IMPROVING MEDICATION SAFETY IN COMMUNITY PHARMACY:

ASSESSING RISK AND OPPORTUNITIES FOR CHANGE

Institute for Safe Medication Practices
a nonprofit organization

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Introduction

The Importance of Systematic Analysis of Errors in Pharmacy Practice

The 2006 Institute of Medicine (IOM) report *Preventing Medication Errors* estimated that, based on studies and referenced research, 51.5 million errors occur per 3 billion prescriptions per year.[1] This amounts to four errors per 250 prescriptions per pharmacy per day. The IOM further estimated that 6.5% of these errors were clinically significant. By extension, this translates to one clinically significant error per 962 prescriptions.

Using these estimates, a typical community pharmacy that fills about 2,000 prescriptions per week may generate up to two clinically significant prescription errors every week.

Surely there is room for improvement. This manual has been designed to assist community pharmacy practitioners and operators to assess their current practices and enhance their procedures for improving safety in their practice settings.

The goal of every community pharmacy should be to continually improve their medication-use system in order to help ensure the safest, highest quality of care possible. To accomplish this, community pharmacies must assess their risks associated with the medication-use process by monitoring actual and potential medication errors and adverse events that occur within their organization. Analysis and investigation of root causes of these events must then occur so that strategies to improve the medication-use process and prevent future events may be identified and implemented. Key to success is the quality of the information collected in the reports, the analysis of the information, and the subsequent actions taken to improve the system and prevent harm to patients.

The ISMP Medication Safety Self Assessment™ for Community/ Ambulatory Pharmacy was developed in 2001 and made available to community and ambulatory pharmacies for the purpose of encouraging individual pharmacies to self evaluate their processes. Data collected from the more than 5000 pharmacies that completed the self assessment indicates a lack of implementation of patient safety initiatives in current practice. (To view examples of data that was collected from the ISMP Medication Safety Self Assessment™ for Community/Ambulatory Pharmacy in each of the key elements, see Appendix 5.) Therefore this "Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change" manual was developed to educate community pharmacists on the key elements of the medication-use system in order to self analyze errors and prioritize safety changes that should be employed.

Goals

The goals of this manual are to:

- Raise awareness of error-prone processes in the medication delivery system.
- Build awareness of risk-identification opportunities in the community pharmacy setting.
- Maximize the appropriate application of system strategies to reduce organizational risk.

Outcomes

After utilizing this manual, community pharmacy personnel will be able to:

- Initiate a risk assessment process to identify medication safety improvements in the community pharmacy setting.
- Use *ISMP's Key Elements of the Medication Use System*™ to help identify and prevent risk in daily practice.
- Examine flow diagrams or flow charts of the medication process to identify variability in current medication-use processes.
- Select effective error reduction strategies that can prevent patient harm.
- Review case scenario(s) of medication error or near miss events and apply knowledge of *ISMP's Key Elements* to identify breakdowns in the system that have contributed to the error.
- Utilize the Assess-ERR™ for a medication error or near miss that has occurred in your practice

This manual is designed to help community pharmacy personnel identify potential medication safety risks and prevent error. Pharmacists can use the materials and tools in this manual to pinpoint specific areas of weakness in their medication delivery systems and to provide a starting point for successful organizational improvements.

Illustrating the Application of Key Elements of the Medication Use System™ to Assess Risk

Background

This manual contains modules pertaining to *ISMP's Key Elements of the Medication Use System*™ (table below). These are the factors that most significantly influence the medication-use process and safe medication use. The interrelationships among these key elements form the structure within which medications are used.[2,3]

ISMP's Key Elements of the Medication Use System™	
I	Patient information
II	Drug information
III	Communication of drug orders and other drug information
IV	Drug labeling, packaging, and nomenclature
V	Drug standardization, storage, and distribution
VI	Medication device acquisition, use, and monitoring
VII	Environmental factors, workflow and staffing patterns
VIII	Staff competency and education
IX	Patient education
X	Quality processes and risk management

The following individual key element sections contain:

- An example of an actual reported error involving the identified element and recommendations specific to the reported error.
- Printable charts containing contributing factors and strategies of recommended actions pharmacists can take to advance medication safety in that particular key element.
- A "Quick Check" risk assessment question related to that element.

Key Elements provide learning experiences

To identify common failure points that lead to errors, the contributing factors in each key element that follow can be used as learning tools when evaluating the safety of medication use within your pharmacy. The subsequent risk reduction strategy charts are valuable aids to identify risk and prevent future error. These contributing factors and error prevention strategies may also be used to stimulate

discussion regarding day-to-day safe practices in conversations among frontline staff and during supervisor field visits.

Improving patient safety is an ongoing process that demands continual review. The content in the following modules will provide you with proven strategies that can be implemented to practice in a more patient safety-focused environment.

Key Element I: Patient Information

Essential patient information is obtained, readily available in useful form, and considered when dispensing medications.

Background

Information about the patient guides the appropriate selection of medications, doses, and routes of administration. Of significant importance is basic demographic and clinical information (e.g., age, weight, allergies, diagnoses and pregnancy status) as well as patient monitoring information (e.g., laboratory values, vital signs and other parameters) that gauge the effects of medications and the patients' underlying disease processes.

Studies have shown that as many as 18% of serious, preventable adverse drug events (ADEs) stem from practitioners having insufficient information about the patient before prescribing, dispensing and administering medications.[4] Twenty-nine percent of prescribing errors alone are directly associated with inadequate patient information.[5] Narcotics and antimicrobials are the two drug categories most frequently involved in errors related to insufficient patient information. Most serious injuries are due to prescribing these drugs for patients allergic to them.

Error with *Patient Information* causative factors

Patients with very similar names and very similar dates of birth led to a dispensing error. Jane F. Doe, (date of birth 6/17/1955) was given Jane S. Doe's (date of birth 6/13/1955) medication in error at the check out window. Patient took one tablet (glipizide extended release 10mg) and was admitted to the hospital with low blood sugar. Neither patient had an up-to-date profile indicating health condition; neither patient accepted the offer to counsel and there was no notation in the pharmacy computer system indicating or warning of patients with same/similar names.

Recommendations

Correctly dispensed prescription handed to a patient for whom it was not intended is an error that can be avoided by consistent use of a second patient identifier. Pharmacy personnel should ask the person receiving the prescription to state the patient's address or date of birth, and compare their answer to the information on the prescription receipt. Do not tell the patient the address or date of birth and ask them to confirm the information. The ISMP MERP has received numerous reports of patients who have indicated "yes" that the address was correct only to take home someone else's medication. Prescribers and pharmacists should have computerized notes to warn about previously detected patients with similar names. Flags should appear when these patients are selected during patient data entry. Patient education sessions should include discussion of the purpose of the medication, to

help ensure the correct medication is being dispensed to the correct patient. In addition, patient demographics, including health condition codes, should be updated on a regular basis in each patient's profile. Medication indications should match health conditions, unless the medication is knowingly being prescribed off-label.

I. Common Contributing Factors Involving *Patient Information*
Absent or unclear patient identity
Missing patient address
Age (date of birth), especially if child under 6, not noted or taken into consideration
Weight (pediatric) unavailable or unit-of-measure not indicated (lbs vs. kg) for proper dosing calculations
Allergies unknown or not updated
Allergy information is not integrated into the pharmacy computer system
Pregnancy status not known or considered
Co-morbid conditions (e.g. diabetes, hypertension) not known
Demographic and health information not collected on new patients
Previous drug history not known
Health conditions, diagnosis, allergies in computer system or on hard copy prescription but system not integrated, so drug alerts do not appear
Diagnosis not clear
Unique patient identifiers not used at point of sale

I. *Patient Information* Risk Reduction Strategies
Prescription Drop-Off Stage
Ask for patient allergy information at every visit and validate against the patient profile; distinguish between No Known Allergies (NKA) and Unknown Allergies
For visually or hearing impaired patients, provide alternate means of communication so available patient information may be obtained
Obtain clinical purpose of each prescription before the medication is dispensed, to assure that the prescribed therapy is appropriate for the patient's condition and to help distinguish medications with similar packaging and look-alike or sound-alike names
Obtain alternate means of communicating with patient; in addition to home phone number collect and store cell and work phone numbers and email addresses as applicable

I. *Patient Information* Risk Reduction Strategies
Routinely ask for patient diagnosis and co-morbid conditions, including pregnancy, and add this information to computerized patient profile
When transcribing spoken orders, use telephone prescription pads that are designed with prompts for allergy information, weight in kg for children under six years old, and drug indication
Ask for two patient identifiers when receiving telephonic prescription orders
Implement policies and procedures or system enhancements to insure one profile per person exists in system; be cognizant of name suffixes (Jr.), first/last name interchanges and incorrect assignment of first and last name (James John or Ikembe Fintumbo); if applicable utilize legal name or name on insurance card
Be sure date-of-birth is noted on every prescription hard copy and clearly visible on prescription receipt
Obtain/validate patient weight when filling pediatric medications
Annually update patient demographic information
Order Entry Stage
Properly code allergy information in computer system to allow for computer system screening
Design a computer system that prohibits dispensing when no allergy information is in the patient profile
Drug Utilization Review (DUR) Stage
Ensure that the drug ordered matches the clinical indication provided and does not interact with other medications on the patient profile
Ask patient for medication (other prescriptions, over-the-counter [OTCs], herbal and dietary supplements) not filled as prescriptions at this pharmacy, and add them into the computer system to be part of the drug utilization review (DUR) screening
Highlight the date-of-birth, for children under the age of six, in computer system, on receipt and on prescription hard copy to avoid errors in dosing and dosage forms
Identify patients who are eligible for Medication Therapy Management Services (MTMS)
Pick-up Stage
Confirm allergies at pick up
Provide patient with updated medication list annually; confirm list with patient
Know each patient's language of preference, education or reading ability level, and if any visual or hearing impairments exist, in order to counsel at their level of competency
Use two unique patient identifiers at point of sale

Quick Check Question: *Patient Information*

1. Other than patient age and allergy information, what key piece(s) of information should be documented when filling a prescription for a pediatric patient?

    A. Indication for prescription
    B. Patient's current weight
    C. Co-morbid conditions
    D. All of the above

Answer: D. All of these are key pieces of patient information needed to properly screen a prescription for appropriateness and safety. Obtaining the patient's weight is crucial when filling pediatric prescriptions because most drugs are dosed based on weight. Also having the knowledge of what the physician is treating will allow determination of whether or not the dose is within an acceptable range. Co-morbid conditions, such as renal failure, will also aid in determining the appropriateness of the dose.

Key Element II: Drug Information

Essential drug information is readily available in useful form and considered when dispensing medications. Practitioners are familiar with or are able to review, prior to dispensing, information about the product's known risks and hazards.

Background

Research demonstrates that more than one-third (35%) of all preventable adverse drug events (ADEs) are directly related to inadequate dissemination of drug information.[4] Overall lack of knowledge about drug therapy was the most common cause of medication errors during both drug prescribing and drug administration, with dosing errors occurring most frequently. One in six ADEs were caused by the combination of insufficient knowledge about usual drug doses with miscalculations or incorrect expression of measurement or drug concentration.[5] The wrong dose and wrong drug choice were most likely to cause serious injury to patients.

Errors with *Drug Information* causative factors

Example II-1: An error which could have resulted in a significant, harm-causing opioid overdose was reported. The prescriber added "IR" (to indicate immediate release) to an order for OPANA (oxymorphone). The pharmacist interpreted the "IR" to be "ER," the common suffix used to indicate the extended release product.

Recommendations

Example II-1: Prescribers should use a suffix to differentiate a product only when this designation is linked to a specific product and represents the FDA-approved name for the prescribed agent. When confronted with a non-standard or unrecognizable suffix, pharmacists should verify the intended product and dose with the prescriber.

Errors with *Drug Information* causative factors

Example II-2: A prescription for SINEQUAN (doxepin) 10 mg, with the directions to take 5 capsules daily, was mistakenly entered into the computer and dispensed as Sinequan 100 mg. Upon entering "Sinequan" on the product line in the pharmacy software system, the list of matching results placed Sinequan 100 mg on the first line followed by Sinequan 10 mg. It's believed that the sequential listing of both strengths, with a tenfold difference, contributed to the selection of the wrong strength, as did the listing of the higher strength first.

Recommendations

Example II-2: Ask your pharmacy software vendor about the logic used by its system when sorting drug information (e.g., alphabetical vs. numerical listings). Until this issue can be resolved by software vendors, consider adding an asterisk to the doxepin 100 mg strength name (doxepin *100 mg) to cause it to fall to the bottom of the alphabetical sort. However, this may not be a safe option if electronic

calculations of doses and dose limits originate with information in the field that contains the asterisk. In these cases, the asterisk may interrupt or alter the calculation process.

II. Common Contributing Factors Involving *Drug Information*
Outdated/absent references
Inaccessible or non-accessed drug references
Inadequate computer alerts for allergies, health conditions, minimum or maximum doses and non-pharmaceutical drug interactions
No internet access available to obtain current drug information for OTCs, herbals, and dietary supplements
Independent checks for high-alert drugs and high-risk patient populations not performed
Lack of staff awareness of special precautions on new medications
Computer warnings about unsafe doses overlooked or ignored
Serious drug interaction unknown or overlooked
Computer system provides too many alerts resulting in alert fatigue and automatic overrides by pharmacy staff
A drug information center staffed with clinical pharmacist is not available during all hours of operation
On-line, immediate clinical information is not available, accessible or appreciated by staff

II. *Drug Information* Suggested Risk Reduction Strategies
Quality Improvement Activities by Staff
Educate all staff, including technicians, about new drug products coming to market and/or being stocked in the pharmacy. See Figure II-1
A designated pharmacist or corporate level staff routinely reviews, for quality improvement purposes, reports of computer warnings that are overridden by pharmacists
Manually check the patient's profile during the DUR process, for medications and health conditions which may not be included in the DUR software
The most current electronic drug references are available in the pharmacy; all outdated paper references are thrown out or taken home by staff

II. *Drug Information* Suggested Risk Reduction Strategies
Provide pharmacy staff with access to drug information center staffed with clinical pharmacists during all hours of operation; alternately, provide up to date clinical information available via internet and/or printed material and ensure all pharmacists, interns, etc. are aware of the resources and trained in accessing and reviewing available drug information databases
Provide resources, time, and encouragement to staff to participate in MTMS
Review external error reports for potential risk within your own pharmacy
Technology Considerations
Provide easy access to online drug information at every computer terminal. Provide an easy access icon, so the link is readily accessible
Allow pharmacy staff the ability to enter, or request the addition of look- and sound-alike and other targeted drug warnings into the pharmacy computer system
Configure the pharmacy computer system to offer alerts for maximum and minimum doses of medications, drug interactions, age, allergies and dose related interactions
Invest in a computer system that prompts DUR alerts for women of childbearing age when Category X drugs are being dispensed
Carefully select alert severity levels to avoid alert fatigue; consider refining the computer system to allow only clinically significant alerts to fire (Combine with above)
Evaluate how drug information appears on computer screen: do not use dangerous mnemonic speed codes i.e. 'novo7030' should not be a mnemonic speed code because it could be for Novo**LIN** 70 30 or Novo**LOG** 70 30; consider tall man lettering for look-alike drug names, such as hydr**OXY**zine and hydr**ALA**zine; be aware of the number of characters that will appear on the screen before the drug identification is truncated
Routinely run report of system speed codes in use and review for dangerous short codes; use the ISMP commonly confused drug list for examples of drug product names that could lead to error, if codes can be interchanged, linking to unintended products.
Speed codes should only be added by administrative personnel using a standardized process, not at store level
Mandate a pharmacist review of clinically significant computer warnings and have the ability to trace and document all steps in the DUR process
Provide internet access for current information on OTC, herbal, and dietary supplements

Figure II-1 All of these bupropion products are not equivalent

Quick Check Question: *Drug Information*

1. Prescribers and pharmacists should review medication safety websites, newsletters, and look-alike/sound-alike (LASA) lists annually for potential drug confusion associated with the medications they use most frequently.

    A. True
    B. False

Answer: B. Pharmacists should be proactive and review external sources of medication safety information and LASA lists *more frequently* than once a year. Drug names can be cumbersome and confusing and look and sound like one another. This is a particular risk with new drugs, because it is more likely that pharmacists and technicians are unaware of the new drug. See Figure II-2. *Any time* a new drug is first dispensed, pharmacists should consider the potential for drug-drug interactions, duplication of therapy, and LASA name confusion. In addition, safety information should be reviewed and communicated to technicians.

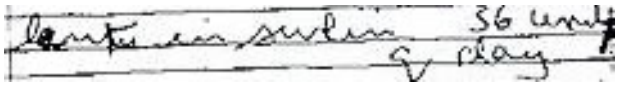


Figure II-2 Lantus insulin order interpreted as Lente insulin by pharmacy staff unaware of new insulin type on formulary

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

Methods of communicating prescription orders and other drug information are standardized and automated to minimize the risk for error.

Background

Miscommunication between physicians, pharmacists and nurses is a common cause of medication errors. Failure to control and standardize prescribing vocabulary often leads to inappropriate use of dangerous abbreviations, acronyms, coined names and other ambiguous methods of communicating drug information that can easily be misinterpreted. Studies have identified that greater than one in ten medication errors are directly related to the use of incorrect drug names, confusing expressions of dosage forms, and misunderstood abbreviations.[5] The same study also identified that misinterpreting decimal point placement, often resulting in ten-fold overdoses, was one of the leading factors causing errors that could seriously harm patients.

Spoken orders, fraught with danger of being misheard, are another method of communicating orders that is often misinterpreted. While spoken orders may be convenient to those prescribing medications, their use should be reserved for true emergency situations, to minimize unnecessary obstacles to clear communication. When reducing telephone orders to writing, pharmacists should never abbreviate drug names or use dangerous abbreviations when transcribing the patient administration directions. See Figure III-1. Internal use of dangerous abbreviations and dosage forms can lead to misinterpretation by staff, and by patients if incorrectly translated onto prescription labels. Store-specific training guides and company policies should not allow nor promote the use of dangerous abbreviations. See Appendix 1 or www.ismp.org/Tools/errorproneabbreviations.pdf for a complete list of abbreviations that have been misunderstood and led to prescribing and dispensing errors.

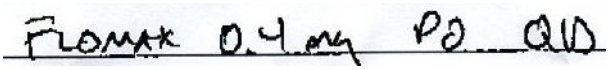


Figure III-1 "QD" for "daily" transcribed by pharmacist when taking spoken order entered as "QID" or four times a day by technician, due to inappropriate use of dangerous abbreviation and illegible handwriting.

There is also a significant problem of illegible handwriting. The current paper-based system for recording and communicating drug prescriptions in the United States is a poor medium of communication and is associated with inefficient workflows.[6] MEDMARX® is a national, Internet-accessible database that hospitals and health care systems use to track and trend adverse drug reactions and medication errors. MEDMARX® data reports there are 1,470 different drugs implicated in medication

errors due to brand and/or generic names that looked or sounded alike. From this data, USP has compiled a list of 3,170 pairs of names that look and/or sound alike.

Errors are much more likely when handwriting is legible but conceals something that is dangerous. In many cases drug name mix-ups happen when the handwriting is legible but still makes one drug name look like another. While it may seem unlikely, a prescription for the antidiabetic agent AVANDIA (rosiglitazone) may be mistaken for the anticoagulant COUMADIN (warfarin) due to look-alike tendencies when handwritten in cursive.[7] (Figure III-2).

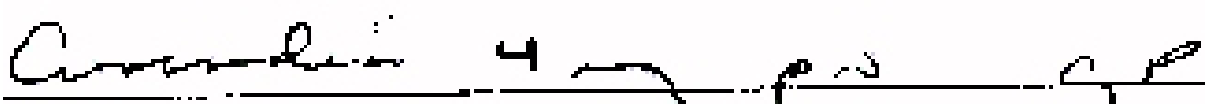


Figure III-2 Handwritten "AVANDIA" can look surprisingly like "COUMADIN."

In order to prevent such errors, additional system enhancement steps must be incorporated; such as electronic prescribing, assuring the drug corresponds with therapy given for the patient's condition, patient counseling, etc.

Electronic prescribing, also known as e-prescribing, eliminates incorrect handwriting interpretation, and ensures that vital fields include meaningful and relevant data.[1] However, development and testing of e-prescribing standards have fallen short of ensuring transmission of error-free prescriptions.

Types of Errors Reported from Electronically Produced and Transmitted Prescriptions	Example
Missing or mismatched quantities	Prescriber selects quantity of "1" for 10 mL insulin vial
Mismatches between drug dose type ordered and dosage units ordered (solution ordered with quantity as tablets)	Prescriber selects Amoxicillin Suspension and selects quantity as 30 "tablets"
Wrong drug selected by prescriber due to "stemming" (i.e., enters first few letters of drug name) at order entry and subsequent incorrect selection	Prescriber enters "met" and then selects metoprolol tartrate (LOPRESSOR) instead of intended metoprolol succinate (TOPROL XL)
Wrong drug selected from drop down menu of medications listed alphabetically	Prescriber selected procarbazine from drop down menu of medications, but intended to prescribe PROCARDIA

Types of Errors Reported from Electronically Produced and Transmitted Prescriptions	Example
Wrong drug selected because entire medication name not visible on selection screen, and prescriber does not scroll field to read entire drug name being ordered	Prescriber chooses "Met**FORMIN** 500 mg" tablets, but intended "Met**FORMIN** 500 mg ER"
Instructions sent in the *SIG* field contradict what is sent in the notes field	"Take 1 tablet twice a day" in *SIG*, but the notes field states "Take 1 tablet in the morning and 2 tablets at bedtime"

Patient instructions for taking medications are called the *signatura*, commonly abbreviated *SIG*. Currently, there is no standardized format for vocabulary for *SIG*s. Mistranslations and contradictions in dosage/timing directions leave room for misinterpretation and error.[8] See Figure III-7 for an example of complications from an electronically generated prescription, which could result in administration errors.

In all healthcare settings, communication barriers, such as intimidation, often precipitate ineffective communication between health care professionals. In a recent ISMP survey on workplace intimidation, 40% of the respondents reported they had questions about the safety of an order in the past year but chose to assume the order was correct rather than interact with a prescriber they perceived as intimidating.[9] Any questionable prescription should be discussed directly with the prescriber. A pharmacist's persistence in communicating recognized problems, even when met with opposition from experts, can clearly prevent harmful errors from reaching patients. If applicable, the pharmacist should ask the prescriber for documentation (e.g., protocols, journal articles) supporting the order and read any materials provided. The prescriber may have misinterpreted published information or used references that contain misprints.

Errors with *Communication* causative factors

Example III-1: A physician wrote a prescription for lamo**TRI**gine 100 mg (see order #2 in Figure III-3). Subsequently, a pharmacist misread the handwritten order as levothyroxine 100 mcg. The drugs have overlapping dosage strength numbers (25, 100, 150, and 200) and are administered orally once daily, increasing the risk of mix-ups.

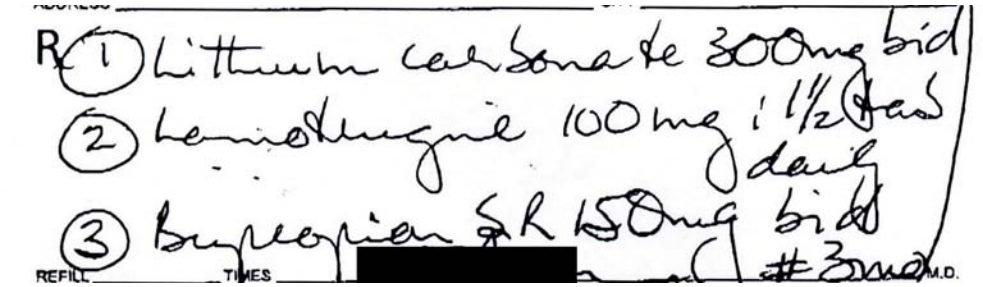


Figure III-3 Order #2 for lamo**TRI**gine was misinterpreted as levothyroxine

Recommendations
Example III-1: Warn practitioners about the potential for mix-ups with these products. Encourage prescribers to include the indication for use on prescriptions for these drugs, and write only one medication order per prescription blank. When receiving spoken orders for these medications, ask the prescriber or agent for the purpose and write it on the prescription pad. Pharmacists should always counsel patients on these medications (new and refill) to help avoid mix-ups; the prescription may have originally been filled correctly, yet still misread and picked incorrectly on refills.

Errors with *Communication* causative factors
Example III-2: A pregnant patient had been given a prescription for "PNV" tablets ("prenatal vitamins"). The pharmacist receiving the prescription assumed that PNV stood for "penicillin VK" and dispensed penicillin tablets in error.

Recommendations
Example III-2: Abbreviating drug names is an unsafe practice that should be avoided. Prescribers should never use them, and pharmacists should always check with prescribers as to the intended meaning of any drug name abbreviation.

Errors with *Communication* causative factors
Example III-3: During a patient counseling session, a pharmacist realized that he had nearly dispensed PROGRAF (tacrolimus) instead of **PRO**zac (fluoxetine). Sound-alike drug names communicated over the telephone, without any opportunity to read back, contributed to the near-miss.

Recommendations
Example III-3: Repeating and verifying drug information communicated by telephone may help prevent this type of error. Pharmacies which use prescriber voicemails to leave oral prescriptions should consider utilizing a second person to listen to spoken orders left on the Integrated Voice Response (IVR) system. Patient counseling sessions that include reviewing the indication for therapy and the prescribed medication give pharmacists the opportunity to catch errors before harm occurs.

III. Common Contributing Factors Involving *Communication*
Ambiguous directions
Poor handwriting; see Figure III-4
Misread prescription; see Figure III-5
Oral Rx misheard, see below: "Avinza 60 mg daily" misheard as: "Evista 60 mg daily"
Typing mistake (incorrect data entry code or mnemonic)
Poor fax quality; see Figure III-6
Incomplete e-Rx
Ambiguous e-Rx; see Figure III-7
Prescriber error
Use of previous drug/dose on profile
Wrong drug, wrong dose, wrong route
Use of error-prone *sig* and drug name abbreviations or dosage designations; see Figure III-8
Intimidation/faulty interaction with prescriber or agent
Unable to clarify with physician
No policy on how to resolve conflicts on potentially unsafe prescription orders

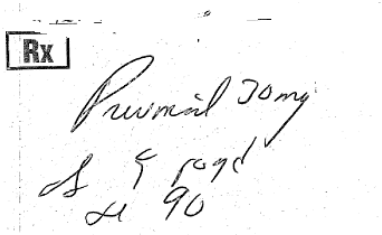


Figure III-4 Written as PREVACID, interpreted and filled as PRINIVIL

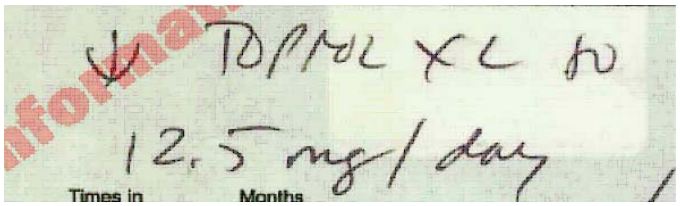


Figure III-5 Interpreted and dispensed as Toprol XL 50 mg; written as "decrease Toprol XL to 12.5 mg each day"

Figure III-6 Written for 40 mg, dispensed as 10 mg due to fax "noise" (i.e., vertical line)

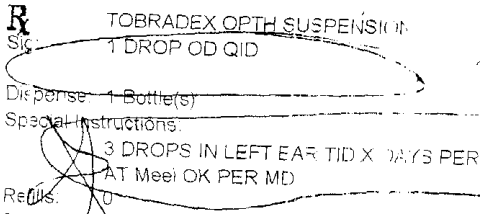


Figure III-7 *SIG* and special instructions indicated conflicting patient administration instructions

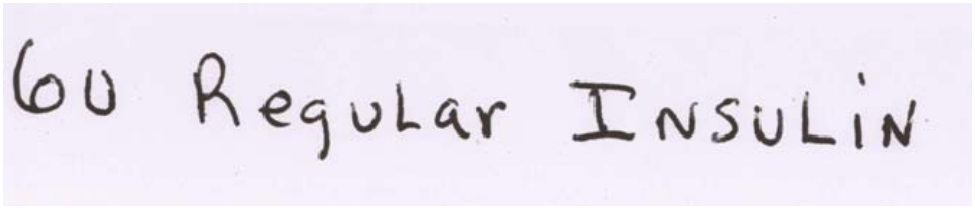


Figure III-8 Inappropriate use of "U" for units. "6 units" confused and entered as "60 units" and led to a ten-fold overdose

III. *Communication* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Incorporate mandatory read back procedures when accepting spoken prescription orders to confirm understanding; incorporate patient validation and second patient identifier with prescriber or agent
Repeat numbers in digits when receiving oral prescription orders (16 is stated "one-six", 60 is stated "six-zero")

III. *Communication* Suggested Risk Reduction Strategies
Spell sound-alike drug names back to caller and obtain indication for use from caller for sound-alike medications
Immediately call prescribers when prescriptions are written illegibly or ambiguously; do not fill the prescription until the order is confirmed
Inform prescribers when eRxs are continuously received with ambiguous patient directions (contain both a *sig* and *special instructions* which may conflict)
Maintain fax equipment to ensure clear images: educate users about potential errors with margins, numbering, etc.
Instruct staff never to use error-prone abbreviations or error-prone dose designations (trailing zeros and lack of leading zeros), drug name abbreviations or abbreviated *sig* codes when reducing oral prescriptions to writing; prohibit the use of dangerous abbreviations and dose expressions on patient prescription labels
Prohibit staff from coining abbreviations for drug names or entering new *sig* or speed codes
Establish procedures that specify the steps that should be taken when there is question as to the safety of a prescription order
Prohibit the use of dangerous mnemonics and stemming during data entry; to avoid product selection errors if mnemonics are allowed and used, consider programming computer entry screens to display the specific brand names along with the generic names whenever a stem or mnemonic is entered or apply tall man lettering to the drug names on the selection screen
Corporate / Owner Action
Incorporate IVR systems that have hard prompts to require the physician or agent to stop and spell all names (prescriber, patient, drug, strength) when leaving a spoken prescription order
Use prescription phone pads that prompt receiver to ask caller for allergies, date of birth, and indication for use or purpose of drug
Implement a true electronic transmission system with minimum data entry/transcription required
Evaluate *sig* codes and speed codes for error potential
Incorporate the use of scanning procedures so that original prescriptions can be viewed during each refill process
Ensure adequate fax scanning technology equipment and procedures

Quick Check Question: *Communication*

1. Which is NOT an appropriate way of preventing medication errors associated with spoken orders?

    A. Read back order
    B. Spell drug names back to caller
    C. Use abbreviations
    D. Obtain indication for therapy

Answer: C. Although prescribers often speak much faster than one can write, it is important to avoid using error-prone abbreviations and dose designations. In many pharmacies, the hard copy of the prescription is scanned into the pharmacy computer system. This image is then used during final verification. Error-prone abbreviations used on the prescription can be misinterpreted by a different pharmacist, which may result in an error. Therefore, it is important not to use abbreviations and clearly write out complete drug names and directions for use.

Telephone orders should be immediately written on a blank prescription pad or electronically documented. Require staff to perform a read back of the medication name, strength, dose, and frequency of administration for verification, to avoid misinterpretation. This step is absolutely essential and should become a habit, even if the recipient is confident that he or she has heard the order correctly. As an extra check, either the prescriber or recipient should spell out unfamiliar drug names, using “T as in Tom,” “C as in Charlie,” and so forth. Pronounce each numerical digit separately, for example, “one six” instead of “sixteen” to avoid confusion with “sixty.” Have a second person listen to the order. This should be a requirement if the recipient is inexperienced. Obtain the purpose of the prescribed medication to ensure that the order makes sense in the context of the patient’s condition. Most reported sound-alike name pairs have different indications. The recipient should note the date, time, and name of the caller on the prescription when it is received.

Key Element IV: Drug Labeling, Packaging, and Nomenclature

Strategies are undertaken to minimize the possibility of errors with drug products that have similar or confusing manufacturer labeling/packaging and/or drug names that look and/or sound alike.

Prescription labels clearly identify the patient, product, directions for use, the dispensing pharmacy, and any other important information that the patient may need to take the medication accurately and safely.

Background

Drug names that look and sound alike, confusing or absent drug labeling, and non-distinct or ambiguous drug packaging significantly contribute to medication errors. These conditions have led to serious drug mix-ups and deaths. Research has identified that one of the most frequent causes of pharmacy drug dispensing errors (29%) is failure to accurately identify drugs, most prominently due to look-alike and sound-alike drug names.[4]

Many medications are packaged in bottles with similar shapes and similar labels, making it easy to confuse one drug with another. See Figure IV-1.

Figure IV-1 Similar looking drug bottles are easily confused.

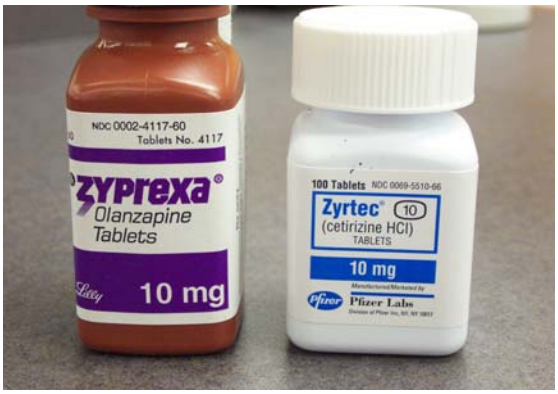
The problem is aggravated by what is referred to as *confirmation bias*: when choosing an item or verifying a name, you see what you are looking for, and once you find what you are looking for, you stop looking, not recognizing any disconfirming evidence. Often pharmacy staff chooses a medication container based on a mental picture of the item, whether it is a characteristic of the drug label, the

shape and size or color of the container, or the location of the item on a shelf.[10] Many errors often occur when practitioners, due to familiarity with certain products, see what they think is correct rather than what is really there. It is human nature for people to associate items by certain characteristics.[11] Physically separating drugs with look-alike labels and packaging helps to reduce this contributing factor.[12]

Changing a product's name or appearance may help prevent LASA medication errors. For example, tall man (mixed case) letters call attention to a drug's name and distinguish it from its LASA name pair. Several studies have shown that highlighting sections of drug names using tall man letters can help distinguish similar drug names,[13] making them less prone to mix-ups.[14,15] ISMP, FDA, The Joint Commission, and other safety-conscious organizations have promoted the use of tall man letters as one means of reducing confusion between similar drug names. In fact, the FDA has compiled a list of look-alike drug name pairs in which tall man lettering is recommended. One such name pair is diphenhydramine and dimenhydrinate. According to FDA's tall man lettering scheme, diphenhydramine would be presented as diphenhydr**AMINE**, whereas dimenhydrinate would be dimenhy**DRINATE** (see Figure IV-2). The unique letter characters in look-alike drug name pairs may also be highlighted using color, reverse color background, italics, underline, and other distinguishing delineations.

Figure IV-2 "Tall man" letters and reverse color background help distinguish one drug from another.

With FDA approval, other manufacturers have employed tall man lettering schemes to differentiate look-alike brand names when medication errors were recognized post-market. For example, Eli Lilly uses reverse-color background, italics, and tall man lettering to help differentiate Zy**PREXA** from Zyr**TEC**. See Figure IV-3.



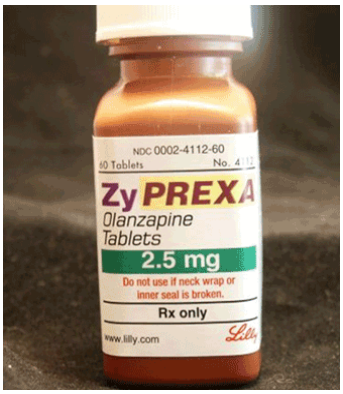


Figure IV-3 Former Zy**PREXA** label (left) next to Zyr**TEC** label. New Zy**PREXA** label (right).

One of the difficulties with the use of tall man letters is the lack of scientific evidence regarding which name pairs would most benefit from this error-reduction strategy as well as which letters to present in uppercase. To help promote standardization, ISMP suggests that the tall man lettering scheme provided by FDA and ISMP for the drug name pairs listed in Appendix 2 be followed consistently. This list can also be found at www.ismp.org/tools/tallmanletters.pdf.

Error with *Drug Labeling, Packaging, and Nomenclature* causative factors

Two formulations of BYETTA (exenatide) are distributed in pen injectors (Figure IV-4), one delivering 5 mcg/injection and one delivering 10 mcg/injection. The wrong strength may be dispensed because both pens have similar NDC numbers. The middle four numbers, which usually represent the distinct drug product, are actually the same for both strengths of the BYETTA pen. Only the final two digits of the NDC numbers are different which may not be read by certain barcode scanning programs.

Figure IV-4 The two Byetta pens deliver different doses.

Recommendations

Manual double-checks of BYETTA products, to include the entire NDC number, are warranted to ensure the correct strength is dispensed, especially in community settings where erroneous dispensing could lead to repeated dosing errors.

IV. Common Contributing Factors Involving *Drug Labeling, Packaging, and Nomenclature*
Look/sound-alike names and mnemonics
Look-alike packaging; see Figures IV-5, IV-6, IV-7
Generics manufactured by one company using similar packaging and labeling throughout product line; see Figure IV-8
Unclear/absent labeling
Faulty drug identification (no drug image, drug image not updated, selection not verified by NDC or bar-coding)
Branded/generic drug name confusion
Lack of special precaution labels on high-alert medications
Labels on wrong vials but for right person (swapped)
Directions on patient label not easily understood (e.g., 1 ½)
Correctly typed labels put on different person's prescription
Confusing, incorrect or misunderstood auxiliary labels on patient vials

Figure IV-5 Very little differentiation within product line

Figure IV-6 Look-alike packaging

Figure IV-7 Internal use and "external use only" products packaged in look-alike bottles

Figure IV-8 Generic line by Teva has look-alike labeling for manufacturer recognition, but non-differentiation of labels can lead to selection errors

IV. *Drug Labeling, Packaging, and Nomenclature* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Include the purpose of the medication on the patient's prescription label, if provided by the prescriber
Provide auxiliary warning labels with exaggerated fonts, or use other label enhancements on packages and storage bins of drugs with problematic names, packages, and labels; see Figure IV-9
Use shelf dividers to separate products with look-alike names/packaging in all storage areas, including refrigerators and narcotic cabinets; see Figure IV-10
When drugs have the same name but different routes of administration (e.g., ophthalmic vs. otic), steps are taken (e.g., auxiliary labels, change in storage location, purchase from different manufacturer, notation in the computer, etc.) to prevent dispensing errors
When dispensing unit-of-use packaging to patients, avoid placing pharmacy label on top of pertinent manufacturer's information
Prescriptions are dispensed using the original prescription order and the computer-generated drug label together; a pharmacist compares the label and product with the original prescription before drugs are dispensed to the patient
Corporate/Owner Action
When possible, avoid stocking generic manufacturers who incorporate same size stock bottle, and label colors and fonts, in their complete product line
Avoid stocking branded generic drug products
Use labels with special precautions on the stock bottles of high-alert medications (those whose inadvertent dispensing could cause serious harm if used in error)
Design prescription labels for patients that are easy to read, have enough "white" space, have a font size that is legible to older patients, and which contain the proper information for safe drug administration; refer to ISMP website for specific label guidelines www.ismp.org/Tools/guidelines/labelFormats/comments/default.asp
Perform Failure Mode and Effects Analysis (FMEA) on packaging and labeling of new drugs being considered for addition to pharmacy stock
Use FDA/ISMP-recommended tall man lettering on repackaged products
Identify stock bottle labels that are ambiguous or unsafe, and contact manufacturer or discontinue stocking from this manufacturer if safety features cannot be adequately employed; in addition, report these hazardous labels to ISMP
Regularly review current external literature for noted problems with drug labeling, packaging and nomenclature; and incorporate actions to prevent errors stemming from these issues

IV. *Drug Labeling, Packaging, and Nomenclature* Suggested Risk Reduction Strategies
Technology to Consider
Implement bar-coding technology for the verification process of drug selection; provide and train staff on policies and procedures to be implemented when stock product does not have a barcode or has a barcode that is not readable
Implement tablet imaging on final verification screen; see Figures IV-11, IV-12, IV-13
The pharmacy computer system produces clear and distinctive labels that are free of abbreviations or dose expressions that may not be easily understood by a patient
Use a pharmacy computer system that employs up-to-date drug/pill imaging technology during the checking process
Employ a pharmacy system which allows alerts to be built in, as necessary, regarding problematic drug packaging; see Figure IV-14
When applicable, print patient prescription label in patient's language
A system that compares computer-generated NDC codes on prescription labels and NDC codes on manufacturers' containers is employed to verify that the appropriate drug has been selected and dispensed

Prem PHASE0.625mg/5mg
-2570-
PREMpro 0.625mg/2.5mg
-2572-
PREMPRO 0.625mg/5mg
-0975-

Figure IV-9 Examples of store-made shelf labels used to differentiate product on stock shelves

Figure IV-10 Shelf dividers (left); refrigerator bin with plastic dividers between rows of look-alike manufacturer labeled product (right)

Figure IV-11 Image of medication selected at data entry is shown at final verification stage

Figure IV-12 Image can be enlarged on computer screen; both front and back are depicted with the narrative description “This medicine is a PINK, ROUND-shaped TAB imprinted with COUMADIN 1.”

Figure IV-13 Image can be enlarged on computer screen; both front and back are depicted with the narrative description "Front: Corgard 40 mg , Back: BL/207."

Figure IV-14 Depicts pharmacy computer system with tablet image and special alerts for medication being dispensed

Quick Check Question: *Drug Labeling, Packaging, and Nomenclature*

1. All of the following techniques may help prevent a mix-up between diphenhydramine and dimenhydrinate EXCEPT?

    A. Computer alerts that warn for the potential LASA mix-up
    B. Use of tall man letters on drug selection and verification screens
    C. Using a bar-code scanning system to identify the drug
    D. Storing bottles on a fast rack section where there is better lighting
    E. All of the above are acceptable

Answer: D. Perhaps there is better lighting in the fast rack section, but these two drugs could potentially still be next to each other on the shelf. By physically separating the two medications, this will help to reduce the contributing factor for error.

Key Element V: Drug Standardization, Storage, and Distribution

Prescribed medications are accessible to patients and dispensed in a safe and secure manner. Medications and other necessary drug supplies are stored, dispensed, and returned to stock in a manner that reduces the likelihood of an error.

Hazardous drugs and chemicals are safely sequestered and accessible in drug product preparation areas.

Background

All areas of storage including shelves, refrigerators, narcotic safes and will-call bins should be of adequate size to avoid clutter. Recommendations include having separate glass-front refrigerators for stock and filled prescriptions, and narcotic safes or cabinets that are of adequate size to meet the needs of the particular pharmacy. Both refrigerators and safes should have shelf dividers or baskets that allow for well-spaced stock that can easily be seen. Never allow employees to store food in any refrigerator used to store medications. Past error reports indicate one pharmacy mistaking a dangerous refrigerated chemical for drinking water, and subsequent accidental ingestion of that chemical.

Each pharmacy should develop a process to regularly review stock for short-dated products that need to be removed from active inventory. Expired, returned, and recalled medications waiting return to wholesaler or manufacturer, need to be stored in areas clearly differentiated from regular stock.

Separation of regular stock needs careful consideration. Cluttered shelf stock and drawers increase the possibility of picking errors. Recommendations include the use of cost-effective shelf dividers and sloping pull-out drawers to enable stock to be easily seen and retrieved. Sloping pull-out drawers should be considered for smaller items such as eye drops and eye ointments.

If adequate space for receiving and checking in new stock does not exist, there is a greater chance medication will be incorrectly slotted on the stock shelves. Since people are wired for automaticity in stock retrieval, there is a greater chance for product mis-selection when stock is placed in the wrong spot. Unopened or partially opened tote boxes of replacement stock on the pharmacy floor are both a distraction and a hazard. A dedicated bench for unpacking and checking stock is recommended to reduce the potential for product mix-ups. Technology which allows for automatic stock replenishment without the need to check off incoming stock should be considered as a future enhancement.

A simple, consistent alphabetical system is easy for all staff to use for both stocking and retrieval of product. Recommendations include a straightforward A-Z stock storage system by proprietary or generic name with no regard for dosage type, i.e., inhalers, birth-control packages, topicals, liquids, etc., intermixed with tablets and capsules. Medications with more than one active ingredient should be stocked alphabetically by the first product that would appear on the computer generated label. Care should be given to look- and sound-alike names and packaging, with known problematic drug pairs being sufficiently separated, regardless of normal alphabetical placement. Staff should be informed as to the safety motive for these "mis-alphabetized" items. Shelf-talkers that note a different strength is available and where it is located in the pharmacy would be helpful and promote safety. A simple statement such as "another strength available" is advisable, since specifying "concentrated strength" or listing the actual strength of the moved product could cause staff to identify the information on the shelf-talker with the product in the bin above the shelf-talker.

Error with *Drug Standardization, Storage, and Distribution* causative factors

An error was reported in which methylphenidate 5mg was dispensed instead of oxy**CODONE** 5mg. The error was due to look-alike container labels from the same manufacturer being misread. (see Figure V-1)

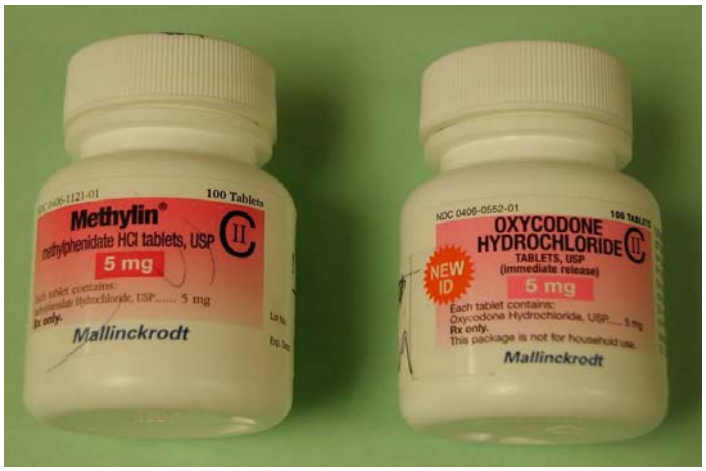


Figure V-1 Both products manufactured by Mallinkrodt, bearing same pink label with CII prominent in upper right corner

In addition, both drugs are schedule II and stored next to each other in a crowded narcotic cabinet. The staff had put the strength of the tablet on the top of the vial container for easier retrieval. In this case, both stock bottles had the number "5" handwritten on them. See Figure V-2.

Figure V-2 Crowded narcotic cabinet

Recommendations

Store the containers of these products apart from one another; add reminders to stock bottles and computer screens about the potential for error.

V. Common Contributing Factors Involving *Drug Standardization, Storage, and Distribution*
Picked next drug on shelf
Drug stocked incorrectly
No shelf dividers used on crowded shelves; see Figure V-3
No dividers used to separate sound- or look-alike products; see Figure V-4
Ophthalmic and otic products stored next to each other without warning labels or dividers
Stock drugs and filled prescriptions stored in same refrigerator
Disorganized and unlabeled refrigerator storage
Crowded will-call/pick up area; see Figure V-5
Filled prescriptions not returned to stock in timely manner
Recalled and discontinued drugs not segregated from active stock
"Basket" system not used (or inadequate size baskets used) to separate patient orders; see Figure V-6

V. Common Contributing Factors Involving *Drug Standardization, Storage, and Distribution*
Inadequate double-checks when restocking automated dispensing units
High-alert and look- and sound-alike medications stocked in "fast mover" section
No signage used for high-alert or look-alike drug products
Reconstitution and compounding ingredients stored in close proximity

Figure V-3 Crowded, haphazardly stocked shelves; products not oriented for viewing label

Figure V-4 Crowded shelves; no dividers between similar packages; products not oriented for viewing label contents

Figure V-5 Crowded will-call area can lead to wrong bag/receipt being selected

Figure V-6 Lack of separation of patient orders can lead to mislabeling vials

V. *Drug Standardization, Storage, & Distribution* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Implement a stocking program which completely separates ophthalmic and otic products that have been reported as being confused for one another
Institute a "shelf talker" or signing program that brings attention to sound- and look-alike drug products during stocking and retrieval procedures; see Figure V-7
Eliminate from storage potentially dangerous chemicals no longer necessary for compounding
Do not store non-drug supplies, such as alcohol, near diluents and products that require reconstitution
Immediately remove from current inventory outdated, recalled and discontinued drug products, and secure away from current stock
Store in separate bins in the refrigerator different types of insulin and other similar items

V. *Drug Standardization, Storage, & Distribution* Suggested Risk Reduction Strategies
Never stock any part of a product line of a sound- or look-alike drug in the "fast mover" section (unless automation is employed)
Never place stickers or cross-out lines, which would obliterate key information, on any part of the stock bottle label
All stock, including return-to-stock vials, are always labeled with drug name, strength, expiration date, and NDC number or bar coding if possible
Never leave medication unlabeled (including blister packages) for any length of time
Utilize dividers on crowded stock shelves, in narcotic cabinets and in the refrigerators as needed; see Figure V-8
Always stock product with manufacturer label showing (never place product face down due to crowding on shelves)
Utilize adjustable shelving to fit height of product
Maintain a prescription pick-up/will-call area that is free from clutter, and contains enough space to prevent "spillage" into the next basket or bin
Institute "Return to Stock" procedures that include contacting the patient to pick up filled prescription, and subsequently within seven days, physically removing filled prescriptions not picked up or no longer wanted by patient
Corporate / Owner Action
Maintain temperature-alarmed, well-lighted, organized and shelf-labeled refrigerators of adequate size with bins or shelf dividers, as needed
Maintain separate refrigerators for stock and prepared prescriptions waiting to be dispensed to the patient
Consider implementing an automated dispensing system that incorporates robotics and/or bar-code verification systems to support the dispensing system in the pharmacy
Implement computer graphics (pill imaging) on the verification screen with each prescription, to show the appearance of the product, to guide selection of the proper drug
Institute procedures that allow only the verifying pharmacist to "bag" the filled prescriptions
Implement and distribute procedures to be followed in manufacturer out-of-stock situations
Institute policies and procedures to notify affected patients of manufacturer recall situations

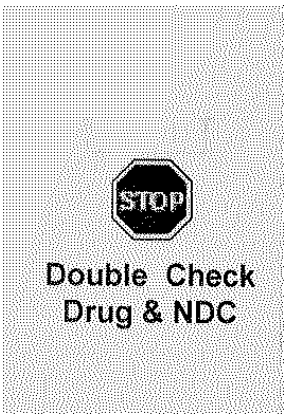


Figure V-7 Example of tag that can be placed on shelf where known look-alike products are stored near one another

Figure V-8 Narcotic safe with pull-out drawers and adjustable plastic dividers

Quick Check Question: *Drug Standardization, Storage, and Distribution*

1. Which of the following are ways to prevent medication errors associated with drug standardization, storage, and distribution?

   I. Use shelf dividers to separate all medications
   II. Incorporate alerts in your pharmacy computer system for medications that have caused errors in your pharmacy
   III. Store look-alike medications in fast mover section

   A. I only
   B. III only
   C. I and II
   D. II and III
   E. I, II and III

Answer: C. It is important to always separate each medication in stock and never place multiple different medications in the same shelf bins. Adding alerts for problem LASA medications in your computer system is another way to help prevent errors. The alert may say "obtain or check indication", "this drug has been confused with . . .", or some other wording to alert technicians and pharmacists to an error that may be frequent. Storing look-alike medications in the fast mover section does not solve the problem. Even though the products would be in the fast mover section, there is still potential that the drugs would be stored next to each other.

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

The potential for human error is mitigated through careful procurement, maintenance, use, and standardization of devices used to prepare and deliver medications.

Sanitary practices are followed when using devices and equipment to store and prepare medications.

Background

Appropriate safety assessment of drug delivery devices prior to their purchase and during their use is key to safe medication administration. Competency in using drug delivery devices is paramount. For example, error reports from ISMP MERP indicate that a frequent cause of medication errors during drug administration is unfamiliarity with devices by both healthcare professionals and patients. When the variety and type of drug delivery devices are kept to a minimum, it is easier for staff to maintain the necessary expertise to safely administer medications. However, as new devices come to the market, it is essential that training tools for proper use and potential hazards be available to the trainers and to the patients.

Errors with *Medication Device Acquisition, Use, and Monitoring* causative factors

Example VI-1: ISMP has received reports of medication errors that have occurred when using pen injectors. Problems reported with the devices include error-prone device design, dispensing errors due to look-alike names, and mistaking multi-dose devices as single dose.

Recommendations

Example VI-1: Patient education with face to face counseling and actual demonstration of the device is crucial when prescribing or dispensing pen injectors. Some injectors come with a “demo” device for the patient to practice correct technique. Pharmacies should make sure they have “demo” devices to use for patient training.

Error-prone device design:

Figure VI-1 Pen is marked in mL but the drug is actually dosed in mg

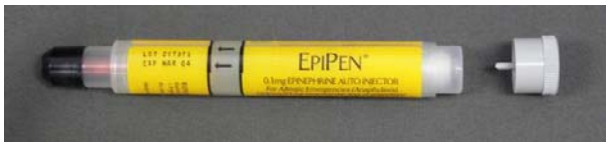


Figure VI-2 The black end (left) shields the needle. The grey safety cap (right) must be removed before use – not an intuitive design for patients

Figure VI-3 Notation that the pen contains a 28-day supply is small and has been overlooked resulting in the entire contents being delivered as a single dose

Errors with *Medication Device Acquisition, Use, and Monitoring* causative factors

Example VI-2: A mother discovered she had been incorrectly measuring her child's dose of ranitidine syrup. The mother had been given a MONOJECT oral syringe (Tyco/Kendall) with metric and apothecary (minim) scales and had been measuring 3.5 minims (0.22 mL) using the apothecary scale on the syringe, rather than the correct dose of 3.5 mL.

Recommendations

Example VI-2: Tyco/Kendall has agreed to remove the minim scale from any syringes where it remains. They are also removing a terminal zero (1.0) on the syringe's metric scale. Pharmacists should provide a hands-on demonstration of how to measure liquid doses and require a return demonstration by the patient to ensure understanding of proper use of oral syringes.

VI. Common Contributing Factors Involving *Medication Device Acquisition, Use, and Monitoring*
Measuring device not dispensed with oral liquid medication
Automated dispensing devices not calibrated, maintained or cleaned
Compounding equipment not cleaned after use, resulting in next compounded product being contaminated or adulterated
Written instructions from manufacturer to patient/user limited or incomplete
Samples of devices not available for pharmacists to use for patient education during counseling sessions

VI. *Medication Device Acquisition, Use, and Monitoring* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Using the "teach back" method, teach patients how to use measurement and monitoring devices
Perform manufacturers' suggested maintenance, calibration and cleaning schedules on all automated dispensing devices
Ensure newly cleaned equipment and measuring devices are used for each compound
Staff members use gloves or proper hand washing when handling individual loose oral solid products (e.g., capsules, tablets, etc.)
Staff members use appropriate hand washing procedures prior to compounding any prescription products (e.g., liquids, ointments, capsules, etc.)
Dispensing devices (e.g., counting trays, mortar and pestle, etc.) are washed after being used to prepare chemotherapy, penicillin, sulfonamide, opiate, or NSAID prescriptions
Only clean (washed) measuring devices are used for compounding liquids, ointments and capsules
Corporate/Owner Action
Institute policy to dispense all oral solutions with appropriate measuring device
Perform failure mode and effects analysis (see glossary, FMEA) on all automated dispensing devices and computer systems before purchase or implementation
Institute hand washing policies prior to and during shifts as needed
Obtain sample devices from manufacturers to be used for patient education/demonstration

Quick Check Question: *Medication Device Acquisition, Use, and Monitoring*

1. Pen injectors that deliver medication in specified doses are error-proof.

    A. True
    B. False

Answer: B. Pen injectors that deliver medication in specified doses are far from error-proof. The wide variety of pen injector designs makes it difficult for healthcare practitioners to learn how to use them properly and maintain competency. In fact, there have been many medication error reports describing misuse of pen injectors. For example, unintentional epinephrine injections from epinephrine pen injectors have occurred many times in patients, health care

professionals, and innocent bystanders.[16] Pharmacies should make sure they have "demo" devices to use for staff education and patient training, and, of course, any healthcare practitioner who is prescribing or dispensing these injectors should be familiar with their use. Providing patient education for all medical devices and utilizing the "teach back" method are ways to minimize the risk of error with these injectors.

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

Medications are prepared and dispensed in a safe and orderly physical space and in an environment that allows practitioners to remain focused on medication use without unnecessary distractions.

The process and flow of work have been designed to enhance safety and worker efficiency.

The complement of qualified, well-rested practitioners and supportive staff matches the workload without compromising patient safety. Minimum time limits for filling prescriptions and/or other services should not be imposed on pharmacists or staff.

Background

Environmental factors, such as poor lighting, cluttered work spaces, noise, interruptions, and non-stop pharmacy activity often contribute to medication errors when staff are unable to remain focused on the tasks involved with medication use. Studies have shown that when light intensity is increased, medication errors are reduced.[17] Another study confirmed that simple slips due to inattention are responsible for 11% of prescribing errors, 12% of administration errors, and 73% of transcription errors.[4] (see glossary for definitions of error types) The process of transcribing orders and order entry is particularly vulnerable to distractions in the environment, as pharmacy staff are frequently answering telephones and requests for information while carrying out these responsibilities.

Reduced staff levels and increased workload can contribute to errors. Poorly designed systems, processes and workflow often prevent corrections to these situations. Well constructed workflow patterns and processes can help to reduce the chance of errors. Inefficiencies in workflow are at the root of rework, interruptions, inadequate information and supervision, poor prioritization and unproductive time management. The result is often an environment fraught with error-prone, complex work processes that significantly increase the risk of errors. An uninterrupted and logical workflow will create an intuitive progression that will help to reduce the chance of errors resulting from unclear processes. Cushioned flooring helps to alleviate fatigue. Safety recommendations suggest working temperatures should be no less than 16°C, 61°F and medication should not be stored at temperatures greater than 25°C, 77°F. Consider non-white bench colors, such as cream or grey, which provide more contrast to labels, packaging and medications.[12]

For more information on environmental conditions see USP proposed general chapter 1066 “Physical Environments that Promote Safe Medication Use” at: www.usp.org/pdf/EN/USPNF/PF34(6)Combined.pdf.

Error with *Environmental Factors, Workflow, and Staffing Patterns* causative factors

A patient received, from a local pharmacy, generic BIAXIN tablets 500 mg for a UTI, with the directions to take two tablets once daily. The prescription was actually written for BIAXIN XL. A pharmacy technician performed the data entry and product selection; the checking pharmacist missed the error during verification. According to the patient, this pharmacy is part of a chain where the work environment is typically very high pressured and fast paced. It appeared to the patient that the pressure of the workload caused the pharmacist to perform the checking too hurriedly.

Recommendations

Even in fast paced environments, steps can be taken to ensure adequate time for the verification process. Measures should include reducing clutter and crowding, matching workload with appropriate staffing levels, and improving lighting and technology so that errors can be "seen."

VII. Common Contributing Factors Involving *Environmental Factors, Workflow, and Staffing Patterns*
Inadequate lighting
Uncomfortable temperature
Excessive noise
Clutter and crowding
Interruptions
Workload inappropriate for staff
Inefficient workflow
Lack of consideration for employee safety; number and schedule of shifts worked not considered when creating work schedule
Meal breaks not scheduled or taken
Floater (substitute staff) unfamiliar with practice site
Lack of staffing contingency plans to cover illnesses and vacations, resulting in short staffing
Older technology not replaced
Managers not considerate of human factors when scheduling

VII. Common Contributing Factors Involving *Environmental Factors, Workflow, and Staffing Patterns*
Phone headsets missing volume adjustment
Staff not healthy or working when ill
Staff issues of visual acuity or hearing impairment

VII. *Environmental Factors, Workflow, and Staffing Patterns* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Clearly identify workflow patterns that prevent overlap and crossover
Identify and reconfigure workstations which are adequately spaced to avoid crossover foot traffic
Avoid storage that requires staff to reach over their heads or to climb up to retrieve products
When creating the work schedule, consideration is given to the use of supportive dispensing technology and prescription volume, and pharmacist/technician ratios are ideally suited to minimize dispensing errors
Maintain workstations that are free of clutter
Identify high-risk situations, such as pediatric dose calculations, or areas of vulnerability that will require a double-check as a redundancy
Use devices that allow prescriptions to be read at eye level when being entered in computer
Utilize phone headsets which have adjustable volume control
Utilize the "basket" or other system to keep patient orders separate from each other during the dispensing process
Corporate/Owner Action
Consider ergonomics of work area to include: use of fatigue mats, and placement of vials, caps, phones, monitors, and trash receptacles
Control climate temperature and humidity for staff comfort and to conform to drug storage requirements
Utilize adjustable computer screens for staff comfort and safety, and to prevent glare
Establish a realistic staffing plan taking into consideration staff vacations, illnesses and meal breaks
Periodically examine prescription volume data to determine appropriate staffing levels, even during peak times when demand is highest

VII. *Environmental Factors, Workflow, and Staffing Patterns* Suggested Risk Reduction Strategies
Encourage staff to plan for and take needed meal breaks
Utilize consistent floaters, familiar to and assigned to particular store locations and workstations
Ensure adequate space, storage and lighting (10,000 ft candles) in medication stock and dispensing areas
Provide verification workstations that are free of disruptions and distractions
Replace old technology with new and improved technology when available (flat screen monitors, laser printers, new automated counting devices)
Enhance the workflow; implement technology such as fax machines, voice mail, touch tone telephone prompts, and e-mail for patients to request refills; to minimize staff interruptions
Implement IVR systems that are integrated with the computer system, to streamline priority in processing new (IVR doctor calls) and refill (IVR patient calls) prescriptions
Recognize under-worked (bored) or overstressed employees may have increased vulnerability to error
Provide a staff educational program on stress management
Provide an employee assistance program and encourage participation, to help staff who are experiencing stress that may affect work performance
Consider using staff located outside the dispensing area to resolve third party and prior authorization issues
Provide confidential area for patient counseling and MTMS
Consider refill reminder programs that automatically prioritize and refill patient prescriptions in a timely manner
Consider centralized filling processes and a common database to shift prescription filling to other locations
Encourage staff to have annual physicals to include visual and hearing screenings
Establish and publicize procedures to handle sudden staffing shortages due to illnesses and emergencies

Quick Check Question: *Environmental Factors, Workflow, and Staffing Patterns*

1. Under-worked staff may have an increased vulnerability to error.

    A. True
    B. False

Answer: A. It is often thought that only pharmacies with high workloads are error prone. However, under-worked staff also has a vulnerability to error. As reported in a study by Grasha, pharmacists were more vulnerable to mistakes under low workload conditions and when shifting from high to low activity. Boredom, reduced task focus, and disruptions in personal work rhythms made it hard to focus on tasks, even though pharmacists with both low and high workload were equally concerned about their performance and motivated to do well.[18]

2. Which of the following are risk reduction strategies that can be implemented to reduce errors associated with environmental factors?

    I. To reduce clutter, place labeled vial on top of patient receipt, in a neat row, on dispensing counter for pharmacist to verify
    II. Reconfigure work stations to prevent crossover foot traffic among staff
    III. Store products in a way to limit excessive reaching and climbing on stools

    A. I only
    B. III only
    C. I and II
    D. II and III
    E. I, II and III

Answer: D. Lining prescriptions up next to one another on the counter increases the risk of mix-ups and confusion. The use of a "basket" system should not depend on the volume of prescriptions being filled. This system allows for separation of each prescription order and reduces the chance of error. Unfortunately, in a community setting, it is difficult to predict when the volume will increase. Any situation can be managed by having routine strategies in place.

Key Element VIII: Staff Competency and Education

Practitioners and support staff receive sufficient training and orientation to the dispensing process and medication error prevention, and undergo baseline and annual evaluation of knowledge and skills related to safe medication practices.

Background

Staff education can be an important error prevention strategy when combined with other strategies that strengthen the medication-use system. However, it is a weak link with little leverage to prevent errors when attempting to use *only* this strategy for reducing errors. It is an impossible task to educate all practitioners about all things that they need to know to perform flawlessly when prescribing or dispensing medications. Thus, over the course of time, even the most educated, experienced, and careful healthcare professionals will make errors.

Staff education can effectively augment other error prevention strategies when it is focused on priority topics, such as the following:

- New medications being used in the pharmacy
- High-alert medications which have the greatest potential to cause patient harm if an error occurs, or drugs with unusual or critical dosing considerations
- Protocols, policies and procedures related to medication use, including those related to the use of drug delivery/administration devices
- Medication errors that have occurred within the organization or occurred in other organizations, and the error prevention strategies.

In addition, it is important to assess the baseline competency of all practitioners involved in the medication-use process. While demonstrating competence does not assure that errors will not occur, the process itself is educational and can help better prepare practitioners for safe medication practices. It can also help the organization develop an orientation program that meets the individual needs of all practitioners involved in the medication-use process. Adequate training and the ability to develop systematic procedures are essential to ensure that everyone conducts work in similar fashion.

Errors with *Staff Competency and Education* causative factors
Example VIII-1: When prescriptions for oral antibiotics requiring reconstitution are received by a pharmacy, the pharmacist often bags the patient-specific labeled medication with a “mix card” that informs the clerk that the medication requires mixing. Once the patient arrives at the pharmacy, the medication is reconstituted and dispensed. We received a report where a clerk gave an unmixed antibiotic to the patient’s father who then accidentally measured 9 mL of *powder*, not 9 mL of liquid and administered it to his son.

Example VIII-2: An 8-month-old girl was prescribed amoxicillin/clavulanate potassium (AUGMENTIN) suspension to treat an ear infection. The prescription was taken to the family's local community pharmacy where a medication bottle labeled with the instructions to give the child a half teaspoonful twice daily was dispensed. When the family arrived home, they measured out a half teaspoonful of the *powder* and administered it to the girl. The pharmacy had failed to mix the powder with water prior to dispensing the medication. The girl was rushed to the emergency department where she recovered.

Recommendations

Examples VIII-1, VIII-2: Training and procedural issues should include consideration of placing new prescriptions for oral liquid medications, especially those that need to be reconstituted, in a separate area away from other prescriptions waiting to be picked up. Mark the area as "not to be dispensed without speaking to the pharmacist." This may help remind staff that the product needs to be mixed and that a pharmacist should review directions with the patient or caregiver. Other options include bagging in clear plastic bags, and inserting stops along the way at verification and at the cash register reminding of the need to mix. Include specific product descriptions on the prescription label (e.g., orange-flavored, white, thick liquid). Review the label and directions for use with the patient. Open the bottle with the patient and/or caregiver. Ensure that oral syringes (without caps) or other appropriate measuring devices are readily available with the product or for purchase at your practice site. Provide education to patients and caregivers regarding proper use of the measuring device. Have the caregiver or patient provide a return demonstration of how to measure and administer the dose. Inform caregivers how to clean the device, if it is to be reused.

Errors with *Staff Competency and Education* causative factors

Example VIII-3: Reliant Pharmaceuticals changed its brand name OMACOR (omega-3-acid ethyl esters) to LOVAZA to prevent confusion with AMICAR (aminocaproic acid) (see Figure VIII-1).

Figure VIII-1

A pharmacist who wasn't familiar with the new name misread a handwritten prescription for Lovaza 1 gram as **LOR**azepam 1 mg (see Figure VIII-2). Patient

counseling was offered when the prescription was picked up, but the patient declined. Fortunately, the patient discovered the error right away after reading the drug monograph at home. He returned to the pharmacy and was given the correct medication.

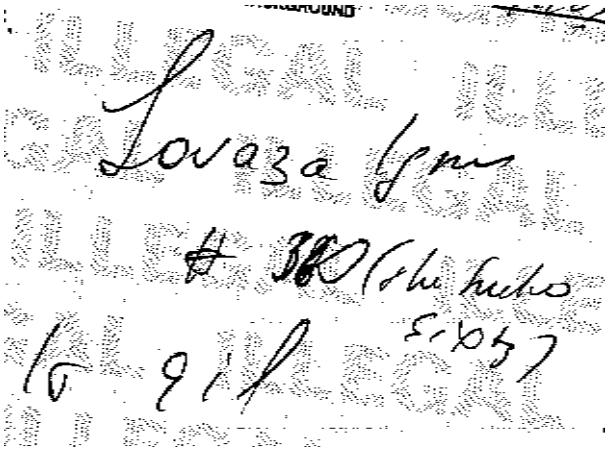


Figure VIII-2

Recommendations

Example VIII-3: One downside of changing the name of a well-known product like OMACOR is that it takes time before everyone becomes aware of the new name, just as it does with new products. Because of confirmation bias (seeing what is familiar while missing what is not), the possibility that the name will be misread increases during this "learning phase" if the new name is similar to another familiar product name. All staff and corporate personnel need to assure awareness of new product names and name changes, while promoting patient understanding about the importance of speaking to a pharmacist when medications are dispensed.

VIII. Common Contributing Factors Involving *Staff Competency and Education*
Insufficient competency validation
New or unfamiliar drugs/devices
Lack of orientation process; not trained for specific duties
No feedback about errors/prevention provided
Training on procedures and processes is insufficient
No training offered on how to handle or respond to medication errors
New drug information not communicated
Information regarding newly stocked drugs not communicated

VIII. Common Contributing Factors Involving *Staff Competency and Education*
Technician unfamiliar with prescription and OTC drug names
Previous internal and external errors and safety strategies not communicated
Continuing education not maintained

VIII. *Staff Competency and Education* Suggested Risk Reduction Strategies
Onsite Staff Implementation
Provide technician and pharmacist with on-the-job, side-by-side team training; and classroom training to meet the needs of the practice
Use technicians only in areas and for functions for which they have documented training
Arrange staffing so that trainers have reduced workload while performing on-the-job training
A supervisor evaluates each pharmacy staff member, at least annually, to assess his/her skills and knowledge related to safe medication practices
Pharmacists and technicians seek and receive ongoing information about medication errors occurring within the organization, error-prone situations, errors occurring in other pharmacies, and strategies to prevent such errors
Discuss potential medication errors and ways to avoid them during staff meetings
Encourage pharmacists to routinely provide technicians with new drug information, OTC medication information and recent Rx to OTC switches
When errors occur, offer education and suggestions to all staff, not just the staff directly involved in the error
Corporate/Owner Action
Provide practice site, competency-based orientation regarding stocking, dispensing, preparation, verifying and delivery procedures to all newly hired staff
Require staff scheduler to refer to documented levels of training before assigning tasks and shifts
Require minimum level of technician training before independent scheduling is initiated
Provide staff with on-line, readily accessible, current information about newly marketed or stocked drug products and devices to include guidelines, restrictions, and special precautions

VIII. *Staff Competency and Education* Suggested Risk Reduction Strategies
Provide staff with computerized timely updates on medications on back order or manufacturer mergers and any other pertinent "Inventory news"
Continually monitor corporate/owner training programs to include new tasks and procedures added to the dispensing process
Train staff and have policies and procedures in place on how to respond to internal medication errors
Provide staff with time and resources to attend educational programs related to medication use and error prevention
Pharmacy management supports educational programs for staff, such as live continuing education courses, professional meetings, journal club or in-services on new drugs and/or important drug safety issues
Evaluate each staff member's skills and knowledge regarding safe medication practices during annual employment review; address at-risk behaviors (see glossary) on an ongoing basis. Visit www.justculture.org for more information about this methodology
Provide pharmacists and technicians with a live educational program on ways to avoid errors with high-alert drugs, medications with a narrow therapeutic index, and other problem-prone products
When errors occur, educational efforts are widespread among all pharmacy personnel who may make a similar error, rather than remedial and directed at only those who were involved in an error
On an annual basis, provide staff with continuing education on internal and external reported medication errors, safety practices, high-alert medications, and strategies to reduce the potential for errors

Quick Check Question: *Staff Competency and Education*

1. When a medication error occurs, the most important step is to educate the person involved in the error.

    A. True
    B. False

Answer: B. Education of only the person involved with the error is considered a low leverage strategy to prevent error. (For more information on high and low leverage strategies, see Using the *Assess-ERR*™ Tool in Community Pharmacy.) Staff education combined with higher leverage error-reduction strategies is a much more effective way to reduce medication errors. Staff competency should be assessed with regards to protocols, policies and procedures related to medication use,

including those related to the use of drug delivery/administration devices. Use tools such as the ISMP® Medication Safety Self Assessment® for Community/Ambulatory Pharmacy to gauge how well your pharmacy performs on key medication safety items.

Key Element IX: Patient Education

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

Pharmacists establish and participate in community-based disease prevention and monitoring programs to promote health and ensure appropriate therapy and outcomes of medication use.

Background

Patients should be advised that medication errors can occur, and that they can play a role in preventing these errors. The patient is the final link in the medication-use process. As such, an alert and knowledgeable patient can serve as the last line of defense in preventing medication errors. We have many reports in our database of errors that were prevented by observant and informed patients or their families. Thus, to prevent errors, patients must receive ongoing education by physicians, pharmacists and nurses about drug brand and generic names, indications, usual and actual doses, expected and possible adverse effects, drug or food interactions and how to protect themselves from errors. Table IX-1 lists strategies that patients should use.

Table IX-1

Consumer Measures for Error Prevention[19,20]
Be aware that medicine mix-ups due to look- and sound-alike names are not uncommon
Know what medications you are taking and why
Make sure your doctor tells you the purpose for each medication and writes it on the prescription itself
Know the name and strength of a prescription before leaving prescriber's office
When you pick up a prescription, always speak to the pharmacist to review the medication and directions for taking it
Make sure the pharmacist mentions the same purpose the doctor mentioned to assure that the right drug has been dispensed
Know how to take medications and understand directions
Ask questions, if in doubt, and persist with questioning until you are certain you are receiving the correct drug
Keep a list of medications you take, including dietary supplements and over-the-counter medications
Update the medication list whenever a change occurs

Consumer Measures for Error Prevention[19,20]
Give an updated copy of your medication list to all healthcare providers at every visit
Learn generic drug names as key identifiers
Tell all practitioners who care for you about changes in your health
Ensure that refilled prescriptions contain the drug you were expecting
Ask for written information about prescribed medications
Contact health professionals if a look- and or sound-alike error is suspected

Patients can play a vital role in preventing medication errors when they have been encouraged to ask questions and seek satisfactory answers about their medications before drugs are dispensed at a pharmacy. If patients question any part of the medication dispensing process, whether it be to question the drug appearance or the correct dose, pharmacists must be receptive and responsive, not defensive. All patient inquiries should be thoroughly investigated before the medication is dispensed.

Error with *Patient Education* causative factors
Example IX-1: A 17-year-old female track star died following the use of OTC muscle pain relief cream (e.g., Bengay, Icy Hot). The high school teen reportedly used a methyl salicylate cream to treat muscle pain following track meets. In addition to spreading the cream on her legs, she was using other methyl salicylate-containing products as well.

Recommendations
Example IX-1: Use this event as a "wake up" for educating patients about their use of OTC products. Pharmacists should be easily accessible to speak with patients when they select OTC medications. Educate patients about the dangers of methyl salicylate overuse and that it is available in many OTC products. Utilize "shelf talkers" near methyl salicylate and other selected OTC products to raise awareness.

Error with *Patient Education* causative factors
Example IX-2: A tragic event occurred in which a 6-year-old girl died of an accidental overdose of fenta**NYL**. When the child complained of neck pain late one evening, her foster mother gave her an appropriate dose of ibuprofen but also placed a leftover fenta**NYL** patch on the child's neck to help treat the pain. The next day, the child was found unconscious in bed and was pronounced dead by the time she arrived in the emergency department. The child's foster mother had been given a prescription for fenta**NYL** patches several years earlier to treat chronic pain after an accident. The patch she placed on the child was left over from that prescription.

Recommendations

Example IX-2: This tragedy could have been avoided had the foster mother received adequate education when the fenta**NYL** patches were first prescribed and dispensed. Patient education at time of dispensing should include oral and written instructions on the proper disposal technique (fold and flush), the fact that fenta**NYL** can be fatal if given to another (opiate naive) person and that fenta**NYL** is not indicated for short term pain relief.

IX. Common Contributing Factors Involving *Patient Education*
Lack of information given to patient
Non-compliance not addressed
Patients not encouraged to ask questions
Lack of pharmacy staff identification (technician vs. pharmacist name tags)
Lack of response to patient inquiries
Lack of encouragement from pharmacy staff for patients to engage with pharmacist
Patient did not properly identify self at pick up
Counseling not encouraged or accepted
No mandatory counseling on high-alert medications
Lack of understanding of written information due to low health literacy or poor reading skills
Patients lack recall of spoken directions
Patient language barrier
No instructions given for devices purchased at pharmacy counter
Patients not given information on medication errors and ways they can help prevent them
No follow up with patients considered to be high-risk or on high-alert (see glossary) medications
Patients eligible for MTM services are not identified

IX. *Patient Education* Suggested Risk Reduction Strategies

Onsite Staff Implementation

Provide pharmacy applied auxiliary warning labels in a consistent location for patient routine expectation

Use vial size large enough to contain all of the medication and also large enough to have all necessary labels comfortably affixed

Use common sense when applying auto-printed patient warning labels to patient vials

> Example from a community pharmacy: A 16-year-old patient brought in a prescription for PLAN B (levonorgestrel), used for emergency contraception. Pharmacy staff applied an auxiliary label that read "*Do not take if you are pregnant or think you may be pregnant''* to the product.

Teach patients how to actively participate in their proper identification before accepting medication at pick up

Provide patients and caregivers with brand and generic names of their medications, the purpose of the medication, dosing, and important adverse effects of their medication, orally and/or in writing

Update patient profiles in the computer system to include all drug products currently being taken whether prescription or not, whether received from this pharmacy or not, and keep these other products in mind when counseling and performing DUR; inform patients of interactions, duplications, and dangers

When dispensing oral liquid medications for children or geriatric patients, a proper measuring device is provided (e.g., dropper) or suggested (e.g., oral syringe) and caregivers are instructed on its use to measure the prescribed dose; consider using only metric quantities and providing metric measuring devices for consistency and accuracy (avoid "teaspoonful" and "cc" terms)

Utilizing a "teach back" method, provide patients with instruction on proper use and maintenance of devices dispensed from the pharmacy; see Figures IX-1, IX-2

Corporate/Owner Action

Encourage staff to solicit patient questions about their prescriptions, OTC, herbal and dietary supplements

Provide pharmacy's telephone number, and the number of an on-call pharmacist or a 24-hour pharmacy if a pharmacist onsite cannot be reached after hours for an emergency

Encourage patients to call for any drug therapy concerns or questions that arise after they leave the pharmacy

Provide adequate staff time for patient counseling activities

Insist on mandatory counseling for patients receiving high-alert medications or for patients considered to be high-risk

IX. *Patient Education* Suggested Risk Reduction Strategies
Provide a private, confidential area near the pharmacy for patient counseling, MTM services, and educational classes for patients
Provide written information about their medications at a reading level that is comprehendible to patients
Provide pictograms or other means of instruction to patients who do not speak English or are unable to read English
Provide educational classes to patients on medication, disease states or medication safety
Encourage pharmacists with time and resources, to seek out patients who would benefit from MTM services and include MTM services delivery as part of the pharmacist staffing schedule
Encourage pharmacists to participate in promoting, facilitating and providing immunizations to the local community and screening clinics to promote early detection of disease
Encourage personnel to develop and conduct at least one annual educational program or other proactive public health effort designed to improve safe use of medications in the community; see Figures IX-3, IX-4, IX-5

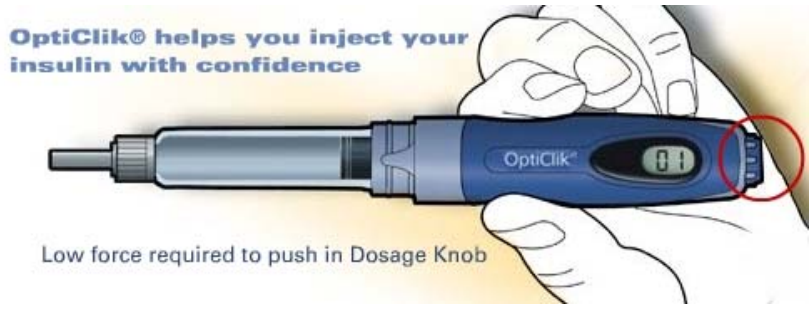


Figure IX-1 OptiClik device as pictured on sanofi aventis website does not warn patients that when held upside down (such as by a left handed person), the dial-up dose could be mistaken due to digital numbers

Figure IX-2 Inform patients that the dose dialed for 52 units appears as only 25 units if held upside down; mistaken doses could result in hypo or hyperglycemia, depending on the digit configuration and the actual amount administered (12 misinterpreted as 21, 51 misinterpreted as 15, etc.)

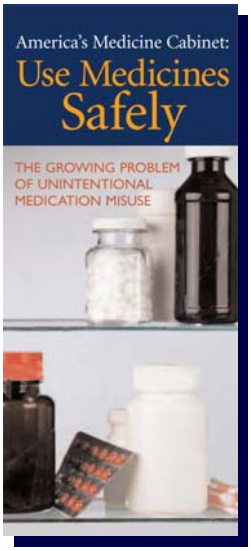
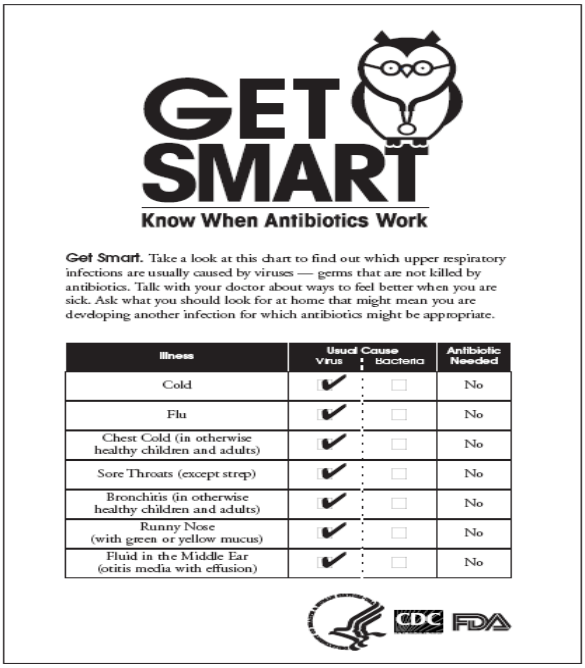


Figure IX-3 America's Medicine Cabinet *Proceed with (Pharmaceutical) Care*, a program created by APhA and ISMP, emphasizes the importance of reading medicine labels (especially the Drug Facts label) and involving the community pharmacist in medicine decisions. The program introduces consumers to information about and an approach to medicine use that may help them with self-medication choices for themselves and in their role as caregiver. The lesson uses scenarios to teach the importance of reading label warnings and not taking two medicines that contain the same active ingredients. This free program is available at: www.pharmacist.com/Content/NavigationMenu3/Newsroom/PublicRelationsResources/Use_Medicines_Safely.htm.

Figure IX-4 CDC resource page. Centers for Disease Control and Prevention Web site. Available at: www.cdc.gov/flu/freeresources/print.htm.



Illness	Usual Cause: Virus	Usual Cause: Bacteria	Antibiotic Needed
Cold	✔		No
Flu	✔		No
Chest Cold (in otherwise healthy children and adults)	✔		No
Sore Throats (except strep)	✔		No
Bronchitis (in otherwise healthy children and adults)	✔		No
Runny Nose (with green or yellow mucus)	✔		No
Fluid in the Middle Ear (otitis media with effusion)	✔		No

Figure IX-5 CDC Resource page. Centers for Disease Control and Prevention Web site. Available at: www.cdc.gov/getsmart/campaign-materials/onepage-sheets.html.

Quick Check Question: *Patient Education*

1. The last line of defense in preventing a medication error is the:

    A. Nurse
    B. Prescriber
    C. Patient
    D. Pharmacist

Answer: C. Patients are the last line of defense in preventing a medication error. They are an integral part of their medication safety team and should be treated as valued team members.

2. Which of the following are ways to prevent medication errors through patient education?

    I. Provide education for all medications dispensed
    II. Provide education for all high-alert medications
    III. Encourage patients to review prescriptions before leaving the pharmacy

    A. I only
    B. III only
    C. I and II
    D. II and III
    E. I, II, and III

Answer: E. Patients are routinely asked if they have any questions for the pharmacist and they often say no. However, this question places the responsibility on the patient to know that he or she should ask questions or what questions need to be asked. Pharmacists should be proactive and provide patient counseling, especially for high-alert medications or ones that use a device. This prepares the patient to appropriately and safely use the product. It also provides an environment in which a patient can ask questions and a pharmacist can identify potential problems before the patient leaves the pharmacy.

Key Element X: Quality Processes and Risk Management

A non-punitive, systems-based approach to error reduction is in place and supported by pharmacy owners or senior management.

Practitioners are motivated to detect and report errors, and teams or individualized practitioners in small pharmacies regularly analyze errors that have occurred within the organization and in other organizations for the purpose of redesigning systems to best support safe practitioner performance.

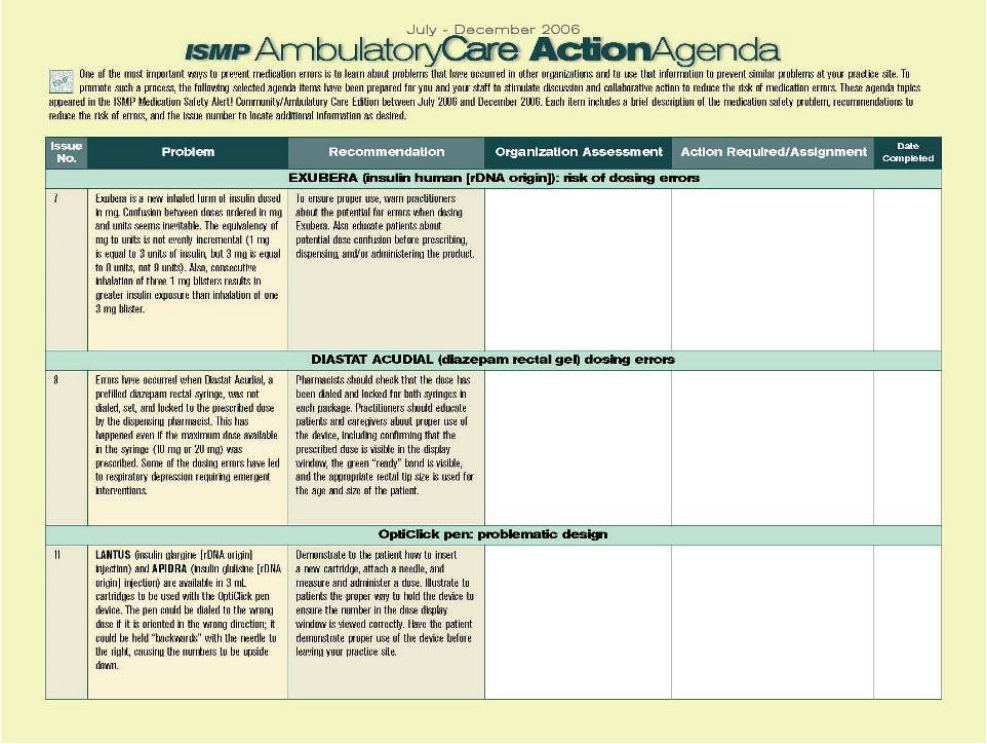
Simple redundancies that support a system of independent double-checks or an automated verification process are used for vulnerable parts of the dispensing system, to detect and correct serious errors before they reach patients.

Background

Traditional efforts at error reduction have focused on individual practitioners, using training, exhortation, rules and disciplinary action to improve performance. Human factors specialists and error experts reject this approach because it is more effective to change the system as a whole than to target individuals for improvement.[21] Since most of what people do is governed by the system, the causes of error belong to failures in the system and often lie outside the direct control of the individual workforce. Therefore, the way to prevent errors is to redesign the systems and processes that lead to errors rather than focus efforts on correcting the individuals who make errors. Effective strategies for reducing errors include making it impossible or difficult for staff to make an error, and promoting the detection and correction of errors before they reach a patient and cause harm.

Although reducing complexity in processes is important to error reduction, simple redundancies that support a system of independent double-checks promote the detection and correction of errors before they reach patients. These checks are most effective when used for drugs which have the potential to cause serious patient injury.

Learning about errors and near misses that have occurred in other organizations, and reviewing safeguards others may have implemented, can help prevent similar errors from occurring in other practice settings. Each organization needs to accurately assess how susceptible its systems are to the same errors that have happened in other organizations, and acknowledge that the absence of similar errors is not evidence of safety. Personal experience is a powerful teacher, but the price is too high to learn all we need to know from firsthand experiences. Learning from the mistakes of others is imperative. Pharmacy teams should review items from the most recent *ISMP Ambulatory Care Action Agenda* (see Figure X-1) in order to stimulate discussion on what type of actions may reduce the risk of medication errors.



July - December 2006

ISMP AmbulatoryCare ActionAgenda

One of the most important ways to prevent medication errors is to learn about problems that have occurred in other organizations and to use that information to prevent similar problems at your practice site. To promote such a process, the following selected agenda items have been prepared for you and your staff to stimulate discussion and collaborative action to reduce the risk of medication errors. These agenda topics appeared in the ISMP Medication Safety Alert! Community/Ambulatory Care Edition between July 2006 and December 2006. Each item includes a brief description of the medication safety problem, recommendations to reduce the risk of errors, and the issue number to locate additional information as desired.

Issue No.	Problem	Recommendation	Organization Assessment	Action Required/Assignment	Date Completed
EXUBERA (insulin human [rDNA origin]): risk of dosing errors					
7	Exubera is a new inhaled form of insulin dosed in mg. Confusion between doses ordered in mg and units seems inevitable. The equivalency of mg to units is not evenly incremental (1 mg is equal to 3 units of insulin, but 3 mg is equal to 8 units, not 9 units). Also, consecutive inhalation of three 1 mg blisters results in greater insulin exposure than inhalation of one 3 mg blister.	To ensure proper use, warn practitioners about the potential for errors when dosing Exubera. Also educate patients about potential dose confusion before prescribing, dispensing, and/or administering the product.			
DIASTAT ACUDIAL (diazepam rectal gel) dosing errors					
8	Errors have occurred when Diastat Acudial, a prefilled diazepam rectal syringe, was not dialed, set, and locked to the prescribed dose by the dispensing pharmacist. This has happened even if the maximum dose available in the syringe (10 mg or 20 mg) was prescribed. Some of the dosing errors have led to respiratory depression requiring emergent interventions.	Pharmacists should check that the dose has been dialed and locked for both syringes in each package. Practitioners should educate patients and caregivers about proper use of the device, including confirming that the prescribed dose is visible in the display window, the green "ready" band is visible, and the appropriate rectal tip size is used for the age and size of the patient.			
OptiClick pen: problematic design					
11	**LANTUS** (insulin glargine [rDNA origin] injection) and **APIDRA** (insulin glulisine [rDNA origin] injection) are available in 3 mL cartridges to be used with the OptiClick pen device. The pen could be dialed to the wrong dose if it is oriented in the wrong direction; it could be held "backwards" with the needle to the right, causing the numbers to be upside down.	Demonstrate to the patient how to insert a new cartridge, attach a needle, and measure and administer a dose. Illustrate to patients the proper way to hold the device to ensure the number in the dose display window is viewed correctly. Have the patient demonstrate proper use of the device before leaving your practice site.			

Figure X-1 The ISMP Ambulatory Care Action Agenda. The Action Agenda is presented in a format that allows community practice sites to document their medication safety activities, which is important for internal quality improvement efforts as well as for any external accrediting or regulatory organizations. Each pharmacy practice site should convene a staff meeting to discuss each item in the Action Agenda. The staff should ask themselves, "Can this error occur at our site?" If the answer is "yes," the ISMP recommendations for prevention should be reviewed for applicability at that specific site. If the recommendations are germane to the practice site, the columns on the Action Agenda indicating "Organization Assessment" and "Action required/Assignment" should be completed and a reasonable time set for completion.

It is important to explore how to use reported medication error information to identify potential areas of opportunity within pharmacies and/or the organization. Organizations must support a culture of safety and establish a non-punitive approach to internal reporting of errors in order to detect, document, assess and prevent prescription errors and to determine the causes and appropriate responses.

Voluntary adverse event reports often lead to corrective actions such as widespread dissemination of hazard alerts by ISMP, FDA, and manufacturers (see Figure X-2); product label revisions, and even changes in drug names. For example, after several deaths were reported following mix-ups between amrinone and amiodarone, ISMP petitioned United States Adopted Names (USAN) to change the proper name, amrinone, to inamrinone. This has effectively eliminated this problem name-pair, along with associated deaths. LEVOXINE, a thyroid product, was

occasionally confused with LANOXIN, a digitalis product, until the maker of LEVOXINE agreed, in 1994, to change the name to LEVOXYL.

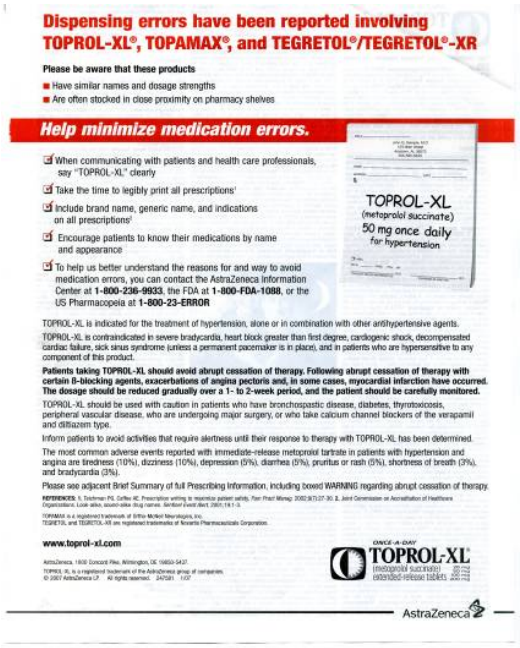


Figure X-2 AstraZeneca's one page magazine campaign toward awareness of look-alike drug names, after error reports involving their product were brought to their attention

Internal error reporting can help identify error-prone conditions in an organization's medication-use system. Once system deficits are identified, proactive measures such as auxiliary labeling, drug storage changes, or pharmacist/staff education may be undertaken to remedy these conditions and prevent similar future mishaps.

Reports to voluntary reporting programs, such as the ISMP MERP, from frontline pharmacy staff are especially important when errors involve LASA products because high-level, error-reduction strategies, such as drug name changes or packaging alterations (see Figure X-3), are sometimes needed to prevent future errors. Product problems may occur with a frequency that should constitute a "call to action," but the incidence or significance of those problems may be lost within the construct of individual practice settings.

Figure X-3 Apidra/Lantus labeling and packaging before error reports (left) and after error reports (right); accumulated medication error reports both by pharmacy staff and patients, indicating look-alike packaging contributed to selection errors, convinced manufacturer to change label and box appearance

Voluntary reporting programs have learned that many errors are caused by factors outside the healthcare practice site and beyond the direct control of a pharmacist. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, healthcare reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care. Take the time to report errors and potential errors to ISMP. Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, close calls, or hazardous conditions may be reported through the ISMP web site (www.ismp.org) or communicated directly to ISMP by calling 1-800-FAIL SAFE or via e-mail at merp@ismp.org. ISMP guarantees the confidentiality and security of the information received.

Error with *Quality Processes and Risk Management* causative factors

A patient reported being very dissatisfied with the way his community pharmacist responded when a dispensing error resulted in nearly 30 days of erroneous therapy. Unfortunately, this pharmacist's sense of infallibility contributed to the original error, and the perception that she was uncaring impeded an appropriate apology and service recovery actions when the error was discovered.

Recommendations

Investigate patient concerns when prescriptions are picked up; use patient counseling sessions as a final check of prescription accuracy. Schools of pharmacy and employers should provide education to pharmacists to ensure they possess requisite knowledge and skills to respond when errors occur. Conveying sympathy, preserving relationships, and fostering trust should be seen as appropriate

professional actions in the aftermath of an error. Report and discuss errors with all staff. Lead group discussions on prevention strategies and implement workable solutions.

X. Common Contributing Factors Involving *Quality Processes and Risk Management*
No clear culture of safety (see glossary)
Lack of leadership and budgetary support for medication safety
Incentives and positive feedback not given to individuals who report errors and hazardous situations
Fear of error reporting (blame, humiliation, retribution; tied directly to performance reviews, continuation of employment and monetary compensation)
Error prevention strategies focus on individual performance improvement rather than systems improvement
Error rates are used for benchmarking and kept in employee files
Independent double-checks on calculations for pediatrics or compounds not performed
Lack of automated or manual double-checks in critical processing steps
System-based causes of errors not analyzed
System-based enhancements not sought or implemented
Misuse of double-checks, in place of system enhancements that would prevent errors
Over reliance on scan accuracy of system technology (when overrides of the system are allowed)

X. *Quality Processes and Risk Management* Suggested Risk Reduction Strategies
Onsite Staff Implementation
When possible, (i.e., during pharmacist staffing overlap or via contact with off-site colleagues*), ask fellow pharmacists to double-check all calculations
During staff meetings, promote and reward reporting of errors and their prevention
Do not permit assigning of blame to prescription incidents
On a daily basis, a pharmacist compares the previous day's prescription orders listed on a computer-generated printout with hard or scanned copies of the prescriptions, to verify data entry accuracy

X. *Quality Processes and Risk Management* Suggested Risk Reduction Strategies
Pharmacists periodically perform quality control checks by reviewing completed prescriptions in the will-call area; examining typed labels, computer entries, and location of stock bottles replaced in inventory; and other forms of random checks that promote detection of errors
Corporate/Owner Action
Promote patient safety and quality of work as manager's (corporation's) objectives and mission
Promote a culture of safety from top management down to staff in pharmacies
Practice and promote just culture and shared accountability when discussing errors
Identify and coach at-risk behaviors
Management provides positive incentives for individuals to report errors, and pharmacists and technicians are thanked and praised for detecting and reporting errors
Pharmacists and technicians are periodically and anonymously surveyed to determine their level of anxiety and fear with making and reporting errors
Pharmacists and technicians involved in serious errors that cause patient harm are emotionally supported by their colleagues, and offered psychological counseling through an Employee Assistance Plan
Encourage management to be skilled in "human factors" to recognize when staff needs "filters" added for safety
Encourage staff to notify management when unsafe environmental conditions exist
Reward staff when reporting near misses and errors for educational and training purposes
Train pharmacists and technicians in the clinical and administrative procedures for responding to a serious medication error
Use discipline in cases of malicious or illegal activity, using the Just Culture process and algorithms
Encourage regular visits of upper management to the pharmacy, to seek staff input on ways to help prevent medication errors, improve processes and decrease hazardous situations
Do not allow fear of retribution in the reporting of errors and near misses
If the pharmacy discovers that an error has led to improper medication dispensing, regardless of the level of harm that results, disclose the error to the patient/caregiver/family in a timely manner
Convene a medication event team to routinely review and analyze errors, to identify system-based causes and facilitate implementation of system-based enhancements

X. *Quality Processes and Risk Management* Suggested Risk Reduction Strategies
Continually disseminate information throughout the organization about system-based errors and high-leverage safety strategies
Develop a system of independent double-checks even if only one pharmacist is staffing each shift
Seek and disseminate external error reports which identify errors and safety strategies that could affect the organization

*Off-site colleagues could include remote fill sites, remote data entry sites, etc. The pharmacist doing data entry does a final check prior to the transmission of data to the remote filling site. At the remote site, a second review by a pharmacist takes place. On remote data entry the same occurs. The prescription is scanned, all patient data is available to the remote data entry site, and the pharmacist at the filling site reviews the remote data entry information for completeness and accuracy once the remote data entry information is transmitted back to the filling site.

Quick Check Question: *Quality Processes and Risk Management*

1. Which of the following could occur as a result of voluntary internal or external medication error reporting?

    A. The FDA could mandate the manufacturer change the medication name to avoid nomenclature confusion.
    B. Hazard alerts could be disseminated by FDA, ISMP and manufacturers.
    C. Internal, site-specific actions such as auxiliary labeling, drug storage changes, or pharmacist/staff education may be undertaken to remedy reported errors, to prevent similar future mishaps.
    D. All of the above

Answer: D. As you can see, there are many benefits to voluntary error reporting. Without reporting medication errors, near misses, and hazardous conditions; there is no way to identify and fix faulty systems. Work to develop a Just Culture. Engage staff in uncovering and repairing system design flaws before human errors occur. These steps will encourage open communication, making it easier to create and implement error-reduction strategies.

Final Quick Check Question

1. A prescription for Zy**PREXA** (olanzapine) is telephoned to a community pharmacy. Zy**PREXA** has been reportedly mixed up with both Zantac (ranitidine) and Zyr**TEC** (cetirizine). Which of the following will help limit errors in this situation?

   I. The dispensing pharmacist reads back the drug name, dose, label instructions and purpose of the medication to the prescriber, who verifies that all elements have been heard correctly.
   II. The doctor's office calls the patient to inform them that their prescription has been called in and will be ready for them.
   III. The pharmacist counsels the patient and makes sure the patient knows why he/she is taking this medication.

      A. I and II
      B. I and III
      C. II and III
      D. I, II and III

The answer is B. Option II is incorrect because even though the doctor provided great customer service by calling the patient to let them know their prescription was ready, the patient did not know the name or type of medication that was called in to the pharmacy.

Using the Assess-ERR™ Tool in Community Pharmacy

The **ISMP *ASSESS-ERR*™** found in Appendix 3 is a simple three step medication system worksheet designed to assist pharmacists and pharmacy operators with error report investigations. Use the *Assess-ERR*™ tool to record errors, near-errors, and/or hazardous conditions. Examples of errors to address with the *Assess-ERR*™ tool include dispensing the wrong drug, strength, or dose; look-alike/sound-alike errors; calculation or preparation errors; misuse of devices; and errors in prescribing, transcribing, dispensing, and/or monitoring of medications.

Using the *Assess-ERR*™ helps a pharmacy convert a negative error experience into a positive learning experience that enhances the overall future safety of that pharmacy's practice. The tool aids in developing a standardized approach to documenting error incidents and helps to reveal the underlying system deficiencies that may have caused or contributed to the error. Additionally, the tool can help raise awareness of issues that have become so familiar to pharmacists in a particular practice setting that the issues are no longer even recognized as risks.

The suggested actions mentioned in each Key Element can be used to help identify the risk-reduction strategies called for in the *Assess-ERR*™ tool. Space is provided on the *Assess-ERR*™ form to document proposed interventions, staff responsibilities, the implementation process, and any immediate required actions (changes to policies, procedures, systems or processes).

Once the problems are identified using the *Assess-ERR*™ tool, use the strategies below to establish appropriate action.

- **Fail-safes and constraints** involve true system changes in the design of products or how individuals interact within the system. For instance, when the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

- **Forcing functions** are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (e.g., patient-specific indication must be entered if high-alert medication selected)

- **Automation and computerization** of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy; and robotic dispensing devices.

- **Standardization** creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication or to enhance the safety of giving or receiving a telephoned medication order.

- **Redundancies** incorporate duplicate steps or add another individual to a process, to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. However, the potential for error still exists since the redundant step may be omitted or ignored. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

- **Reminders and checklists** help make important information readily available. For example, prescription blanks that include prompts for important information (e.g., medication indication, allergies, patient birth date).

- **Rules and policies** are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

- **Education and information** are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors. An example of an education strategy would be having pharmacy personnel read and review policies and procedures on how to correctly perform a function such as prescription verification.

Use a variety of the above strategies to focus on system issues and human factors, to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

Illustrating the Application of the Key Elements through the Medication Flow Process

Medication flow process, case scenarios and key element causative factors

Two ways to employ risk assessment are to develop a flow diagram and present a case scenario utilizing the actual or potential adverse drug event information. This section presents an example of a flow diagram, and the next section presents two case scenarios with completed sample *Assess-ERR*™ tool documents, to illustrate how the risk assessment thought process can be used to further help a pharmacy in medication error prevention.

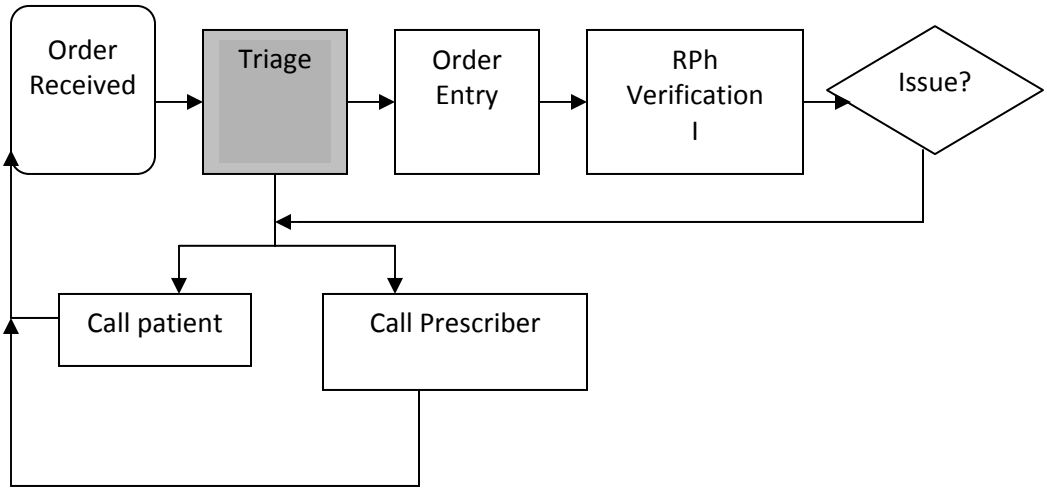
Process Flow Diagrams

An easy method to help identify the steps in a pharmacy's medication-use system is to develop a process flow diagram of the system. The diagram should be created with the help of all the individuals involved in the medication-use process (pharmacists, pharmacy support staff, interns, etc.). The diagram can be very detailed or may include just the basic steps in the process.

Questions for Exploring the Process

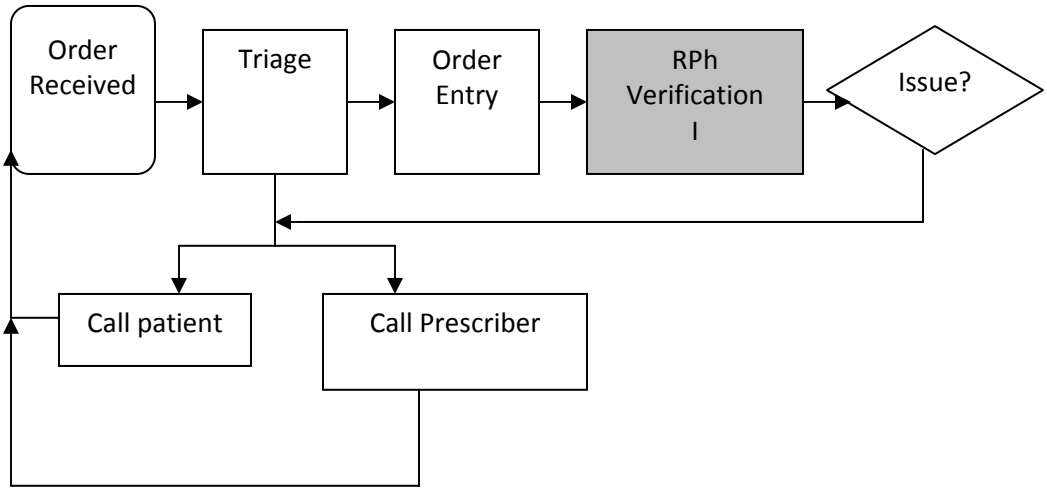
The questions used in the following section are to be used during the analysis of a medication incident and are not meant to be all-inclusive; they should help the assessment team begin thinking of safety characteristics that should be incorporated in their process. The questions within each process may be directed to each staff person most actively involved in the process being described.

A. Triage and Order Entry



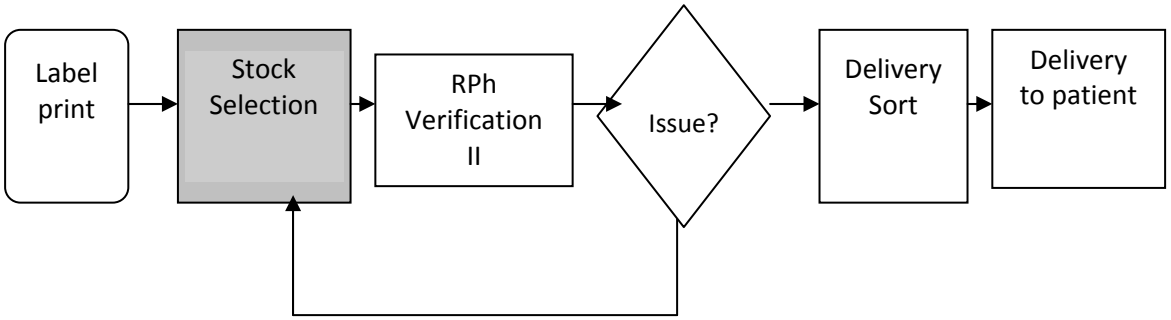
- Is a complete medication history taken on all new patients that includes prescriptions, OTC medications, vitamins, herbals and dietary supplements?
- Are allergies verified and documented in the computerized patient profile?
- Does pharmacy staff inquire from patient, prescriber or prescriber's agent the indication for use or diagnosis?
- Is staff aware of and instructed never to use dangerous abbreviations and dosage designations?
- Is patient date-of-birth on each hard copy prescription and correctly inputted in pharmacy system, and highlighted if patient under 6 years of age?
- Is female patient's pregnancy status known if applicable (prescribed a category X drug)?
- Does technician/pharmacist repeat back and spell out all spoken medication orders?
- Are prescribers immediately contacted to verify missing, illegible or ambiguous prescriptions?

B. Pharmacist Verification I – Verifying pharmacist



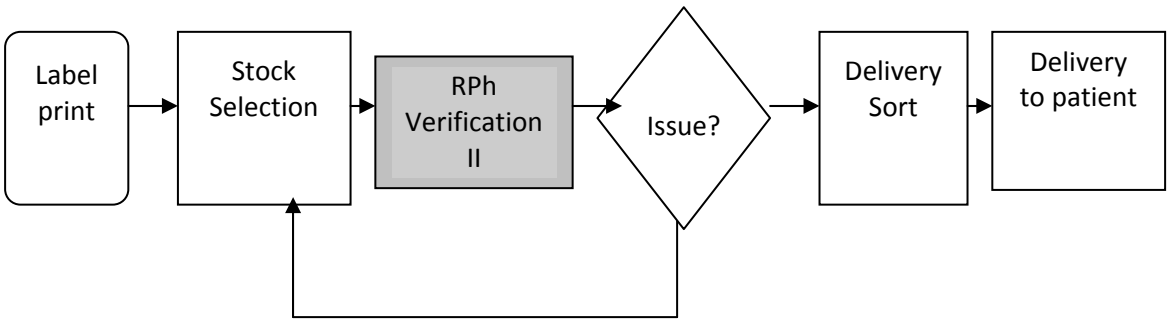
- Are all reference texts current and up-to-date?
- Is there online reference available?
- Is the patient profile readily accessible (number of keystrokes is limited to access profile in system) when verifying new prescription?
- Is the original prescription readily accessible (scanned image or hard copy) for confirmation of data entry?
- Does the computer automatically screen for allergies, drug interactions, maximum doses, etc.?
- Is pharmacist able to distinguish and resolve, via the computer system or manually, issues with interactions, allergies, duplicate therapy and other drug utilization alerts?
- Does the computer system contain warnings and alerts for look- and sound-alike drug products?
- Does the computer system warn when high-alert medications are being dispensed?
- Are independent double-checks performed on all high-alert medications?

C. Product Pick – Technician



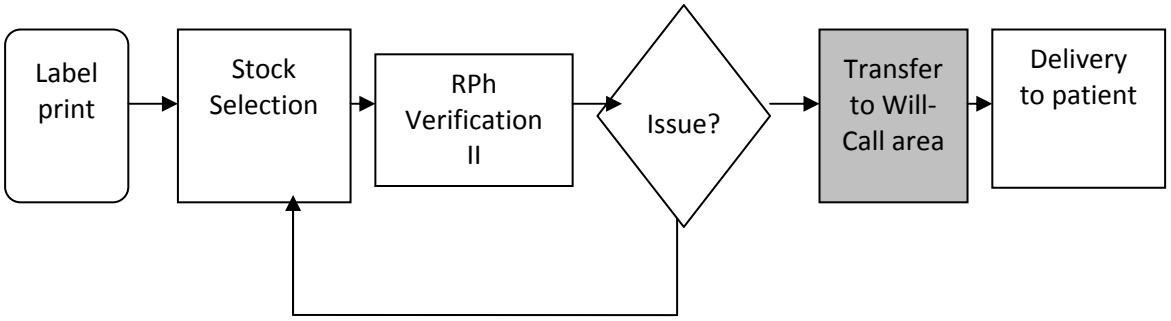
- Does the pharmacy buy product with potentially confusing names and packages?
- Is staff properly trained to initiate extemporaneous compounding?
- Are stock bottles with approaching expiration dates easily recognized?
- Is the workspace and lighting adequate for medication storage and preparation?
- Are medications with look- and sound-alike names and packaging stored separately?
- Are refrigerator and compounding stock stored safely in well-lighted, appropriately labeled shelves?
- Are automated dispensing and counting devices kept on manufacturers' suggested maintenance schedules for cleaning and calibrating?
- Are shelf dividers used in crowded areas?

D. Pharmacist Verification II – Verifying pharmacist



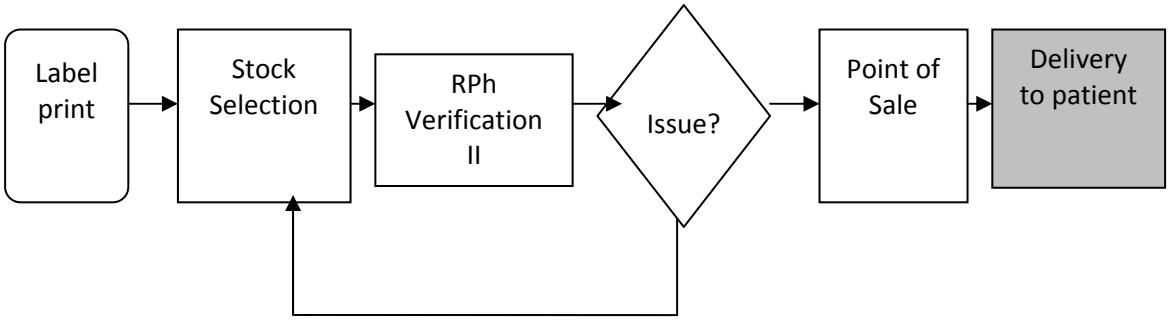
- Are medications checked against the label and the original order before they are dispensed?
- When issues or discrepancies are noted, is the product sent back to the stock selection stage and the problem used as a teaching/training opportunity for the entire staff?
- Is there an independent double-check performed when high-alert or look- and sound-alike medications are being verified?
- Is product verification bar coding available?
- Is there a method to ensure that correctly-typed labels are applied to the correct person's prescription vial (labels not inadvertently switched for same patient or different patient)?
- Are prescription orders separated by person and worked on one at a time (basket system)?
- If the manufacturer does not provide a barcode or NDC number on the unit-of-use package, is there a fall back procedure to ensure correct product is being dispensed?
- Are ergonomic factors considered in the verification work space: lighting, temperature, work space sufficient and free of clutter, magnifiers, computer terminals, trash receptacles, fatigue mats, etc.?

E. Transfer to Will-Call Area



- Is the will-call/pick-up area neatly organized and spacious enough so bagged prescriptions are not misplaced?
- Is there a system to ensure split orders for the same patient are put together at pick-up so patient does not leave with only part of their order (waiting for prescriber call back, out of stock, etc.)?
- Are patient-specific labeled prescriptions needing reconstitution, refrigeration or pharmacist intervention/counseling flagged as such and stored separately?
- Is there a return to stock policy to ensure timely pick-up of completed medication orders?
- Are the bins, drawers, baskets, etc. large enough to accommodate the filled prescriptions waiting to be picked up?
- Is this pick-up area a candidate for see-through hanging bag system of retrieval?
- Are completed prescriptions segregated so that “filled today” are separated and easily retrieved?
- Is the pick-up area confidential? Can patient receipts be seen by others at the counter?
- Is the pick-up area well lit?

F. Point of Sale



- Has staff been trained to ask for two forms of patient identifiers?
- Have patients been trained to give two forms of patient identifiers and educated as to why it is important for them to verify the filled prescriptions are theirs before leaving the pharmacy?
- Has staff been trained to deliver oral measuring devices when dispensing oral liquid medications?
- Are refrigerated or reconstituted items retrieved and given to the pharmacist to verify/reconstitute?
- Does staff open contents of bag and cross-check for omitted items, extra items and that labeled vial(s) match attached receipt(s)?
- Is the offer to counsel made in a positive manner to encourage an affirmative response?
- Is the complete consumer medication information (all pages) dispensed with the filled prescriptions?
- Are medication guides dispensed as required by law?
- Are pharmacists called upon to counsel on all prescriptions indicating "mandatory" counseling or when the patient requests counseling?
- Are patients informed about look- and sound-alike medications that could be confused with their current medication?
- Are patients encouraged to ask questions and to notify the pharmacist if they experience any problems with their medication?
- Are patients directed to a private consultation area when the prescription receipt indicates mandatory counseling by the pharmacist or when a patient accepts the offer of counseling?
- Are there certain medications that trigger a consult with a pharmacist for patient education?
- Are technicians aware of the high-alert medications or if a medication has a heightened error potential so that they can take extra precautions when dispensing?

Utilizing the Assess-ERR™ (Case Study)

Introduction

The "case study" is a mechanism to teach pharmacy staff about risk assessment and identifying failures in the medication dispensing system. The case could involve an actual medication error or near miss that occurred internally, one obtained from the literature (such as reports in the *ISMP Medication Safety Alert!*® and The Joint Commission Sentinel Event Alerts), or an error or near miss that could happen (for example, one discussed while performing an FMEA).

The case examples below will illustrate where system breakdowns occurred in relation to the *Key Elements of the Medication Use System*™. An error description is provided for each case. To illustrate analysis of the error example, system risks and failures are identified for each step in the dispensing process.

In order to identify potential systems-based risk-reduction strategies, use the appropriate Key Element recommendation charts provided in previous sections.

ISMP's Key Elements of the Medication Use System™	
I	Patient information
II	Drug information
III	Communication of drug orders and other drug information
IV	Drug labeling, packaging, and nomenclature
V	Drug standardization, storage, and distribution
VI	Medication device acquisition, use, and monitoring
VII	Environmental factors, workflow and staffing patterns
VIII	Staff competency and education
IX	Patient education
X	Quality processes and risk management

These case study examples are not meant to be Root Cause Analyses or all inclusive of possible risks or causes that could have contributed to the error. They are intended to serve as a review of the medication flow process and to stimulate thought and discussion on the risks involved in actual cases. Hopefully it will be used as a risk assessment tool to identify failure points in the medication-use system before they can lead to serious harm.

The following case study examples have been entered into the *Assess-ERR*™ tool found in Appendix 3.

Case Study Example One: Description

The Error

A patient living in a group home was acting "differently" and was clearly more agitated. The prescriber ordered a test of Lithium levels done on the patient. As a result of the low level, the prescriber called the pharmacy to insure that medication had been dispensed correctly. It was then discovered that the wrong medication had been given. Lithium Citrate 8 mEq/5 mL was filled with Chloral Hydrate (Noctec) 500 mg/5 mL, in error.

Review of the Error

Consider where in the process the error occurred, consider contributing factors based on the previous modules, identify the key element (use Key Element table above to reference element numbers when assigning causative factor to *Assess-ERR*™ tool)

Process Step: Triage and Order Entry	
Contributing Factor	**Key Element**
Past medical information, which would have listed the previous therapy of "Lithium" was not readily available	*I*
Drug name was entered by a technician using the NDC number from a stock bottle and not the drug name indicated on the actual prescription hard copy	*II, III, IV*
Purpose or indication for medication was not written on hard copy prescription	*I, III*

Process Step: Pharmacist Verification I	
Contributing Factor	**Key Element**
Prescription was not verified by comparing the input script information to the original prescribed order	*II*
Prescription was not reviewed for therapeutic appropriateness based on health conditions noted in patient profile	*I*

Process Step: Pharmacist Verification I	
Contributing Factor	**Key Element**
Both medications dosed as "teaspoonfuls" at bedtime	*II*
The patient's computer profile was not reviewed because it was not easily accessible (took a number of keystrokes to access)	*I*

Process Step: Product Pick (Selection)	
Contributing Factor	**Key Element**
Medication selected by NDC number on label and not verified to hard copy prescription	*V*
Lighting in the "liquid section" was inadequate and stock bottles were crowded; there were no shelf dividers between products	*V*
The drugs are stored alphabetically. The two drugs were in close proximity on the shelf (Lithium and Noctec), and had similar labels; both manufactured by MGP, and similar look and packaging: both pint-size, plastic, amber-colored bottles with same-colored labeling	*V*

Process Step: Pharmacist Verification II	
Contributing Factor	**Key Element**
Medication was not checked against the label and the original order	*VIII*
Ergonomic factors: inadequate lighting, cluttered verification workspace, magnifiers not available	*VII*

Process Step: Transfer to Will-Call Area	
Contributing Factor	**Key Element**
Patient lived in group home; drug name not visible on receipt	*I*
No additional final checks done prior to bagging and delivering filled prescriptions	*X*
Previous errors involving group home patients were not communicated to entire pharmacy staff	*X*

Process Step: Point of Sale	
Contributing Factor	**Key Element**
Medication delivered to group home; no interaction/counseling between pharmacist and patient, or pharmacist and group home worker; no offer to counsel given	*VIII, IX*
Patient in group home not given written consumer medication information (CMI); group home healthcare worker did not read CMI	*IX*
Medication administrators in group home are not licensed and have no minimum level of education required to administer drugs, do not check patients' medication charts for accuracy, do not know common indications for drugs, do not check treatment	*VIII*

Assess-ERR™ tool completed for Example One:

Assess-ERR™
Community Pharmacy version

Medication System Worksheet Example One

Rx # 1234

Date of error: 5-09-09 Date information obtained: 5-10-09 Patient age: 42

Drug(s) involved in error: Lithium Citrate 8 mEq/5 mL, Chloral Hydrate 500 mg/5 mL

STEP 1

Was indication for use on the prescription?	☐ Yes	☒ No
Was the prescription obtained electronically?	☐ Yes	☒ No
Were two unique patient identifiers used at pickup?	☒Yes	☐ No
Did the patient accept the offer to counsel?	☐ Yes	☒ No
Did the error reach the patient?	☒Yes	☐ No
Was the prescriber notified of the incident?	☒Yes	☐ No

Brief description of the event (what, when, and why): Patient living in group home received the wrong medication. Lithium Citrate 8 mEq/5 mL was filled with Chloral Hydrate 500 mg/5 mL (generic for Noctec), in error.

STEP 2

Key Element	Possible Causes	Y / N	Comments
I	**Critical patient information missing?** (age, weight, allergies, pregnancy, patient identity, address, indication for use, etc.)	Y	*No indication for use on hard copy prescription and no health condition information in pharmacy computer system; patient lived in group home; drug name not visible on receipt*
II	**Critical drug information missing?** (outdated/absent references, inadequate computer alerts, independent checks for high-alert drugs/high-risk patient, etc.)	Y	*Elderly patient should have been considered high-alert; past patient profile not reviewed for therapeutic appropriateness prior to dispensing (too difficult to access); both medications can be dosed as "teaspoonfuls at bedtime"*
III	**Miscommunication of drug order?** (illegible, ambiguous, incomplete, misheard, or misunderstood spoken rx, poor fax, unable to clarify with prescriber, etc.)	N	
IV	**Drug name, label, packaging problem?** (look-/sound-alike names, look-alike packaging, no drug image ,NDC or barcode not available or not used, etc.)	Y	*Similar labels; both manufactured by MGP; similar look and packaging: both pint-size, plastic, amber-colored bottles with same-colored labeling*
V	**Drug storage or delivery problem?** (drug stocked incorrectly, stock on crowded shelves, look-alike products stored next to each other, etc.)	Y	*The drugs are stored alphabetically. The two drugs were in close proximity on the shelf (Lithium and Noctec); lighting in the "liquid section" was inadequate and stock bottles were crowded; there were no shelf dividers between products*
VI	**Drug delivery device problem?** (automated dispensing devices not calibrated or maintained, oral measuring device not dispensed, etc.)	N	
VII	**Environmental, staffing, or workflow problems?** (poor lighting, excessive noise, clutter, interruptions, human factors, workload, inefficient workflow, breaks not scheduled, etc.)	Y	*Inadequate lighting, cluttered verification workspace, magnifiers not available*

Key Element	Possible Causes	Y / N	Comments
VIII	**Lack of staff education?** (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)	Y	*Staff entered NDC from stock bottle, not drug name on prescription. Medication administrators in group home are not licensed and have no minimum level of education required to administer drugs; they do not check patients' medication charts for accuracy; they do not know common indications for drugs; they do not check treatment*
IX	**Patient education problem?** (lack of information, non-adherence, not encouraged to ask questions, lack of investigating patient inquiries, patient barriers, etc.)	Y	*Medication delivered to group home; no interaction/counseling between pharmacist and patient, or pharmacist and group home worker; no offer to counsel given. Patient in group home not given written consumer medication information (CMI); group home healthcare worker did not read CMI*
X	**Quality processes and risk management?** (No culture of safety, fear of error reporting, system-based causes not analyzed, independent double-check not performed, etc.)	Y	*Previous errors involving group home patients were not communicated to entire staff; no additional final checks done prior to bagging and delivering filled prescriptions*

Patient Outcome: Patient treated for low lithium levels

Assess-ERR™
Community Pharmacy version

Medication System Worksheet

STEP 3
As a team, identify, prioritize and record "Identified Problem" from the "Comment" section in Step 2. Using the specific key element for those comments, refer to the recommendation strategies chart and select the most appropriate and effective interventions. Write selected strategies in the "Interventions Implemented" column below. This table will be used to document medication safety activities. Recommended interventions should address breakdowns in the *Key Elements* identified during event investigation. The staff should reconvene in three months time to determine if the proposed strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial review. Use a variety of strategies, as found in Appendix 4, to help generate appropriate interventions.

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
Past patient profile not reviewed for therapeutic appropriateness prior to dispensing (too difficult to access)	*I*	*Obtain clinical purpose of each prescription before the medication is dispensed, to assure that the prescribed therapy is appropriate for the patient's condition and to help distinguish medications with similar packaging and look-alike or sound-alike names.* (redundancy) *Ensure that the drug ordered matches the clinical indication provided.* (redundancy) *During the DUR process, manually check the patient's profile for medications and health conditions which may not be included in the DUR software.* (reminder & checklist)		
Similar labels, both manufactured by MGP; and look and packaging: both pint-size, plastic, amber-colored bottles with same-colored labeling	*IV*	*Provide auxiliary warning labels with exaggerated fonts, or use other label enhancements on packages and storage bins of drugs with problematic names, packages, and labels.* (standardization) *Use shelf dividers to separate products with look-alike names/packaging in all storage areas, including refrigerators and narcotic cabinets.* (standardization) *Avoid stocking generic manufacturers who incorporate same size stock bottle, and label colors and fonts, in their complete product line.* (rules and policy or constraint)		

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
		Use labels with special precautions on the stock bottles of high-alert medications (those whose inadvertent dispensing could cause serious harm if used in error). (reminder & checklist) *Identify stock bottle labels that are ambiguous or unsafe, and contact manufacturer or discontinue stocking from this manufacturer if safety features cannot be adequately employed; in addition, report these hazardous labels to ISMP.* (standardization)		
Staff entered NDC from stock bottle, not drug name on prescription order	*IV, VIII*	*Prescriptions are dispensed using the original prescription order and the computer-generated drug label together. A pharmacist compares the label and product with the original prescription before drugs are dispensed to the patient.* (standardization) *Use technicians only in areas and functions for which they have documented training.* (standardization) *Pharmacists and technicians seek and receive ongoing information about medication errors occurring within the organization, error-prone situations, errors occurring in other pharmacies, and strategies to prevent such errors.* (standardization) *During staff meetings, discuss potential medication errors and ways to avoid them.* (education) *When errors occur, offer education and suggestions to all staff, not just the staff directly involved in the error.* (education)		
Medication administrators in group home are not licensed and have no minimum level of education required to administer drugs, do not check patients' medication charts for accuracy, do not know	*IX*	*Provide patients and caregivers with brand and generic names of their medications, the purpose of the medication, and the dosing and important adverse effects of their medication, orally and/or in writing.* (education) *When dispensing oral liquid medications for children or geriatric patients, a proper measuring device is provided (e.g., dropper) or suggested (e.g., oral syringe) and caregivers are instructed in its use to measure the prescribed dose.* (standardization)		

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
common indications for drugs, do not check treatment		*Insist on mandatory counseling to patients receiving high-alert medications or to patients considered to be high-risk.* (standardization) *Provide written information about their medications at a reading level that is comprehendible to patients.* (education) *Encourage personnel to develop and conduct at least one annual educational program or other proactive public health effort designed to improve safe use of medications in the community.* (rules & policy)		
The drugs are stored alphabetically. The two drugs were in close proximity on the shelf (Lithium and Noctec); lighting in the "liquid section" was inadequate and stock bottles were crowded; there were no shelf dividers between products	*V, VII*	*Institute a "shelf talker" or sign program that brings attention to sound- and look-alike drug products during stocking and retrieval procedures.* (standardization) *Ensure adequate space, storage and lighting (10,000 ft candles) in medication stock and dispensing areas.* (standardization)		

ISMP's Key Elements of the Medication Use System™	
I	Patient information
II	Drug information
III	Communication of drug orders and other drug information
IV	Drug labeling, packaging, and nomenclature
V	Drug standardization, storage, and distribution
VI	Medication device acquisition, use, and monitoring
VII	Environmental factors, workflow and staffing patterns
VIII	Staff competency and education
IX	Patient education
X	Quality processes and risk management

Case Study Example Two: Description

The Error (use Key Element table above to reference element numbers when assigning causative factor to *Assess-ERR*™ tool)

A patient brought in a written prescription for ALDARA (imiquimod), to treat plantar warts, to her community pharmacy for filling and dispensing. After purchasing the product from the pharmacy associate, she sat down in the pharmacy waiting area to read the consumer medication information (CMI) sheet(s) as provided by the pharmacy, to ascertain if she might have any questions for the pharmacist before leaving the pharmacy. There was only one CMI sheet attached. She returned to the pharmacy counter to ask for the second, continuation, page of information. The directions on the pharmacy label indicated "Apply 4 times daily for 4 weeks." She then noticed that there were twelve "doses" of this cream provided by the package size dispensed with provision for 2 refills, for a total of 36 applications. With the dosage of 4 times daily, even with the refills, she realized that the medication would have "lasted" just 9 days—not the 4 weeks specified on the label. She went back to the pharmacy counter and asked to speak with the pharmacist. The pharmacist on duty took the prescription back to "check his records" and discovered that the correct dosage as written by the prescriber was "Apply four times per WEEK for 4 weeks." When the pharmacist returned the prescription to her with the corrected dosage label, he had simply attached the "new" one over the incorrect one. Because the patient was able to peel the correct one off to reveal the "overdose"/incorrect label, an error could occur with future at-home use if the "new" label became adulterated and peeled off.

Review of the Error

Consider where in the process the error occurred, consider contributing factors based on the previous modules, identify the key element (use Key Element table above to reference element numbers when assigning causative factor to *Assess-ERR*™ tool)

Process Step: Triage and Order Entry	
Contributing Factor	**Key Element**
Legibility: prescription written "qw" misread as "qd"; inappropriate abbreviation used	*III*
No indication for use on the prescription; patient not asked why medication was being prescribed	*I, III*
Data entry by technician not familiar with product or dosing instructions	*VIII*
Prescriber not contacted to verify illegible directions	*III*

Process Step: Pharmacist Verification I	
Contributing Factor	**Key Element**
Pharmacist did not have online reference available to check drug dosing	*II*
Computer did not screen for maximum daily dose exceeded	*II*
Order not verified by comparing data entry information to original prescription order	*I*

Process Step: Product Pick (Selection)	
Contributing Factor	**Key Element**
Unit-of-use product had manufacturer's instructions that were not read by staff and compared to pharmacy label instructions	*IV, VIII*
Second (correct) label was placed on top of incorrect label, and incorrect label was allowed to remain on final dispensed product	*V*

Process Step: Pharmacist Verification II	
Contributing Factor	**Key Element**
Medication not checked against label and original order before dispensing	*VIII*
Magnifiers not available to read hard copy prescriptions	*VII*
Pharmacist did not verify dosing instructions to product information	*II*

Process Step: Transfer to Will-Call Area	
Contributing Factor	**Key Element**
CMI not completely dispensed to patient (2nd page was "thrown out" by pharmacy associate because it made the receipt "too bulky")	*IX*
Pharmacists accumulate demerits or points for making dispensing errors, so error "covered up" and not reported	*X*
Pick-up area too crowded; complete CMIs not always given, in order to reduce area needed for storage	*VII*

Process Step: Point of Sale	
Contributing Factor	**Key Element**
Offer to counsel not made in a positive manner	*VIII, IX*
CMI not completely dispensed to patient	*X*

Assess-ERR™ tool completed for Example Two

Assess-ERR™
Community Pharmacy version

Medication System Worksheet Example Two

Rx # 1234

Date of error: 5-09-09 Date information obtained: 5-10-09 Patient age: 42

Drug(s) involved in error:

STEP 1

Was indication for use on the prescription?	☒Yes	☐ No
Was the prescription obtained electronically?	☐ Yes	☒ No
Were two unique patient identifiers used at pickup?	☒Yes	☐ No
Did the patient accept the offer to counsel?	☒Yes	☐ No
Did the error reach the patient?	☒Yes	☐ No
Was the prescriber notified of the incident?	☐ Yes	☒ No

Brief description of the event (what, when, and why): Prescription for Aldara cream labeled, with directions on the pharmacy label indicating "Apply 4 times daily for 4 weeks." Correct dosage as written by the prescriber was "Apply four times per WEEK for 4 weeks"

STEP 2

Key Element	Possible Causes	Y / N	Comments
I	**Critical patient information missing?** (age, weight, allergies, pregnancy, patient identity, address, indication for use, etc.)	Y	*No indication for use on the prescription; patient not asked why medication was being prescribed* *Order not verified by comparing data entry information to original prescription order*

Key Element	Possible Causes	Y / N	Comments
II	**Critical drug information missing?** (outdated/absent references, inadequate computer alerts, independent checks for high-alert drugs/high-risk patient, etc.)	Y	*Pharmacist did not have online reference available to check drug dosing; computer did not screen for maximum daily dose exceeded* *Pharmacist did not verify dosing instructions to product information*
III	**Miscommunication of drug order?** (illegible, ambiguous, incomplete, misheard, or misunderstood spoken rx, poor fax, unable to clarify with prescriber, etc.)	Y	*Legibility: prescription written "qw" misread as "qd"; inappropriate abbreviation used* *Prescriber not contacted to verify illegible directions*
IV	**Drug name, label, packaging problem?** (look-/sound-alike names, look-alike packaging, no drug image ,NDC or barcode not available or not used, etc.)	Y	*Unit-of-use product had manufacturer's instructions that were not read by staff and compared to pharmacy label instructions* *Second (correct) label was placed on top of incorrect label, and incorrect label was allowed to remain on final dispensed product* *Pharmacist did not verify dosing instructions to product information*
V	**Drug storage or delivery problem?** (drug stocked incorrectly, stock on crowded shelves, look-alike products stored next to each other, etc.)	Y	*Pick-up area too crowded; complete CMIs not always given in order to reduce area needed for storage*
VI	**Drug delivery device problem?** (automated dispensing devices not calibrated or maintained, oral measuring device not dispensed, etc.)	N	
VII	**Environmental, staffing, or workflow problems?** (poor lighting, excessive noise, clutter, interruptions, human factors, workload, inefficient workflow, breaks not scheduled, etc.)	Y	*Magnifiers not available to read hard copy prescriptions* *Pick-up area too crowded*
VIII	**Lack of staff education?** (competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention, etc.)	Y	*Data entry by technician not familiar with product or dosing instructions* *Medication not checked against label and original order before dispensing*
IX	**Patient education**	Y	*CMI not completely dispensed to patient (2nd page was*

Key Element	Possible Causes	Y / N	Comments
	problem? (lack of information, non-adherence, not encouraged to ask questions, lack of investigating patient inquiries, patient barriers, etc.)		*"thrown out" by pharmacy associate because it made the receipt "too bulky")*
X	**Quality processes and risk management?** (No culture of safety, fear of error reporting, system-based causes not analyzed, independent double-check not performed, etc.)	Y	*Pharmacists accumulate demerits or points for making dispensing errors, so error "covered up" and not reported*

Patient Outcome: Error caught by patient at check out and corrected by pharmacy staff on duty

STEP 3

As a team, identify, prioritize and record "Identified Problem" from the "Comment" section in Step 2. Using the specific key element for those comments, refer to the recommendation strategies chart and select the most appropriate and effective interventions. Write selected strategies in the "Interventions Implemented" column below. This table will be used to document medication safety activities. Recommended interventions should address breakdowns in the *Key Elements* identified during event investigation. The staff should reconvene in three months time to determine if the proposed strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial review. Use a variety of strategies, as found in Appendix 4, to help generate appropriate interventions.

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
Pharmacist did not have online reference available to check drug dosing *Pharmacist not aware of how often drug/device was to be used* *Pharmacist did not verify dosing instructions to product information*	*II*	*The most current electronic drug references are available in the pharmacy; all outdated paper references are thrown out or taken home by staff.* (education) *Provide pharmacy staff with access to drug information center staffed with clinical pharmacists during all hours of operation.* (redundancy)		

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
Computer did not screen for maximum daily dose exceeded	*II*	*Configure the pharmacy computer system to offer alerts for maximum and minimum doses of medications, drug interactions, age, allergies and dose-related interactions.* (forcing functions)		
Pharmacist did not verify dosing instructions to product information	*II, IV*	*Provide easy access to online drug information at every computer terminal. Provide an easy access icon, so the link to on-line information is readily accessible.* (education) *When dispensing unit-of-use packaging to patients, avoid placing pharmacy label on top of pertinent manufacturer's information.* (rules & policy) *Prescriptions are dispensed using the original prescription order and the computer-generated drug label together. A pharmacist compares the label and product with the original prescription before drugs are dispensed to the patient.* (standardization)		
Legibility: prescription written "qw" misread as "qd"; inappropriate abbreviation used; prescriber not contacted to verify illegible directions	*III*	*Instruct staff never to use error-prone abbreviations or error-prone dose designations (trailing zeros and lack of leading zeros), drug name abbreviations or abbreviated sig codes when reducing oral prescriptions to writing.* (rules & policy) *Immediately call prescribers when prescriptions are written illegibly or ambiguously; confirm prescriptions written with error-prone abbreviations with either prescriber or patient; do not fill the prescription until the order is confirmed.* (redundancy) *Incorporate the use of scanning procedures so that original prescriptions can be viewed during each refill process.* (automation & computerization)		
Pick-up area too crowded; complete CMIs not always given in order to reduce area needed for storage	*V, VII*	*Maintain a prescription pick-up/will-call area that is free from clutter, and contains enough space to prevent "spillage" into the next basket or bin, and institute a return to stock program that physically removes filled prescriptions not picked up within seven days.* (rules & policy)		

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed
		Institute "Return to Stock" procedures that include contacting the patient to pick up filled prescription. (standardization) *Maintain separate refrigerators for stock and prepared prescriptions waiting to be dispensed* (standardization) *Ensure adequate space, storage and lighting (10,000 ft candles) in medication stock and dispensing areas.* (standardization)		
Data entry by technician not familiar with product or dosing instructions Medication not checked against label and original order before dispensing	*VIII*	*Use technicians only in areas and for functions for which they have documented training.* (standardization) *Pharmacists and technicians seek and receive ongoing information about medication errors occurring within the organization, error-prone situations, errors occurring in other pharmacies, and strategies to prevent such errors.* (education) *Provide practice site, competency-based orientation regarding stocking, dispensing, preparation, verifying and delivery procedures to all newly hired staff.* (education) *Evaluate each staff member's skills and knowledge regarding safe medication practices during annual employment review; address at-risk behaviors (www.justculture.org) on an ongoing basis.* (education) *When errors occur, educational efforts are widespread among all pharmacy personnel who may make a similar error, rather than remedial and directed at only those who were involved in an error.* (education)		

Conclusion

Systematic assessment of error prevention is vital to safety. It is not enough for pharmacy practitioners and operators to simply strive to prevent error. To maximize safety, pharmacists at all levels must also strive to *learn* from those errors that have occurred. It may be fair to say that the most egregious error made in a pharmacy is one that has been made before.

The educational modules introduced here have been designed to heighten awareness of potential failures in the medication-use system and identify distinctive characteristics of safe pharmacy systems. Knowledge gained by completing these modules will help pharmacy staff identify and evaluate potential risk-reduction strategies. Additionally, the modules will assist pharmacy staff to assess the degree to which safe practices already have been implemented in their settings, and to assess the degree to which the practices provide tangible evidence of patient safety improvement and increased patient satisfaction and loyalty. These tools are to be used by pharmacy staff to proactively review the safety of their practice site and their own knowledge of contributing factors of errors, and to take action to continually improve the safety and thus the quality of care they provide. Implementation of these tools will improve patient safety.

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Glossary

Administration Error: Medication dosages that are given to the patient in error, usually by the direct caregiver.

At-Risk Behavior: Behavioral choices that increase risk where risk is not recognized, or is mistakenly believed to be justified; emerge because of system-based problems such as complexity, understaffing, rushing, problems with technology, etc.

Basket System: A container system that separates orders to be filled by patient and can include a written prescription, printed material provided by a computer printer in response to data input including the patient specific label, stock bottle of medication to be dispensed or the completely labeled and filled prescription vial(s) for one patient; the basket system also sets the stage for the workflow by identifying whether a customer is waiting or not.

Culture of Safety: An atmosphere of mutual trust in which all staff members can talk freely about safety problems and how to solve them, without fear of reprisal.

Competency Validation: The process of ensuring that staff possesses the skill set identified in his or her job description, and performs the tasks or activities for the position according to established standards.

Dispensing Error: Deviations from the prescriber's order, made by staff in the pharmacy when distributing medication to nursing units or to patients in ambulatory settings.

Failure Mode and Effects Analysis (FMEA): A proactive process to identify potential errors and determine possible effects; a team-based, systematic approach. Identify the ways that a process or design: can fail, why it might fail, what will happen if it fails, and how it can be made safer.

Because of its proactive nature, FMEA and other risk assessment tools are the focus of these modules.

Filters: A device or program that allows passage of some signals but not others. In relation to pharmacy, being put on "filter" refers to an order screening process or training tool where orders processed by new or inexperienced employees, or employees having difficulty focusing due to personal issues such as illness or death of a loved one, are systematically passed by or routed to an experienced employee for approval or oversight before being sent for further processing.

High-alert Medication: Drugs that bear a heightened risk of causing significant patient harm when they are prescribed, dispensed, administered or used in error;

such medications in community pharmacy may include warfarin, insulin, fentanyl patches and methotrexate.

High-Leverage Safety Strategies: Safety strategies that have the ability to consistently impact safety because they are not dependent on human vigilance to be successful; strategies such as forcing functions, fail-safes, and constraints.

Human Factors: An umbrella term for several areas of research that include human performance, technology design, and human-computer interaction (engineering). This area of knowledge deals with the capabilities and limitations of human performance in relation to design of machines, jobs, and other modifications of the human's physical environment; also known as human engineering. Often referred to as "ergonomics", this field includes, but is not limited to ergonomics.

Just Culture: An organizational model of accountability whereby a learning environment is established, and staff are encouraged to recognize and report safety hazards, design safe systems, and make safe behavioral choices.

Just Culture Process and Algorithms: Structured process to guide managers through the evaluation of an event, near miss, or simply the analysis of a risky behavior. It is a process for conducting an investigation of the event, for identifying system contributions, and for assessing accountability for those involved in the event. See www.justculture.org/algorithm.aspx for more information and training.

Medication Error: 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; or procedures and systems including prescribing, order communication, product labeling, packaging and nomenclature; compounding, dispensing, distribution, administration, education, monitoring and use.

Medication Therapy Management Services (MTMS): Services provided by pharmacists that improve treatment outcomes and promote the safe and effective use of medications; for more information go to www.pharmacist.com/MTM.

Prescribing Error: Mistakes made by the prescriber when ordering a medication (e.g., miscalculation of a dose, misspelling of a drug name, choosing the wrong product for the diagnosis).

Root Cause Analysis (RCA): A process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event or adverse event. RCA is a retrospective investigative process that teaches us what went wrong within any given process.

As a tool, RCA is designed to:

- describe *what* happened during a particular occurrence;
- determine *how* it happened;
- understand *why* it happened; and
- recommend actions to *prevent* it from happening again.

Root cause analysis is an essential process to use after an error or sentinel event has occurred. However, providers and clinicians realize that when they're dealing with human life, a prospective strategy for identifying risk is preferred.

Shared Accountability: All members of the organization, executives, managers and staff, will work together toward the organization's mission of quality patient care and safe practices. Both the rewards of success and losses associated with failure will be shared by the entire executive team, managers and staff.

Slip: An error at the (task) execution stage of cognition; to mentally fall into fault or error. Usually used with "up". Example is putting the cereal back in the refrigerator and the milk away in the cupboard.

Teach Back Method: A technique to check patient understanding and comprehension through a non-threatening approach, by asking patients to repeat *in their own words* what they need to do with medication and devices when they leave the pharmacy.

Appendix 1: ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations*

The abbreviations, symbols, and dose designations found in this table have been reported to ISMP through the ISMP Medication Errors Reporting Program (MERP) as being frequently misinterpreted and involved in harmful medication errors. They should NEVER be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

The Joint Commission (TJC) has established a National Patient Safety Goal that specifies that certain abbreviations must appear on an accredited organization's do-not-use list; we have highlighted these items with a double asterisk (**). However, we hope that you will consider others beyond the minimum TJC requirements. By using and promoting safe practices and by educating one another about hazards, we can better protect our patients.

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS **hs**	Half-strength At bedtime, hours of sleep	Mistaken as bedtime Mistaken as half-strength	Use "half-strength" or "bedtime"
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"
OJ	Orange juice	Mistaken as OD or OS (right or left eye); drugs meant to be diluted in orange juice may be given in the eye	Use "orange juice"
Per os	By mouth, orally	The "os" can be mistaken as "left eye" (OS-oculus sinister)	Use "PO," "by mouth," or "orally"
q.d. or QD**	Every day	Mistaken as q.i.d., especially if the period after the "q" or the tail of the "q" is misunderstood as an "i"	Use "daily"
qhs	Nightly at bedtime	Mistaken as "qhr" or every hour	Use "nightly"
qn	Nightly or at bedtime	Mistaken as "qh" (every hour)	Use "nightly" or "at bedtime"
q.o.d. or QOD**	Every other day	Mistaken as "q.d." (daily) or "q.i.d. (four times daily) if the "o" is poorly written	Use "every other day"
q1d	Daily	Mistaken as q.i.d. (four times daily)	Use "daily"
q6PM, etc.	Every evening at 6 PM	Mistaken as every 6 hours	Use "6 PM nightly" or "6 PM daily"
SC, SQ, sub q	Subcutaneous	SC mistaken as SL (sublingual); SQ mistaken as "5 every;" the "q" in "sub q" has been mistaken as "every" (e.g., a heparin dose ordered "sub q 2 hours before surgery" misunderstood as every 2 hours before surgery)	Use "subcut" or "subcutaneously"
ss	Sliding scale (insulin) or ½ (apothecary)	Mistaken as "55"	Spell out "sliding scale;" use "one-half" or "½"
SSRI **SSI**	Sliding scale regular insulin Sliding scale insulin	Mistaken as selective-serotonin reuptake inhibitor Mistaken as Strong Solution of Iodine (Lugol's)	Spell out "sliding scale (insulin)"
i/d	One daily	Mistaken as "tid"	Use "1 daily"
TIW or tiw	3 times a week	Mistaken as "3 times a day" or "twice in a week"	Use "3 times weekly"
U or u**	Unit	Mistaken as the number 0 or 4, causing a 10-fold overdose or greater (e.g., 4U seen as "40" or 4u seen as "44"); mistaken as "cc" so dose given in volume instead of units (e.g., 4u seen as 4cc)	Use "unit"
Dose Designations and Other Information	**Intended Meaning**	**Misinterpretation**	**Correction**
Trailing zero after decimal point (e.g., 1.0 mg)**	1 mg	Mistaken as 10 mg if the decimal point is not seen	Do not use trailing zeros for doses expressed in whole numbers"
"Naked" decimal point (e.g., .5 mg)**	0.5 mg	Mistaken as 5 mg if the decimal point is not seen	Use zero before a decimal point when the dose is less than a whole unit

ISMP's List of *Error-Prone Abbreviations, Symbols,* and *Dose Designations* (continued)

Dose Designations and Other Information	Intended Meaning	Misinterpretation	Correction
Drug name and dose run together (especially problematic for drug names that end in "l" such as Inderal40 mg; Tegretol300 mg)	Inderal 40 mg Tegretol 300 mg	Mistaken as Inderal 140 mg Mistaken as Tegretol 1300 mg	Place adequate space between the drug name, dose, and unit of measure
Numerical dose and unit of measure run together (e.g., 10mg, 100mL)	10 mg 100 mL	The "m" is sometimes mistaken as a zero or two zeros, risking a 10- to 100-fold overdose	Place adequate space between the dose and unit of measure
Abbreviations such as mg. or mL. with a period following the abbreviation	mg mL	The period is unnecessary and could be mistaken as the number 1 if written poorly	Use mg, mL, etc. without a terminal period
Large doses without properly placed commas (e.g., 100000 units; 1000000 units)	100,000 units 1,000,000 units	100000 has been mistaken as 10,000 or 1,000,000; 1000000 has been mistaken as 100,000	Use commas for dosing units at or above 1,000, or use words such as 100 "thousand" or 1 "million" to improve readability
Drug Name Abbreviations	**Intended Meaning**	**Misinterpretation**	**Correction**
ARA A	vidarabine	Mistaken as cytarabine (ARA C)	Use complete drug name
AZT	zidovudine (Retrovir)	Mistaken as azathioprine or aztreonam	Use complete drug name
CPZ	Compazine (prochlorperazine)	Mistaken as chlorpromazine	Use complete drug name
DPT	Demerol-Phenergan-Thorazine	Mistaken as diphtheria-pertussis-tetanus (vaccine)	Use complete drug name
DTO	Diluted tincture of opium, or deodorized tincture of opium (Paregoric)	Mistaken as tincture of opium	Use complete drug name
HCl	hydrochloric acid or hydrochloride	Mistaken as potassium chloride (The "H" is misinterpreted as "K")	Use complete drug name unless expressed as a salt of a drug
HCT	hydrocortisone	Mistaken as hydrochlorothiazide	Use complete drug name
HCTZ	hydrochlorothiazide	Mistaken as hydrocortisone (seen as HCT250 mg)	Use complete drug name
MgSO4**	magnesium sulfate	Mistaken as morphine sulfate	Use complete drug name
MS, MSO4**	morphine sulfate	Mistaken as magnesium sulfate	Use complete drug name
MTX	methotrexate	Mistaken as mitoxantrone	Use complete drug name
PCA	procainamide	Mistaken as patient controlled analgesia	Use complete drug name
PTU	propylthiouracil	Mistaken as mercaptopurine	Use complete drug name
T3	Tylenol with codeine No. 3	Mistaken as liothyronine	Use complete drug name
TAC	triamcinolone	Mistaken as tetracaine, Adrenalin, cocaine	Use complete drug name
TNK	TNKase	Mistaken as "TPA"	Use complete drug name
ZnSO4	zinc sulfate	Mistaken as morphine sulfate	Use complete drug name
Stemmed Drug Names	**Intended Meaning**	**Misinterpretation**	**Correction**
"Nitro" drip	nitroglycerin infusion	Mistaken as sodium nitroprusside infusion	Use complete drug name
"Norflox"	norfloxacin	Mistaken as Norflex	Use complete drug name
"IV Vanc"	intravenous vancomycin	Mistaken as Invanz	Use complete drug name
Symbols	**Intended Meaning**	**Misinterpretation**	**Correction**
ʒ ♏	Dram Minim	Symbol for dram mistaken as "3" Symbol for minim mistaken as "mL"	Use the metric system
x3d	For three days	Mistaken as "3 doses"	Use "for three days"
> and <	Greater than and less than	Mistaken as opposite of intended; mistakenly use incorrect symbol; "< 10" mistaken as "40"	Use "greater than" or "less than"
/ (slash mark)	Separates two doses or indicates "per"	Mistaken as the number 1 (e.g., "25 units/10 units" misread as "25 units and 110" units)	Use "per" rather than a slash mark to separate doses
@	At	Mistaken as "2"	Use "at"
&	And	Mistaken as "2"	Use "and"
+	Plus or and	Mistaken as "4"	Use "and"
°	Hour	Mistaken as a zero (e.g., q2° seen as q 20)	Use "hr," "h," or "hour"

**These abbreviations are included on TJC's "minimum list" of dangerous abbreviations, acronyms and symbols that must be included on an organization's "Do Not Use" list, effective January 1, 2004. Visit www.jointcommission.org for more information about this TJC requirement.

Institute for Safe Medication Practices
www.ismp.org

Appendix 2: FDA and ISMP Lists of Look-Alike Drug Name Sets with Recommended Tall Man Letters

FDA and ISMP Lists of *Look-Alike Drug Name Sets With Recommended Tall Man Letters*

The sets of look-alike drug names in the Tables below have been modified using "tall man" letters to help draw attention to the dissimilarities in their names. Several studies have shown that highlighting sections of drug names using tall man (mixed case) letters can help distinguish similar drug names,[1] making them less prone to mix-ups.[2-3] ISMP, FDA, The Joint Commission, and other safety-conscious organizations have promoted the use of tall man letters as one means of reducing confusion between similar drug names.

Table 1 provides a list of FDA-approved established drug name sets with recommended tall man letters, which were first identified during the FDA Name Differentiation Project (www.fda.gov/CDER/Drug/MedErrors/nameDiff.htm).

Table 2 provides a list of additional drug name sets with recommendations from ISMP regarding the use and placement of tall man letters. This is not an official list approved by FDA. It is intended for voluntary use by healthcare practitioners and drug information vendors. Any product label changes by manufacturers require FDA approval.

Table 1. FDA-Approved List of Established Drug Names with Tall Man Letters

aceto**HEXAMIDE** - aceta**ZOLAMIDE**	hydr**ALAZINE** – hydr**OXY**zine
bu**PROP**ion - bus**PIR**one	medroxy**PROGESTER**one methyl**PREDNIS**olone methyl**TESTOSTER**one
chlorpro**MAZINE** – chlorpro**PAMIDE**	
clomi**PHENE** – clomi**PRAMINE**	
cyclo**SPORINE** – cyclo**SERINE**	ni**CAR**dipine – **NIFE**dipine
DAUNOrubicin – **DOXO**rubicin	predni**SONE** – predniso**LONE**
dimenhy**DRINATE** – diphenhydr**AMINE**	sulf**ADIAZINE** – sulfi**SOXAZOLE**
DOBUTamine – **DOP**amine	**TOLAZ**amide – **TOLBUT**amide
glipi**ZIDE** – gly**BURIDE**	vin**BLAS**tine – vin**CRIS**tine

References: 1) Filik R, Purdy K, Gale A, Gerrett D. Drug name confusion: evaluating the effectiveness of capital ("Tall Man") letters using eye movement data. *Social Science & Medicine* 2004;59(12):2597-2601. 2) Filik R, Purdy K, Gale A, Gerrett D. Labeling of medicines and patient safety: evaluating methods of reducing drug name confusion. *Human Factors* 2006;48(1):39-47. 3) Grasha A. Cognitive systems perspective on human performance in the pharmacy: implications for accuracy, effectiveness, and job satisfaction. Alexandria (VA): NACDS; 2000 Report No. 062100.

One of the difficulties with the use of tall man letters is the lack of scientific evidence regarding which name pairs would most benefit from this error-reduction strategy as well as which letters to present in uppercase. Until further evidence is available, ISMP suggests that the tall man lettering scheme provided in these Tables be followed to promote consistency.

Table 2. ISMP List of Additional Drug Names with Tall Man Letters

ALPRAZolam - **LOR**azepam	metro**NIDAZOLE** – met**FORMIN**
am**LODIP**ine – a**MIL**oride	morphine – **HYDRO**morphone
aza**CITID**ine – aza**THIO**prine	Nex**IUM*** – Nex**AVAR***
ce**FAZ**olin – cef**TRIAX**one	ni**MOD**ipine – **NIFE**dipine
Cele**BREX*** – Cele**XA***	Novo**LOG*** – Novo**LIN***
chlorpro**MAZINE** – chlordiaze**POXIDE**	**OX**carbazepine – car**BAM**azepine
CISplatin – **CARBO**platin	oxy**CODONE** – Oxy**CONTIN***
clonaze**PAM** – clo**NID**ine	**PAR**oxetine – **FLU**oxetine
clonaze**PAM** - **LOR**azepam	**PENT**obarbital – **PHEN**obarbital
clo**NID**ine – Klono**PIN***	Pri**LOSEC*** – **PRO**zac*
DACTINomycin – **DAPTO**mycin	**QUE**tiapine – **OLANZ**apine
e**PHED**rine – **EPINEPH**rine	qui**NINE** – qui**NID**ine
fenta**NYL** – **SUF**entanil	ri**TUX**imab in**FLIX**imab
FLUoxetine – **DUL**oxetine	Sand**IMMUNE*** – Sando**STATIN***
guan**FACINE** – guai**FEN**esin	**SERO**quel* – **SINE**quan*
Huma**LOG*** – Humu**LIN***	Solu-**MEDROL*** – Solu-**CORTEF***
HYDROcodone – oxy**CODONE**	**SUMA**triptan – sita**GLIP**tin
IDArubicin – **DOXO**rubicin	ti**ZAN**idine - tia**GAB**ine
INVanz* – **AVIN**za*	tra**ZOD**one - tra**MAD**ol
La**MICT**al* – Lam**ISIL***	**TREN**tal – **TEG**retol*
lami**VUD**ine – lamo**TRI**gine	Zy**PREXA*** – Zyr**TEC***

** Brand names always start with an uppercase letter. Some brand names incorporate tall man letters in initial characters and may not be readily recognized as brand names. An asterisk follows all brand names in Table 2.*

Appendix 3: Assess-ERR™ (Community Pharmacy Version)

The Assess-ERR™ Medication System Worksheet for community pharmacy can be found on the following three pages. Use this worksheet to collect initial error information, guide event investigation, and focus risk-reduction strategies. A Microsoft Word version is available at: www.ismp.org/Tools/Community_AssessErr.

Assess-ERR™

Community Pharmacy Version

Medication System Worksheet

Rx # _____

Date of error: _____ Date information obtained: _____

Patient age: _____

Drug(s) involved in error: _____

STEP 1

Was indication for use on the prescription?	☐ Yes	☐ No
Was the prescription obtained electronically?	☐ Yes	☐ No
Were two unique patient identifiers used at pickup?	☐ Yes	☐ No
Did the patient accept the offer to counsel?	☐ Yes	☐ No
Did the error reach the patient?	☐ Yes	☐ No
Was the prescriber notified of the incident?	☐ Yes	☐ No

Brief description of the event (what, when, and why):

_____

_____

_____

STEP 2

Key Element	Possible Causes	Y / N	Comments
I	**Critical patient information missing?** (e.g., age, weight, allergies, pregnancy, patient identity, address, indication for use)		
II	**Critical drug information missing?** (e.g., outdated/absent references, inadequate computer alerts, independent checks for high-alert drugs/high-risk patient)		
III	**Miscommunication of drug order?** (e.g., illegible, ambiguous, incomplete, misheard, or misunderstood spoken rx, poor fax, unable to clarify with prescriber)		
IV	**Drug name, label, packaging problem?** (e.g., look- and sound-alike names, look-alike packaging, no drug image, NDC or barcode not available or not used)		

Key Element	Possible Causes	Y / N	Comments
V	**Drug storage or delivery problem?** (e.g., drug stocked incorrectly, stock on crowded shelves, look-alike products stored next to each other)		
VI	**Drug delivery device problem?** (e.g., automated dispensing devices not calibrated or maintained, oral measuring device not dispensed)		
VII	**Environmental, staffing, or workflow problems?** (e.g., poor lighting, excessive noise, clutter, interruptions, human factors, workload, inefficient workflow, breaks not scheduled)		
VIII	**Lack of staff education?** (e.g., competency validation, new or unfamiliar drugs/devices, orientation process, feedback about errors/prevention)		
IX	**Patient education problem?** (e.g., lack of information, non-adherence, not encouraged to ask questions, lack of investigating patient inquiries, patient barriers)		
X	**Quality processes and risk management?** (e.g., no culture of safety, fear of error reporting, system-based causes not analyzed, independent double-check not performed)		

Patient Outcome: _____

_____

_____

***Assess-ERR*™**
Community Pharmacy Version

Medication System Worksheet

STEP 3
As a team, identify, prioritize and record "Identified Problem" from the "Comment" section in Step 2. Using the specific key element for those comments, refer to the recommendation strategies chart and select the most appropriate and effective interventions. Write selected strategies in the "Interventions Implemented" column below. This table will be used to document medication safety activities. Recommended interventions should address breakdowns in the *Key Elements* identified during event investigation. The staff should reconvene in three months time to determine if the proposed strategies have been implemented, if they are still pertinent, and if other strategies have been offered or considered since the initial review. Use a variety of strategies, as found in Appendix 4, to help generate appropriate interventions.

Identified Problem (from Comments, above)	Key Element	Interventions Implemented	Person/Dept. Responsible for Follow Up	Date Completed

Appendix 4: Strategies to be used with the Assess-ERR™ (Community Pharmacy Version)

Use a variety of the following strategies to focus on system issues and human factors in order to continually enhance safety procedures in your pharmacy. Share this information with colleagues at your site and within your greater organization.

- **Fail-safes and constraints** involve true system changes in the design of products or how individuals interact within the system. When the pharmacy computer system is integrated with the cash register, a fail-safe would prevent the clerk from "ringing up" the prescription unless final verification by a pharmacist had occurred.

- **Forcing functions** are procedures that create a "hard stop" during a process to help ensure that important information is provided before proceeding. For example, a pharmacy computer system that prevents overriding selected high-alert messages without a notation (e.g., patient-specific indication must be entered if high-alert medication selected).

- **Automation and computerization** of medication-use processes can reduce reliance on memory. Examples include true electronic systems that can receive electronic prescriptions from a prescriber, thus eliminating data entry misinterpretation at the pharmacy; and robotic dispensing devices.

- **Standardization** creates a uniform model to adhere to when performing various functions and to reduce the complexity and variation of a specific process. For example, create standardized processes to guide the pharmacist's final verification of a medication or to enhance the safety of giving or receiving a telephoned medication order.

- **Redundancies** incorporate duplicate steps or add another individual to a process to force additional checks in the system. Involving two individuals in a process reduces the likelihood that both will make the same error with the same medication for the same patient. However, the potential for error still exists since the redundant step may be omitted or ignored. Examples include use of both brand and generic names when communicating medication information. Patient counseling is often an underutilized redundancy that can detect many errors.

- **Reminders and checklists** help make important information readily available. For example, prescription blanks that include prompts for important information (e.g., medication indication, allergies, patient birth date).

- **Rules and policies** are useful and necessary in organizations. Effective rules and policies should guide staff toward an intended positive outcome. However, some may add unnecessary complexity and may be met with resistance, especially when implemented in haste in response to an error. Because their use relies on memory, they should be used as a foundation to support other strategies that target system issues.

- **Education and information** are important tactics when combined with other strategies that strengthen the medication-use system. The effectiveness of these tactics relies on an individual's ability to remember what has been presented. Thus, on their own, they offer little leverage to prevent errors.

Rank Order of Error Reduction Strategies	
Fail-safes and constraints	High Leverage
Forcing functions	
Automation and computerization	
Standardization	
Redundancies	
Reminders and checklists	
Rules and policies	
Education and information	Low Leverage
Items at the top of the list, such as fail-safes, forcing functions, and automation, are more powerful strategies because they focus on systems. The tools in the middle attempt to fix the system yet rely in some part on human vigilance and memory. Items at the bottom, such as education, are old, familiar tools that focus on individual performance and therefore are weak and ineffective when used alone.	

Appendix 5: Selected Data from ISMP Medication Safety Self Assessment™ for Community/Ambulatory Pharmacy

The content of each module in the *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change* (tool) was developed using national aggregate data collected from the *ISMP Medication Safety Self Assessment™ for Community/Ambulatory Pharmacy* (self assessment). The self assessment (www.ismp.org/Survey/NewMssacap/Index.asp) was developed and made available to community and ambulatory pharmacies in 2001 for the purpose of encouraging individual pharmacies to self evaluate their processes and look for opportunities for safety improvements. The *Assessment* is divided into sections that represent each *Key Element*. Participants were asked to score their success with each safety characteristic by entering their findings on ISMP's website using the following scoring key:

A. There has been no activity to implement this characteristic in the pharmacy or for any patients, prescriptions, drugs, or staff.
B. This characteristic has been discussed for possible implementation in the pharmacy, but is not implemented at this time.
C. This characteristic has been partially implemented in the pharmacy for some or all patients, prescriptions, drugs, or staff.
D. This characteristic has been fully implemented in the pharmacy for some patients, prescriptions, drugs, or staff.
E. This characteristic has been fully implemented in the pharmacy for all patients, prescriptions, drugs, or staff.

In order to simplify the reported scores for use in these modules, the aggregate scores were bundled/categorized as:

- **A** and **B** = no implementation
- **C** and **D** = partial implementation
- **E** = full implementation

Selected examples of data collected

Specific items in self assessment - report of current activities: Patient Information

	Degree of Implementation		
	None	**Partial**	**Full**
When taking orders over the telephone, the prescriber (or designee) is specifically queried about co-morbid conditions, allergies, and the patient's weight.	62%	33%	5%
Prescription orders cannot be entered into the pharmacy computer system until the patient's allergies have been properly entered and coded (patient allergies is a required field).	84%	—	16%
The clinical purpose of each prescription is ascertained before the medication is dispensed to assure that the prescribed therapy is appropriate for the patient's condition and to help distinguish medications with similar packaging and look-alike or sound-alike names.	28%	52%	20%

Specific items in self assessment - report of current activities: Drug Information

	Degree of Implementation		
	None	**Partial**	**Full**
A designated pharmacist or corporate level staff routinely reviews, for quality improvement purposes, reports of computer warnings that are overridden by pharmacists.	51%	16%	32%
Pharmacy staff tests the computer system at least twice annually to assure that maximum dose alerts are present for high-alert and drugs with a narrow therapeutic index and builds alerts for those that are not present, or provides feedback to corporate level staff or drug information system vendors when appropriate.	67%	12%	22%

Specific items in self assessment - report of current activities: Communication

	Degree of Implementation		
	None	**Partial**	**Full**
A list of prohibited, dangerous abbreviations and error-prone dose designations is established for internal communication and documentation of prescription orders, computer systems and pharmacy labels.	55%	25%	20%
Feedback is provided, at least annually, to community physicians to educate them about unsafe prescription writing practices.	75%	15%	10%

Specific items in self assessment - report of current activities: Drug Packaging and Labeling

	Degree of Implementation		
	None	**Partial**	**Full**
Pharmacists regularly examine the package and label of new drugs to identify any potential for confusion.	23%	37%	40%
When two different products exist that have dangerously similar labeling/packaging, pharmacy seeks an alternate manufacturer for one of the products.	45%	30%	25%
Products with known look-alike drug names are stored separately and not alphabetically, **or** are clearly differentiated if they remain next to each other.	23%	38%	40%
Auxiliary warnings, labels with exaggerated fonts, or other label enhancements are used on packages and storage bins of drugs with problematic names, packages, and labels.	22%	39%	39%
Special alerts are built into the computer, as necessary, to remind practitioners about problematic or look-alike drug names, packaging, or labeling.	37%	25%	39%

	Degree of Implementation		
	None	Partial	Full
Computer mnemonics are designed to minimize selection of the wrong medication or strength.	47%	26%	28%

Specific items in self assessment - report of current activities: Standardization, Storage, & Distribution

	Degree of Implementation		
	None	Partial	Full
Access to targeted high-alert medications such as anti-coagulants and oral hypoglycemic drugs, and other problem products, has been safeguarded through constraints (such as drug placement in locked area, removal from "fast mover" areas where it might be "grabbed" incorrectly, etc.) to reduce potential for dispensing errors.	47%	30%	22%
An automated dispensing system that incorporates robotics and/or bar-code verification systems is used to support the dispensing system in the pharmacy.	44%	19%	37%
A mechanism exists to identify the reasons that a prescription has not been picked up after being prepared.	33%	26%	41%

Specific items in self assessment - report of current activities: Medication Device Acquisition, Use, and Monitoring

	Degree of Implementation		
	None	Partial	Full
Patients are instructed on the proper use and maintenance of devices dispensed from the pharmacy (e.g., glucose monitors, humidifiers, spacers used with inhalers, etc.).	8%	58%	34%

Specific items in self assessment - report of current activities: Environmental Factors

	Degree of Implementation		
	None	**Partial**	**Full**
Areas where drug orders are transcribed and/or entered into computer systems are isolated and relatively free of distractions, noises, and unnecessary chatter.	31%	42%	27%
The physical layout of the pharmacy is designed to minimize distractions for pharmacists during the final check in the prescription verification process.	29%	36%	35%
When dispensing prescriptions, staff work with one drug product at a time and affix the label to the patient's prescription container before working on the next prescription.	7%	35%	58%
A device is available and used to hold prescription information near the computer monitor, at eye level, in order to improve visibility when entering orders.	21%	16%	61%
Prescriptions are scanned into the computer or received electronically via a hand held device or computer.	86%	3%	10%
A magnifying box or lens is in a fixed location and used to facilitate readability of prescriptions and labels.	33%	10%	57%

Specific items in self assessment - report of current activities: Staff Competency and Education

	Degree of Implementation		
	None	**Partial**	**Full**
Pharmacy staff is sufficiently trained on the proper use and maintenance of devices dispensed from the pharmacy (e.g., glucose monitors, humidifiers, spacers used with inhalers, etc.)	21%	56%	22%

	Degree of Implementation		
	None	**Partial**	**Full**
Pharmacists and technicians receive ongoing information about: • Medication errors occurring within the organization • Error-prone situations • Errors occurring in other pharmacies • Strategies to prevent such errors	20%	45%	34%
Medication errors and ways to avoid them are routinely discussed at staff meetings and among pharmacists, technicians, and managers.	16%	43%	42%

Specific items in self assessment - report of current activities: Patient Education

	Degree of Implementation		
	None	**Partial**	**Full**
Adequate time is budgeted by management for patient counseling activities.	14%	54%	32%
A suitable private area with minimal distractions is available to provide patient counseling.	25%	41%	34%
Clerks fully disclose the intent of the proof of counseling log before asking patients or caregivers to sign the log.	45%	24%	30%
Criteria have been established to trigger required counseling and a system is in place to alert the pharmacist of this need.	21%	31%	47%
When counseling is provided, the patient's drug container is opened in front of the patient/caregiver to verify the appearance of the medication.	28%	56%	16%
Patients are informed about the potential for error with drugs that have been known to be problematic and are provided with strategies to help prevent such an occurrence.	35%	44%	21%

Specific items in self assessment - report of current activities: Quality Processes

	Degree of Implementation		
	None	**Partial**	**Full**
Pharmacists and technicians are provided with regular feedback about errors reported in the pharmacy, hazardous situations, and error reduction strategies that are being implemented.	20%	39%	41%
Management and staff routinely read and use published error experiences from other organizations to proactively target improvements in the medication dispensing process.	37%	38%	25%
Pharmacists recognize the value of reporting via external reporting programs such as the ISMP MERP.	40%	26%	34%
Pharmacy management supports practitioner reporting via external reporting programs such as the ISMP MERP.	43%	22%	35%