Quality Assurance

Preventing Medication Errors - Now and for Tomorrow

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ISMP

Mission of ISMP

• Translate errors into education
• Encourage voluntary reporting of medication errors
• Disseminate information for medication error prevention
• Encourage a non-punitive, system-based approach to medication error reduction
10 Key Elements of the Medication SYSTEM

1. Patient Information
2. Drug Information
3. Communication
4. Drug Labeling, Packaging and Nomenclature
5. Drug Standardization, Storage and Distribution
6. Device Acquisition, Use and Monitoring
7. Environmental Factors, Workflow and Staffing Patterns
8. Staff Competency and Education
9. Patient Education
10. Quality Processes and Risk Management

ISMP’s Message

• Recognize that behind every pharmacy procedure violation there is probably a system-based cause
• Mandate continuous quality improvement activities at the practice site
• Promote and disseminate system-based safety recommendations
• Target the System, not the Workforce
Key Element #1: Patient Information SOP

- All prescriptions are reviewed for appropriateness
  - Drug, dose, frequency, and route
  - Real or potential allergies or sensitivities
  - Real or potential drug interactions
  - Other contraindications
  - Identification of patient using 2 identifiers

Example of errors due to lack of Patient Information

- A pregnant woman receives a prescription for Cytotec (misoprostol).
- A technician dispenses the wrong prescription at point of sale because there are two patients with the same name.
- New prescription was brought in Brevoxyl 8 wash. The medication was filled for the wrong sibling.
Patient ID Card

- Bypasses language barrier
- Avoid awkward situations
- Convenience
- ID cards that contain:
  - Name
  - Date of Birth
  - Address

Written Multilingual Questionnaires

- Contain basic phrases
  - Name
  - Address
  - Birth date
- Negates need for patients to repeat themselves
Key Element #2: Drug Information SOP

• Easily accessible, updated drug reference texts available and all outdated texts are removed
• 35% ADEs related to inadequate drug info
• Computer system warns
  – about clinically significant drug interactions
  – about overdoses and under doses for targeted high alert or narrow therapeutic index medications
  – screens and detects for drug allergies
Key Element #3
Communication: Phone Orders

• Make them illegal 😊
• Always ask for read back
• Enunciate slowly and distinctly
• State numbers like pilots
  (i.e., “one-five mg” for 15 mg)
• Spell out difficult drug names
• Specify exact doses

Key Element #3
Communication: Electronic

• Use fax machines that are
  – high quality
  – routinely cleaned and maintained
• Monitor electronically sent prescriptions for problems
  – potential wrong drug selected by the prescriber (one above or below intended drug)
  – wrong or duplicate directions
What Do You Think This Prescription Is For?

There was a blank spot on the prescription next to the "L".

There was a fax problem from doctor's office when they faxed the prescription in.
E-Rx Introduces New Errors

• RPh and Tech presume them to be error free since they were generated by a computer
• Prescriber selects drug by typing in only the first few letters
• Selects first match on the screen, not necessarily the drug intended
• How is an RPh to know?

Examples sent to ISMP

• methohexital for methotrexate
• propofol for propranolol
• procarbazine for procardia
• dilaudid for dilantin
• imuran for imdur
• quinidine for quinine
• aminophylline for amiodarone
• hydralazine for hydroxyzine (and reverse)
• oxybutinin for oxycodone

Consider cross link DX codes and send alert?
Generic Salts Create Problems

- Physician selects metoprolol tartrate
- Patient on succinate previously
- Filled appropriately and correctly
- No error detected by Rx staff
- Not clinically inappropriate either way
- Just not what the patient was expecting

Other Documented Errors

- NDC mismatches
  - RxNorm issues vs NDC#
- Patient mis-selections
  - RxHub = PBM switch for the Rxs to go to Medco, Caremark, ESI, etc. (200 million lives; RxHub selects patient by member id number)
  - SureScripts = retail pharmacy switch for patients to go to their local store

(enrollment numbers are by physician office and/or pharmacy store numbers, not covered lives; pharmacy confirms patient identity)
### New Prescription Form

**Prescription as follows:**
- **Drug Prescribed:** Ipratropium Bromide SOLN 0.02%
- **Quantity:** 3, Three Bottles
- **Days Supply:** 30
- **Directions:** 6 times a day, 1 pull 4 times daily pm
- **Refills:** 1, One Refill
- **Diagnosis:** Not Supplied
- **Route of Administration:** Not Supplied
- **Brand-matched necessary dispense as written**

**Signed electronically by:** 

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**STEP 1**

Please review and enter the information in order to complete the prescription process:

- **Patient:** [Blank]
- **Drug:** IFRATROPIM INH SOLN 0.02%
- **Strength:** 0.02%
- **Quantity:** 110
- **Directions:** [Blank] REQUIRED

**Refills:** [Blank]

**STEP 2**

Prescriber Signature & Date REQUIRED.

**Substitution Permitted:** [Blank]

**Dispense as Written:** [NPI NEEDED]

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E-Rx Issues Reported to ISMP

• Not ‘True’ E-Rx
• Result of electronically produced prescriptions that are either faxed or printed and brought to the pharmacy

Electronically-generated prescriptions: An Rx for E-rror?

Use of electronically-generated prescriptions may lead to unintended consequences that impair prescribing safety. Problems with misspelled drug names, the use of error-prone abbreviations, and pre-programmed “sips” that conflict with manually entered special instructions must be addressed.

Pharmacists should communicate deficits—such as trailing zeros, Latin abbreviations, and confusing information—found in electronically-generated prescriptions with prescribers, vendors, and ISMP so we can inform others and advocate for change by vendors. Seeing prescription problems that arise through real-time use of the system allows prescribers to adapt how they use the system and can drive software changes.
Dangerous Abbreviations

- Often improperly used, misunderstood and poorly written
- Have resulted in patient harm
- Delays the start of therapy - work flow interruption

Why Latin? Why Abbreviate?

- Electronically generated, the sigs should be printed in English, not Latin codes, spelled correctly, no trailing zeros, no abbreviations
Key Element #4: Drug Packaging

• Products with known look-alike drug names are stored separately and not alphabetically*, or are clearly differentiated if they remain next to each other.

medication error waiting to happen
Confirmation Bias with Drug Product Selection

A case for shelf dividers ($)...
AutoMed FastFill™  
ScriptPro SP200 ®  

...or technology ($$-$$)
Key Element #5: Drug Storage

Observe pharmacy storage conditions for areas of potential risk of error:

- Look-alike labeling and packaging
- Fast-moving section
- Refrigerator
- Narcotics Safe
2.6.1 Storage of medicines

Refrigerators

**Issues**

- Cabinet and ordered refrigerators make selecting the correct medicine for dispensing very difficult.
- Considered one box could get mixed up with stock if many in the same refrigerator.

**Recommendations**

- Implement refrigeration for stock and compliant prescriptions.
- Use a front-loading refrigerator where you can see what is inside.
- Store the actual refrigerator outside the dispensing area to reduce the temperature fluctuations collection point. (Space is an issue with an environment of dispensing dispensed medicines from various sites, such as the pharmacist with storage devices.)
- Maintain to test and ensure refrigerator temperature regularly.

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2.6.2 Storage of medicines
Controlled drug (CD) cupboards

**Issues**
- Partitioned CD cupboards make it difficult to assess stock, security, leading to a possible increase inlicate stock.

**Recommendations**
- Ensure that CD cupboards are large enough to meet the needs of the dispensing team and allow for an orderly and secure process.
- Provide an overview of CD cupboard use without evidence.

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28 A guide to the design of the dispensing environment.
A guide to the design of the dispensing environment 28
simple, consistent alphabetical system is easy for all staff

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Key Element #6: Medication Device, Use and Monitoring

- Careful procurement, maintenance, use, and standardization of medication delivery devices (measuring “devices” – oral syringes)
- Rx Staff familiar with and can educate others about devices sold at the pharmacy
The numbers visible in the dose indicator window in Pulmictor Flexhaler (budesonide inhalation powder) provide confusing information to patients. The dial is labeled in increments of 20, and actual movement of the dose-counter may not be discernable. Patients may have difficulty telling if a dose has been received.

Patients who use Pulmictor Flexhaler should receive explicit instructions about how to actuate the device, the slow-moving design of the dose counter, and how to tell when the device is empty. The manufacturer will provide tear sheets and updated information on the Pulmictor Flexhaler website once patient instruction revisions are approved by FDA.
Key Element #7: Environment, Workflow, Staffing Patterns

- Must allow pharmacy staff to remain focused without unnecessary distractions.
- 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.

Environmental Considerations

- Adequate lighting
- Clean work area
- Distractions
  - Noise (page speaker, radio, excessive talking)
  - Telephone
  - Interruptions
- Pharmacy layout
- Temperature
- Schedule/Shifts
  - Stress
  - Fatigue
- Workload
Determine flow of traffic and where work occurs. Reduce travel and increase efficiency. Where can technology be added?
What does this image portray?
Pharmacy Layout

Well-signed areas for: drop off, pick up, and counseling

Increase efficiency, reduce consumer wait time (in the right line!), decrease staff stress, and decrease interruptions and errors
Key Element #8: Staff Competency

- Lack of new drug information by staff results in errors
  - What is the education process for RPh and technician when new drugs come to market?
  - How do you receive and communicate new drug information to your staff?

Error with Lovaza (formerly Omacor)
Key Element #8: Staff Training

- Special alerts are built into the computer to remind practitioners about
  - problematic or look-alike drug names
  - packaging
  - labeling
- Pharmacist entered ACTO30 for prescribed Actonel 30 mg
  - patient received Actos 30mg
- Computer mnemonics are designed to minimize selection of the wrong medication or strength.

2 or 3 Letter Mnemonics Contribute to Data Entry Errors

- methohexital for methotrexate
- propofol for propranolol
- procarbazine for procardia
- dilaudid for dilantin
- imuran for imdur
- quinidine for quinine
- aminophylline for amiodarone
- hydralazine for hydroxyzine (and reverse)
- oxybutinin for oxycodone
- simvastatin for simethicone
Activella

- Activella combination drug, comes in 2 strengths, 1.0mg/0.5mg and 0.5mg/0.1mg
- First drug listed is estradiol and the second is norethindrone
- 00169-5174-01 Activella 1.0mg/0.5mg
- 00169-5175-11 Activella 0.5mg/0.1mg
- Trailing zero, similar numbers= rx for error

Key Element #9: Patient Education SOP

- Open containers while in store
- Ask open-ended questions
  - Do not ask “yes/no” questions
  - Return demonstrations
- Mandatory counseling for…
  - High-alert medications
  - High-risk patient populations
Fentanyl Patch: High-alert Med
Appropriate candidate for therapy?

- 77-year-old woman given VICODIN for sciatic pain. She took about 4 doses daily for a week, but was still in pain.
- She contacted physician who, by telephone, prescribed fentanyl 50 mcg per hour patches to be applied every 48-72 hours.
- Woman’s friend helped her place one of the patches on the site of her pain, the buttock.
- When the woman went to bed she used a heating pad on her lower back/buttock area.
- After 2 days of not hearing from the woman, friends found her dead in bed.


Emergency Department Visits for Adverse Drug Events in the Elderly

- Nine of the ten most commonly implicated medications may be categorized in 3 classes
  - oral anticoagulant or antiplatelet drugs (warfarin, aspirin, and clopidogrel)
  - antidiabetic agents (insulin, metformin, glyburide and glipizide)
  - narrow therapeutic index agents (digoxin and phenytoin)
High-alert Medications Specific to Community Practice

- Anticoagulants
- Methotrexate, oral, non-oncologic use
- Insulin, oral agents
- Narcotics/opiates
- Chemotherapeutic agents
- Drugs with black box warnings
- Known drug name confusion

Key Element #10: Quality Processes and Risk Management

- ‘Just’ culture
- Committees and leadership support for medication safety
- Detection, reporting, and analysis of medication errors
- Medication error reduction activities
- Feedback about errors and error reduction strategies
- System of independent double checks
What Can You Do Now?

- Encourage or expect each pharmacy to complete the Self Assessment
- Recommend RPhs access externally reported errors to use to assess their practice site for potential
- Provide CE for medication safety
- Promote legislation for peer review protection
Available FREE ISMP.org
Stimulate thought about safe practices for each pharmacy as part of a CQI program

Heighten awareness of a safe community pharmacy practice

Elements of a Community Pharmacy Medication Safety Program/Plan

- Tools to Build a Community Pharmacy Medication Safety Program