Embrace Changes and Prevent Overdose: A Basic Blueprint for Legal Risk Mitigation and Response

Created and presented by:
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PainWeek and PainWeekEnd 2019

3/3/19

Disclosures for Jennifer Bolen, JD (as of 03/01/2019)

- Consultant: Paradigm Labs

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Course Objectives

- Identify: Identify common trends in legal actions against opioid prescribers.
- List and Describe: List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy, and describe how they can contribute to bad legal outcomes.
- Explain: Explain how to create a risk evaluation action plan and supporting documentation.

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OBJECTIVE 1:

Identify common trends in legal actions against opioid prescribers.

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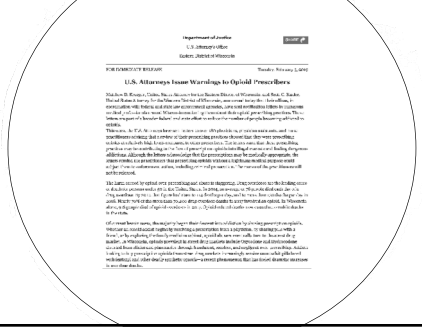

Department of Justice

U.S. Attorney's Office

Eastern District of Wisconsin

FOR IMMEDIATE RELEASE

Thursday, February 5, 2015

U.S. Attorneys Issue Warnings to Opioid Prescribers

3/3/19

Department of Justice

U.S. Attorney's Office

Middle District of Florida

FOR IMMEDIATE RELEASE

Wednesday, January 30, 2019

Clearwater Doctor Sentenced To Prison For Health Care Fraud

3/3/19

Legitimate Medical Purpose

- One or more generally recognized medical indication for the use of the controlled substance

Usual Course of Professional Practice

- According to licensing and professional standards, including consideration of licensing board material;
- Steps of a "Reasonably Prudent" Practitioner

Reasonable Steps to Prevent Abuse and Diversion

- Proper Risk Evaluation, Stratification, and Monitoring Protocols, including overdose risk evaluation
- PDMP, UDT, NALOXONE, OPIOID TRIAL, VISIT FREQUENCY
- Many other "reasonable steps"

DEA "Standards" for Registrants who Prescribe Controlled Substances

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POSITION OF TRUST

Reminder:

Core Responsibilities when Prescribing Controlled Substances

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State Overview –

ARIZONA
CALIFORNIA
COLORADO
TEXAS

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INSERT STATE UPDATES FOR EACH LOCATION

- STATE-SPECIFIC SLIDES WILL BE INSERTED FOLLOWING RESEARCH JUST PRIOR TO THE PRESENTATION.
- THIS KEEPS THE MATERIAL CURRENT FOR ATTENDEES.
- BOLEN WILL UPLOAD USEFUL HANDOUTS AND CITE LINKS.
- ADDENDUM: I REMOVED HEAVY GRAPHICS (PDF CLIPS) FROM THIS SECTION TO REDUCE SIZE OF FILE. NONE REFERENCED ANY COMPANY OR MEDICATION BRAND. ALL LICENSING BOARD RELATED.

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OBJECTIVE 2:

List three common weaknesses associated with documentation of risk assessment of patients for chronic opioid therapy, and describe how they can contribute to bad legal outcomes.

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LEGAL PERSPECTIVE:

Three common risk mitigation weaknesses – chronic opioid therapy

1. Poor Risk Assessment Process and Follow Through.
2. Untimely Use of Information gathered through Risk Assessment/Evaluation and Patient Encounters.
3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Coordination of Care Issues.

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REALITIES OF RISK ASSESSMENT

A LEGAL PERSPECTIVE ON THE RISK "ECOSYSTEM" AND CHRONIC OPIOID THERAPY

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What does risk assessment and monitoring mean to you?

Audience input

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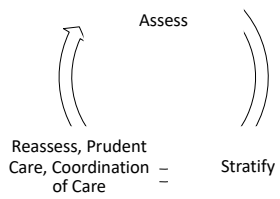
Basic Risk Mitigation Process



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CDC Says Risk Assessment is . . .

https://www.cdc.gov/drugoverdose/pdf/Guidelines_Factsheet-a.pdf.

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

8 Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.

9 Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months.

10 When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.

11 Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

CLINICAL REMINDERS

- Evaluate risk factors for opioid-related harms
- Check PDMP for high dosages and prescriptions from other providers
- Use urine drug testing to identify prescribed substances and undisclosed use
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

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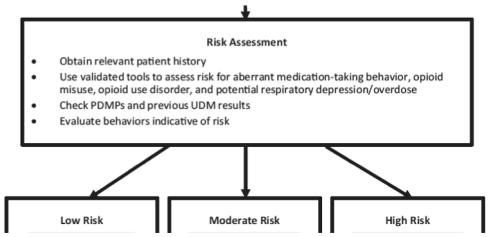
American Academy of Pain Medicine Says Risk Assessment is . . .



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American Academy of Pain Medicine Says Risk Factors of Opioid Misuse and Opioid Use Disorder Include . . .

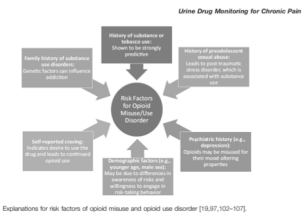

Figure 3 Explanations for risk factors of opioid misuse and opioid use disorder [19,97,102–107].

Charles E Argoff, Daniel P Alford, Jeffrey Fudin, Jeremy A Adler, Matthew J Bair, Richard C Dart, Roy Gandolfi, Bill H McCarberg, Steven P Stanos, Jeffrey A Gudin, Rosemary C Polomano, Lynn R Webster; Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, *Pain Medicine*, Volume 19, Issue 1, 1 January 2018, Pages 97–117, https://doi.org/10.1093/pm/pnx285

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Arizona Says Risk Mitigation is . . .

RISK MITIGATION

7 **For patients on long-term opioid therapy, document informed consent which includes the risks of opioid use, options for alternative therapies and therapeutic boundaries.**

The degree of risk associated with long-term opioid therapy (see Guideline #5) warrants completion of informed consent to ensure and document patient and provider understanding of the risks and benefits of opioid therapy. Informed consent should be obtained prior to initiation and following any changes to the treatment plan.

A risk stratification should be performed as part of a risk/benefit assessment prior to initiating or continuing opioid therapy in patients with chronic pain. Risk assessment can be accomplished either by using existing opioid risk assessment tools such as the Opioid Risk Tool or the Screener and Opioid Assessment for Patients with Pain – Revised (SOAPP-R). There are known limitations of risk tools, including low-sensitivity for the ORT and patient burden for longer tools like the SOAPP-R.

The care of patients with chronic pain should include a comprehensive medical and pain related evaluation that includes assessing for substance use, psychiatric comorbidities and functional status. Comorbidities of anxiety and depression in particular may influence pain perception and exacerbate pain complaints.

DO IT Incorporate an informed consent document for regular clinic use.

8 **Do not use long-term opioid therapy in patients with untreated substance use disorders.**

The recommendation against long-term opioid therapy for patients with substance use disorders is supported by at least five large studies and national recommendations. Among patients with untreated substance use disorder, opioids carry a significant risk for adverse outcomes including opioid use disorder, opioid overdose and death. The lack of evidence of efficacy of long-term opioid therapy (see Guideline #5) and considerable evidence of significant harms of overdose, death and suicide outweighs any potential modest benefit of prescribing long term opioid therapy in this population. In these patients, treatment of pain should optimize non-pharmacologic and non-opioid pharmacotherapy.

For patients already receiving long-term opioid therapy who are diagnosed with an untreated substance use disorder, clinicians should monitor closely, offer or arrange for substance use disorder treatment, and proceed with an exit strategy from the use of long-term opioid therapy for chronic pain (see Guideline #17).

9 **Avoid concurrent use of opioids and benzodiazepines. If patients are currently prescribed both agents, evaluate tapering or an exit strategy for one or both medications.**

https://azdhs.gov/documents/audiences/clinicians/clinical-guidelines-recommendations/prescribing-guidelines/az-opioid-prescribing-guidelines.pdf Page

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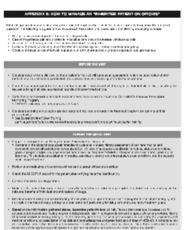
ARIZONA Says Risk Mitigation in the Inherited Patient is . . .



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Additional Examples

- Washington State
- California
- Tennessee
- Texas
- Florida

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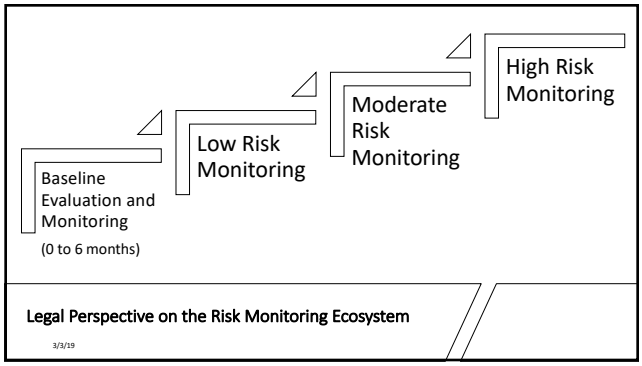

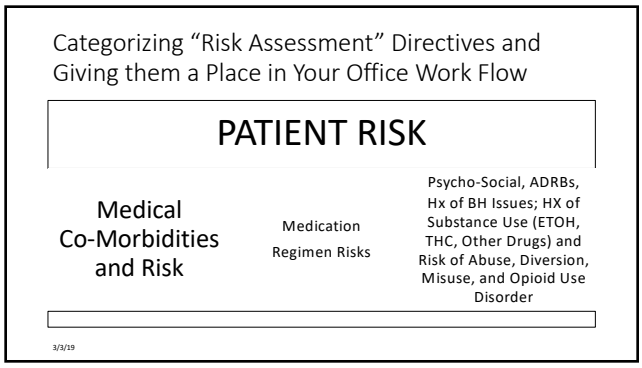

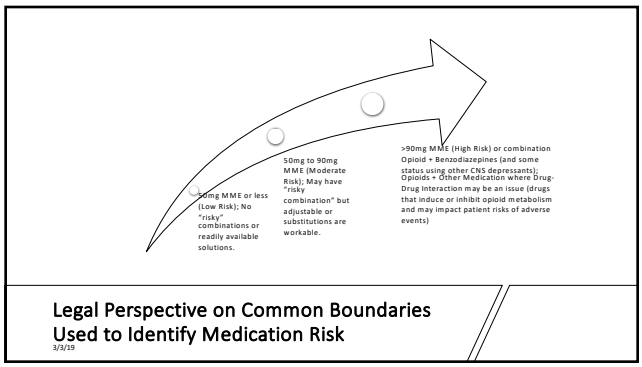

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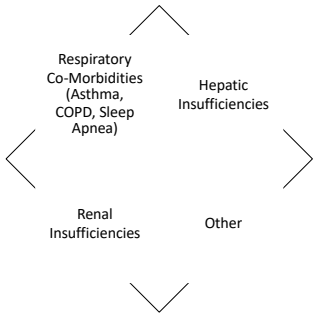
Legal Perspective on Commonly Referenced Medical Co-Morbidities that Enhance Risk of Overdose Event



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Legal Perspective: Commonly Referenced Psycho-Social Factors and Risk

- Behavioral Health History
- Aberrant, Drug Related Behaviors (PDMP-Doctor-shopping, Discharge for self-escalation, other behaviors tied to patient's relationship with prescription drugs and other substances)
- Smoking, Drinking - Personal and First Degree Relative History; Substance Use Disorder, Treatment, Etc.
- Other

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Quick Sorting of "Risk Assessment" Tools

- Questions you should ask yourself when you reexamine the "risk assessment" process and tools you use:
  - Which Risk Domain am I Addressing with a Particular Process or Tool?
  - How often do I use the tool? What should I do if I used the tool too often and the patient has given different answers?
  - How will I document that I addressed the same?
  - How will I factor the patient's "risk" under that domain into my overall risk evaluation of him/her?
    - How will I do so without inappropriately labeling the patient?
    - Do I need outside peer support to properly evaluate the patient?
  - How will I structure my "risk levels" –
    - Low, moderate, high?
    - Low and Mod/high?
    - Low and High?
  - How will I establish my treatment plan boundaries for each risk level? How will I keep this information current, so I can see it before each visit or procedure?

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A Quick Glance at a Couple of Tools Focused on Abuse, Misuse, Diversion, Opioid Use Disorders

Read the fine print

Opioid Risk Tool (ORT)

- Background
- What "risk" does it assess?
- How does it "rank" risk?
- How should that factor into the "rest of the story"?

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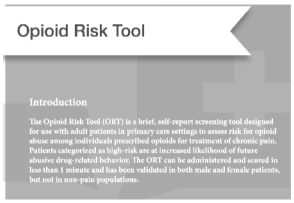

BIG HINT . . .

- DO. NOT.
- GIVE THE QUESTIONNAIRE WITH THE SCORING INFORMATION.
- TO. THE. PATIENT.

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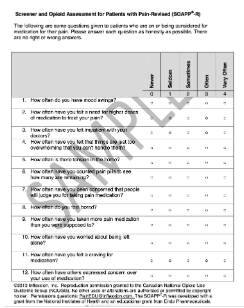
Opioid Risk Tool

This tool should be administered to patients upon an initial visit prior to beginning opioid therapy for pain management. A score of 3 or lower indicates low risk for future opioid abuse, a score of 4 to 7 indicates moderate risk for opioid abuse, and a score of 8 or higher indicates a high risk for opioid abuse.

Mark each box that applies	Female	Male
Family history of substance abuse		
Alcohol	1	3
Illegal drugs	2	3
Rx drugs	4	4
Personal history of substance abuse		
Alcohol	3	3
Illegal drugs	4	4
Rx drugs	5	5
Age between 16—45 years	1	1
History of preadolescent sexual abuse	3	0
Psychological disease		
ADD, OCD, bipolar, schizophrenia	2	2
Depression	1	1
Scoring totals		

THE SOAPP FAMILY

Screening and Opioid Assessment for Patients with Pain



Screener and Opioid Assessment for Patients with Pain-Revised (SOAPP®-R)

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
1. How often do you have mood swings?	○	○	○	○	○
2. How often have you felt a need for higher doses of medication to treat your pain?	○	○	○	○	○
3. How often have you felt impatient with your doctors?	○	○	○	○	○
4. How often have you felt that things are just too overwhelming that you can't handle them?	○	○	○	○	○
5. How often is there tension in the home?	○	○	○	○	○
6. How often have you counted pain pills to see how many are remaining?	○	○	○	○	○
7. How often have you been concerned that people will judge you for taking pain medication?	○	○	○	○	○
8. How often do you feel bored?	○	○	○	○	○
9. How often have you taken more pain medication than you were supposed to?	○	○	○	○	○
10. How often have you worried about being left alone?	○	○	○	○	○
11. How often have you felt a craving for medication?	○	○	○	○	○
12. How often have others expressed concern over your use of medication?	○	○	○	○	○

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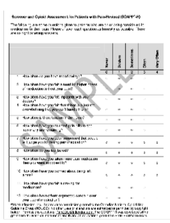
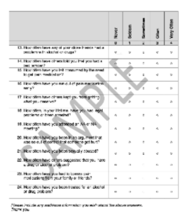
A Closer Look at SOAPP-R





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NEW SOAPP-8 and OTHERS

- Cannot access SOAPP-8 publicly; Paid access unless other arrangements are made.
- Differences between SOAPP-8 and SOAPP-R
- Additional Discussion

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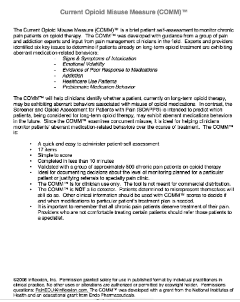
SOAPP's Sister Tool – COMM

Current Opioid Misuse Measure



Current Opioid Misuse Measure (COMM)™

The Current Opioid Misuse Measure (COMM)™ is a brief patient self-assessment to monitor chronic pain patients on opioid therapy. The COMM™ was developed with guidance from a group of pain and addiction experts and input from pain management clinicians in the field. Experts and providers identified six key issues to determine if patients already on long-term opioid treatment are exhibiting aberrant medication-related behaviors:

- *Signs & Symptoms of Intoxication*
- *Emotional Volatility*
- *Evidence of Poor Response to Medications*
- *Addiction*
- *Healthcare Use Patterns*
- *Problematic Medication Behavior*

The COMM™ will help clinicians identify whether a patient, currently on long-term opioid therapy, may be exhibiting aberrant behaviors associated with misuse of opioid medications. In contrast, the Screener and Opioid Assessment for Patients with Pain (SOAPP®) is intended to predict which patients, being considered for long-term opioid therapy, may exhibit aberrant medications behaviors in the future. Since the COMM™ examines concurrent misuse, it is ideal for helping clinicians monitor patients' aberrant medication-related behaviors over the course of treatment. The COMM™ is:

- A quick and easy to administer patient-self assessment
- 17 items
- Simple to score
- Completed in less than 10 minutes
- Validated with a group of approximately 500 chronic pain patients on opioid therapy
- Ideal for documenting decisions about the level of monitoring planned for a particular patient or justifying referrals to specialty pain clinic.
- The COMM™ is for clinician use only. The tool is not meant for commercial distribution.
- The COMM™ is NOT a lie detector. Patients determined to misrepresent themselves will still do so. Other clinical information should be used with COMM™ scores to decide if and when modifications to particular patient's treatment plan is needed.
- It is important to remember that all chronic pain patients deserve treatment of their pain. Providers who are not comfortable treating certain patients should refer those patients to a specialist.

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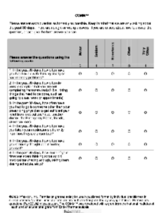
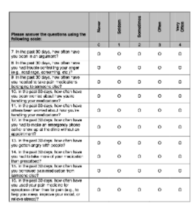
SOAPP's Sister Tool – COMM





Please answer the questions using the following scale:	Never	Seldom	Sometimes	Often	Very Often
	0	1	2	3	4
7. In the past 30 days, how often have you been in an argument?	O	O	O	O	O
8. In the past 30 days, how often have you had trouble controlling your anger (e.g., road rage, screaming, etc.)?	O	O	O	O	O
9. In the past 30 days, how often have you needed to take pain medications belonging to someone else?	O	O	O	O	O
10. In the past 30 days, how often have you been worried about how you're handling your medications?	O	O	O	O	O
11. In the past 30 days, how often have others been worried about how you're handling your medications?	O	O	O	O	O
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?	O	O	O	O	O
13. In the past 30 days, how often have you gotten angry with people?	O	O	O	O	O
14. In the past 30 days, how often have you had to take more of your medication than prescribed?	O	O	O	O	O
15. In the past 30 days, how often have you borrowed pain medication from someone else?	O	O	O	O	O
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)?	O	O	O	O	O

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Sample Tools Focused on Medical and Medication-Related Risks

Read the fine print

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General Resources for Tools on Medication and Medical Risks: Evaluation and Monitoring

- CDC
- SAMHSA (focus for purpose of lecture)
- FSMB
- State Licensing Boards
- Local Medical Associations

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SAMHSA
Opioid Overdose
TOOLKIT:
Information for Prescribers

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SAMHSA Original Toolkit and Link to 2016 Kit

https://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2016/All-New-Products/SMA16-4742.

CONSIDER PRESCRIBING NALOXONE ALONG WITH THE PATIENT'S INITIAL OPIOID PRESCRIPTION. Naloxone competitively binds opioid receptors and is the antidote to acute opioid toxicity. With proper education, patients on long-term opioid therapy and others at risk for overdose may benefit from having a naloxone kit containing naloxone, syringes and needles or prescribing Evzio® which delivers a single dose of naloxone via a hand-held auto-injector that can be carried in a pocket or stored in a medicine cabinet to use in the event of known or suspected overdose [6].

Patients who are candidates for such kits include those who are:

- Taking high doses of opioids for long-term management of chronic malignant or non- malignant pain.
- Receiving rotating opioid medication regimens (and thus are at risk for incomplete cross-tolerance).
- Discharged from emergency medical care following opioid intoxication or poisoning.
- At high risk for overdose because of a legitimate medical need for analgesia, coupled with a suspected or confirmed history of substance abuse, dependence, or non-medical use of prescription or illicit opioids.
- On certain opioid preparations that may increase risk for opioid overdose such as extended release/long-acting preparations.
- Completing mandatory opioid detoxification or abstinence programs.

For further information about Evzio® visit www.evzio.com

OPIOID OVERDOSE

The risk of opioid overdose can be minimized through adherence to the following clinical practices, which are supported by a considerable body of evidence [3-5].

ASSESS THE PATIENT. Obtaining a history of the patient's past use of drugs (either illicit drugs or prescribed medications with abuse potential) is an essential first step in appropriate prescribing. Such a history should include very specific questions. For example:

- "In the past 6 months, have you taken any medications to help you calm down, keep from getting nervous or upset, raise your spirits, make you feel better, and the like?"
- "Have you been taking any medications to help you sleep? Have you been using alcohol for this purpose?"
- "Have you ever taken a medication to help you with a drug or alcohol problem?"
- "Have you ever taken a medication for a nervous stomach?"
- "Have you taken a medication to give you more energy or to cut down on your appetite?"
- Have you ever been treated for a possible or suspected opioid overdose?

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SAMHSA Opioid Overdose Toolkit

SAMHSA
(Substance Abuse and Mental Health Services Administration)

"REDUCE THE RISK"

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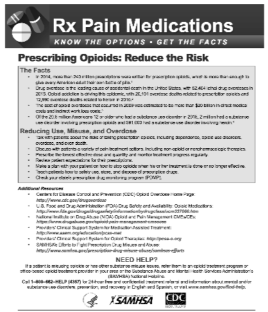

SAMHSA
(Substance Abuse and Mental Health Services Administration)

- Medication and Substance Use Risks
- Dangerous Drug Interactions

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SAMHSA
(Substance Abuse and Mental Health Services Administration)

A simple treatment agreement

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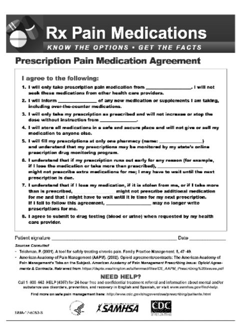

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SAMHSA Medication List

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Rx Pain Medications
KNOW THE OPTIONS • GET THE FACTS
My Medications
NEED HELP?
SAMHSA
CDC

Resources: Websites

CDC
http://www.cdc.gov/drugoverdose/prescribing/providers.htm
- Provider and patient materials, including prescribing checklists, flyers, and posters

SAMHSA
http://www.samhsa.gov/atod/opioids

DHMH Opioid Website
dhmh.maryland.gov/medicaid-opioid-dur

MARYLAND DEPARTMENT OF HEALTH & MENTAL HYGIENE

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A FEW CASE EXAMPLES OF MISSED OPPORTUNITIES IN RISK EVALUATION/MONITORING

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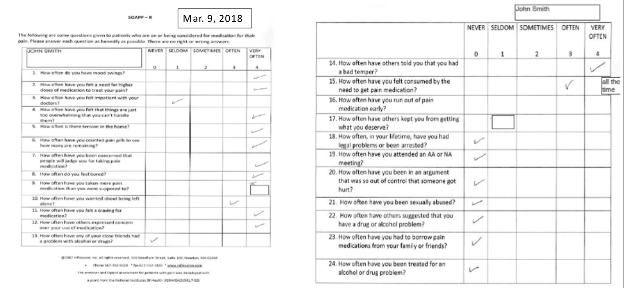
John Smith's Last Risk Assessment Responses Mar. 9, 2018


SOAPP – R   Mar. 9, 2018

The following are some questions given to patients who are on or being considered for medication for their pain. Please answer each question as honestly as possible. There are no right or wrong answers.

JOHN SMITH	NEVER 0	SELDOM 1	SOMETIMES 2	OFTEN 3	VERY OFTEN 4
1. How often do you have mood swings?					✓
2. How often have you felt a need for higher doses of medication to treat your pain?					✓
3. How often have you felt impatient with your doctors?		✓			
4. How often have you felt that things are just too overwhelming that you can't handle them?					✓
5. How often is there tension in the home?					✓
6. How often have you counted pain pills to see how many are remaining?					✓
7. How often have you been concerned that people will judge you for taking pain medication?					✓
8. How often do you feel bored?					✓
9. How often have you taken more pain medication than you were supposed to?					✓
10. How often have you worried about being left alone?				✓	
11. How often have you felt a craving for medication?					✓
12. How often have others expressed concern over your use of medication?					✓
13. How often have any of your close friends had a problem with alcohol or drugs?	✓				

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The screener and Opioid assessment for patients with pain was developed with a grant from the National Institutes Of Health (#2R44DA0158L7-02)

John Smith

	NEVER 0	SELDOM 1	SOMETIMES 2	OFTEN 3	VERY OFTEN 4
14. How often have others told you that you had a bad temper?					✓
15. How often have you felt consumed by the need to get pain medication?				✓	all the time
16. How often have you run out of pain medication early?					
17. How often have others kept you from getting what you deserve?					
18. How often, in your lifetime, have you had legal problems or been arrested?	✓				
19. How often have you attended an AA or NA meeting?	✓				
20. How often have you been in an argument that was so out of control that someone got hurt?	✓				
21. How often have you been sexually abused?	✓				
22. How often have others suggested that you have a drug or alcohol problem?	✓				
23. How often have you had to borrow pain medications from your family or friends?	✓				
24. How often have you been treated for an alcohol or drug problem?	✓				

3/3/19

John Smith's Last Office Visit 3/9/18

- Complained of anxiety, lack of sleep, pain, and alcohol troubles.
- Concerned about running out of alprazolam because his prescribing physician is not available.
- Total MME is 180mg/day
- Requested Drug Test
- **Updated SOAPP-R**
- **Patient's BP was 88/64**
- **During visit, provider:**
  - Rx FENTANYL, 50mcg Q72 = 120 mg MME
  - Rx Oxycodone, 10mg Q6 hours (40mg) = 60mg MME
  - **Rx Alprazolam to keep patient from having seizures; supply covers 7 days (1 tablet BID)**

3/3/19

John Smith's Last UDT Timeline

- LAST OV and UDT SAMPLE — Mar. 9, 2018
- LAST UDT REPORT — Mar. 12, 2018
- Patient Overdosed and died — Mar. 18, 2018
- Test Results Reviewed — Mar. 31, 2018

3/3/19

Explain how to create a risk evaluation action plan and supporting documentation.

Objective 3

3/3/19

Key is TIMELY Assessment and Evaluation for use in treatment of patient and Physician Involvement

The picture can't be displayed.

3/3/19

3/3/19

Legal Perspective: Critical Risk Monitoring Considerations

- Frequency of visit AND Frequency of re-evaluation with MD
- Frequency of PDMP check if state does not require specific frequency
- Frequency of Drug Testing and Nature of Drug Testing Menu
- Type of medications that will be allowed
- Dose and Combination of medications that will be allowed without additional monitoring and provider support, including consults/referrals
- Issuance and Confirmation of Naloxone Prescription
- Exit or Additional Provider Support Strategies

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PHYSICIAN DIRECT INVOLVEMENT IN PATIENT RISK MONITORING

How often does the MD see the patient?

- Initial visit?
- Thereafter?

How often should the MD see the patient?

- Relative to patient risk level?
- Relative to patient progress/lack thereof with Tx plan?
- Both?

3/3/19

Naloxone and Minimizing Risk

Quick Reminder

3/3/19

REMEMBER:

It does not do any good to issue a Naloxone prescription to a high risk patient without making sure they filled it.

Some states may provide a limited immunity here; Most do not.

3/3/19

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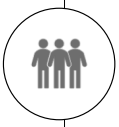
Education: It's a Process and Not a One-Time Thing

Parents and Staff

3/3/19

EDUCATE PATIENTS (and HIPAA-Consented Family/Friends) FROM THE START

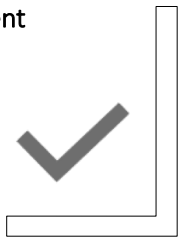
- SAFE USE
- SAFE STORAGE
- SAFE DISPOSAL
- NALOXONE



3/3/19

Adjust your Written Treatment Agreement

- **Patient's agreement NOT TO ABUSE ALCOHOL**
  - Test for it
  - Deal with it relative to ongoing opioid therapy (or BZO therapy)
- **Patient's agreement TO NOT USE OTHER MEDICALLY UNAUTHORIZED SUBSTANCES (including THC)**
  - Test for THC
  - Deal with it relative to ongoing opioid therapy (or BZO therapy)



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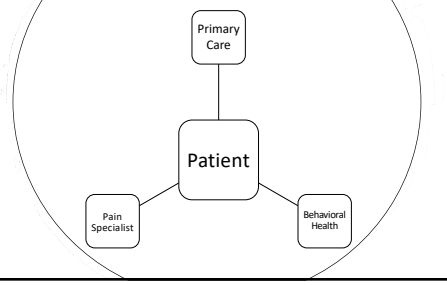
Coordination of Care

Addressing the Weaknesses

3/3/19

CONSULTATION & COORDINATION OF CARE



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Addressing Adverse Patient Events in a Timely Fashion

With your staff

In your practice processes and work flows

In your documentation practices

3/3/19

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REMINDER

Individualized Patient Care:

1. Looks backwards and constantly reevaluates the data points

2. And moves forward with the patient's best interests in mind, carefully balancing risks and benefits

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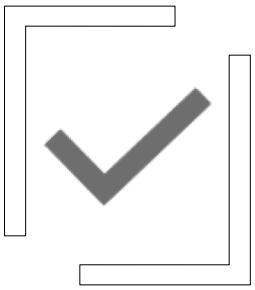

Questions?

- Thank you!

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