March 21, 2019.
22. American Society of Health-System Pharmacists. ASHP guidelines: minimum standard for pharmacies in hospitals. *Am J Health-Syst Pharm.* 2013;70:1619-1630.
23. Johns Hopkins University School of Medicine, Graduate Medical Education Committee. *Guidelines for Patient Handoffs*. July 1, 2011.