Medication Errors

Prevention and Reduction Guidelines

Approved by PEIPB
November 2004
Medication Error Reduction

Given the complexity of the processes required to safely and accurately process a prescription from receipt of the order to issuing to the patient, it is critical that pharmacists be alert and focused at all times while working. Data has shown that more errors occur when pharmacists are either very busy or relatively quiet with regard to prescription workload.

The major components identified in the prescription process include

- Access to information
- Prescription filling process
- Counseling
- Environment
- Policies & Procedures
- People (individuals)

Each of these components is composed of various factors (see Appendix A). A failure, or breakdown, in any one of these factors may lead to a medication error. Most of the components can be controlled, or standardized, thereby minimizing potential for errors to occur. Defined policies and procedures, staff training, standardized routines, assignment of activities etc can minimize the potential for errors.

Environments in which medication errors are more likely to occur tend to be characterized by\(^1\):

- disorganized work flow
- fatigued staff
- frequent interruptions and distractions
- poor physician handwriting
- emphasis on volume over service quality
- stress
- ineffective communication with patients
- improper technician training
- a pattern of inadequate staffing.

The greatest challenges facing the pharmacist today are:

1. Lack of time/unmanageable workload
2. Shortage of pharmacists
3. Lack of adequate payment for service

The Board is concerned about the impact of these challenges on the frequency of medication errors. This document discusses medication errors, causes and recommendations to minimize the potential for errors given these challenges.

The impact of these challenges primarily affects two components - Environment and Counseling.

Overworked staff end up working too many hours and as a result, stress increases and quality of work life, as well as personal, decreases. Accurate and safe performance of required duties may be an issue. Prescription checks, counseling sessions etc are rushed. The possibility of an error occurring is significantly increased.

The principles and guidelines stated below are aimed at assuring that the pharmacy workplace environment and pharmacy staff are optimally utilized to maximize the protection of the health, safety and welfare of patients. These principles and guidelines define minimum requirements to assure that the pharmacist has the greatest potential to provide safe and responsible pharmacy services.

“Pharmacists who are overburdened and understaffed present a very real threat of harm not only to themselves, but also to the patients who depend on them.”

Adherence to these principles and guidelines will help reduce the number of medication errors that go undetected until they cause harm to the patient.

It has been identified that the current pharmacist shortage has put a premium on pharmacists' time and that prescription volume keeps increasing. There is a maximum amount of work any individual can perform; work performed beyond a person’s limitations is more likely to contain mistakes. The workplace standards dictate that systems, personnel (including trained pharmacy technicians), and procedures be in place for the pharmacist to be able to prevent workload burnout and, ultimately, potentially dangerous medication errors.

The following principles and guidelines have been developed to assure patient safety. They are created as a minimum requirement to assure that the

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2 Trends 2002: The Pharmacy Report
3 Larry Wagenknecht, CEO, Michigan Pharmacists Association
4 Pharmacy Trends 2003
5 Health Human Resources Supply and Demand Analysis (Fujitsu Report)
pharmacist has the greatest potential to provide safe and responsible pharmacy services:

1. The pharmacist is ultimately responsible for the prevention of errors and the safe provision of care to the patient.

2. The pharmacist must be empowered to make decisions that ensure patient safety and provide appropriate patient care.

3. The environment of the pharmacy must allow and encourage the exercise of the pharmacist's professional judgment.

4. Pharmacist and pharmacy technician staffing must be appropriate to the situation, with pharmacists having input on staffing requirements, including the use of pharmacy technicians and other supportive help.

5. Authority over pharmacy working conditions must be shared between management and pharmacist with public safety being the primary objective.

6. A professional environment must exist with well defined workflow patterns to maximize pharmacist/patient interaction and to ensure patient safety.

7. The pharmacy site must comply with all laws and administrative rules and provide pharmacist access to appropriate pharmacy technology – professional resource materials and appropriate computer software that recognizes the current legal and professional practice of pharmacy.

8. Job descriptions for pharmacists, pharmacy technicians and other pharmacy support personnel must be specific and not be open-ended.

9. Policies and procedures within the pharmacy must provide for the pharmacist's professional judgment in the delivery of patient care.

10. The technical aspects of the dispensing process should be performed by technicians, while the pharmacist attends to the cognitive aspects of the process. This minimizes the potential for errors to occur by having two independent checks in the dispensing process.
Discussion

A study published in the Canadian Pharmaceutical Journal⁶ discusses pharmacy workload as a factor contributing to medications errors. The author concludes there is no simple relationship, and that “… pharmacists have different thresholds for workload and how much they can do safely and without burning out.”

A study of medication errors completed by the Massachusetts Board of Pharmacy reveals some interesting statistics. (see Appendix B). Key findings of this review were that errors increased with workload; more errors occurred when pharmacists actively became involved in the technical aspects of dispensing.

Pharmacists interested in assessing their practice should review the self-assessment tool at http://www.ismp.org/pages/mssacaprdf.html. This tool examines the various components of practice and identifies individual activities for assessment. This site provides a comparison between answers provided and peer evaluations. Note that the comparative data is for US sites, not Canadian, at the present time.

A sample Incident documentation form is presented. (see Appendix C) There are many actions and activities pharmacists can incorporate into their daily practice to assure accurate dispensing of medications to patients and assisting patients with their medication use. Appendix D provides a list of these activities.

Incorporation of these activities into daily practice would help minimize and prevent medication errors.

“Lock and Leave” provides an opportunity for pharmacists working alone to schedule their breaks.

From the above discussion and an extensive search for other information on this topic, the following guidelines are proposed, recognizing that any one individual may perform at a much different level than another individual.

Hours of work

In order to limit the stress pharmacists work under to a safe level, the following recommendations for hours of work are defined:

- A pharmacist should work a maximum of forty-eight (48) hours in a week.
- An eight (8) hour shift is considered appropriate and desirable.

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- A pharmacist may work a ten (10) hour shift to cover short term contingencies.

- Twelve (12) hour shifts should be avoided. In extenuating circumstances, adequate time for breaks is encouraged.

- A pharmacist may work longer than a scheduled shift if presented with a prescription or prescriptions which require immediate attention, in order to act in the best interest of the patient.

- Meal and rest breaks provide an opportunity for the pharmacist to regroup, refocus and sharpen their cognitive skills thereby minimizing occurrence of errors. As a guideline that a shift of more than 6 hours should include a 30-minute meal break and a 15 minute break.

- A pharmacist should not, on average, be scheduled for more than a maximum of four consecutive 10-hour shifts, nor more than 48 hours per week. Pharmacists may make alternative shift arrangements in advance, considering limits on personal capabilities, patient safety and professional obligations.

**Prescription volumes**

It is recognized that different pharmacists have different abilities and may perform different quantities of work more effectively and safely than others. However, there is an optimum workload that pharmacists may perform, after which, the potential for increasing errors rises. With regard to prescription volumes, the following guidelines are suggested:

A pharmacist working alone, with no technician assistance, should reasonably be able to dispense approximately 10 prescriptions per hour as a consistent, daily average.

A pharmacist working with technician support (one or more), should reasonably be able to dispense an average of 15-20 prescriptions per hour.

These figures assume work interruptions such as phone calls, clarification of prescription orders, questions from patients, counseling patients, etc. that are average and consistent in daily frequency.

**Patient Counseling**

Patient counseling is an activity that provides the pharmacist an opportunity to develop and maintain a professional relationship with the patient while discussing the patients therapy, providing information and answering questions. It is also the
last opportunity the pharmacist has to identify a potential or actual medication error by reviewing the medication, its use and directions, identification of the physical product itself, identifying changes in therapy the physician and patient have implemented that may be different from the current pharmacy record.

The patient counseling interchange should do the following:\(^7\):

- Ensure patient receives counseling regarding the safe and effective use of each prescribed medication and include both oral and written information.
- Assess the patient’s level of understanding of medication information provided. Confirm what information was presented by prescriber and identify gaps and opportunities for reinforcement.
- Encourage patients to ask questions and provide information regarding purpose of medication, dosage, side effects, use of other medications, duration of treatment, storage of supply, effects and actions with missed doses, effects of food and compliance issues.
- Suggest that patients keep a journal regarding the effects and use of all their medications and use of over-the-counter products. Discuss these observations with them as they return for refills.

This interaction should occur at each patient encounter, whether for a new prescription or a refill. Although it would be ideal for the pharmacist to see the patient for refill prescriptions, the opportunity for a patient to receive counseling on refills may be served by having the technician enquire if the patient wishes to speak to the pharmacist about any medication related concerns.

Investigation process

The process the Board follows when notified of a potential medication error (usually by a patient) is as follows. When the Board receives a complaint concerning a medication error, the various components and factors identified in Appendix A, particularly Environment and Counseling, are investigated and evaluated in an attempt to determine what factors contributed to the error, and, more importantly, what actions can be taken to prevent such errors from reoccurring in the future.

The hours a pharmacist has worked in the preceding month, the length of shifts worked, and the time of occurrence of the incident ie number of hours worked in the shift prior to the error occurring, dispensary organization, availability and use of support staff, documentation on the prescription or in the computer system are key determinants relating to the cause of the error and have more importance attached to them.

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The pharmacist involved in the incident may be required, as a minimum, to complete educational courses on preventing medication errors, proper counseling techniques, or, given evidence of negligence, be fined and/or face suspension for a specified period of time or other action recommended by the Discipline Committee.
Appendix B - Massachusetts Medication Error Study

Results

Forty-six of the 51 pharmacists involved in medication errors occurring in 1996-97 agreed to participate in the study. Thirty-four of these pharmacists provided valid data appropriate for statistical analysis.

Demographics

41% were female and 59% were male;

ages in years ranged from 25 and under (3%), 26-30 (12%), 31-40 (43%), 41-50 (18%), and over 50 (24%);

The year of graduation from pharmacy school by decades is represented by the following percents: 1950-1959 (9%), 1960-1969 (12%), 1970-1979 (17%), 1980-1989 (24%), 1990-1997 (38%);

Job status encompassed floating (18%), manager of record (30%), part-time (9%), and full-time (43%);

6% were non-English speaking.

Prescription Information

Fisher's Exact Test found no statistically significant differences between the number of prescriptions filled on the day of the alleged incident versus a typical working day (p>0.05).

The study indicated that 63% of the errors were made filling new prescriptions while 37% were made on refills.

Handwritten prescriptions accounted for 45% of errors and 37% of errors were made on prescriptions phoned into the pharmacy.

In addition, the dispensing of incorrect drugs and/or incorrect strengths accounted for 88% of errors made.

Fisher's Exact Test revealed no statistically significant difference in dispensing errors due to incorrect drug and/or incorrect strength between new and refill prescriptions (p>0.05).
Reasons for Prescription Errors

The study revealed that pharmacists perceived the following as causative factors for medication errors (Figures 1,2,3):

Figure 1

- Wrong Interpretation of Abbreviations: 3%
- Lack of Experience: 3%
- Lack of Knowledge: 3%
- Illegible Rx: 20%
- Incomplete Patient Profile: 4%
- No One Available to Double Check: 15%
- No Time to Counsel: 30%
- Untrained Support Staff: 5%
- Overload/Unusually Busy Day: 59%
- Staff Shortage: 32%

Figure 2

- Counseled Incorrectly: 15%
- Misinterpreted Rx: 24%
- Transcribed Incorrectly: 15%
- Poor Packaging and Labeling: 15%
- Similar Drug Names: 29%
- Inadequate Software: 3%
- Lack of Organization: 15%
- Pharmacy Cluttered: 15%
- Container Location on Shelf: 15%
- Inadequate Lighting: 5%
Chi-square Test of Independence revealed statistically significant associations between an overload/unusually busy day to the volume of telephone calls \( (p<0.01) \) and volume of customers \( (p<0.01) \). Lack of concentration was also significantly associated with an overload/unusually busy day \( (p<0.05) \).

**Prescription Fill Process**

Chi-square test of two proportions found that significantly more pharmacists were involved with the prescription fill process on the day of the incident versus a typical day (Figures 4, 5, 6):

- Selecting the medication from the shelf 76% versus 41% \( (p<0.05) \);
- Counting the medication 62% versus 4% \( (p<0.0001) \);
- And placing the medication in the bottle 62% versus 19% \( (p<0.01) \).

In contrast there were significantly fewer support staff (technicians/interns) available to perform these same tasks on the day of the incident versus a typical day.

From the charts it is seen that technicians more accurately perform the technical activities of dispensing than pharmacists:

- Selecting the medication from the shelf 24% versus 59% \( (p<0.05) \);
- Counting the medication 38% versus 96% \( (p<0.0001) \);
- Placing the medication in the bottle 38% versus 81% \( (p<0.01) \).
### Appendix C - Incident Report Form

**Incident Documentation Form** *(Please print legibly)*

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>Address</th>
<th>Patient age</th>
<th>Telephone #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug name / strength</td>
<td>Physician</td>
<td>Dispensing pharmacist</td>
<td>Prescription #</td>
</tr>
<tr>
<td>Incident reported by:</td>
<td>New Rx</td>
<td>Repeat Rx</td>
<td>Transaction #</td>
</tr>
<tr>
<td><strong>Nature of Incident:</strong></td>
<td>Incorrect strength</td>
<td>Verbal disagreement</td>
<td></td>
</tr>
<tr>
<td>Incorrect drug</td>
<td>Incorrect brand</td>
<td>Drug interaction</td>
<td></td>
</tr>
<tr>
<td>Incorrect directions</td>
<td>Incorrect quantity</td>
<td>Counseling issue</td>
<td></td>
</tr>
<tr>
<td>Incorrect dosage form</td>
<td>Outdated medication</td>
<td>Other (please specify)</td>
<td></td>
</tr>
<tr>
<td>Incorrect patient</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Factors contributing to Incident:** (check all that apply)

- Illegible handwriting
- Failure to clarify order
- Rushing
- Error in recording verbal order
- Sound-alike product name
- Shift change
- Order misread/misinterpreted
- Look-alike product name
- Noise
- Failure to verify patient info
- DIN check failure
- Interruptions
- Incomplete patient profile (eg allergy not noted)
- Pharmacist inattention
- Phones
- Technician inattention
- Illness
- Labelling problem (mfg'er)
- Calculation error
- Other:

**Additional detail on incident and contributing factors:**

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<table>
<thead>
<tr>
<th>Was drug ingested?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>If yes, was medical attention required?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Patient contacted by:**

Date/Time:

**Prescriber contacted by:**

Date/Time: Telephone #

**Prescriber’s comments:**

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**Date incident discovered**

**Date / Time of dispensing**

**Work activity at the time was:**

- Light
- Average
- Heavy

**Was the pharmacist working alone?**

- Yes
- No

**Were support staff involved?**

- Yes
- No

**How many days in a row had the pharmacist been working?**

**On the day of the incident, how many hours had the pharmacist been working?**

**Did the pharmacist have any breaks on that day?**

- Yes
- No
## Corrective action Plan (Detail action steps to prevent recurrence of incident)

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## Incident analysis summary:

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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</thead>
<tbody>
<tr>
<td>1. Patient counseled</td>
<td>Yes</td>
<td>No</td>
<td>Patient declined</td>
</tr>
<tr>
<td>2. Information leaflet given</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>3. Dispensing checks performed</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>4. Physician notified</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>5. Patient at risk</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>6. Patient contacted</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>7. Incident reviewed with all staff involved</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>8. Medication was returned</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>9. Incident reviewed with staff for suggestion</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>10. Corrective action(s) implemented</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>11. Follow-up required</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>12. Patient claiming injury or damage</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>13. Insurer notified</td>
<td>Yes</td>
<td>No</td>
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## Follow up activity:

<p>| | | | |</p>
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## What to do when an incident occurs:

- Stay calm
- Patient safety is the first priority
- Move the discussion to a private area if possible
- Acknowledge the problem; show concern and empathy; focus on what the patient is saying
- Find out what happened by getting the facts, asking questions, and listening carefully to the answers
- Identify the appropriate steps to be taken, keeping in mind policy, patients’ expectations, and what is possible
- Describe what will be done and when, if the problem cannot be solved immediately. Be realistic!
- Apologize again, and thank the patient for bringing to your attention
- Record the steps taken to investigate and address the problem
- Follow up with those involved to assure satisfaction
Appendix D - Pharmacist actions to reduce medication errors

The Institute for Safe Medication Practice\(^8\) has developed a list of actions and activities to reduce errors. Incorporating the following activities and actions into daily practice will help minimize and prevent medication errors from happening.

**General**

- Accept central role as patient safety advocate.
- Recognize individual capacity for error.
- Recognize limitations of systems to prevent errors.

**Professional Practice**

- Develop appropriate level of suspicion (if it "feels" wrong to you, it has a high likelihood of being wrong).
- Actively provide feedback to organization regarding potential "error prone" processes and suggestions for improvements to increase patient safety.
- Develop effective and efficient skills for using drug therapy references.
- Do not use out-of-date references.
- Develop work patterns that help you focus on the task at hand.
- Never "work around" established safety procedures.
- Establish work patterns and environment that reduce chance for errors when reviewing orders.
- Establish process for systematically reviewing prescriptions/orders.
- Never "guess" when filling an illegibly, poorly written, or confusing prescription.
- Always write down verbal/telephone order immediately. Read transcribed prescription back to prescriber/prescriber agent.
- Always know the intended indication for medication use; record on prescription /profile.

**Continuing Competency**

- Consistently upgrade knowledge of medications and drug therapy.

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\(^8\) www.ismp.org
• Thoroughly evaluate all "warnings" or "alerts" detected by the pharmacy computer (dose, allergies, cross-allergies, duplicate therapies, contraindications, drug interactions, etc.).

• Develop excellent problem/error detection skills.

• Develop excellent problem definition skills.

• Develop excellent problem resolution and communication skills.

• Have pre-planned process for reducing chance for errors with highly toxic or critical drug therapies.

Documentation

• Have pre-planned process or approach to delay or refuse to fill prescriptions until problem resolution has occurred to your satisfaction.

• Record all conversations related to prescription clarification and error correction.

• Record important patient characteristics in patient profile.

Medication Order Processing and Preparation

• Establish work patterns and environment that reduce chance for errors when entering orders into pharmacy computer.

• Develop effective medication profile review skills.

• Establish work patterns to "double" check all computer entries against original order.

• Be aware of prescriptions, drugs, abbreviations, dose expressions, dose units, labels, drug storage, drug preparation, drug labeling, and communication situations that have high risk for error.

• Always check dose equation and dose calculation when used by prescribers (i.e., pediatric dosing, chemotherapy, critical care drugs)

• Double check all calculations used in drug preparation.

• Always be wary of "decimal point" errors.

• Be aware of known "sound-alikes" and "look-alikes."

• Re-read all labels on finished product for clarity and accuracy.
• Do not readily accept unsatisfactory explanations for unusual drug therapies or doses (such as "that's what they always take," "it is a special protocol," or "a specialist recommended it").

• Confusing or hard to read labeling of drug products or patient prescription vials.

• Complicated drug dosing regimens, preparation procedures, and administration procedures.

• Prescriptions for dose in volume ("ml") instead of weight ("mg").

• Inappropriate use of dosage forms (sustained release morphine "as needed," "Diltiazem CD 240 mg per tube daily.").

• Administration route-dose conversion ("switch labetolol 200mg q12h from oral to IV").

• Failure to specify stop order or maximum daily doses for drugs with dose limits ("colchicine 1mg IV q6 hours, Darvocet-N 100 2 tabs q3-4 as needed").

• Failure to adjust drug therapy for patient characteristics (age, renal function, weight).

• Complex multi-drug regimens (such as HIV patients).

• Always use excellent sterile technique when preparing sterile products.

**Work Flow**

• Appropriate drug preparation and dispensing work patterns and environment reduce chance for error.

• Establish work patterns and environment that reduce chance for error when selecting medications from stock.

• Establish work patterns and environment that reduce chance for error when returning medications to stock.

• Establish work patterns and environment that reduce chance for error when reading labels and preparation instructions.

• Establish work patterns and environment that reduce chance for error when measuring and mixing.

• Establish processes for independent double check when possible.
- Establish "individual" “triple check” process – check when selecting the right drug, when checking the prescription, and when replacing the drug. Additional checks may be incorporated into the dispensing and checking process.

- Establish work patterns that routinely include checking of expiration date and storage conditions.

- Establish work patterns that reduce chance for error when checking prepared medications.

- Have pre-planned process for reducing chance for errors with highly toxic or critical drug therapies.

**Patient Counseling**

- Patient counseling is a key error-prevention step. Create appropriate environment, then communicate, educate, and listen to patients effectively.

- Always ask about allergies to medications.

- Always ask the patients if they have had any significant adverse drug reactions.

- Always ask the patients if they have problems with being compliant with drug therapies.

- Always ask the patients for a complete drug history -- including OTC, topicals, herbals, alternative medicines, nutritional supplements, and homeopathic medications.

- Always provide written information that is at appropriate reading level.

- Have the patients recite back instructions and encourage patients to ask questions about their drug therapy.

- Always assure patient understanding of proper drug preparation and storage.

- Provide complete drug administration schedules that are clear and minimize number of times medications must be taken, reduce chance for drug-drug and drug-food interactions, and match patient lifestyle needs.

- Be sure patients know who to call when questions or problems arise with drug therapy.

- Fully investigate all patient concerns about drug therapy.
Appendix X  Suggested protocol for Handling of Dispensing Errors

Suggested Protocol for Handling of Dispensing Errors

1. **Patient/agent alleges dispensing error**
   - Compare contents of medication container with drug name on prescription label

2. **Discrepancy identified**
   - If patient/agent is present, escort to private area of pharmacy
     - Inform patient/agent that a dispensing error has taken place. Offer a sincere apology
     - Establish if drug has been ingested

3. **Drug ingested**
   - Establish risk from ingestion to patient (number of doses ingested. Contact Poison Information Centre if necessary
     - **High Risk**
       - Refer to physician and/or hospital emergency department
     - **Low Risk**
       - Reassure patient/agent (Notify prescriber if necessary)

4. **Advising patient/agent that incident will be investigated**
   - Investigate cause of error (Use OCP Incident Form)
   - Develop action plan to prevent future errors
   - Discuss with entire dispensing staff
   - Advise patient/agent of action taken (verbally and/or in writing)

5. **No discrepancy**
   - Compare original prescription with label for drug name, dosage form, strength, quantity and directions

6. **Drug not ingested**
   - Reassure patient/agent

In All Cases, the Pharmacist Should Deal with the Situation