Medication Safety

Patients no longer take only one or two medications prescribed by and known to their primary physician.

A patient’s regime may encompass multiple medications that include over-the-counter, herbal supplements, and nutraceuticals, along with myriad prescription medications, many of which may be unknown to several of the patient’s prescribing physicians and could result in dangerous interactions when combined.

Medication safety is a critical component of safe patient care, whether it is general medication knowledge or a provider’s awareness of all medications that a patient is taking.

The Institute of Medicine studied the prevalence of medication errors and found that they are surprisingly common and costly. When all types of errors are taken into account, a hospital patient can expect on average to be subjected to more than one medication error each day. One study estimated 450,000 preventable adverse drug events (ADEs) in hospitals each year, and another found that, among outpatient Medicare patients, there are about 530,000 preventable ADEs each year.

These medication errors are undoubtedly costly. In the Medicare group, one study found that the annual cost of treating ADEs was $887 million. The Joint Commission’s sentinel event database has over 350 medication errors resulting in death or major injury. The most common causes of errors involved medication management and medication reconciliation. A majority of medication reconciliation errors resulted from an improper dose or quantity, followed by omission error and prescribing error.

Improving Medication Safety

Both The Joint Commission and the Institute for Healthcare Improvement (IHI) are focusing on improving medication systems across the continuum of health care. The IHI has challenged health care organizations and practitioners to make changes to improve four fundamental areas in parallel:

- Culture: Develop a culture of safety where staff and leaders are committed to safety and staff are safety conscious and freely report concerns.
- High-Hazard Medications: Decrease risk of harm from those medications known to cause the most severe adverse drug events.
- Core Medication Processes: Improve processes for ordering, dispensing, and administering medications.
- Reconciliation: Ensure that medication information is reconciled at transition points.

The Joint Commission’s 2011 National Patient Safety Goals for Ambulatory Care addressed medication safety for the ambulatory clinical setting. “Medications,” for purposes of the goal in the outpatient setting, would include any prescription medication, over-the-counter, herbal, sample, vitamins, nutraceutical, vaccines, parenteral nutrition, and any product designated by the Food and Drug Administration as a drug.

Appropriate Medication Management

As medications are commonly a part of the patient’s treatment plan, appropriate management is vital to patient safety. Developing standardized systems to ensure safe retrieval and preparation that address similar medications, or “look-alike/sound-alike” medications, and labeling have shown to decrease error and improve outcomes.

Similar Drugs

Maintaining look-alike and sound-alike medications or medications of multiple concentrations in the same area can result in a patient receiving an incorrect medication. The following case illustrates what can happen if “look-alike” medications are stored in the same place:

The patient with a history of elevated intraocular pressure presents to his physician. The patient is prepared for Schiotz tonometry. The physician, who is running 30 minutes behind schedule, reaches into the supply cabinet drawer for the topical anesthetic but instead picks up the hemoccult developer, which is stored in the same drawer. It is dispensed in a small plastic squeeze bottle that is similar to the topical anesthetic. The hemoccult developer is applied to the patient’s eyes, and it produces an immediate and intense pain. The physician, realizing the error, quickly irrigates the patient’s eyes and sends him to the emergency room. Because the squeeze bottles look very similar, the physician did not notice that the bottle he picked up was not the topical anesthetic.

Providers should review all medications in the clinic—both routine and sample medications—for look-alike and sound-alike products and standardize and limit the number of medications and concentrations that will be available in the clinic or surgery.
Labeling
Safe medication practices in labeling all medications, containers, and solutions on and off the sterile field will affect not only outpatient surgery centers but also clinics with minor surgery procedure rooms and general examination rooms. The purpose of this requirement is to ensure that the patient does not receive an incorrect medication or solution because the person administering it was unaware of the container’s actual contents. An example of this is when one person draws a syringe of medication or prepares a solution but another person administers the medication or utilizes the solution.

Consider the 44-year-old, ASA Class II patient scheduled for pain management injection therapy in the physician’s clinic surgical suite. Conscious sedation is provided by a registered nurse under the supervision of the physician. After IV access is obtained, the nurse prepares a syringe of Versed for sedation, plus a 20 cc syringe of saline to serve as a “flush” after administration of the Versed. The physician prepares another 20 cc syringe with lidocaine for the injection. Both syringes are placed on a tray in the surgical field but not labeled. The nurse administers the lidocaine intravenously instead of the saline, resulting in ventricular tachycardia. The patient is admitted post-resuscitation.

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Labeling is to occur when a medication or solution is transferred from the original packaging to another container, for example, into a syringe. Include the drug name, strength, amount, expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours on the label. Medications should be stored with an expiration date (the last date the product is to be used if it has not been opened). If the product has been opened, a revised expiration date needs to be marked clearly on the vial. The U.S. Pharmacopeia and the Association for Professionals in Infection Control recommend that open vials be used within 28 days of opening, unless otherwise specified by the manufacturer. Conversely, if the manufacturer has specified an earlier expiration date, that date must be respected. If any question arises as to the sterility of the vial, it should be discarded immediately. It may be beneficial to assign a clinical staff member the responsibility of monitoring medication vials for date and expiration. Properly dispose of expired medications as identified by the manufacturer, local pharmacy, local hospital pharmacy, or local department of health and environment.

Medication Storage
Medications should be stored at the appropriate temperature to maintain efficacy. There are reliable alarming and recording thermometers readily available. Also, wireless thermometers are available that send updates to a central computer. Other options, such as min/max thermometers, should also be considered.

Using the “penny in the cup” method does not provide adequate monitoring due to differences in appropriate temperatures or refrigerator construction. In addition, without the use of continuous monitoring, there is no way to tell how long the temperature was out of standards. In addition to monitoring the unit’s temperature, procedures should be in place for taking action if the temperature range is found to be out of compliance.

Multidose Medication Vials
Multidose vials present both an infection control and an efficacy concern. Medications can lose effectiveness, and multiple punctures may introduce bacteria if used beyond 28 days. All medications should be stored with an expiration date (the last date the product is to be used if it has not been opened). If the product has been opened, a revised expiration date needs to be marked clearly on the vial. The U.S. Pharmacopeia and the Association for Professionals in Infection Control recommend that open vials be used within 28 days of opening, unless otherwise specified by the manufacturer. Conversely, if the manufacturer has specified an earlier expiration date, that date must be respected. If any question arises as to the sterility of the vial, it should be discarded immediately. It may be beneficial to assign a clinical staff member the responsibility of monitoring medication vials for date and expiration. Properly dispose of expired medications as identified by the manufacturer, local pharmacy, local hospital pharmacy, or local department of health and environment.

Medication Reconciliation
Another major area for patient risk is medication error during transitions in care, also known as handoffs. This occurs whether it is a new patient coming to a clinic for the first time, transferring care to another provider, or admitting the patient to the hospital. Development, reconciliation, and communication of an accurate medication list throughout the continuum of care are essential steps to reduce transition-related adverse drug events. Reconciliation avoids medication errors such as omissions, duplications, dosing errors, or drug interactions and improves medication safety. The continuum of care includes any change in setting, service, practitioner, or level of care.

The medication reconciliation process has five steps:
1. Develop a list of current medications the patient is taking.
2. Develop a list of medications to be prescribed, if applicable.
3. Compare the medications on the two lists.
4. Make clinical decisions based on the comparison.
5. Communicate the new list to appropriate caregivers and to the patient.

Physicians should obtain and document a complete list of the patient’s current medications at the initial appointment. Instruct the patient to bring a list of current medications to the first
visit, including the name of the medication and its dose, route, frequency, and purpose. Ask the patient to bring in all medication containers, if possible, to ensure accuracy of the list. Review the list with the patient to verify that all medications continue to be taken at the time of the appointment. As noted previously, medications include prescription, over-the-counter medications, and herbal supplements.

The medication list, or reconciling form, is not intended to be a patient’s entire lifetime medication history. Rather, it is a list of only those medications the patient is taking at the time. A nurse or physician can complete the list, and no specific form is required or necessary. The critical points to document are the medication name and its dose, route, frequency, and purpose. Include the patient’s allergies or sensitivities as another patient safety measure. Use this reconciling form when prescribing new medications or necessary. The critical points to document are the medication name and its dose, route, frequency, and purpose. Include the patient’s allergies or sensitivities as another patient safety measure. Use this reconciling form when prescribing new medications or treatment orders for the patient.

When a patient is referred to another practitioner, level of care, or service, such as diagnostic testing, forward a copy of the reconciling form to the next provider of service. If the patient is to return for further care, reconcile any newly ordered medications or those administered by the referring practitioner within a specified time frame that is consistent with the anticipated follow-up activities.

Physicians should place the reconciling form in a consistent, highly visible location in the patient’s medical record. A copy should be provided to the patient after the initial visit and whenever there has been a change, whether it is a new medication ordered or a medication discontinued.

The process for reconciling medications in outpatient settings (including the emergency department for patients who are not admitted) is a bit different from the process for inpatient transitions.

Once a medication list is completed at the end of the outpatient visit, a clinician needs to verify two questions:
1. Based on what occurred in the visit, should any medication that the patient was taking or receiving prior to the visit be discontinued, altered, or held pending consultation with the prescriber?
2. Have any new prescriptions been added today?

These questions should be reviewed by the physician who completed the procedure (when one occurs) or by the physician who evaluated and treated the patient:
- If the answer to **both questions** is “no,” the process is complete.
- If the answer to **either question** is “yes,” the patient needs to receive clear instructions about what to do—changes, holds, and discontinuations of medications should be specifically noted. Include any follow-up required, such as calling or making appointments with other practitioners, and a time frame for doing so.

When patients are recurring outpatients, a medication list can be kept on file rather than re-created on every visit. Each time the patient comes for a visit, the list should be re-verified for any additions, deletions, or changes to medications, doses, frequencies, routes, and alterations from original prescription or instructions.11

**Special Circumstances**

Medication reconciliation is not necessary under all circumstances, as when a patient is referred for non-contrast radiologic procedures or for laboratory venipuncture. However, when a patient is referred to radiology where IV conscious sedation or contrast agents are to be administered, a list of medications is to be forwarded and reviewed by either a pharmacist or a physician who is physically present at the patient’s side and can complete the medication review.

Under the following conditions, a discharge reconciliation or communication of the list of the patient’s current medications is not necessary:
- When the encounter is a brief outpatient encounter.
- When the medications administered act locally with negligible system effect.
- When the medications are administered under the direct control of a licensed independent practitioner or reviewed by a pharmacist prior to administration.
- In situations where no other medications are used during the encounter.
- When no new medications are prescribed for or provided to the patient for use after discharge.
- If there are no changes to the patient’s current medications.
- When any provider of care to whom the patient is being referred already has the patient’s current medication information.

For patients who are seen frequently, such as diabetics or prenatal checks, obtain a complete list at the initial visit and update the list when new medications are ordered.

**Patient Safety Recommendations**

The following additional recommendations are provided to improve safe medication use in the outpatient clinic setting:
- Obtain a medication history and enter it into the chart. Include prescription medication, over-the-counter medications, vitamins, herbal products, dietary supplements, alternative medicine, and homeopathic medications.
- Have staff update this list at each patient encounter.
- Provide the patient with an up-to-date list at the end of each encounter.
- When telephoning prescription orders, inform the pharmacy about the patient’s co-morbid conditions, allergies, weight, date of birth, and the indication for use.
- Prepare a prescription label for medication samples for the patient to take home each time a sample is given.
• Provide medication counseling to the patient/caregiver through a medium that he or she can understand.
• Do not store drugs (sample medications or clinic medications) that look alike or sound alike adjacent to each other. Drugs with different concentrations or routes should not be stored adjacent to each other.
• Secure all medications that are in the clinic, whether routine or sample medications, in lockable closets or cabinets to prevent unauthorized access by patients or visitors. Controlled substances should be maintained in double-locked locations and counted daily whenever patients are present to ensure all narcotics are there.
• Review all medications at least monthly for their expiration dates. Dispose of outdated medications properly. Assign a clinical person to review all medications and rotate the task to ensure compliance.
• Document all medications administered to the patient during the clinic visit, including vaccines and sample medications. Ask the patient about medication allergies or sensitivities to substances at each visit or at least yearly, and document the information on the medication form for easy access.
• Provide education to the patient on the medications he or she is taking and any potential interactions, such as with herbal and nutritional substances. Also include signs and symptoms of untoward reaction with instructions to call the clinic for further care. Involving the patient as an active participant in his or her own medication knowledge is a critical aspect of medication safety.

References
3. Ibid.
7. Ibid.
9. Ibid.
10. Ibid.

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The guidelines suggested here are not rules, do not constitute legal advice, and do not ensure a successful outcome. The ultimate decision regarding the appropriateness of any treatment must be made by each health care provider in light of all circumstances prevailing in the individual situation and in accordance with the laws of the jurisdiction in which the care is rendered.