Resources Encouraging Safe Prescription

Opioid & Naloxone Dispensing: Results from the RESPOND Study

Nicole O’Kane, PharmD, Clinical Director

Daniel Hartung, PharmD, MPH, Associate Professor
Disclosure Statement

Nicole O’Kane, PharmD, has disclosed no relevant, real or apparent personal or professional financial relationships with proprietary entities that produce health care goods and services.

Daniel Hartung, PharmD, MPH, serves on a Scientific Advisory Committee for MedSavvy™, and otherwise has no relevant, real or apparent personal or professional financial relationships with proprietary entities that produce health care goods and services.
Learning Objectives

1. Describe educational components of the RESPOND Toolkit
2. Summarize findings from the RESPOND Toolkit pilot study
3. Discuss implications of RESPOND pilot study findings on community pharmacy practice
Response to Opioid Epidemic – Prescribing Trends

- Development and dissemination of prescribing guidelines
- Payer and health system policies
- Changing state laws and mandates
- Community efforts and interventions
- Growth and expansion of PDMPs
Opioid Prescriptions Have Declined, but Remain High in Many Locations

https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html
Where Does Pharmacist Fit?

- Pharmacists play a critical role in medication safety
- Role in opioid safety is poorly defined
  - Pharmacy-based naloxone distribution
  - Identification and referral for treatment
  - Promoting $R_x$ opioid safety
Corresponding Responsibility

“The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” CFR 21; 1306.04

- Determine legitimacy of controlled substance prescriptions
- Do not deliberately ignore a questionable prescription not issued for legitimate medical purpose
Safe Opioid Use: Pharmacy’s Challenge

- Pharmacists are frequently mentioned in conversations around opioid risk reduction activities
  - Educate patients
  - Support safe medication storage and disposal
  - Distribute naloxone
  - “Last Defense” against high-risk medication use

- Barriers
  - Training
  - Communication skills
  - Workflow processes
Pharmacy’s Challenge:

What can community pharmacists do to improve the safety of opioid use for their patients?
Oregon Pharmacist PDMP Toolkit Grant

- **Funding and timeline:**
  - Agency for Healthcare Research and Quality (R18 HS24227-01)
  - October 2015—September 2018

- **Grant objective:** Develop a toolkit intended to help community pharmacists dispense opioids safely and appropriately:
  - **Identify** patients for whom dispensing an opioid prescription presents a safety risk
  - **Communicate** with patients at the point of care
  - **Coordinate** with the primary prescriber to maximize patient safety in use of opioid analgesics
Aim 1: Toolkit Development (Year 1)

Focus Groups

Toolkit Development

Expert Advisory Committee

Aim 2: Implementation (Years 2 - 3)

Phase 1

Phase 2

Refinement

Control

Control

Aim 3: Evaluation (Year 3)

• Focus groups of pharmacists, prescribers, patients
• Toolkit development

• Self-reported knowledge, attitudes, behavior
• PDMP query rates
• Opioid dispensing
Preliminary Research: Focus Groups

- **Purpose:** To explore cross-party communication patterns, barriers to care, and other issues related to PDMP use and opioid safety
  - Pharmacists’ opioid- and PDMP-related experiences
  - Prescribers’ opioid- and PDMP-related experiences
  - Patients’ opioid-related experiences with healthcare providers

- **Sample:**
  - Pharmacists: 2 groups of 7-12 (N=19; \( M_{age} = 39.0 \); 58% female)
  - Prescribers: 1 group of 9 (\( M_{age} = 47.9 \); 75% female)
  - Patients: 3 groups of 4-8 (N=18; \( M_{age} = 60.1 \); 71% female)

- **Analysis Method:**
  - Immersion-crystallization
Original Research Article

Pharmacists’ Role in Opioid Safety: A Focus Group Investigation

PDMP Use / Workflow  →  Barriers to Care & Communication  →  Role of the Pharmacist  →  Patient Stigma
We do not have or adhere to specific internal guidelines in our store. Use of PDMP is up to the discretion of the pharmacist. As pharmacist in charge of my store, I personally use PDMP on every new patient, almost every dental and ER prescription, with everyone known to me to use multiple pharmacies, and randomly on well-known regular customers.

(Pharmacist 6)
Barriers to Care & Communication

**Prescriber**
- Time
- Lack of consultation
- Focus on diversion

**Pharmacist**
- Time
- Uncertainty of role
- Gatekeeper

**Patient**
- Frustration
- Lack of opioid safety knowledge
- Cynicism
Role of the Pharmacist

Monitor  Prevent  Identify

Collaborate  Educate
Pharmacists, I think they’re getting too far in the way. Their job is to dispense the medicine. And then tell you about it, right? They’re not there to control it. That’s the doctor’s… and I feel that they are over taking their power. (Patient 21)
Patient stigma

Affect:
- Fear / frustration
- Pain
- Desire for change

“People are looking at me like I’m doing something wrong.”

Workaround:
- Track medications
- Advocate
- Conduct research
Focus Group Main Takeaways

- **Consistent policies are needed**
  - Prescription opioid safety screenings for all patients to minimize stigma

- **Targeted prescriber and pharmacist trainings are needed**
  - Should define stakeholders’ unique roles in addressing opioid safety
  - Should emphasize the risks of prescription opioid utilization *for all users*
  - Should include between-party communication strategies

- **Research needed to build evidence base**
  - Interventions to enhance opioid safety communication for providers
  - Evaluations on impact of training and utilization on patient outcomes
Aim 1: Toolkit Development (Year 1)
- Focus groups of pharmacists, prescribers, patients
- Toolkit development

Aim 2: Implementation (Years 2 - 3)
- Phase 1 Refinement
- Phase 2
- Control
- Control

Aim 3: Evaluation (Year 3)
- Self-reported knowledge, attitudes, behavior
- PDMP query rates
- Opioid dispensing
RESPOND Toolkit

Conduct Prospective Drug Utilization Review (DUR)

Step 1: Initial Screening

<table>
<thead>
<tr>
<th>The Prescription</th>
<th>The Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has missing or unreadable info</td>
<td>Is new to the pharmacy</td>
</tr>
<tr>
<td>Appears altered or irregular</td>
<td>Refuses to show identification</td>
</tr>
<tr>
<td>Is from an unfamiliar prescriber</td>
<td>Is picking up Rx for multiple people</td>
</tr>
<tr>
<td>Requests a risky combination</td>
<td>Insurance claim was denied</td>
</tr>
<tr>
<td>Is from outside surrounding area</td>
<td>Is paying cash</td>
</tr>
</tbody>
</table>

PDMP STOP

Step 2: Safety Trigger Review

- Opioid dosage significantly higher than necessary for a new or chronic user
- Combination of medications poses risk
  - Opioid with benzodiazepine and/or muscle relaxant
  - Long-acting and short-acting dosage forms
  - Prescriptions have been filled too frequently
  - Combination of contradicting medications
  - Patient is seeing multiple prescribers and/or pharmacies

NO

Steps to RESPOND in All Situations...
1. Introduce yourself to the patient
2. Define your role in their healthcare team
3. Introduce the PDMP and its purpose
4. Discuss opioid risks and potential safety triggers
5. Normalize expressed feelings and concerns
6. Ask permission to give information or advice
7. Offer naloxone as a safety recommendation.

YES

Steps to RESPOND in Difficult Situations....
1. Share safety concerns in a non-judgmental tone
2. Ask the patient open-ended questions
3. Reflect patients' responses back to them
4. Support patients' belief in ability to succeed
5. Communicate safety concerns to the prescriber
6. Include the patient and prescriber in decisions
7. Clearly articulate expectations and next steps.
Decision Support

**Decision Support Process**

**Step 1: Initial Screening**
- **Prescription**
  - Has missing or unreadable info
  - Appears altered or irregular
  - Is from an unfamiliar prescriber
  - Requests a risky combination
  - Is from outside surrounding area
- **Patient**
  - Is new to the pharmacy
  - Refuses to show identification
  - Is picking up RXs for multiple people
  - Insurance claim was denied
  - Is paying cash

**Step 2: Safety Trigger Review**
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7. Clearly articulate expectations and next steps
Provider Communication

<table>
<thead>
<tr>
<th>RxSOPND</th>
<th>Prescriber Communication Strategy</th>
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<tbody>
<tr>
<td>RES</td>
<td>S</td>
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<tr>
<td>P</td>
<td>S</td>
</tr>
<tr>
<td>Respond</td>
<td>Subjective Information</td>
</tr>
<tr>
<td>Resources Encouraging Safe Prescription Opioid &amp; Naloxone Dispensing</td>
<td>The Prescription:</td>
</tr>
<tr>
<td>Provider Communication</td>
<td>- Has missing or unreadable information</td>
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<tr>
<td></td>
<td>- Appears altered or irregular</td>
</tr>
<tr>
<td></td>
<td>- Is from outside the surrounding area</td>
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<tr>
<td>The Patient:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Is paying in cash</td>
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<tr>
<td></td>
<td>- Has physical presentation of withdrawal</td>
</tr>
<tr>
<td></td>
<td>- Refuses to show identification</td>
</tr>
<tr>
<td>Action Item:</td>
<td>Consult with the Patient</td>
</tr>
<tr>
<td>Safety Triggers:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Opioid dosage significantly higher than necessary</td>
</tr>
<tr>
<td></td>
<td>- Combination of medications poses risk</td>
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<tr>
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<td>- Prescriptions have been filled too frequently</td>
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<tr>
<td></td>
<td>- Combination of contradicting medications</td>
</tr>
<tr>
<td></td>
<td>- Patient is seeing multiple prescribers / pharmacies</td>
</tr>
<tr>
<td>Action Item:</td>
<td>Fax report &amp; notes to prescriber</td>
</tr>
<tr>
<td>Come to the conversation with recommendations:</td>
<td></td>
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<tr>
<td></td>
<td>- “Based on the information I have access to...”</td>
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<tr>
<td></td>
<td>- “I recommend...”</td>
</tr>
<tr>
<td>Action Item:</td>
<td>Create plan for follow-up</td>
</tr>
<tr>
<td>With the prescriber, decide on a plan:</td>
<td></td>
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<tr>
<td></td>
<td>- Cancel or fill prescription?</td>
</tr>
<tr>
<td></td>
<td>- Refer patient back to prescriber?</td>
</tr>
<tr>
<td></td>
<td>- Recommend naloxone?</td>
</tr>
<tr>
<td>Action Item:</td>
<td>Communicate plan to patient</td>
</tr>
</tbody>
</table>

See the RESPOND Algorithm for Patient Communication Tips
Course Communication Strategies

Remind patients’ that you are concerned about their safety, first and foremost.

**Ask open-ended questions**
- When your doctor wrote this prescription, what did he/she tell you about how to manage all of your current medications?

**Use reflective listening**
- It sounds like your doctor talked to you about the medications they were prescribing at this appointment, but maybe forgot to check that you were already on some other prescriptions at this time.

**Combine the two techniques**
- It sounds like you’ve had a difficult time finding a treatment for your pain that works for you. What concerns do you have about adding (more) pain pills to your current list of medications?

**Ask permission before giving unsolicited advice**
- Those are great concerns to be thinking about. Can I offer some information about opioid risks and/or management that you may find helpful?
Communication Training Video
Aim 1: Toolkit Development (Year 1)

- Focus groups
- Toolkit development

Expert Advisory Committee

Aim 2: Implementation (Years 2 - 3)

- Phase 1: Refinement
- Phase 2

Control

Aim 3: Evaluation (Year 3)

- Self-reported knowledge, attitudes, behavior
- PDMP query rates
- Opioid dispensing

- Focus groups of pharmacists, prescribers, patients
- Toolkit development

#Rx Summit www.NationalRxDrugAbuseSummit.org
## Project Timeline

### Phase 1 Findings

<table>
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<tr>
<td>Phase 1 baseline survey</td>
<td>Oct</td>
<td>Oct</td>
</tr>
<tr>
<td>Phase 1 readiness assessment</td>
<td>Nov</td>
<td>Nov</td>
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<tr>
<td>Phase 1 implementation</td>
<td>Dec</td>
<td>Dec</td>
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<tr>
<td>Phase 1 post survey</td>
<td>Jan</td>
<td>Jan</td>
</tr>
<tr>
<td>Phase 1 interviews</td>
<td>Feb</td>
<td>Feb</td>
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<tr>
<td>Refine toolkit for Phase 2</td>
<td>Mar</td>
<td>Mar</td>
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<tr>
<td>Phase 2 baseline survey</td>
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</table>
Readiness Assessment

Target: Pharmacy Managers

Purpose: Gauge support and ensure buy-in

Pharmacy Readiness Assessment Worksheet

Interview: To be completed with research staff member.

1) How would you describe the workplace culture around using the PDMP in your pharmacy?

2) Are policies in place for how and when to access the PDMP?

3) Are policies in place for how to discuss PDMP reports with a patient?

4) Are policies in place for how to access the PDMP?

5) What, if any, training does pharmacy use the PDMP?

6) What, if any, training does your pharmacy staff receive on how to use the PDMP?

7) How, if at all, does your pharmacy currently promote use of the PDMP?

8) Do you feel like the Toolkit will be well-received by pharmacy staff?

9) What other things should we know before we test the Toolkit in your pharmacy?

Brief Survey: To what extent do you feel...? (1=Strongly Disagree; 10=Strongly Agree)

1) Teaching your staff how to use the PDMP more effectively in their daily workflow is important to you.

2) Your staff learn how to use the PDMP toolkit to integrate the PDMP in their daily workflow is important to your pharmacy staff.

3) You currently offer ongoing, effective PDMP trainings for your pharmacy staff.
Readiness Assessment Scores

**STORE 1**

![Score 8.33 for Store 1](image)

**STORE 2**

![Score 8.33 for Store 2](image)

**STORE 3**

![Score 10.00 for Store 3](image)

*Note. Based on the Transtheoretical Model (Prochaska & DiClemente, 2005); mean scores calculated across Contemplation and Preparation items.*
Readiness Assessments

- Feedback on current PDMP training:
  - "We are all self-taught."
  - "I think we had web-based training, but nothing very official."
  - "We do the initial PDMP website training that’s all. No corporate or peer to peer training exists."
Readiness Assessments

- Feedback on potential gains from RESPOND Toolkit
  - “Communication strategies for destigmatizing, and as a pharmacist we appreciate being considered part of the healthcare team.”
  - "More literacy of [PDMP] use."
  - "We hope that RESPOND will replace the current form that we use. Algorithm looks useful and helpful in improving communication."
Implementation

- **Dissemination of Materials**
  - Checklist and algorithm delivered on site
  - Hard copy of course guide bound and mailed
  - Course registration information via email

- **Course Registration & Tracking**
  - 7 of 9 pharmacists registered in course
  - Progress tracked weekly with follow-up calls
  - All completed within two months of registration
Aim 1: Toolkit Development (Year 1)

- Focus groups of pharmacists, prescribers, patients
- Toolkit development

Aim 2: Implementation (Years 2 - 3)

- Phase 1: Refinement
  - Focus groups of pharmacists, prescribers, patients
  - Toolkit development

Aim 3: Evaluation (Year 3)

- Self-reported knowledge, attitudes, behavior
- PDMP query rates
- Opioid dispensing
Method: Pre-Post Course Quizzes

- Opioid Safety and PDMP knowledge
- Communication strategy knowledge

Method: Pre-Post Survey Assessments

- PDMP Knowledge
- Attitudes towards PDMP
- Perceived behavioral control
- Subjective norms around PDMP use
Method: Behavior Change Outcomes

- Longitudinal analysis of PDMP query rates and opioid dispensing data 6 months before, during, and following implementation
- Three non-intervention pharmacies selected as a comparison group

Outcome categories
- Pharmacist (delegate) specific PDMP query rates
- Pharmacy specific opioid dispensing
  - Total opioid dispensing volume
  - High dose opioid dispensing
## Results: Course Quiz Grades

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<th>ID</th>
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<th>Post-Test Score</th>
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<td>68.75</td>
<td>81.25</td>
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<td>87.5</td>
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<td>7</td>
<td>62.5</td>
<td>87.5</td>
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<table>
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<th>Mean</th>
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<td></td>
<td>59.82</td>
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<td></td>
<td>8.09</td>
<td>5.50</td>
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\[ t(6)=6.13 \quad p<.001 \]

Cohen's \( d=3.35 \)  \( \text{effect-size} \ \ r=.86 \)
Survey Pre-Post Mean Comparisons

Perceived Knowledge of Opioid Abuse | General Attitude Towards PDMP | Subjective Norm towards PDMP use | PDMP Knowledge | PDMP Perceived Behavioral Control

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 2</th>
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<td>3.29</td>
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<td>4.13</td>
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Note. Cohen’s d: .2 = small, .5 = medium, .8 = large
Mean Query Count – PDMP Non-mandate Stores

Group
- Control
- Intervention

Query Count

Pre | Implementation | Post
--- | --- | ---
40 | 40 | 40

#Rx Summit  www.NationalRxDrugAbuseSummit.org
Mean Opioid Fills per Site
Mean Proportion Opioid Fills >100 MED

- Pre
- Implementation
- Post

Group
- Control
- Intervention

Percent Fills >100 MED per Day
Conclusions and Implications

- Pilot pharmacies were receptive to training material
  - Patterns of use vary dramatically
  - Existing policies and training were generally insufficient

- Use of toolkit resulted in self-reported improvements in
  - Knowledge
  - Trends in attitudes, perceived behavioral control

- No changes in PDMP query rates or dispensing practices

- Additional educational enhancements may be required to improve outcomes (e.g. educational outreach)
## Exit Interviews

<table>
<thead>
<tr>
<th>Likes</th>
<th>Dislikes</th>
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</thead>
<tbody>
<tr>
<td>• Encouraged conversations with Providers and between pharmacists.</td>
<td>• Needed more in-person support from management.</td>
</tr>
<tr>
<td>• Ended up using the PDMP more.</td>
<td>• Difficulty finishing trainings due to time constraints.</td>
</tr>
<tr>
<td>• Made pharmacists think more about legal responsibility.</td>
<td>• Prescriber communication strategy worked for people comfortable talking to physicians, but didn’t empower those who aren’t comfortable.</td>
</tr>
</tbody>
</table>

**Target:** At least one participant per study site

**Purpose:** Gather feedback on toolkit materials, course, and dissemination for Phase 2 modification strategy.
RESPOND Revisions – Phase 2

- **Course modifications:**
  - Shortened: 2 hours $\rightarrow$ 1.5 hours
  - Fourth module added: Naloxone Distribution
  - Streamlined and visually enhanced

- **Materials updated:**
  - Design improved and naloxone added
  - Website developed: [https://PharmacistRespond.org](https://PharmacistRespond.org)

- **Process modifications:**
  - Manager outreach to allow training time
  - Pharmacy managers recruited
Current Progress & Next Steps

- Finalize Phase 1 & 2 quantitative analyses
- **RESPOND Toolkit**
  - Online resource PharmacistRESPOND.org
  - ACPE CE available through Oregon State University
- **MOON+ Collaboration**
  - Intervention to Increase Naloxone Engagement and Distribution in Community Pharmacies: A Four-State Randomized Trial (NIDA)
  - 160 community pharmacies across MA, RI, OR, WA (40 sites / state)
Thank You!

Research Team
(PI) Daniel Hartung, MPH, PharmD
(Co-I) Nicole O’Kane, PharmD
Lindsey Alley, MS
Jennifer Hall, MS
Kirbee Johnston, MPH
Deborah Cohen, PhD
Thuan Nguyen, MD, PhD
Christi Hildebran, LMSW, CADC III
Jody Carson, RN, MSW, CPHQ
Adriane Irwin, MS, PharmD, BCACP

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Melissa Hansen, PharmD
Laura Machado, MA
Melanie Mitchell
Paige Clarke, RPh
Michelle Marikos
David Sobieralski

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External Advisory Committee

Benjamin Sun, MD
Oregon Health & Science University

Melissa Weimer, DO, MCR
St. Peter’s Health Partners

Kathy Hahn, PharmD, DAAPM, CPE
Community Pharmacist
Affiliate Faculty, Oregon State University
College of Pharmacy

Michelle Koder, PharmD
Multnomah County Health Department

Roberto Linares, RPh
State of Oregon Board of Pharmacy

Lisa Millet, MHS
Oregon Health Authority, Public Health Division

Gwen Cox
Oregon Patient Safety Commission
Contact Us

Daniel Hartung (PI)
Oregon State University
College of Pharmacy
hartungd@ohsu.edu
(503) 494-4720

Nicole O’Kane (Co-I)
HealthInsight Oregon
Research Department
nokane@healthinsight.org
(503) 382-3964

http://pharmacistrespond.org/
Oregon Resources for Opioid Safety

1. Oregon Health Authority (OHA)
   Reducing Opioid Overdose and Misuse main page
   www.healthoregon.org/opioids
   OHA Oregon Prescribing and Drug Overdose Data Dashboard
   http://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Pages/data.aspx
   OHA Naloxone Guidance
   http://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Pages/naloxone.aspx#pharmacytoolkit
   OHA Regional CCO collaborative for safer opioid prescribing
   OHA Health Evidence Review Commission

2. Oregon Board of Pharmacy
   Information for pharmacists on prescribing naloxone
   https://www.oregon.gov/pharmacy/Pages/Naloxone.aspx

3. Oregon Pain Guidance
   Multidisciplinary website acting as a hub for communities in Oregon to coordinate and share best practices and resources related to opioid safety
   https://www.oregonpainguidance.org/

4. Oregon Coalition for Responsible Use of Meds
   Prescription disposal instructions for pharmacies and clinics
   https://orcrm.oregonpainguidance.org/rx-disposal/rx-disposal-pharmacists-clinics/
National Resources for Opioid Safety

1. Centers for Disease Control and Prevention
   One stop for various useful resources including data reports, information for patients, guidelines, publications, resources, online training for professionals
   https://www.cdc.gov/drugoverdose/data/index.html

2. Substance Abuse and Mental Health Services Administration (SAMHSA)
   SAMHSA Behavioral health treatment services locator and help line
   https://www.findtreatment.samhsa.gov/
   SAMHSA Medication-assisted treatment (MAT)
   https://www.samhsa.gov/medication-assisted-treatment
   SAMHSA Overdose prevention toolkit
   https://store.samhsa.gov/shin/content//SMA16-4742/SMA16-4742.pdf

   Opioid safety resources for health professionals, law enforcement and the public
   https://www.hhs.gov/opioids/index.html

4. Prescribe to Prevent
   Naloxone and overdose prevention training resources for prescribers, pharmacists, patients, families
   http://prescribetoprevent.org/

5. US Department of Justice Drug Enforcement Administration (DEA)
   Diversion control division
   https://www.deadiversion.usdoj.gov/
   DEA Drug disposal fact sheet