Medication Errors, Pharmacy-Related Crimes and the Opioid Overdose Epidemic

Kris Mossberg, State Drug Inspector

- Critical in preventing future medication errors
- Most Boards of Pharmacy require hospital & medical facilities (including pharmacies) to report med errors
- NMBOP requires reporting of significant adverse drug events

16.19.25 ADVERSE DRUG EVENT

- Incident - a drug that is dispensed in error, that is administered and results in harm, injury or death
- Harm - temporary or permanent impairment requiring intervention

The Pharmacist in Charge shall:
A. Develop and implement written error prevention procedures as part of the Policy and Procedures Manual.
B. Report incidents, including relevant status updates, to the Board on Board approved forms within fifteen (15) days of discovery.

The Board shall:
A. Maintain confidentiality of information relating to the reporter and the patient identifiers.
B. Compile and publish, in the newsletter and on the Board web site, report information and prevention recommendations.
C. Ensure reports are used in a constructive and non-punitive manner.

Prospective drug review

(1) Prior to dispensing any prescription, a pharmacist shall review the patient profile for the purpose of identifying:
(a) clinical abuse/misuse;
(b) therapeutic duplication;
(c) drug-disease contraindications;
(d) drug-drug interactions;
(e) incorrect drug dosage;
(f) incorrect duration of drug treatment;
(g) drug-allergy interactions;
(h) appropriate medication indication.

Source: NMAC 16.19.4.16 (D)

ONLY THE RPh CAN COUNSEL

All clerks and technicians are taught that if there is a question regarding a prescription, the RPh (or intern) must take the question.
Patients need to know:
- The name of the medication
- How to take it
- What it's for
- If the medication looks different, talk to the pharmacist

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm096403.htm accessed 6/3/16

Estimate: half of medication-related deaths could have been prevented by appropriate and timely counseling. *

Show the patient the drug while asking:
1) Tell me what you take this drug for?
2) Tell me how you take the medication? - how often, and - directions for taking the medication

http://www.uspharmacist.com/continuing_education/ceviewtest/lessonid/105916


Patients provide a major safety check
- Counseling – not a “veiled offer”
- Wrong patient errors: Not opening the bag at the point of sale
- Risk of dispensing a correctly filled Rx to the wrong patient at POS – about 6 per month per (community) pharmacy


To Err is Human
Building a Safer Health System
- the majority of medical errors are caused by faulty systems, processes, and conditions that:
  * lead people to make mistakes
  * fail to prevent mistakes
When an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

When an error occurs
- Be compassionate
- ISMP persistent safety gaffe #4 – respond with empathy and concern
- Evaluate and address medication use system issues
- Root cause analysis

Root cause analysis (RCA):
- Process for identifying the basic or causal factors that underlie variation in performance, including the occurrence or risk of occurrence of a sentinel event.
- Focus is on systems and processes, not individual performance
- Identifying root causes illuminates significant, underlying, fundamental conditions that increase the risk of adverse consequences.
- RCA facilitates system evaluation, analysis of need for corrective action, tracking and trending
Case Study:
- Patient experienced sudden shortness of breath, chest pain (breathing worsened pain), dizziness, lightheadedness, anxiety and heart palpitations.
- Patient went to ER, treated for a submassive pulmonary embolism.
- Admitted and Discharged after 5 days with prescriptions for atorvastatin 80 mg, Toprol XL 25 mg, lisinopril 5 mg and apixaban (Eliquis) 5 mg.
- Hospital sent Rxs electronically to pharmacy.

Case Study continued:
- Pharmacist dispensed medications and counseled patient.
- Patient received an automated message that a prescription was ready 5 days later.
- Went to pharmacy and received apixaban prescription. Claimed not aware of apixaban Rx.
- Physician upset and contacted pharmacy about delay. RPh said did not dispense apixaban because did not have full quantity to fill Rx and patient said he would wait.

Pharmacist's actions appropriate? Was this a misfilled prescription?
- Does patient have enough knowledge of medications to know which are critical? What does the pharmacist have?
- Pharmacist's other options.
  - Partial fill...what else?

New England Compounding Center (NECC) – Framingham, Massachusetts

- 753 patients were diagnosed with fungal meningitis after receiving injections of NECC's preservative free MPA (methylprednisolone acetate). Out of 753 patients 54 patients in nine states died.
- December 17, 2014 – United States attorney’s office charged owner and head pharmacist Barry J. Cadden, and Glenn A. Chin, a supervisory pharmacist, with 25 acts of second-degree murder in seven states.
- Twelve other individuals, all associated with NECC, were charged with additional crimes including racketeering, mail fraud, conspiracy, contempt, structuring, and violations of the Food, Drug and Cosmetic Act. (6 other pharmacists, 2 owners and 1 unlicensed technician).

https://www.cdc.gov/hai/outbreaks/clinicians/index.html
Cadden directed and authorized the shipping of contaminated MPA to NECC customers nationwide — before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients.

CDC identified 18 different types of fungi from MPA vials and patient samples. In the words of one public health official, NECC was a “fungal zoo.”

Cadden directed and authorized the shipping of contaminated MPA to NECC customers nationwide — before test results confirming their sterility were returned, never notified customers of nonsterile results, and compounded drugs with expired ingredients.

In fact, NECC routinely dispensed drugs in bulk without valid prescriptions. NECC even used fictional and celebrity names on fake prescriptions to dispense drugs, such as “Michael Jackson,” “Freddie Mae” and “Diana Ross.”

Chin improperly sterilized the MPA, failed to verify the sterilization process, and improperly tested it to ensure sterility. Despite knowing these deficiencies, Chin directed the MPA to be filled into thousands of vials and shipped to NECC customers nationwide.

Chin directed the shipping of drugs prior to receiving test results confirming their sterility, and he directed NECC staff to mislabel drugs to conceal this practice. He also directed the compounding of drugs with expired ingredients, including chemotherapy drugs that had expired several years prior. Chin forged cleaning logs and routinely ignored mold and bacteria found inside the clean rooms.

Head Pharmacist — Barry Cadden

• March 22, 2017 — Cadden convicted of racketeering, conspiracy, mail fraud and introduction of misbranded drugs into interstate commerce. Acquitted of murder charges.
• June 26, 2017 - Cadden sentenced to 9 years in prison

https://www.fda.gov/ICECI/CriminalInvestigations/ucm564768.htm

Supervisor RPh — Glenn Chin

October 25, 2017, Chin was convicted of racketeering, racketeering conspiracy, mail fraud and false labeling. Acquitted of 2nd degree murder also.

On January 31, 2018, Chin was sentenced to 8 years in prison, two years of supervised release, and forfeiture and restitution in an amount to be determined later.

https://www.fda.gov/ICECI/CriminalInvestigations/ucm564768.htm

FDA Guidance — Insanitary Conditions

• Putting on gowning apparel in a way that may cause the gowning apparel to become contaminated
• Leaving the cleanroom and re-entering from a non-classified area without first replacing gowning apparel
• Performing aseptic manipulations outside of a certified ISO 5 area
• Failing to disinfect containers of sterile drug components or supplies immediately prior to opening
• Lack of adequate routine environmental monitoring - nonviable airborne particulate sampling; viable airborne sampling; and surface sampling, including but not limited to equipment, work surfaces, and room surfaces
**Insanitary Conditions - Continued**

- Lack of adequate personnel sampling (including glove fingertip sampling)
- Lack of routine certification of the ISO 5 area, including smoke studies performed under dynamic conditions
- Lack of HEPA-filtered air, or inadequate HEPA filter coverage or airflow, over the critical area
- Buffer room or ISO 5 areas that contain overhangs or ledges capable of collecting dust (pipes and window sills)
- Failing to appropriately and regularly clean and disinfect (or sterilize) equipment located in the ISO 5 area
- Lack of disinfection of equipment and/or supplies at each transition from areas of lower quality air to areas of higher quality

**Serious condition - HFS recommendation includes immediate recall and cease sterile operation**

- Vermin (e.g., insects, rodents) or other animals (e.g., dogs) in ISO 5 areas or areas immediately accessible to production
- Visible microbial growth (e.g., bacteria, mold) in the ISO 5 area or in immediately adjacent areas
- Sources of non-microbial contamination in the ISO 5 area (e.g., rust, glass shavings, hair, paint chips)
- Performing aseptic manipulations outside of a certified ISO 5 area
- Personnel aseptic practices that are a contamination hazard to an exposed sterile drug product or its constituent sterile components
- Exposing sterile drugs and materials to lower than ISO 5 quality air for any length of time (e.g., exposing partially stoppered drug products or stock solutions in a container/closure system that is not fully closed)

**Rogue Online Pharmacies**

- Consumer protection program operated by NABP
- Only 5% of 12,000 online pharmacies reviewed by NABP are in compliance with US pharmacy laws and practice standards
- Rogue online drug sellers put consumers at risk:
  - Fillers used: dry wall and rat poison
  - Consumer’s financial and personal information stolen
  - Spam mail infect home computers with viruses
  - Counterfeit medications did not treat their medical condition and patients have died

**The Internet Pharmacy Market in 2016**

- Trends, Challenges, and Opportunities

- Every day, illicit online pharmacy operators create approximately 20 new websites worldwide.
- Of 30,000 to 35,000 illicit online pharmacies, 96% (globally and in the US) fail to adhere to applicable legal requirements.
- 92% of those operating illegally are doing so in a blatantly illicit manner — e.g., as the sale of prescription drugs without a valid prescription.
- Among the 92% of “blatantly illicit” online pharmacies, about 9% are selling controlled-substance prescription drugs
India was the most common point of origin for the drug shipments. Other countries included Germany, Singapore, the US, Canada, and the UK, although they were not always the original source of the drugs.

- EVApharmacy, the largest illegal online pharmacy network, has from 3,000 to 10,000 online pharmacies at one time that sell prescription drugs without a prescription. They persuade customers that it is a safe Canadian online pharmacy but is primarily run out of Russia and Eastern Europe.

  Reynolds Drug
  - EVApharmacy hijacked a website previously operated by a real pharmacy (Reynolds Drug in South Carolina): reynoldsdrug.com, which retained the pharmacy’s address and branding.
  - Orders placed on the website are filled by EVApharmacy with drugs being shipped from Pakistan and China.

**VIPPS Accredited Pharmacies**

- Verified Internet Pharmacy Practice Sites (VIPPS) enables consumers to confidently access legitimate internet pharmacies.

**Diversion**

- **What is diversion?**
- **Definition:** Transfer of a prescription drug from a lawful to an unlawful channel of distribution or use.
**Who Diverts Drugs?**

- **Doctor Shoppers** – Person who visits several different practitioners (ERs, Clinics and pharmacies) and fakes illnesses which are usually treated with a controlled substance

- **Professional Patients** – Use genuine illnesses or an obvious physical deformity to convince physicians to prescribe controlled substances

- **Chemically Dependent Patients** – Compulsive users who hoard a supply for fear of running out/withdrawal. Less likely to sell drugs on street but seek out substitute doctors in case they get cut off by their current doctor

- **Impaired Professionals**
  - Physicians, nurses, pharmacists
  - Almost 50% of all diversion cases involve healthcare professionals (National Association of Drug Diversion Investigators)
  - Either divert drugs to:
    - Maintain their chemical dependence
    - Sell on black market for monetary gain

- **Preventing/Catching Forgeries**
  - **Tamper-/Copy-Resistant Rx Pads**
    - Holograms (similar to those on credit cards)
    - Copy-resistant paper (micro printing)
    - "VOID" appears when prescription is copied
  - **Thermo-chromic ink** ("disappearing Rx"

- **PMP**
  - A RPh shall request and review a PMP report if (at least 1 year time period):
    - PERSON EXHIBITS POTENTIAL ABUSE/MISUSE OF OPIATES
      - OVER-UTILIZATION
      - EARLY REFILLS
      - MULTIPLE PRESCRIBERS
      - SEDATED/INTOXICATED
      - UNFAMILIAR PATIENT
      - PAYING CASH INSTEAD OF INSURANCE
PMP

• A RPh Shall request and review a PMP report if (at least 1 year time period):
  • OPIATE Rx FROM UNFAMILIAR PRACTITIONER
    • OUT OF STATE OR USUAL GEOGRAPHIC AREA
  • OPIATE Rx FROM UNFAMILIAR PATIENT
    • OUTSIDE USUAL PHARMACY GEOGRAPHIC PATIENT POPULATION AREA

PMP

• A RPh Shall request and review a PMP report if (at least 1 year time period):
  • INITIAL RX FOR ANY LONG-ACTING OPIOID FORMULATION
    • INCLUDES ORAL AND TRANSDERMAL DOSAGE FORMS
  • BECOME AWARE PATIENT IS RECEIVING AN OPIOID CONCURRENTLY WITH A BENZODIAZEPINE OR CARISOPRODOL

  • PMP reports shall be reviewed a minimum of once every three months during the continuous use of opioids for each established patient

FORGERIES

• WHAT ARE THE FOLLOWING PRESCRIPTIONS?
  • STOLEN Rx FORMS
  • PHOTOCOPIED/SCANNED PRESCRIPTIONS
  • COMPUTER GENERATED PRESCRIPTIONS

Pharmacy Robberies

Albuquerque

• April 29, 2015 - Six Albuquerque Residents Indicted on Federal Robbery, Firearms, and Prescription Drug Trafficking Crimes Arising Out of Pharmacy Robberies - FBI.gov
  • 3 fugitives at time of indictment
  • Last suspect (Blake Gallardo) was arrested June 11, 2015
  • Stole over 68,000 tablets of oxycodone

Pharmacy Safety

• Train employees and new hires
• Have procedures for a robbery in progress – Post for pharmacy staff
• Awareness: develop an early warning system to alert pharmacy employees to a suspicious individual
**CCTV / Surveillance**
Cameras reassigned to give a better angle of view
- Bring cameras to eye level
- Install eye level entrance and exit cameras

**Barriers**
- Ensure good physical barriers between the robber and pharmacy personnel.
- Clear the line of sight to the pharmacy
- Convex mirrors to allow line of sight to blind spots around the pharmacy

**What to Do During a Robbery**
- Cooperate fully with the robber
- Do not argue or make insulting comments
- Do not attempt to thwart the robbery or apprehend the criminal yourself
- Do exactly what you are told to do, nothing more and nothing less
- Try to remain calm and avoid sudden movements that might cause further conflict
- Try to notice identifiable aspects of the robber: race, gender, age, size, build, SMTI’s, clothing

**Evidence**
- Preserve the crime scene if a robbery does occur.
- Don’t return robbery note or other evidence unless solicited.
After

- Call 911 immediately and stay on the phone until dispatchers allow you to get off the phone.
- Lock down the store.
- Stay calm, cooperate, and be a good witness.

Preserve evidence

- Preserve witness statements - have employees document the incident.
- DO NOT share events with each other, until Officers conduct interviews.

Burglaries in the Pharmacy

What to do if your pharmacy experiences a burglary/break-in:

- Call the local police immediately and preserve any evidence (do not start clean up until they give you clearance).
- Call the Drug Enforcement Administration (DEA) Albuquerque District Office at 505-452-4500, the day the burglary occurs.
- Do a complete CS inventory as soon as the police are done with their work.
- E-mail or fax a copy of the completed DEA Form 106 to the Board office after filling it with DEA.

RxPATROL.COM

Pharmacy Security Checklist

- Make a list of all controlled substances and keep it with you.
- Keep a copy of the DEA registration number handy.
- Secure all entrances and exits.
- Use security cameras and motion detectors.
- Install a security key card system.
- Lock the doors at night.
- Use a security company for added protection.
- Report any suspicious activity to the police.
- Keep a log of all incidents.

RxPATROL.COM

North Dakota BOP Newsletter Dec. 2013
Robbery Awareness Training

APD Offered Training
Robbery Awareness Training
Sergeant Lowe
clowe@cabq.gov

Scam Phone Calls — BOP, DEA, FBI or other LE
• Callers identifying themselves as Board of Pharmacy Investigators, Inspectors or Agents
• Callers “spoofing” the Board of Pharmacy phone number
• Tells licensees they are under investigation and their license may be suspended or arrest warrant was issued and they demand money
• NMBOP will never contact licensees by telephone to demand money or payment of any form.

• Do not give them money!
• Do not give them any information!
• Contact an inspector or e-mail pharmacy.board@state.nm.us to inquire if there is an official investigation being conducted
• If the caller is stating they are from the DEA, you can report the scam using the DEA Extortion Scam Online Reporting Form
• If the caller is stating they are from the FBI, you can report the scam using the FBI Internet Crime Complaint Reporting Form
• If the phone number of the caller appears to be a New Mexico Board of Pharmacy telephone number, you can report the scam using the Federal Communications Commission Consumer Complaint Form

United States Prescription Opioid Overdose Epidemic
Figure 1. National Drug-Involved Overdose Deaths*, Number Among All Ages, by Gender, 1999-2019


Figure 2. National Drug-Involved Overdose Deaths*, Number Among All Ages, 1999-2019


RISE IN OPIOID OVERDOSE DEATHS IN AMERICA

A Multi-Layered Problem in Three Distinct Waves

1990s
- First wave of opioid overdose deaths
- Fentanyl
- Synthetic opioids

2010s
- Second wave of opioid overdose deaths
- Fentanyl
- Heroin

2013
- Third wave of opioid overdose deaths
- Fentanyl
- Heroin

Learn more about the rising opioid overdose crisis at: www.cdc.gov/drugoverdose

Overdose Death Rates Involving Opioids, by Type, United States, 1999-2019

Figure 3. National Drug Overdose Deaths Involving Any Opioid, Number Among All Ages, by Gender, 1999-2019

*Among deaths with drug overdose as the underlying cause, the any opioid subcategory was determined by the following ICD-10 multiple cause of death codes: natural and semi-synthetic opioids (T40.0-T40.9), methadone (T40.0), other synthetic opioids (other than methadone) (T40.1-T40.9), or heroin (T41.0-T41.9). Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2019. U.S. Department of Health and Human Services. Retrieved 6/18/2021.

FENTANYL: Overdoses On The Rise

Fentanyl is a synthetic opioid approved for treating cancer pain, such as advanced cancer pain. It is a stronger opioid than heroin and is 50-100 times more potent than morphine. It is said to be used in licit and illicit drug use. The DEA lists it as a Schedule II drug. The US government has issued a warning about its use. It is not legal to sell or distribute Fentanyl. It is also classified as a controlled substance. It has a street value of $1,000 per gram. The DEA has listed it as a Schedule II drug since 2016. The US government has issued a warning about its use. It is not legal to sell or distribute Fentanyl. It is also classified as a controlled substance. It has a street value of $1,000 per gram. The DEA has listed it as a Schedule II drug since 2016.
New Mexico Prescription Drug Overdose Epidemic

The State of New Mexico compared to the United States average:

- In 2016, New Mexico had the twelfth highest drug overdose death rate (25.2 deaths per 100,000 age-adjusted population).
- In 2017, New Mexico had the seventeenth highest drug overdose death rate (24.8 deaths per 100,000 age-adjusted population).
- In 2018, New Mexico had the sixteenth highest drug overdose death rate (26.7 deaths per 100,000 age-adjusted population).
- In 2019, New Mexico had the twelfth highest drug overdose death rate (30.2 deaths per 100,000 age-adjusted population).


Other States: WV, OH, PA, KY, NH, DE, MD, ME, MA, RI, CT, NJ, IN, MI, TN, FL
High Risk Prescribing Patterns

- Long term use of opioids (≥ 90 days)
- High doses of opioids (≥ 90 MME/day)
- Overlapping prescriptions of opioids from different prescribers
- Multiple Provider Episodes (MPE: Doctor and pharmacy shopping)
- The combination of opioids and sedative-hypnotics
- The combination of opioids, benzodiazepines and muscle relaxants

Prescription Drug Information and Statistics

In NM, the rate of Neonatal Abstinence Syndrome increased 324% between 2008 (3.3 per 1,000 livebirths) and 2017 (14.0). In the US, the rate increased by 207% between 2008 (2.6) and 2016 (8.6) (Figure 1).

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OPIOID OVERDOSE EPIDEMIC RESPONSE

Prescription Drug Abuse Prevention Plan

• expands upon the Administration's National Drug Control Strategy and includes action in four major areas to reduce prescription drug abuse:
  • Education
  • Tracking and monitoring
  • Proper medication disposal
  • Enforcement


Prescription Drug Abuse: Strategies to Stop the Epidemic

October 2013

Key recommendations
• Educate the public to understand the risks of Rx drug use to avoid misuse in the first place;
• Ensure responsible prescribing practices, including increasing education of healthcare providers and prescribers to better understand how medications can be misused and to identify patients in need of treatment;
• Increase understanding about safe storage of medication and proper disposal of unused medications, such as through "take back" programs;
• Make sure patients do receive the pain and other medications they need, and that patients have access to safe and effective drugs

http://healthyamericans.org/reports/drugabuse2013/

Teen Prescription Drug Abuse and Misuse

• 23% Report having abused Rx medications at least once in their lifetime.
• More than half of teens (73%) indicate that it's easy to get prescription drugs from their parent's medicine cabinet.
• Almost four in 10 teens (38%) who have misused or abused a prescription drug obtained it from their parent's medicine cabinet.


Past 30-day Painkiller Use to Get High Grades 9-12, New Mexico, 2007-2015
In 2001, New Mexico - first state to amend its laws to make it easier for medical professionals to provide naloxone, and for lay administrators to use it without fear of legal repercussions.

In 2007, New Mexico - first state to amend its laws to encourage Good Samaritans to summon aid in the event of an overdose. Provides criminal immunity for both the person in need and the person who sought help.

Source: Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws; The Network for Public Health Law May 2013

• March 2016, SB 262 / HB 277 signed into law: significantly expanded naloxone access (possess, store, distribute, prescribe, administer), NMSA 24-23-1

• Naloxone standing orders (issued NM DOH March 2016)

• Any person acting under a standing order issued by a licensed prescriber may store or distribute an opioid antagonist

• A licensed prescriber may directly or by SO prescribe, dispense, or distribute an opioid antagonist to (several categories)

Source: SB 262, HB 277; Legal Interventions to Reduce Overdose Mortality: Naloxone Access and Overdose Good Samaritan Laws; The Network for Public Health Law May 2013
