PROTECTING PATIENTS AND COMMUNITIES THROUGH THE RI PRESCRIPTION MONITORING PROGRAM (PMP)

KIMBERLY MCDONOUGH
RIPF SPRING SEMINAR
6 MAY 2015

OBJECTIVES

- Discuss the role of the PMP as part of a comprehensive patient and community safety strategy to reduce misuse, abuse, diversion, and overdose from Rx opioids
- Compare and contrast ideal PMP characteristics and outcomes with the RI PMP
- Discuss and apply successful examples of RI PMP utilization to pharmacy practice

ADDITION: WHO IS AT RISK?

- 10% of the population are genetically or psychologically susceptible to addiction.
- 2-3% are addicted at any one time (about 20,000 Rhode Islanders)
- Addiction is a chronic relapsing disease which requires multiple rounds of treatment, significant effort at chronic disease management, which we also call recovery.

Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.
Nine in 10 opioid painkiller users are unconcerned about addiction

Specific Concerns about Opioid Prescription

- Side effects: 21%
- Addiction: 12%
- Grogginess/sleepy to function: 12%
- Stomach upset: 12%
- Interaction of other meds: 5%
- Efficacy (would not work): 3%
- Misuse: 8%
- Not Concerned about Side Effects: 90%

Actual usage is much higher when users are told which painkillers contain opioids.

Names of Common Opioid Painkillers

- Codeine
- Fentanyl (Actiq, Duragesic, Fentanyl)
- Hydrocodone (Lorcet, Lo书画, Vicodin, Vicodin ER)
- Oxycodone and Acetaminophen (Lorcet, Lorab, Tylenol, Vicodin)
- Hydroxapronine (Dilaudid, Oxygas)
- Morphine (Dilaudid, Methadone)
- Oxycodone (OxyContin, OxyContin, Percoco, Percocet)
- Oxycodone and Acetaminophen (Percocet)
- Oxycodone and Naloxone (Xargyn)

Only one in five Americans consider prescription pain medication to be a serious safety threat.
SOURCE OF MOST RECENT RX OPIOIDS AMONG PAST-YEAR USERS AGE 12-17

- 54.2% Free: friend/relative
- 18.1% 1 doctor
- 16.6% Bought/took: friend/relative
- 9% Other
- 5.8% Drug dealer
- 0.3% > 1 doctor
- 0.2% Bought on Internet


Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.

PAST MONTH NONMEDICAL USE AND OVERDOSE DEATHS BY AGE


[Accessed on 5 April 2015]
Every day in the United States, 44 people die as a result of prescription opioid overdose.

Men were more likely to die from prescription opioid overdose.

Deaths from prescription opioid overdoses among women increased more than 400% during 1999–2010, compared to 237% among men.

People who died of drug overdoses often had a combination of benzodiazepines and opioid pain medications in their bodies.¹


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ACCIDENTAL DRUG DEATHS IN RHODE ISLAND 2014 BY AGE

THE RHODE ISLAND DRUG OVERDOSE EPIDEMIC OF 2014

- 238 deaths 2014  76 Deaths mid-April 2015
  (90% involve an opioid/prescription drug)
- 2014* least 83 associated with illicit form of fentanyl (37%)
- Residents from 31 cities and towns
- Diverse group regarding demographics and SES
- Ages 19-65

Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.
Accidental prescription drug overdose fatalities
(includes prescription drugs combined with illicit drugs and with and without alcohol)

For every overdose death:

- 10 admissions to treatment
- 32 ED visits
- 130 addicted or dependent
- 825 non-medical users

THE PMP

- Housed at the Dept. of Health
- Operated by the Board of Pharmacy
  - Perpetual database
  - Updated q72 hours
  - Data transmitted by pharmacies
- The PMP is tool for:
  - Overprescribing
  - Diversion
  - Fraud
- All Schedule II-IV Rx

- Patient Specific
  - Independent of payer
  - ALL Pharmacies that dispense WITHIN OR INTO the State
- Available to Multiple Stakeholders
  - Prescribers
  - Pharmacists
  - Law enforcement by search warrant
  - Selected administrators (Scott, James, Jackie)
- Delegation
  - Prescribers
  - Pharmacists

Slide modified, original courtesy RI Department of Health, Patrick Kelley, PharmD. Used with permission.
CONTROLLED SUBSTANCES SCHEDULES

Schedule | Examples
--- | ---
Schedule I: High abuse potential | Heroin, Ecstasy, LSD
No current acceptable medical use
Schedule II: High abuse potential, restrictions on prescribing and refills | Stimulants (Ritalin, Adderall), Oxycontin, Dilaudid, Demerol
Schedule III: Moderate potential for abuse | Products containing less than 15 mg of hydrocodone per dose (Vicodin), Tylenol with Codeine, Suboxone, anabolic steroids
Schedule IV: Low abuse potential | Benzodiazepines (lorazepam, diazepam, alprazolam), sleeping pills (Halcion, Ambien, Lunesta)
Schedule V: Lowest abuse potential, contain limited quantities of narcotics | Cough syrups with codeine, anti-diarrheals

(Worley, 2012)

CONTROLLED SUBSTANCE PRESCRIPTIONS WRITTEN BY PHYSICIANS

<table>
<thead>
<tr>
<th>Schedule</th>
<th>November 2014</th>
<th>December 2014</th>
<th>January 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schedule II prescriptions</td>
<td>37,237</td>
<td>39,693</td>
<td>33,433</td>
</tr>
<tr>
<td>Schedule III prescriptions</td>
<td>5,442</td>
<td>5,874</td>
<td>4,783</td>
</tr>
<tr>
<td>Schedule IV prescriptions</td>
<td>44,634</td>
<td>47,481</td>
<td>40,056</td>
</tr>
<tr>
<td>Total prescriptions written by physicians</td>
<td>87,313</td>
<td>93,048</td>
<td>78,272</td>
</tr>
<tr>
<td>Of prescriptions written by all providers, percentage written by physicians</td>
<td>78.7%</td>
<td>75.5%</td>
<td>68.7%</td>
</tr>
</tbody>
</table>

Data Source: Rhode Island Prescription Monitoring Program

Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.
**All prescribers**

Hydrocodone Rescheduled From III -> II Oct 2014

Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances. 2015.

Presentation of Prescription
Patient Behavior
Medication Taking/Supply
Illicit/Illegal
RED FLAGS: PRESENTATION OF PRESCRIPTION

- Patients travel in groups to dispensing location
  - Unknown relationships
  - Same controlled substance from same prescriber
- Prescriptions for CS written in names of other people (NOT designated caregivers)
- Handwritten prescription
  - Flawless
  - Altered
- Prescription thought to be refused to be filled elsewhere
- Prescriber’s DEA, suspended, revoked, or pending actions

RED FLAGS: PATIENT BEHAVIOR

- Pharmacist threatened
- Patient shows physical signs of substance use
- Patient presents with either signs of intoxication or withdrawal
- Multiple prescribers and/or pharmacies used
- Prescriptions for “highly abused” CS medications
- Controlled and non-controlled Rx filled, patient only wants CS
- History of untruthfulness regarding CS Rx’s

RED FLAGS: MEDICATION SUPPLY AND/OR ILLEGAL BEHAVIORS

- Rx for large quantities and/or large number of CS Rx’s
- Therapeutic duplication of two or more long-acting and/or two or more short-acting opioids
- Rx cocktails: Opioid + benzodiazepine + muscle relaxant
- Patient indicates drugs will be shared or sold
- Prescriber is prescribing outside their scope of practice
- Prescriber state license expired/suspended/revoked
- Patient alters, forges, sells, or re-writes Rx’s for CS
- Patient is diverting/selling CS medications
RISK FACTORS RX DRUG ABUSE/OVERDOSE

- Obtaining overlapping prescriptions from multiple providers and pharmacies
- Taking high daily dosages of prescription pain medications
- Having mental illness or a history of alcohol or other substance abuse
- Living in rural areas, having low income

Hall AJ et al. JAMA 2010;303(20):2063-10.
Budnick MI et al. JAMA 2010;303(20):2063-10.


RISK FACTORS RX DRUG ABUSE/OVERDOSE

- Observed patterns in Medicaid
  - 2010 - 40% of Medicaid enrollees with painkiller prescriptions had at least one indicator of potentially inappropriate use or prescribing:
    - overlapping opioid analgesic prescriptions
    - overlapping opioid analgesic and benzodiazepine prescriptions
    - long-acting or extended release prescription pain medications for acute pain, any methadone, and high daily doses


RISK FACTORS FOR OPIOID OVERDOSE: INDICATIONS FOR NALOXONE

- Opioid prescription and:
  - history of smoking
  - COPD
  - Respiratory illness or obstruction
  - renal dysfunction or hepatic disease
  - Known or suspected concurrent alcohol abuse
  - Concurrent benzodiazepine prescription
  - Concurrent SSRI or TCA anti-depressant prescription

  - Pharmacist Interactions
    - Syringe purchase, medication lock box purchase, medication disposal
  - Pharmacy Records show:
    - Nicotine replacement therapy
    - Varenicline, bupropion
    - Inhalers, corticosteroids
    - Respiratory antibiotics
    - Dialysis medications
    - Cirrhosis medications
    - Naltrexone, disulfiram
    - Concurrent benzodiazepine prescription
    - Concurrent SSRI or TCA anti-depressant prescription
OFFER NALOXONE TO EVERYONE

- Any opioid prescription
- Has prescription for IR & ER opioid
- Any opioid/benzo rx combination
- Any methadone
- Any buprenorphine
- Syringe purchase

Methods
- Standing order/QPA
- Prescriber request
- EMR
- Transitions of care

REGISTRATION: PHARMACIST + STORE DEA

Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.
WHAT DATA TO ENTER...

PRACTICAL TOOLS TO PREVENT DIVERSION:
PATIENT LOOK UP ON THE PMP

- Here is what 1 patient did in a 10 month period
- Deliberate
- Is this the extreme?
- How many prescribers were registered for the PMP who saw this patient?
Summary of a 10 Month Period

- **49 Prescribers**
  - 27 Dentists
  - 16 MD/DO
  - 3 Physician Assistants
  - 3 Podiatrists
  - 1 Nurse Practitioner

- 32 Pharmacies
- 84 Prescriptions Filled (25 Private Pay)
- Received 500 Days of Drugs in 322 Days

What is the Problem?

<table>
<thead>
<tr>
<th>Date</th>
<th>Rx Date</th>
<th>Days Supply</th>
<th>Product Name</th>
<th>Pharmacy Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/1/12</td>
<td>1/1/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-325MG TAB</td>
<td>22 FUGUSS PHARMACY</td>
</tr>
<tr>
<td>1/5/12</td>
<td>1/5/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-650MG TAB</td>
<td>CRUE PHARMACY</td>
</tr>
<tr>
<td>1/9/12</td>
<td>1/8/12</td>
<td>30</td>
<td>OXYCODONE-APAP 5-325MG TAB</td>
<td>PAIN PHARMACY</td>
</tr>
<tr>
<td>1/12/12</td>
<td>1/12/12</td>
<td>30</td>
<td>OXYCODONE-APAP 7.5-325MG TAB</td>
<td>SMITH PHARMACY</td>
</tr>
<tr>
<td>1/15/12</td>
<td>1/15/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-650MG TAB</td>
<td>QUINN PHARMACY</td>
</tr>
<tr>
<td>1/20/12</td>
<td>1/20/12</td>
<td>30</td>
<td>OXYCODONE-APAP 5-325MG TAB</td>
<td>PHIL PHARMACY</td>
</tr>
<tr>
<td>1/21/12</td>
<td>1/21/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-325MG TAB</td>
<td>SOUTH SIDE PHARMACY</td>
</tr>
<tr>
<td>1/25/12</td>
<td>1/24/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-650MG TAB</td>
<td>SEUSS PHARMACY</td>
</tr>
<tr>
<td>1/28/12</td>
<td>1/28/12</td>
<td>30</td>
<td>OXYCODONE-APAP 5-325MG TAB</td>
<td>ABC PHARMACY</td>
</tr>
<tr>
<td>1/31/12</td>
<td>1/31/12</td>
<td>30</td>
<td>OXYCODONE-APAP 10-325MG TAB</td>
<td>TIMEWARP PHARMACY</td>
</tr>
</tbody>
</table>

Slide courtesy of Dr. James McDonald, RI Dept of Health. Used with permission.

Slide courtesy of RI Department of Health, Patrick Kelley, PharmD.
Physician Use of Prescription Monitoring Program

<table>
<thead>
<tr>
<th></th>
<th>November 2014</th>
<th>December 2014</th>
<th>January 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reports run by physicians</td>
<td>7,737</td>
<td>8,942</td>
<td>8,899</td>
</tr>
<tr>
<td>Total Schedule II prescriptions written by physicians</td>
<td>37,237</td>
<td>39,693</td>
<td>33,433</td>
</tr>
<tr>
<td>Percentage of reports run by physicians for Schedule II prescriptions written</td>
<td>20.8%</td>
<td>22.5%</td>
<td>26.6%</td>
</tr>
<tr>
<td>Percentages of reports needed to minimize drug overdose deaths</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Note: Source: Rhode Island Prescription Monitoring Program

Slide courtesy of Dr. James McDonald; RI Dept of Health; Used with permission.

Number of reports by pharmacists and prescribers and number of individuals who filled prescriptions for Schedule 2 drugs

RI PMP FACTSHEET

Number of PMP Reports by Pharmacists and Prescribers

Slide courtesy of Dr. James McDonald; RI Dept of Health; Used with permission.
### Pharmacist Use of Prescription Monitoring Program

<table>
<thead>
<tr>
<th></th>
<th>January 2015</th>
<th>February 2015</th>
<th>March 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists enrolled in PMP</td>
<td>775</td>
<td>775</td>
<td>831</td>
</tr>
<tr>
<td>Pharmacists who ran PMP report</td>
<td>355</td>
<td>336</td>
<td>336</td>
</tr>
<tr>
<td>Total reports run by all pharmacists</td>
<td>10,122</td>
<td>8,998</td>
<td>11,752</td>
</tr>
<tr>
<td>Percentage reports run by pharmacists for prescriptions written</td>
<td>8.9%</td>
<td>8.3%</td>
<td>9.9%</td>
</tr>
<tr>
<td>Percentage of reports needed to minimize drug overdose deaths</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

Data Source: Rhode Island Prescription Monitoring Program

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### Table 2. Pharmacists' reported mean and frequency distribution of events that would prompt ROPM use (n = 350)

<table>
<thead>
<tr>
<th>Events</th>
<th>Mean ± SD</th>
<th>Frequency distribution of response choices n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient refuses to pay cost</td>
<td>4.2 ± 1.1</td>
<td>Mean: 2 (1.0), 3 (2.3), 4 (15.7), 5 (30.3), 6 (21.1), 7 (12.1)</td>
</tr>
<tr>
<td>Medication or drug mix in the written instruction*</td>
<td>4.9 ± 0.8</td>
<td>5 (10.2), 6 (12.2), 7 (15.7), 8 (23.7), 9 (17.7), 10 (8.6)</td>
</tr>
<tr>
<td>Rxhold that is too strict†</td>
<td>4.5 ± 0.5</td>
<td>2 (0.8), 3 (1.0), 4 (2.4), 5 (24.8), 6 (32.4), 7 (23.5)</td>
</tr>
</tbody>
</table>

* Only those not across 21 days requiring response<br>
† Excludes percentage not equal to 100% due to rounding<br>
‡ Mean calculated based on 100 responses
LEADING A HORSE TO WATER: FACILITATING REGISTRATION AND USE OF A PMP

Reasons identified by non-users for not registering to use the PMP
Respondents could select multiple reasons (n=439)

- No Internet access at work: 1.1%
- Object to surveillance: 2.3%
- Limited resources to act on info: 2.7%
- Cannot delegate access: 6.8%
- No benefits: 13.4%
- Rarely prescribe: 23.7%
- Too busy: 26.0%
- Unaware could register: 46.7%

LEADING A HORSE TO WATER: FACILITATING REGISTRATION AND USE OF A PMP

Reported barriers to using the PMP according to user group

- Lack of training on access or use
- Cannot share account
- Time constraints
- Application naturalization request*
- System difficult to navigate*
- Frequent password changes*
- System difficult to access*

*These questions were only asked of registered users

HOW DOES USE OF A PMP CHANGE PHARMACY PRACTICE?

- Pharmacists surveyed
  - CT & RI
  - ~84% opioid rx dispensed “Several times/day”
- Significant Results:
  - PMP Users 82% LESS LIKELY to discuss concerns with patient

Table 4. Differences in response when suspect diversion doctor shopping by PMP use

<table>
<thead>
<tr>
<th>Response</th>
<th>Typical PMP user actions</th>
<th>Typical nonuser actions</th>
<th>Reference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact the patient’s physician(s) (if known)</td>
<td>0.86 (0.21–3.47)</td>
<td>6.02</td>
<td>8.97 (0.25–2.62)</td>
</tr>
<tr>
<td>Discuss the concerns with the patient</td>
<td>0.48 (0.25–0.98)</td>
<td>1.00</td>
<td>1.50 (0.79–2.62)</td>
</tr>
<tr>
<td>Refer the patient back to provider</td>
<td>0.03 (0.00–1.15)</td>
<td>1.00</td>
<td>1.03 (0.00–1.16)</td>
</tr>
<tr>
<td>Refuse to fill the prescription</td>
<td>0.27 (0.12–0.59)</td>
<td>1.00</td>
<td>1.77 (0.89–3.52)</td>
</tr>
<tr>
<td>Dispose of stock of the drug</td>
<td>0.37 (0.16–0.83)</td>
<td>1.00</td>
<td>2.16 (1.02–4.57)</td>
</tr>
<tr>
<td>Cautious the patient on potential overdose risk</td>
<td>0.27 (0.07–1.27)</td>
<td>1.00</td>
<td>3.00 (0.07–12.50)</td>
</tr>
<tr>
<td>Refer the patient to substance abuse treatment</td>
<td>1.29 (0.25–6.52)</td>
<td>1.00</td>
<td>1.29 (0.25–6.52)</td>
</tr>
<tr>
<td>Ask the patient to leave the pharmacy</td>
<td>0.46 (0.17–1.32)</td>
<td>1.00</td>
<td>1.03 (0.00–1.16)</td>
</tr>
<tr>
<td>Notify law enforcement</td>
<td>0.81 (0.39–2.01)</td>
<td>1.00</td>
<td>1.03 (0.00–1.16)</td>
</tr>
</tbody>
</table>

*Odds ratios used; adjusted odds ratio, PMP, prescription monitoring program

Models are adjusted for age, gender, years practicing pharmacy, drug above threshold prescription, frequency of dispensing opioids, and state.
### AN INEVITABLE WAVE OF PMP’S IN THE CONTEXT OF RX OPIOIDS: PROS, CONS AND TENSIONS

<table>
<thead>
<tr>
<th>PRO</th>
<th>CON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Informed and safe prescribing for patients</td>
<td>Patient may not receive sufficient meds due to prescriber fear of legal retribution (“chilling effect”)</td>
</tr>
<tr>
<td>Appropriately designed real-time PMP is likely to reduce diversion, MD shopping, and OD deaths</td>
<td>Inappropriate or inadequate alternative medications prescribed (Substitution effect)</td>
</tr>
</tbody>
</table>


### AN INEVITABLE WAVE OF PMP’S IN THE CONTEXT OF RX OPIOIDS: PROS, CONS AND TENSIONS

<table>
<thead>
<tr>
<th>PRO</th>
<th>CON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduction of overprescribing by prescribers</td>
<td>Legitimate prescribing deterred by confusion between concepts of addiction, pseudo-addiction</td>
</tr>
<tr>
<td>Reduced risk of polypharmacy</td>
<td>Patients may fear law enforcement scrutiny and/or be deprived of necessary medications</td>
</tr>
</tbody>
</table>


### AN INEVITABLE WAVE OF PMP’S IN THE CONTEXT OF RX OPIOIDS: PROS, CONS AND TENSIONS

<table>
<thead>
<tr>
<th>PRO</th>
<th>CON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Help monitor and deter forged/stolen controlled substance Rx</td>
<td>PMP-induced reduction of Rx opioids may increase crime/push pain patients into illicit market (heroin)</td>
</tr>
<tr>
<td>Reduce fraudulent prescribing and inform licensing boards about inappropriate Rx/dispensing</td>
<td>Fear among prescribers of being categorized as fraudulent prescribers when only lack training</td>
</tr>
</tbody>
</table>

OBJECTIVES

- Discuss the role of the PMP as part of a comprehensive patient and community safety strategy to reduce misuse, abuse, diversion, and overdose from Rx opioids
- Compare and contrast ideal PMP characteristics and outcomes with the RI PMP
- Discuss and apply successful examples of RI PMP utilization to pharmacy practice

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