Right Patient.
Right Test.
Right Prescription.

Understanding the Opioid Epidemic: Size of the Problem, Challenging Requirements for Patient Management, and Ways for Labs to Add Value to Physicians, Payers, and Patients
Community Health Network (CHN) is not a client of hc1.com and does not endorse hc1.com in any way. CHN is only a co-presenting.
Outline

• The Opioid Epidemic in Numbers & Pictures
• New Challenging Clinical Guidelines
• How Laboratories Can Better Help Providers
• **Case Study: Community Health Network**
  Monitoring Patients More Closely Produces Better Patient Behavior
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Opioid Epidemic by The Numbers - People

- **24 Million** Americans on Chronic Opioid Therapy (COT)
- **11.5 Million** Americans Misusing Opioids
- **72,000** Drug Overdose Deaths in 2017 – 68% are Opioid Related
- **71% Increase** in Opioid Deaths from 2013 to 2017
- **1.7 Million** Americans Suffer Opioid Use Disorder (addiction)
- **652,000** Americans Abusing Heroin

Opioid Epidemic by The Numbers - Costs

- **$72 Billion** 2017, the Executive Office of the President of the United States, Council of Economic Advisors
- **$95.8 Billion** 2017, the Altarum Institute, independent study on the national economic burden of the opioid crisis
- **$78.5 Billion** 2016, the CDC estimate of total costs

“Call it $80 Billion per Year”

1999


2000

Estimated Age-Adjusted Death Rate per 100,000

<2
2-3.9
4-5.9
6-7.9
8-9.9
10-11.9
12-13.9
14-15.9
16-17.9
18-19.9
20-21.9
22-23.9
24-25.9
26-27.9
28-29.9
30+


2003


2007


2009


2010


2012


2014


2015


2016


2016


There are hot zones.

- Appalachia, New England, Florida, Oklahoma, Southwest, Pacific Northwest

The problem continues unabated despite all efforts.

- 56,000 county-years of data and not one example of a county dropping back to a lower death rate category.
Focus on Prevention

The problem is complex and multifaceted. Illicit drugs are a major contributor to the growth in drug overdose deaths.

However, when it comes to prescribing opioids, prevention starts with more deliberate patient monitoring—watching for signs of misuse and intervening as soon as problems are detected.
What does it mean to watch for signs of misuse?

1. **Risk Assessments**: Assess each patient for the risk of misuse, stratify them into risk levels, and monitor them accordingly.

2. **Opioid Agreements**: Make sure every patient understands the rules, the “do’s and don’ts”, document it in the medical record.

3. **PDMP Checks**: Consult the PDMP before prescribing or refilling a prescription for controlled substances.

4. **Urine Drug Testing**: Conduct randomized urine drug tests periodically over the course of treatment.

5. **Pill Counts**: Count the pills a patient has on-hand to ensure quantity is correct compared to prescription (not over or under)
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CAGE-AID Questionnaire

Patient Name __________________________ Date of Visit _______________________

When thinking about drug use, include illegal drug use as well as more than prescribed.

Questions:

1. Have you ever felt that you ought to cut down on your drinking or drug use?
2. Have people annoyed you by criticizing your drinking?
3. Have you ever felt guilty about drinking?
4. Have you ever had a drink or used drugs first thing in the morning (Eye-opener) to steady your nerves or to get rid of a hangover?

Scoring

Consider one or more positive responses to the CAGE-AID as indicative of alcohol problems.

Psychometric Properties

The CAGE-AID exhibited:

One or more Yes responses: Sensitivity = 0.79, Specificity = 0.77 (Brown 1995)
Two or more Yes responses: Sensitivity = 0.70, Specificity = 0.85 (Brown 1995)

Questions: YES NO

1. Have you ever felt that you ought to cut down on your drinking or drug use?
2. Have people annoyed you by criticizing your drinking?
3. Have you ever felt guilty about drinking?
4. Have you ever had a drink or used drugs first thing in the morning (Eye-opener) to steady your nerves or to get rid of a hangover?
## Opioid Risk Tool (ORT)

<table>
<thead>
<tr>
<th>Mark each box that applies</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Family history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>Personal history of substance abuse</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Illegal drugs</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Rx drugs</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td><strong>Age between 16—45 years</strong></td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>History of preadolescent sexual abuse</strong></td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td><strong>Psychological disease</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADD, OCD, bipolar, schizophrenia</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Depression</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Scoring totals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>These questions refer to the past 12 months.</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----</td>
<td>-----</td>
</tr>
<tr>
<td>1. Have you used drugs other than those required for medical reasons?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2. Do you abuse more than one drug at a time?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3. Are you always able to stop using drugs when you want to? (If never use drugs, answer “Yes.”)</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>4. Have you had &quot;blackouts&quot; or &quot;flashbacks&quot; as a result of drug use?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5. Do you ever feel bad or guilty about your drug use? If never use drugs, choose “No.”</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6. Does your spouse (or parents) ever complain about your involvement with drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>7. Have you neglected your family because of your use of drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>8. Have you engaged in illegal activities in order to obtain drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs?</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>10. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)?</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>
## Current Opioid Misuse Measure (COMM™)

<table>
<thead>
<tr>
<th>Please answer the questions using the following scale:</th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. In the past 30 days, how often have you had trouble with thinking clearly or had memory problems? (0 = Never)</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2. In the past 30 days, how often do people complain that you are not completing necessary tasks? (0 = Often)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>3. In the past 30 days, how often have you had to go to someone other than your prescribing physician to get sufficient pain relief from medications? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4. In the past 30 days, how often have you taken your medications differently from how they are prescribed? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>5. In the past 30 days, how often have you seriously thought about hurting yourself? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>6. In the past 30 days, how much of your time was spent thinking about opioid medications (having enough, taking them, dosing schedule, etc.)? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

<table>
<thead>
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<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. In the past 30 days, how often have you been in an argument? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>9. In the past 30 days, how often have you needed to take pain medications belonging to someone else? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10. In the past 30 days, how often have you been worried about how you’re handling your medications? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>11. In the past 30 days, how often have others been worried about how you’re handling your medications? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>12. In the past 30 days, how often have you had to make an emergency phone call or show up at the clinic without an appointment? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>13. In the past 30 days, how often have you gotten angry with people? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>14. In the past 30 days, how often have you had to take more of your medication than prescribed? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>15. In the past 30 days, how often have you borrowed pain medication from someone else? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>16. In the past 30 days, how often have you used your pain medicine for symptoms other than for pain (e.g., to help you sleep, improve your mood, or relieve stress)? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>17. In the past 30 days, how often have you had to visit the Emergency Room? (0 = Never)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
### Screener and Opioid Assessment for Patients with Pain- Revised (SOAPP®R)

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. How often do you have mood swings?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>2. How often have you felt a need for higher doses of medication to treat your pain?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>3. How often have you felt impatient with your doctors?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>4. How often have you felt that things are just too overwhelming that you can’t handle them?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>5. How often is there tension in the home?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>6. How often have you counted pain pills to see how many are remaining?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>7. How often have you been concerned that people will judge you for taking pain medication?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>8. How often do you feel bored?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>9. How often have you taken more pain medication than you were supposed to?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>10. How often have you worried about being left alone?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>11. How often have you felt a craving for medication?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>12. How often have others expressed concern over your use of medication?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Never</th>
<th>Seldom</th>
<th>Sometimes</th>
<th>Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>13. How often have any of your close friends had a problem with alcohol or drugs?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>14. How often have others told you that you had a bad temper?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>15. How often have you felt consumed by the need to get pain medication?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>16. How often have you run out of pain medication early?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>17. How often have others kept you from getting what you deserve?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>18. How often, in your lifetime, have you had legal problems or been arrested?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>19. How often have you attended an AA or NA meeting?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>20. How often have you been in an argument that was so out of control that someone got hurt?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>21. How often have you been sexually abused?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>22. How often have others suggested that you have a drug or alcohol problem?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>23. How often have you had to borrow pain medications from your family or friends?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>24. How often have you been treated for an alcohol or drug problem?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>
Agree these self-reported questionnaires are weak tools?

- If **answered honestly and accurately**, they may be useful tools.
- **But more important than what a patient says is what the patient does.**
- The **lab test, PDMP check, and pill counts** tell the provider what the patient really did.
- Yet these validated **risk assessments are required** to be performed and documented in most states.
What does it mean to watch for signs of misuse?

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Patient Agreement Form

Patient Name: ______________________
Medical Record Number: ____________
Addressograph Stamp: ______________

AGREEMENT FOR LONG TERM CONTROLLED SUBSTANCE PRESCRIPTIONS

The use of __________________________ (print names of medication(s)) may cause addiction and is only one part of the treatment for: __________________________ (print name of condition—e.g., pain, anxiety, etc.).

The goals of this medicine are:
☐ to improve my ability to work and function at home.
☐ to help my __________________________ (print name of condition—e.g., pain, anxiety, etc.) as much as possible without causing dangerous side effects.

I have been told that:
1. If I drink alcohol or use street drugs, I may not be able to think clearly and I could become sleepy and risk personal injury.
2. I may get addicted to this medicine.
3. If I or anyone in my family has a history of drug or alcohol problems, there is a higher chance of addiction.
4. If I need to stop this medicine, I must do it slowly or I may get very sick.

I agree to the following:
- I am responsible for my medicine. I will not share, sell, or trade my medicine. I will not take anyone else’s medicine.
- I will not increase my medicine until I speak with my doctor or nurse.
- My medicine may not be replaced if it is lost, stolen, or used up sooner than prescribed.
- I will keep all appointments set up by my doctor (e.g., primary care, physical therapy, mental health, substance abuse treatment, pain management).
- I will bring the pill bottles with any remaining pills of this medicine to each clinic visit.
- I agree to give a blood or urine sample, if asked, to test for drug use.

Refills

Refills will be made only during regular office hours—Monday through Friday, 8:00 AM-4:30 PM. No refills on nights, holidays, or weekends. I must call at least three (3) working days ahead (M-F) to ask for a refill of my medicine. No exceptions will be made. I will not come to Primary Care for my refill until I am called by the nurse.

I must keep track of my medications. No early or emergency refills may be made.

Pharmacy

I will only use one pharmacy to get my medicine. My doctor may talk with the pharmacist about my medicines.

The name of my pharmacy is ____________________________

Prescriptions from Other Doctors

If I see another doctor who gives me a controlled substance medicine (for example, a dentist, a doctor from the Emergency Room or another hospital, etc.) I must bring this medicine to Primary Care in the original bottle, even if there are no pills left.

Privacy

While I am taking this medicine, my doctor may need to contact other doctors or family members to get information about my care and/or use of this medicine. I will be asked to sign a release at that time.

Termination of Agreement

If I break any of the rules, or if my doctor decides that this medicine is hurting me more than helping me, this medicine may be stopped by my doctor in a safe way.

I have talked about this agreement with my doctor and I understand the above rules.

Provider Responsibilities

As your doctor, I agree to perform regular checks to see how well the medicine is working.

I agree to provide primary care for you even if you are no longer getting controlled medicines from me.

Patient’s signature ______________________ Date __________

Resident Physician’s signature ______________________

Attending Physician’s signature ______________________

☐ This document has been discussed with and signed by the physician and patient. (A signed copy stamped with patient’s card should be sent to the medical records department and a copy given to the patient.)

www.drugabuse.gov
CONTROLLED SUBSTANCES AGREEMENT

1. I, [PHYSICIAN NAME], am a patient of Dr. [PHYSICIAN NAME], have been informed that individuals who are prescribed certain controlled substances, including but not limited to, narcotic pain medicines, stimulants, benzodiazepine tranquilizers, and barbiturate sedatives, can abuse those substances or may allow abuse by others, and have some risk of developing an addictive disorder or suffering a relapse of a prior addiction. Therefore, I have been informed that it is necessary to observe strict rules pertaining to their use, and I agree to follow the terms and procedures described in this Agreement as consideration for, and as a condition of, the willingness of the physician whose signature appears below to consider prescribing or to continue prescribing controlled substances to treat my pain.

2. I will inform my physician of my current or past substance abuse, or any current or past substance abuse of any immediate member of my immediate family.

3. I agree that I may be subject to a voluntary evaluation by psychologists and/or psychiatrists, possibly at my own expense, before any controlled substances will be prescribed to me. I agree that the need to be evaluated by psychologists and/or psychiatrists may be revisited every three (3) to six (6) months thereafter while taking the medication.

4. All controlled substances must come from a physician in [PHYSICIAN PRACTICE/PROVIDER’S] office. My controlled substances will come from the pharmacy whose signature appears below, or during his or her absence, by the covering physician, unless specific written authorization is obtained from the office for an exception.

5. I will obtain all controlled substances from the same pharmacy. Should the need arise to change pharmacies, I will inform the [PHYSICIAN PRACTICE/PROVIDER’S] office.

6. I will inform the [PHYSICIAN PRACTICE/PROVIDER’S] office of any new medications or medical conditions, and of any adverse effects I experience from any of the medications that I take.

7. I will inform my other health care providers that I am taking the controlled substances listed above, and of the existence of this Agreement. In the event of an emergency, I will provide the foregoing information to emergency department providers.

8. I agree that my prescribing physician has permission to discuss all diagnostic and treatment details with other health care providers, pharmacists, or other professionals who provide my health care regarding my use of controlled substances for purposes of maintaining accountability.

9. I will not allow anyone else to have, use, sell, or otherwise have access to these medications. The sharing of medications with anyone is absolutely forbidden and is against the law.

10. I understand that controlled substances may be hazardous or lethal to a person who is not tolerant to their effects, especially a child, and that I must keep them out of reach of such people for their own safety.

11. I understand that tampering with a written prescription is a felony and I will not change or tamper with my doctor’s written prescription.

12. I am aware that attempting to obtain a controlled substance under false pretenses is illegal.

13. I agree not to alter my medication in any way, and I will take my medication whole, and it will not be broken, chewed, crushed, injected, or snorted.

14. I will take my medication as instructed and prescribed, and I will not exceed the maximum prescribed dose. Any change in dosage must be approved by a [PHYSICIAN PRACTICE/PROVIDER] physician.

15. I understand that these drugs should not be stopped abruptly, as withdrawal syndromes may develop.

16. I will cooperate with unannounced urine or serum toxicology screenings as may be requested, as well as any random pill counts of medication by [PHYSICIAN PRACTICE/PROVIDER]. Failure to comply may result in immediate discharge from the practice.

17. I understand that the presence of unprocessed and/or illegal substances in the screenings described in the paragraph above may prompt referral for assessment for a substance abuse disorder or discharge from the practice.

18. I understand that medications may not be replaced if they are lost, damaged, or stolen. If any of these situations arise that cause me to request an early refill of my medication, a copy of a filed police report or a statement from me explaining the circumstances may be required before additional prescriptions are considered. If I request an early refill secondary to lost, damaged, or stolen prescriptions within a year, I may be discharged from the practice.

19. I understand that a prescription may be given early if the physician or the patient will be out of town when the refill is due. These prescriptions will contain instructions to the pharmacist that the prescriptions(s) may not be filled prior to the appropriate date.

20. I will keep my scheduled appointments in order to receive medication refills.

21. I understand that I may be asked to bring my medications in their original container to the [PHYSICIAN PRACTICE/PROVIDER’S] office while I am on controlled medication.

22. Refills generally will not be given over the phone, after office hours, during the weekends, and on holidays.

23. I understand that any medical treatment is initially a trial, with the goal of treatment being to improve the quality of life and ability to function and/or work. These parameters will be assessed periodically to determine the benefits of continued therapy, and continued prescription is contingent on whether my physician believes that the medication usage benefits me. I will comply with all treatments as outlined by my physician at [PHYSICIAN PRACTICE/PROVIDER].

24. I have been explained the risks and potential benefits of these therapies, including, but not limited to, psychological addiction, physical dependence, withdrawal and over dosage.

25. I understand that failure to adhere to these policies and/or failure to comply with physician’s treatment plan may result in cessation of therapy with controlled substance prescribing by this physician or referral for further specialty assessment, as well as possible discharge from the practice.

26. I, the undersigned patient, attest that the foregoing was discussed with me, and that I have read, fully understand, and agree to all of the above requirements and instructions. I affirm that I have the full right and power to sign and be bound by this Agreement.

[Signatures]

Physician Name (printed): __________________________

Physician Signature: __________________________

Patient Name (printed): __________________________

Patient Signature: __________________________

Date: __________________________

Date: __________________________
Agree that these patient contracts are also weak?

- In fairness, these contracts may help some patients. Some patients will want to know the rules and abide by them.
- But these contracts will not help a patient intent on misuse.
- These documents have been criticized as equal parts liability reduction for the provider as they are informative for the patient.
What does it mean to watch for signs of misuse?

1. **Risk Assessments**: Assess each patient for the risk of misuse, stratify them into risk levels, and monitor them accordingly.

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PDMP Examples
PDMP Examples

Fictitious example.
No PHI presented.
## PDMP Examples

### Prescriptions

<table>
<thead>
<tr>
<th>Fill Date</th>
<th>Product, Str, Form</th>
<th>Quantity</th>
<th>Days</th>
<th>Pt ID</th>
<th>Prescriber</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/22/2015</td>
<td>HYDROCODONE BITARTRATE AND ACETAMINOPHEN, 325 MG;7.5 MG, TABLET</td>
<td>75.00</td>
<td>19</td>
<td>0123</td>
<td>CAL JA94</td>
</tr>
<tr>
<td>05/08/2015</td>
<td>HYDROCODONE BITARTRATE AND ACETAMINOPHEN, 325 MG;7.5 MG, TABLET</td>
<td>90.00</td>
<td>12</td>
<td>0123</td>
<td>CAL JA94</td>
</tr>
<tr>
<td>04/25/2015</td>
<td>DIAZEPAM, 5 MG, TABLET</td>
<td>30.00</td>
<td>10</td>
<td>6543</td>
<td>CAL JA94</td>
</tr>
<tr>
<td>04/25/2015</td>
<td>HYDROCODONE BITARTRATE AND ACETAMINOPHEN, 325 MG;7.5 MG, TABLET</td>
<td>90.00</td>
<td>10</td>
<td>6543</td>
<td>CAL JA94</td>
</tr>
<tr>
<td>11/02/2014</td>
<td>TRAMADOL HYDROCHLORIDE, 50 MG, TABLET, COATED</td>
<td>20.00</td>
<td>3</td>
<td>6543</td>
<td>IRI ED10</td>
</tr>
<tr>
<td>08/02/2014</td>
<td>IOPHEN C NR, 100 MG/5ML;10 MG/5ML, LIQUID</td>
<td>120.00</td>
<td>4</td>
<td>6543</td>
<td>BAK WA90</td>
</tr>
<tr>
<td>07/11/2014</td>
<td>IOPHEN C NR, 100 MG/5ML;10 MG/5ML, LIQUID</td>
<td>120.00</td>
<td>4</td>
<td>6543</td>
<td>BAK WA90</td>
</tr>
</tbody>
</table>

N/R: N=New R=Refill
Pay:01=Private Pay 02=Medicaid 03=Medicare 04=Commercial Ins. 05=Military Inst. and VA 06=Workers Comp 07=Indi

Fictitious example.
No PHI presented.
Fictitious example. No PHI presented.
PDMPs may have a deterrent effect, but PDMPs are only detecting inconsistent behavior about 4% of the time.

Study after study shows prescribers simply do not follow the guidelines. When asked “Why?” providers say the PDMP is “too difficult to access” and “too time consuming.”

- **28% of primary care physicians reported not even being aware of their states’ PDMPs.**

- **Prescribers in Kentucky checked the PDMP for only 6% of 2.9 million controlled substance prescriptions dispensed in that state that year.**

- **Physicians identify a number of barriers to PDMP use, including that retrieving the information is too time consuming and difficult.**


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Pill counts are helpful, but rarely used.

- Guidelines recommend a pill count when needed, but very limited guidelines exist for:
  - Frequency of pill counts (how often do you call a patient in for a pill count?)
  - Tolerance for discrepancy (when do you raise a flag? >10%? >25%? etc.)
  - What about patients who do not take their pills unless their pain is intolerable, should they be penalized for being more responsible?
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Lab testing is the most critical tool we have, but…

- CDC Only recommends 1/year
- CMS defines medical necessity as 1-2/year for low risk, 2-4/year for moderate risk, and 4-12/year for high risk.
- No government agency has required urine drug testing.
  - 32 Million Americans on chronic opioid therapy being given a $100 UDT 4 times per year is $12.8 Billion.
Example Toxicology Lab Report
## Example Toxicology Lab Report

### Interpretive Summary
**Inconsistent**
One or more results are INCONSISTENT with supplied medications. Please see the interpretive consultation below for details.

### Interpretive Consultation

**DRUGS EXPECTED:**
- NORCO (HYDROCODONE)

**CONSISTENT with medications provided:**
- NORCO (HYDROCODONE) based on hydrocodone, norhydrocodone

**INCONSISTENT with medications provided:**
- Alpha-OH-Alprazolam
- Alprazolam

**Drugs Not Included in this Assay:**
- Acetaminophen

Interpretation depends on accuracy and completeness of patient medication information on laboratory order.

### Patient Results

<table>
<thead>
<tr>
<th><strong>Collection Date</strong></th>
<th><strong>This Report</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>8/31/2017 4:10:00 PM</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Creatinine, Urine</strong></th>
<th><strong>218.7</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrocodone (cutoff 40 ng/mL)</td>
<td>Present</td>
</tr>
<tr>
<td>Norhydrocodone (cutoff 100 ng/mL)</td>
<td>Present</td>
</tr>
<tr>
<td>Alprazolam (cutoff 40 ng/mL)</td>
<td>Present</td>
</tr>
<tr>
<td>Alpha-OH-Alprazolam (cutoff 20 ng/mL)</td>
<td>Present</td>
</tr>
</tbody>
</table>

**ARUP Accession:** 17-244-401261
## Example Toxicology Lab Report

### OXYCODONE-LIKE, MASS SPEC

<table>
<thead>
<tr>
<th>Compound</th>
<th>Presence</th>
<th>Concentration</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodeone</td>
<td>Not Detected</td>
<td>40 ng/mL</td>
<td>oxycodone metabolite</td>
</tr>
<tr>
<td>--Noroxycodeone</td>
<td>Not Detected</td>
<td>100 ng/mL</td>
<td>eg, Opana; also a metabolite of oxycodone</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>Not Detected</td>
<td>40 ng/mL</td>
<td>oxymorphone metabolite; naloxone metabolite (i.e., normoxaloxone)</td>
</tr>
<tr>
<td>--Noroxymorphone</td>
<td>Not Detected</td>
<td>100 ng/mL</td>
<td>oxymorphone metabolite; naloxone metabolite (i.e., normoxaloxone)</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>Present</td>
<td>40 ng/mL</td>
<td>also a minor metabolite of Codeine; possible impurity of oxycodone</td>
</tr>
<tr>
<td>--Nohydrocodone</td>
<td>Present</td>
<td>100 ng/mL</td>
<td>hydrocodone metabolite</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Not Detected</td>
<td>40 ng/mL</td>
<td>eg, Dilaudid; also a metabolite of hydrocodone, and a minor metabolite of morphine</td>
</tr>
</tbody>
</table>

### OPIOIDS, MASS SPEC

<table>
<thead>
<tr>
<th>Compound</th>
<th>Presence</th>
<th>Concentration</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>Not Detected</td>
<td>5 ng/mL</td>
<td>eg Suboxone, Subutex. Please note: detection of naloxone is not included</td>
</tr>
<tr>
<td>--Norbuprenorphine</td>
<td>Not Detected</td>
<td>20 ng/mL</td>
<td>buprenorphine metabolite</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>Not Detected</td>
<td>2 ng/mL</td>
<td>fentanyl metabolite</td>
</tr>
<tr>
<td>--Norfentanyl</td>
<td>Not Detected</td>
<td>2 ng/mL</td>
<td>fentanyl metabolite</td>
</tr>
</tbody>
</table>
Example Toxicology Lab Report

<table>
<thead>
<tr>
<th>BENZODIAZEPINE-LIKE, MASS SPEC</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Alprazolam</strong></td>
<td>Present</td>
</tr>
<tr>
<td><strong>--Alpha-hydroxyalprazolam</strong></td>
<td>Present</td>
</tr>
<tr>
<td><strong>Clonazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>--7-aminoclonazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Diazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Nordiazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Oxazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Temazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Lorazepam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Midazolam</strong></td>
<td>Not Detected</td>
</tr>
<tr>
<td><strong>Zolpidem</strong></td>
<td>Not Detected</td>
</tr>
</tbody>
</table>

Reference interval

<table>
<thead>
<tr>
<th>Creatinine value (mg/dL)</th>
<th>218.7</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>20.0 - 400.0 mg/dL</td>
</tr>
</tbody>
</table>
National statistics show a 52% inconsistent rate for toxicology testing (2016, Prescription Drug Monitoring)

Comparing national results of both PDMP checks and toxicology tests shows lab results provide a better (13x) view of inconsistent behavior.

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- Be aware of what your providers have to do
  - Know the “five activities” and their value in managing patients
- Help with clinical interpretation and convenience
  - Use the patient med list to provide interpretive results for the provider.
  - Provide patient trend reports or historical results.
  - List common drug brand names as well as compounds on your reports.
  - Identify compounds which are expected metabolites of parent drugs.
  - Make the PDMP data easier to access for your providers, integrate PDMP into the EMR (through Appriss® Health).
  - Pull the PDMP data and compare the results to your lab report for your providers (hc1 Opioid Advisor™).
The Problem | PDMP and Test Results are Complex & Time-Consuming

6 - 9 Minutes, Many “clicks”
High Fatigue, 30% Error Rate

Brand Name vs. Chemical Name
Parent vs. Metabolites
Positive vs. Negative
Supposed to be Present vs. Not Supposed to be Present
Picked-Up at Pharmacy vs. Ingested into Body
The Problem | PDMP and Test Results are Complex & Time-Consuming

Brand Name vs. Chemical Name
Parent vs. Metabolites
Positive vs. Negative
Supposed to be Present vs. Not Supposed to be Present
Picked-Up at Pharmacy vs. Ingested into Body
### Lab Order

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Date Collected</th>
<th>Provider</th>
<th>Date Received</th>
<th>Provider NPI</th>
<th>Location</th>
<th>Location Address</th>
</tr>
</thead>
<tbody>
<tr>
<td>21071</td>
<td>03/16/2018 02:40:00 PM</td>
<td>Stephen Covington</td>
<td>03/17/2018 07:40:00 AM</td>
<td>1023529272</td>
<td>Benton Primary Care</td>
<td>555 South Benton Rd, Benton, XZ 55555</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specimen ID</th>
<th>Date Received</th>
<th>Date Resulted</th>
<th>Performing Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>4A200091</td>
<td>03/17/2018 07:40:00 AM</td>
<td>03/18/2018 08:30:00 AM</td>
<td>Sample Labs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient ID</th>
<th>Date Resulted</th>
<th>MRN</th>
</tr>
</thead>
<tbody>
<tr>
<td>12A2422</td>
<td>03/18/2018 08:30:00 AM</td>
<td>562211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DOB</th>
<th>Gender</th>
<th>Address</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/18/1979</td>
<td>Female</td>
<td>123 Main Street, Metropolis, XZ 55555</td>
<td>413-311-4512</td>
</tr>
</tbody>
</table>

### Drug Consistency

- **Prescribed & Detected**
  - Oxycodone
  - Oxymorphone
  - Noroxycodone
  - Codeine
  - Morphine

- **Prescribed & NOT Detected**

- **NOT Prescribed & Detected**
  - Alprazolam

### NARx Scores

<table>
<thead>
<tr>
<th>Panel</th>
<th>Test</th>
<th>Result</th>
<th>PDMP Prescription</th>
<th>Comments</th>
</tr>
</thead>
</table>

### State PDMP Report Viewed

- [View PDMP Report](#)
### Drug Consistency

#### Prescribed & Detected

<table>
<thead>
<tr>
<th>Drug</th>
<th>Test</th>
<th>Result</th>
<th>PDMP Prescription</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxycodone</td>
<td>Positive</td>
<td>Direct</td>
<td></td>
<td>Oxymorphone is a metabolite of Oxycodone</td>
</tr>
<tr>
<td>Noroxycodone</td>
<td>Positive</td>
<td>Indirect</td>
<td></td>
<td>Noroxycodone is a metabolite of Oxycodone</td>
</tr>
<tr>
<td>Codeine</td>
<td>Positive</td>
<td>Direct</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Morphine</td>
<td>Positive</td>
<td>Direct</td>
<td></td>
<td>Morphine is a metabolite of Codeine</td>
</tr>
<tr>
<td>Alprazolam</td>
<td>Positive</td>
<td>No</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Prescribed & NOT Detected

| Drug Panel Amphetamines | Negative | No |                  |                                                                         |

#### NOT Prescribed & Detected

| Drug Panel Cocaine     | Negative | No |                  |                                                                         |
| Drug Panel Lorazepam   | Negative | No |                  |                                                                         |
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Outline

• The Opioid Epidemic in Numbers & Pictures
• New Challenging Clinical Guidelines
• How Laboratories Can Better Help Providers
• **Case Study: Community Health Network**
  Monitoring Patients More Closely Produces Better Patient Behavior
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• New Challenging Clinical Guidelines
• How Laboratories Can Better Help Providers

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  Monitoring Patients More Closely Produces Better Patient Behavior
Case Study:
Impact of Comprehensive Patient Monitoring on Patients Prescribed Chronic Opioid Therapy
Community Health Network

- Serving Indianapolis and the surrounding area
  - 9 acute care hospitals
  - 12 health pavilions
- Largest primary care network in Indiana
  - Over 200 providers
  - More than 80 clinics
- Over 2 million patient encounters last year
- Recognized innovator in pain management
Abstract

• **Concept:** CHN developed and implemented standardized patient monitoring protocols for all patients prescribed chronic opioid therapy. Our protocols started with national guidelines and state regulations as minimums, then we applied additional rules to cover best practice recommendations and guide clinical decisions.

• **Results:** We experienced a significant decrease in inconsistent toxicology results after implementing our program (lab testing is our primary metric for aberrant patient behavior within the context of this program).

• **Conclusion:** Better patient monitoring led to better patient behavior.
Introduction

• In 2013, Indiana developed and legislated the most comprehensive prescribing guidelines in the country.
• The rules in Indiana include:
  – Patient risk assessments
  – Controlled substance agreements
  – PDMP (“INSPECT”) checks
  – Toxicology testing
  – Pill counts
Introduction

• In addition to state and federal guidelines:
  – Defined lab testing frequency by risk classification
  – Behavior and risk factor-driven classification adjustments
  – Support for providers
  – Continuous management review, analysis, and reporting
Methodology

• Plotted inconsistent toxicology test results over time for all patients actively enrolled in our monitoring program
• Compared the results to national averages published by Quest Diagnostics
Results

- Our data set includes over 3,400 enrolled patients.
- About half (54%) are “low risk”
- Our smallest category (17%) are “high risk”.

![Patients by Risk Classification](image-url)
Results

Q3/2018 Results

PDMP Results
- 98% No Inconsistent Results
- 1% Inconsistent Results
- 1% Potential Concern

Toxicology Results
- 72% No Inconsistent Results
- 19% Inconsistent Results
- 9% Potential Concern
Results

National Average

n = 17,231 patient toxicology results, 61 providers, 17 clinics, from 2/15 through 10/18

* Data from Quest Diagnostics Health Trends™, Drug Misuse in America 2018, Diagnostic Insights from Clinical Drug Monitoring into the Opioid Epidemic, Sep-18

Gina M. Cooper, MSN, RN | March 3, 2019
Conclusion

• These results are incredibly important.
• For the first time, we see a relationship between more closely monitoring patients and better patient behavior.
Outline

• The Opioid Epidemic in Numbers & Pictures
• New Challenging Clinical Guidelines
• How Laboratories Can Better Help Providers

• Case Study: Community Health Network
  Monitoring Patients More Closely Produces Better Patient Behavior
Outline

• The Opioid Epidemic in Numbers & Pictures
• New Challenging Clinical Guidelines
• How Laboratories Can Better Help Providers
• **Case Study: Community Health Network**
  Monitoring Patients More Closely Produces Better Patient Behavior
Here is what we know:

- **24 Million** Americans are on some form of Chronic Opioid Therapy\(^1\)
- **12.5 Million** patients are misusing their prescription opioids today\(^2\)
- Opioid misuse costs the United States **$80 billion** per year\(^3\)
- Following the guidelines has shown a reduction in aberrant behavior by **40\%**\(^4\)

If we can help providers increase their compliance to guidelines **by just 20\%**:

- We would identify **over 1,000,000** patients who are currently misusing opioids, allowing their physicians to safely intervene.
- We would reduce **$6.4 billion per year** in opioid related costs.

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Understanding the Opioid Epidemic: Size of the Problem, Challenging Requirements for Patient Management, and Ways for Labs to Add Value to Physicians, Payers, and Patients