Prioritizing Patient Safety: A Practical Approach

Donna Horn, MS, RPh, DPh
DeAnna (Dixie) Leikach, RPh, MBA, FACA
Disclosures

Donna Horn reports no actual or potential conflicts of interest associated with this presentation.

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CPE Information

- Target Audience: Pharmacists and Pharmacy Technicians
- ACPE#: 0202-0000-19-043-L05-P/T
- Activity Type: Application-based
Learning Objectives

At the completion of this application-based activity, participants will be able to:

1. List the ethical principles recognized as relevant to pharmacy practice.
2. Recite historical examples of patient harm caused by poor ethics.
3. Describe how ethics prioritize patient safety.
4. Identify methodologies and practical steps that will help develop your team’s awareness of patient safety and prevention of medication-related incidents.
5. Develop appropriate responses to address patients’ concerns when errors having the potential of jeopardizing their safety occur.
Assessment Questions

1. If a patient needs to be notified of an error

   A. Focus on how to correct the error for the patient and assure them that efforts will be made to reduce the risk of a similar error occurring in the future.
   B. Respond to the discrepancy only after you have completed a full investigation.
   C. Do not try to remedy the immediate situation until the corporate risk department has been notified.
   D. Tell the patient not to worry, everything will be OK.
Assessment Questions

2. You are a staff pharmacist for a pharmacy that provides LTC services. You provide dispensing and consulting services for your facilities.

During a routine consulting appointment, you discover late in the month that a dispensing error occurred but none of the nursing staff noticed the mistake.

You have checked the patient’s chart and there has not been any change in patient’s condition, demeanor or labs.

What do you do?
2. Question continued..

A. Make no changes at the home site, report to the owner when you return to the pharmacy and double check the next month’s batch that hasn’t left the pharmacy yet.

B. Notify the director/nurse on staff at the home, take the medication back with you to the pharmacy and fix/have redelivered. Don’t tell anyone because you don’t want anyone to get fired.

C. Notify the director/nurse on staff at the home, take the medication back with you and redeliver correct, document incident according to your pharmacy’s policy and procedures.

D. Discipline the nursing staff for being incompetent for not discovering the error on their own.
Assessment Questions

3. The Drug Quality and Security Act was enacted and fast-tracked because:

A. The Government wanted to make life more difficult for health-care workers.
B. In 2012, pharmacy staff was found to be unethical in their compounding practices, which caused the deaths of 76 people and sickened over 700.
C. The FDA needed a project to work on.
D. A mass poisoning occurred in 1937 due to a chemist that added anti-freeze to a medication to make it into a liquid.
4. The ethical principle of doing no harm, based on the Hippocratic maxim *primum non nocere*, is the definition for which term?

A. Beneficence
B. Nonmaleficence
C. Justice
D. Veracity
Assessment Questions

5. The second pharmacist final checking a prescription notices that the bottle pulled for dispensing has actually expired. She decides to properly dispose of the medication stock instead of dispensing. This is an example of which ethical principle in practice?

A. Beneficence  
B. Autonomy  
C. Justice  
D. Veracity
Pharmacy Ethical Principles

How are these determined?

What does this have to do with me?

Who cares?
APhA Code of Ethics

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

Adopted by the membership of the American Pharmacists Association October 27, 1994.

https://pharmacist.com/code-ethics accessed 1/15/2019
I. A pharmacist respects the covenantal relationship between the patient and pharmacist.

Considering the patient-pharmacist relationship as a covenant means that a pharmacist has moral obligations in response to the gift of trust received from society. In return for this gift, a pharmacist promises to help individuals achieve optimum benefit from their medications, to be committed to their welfare, and to maintain their trust.
II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.

A pharmacist places concern for the well-being of the patient at the center of professional practice. In doing so, a pharmacist considers needs stated by the patient as well as those defined by health science. A pharmacist is dedicated to protecting the dignity of the patient. With a caring attitude and a compassionate spirit, a pharmacist focuses on serving the patient in a private and confidential manner.
APhA Code of Ethics

III. A pharmacist respects the autonomy and dignity of each patient.

A pharmacist promotes the right of **self-determination** and recognizes individual self-worth by encouraging patients to participate in decisions about their health. A **pharmacist communicates with patients in terms that are understandable**. In all cases, a pharmacist respects personal and cultural differences among patients.
IV. A pharmacist acts with honesty and integrity in professional relationships.

A pharmacist has a duty to tell the truth and to act with conviction of conscience. A pharmacist avoids discriminatory practices, behavior or work conditions that impair professional judgment, and actions that compromise dedication to the best interests of patients.
V. A pharmacist maintains professional competence.

A pharmacist has a **duty to maintain knowledge and abilities** as new medications, devices, and technologies become available and as health information advances.
VI. A pharmacist respects the values and abilities of colleagues and other health professionals.

When appropriate, a pharmacist asks for the consultation of colleagues or other health professionals or refers the patient. A pharmacist acknowledges that colleagues and other health professionals may differ in the beliefs and values they apply to the care of the patient.
VII. A pharmacist serves individual, community, and societal needs.

The primary obligation of a pharmacist is to individual patients. However, the obligations of a pharmacist may at times extend beyond the individual to the community and society. In these situations, the pharmacist recognizes the responsibilities that accompany these obligations and acts accordingly.
VIII. A pharmacist seeks justice in the distribution of health resources.

When health resources are allocated, a pharmacist is fair and equitable, balancing the needs of patients and society.
Ethical Theories

• **Normative** ethics describe which moral standards SHOULD be accepted.

What the profession determines is acceptable. May vary based on the type of normative ethical theory the individual “subscribes” to. Makes it difficult for an individual to determine the “right” decision.

Ethical Theories

- **Nonnormative** ethics describe which moral standards are CURRENTLY accepted.

What society expects of our profession. Determined by professional associations’ Codes of Ethics, Regulatory Boards/Agencies, published articles, etc.

Fidelity –
Loyalty to the Patient
”Primary Obligation”
Pharmacy Ethical Principles

Nonmaleficence – First Do No Harm
Beneficence –
Do the Most Good
Justice –

Everyone is Treated Equally
Veracity – Tell the Truth
Pharmacy Ethical Principles

Autonomy – Final Control over Health Care Decisions
Pharmacy Ethical Principle - Regulations

- 1938 Food, Drug, and Cosmetic Safety Act
- 1987 Prescription Drug Marketing Act
- 1996 Health Insurance Portability and Accountability Act (HIPAA)
- 1970 Controlled Substance Act
- 1990 Omnibus Budget Reconciliation Act
- 2013 Drug Quality and Security Act

WHAT’S NEXT?
Pharmacy Ethical Principles

What happens when principles collide?

- The lowest level of breach is consistent with the goal of the action
- Provide proper justification
- The proposed action is expected to succeed
- There are no alternative measures available
- There is a minimization of the adverse effects
- All involved are treated with justice
- What would those around you “expect”? 
There Seems to be a Mistake with My Prescription
Ethical Principles Breached?

Non-Maleficence → Beneficence → Veracity → Justice → Autonomy → Loyalty
### Wrong Strength

<table>
<thead>
<tr>
<th>Pharmacist was not very apologetic</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Did not tell patient what he gave her</td>
<td>Told her to bring it in and he would exchange it</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Took wrong dose and hallucinated</th>
<th></th>
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<tbody>
<tr>
<td>Not able to function and slept most of the day</td>
<td>Called the pharmacy and told them</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dispensed amitriptyline 200 mg not 20 mg</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Assumed change in the way it looked because it was generic</td>
<td>On medication for years for migraine prevention</td>
</tr>
</tbody>
</table>

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*Dispensed amitriptyline 200 mg not 20 mg*
Ethical Principles Breached?

Non-Maleficence → Beneficence → Veracity → Justice → Autonomy → Loyalty
Pharmacy left several messages to pickup filled Rx

Curious, I called them back and got the name of the Dr's office, which turned out to be a Woman's Health center

Was someone using my identity?

Same name, date of birth, different middle name

Pharmacy had originally filled the prescription under my name incorrectly

Nonchalant: as if this happens all the time!
Ethical Principles Breached?

Non-Maleficence → Beneficence → Veracity → Justice → Autonomy → Loyalty
• 51 year old woman was dispensed sertraline 100 mg instead of Synthroid® 100 mcg

• Label stated Synthroid® and that it should be round yellow tablet
  • It looked very similar to Synthroid®
  • History of this pharmacy dispensing different generics to her

• Became ill with various gastrointestinal (GI) symptoms including diarrhea after taking it for 4 days
Sertraline vs Synthroid®

https://pillbox.nlm.nih.gov/pillimage/search

https://fdb.rxlist.com/drugs/
Cover Up?

• Pharmacist told her that the National Drug Code (NDC) was the pill imprint number and that “different manufacturers use the same NDC and that this was just a different form of Synthroid® she was reacting to”

• Pharmacist said error was impossible because the pills are filled by a machine

• Pharmacist told her to take Tylenol
  • Has listed allergy to acetaminophen on profile
Adequate Pharmacy Response?

• Pharmacy offered to refund her co-payment and a $35 gift card

• Extremely offended by the pharmacist for not taking her or this error and her symptoms seriously

• Consumer is NOT interested in the money and concerned with the ethical implications of the denial of error and not telling her truthful information. Her goal: to help implement quality procedures at this pharmacy by bringing attention to this mistake

• Patient demanded an incident report be completed and wanted a copy for her records - Store manager said “no”. Corporate manager would call and “read” her the report
Ethical Principles Breached?

- Non-Maleficence
- Beneficence
- Veracity
- Justice
- Autonomy
- Loyalty
Certainly, these are not unusual stories.

When a patient or caregiver thinks a mistake has been made and brings it to your attention, what do you do?

How do you respond?

Does your organization have a policy for how to handle these situations?

All alleged errors or incidents should be handled by a pharmacist, with professionalism, courtesy, and empathy.

The following recommendations will help the pharmacist remain calm and reassured when dealing with a possible incident.
Have written procedures for handling medication errors

These procedures need to be seen, read and understood by every member of the pharmacy team

Reviewed regularly for appropriateness to the specific workplace

Updated to reflect changes in workflow and additions of technology

Contain guidance about what to say and do and, what not to say or do

How to Respond when a Medication Error Occurs
When an Error Occurs: Follow Policy

Policy Principles

• Define staff roles in response to a possible or actual medication error
• Description of how staff should respond to a patient’s questions about what she may assume is an error in dispensing
• Define how management should respond and investigate the cause of an error
Policy Guidelines (cont.)

- Define when others (e.g., prescriber) should be notified of an error
- Assure the patient reporting a potential or actual error that it is important and a priority
- Whether the error is obvious or still a remote possibility, respond to the discrepancy immediately
- Remedy the immediate situation with truth and honesty
- Be direct and open with the patient reporting the error
- Goal is to minimize any negative impact to the patient
Sample Responses

“Please let me explain what we believed happened and how we plan to fix it”

“At this point I can’t answer how this happened, but I promise you I will look into it and get back to you.”
Document and report the event and response

- Document the date, time, and specifics of the event
- Report the event using the pharmacy’s internal reporting system
- Notify supervisors, risk management, and the prescriber when necessary
- Make a note in the patient’s profile so that staff is aware, especially when the patient returns to the pharmacy
When an Error Occurs: Notify the Patient

• What would you do in this situation?
  • Soon after a patient leaves the pharmacy, it is discovered that she received the wrong medication
  • The patient must be contacted immediately to have the wrong medication returned to the pharmacy and have the error corrected
Ethical Principles Breached?

Non-Maleficence → Beneficence → Veracity → Justice → Autonomy → Loyalty
Use Effective Communication

**Don’t**
- Panic
- Blame
- Provide information that you are unsure of

**Do**
- Stay calm
- Be polite and professional
- Be honest
- Be sincere
“Mr. Brown, this is Donna from Family Pharmacy.

I am calling because it came to our attention that you went home with someone else’s medication.

We would like you to come to the pharmacy as soon as possible so we can make sure you have the correct medication.

We are very sorry for the mistake, and we are already looking into ways to prevent this from happening again.”
When the Patient Says, “You Made Mistake!”

• Have the conversation in a private area
• Thank the patient for bringing the error to your attention
• Acknowledge the patient’s efforts for taking part in medication safety
• Listen attentively to the patient, without interrupting and without distractions
• Allow the patient the time they need to express their feelings.
• Show concern, and empathize
• Agree if appropriate, but don’t argue if you disagree
Common Mistakes to Avoid

**Making Excuses**
- Do not say how busy you are
- Staffing problems or other factors

**Speculation**
- Do not try to guess what happened
- Most errors have a number of contributing factors that need to be thoroughly investigated

**Blaming**
- Do not blame the prescriber or your staff members
- Do not blame circumstances
Common Mistakes to Avoid

**Blaming the patient**
- Do not find a way to make the patient responsible for the error e.g., being in a hurry, not checking their medication

**Admitting Fault**
- When an error first comes to your attention, it is too soon to determine all the factors involved in the error
- Explain that a complete investigation will be done
More Common Mistakes to Avoid

Over-agreeing

• Agreeing with everything the patient says, even if you disagree
• Say, “I am sorry you feel that way.”

Making false promises

• Assure the patient that you will work toward making changes that will reduce the risk of this happening again.
• Do not promise compensation or any other action from your employer.
ETHICS Discussion

Why are these “mistakes” to avoid?
Policy Guidelines (cont.)

Establish a Continuous Quality Improvement (CQI) program

- Detect, document, and assess errors
- Determine the cause
- Develop an appropriate response
- Prevent future errors

Follow up and alert staff to the situation

- Support staff involved in the incident
- Employee assistance programs
All staff must bring an error to the attention of the pharmacist immediately, before engaging the patient.

Each staff member involved in the error should be made aware of the incident privately and in a nonjudgmental manner.

Ask staff about factors that may have contributed to the error; ask for suggestions for practical ways to prevent future errors.
When an Error Occurs: Interviewing Staff Involved

- Do not address the person involved in the error in a public place. Avoid negative body language or accusatory words.
- Ask open-ended questions and take notes.
- Prepare for the person to be emotional when discussing the situation.
- Remind the individual that everyone makes mistakes; no one is perfect.
Communicating with Staff

• **Immediate feedback**

  “Bill, Mr. John Brown was given Mr. John Browne’s prescription in error. Please always ask and confirm the patient’s date of birth before ringing up the sale.”

• **Delayed, problem-solving feedback**

  “Bill, I appreciate your efforts to keep up with the high prescription volume and long pick up lines but accuracy is of utmost importance. Please give some thought about what we can do to make sure prescriptions are dispensed correctly. It is our responsibility to make sure we do our best to prevent harm. I will ask others to do the same thing and I want us to discuss some possible strategies the next time we have CQI meeting.”
## Investigative Techniques

<table>
<thead>
<tr>
<th>Start investigation as soon as possible</th>
<th>Devise a strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>• People forget</td>
<td>• Remain calm and focused</td>
</tr>
<tr>
<td>• Hindsight bias sets in</td>
<td>• Gather the facts before people forget and/or physical evidence is lost</td>
</tr>
<tr>
<td></td>
<td>• Identify who you need to talk to and organize your questions. You want to approach people only once.</td>
</tr>
<tr>
<td></td>
<td>• Review and store any physical evidence</td>
</tr>
</tbody>
</table>
“I hope it wasn’t me who made the mistake.”

“Not my responsibility; I’m only a fill in for the sick pharmacist.”
Ethical Principles Breached?

- Non-Maleficence
- Beneficence
- Veracity
- Justice
- Autonomy
- Loyalty
Review Evidence

https://www.thehealthscience.com/topics/

Results of Interviewing Staff

Quantity prescribed 720 mL

Dispensed 480 mL stock bottle PLUS 240 mL “overflow” in brown rx bottle

Valproic Acid stock bottle by Qualitest incorrectly stocked behind open Lactulose (also by Qualitest) stock bottle

Bar code scanner only able to scan one stock bottle
When an Error Occurs: Follow Up

Contacting prescribers

• Ex: Patient received the wrong medication for a month before the error was discovered on a refill

• Provide organized, concise and accurate information to the prescriber using the SBAR approach
Response Tool

• **S**ITUATION What has happened? Be specific.

• **B**ACKGROUND Explain circumstances leading up to this situation.

• **A**SSESSMENT What do you think the problem is? What is concerning you?

• **R**ECOMMENDATION What do you need? What would you do to correct the problem?

http://www.ihi.org/resources/Pages/Tools/SBARToolkit.aspx
## SBAR Explained

<table>
<thead>
<tr>
<th>Situation</th>
<th>Background</th>
<th>Assessment</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| • Identify the person to whom you are speaking  
• Identify yourself, occupation and where you are calling from  
• Identify the patient by name, age, sex, reason for call  
• Identify what is going on with the patient (wrong medication, wrong strength, etc.) | • Give the patient's status  
• Give the patient's relevant past medical history  
• Brief summary of background | • List if any vital signs that are outside of parameters; what is your clinical impression  
• Vital signs: heart rate, respiratory rate, blood pressure, glucose level, pain scale, level of consciousness  
• Severity of patient, additional concern | • Explanation of what you require, how urgent and when action needs to be taken  
• Make suggestions of what action is to be taken  
• Clarify what action you expect to be taken |
Case Study

http://tristatesurgical.com/insulin-lantus-vial-100uml-p-191172.html

https://www.goodrx.com/apidra/images
SBAR Case Study

• **Situation:** Dr. Jones this is Donna, the pharmacist from Family Pharmacy; John Brown, a male patient with date of birth 8/21/59 self-injected Lantus® instead of Apidra®

• **Background:** In error JB received 4 boxes of Lantus®, 3 were labeled as Apidra®; self injected Lantus® 4 times per day

• **Assessment:** Patient feeling dizzy and weak with profuse sweating; blood sugar 57 mg/dL

• **Recommendation:** Correct error; monitor blood glucose levels; drink orange juice to increase blood glucose level and resolve current symptoms
Audience Participation Time

- **S** SITUATION  What has happened? Be specific.
- **B** BACKGROUND  Explain circumstances leading up to this situation.
- **A** ASSESSMENT  What do you think the problem is? What is concerning you?
- **R** RECOMMENDATION  What do you need? What would you do to correct the problem?
How does SBAR help cover Ethical Principles?
Choose One Case per Table

While entering the lot number of the vaccine into the registry, RPh notices she administered Adacel® (Tdap) instead of Daptacel® (DTaP) to a 5-year-old patient. The patient is still in the pharmacy. So close....

A patient brings his medication bottle to the pharmacy for a refill. You realize Aripiprazole 20 mg was ordered (label correct) but 5 mg was dispensed. His bottle is empty. OOPs....
Tdap instead of DTaP

- S
- B
- A
- R

**Also** - What is the most ethical way to initially handle this situation and which ethical principle(s) are most relevant?

Person who woke up the **earliest** this morning is the reporter for the group
Aripiprazole 20 mg v 5 mg

S
B
A
R

Person who woke up the latest this morning is the reporter for the group

Also - What is the most ethical way to initially handle this situation and which ethical principle(s) are most relevant?
When communicating with a patient that may have been involved with an incident:

• Give the situation your undivided attention
• Introduce yourself to the patient/caregiver
• Speak slowly and calmly
• Offer a sincere apology for the distress they are experiencing in regard to the accuracy of their prescription without admitting fault
“It is not uncommon for a patient who has been the subject of a pharmacy error to say, ‘I know that mistakes happen. What upsets me is not so much that the error occurred but that the pharmacist didn’t seem to care when I pointed out the error and asked for help’.”

-D.B. Brushwood
Assessment Questions

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