Combating the Opioid Epidemic: Perspectives from Three Institutions Fighting Battles in the War

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Objectives

1. Understand the scope and depth of the opioid crisis.
2. Describe federal and state law governing CII prescribing.
3. Review the role of pharmacists in the opioid crisis.
4. Introduce institution specific methods of addressing the opioid epidemic.
5. Apply knowledge of the opioid crisis to a patient case.
The Scope and Depth of the Opioid Epidemic
Two nurses died of overdoses inside a Dallas hospital. What went wrong?

Sue Ambrose and Holly K. Hacker

2017 National Survey on Drug Use and Health

- **11.4 million** people misused opioids in 2017
- **62.6%** indicated the main reason they misused opioids the last time was to relieve physical pain
- **53.1%** indicated that they obtained the last opioid they misused from a friend or relative
Past Year Opioid Misuse Among People Aged 12 or Older: 2017

- 11.1 Million People with Past Year Pain Reliever Misuse (97.2% of Opioid Misusers)
- 562,000 People with Past Year Pain Reliever Misuse and Heroin Use (4.9% of Opioid Misusers)
- 886,000 People with Past Year Heroin Use (7.8% of Opioid Misusers)
- 324,000 People with Heroin Use Only (2.8% of Opioid Misusers)
- 10.5 Million People with Pain Reliever Misuse Only (92.2% of Opioid Misusers)

11.4 Million People Aged 12 or Older with Past Year Opioid Misuse

2017 National Survey on Drug Use and Health. Available at http://www.samhsa.gov/data
Drug Related Deaths by Country

2015 Estimated Mortality Rate (per million persons aged 15-64)

- United States
- North America
- Oceania
- Africa
- Eastern and South-Eastern Europe
- Global
- Western and Central Europe
- Asia
- Latin America and Caribbean

National Trends in Opioid Abuse

Why are we talking about this?

- Every day **115 Americans** die from an opioid-related overdose
- **33,000+ Americans died** in 2015 as a result of opioid overdoses including prescription opioids
- Economic annual impact of prescription drug misuse estimated at **$78.5 billion**

Licit and illicit medications

- Overdoses include:
  - Prescription pain relievers
  - Heroin
  - Synthetic morphine derivatives (e.g., oxycodone, fentanyl, carfentanil)
- In 2017, 4.2% of 12th graders reported using narcotics other than heroin

3 Waves of the Rise in Opioid Overdose Deaths

Wave 1: Rise in Prescription Opioid Overdose Deaths
Wave 2: Rise in Heroin Overdose Deaths
Wave 3: Rise in Synthetic Opioid Overdose Deaths

### Increase in Drug Use from 2001 to 2014

<table>
<thead>
<tr>
<th>Drug Type</th>
<th>Increase</th>
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<tbody>
<tr>
<td>Cocaine</td>
<td>42% increase</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>500% increase</td>
</tr>
<tr>
<td>Prescription Opioids</td>
<td>340% increase</td>
</tr>
<tr>
<td>Heroin</td>
<td>600% increase</td>
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</tbody>
</table>

Trends in Texas

Rate of Opioid Related Overdose Deaths in Texas

Deaths, Age Adjusted Rate per 100,000 Persons

Source: CDC WONDER
Trends in Texas

Number of Opioid Related Overdose Deaths in Texas

Source: CDC WONDER
Federal and State Laws Governing CII Prescribing
Federal CII Prescription Requirements

① Dated and signed on the date issued by the prescriber
② Patient’s full name and address
③ Practitioner’s full name, address, and DEA number
④ Drug name
⑤ Strength
⑥ Dosage form
⑦ Quantity prescribed
⑧ Directions for use
⑨ Written in ink or indelible pencil, or typewritten
⑩ Prescribers must manually sign and date the prescription, but can delegate prescription preparations to other personnel

Other Requirements

**Federal**
- CII: no refills
- CII: no specified expiration date on prescription
- CIII-V: up to 5 refills within 6 months of date of issue

**Texas**
- CII: 21 day expiration
- Prescriber may issue multiple prescriptions to receive a 90 day supply of CII:
  - Earliest fill date indicated on each prescription

Title 6 Food, Drugs, Alcohol, and Hazardous Substances. TSBP website. [https://statutes.capitol.texas.gov/Docs/HS/pdf/HS.481.pdf](https://statutes.capitol.texas.gov/Docs/HS/pdf/HS.481.pdf)
CII in Emergencies

- Can be dispensed through an oral prescription
- Quantity must be limited
- Pharmacist must document the oral prescription and verify the identity of the prescriber
- Pharmacy must receive the written prescription within 7 days, and it must state on the face “Authorization for Emergency Dispensing” with the date of the oral order
- Pharmacists must notify the Drug Enforcement Administration if a prescriber fails to deliver the written or electronic prescription on time

CII Prescriptions: What Can Be Altered?

“DEA expects that when information is missing from or needs to be changed on a schedule II controlled substance prescription, pharmacists use their professional judgment and knowledge of state and federal laws and policies to decide whether it is appropriate to make changes to that prescription.”

Varies by state
Tips for Prescribers

- Keep all prescription blanks in a safe place where they cannot be stolen.
- Write out the actual amount prescribed in addition to giving a number to discourage alterations of the prescription order.
- Use prescription blanks only for writing a prescription order and not for notes.
- Never sign prescription blanks in advance.
- Assist the pharmacist when they telephone to verify information about a prescription order.
- Contact the nearest DEA field office (see Appendix E) to obtain or to furnish information regarding suspicious prescription activities.
- Use tamper-resistant prescription pads.

Naloxone Dispensing in Texas

**Rule 295.14**

A pharmacist may dispense an opioid antagonist under a valid prescription, including a prescription issued by a standing order, to:

A. a person at risk of experiencing an opioid-related drug overdose; or

B. a family member, friend, or other person in a position to assist a person
Naloxone Dispensing in Texas

Rule 295.14

A pharmacist who, acting in good faith and with reasonable care, dispenses or does not dispense an opioid antagonist under a valid prescription is not subject to any criminal or civil liability or any professional disciplinary action for:

A. dispensing or failing to dispense the opioid antagonist; or

B. if the pharmacist chooses to dispense an opioid antagonist, any outcome resulting from the eventual administration of the opioid antagonist.

Methadone & Buprenorphine: “The Three Day Rule”

Title 21, Code of Federal Regulations, Part 1306.07

Allows a practitioner who is not separately registered as a narcotic treatment program, to administer (but not prescribe) narcotic drugs to a patient for the purpose of relieving acute withdrawal symptoms while arranging for the patient’s referral for treatment, under the following conditions:

1. Not more than one day’s medication administered or given to a patient at one time
2. This treatment may not be carried out for more than 72 hours and;
3. This 72-hour period cannot be renewed or extended

Methadone & Buprenorphine: “The Three Day Rule”

Title 21, Code of Federal Regulations, Part 1306.07

This section *is not meant to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction*, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

The Role of Pharmacists in the Opioid Crisis
Prescriber and Pharmacist Responsibility

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

The practitioner is responsible for the proper prescribing and dispensing of controlled substances. In addition, a corresponding responsibility rests with the pharmacist who fills the prescription.

Pharmacist Responsibility

“An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a valid prescription within the meaning and intent of the Controlled Substances Act and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.”

What Can the Pharmacist do in the Retail Setting?

- Verify the patient’s ID, address
- Verify the patient’s use of other opiates or controlled substances
- Verify the patient actually sees the provider and that the provider wrote the prescription
- Clarify any concerns about the dose, schedule, drug interactions, etc.
- Check TSBP PMP AWARx®
- Naloxone dispensing
## “Red Flags”

<table>
<thead>
<tr>
<th>Prescribing Factors</th>
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</thead>
<tbody>
<tr>
<td>Prescribing pattern (same prescriber, same/similar quantity)</td>
</tr>
<tr>
<td>Prescriptions presented in groups</td>
</tr>
<tr>
<td>Patient brings in prescription for another patient</td>
</tr>
<tr>
<td>Prescription refused by another pharmacy</td>
</tr>
<tr>
<td>Patient traveling long distance from office or pharmacy</td>
</tr>
<tr>
<td>Handwritten RX looks altered or flawless</td>
</tr>
<tr>
<td>DEA previously suspended or revoked</td>
</tr>
</tbody>
</table>
### “Red Flags”

**Patient Factors/Behavior**

<table>
<thead>
<tr>
<th>Behavior</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient threatens pharmacist</td>
<td></td>
</tr>
<tr>
<td>Shows signs of drug abuse</td>
<td></td>
</tr>
<tr>
<td>Obtains the same or similar RX from other prescriber or pharmacies</td>
<td></td>
</tr>
<tr>
<td>Refers to drugs by slang name or markings</td>
<td></td>
</tr>
<tr>
<td>Claims to require controlled substance (allergy or no response)</td>
<td></td>
</tr>
<tr>
<td>Early refill requests</td>
<td></td>
</tr>
<tr>
<td>Frequently loses or claims lost meds</td>
<td></td>
</tr>
<tr>
<td>Claims pharmacy gave wrong quantity</td>
<td></td>
</tr>
<tr>
<td>The patient has multiple RX but only picks up controlled substance</td>
<td></td>
</tr>
</tbody>
</table>
What Can the Pharmacist Do in the Hospital Setting?

- Recommend supportive treatment for withdrawal symptoms or substitution treatment
- Recommend individualized taper, if appropriate
- Recommend urine drug screens
- Recommend avoiding concurrent benzodiazepines
- Check TSBP PMP AWARxE® in patients with suspected opioid use prior to admission
Texas State Board of Pharmacy Prescription Monitoring Program (TSBP PMP AWARxE®)

- Transition from Texas Department of Public Safety to the Texas State Board of Pharmacy completed in September 2016
- Requires pharmacies to upload filled controlled substance prescriptions within one business day
  - Includes Control Substances Level II-V
- Interfaces with 22 states including the states geographically located around Texas
  - Includes all bordering states of New Mexico, Oklahoma, Arkansas, and Louisiana
TSBP PMP AWARxE® - Statistics

There were a total of 19,928,194 controlled substance prescriptions dispensed as reported to the Texas PMP in FY2018 Q1 & Q2

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<table>
<thead>
<tr>
<th>Controlled Substance</th>
<th>Number of RXs</th>
</tr>
</thead>
<tbody>
<tr>
<td>HYDROCODONE</td>
<td>2,788,744</td>
</tr>
<tr>
<td>CODEINE</td>
<td>2,542,684</td>
</tr>
<tr>
<td>TRAMADOL</td>
<td>2,345,646</td>
</tr>
<tr>
<td>AMPHETAMINE</td>
<td>1,911,066</td>
</tr>
<tr>
<td>ALPRAZOLAM</td>
<td>1,588,943</td>
</tr>
<tr>
<td>ZOLPIDEM</td>
<td>1,277,393</td>
</tr>
<tr>
<td>CLONAZEPAM</td>
<td>986,881</td>
</tr>
<tr>
<td>METHYLPHENIDATE</td>
<td>820,532</td>
</tr>
<tr>
<td>LORAZEPAM</td>
<td>695,767</td>
</tr>
<tr>
<td>PHENTERMINE</td>
<td>600,320</td>
</tr>
<tr>
<td>PREGABALIN</td>
<td>482,046</td>
</tr>
<tr>
<td>OXYCODONE</td>
<td>462,311</td>
</tr>
<tr>
<td>TESTOSTERONE</td>
<td>394,677</td>
</tr>
<tr>
<td>DIAZEPAM</td>
<td>379,743</td>
</tr>
<tr>
<td>TEMAZEPAM</td>
<td>321,705</td>
</tr>
</tbody>
</table>

Texas State Board of Pharmacy PMP FY2018 Q1 & Q2, TSBP, 2018.
Acute Opioid Withdrawal Treatment Recommendations

Dependent Heroin or Prescription Opioid User

Withdrawal with Supportive Measures

Substitution Treatment (Methadone, buprenorphine)

Withdrawal from Substitution Treatment

Post-Withdrawal Interventions (Psychosocial interventions, maintenance treatment, etc.)
Choosing Between Supportive Treatment vs. Substitution Therapy

**Supportive Treatment**
- Intermittent opioid abuse prior to admission
- Expected short hospital stay
- BP >90/50mmHg and HR >50 bpm
- Patients at low risk for experiencing complications from possible electrolyte changes
- Patients presenting to the emergency department solely for treatment of opioid withdrawal

**Substitution Therapy**
- Pregnant patients
- Patients who will be transferred to opioid detoxification facility
- Plan to establish care at Methadone Clinic immediately at discharge
- Patients requesting to leave AMA for the treatment of serious medical condition due to opioid withdrawal
Available Treatment Options for Opioid Withdrawal

- **Methadone PO**
  - Tablets (5mg, 10mg)
  - Oral Solution (10mg/10mL)

- **Buprenorphine**
  - Should not be initiated until patient is experiencing opioid withdrawal symptoms

- **Alternative Opioid**
  - May continue outpatient opioid treatment for chronic pain
  - May be utilized in patients experiencing acute pain during hospital admission

- **Clinical Opiate Withdrawal Scale (COWS) Order Set**
  - Supportive treatment for withdrawal symptoms
Medication Assisted Treatment

<table>
<thead>
<tr>
<th></th>
<th>Mechanism</th>
<th>Prescribing Limits</th>
<th>Cost</th>
<th>Accessibility</th>
</tr>
</thead>
</table>
| **Buprenorphine**   | Mu opioid receptor agonist, kappa opioid receptor antagonist | -X waiver required  
- MD, PA, NP can prescribe  
- Dosed once daily | $$      | Induction and maintenance can be done in outpatient setting |
| **Methadone**       | Mu opioid receptor agonist, kappa opioid receptor agonist | - Strict federal guidelines  
- Only MD can prescribe  
- Dosed once daily, at high doses | $       | Induction usually inpatient or treatment facility, must use methadone clinic for maintenance |

Lexi-Comp Online™, Lexi-Drugs Online™, Hudson, Ohio: Lexi-Comp, Inc; September 25, 2014
Perspectives from Three Institutions in DFW

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Parkland Health & Hospital System – Dallas, TX

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Methodist Health System – Charlton, TX

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JPS Health Network – Fort Worth, TX
INITIATIVES:

• Opioid Registry
• Opioid Dashboard in EPIC
• EPIC enhancements including PDMP link and MEDD calculator
• Education Campaign
  • Chronic opioid policy
  • E prescribing
  • Best practices
  • Opioid dashboard utilization
Methodist Health System

1. Conducted gap analysis
2. Developed multidisciplinary committees:
   ▫ One for each campus
   ▫ Additional system level committee
3. Translate findings in gap analysis into meaningful system changes

Focus: Methodist Charlton Medical Center inpatient perspective
1. Gap Analysis

- Reviewed new and revised standards related to Pain assessment and Management
- Identified areas where we as a system are not meeting standards or could improve upon

**Standard LD.04.03.13**: Pain assessment and pain management, including safe opioid prescribing is identified as an organizational priority for the hospital
  - The hospital has a leader or leadership team that is responsible for pain management and safe opioid prescribing and develops and monitors performance improvement activities
  - The hospital facilitates practitioner and pharmacist access to Prescription Drug Monitoring Program Databases

**Standard PC.01.02.07**: The hospital assesses and manages the patient’s pain and minimizes the risks associated with treatment
  - The hospital has defined criteria to screen, assess, and reassess pain that are consistent with the patient’s age, condition, and ability to understand

**Standard PI.01.01.01**: The hospital collects data to monitor its performance
  - The hospital collects data on pain assessment and pain management including types of interventions and effectiveness
## 2. Develop Multidisciplinary Committees

**Hospital Site-Specific**

- One for each site:
  - Dallas
  - Mansfield
  - Richardson
  - Charlton
- Committee Representation:
  - Physician
    - Anesthesia
    - Hospitalist
    - Surgery
    - Emergency Medicine
  - Nurse
  - Pharmacy
  - Care Management
  - PT/OT
  - Quality

**System Level Committee**

- Supports individual sites in implementing initiatives/changes system wide
- Outpatient Initiatives
  - MHS clinics
  - Community outreach programs
  - Education
3. Meaningful System Changes

Focused on key points for improvement over the year

Recognize inappropriate use of opioids
- Naloxone use review
- Follow trends, perform mini RCA to identify possible causes
- Changes stemming from this include fentanyl patch BPA, development/validation of inpatient opioid risk tool, pharmacy led renal dose adjustment

Incorporate multimodal pain management into protocols and ordersets
- Developed and implemented general pain management order panel to include in multiple admission ordersets
- Implemented in conjunction with a standardized bowel management panel

Monitor pain assessment, management, and reassessment
- Collecting data through audits done by nursing units on pain assessment and reassessment and documentation (often done in real-time)
Other Actions and Pipeline Items

- Response to new and on-going drug shortages
- Full integration of Texas PDMP into EPIC for hospital staff and providers
- Implementation of permanent drug-takeback receptacles in our outpatient pharmacies
- Development of an inpatient opioid-related adverse drug event risk tool
- Update/implement ERAS protocols
- Standardized sickle cell crisis protocol for ED
- Addiction resources
Currently Implemented

- Multimodal approaches to pain management
- Pharmacist documentation of PMP AWARxE® record in EMR
- Pharmacist verification and documentation of Methadone and Suboxone maintenance treatment
- Takeback receptacles at outpatient pharmacies
Pharmacist Documentation – Dosing Verification

Pharmacist Note: Dosing Verification of Methadone for Opioid Dependency

Assessment:

is a y/o who was receiving methadone prior to admission for opioid dependence. Dr. *** has ordered methadone to continue during this patient’s hospitalization.

Renal Function:
Estimated Creatinine Clearance: 89.6 mL/min (based on SCr of 1.1 mg/dL).

Dosing Verification:
A pharmacist has verified the following information regarding this patient’s methadone maintenance treatment:

The verified dose (from the treatment program/facility) is: methadone *** mg daily

Date Verified: [Month:10108] [Number:31396] [Year:2101222201::"2012"]
Name of Treatment Program/Facility (include address if available): ***
Treatment Program/Facility Phone Number (include Fax if available): ***
Name of the Person(s) at the Facility Verifying the Dose (include credentials if available): ***
Patient Last Seen at Facility: [Month:10108] [Number:31396] [Year:2101222201::"2012"]
Is the Patient to be Seen Again: {Yes or No:20729} (if so, when/details: ***)

Methadone Treatment Program Card:
Was the patient able to provide a program card? {Yes or No:20729}
Medications (names and doses) listed on the card NOT to be administered to the patient: ***

Plan:

***A pharmacist was able to verify the methadone dose prior to admission. Therefore, methadone may be continued at the current dose of *** mg during the patient’s hospitalization.

***A pharmacist was provided a copy of methadone card/methadone bottle, but unable to verify the methadone dose prior to admission with treatment program due to ***. Therefore, methadone *** mg daily may only be ordered for 72 hours without obtaining confirmation of this dose prior to admission. A pharmacist will approve current order with stop time of 72 hours from now. A pharmacist will attempt to verify the dose by contacting the treatment program again on ***.

***A pharmacist was not provided a copy of methadone card/methadone bottle, and pharmacist was unable to verify the methadone dose with treatment program prior to admission due to ***. Therefore, methadone dose will be reduced to 30 mg daily. A pharmacist will approve order with stop time of 72 hours from now. A pharmacist will attempt to verify the dose by contacting the treatment program again on ***.

Please contact a pharmacist with any questions or concerns (ext. ***).
Pharmacist Documentation – PMP AWARxE®

Per Prescription Monitoring Program (PMP) record, the following controlled substances were dispensed to this patient prior to admission:

<table>
<thead>
<tr>
<th>Date</th>
<th>Medication</th>
<th>Qty</th>
<th>Days Supply</th>
<th>Prescriber</th>
<th>Pharmacy</th>
</tr>
</thead>
<tbody>
<tr>
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**Recommendations:**

***
Up and Coming

- Addition of Buprenorphine to inpatient formulary
- Updating Opioid Withdrawal Order Set
- Possible Addiction Consult service
Application to a Patient Case
Patient Case

EC is a 28-year-old male with a PMH of polysubstance abuse who is admitted to the hospital with sepsis 2/2 upper extremity cellulitis and abscess. Per chart review, patient has provided varying reports of recent drug use, including daily heroin use and buying methadone off the street, as well as methamphetamine, cocaine, and marijuana use. His urine drug screen is positive for opiates, cocaine, cannabinoids, and amphetamines upon admission.
Patient Case (cont.)

EC was initiated on Methadone 40mg Daily on the day of admission for the prevention of opioid withdrawal. The next day the team decreased the dose to 30mg Daily per hospital protocol, which was continued for the remainder of the patient’s medical stay. After 7 days he was transferred inpatient psychiatry for continued care.
Discussion of Case

- Was the initiation and continuation of Methadone therapy appropriate in this case?
  - Is there any additional information you would like to know about the patient?

- What other medications, if any, could have been started for the treatment of opioid withdrawal?

- Does the “72 Hour Rule” apply in this case?
What Can we do Better?

- Treat underlying illnesses
- Adhering to evidence based treatments
- Using interdisciplinary model and multimodal treatment
- Concerned for abuse/misuse? Address the problem head on
- Listen to your patient
Available Resources and Education


https://www.aha.org/system/files/content/17/opioid-toolkit.pdf

https://www.cdc.gov/drugoverdose/training/online-training.html
  • Free CE

  • Free CE: A Primer on Opioid Morbidity and Mortality Crisis: What Every Prescriber Should Know

https://www.cdc.gov/drugoverdose/prescribing/clinical-tools.html
  • Opioid Prescribing Guideline Mobile App
  • Pocket Guide: Tapering Opioids for Chronic Pain
  • Assessing Benefits and Harms of Opioid Therapy
Questions?

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