Embrace Changes and Mitigate Legal Risks Associated with Opioid Prescribing and the Issue of Overdose:

An Updated Blueprint for the Frontline Pain Practitioner and Medical Directors

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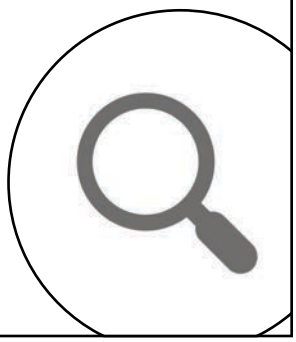
Learning Objectives

Identify	Identify common trends in legal actions against prescribers when a patient overdoses and dies
Describe	Describe critical perspectives around a proper response to the licensing board's request for the chart and a summary of care.
List	List three common risk mitigation weaknesses associated with chronic opioid therapy
Explain	Explain how to create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.
Discuss	Discuss case examples using a before and after application of the three pronged risk mitigation improvement plan.

OBJECTIVES 1 and 2:

1. Identify Common Trends in Legal Actions against a Prescriber when a Patient Overdoses and Dies.

2. Describe Critical Perspectives Around the Licensing Board's Request for the chart and a Summary of Care



Dear Pain Management Practitioner:

- Love, Your licensing board
- PS: You have 21 days to do this!

This office is in receipt of only one version of the allegations contained in t
enclosed information is being submitted to you to provide you the opportunity
recollection of the incident. Therefore, please submit a **narrative** setting forth
and response to the allegations contained in the complaint. **Your response to**
also include copies of all relevant medical treatment records, pursuant to

The typical case goes something like this . . .

Get	Get Letter •Hit the Panic Button •Reality Sets in
Talk	Talk to Lawyer •Gather Files; Hit Panic Button •Denial takes hold, with Anger as a seat buddy
Make	Make a Choice •Approach with Confidence and Send in Fact-Filled, Humble Response; Fight if you have to •OR Continue Denial and Fight without a helpful framework

Necessary framework and path forward

Freeze	Freeze Records • Copy and Review • NOTE THE FACTS; Avoid Opinion at First
Match	Match Facts Against Standards • Evaluate Strengths and Weaknesses • Identify potential expert support
Prepare	Prepare Response* (assuming advice of counsel is to do this) • Carefully mix case facts with humble description of decision-making • Wait and see, but prepare for possible next steps

Licensing Board Inquiry – Understand Perspectives (and the playing field)

What the Board sees through the eyes of the complainant	What you see (and think) when confronted with a Board letter	Reconciling the realities and embracing necessary changes/updates to your program
Someone has died	What? Why didn't they tell me sooner?	
You were prescribing them opioids and other medication	Yes, they were in pain.	What is in your charts that shows your rationale for each medication?
They died within a week or so of getting their last prescription from you	What? Why didn't they tell me sooner?	What type of risk monitoring were you doing? Did anything slip through the cracks? UDT Timing? Risk Status? Coordination of Care?
The complainant is a family member who knows the person who died and the story is compelling	Uh-oh.	Did you have prior contact with the family member? Anything in writing? How about patient education?
The complainant usually articulates facts that you either didn't know, didn't fully explore, or ignored. The Board wants to see the story your records tell.	1. No one told me. 2. They told me, but I didn't respond. 3. They told me, but my lawyer said not to response. 4. I did everything right.	Do your records speak for you?
The board wants a full explanation. You have important legal rights, but the board is watching how you handle your response.	My attorney will solve everything. Right.?!	Does your attorney speak pain? Do you need experts? The answer depends on many things.

If you have done your job . . . Then maybe

I am reporting to you the results of the review by the [SOME STATE] Board of Medical Examiners (the "Board") of the complaint filed regarding the above-referenced individual. In the course of the inquiry, the Board considered your response.

The Board has completed its review of the facts related to this matter and has determined that the issues identified were distressing to the complainant, but do not provide any basis to initiate disciplinary action.

The Board initiated this review because of its duty to safeguard the public by assuring that you, as a physician licensed to practice in this State, are complying with applicable statutes, regulations, and accepted standards of practice. As such, this matter is administratively closed.

This disposition of the complaint is being placed in the confidential files of the Board. Please be aware that, within this context, the complainant will be appropriately advised of the Board's handling of this matter.

What questions does the licensing board investigator try to answer? – Critical Perspectives

- **Does the record show that the Practitioner Issue a Controlled Substance Prescription:**
  - With or Without a proper evaluation, including proper risk assessment, and did he/she arrive at a diagnosis and create a treatment plan with goals and measurable milestones?
  - With or Without ongoing evaluation and risk mitigation, including timely use of the state's PDMP, UDT results, naloxone, and other control measures?
  - With or Without the proper documentation, including rationale for starting, changing, not stopping opioids; Is the rationale for the prescribed drugs clearly stated in the medical record?
  - With or Without Coordinating Care?

Reminder: Core Responsibilities when Prescribing Controlled Substances

DEA Standards

Licensing Board Standards

Position of Trust over the Patient

DEA "Standards" for Registrants who Prescribe Controlled Substances

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"

Licensing Board and Professional "Standards"
and Documentation of Same

Historical Steps with Patient	Active Care Plan Steps	Coordination of Care and Consultations/Referrals
• General medical history • Pain Specific History • Risk of Abuse/Addiction • Risk of Diversion • Risk of Overdose	• Opioid Trial and Some form of Exit Strategy • Treatment Plan for Frequency, Handling MME, PDMP utilization, UDT, etc. • Naloxone and Patient Education • Documentation and Process of Informed Consent and Treatment Agreement	• Scope of Practice Issues • Exchange of documentation between PCP and Specialty providers engaged in chronic MEDICATION therapy (not just limited to opioids) • Dealing with Marijuana issues • Rationale for starting, stopping, changing, etc.

Sample Licensing Board Guidelines/Rules

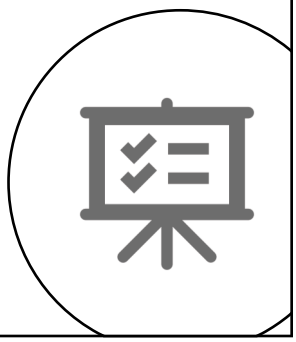
- Example is from California and a comparison between the California Pain Guidelines (2014) to the CDC Guidelines (2016)

California Comparison Continued

OBJECTIVES 3 and 4:

3. List three common risk mitigation weaknesses associated with chronic opioid therapy

4. Create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.



LEGAL PERSPECTIVE:

Three common risk mitigation weaknesses associated with chronic opioid therapy

1. Poor Risk Assessment Process and Follow Through
2. Untimely Use of or Failure to Use Drug Test Results in Risk Monitoring
3. Failure to Coordinate Care with Other Healthcare Providers and Lack of Patient Education Related to Coordination of Care Issues

A QUICK PUB MED SEARCH

Recent Clinical Literature Examining Potentially Inappropriate Prescribing Behavior and Connection to Overdose and Mortality

Six Types of Potentially Inappropriate Opioid Prescribing Behaviors (PIP)

MME >/= 100mg/day in >/= 3 mos.

Overlapping Opioid and Benzodiazepine Prescriptions in >/= 3 mos.	>/= 4 prescribers in any quarter	>/= 4 dispensing pharmacies in any quarter	Cash purchase of opioid prescriptions on >/= 3 occasions	Receipt of opioids in >/= 3 mos. Without a documented pain diagnosis

Potentially Inappropriate Opioid Prescribing, Overdose, and Mortality in Massachusetts, 2011-2015.

Rose A[1,2], Bernson D[3], Chu MH[3], Lanz P[3], Wales R[3,4], LaRochelle MR[3], Bern MD[3,5], Diana T[3,6]

Author information

BACKGROUND: Potentially inappropriate prescribing (PIP) may contribute to opioid overdose.

OBJECTIVE: To examine the association between PIP and adverse events.

DESIGN: Cohort study.

PARTICIPANTS: Three million seventy-eight thousand thirty-four individuals age ≥ 18, without disseminated cancer, who received prescription opioids between 2011 and 2015.

MAIN MEASURES: We defined PIP as (a) morphine equivalent dose ≥ 100 mg/day in ≥ 3 months, (b) overlapping opioid and benzodiazepine prescriptions in ≥ 3 months, (c) ≥ 4 opioid prescribers in any quarter, (d) ≥ 4 opioid-dispensing pharmacies in any quarter, (e) cash purchase of prescription opioids on ≥ 3 occasions, and (f) receipt of opioids in 3 consecutive months without a documented pain diagnosis. We used Cox proportional hazards models to identify PIP practices associated with non-fatal opioid overdose, fatal opioid overdose, and all-cause mortality, controlling for covariates.

KEY RESULTS: All six types of PIP were associated with higher adjusted hazard for all-cause mortality, four of six with non-fatal overdose, and five of six with fatal overdose. Lacking a documented pain diagnosis was associated with non-fatal overdose (adjusted hazard ratio (AHR) 2.21, 95% confidence interval (CI) 2.02-2.41), as was high-dose opioids (AHR 1.85, 95% CI 1.59-1.76). Co-prescription of benzodiazepines was associated with fatal overdose (AHR 4.23, 95% CI 3.55-4.65). High-dose opioids were associated with all-cause mortality (AHR 2.18, 95% CI 2.14-2.23), as was lacking a documented pain diagnosis (AHR 2.05, 95% CI 2.01-2.09). Compared to those who received opioids without PIP, the hazard for fatal opioid overdose with one, two, three, and ≥ four PIP subtypes were 4.24, 7.05, 10.28, and 12.59 (test of linear trend, p < 0.001).

CONCLUSIONS: PIP was associated with higher hazard for all-cause mortality, fatal overdose, and non-fatal overdose. Our study implies the possibility of creating a risk score incorporating multiple PIP subtypes, which could be displayed to prescribers in real time.

KEYWORDS: mortality; opioids; overdose; potentially inappropriate prescribing

PMID: [Indexed for MEDLINE]

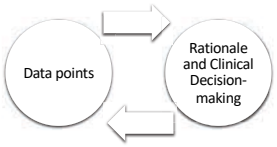
PIP Article	Bolen Group Audit Findings	General Suggestions for Improvement
MME >/= 100mg/day for >/= 3 mos.	Frequent failures to track MME	Track MME
Overlapping Opioid and Benzodiazepine Prescriptions in >/= 3 mos.	Sometimes overlapping involves more than one opioid and more than one Benzodiazepine, along with sleep medication, muscle relaxants, etc. and rationale not documented; coordination of care missing.	1. Document rationale for combination prescribing 2. Coordinate care with BZO prescriber 3. May be appropriate to discuss reducing Benzodiazepines or limiting term of use or time of reevaluation.
>/= 4 prescribers and pharmacists in any quarter	Multiple prescribers often involved people in the same practice or PCP/Internal Medicine, Pain Specialist, and Psychiatrist Multiple pharmacists happen for different reasons. Sometimes not clear in chart.	1. Use PDMP 2. Coordinate care with other physicians and pharmacists, especially for complex patient 3. Discuss need to know who treats patient and where medication is filled, what's prescribed, and why.
Cash purchase of opioids on >/= 3 occasions	Didn't find in our audit	1. Outside scope of lecture
Receipt of opioids in >/= 3 mos. without a documented pain diagnosis	Found mixed results on pain diagnosis. Sometimes specific diagnosis after workup. Other times, general diagnosis and failure to reevaluate after initial opioid trial period.	1. Perform a thorough evaluation 2. Document a specific diagnosis or working diagnosis 3. Evaluate frequently during first year and thereafter per standards

Comparing PIP to Our Anecdotal Audit Findings

Comparing PIP to Our Anecdotal Audit Findings - 2

PIP Article	Bolen Group Audit Findings	Remedy
NOT MENTIONED	INCONSISTENT OR LACK OF USE OF ANY RISK ASSESSMENT PLAN or SUMMARY OF FINDINGS	See Sample Tool
NOT MENTIONED	Delayed timing in review of UDT results and use of those results in treatment of patient	1. UDT Results Triage 2. Ongoing Use of UDT results in Tx 3. Documentation 4. See UDT Lecture

The mindset is to create the "cheese trail" that reflects the prescriber's rationale at various data points



Part 2 – Meet John Smith, Jane Doe, and a Young Guy

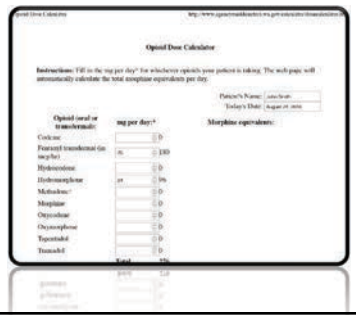
Examining three critical areas of risk mitigation weakness through case examples

Case Example #1 – John Smith

- Patient is a 33 y/o male
- He was crossing the street and got hit by a bus. Rib fractures. Collar bone fracture. Leg fracture. Spent several months in the hospital and undergoing rehabilitation.
- Patient now in chronic pain.
- Rx opioids. Rx benzodiazepines. Occasional Rx antidepressant use.
- Patient has a history of drinking and smoking.
- Patient has a history of aberrant drug related behaviors, including use of diphenhydramine and trazodone.
- Patient has a very high SOAPP-R score (high risk).

John Smith's Risk Assessment History

DATA POINT	Initial OV	6 months in	1 year in	Month of OD
SOAPP/Psych Testing	High risk Depression Scale	SOAPP scores 12 (high risk)	Still high risk	SOAPP-R last OV
Anxiety	Reports anxiety	Reports anxiety	Anxiety not reported/documented	Suffering from insomnia, panic attacks, aneiousness/stress
Depression	Reports feeling more sad than usual (dispressed)	Patient has psych history of depression documented, and reports feeling more sad than usual (depressed)	Continues to see a psychologist	Receiving 3 forms of antidepressant. Patient reports depression
Use of Diphenhydramine	Positive in UDS on second visit	Positive in UDS at 6 months	Positive in UDS at 18 months	Positive in last UDS
Multiple Opioids	Fentanyl and Hydromorphone	Fentanyl and Hydromorphone	Fentanyl and Hydromorphone	Fentanyl and Oxycodone
Use of Benzodiazepines	Taking 1mg Alprazolam BID	Same	Oxazepam appears in UDS along with Alprazolam	Afraid will run out of Alprazolam because prescribing provider unavailable
Smoker	Current every day smoker- 1 PPD	Current every day smoker	Reported as a former smoker, but Cotinine continues to appear positive in UDS	Reported as former smoker
Drinker	Patient drinks 1-13 alcoholic beverages per month	Reported to drink 1-13 alcoholic beverages a month- Alcohol in UDS	Reported as non drinker	Patient reports alcohol abuse- not counseled
MME	267mg MME	267mg MME	216mg MME	180mg MME



John Smith – Initial MME

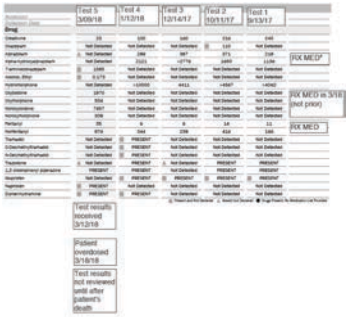
- 75 mcg/day Fentanyl
- 4mg hydromorphone, #6 per day

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.
- 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)
- Total MME is 180mg/day
- Requested Drug Test
- Updated SOAPP-R
- Patient's BP was 88/64

John Smith's Last Risk Assessment Responses Mar. 9, 20178

John Smith's Drug Test Results – Timing and Utility



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

SAMPLE STATE RULE ON USE OF DRUG TEST RESULTS (INDIANA)

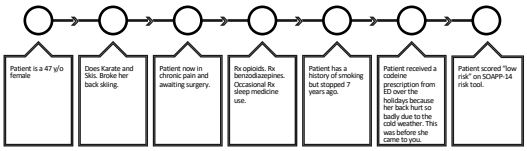
STANDARDS OF PROFESSIONAL CONDUCT AND COMPETENT PRACTICE OF MEDICINE

listed in subsection (b) if the physician reasonably determines following a review of less than all of the factors listed in subsection (b) that a drug monitoring test is medically necessary.

(d) Nothing about subsection (b) shall be construed to prohibit the physician from performing or ordering a drug monitoring test at any other time the physician considers appropriate.

(e) If a test performed under subsection (a), or conducted under subsection (d), reveals inconsistent medication use patterns or the presence of illicit substances, a review of the current treatment plan shall be required. Documentation of the revised treatment plan and discussion with the patient must be recorded in the patient's chart. *(Medical Licensing Board of Indiana; 844 IAC 5-6-8; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.]; filed Aug 22, 2016, 11:30 a.m.: 20160921-IR-844150415FRA)*

Case Example #2 – Meet Jane Doe



CASE STUDY #2 – JANE DOE – UDT Summary

INITIAL OFFICE VISIT and RELEVANT RX	UDT ORDERED	DATE ON LAB REPORT	Date EMR Shows Review	RESULTS	Aberrant?
1/24/15 RX after OV = OXYCODONE Patient had prior Rx Tylenol #3	Yes	1/28/15	**2/24/15**	Gabapentin+ TCA+	Yes, Gabapentin not disclosed, but is Rx from another doctor. Oxycodone Rx given.
2/24/15 Rx is OXYCODONE, Morphine added	Yes	3/1/15	**3/24/15**	Gabapentin+ Oxycodone - TCA+ Dextromethorphan+	Yes, Dextromethorphan; Missing Rx Opioid (Oxy)
3/24/15 Rxs for Oxycodone, Morphine, Gabapentin	Yes	4/2/15	**4/24/15**	Morphine + Gabapentin+ Oxycodone +	Yes, Morphine+ **but 6-MAM-NEG** Oxycodone+
4/24/15 Rxs for Oxycodone, Morphine, Gabapentin	Yes	5/26/1	**Reviewed after Patient's death.**	Morphine+ 6-MAM+ FENTANYL+ Oxycodone+	Patient overdosed and died.

Case Example #3 – Just a young guy

Patient is a 33 y/o male

Adopted. Birth mother was an alcoholic. Served in the Marines. Combat in Iraq. Married and recently divorced.

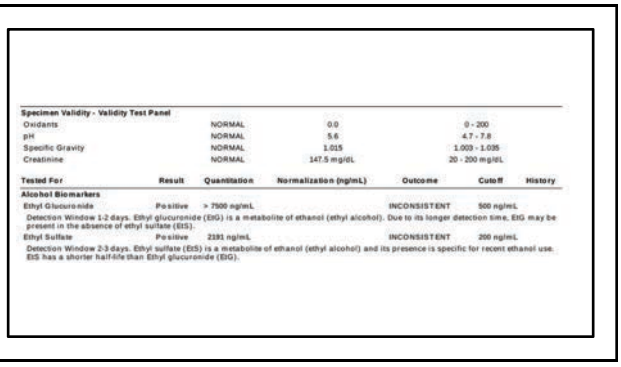
Patient fell off of orphanage roof in early years – fractured spine; unrepaired. Injured in Iraq. Six surgeries since ended tour of duty, including hip replacement. Needs spine surgery. PTSD diagnosis. Liver damage. Necrotizing fasciitis.

Rx opioids – start and DC opioids off and on through care, as add naltrexone. Cannot tolerate Buprenorphine. Rx multiple psychiatric medications. Rx sleep medication. Rx Gabapentin. Multiple suicide attempts.

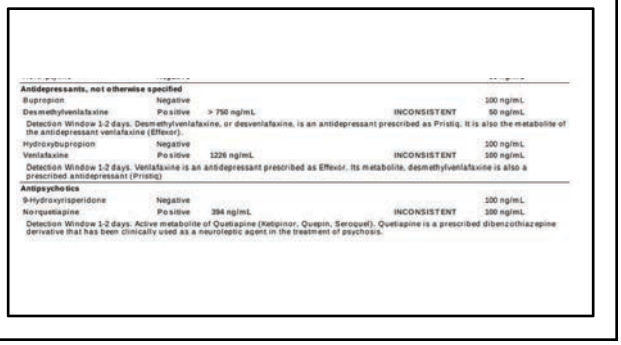
Patient has a history of smoking but now uses chewing tobacco. Prescribed an inhaler.

Patient prescribed naltrexone tablets and Gabapentin (high dose). NSAIDs for pain.

Patient recently back from alcohol rehabilitation. Continued treatment with pain practitioner's office during rehabilitation for psychiatric and pain management.



Specimen Validity - Validity Test Panel						
Oxidants		NORMAL	0.0		0 - 200	
pH		NORMAL	5.6		4.7 - 7.8	
Specific Gravity		NORMAL	1.015		1.003 - 1.035	
Creatinine		NORMAL	147.5 mg/dL		20 - 200 mg/dL	
Tested For	**Result**	**Quantitation**	**Normalization (ng/mL)**	**Outcome**	**Cutoff**	**History**
Alcohol Biomarkers						
Ethyl Glucuronide	Positive	> 7500 ng/mL		INCONSISTENT	500 ng/mL	
Detection Window 1-2 days. Ethyl glucuronide (EtG) is a metabolite of ethanol (ethyl alcohol). Due to its longer detection time, EtG may be present in the absence of ethyl sulfate (EtS).						
Ethyl Sulfate	Positive	2191 ng/mL		INCONSISTENT	200 ng/mL	
Detection Window 2-3 days. Ethyl sulfate (EtS) is a metabolite of ethanol (ethyl alcohol) and its presence is specific for recent ethanol use. EtS has a shorter half-life than Ethyl glucuronide (EtG).						



Antidepressants, not otherwise specified					
Bupropion	Negative				100 ng/mL
Desmethylvenlafaxine	Positive	> 750 ng/mL		INCONSISTENT	50 ng/mL
Detection Window 1-2 days. Desmethylvenlafaxine, or desvenlafaxine, is an antidepressant prescribed as Pristiq. It is also the metabolite of the antidepressant venlafaxine (Effexor).					
Hydroxybupropion	Negative				100 ng/mL
Venlafaxine	Positive	1226 ng/mL		INCONSISTENT	100 ng/mL
Detection Window 1-2 days. Venlafaxine is an antidepressant prescribed as Effexor. Its metabolite, desmethylvenlafaxine is also a prescribed antidepressant (Pristiq)					
Antipsychotics					
9-Hydroxyrisperidone	Negative				100 ng/mL
Norquetiapine	Positive	394 ng/mL		INCONSISTENT	100 ng/mL
Detection Window 1-2 days. Active metabolite of Quetiapine (Ketipinor, Quepin, Seroquel). Quetiapine is a prescribed dibenzothiazepine derivative that has been clinically used as a neuroleptic agent in the treatment of psychosis.					

Opiates					
Codeine	Positive	550 ng/mL	INCONSISTENT	50 ng/mL	
Detection Window 1-2 days. Codeine is an opiate with many therapeutic uses. Codeine is metabolized into morphine, and trace amounts of hydrocodone.					
Dihydrocodeine	Negative			50 ng/mL	
Hydrocodone	Positive	531 ng/mL	INCONSISTENT	50 ng/mL	
Detection Window 1-2 days. Hydrocodone is a semi-synthetic opioid analgesic. It metabolizes into Dihydrocodeine, norhydrocodone, and hydromorphone. Preparations include Vicodin, Lortab and Norco.					
Hydromorphone	Negative			50 ng/mL	
Morphine	Positive	> 750 ng/mL	INCONSISTENT	50 ng/mL	
Detection Window 1-2 days. The presence of Morphine has been confirmed. Possible sources can include (but are not limited to) Morphine drugs, Codeine metabolism., or Heroin Metabolism.					
Norhydrocodone	Negative			50 ng/mL	

Fentanyls					
Carfentanil	Negative			1 ng/mL	
Fentanyl	Negative			2 ng/mL	
Norfentanyl	Negative			8 ng/mL	
Gabapentin					
Gabapentin	Positive	> 15000 ng/mL	INCONSISTENT	1000 ng/mL	
Detection Window 1-2 days. Gabapentin, a GABA analog, is marketed under the brand name Neurontin.					
Heroin Metabolite					
6-MAM	Positive	> 375 ng/mL	INCONSISTENT	25 ng/mL	
Detection Window up to 1 day. 6-MAM is a unique metabolite of the illicit drug heroin. The presence of 6-MAM has been confirmed and indicates recent heroin usage.					

OBJECTIVES 4 and 5:

4. Create an action plan for changing how clinicians address the same with their staff and patients addressing these in daily practice and medical record documentation.

5. Discuss case examples using a before and after application of the three pronged risk mitigation improvement plan.

Do you prescribe opioids and/or benzodiazepines?

Do you have patients with medical co-morbidities, such as sleep apnea, asthma?

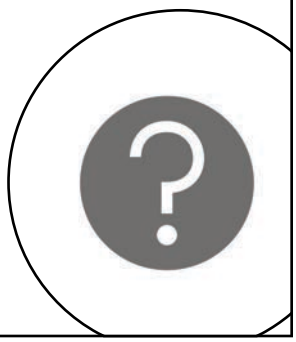
Do you have patients on more than 90mg MME?

Do you have patients with substance abuse histories, including ETOH, 6-AM, and THC?

Do you have patients with psychiatric disorders, including PTSD?

Do you have patients who have been discharged from other practices because of aberrant, drug-related behavior?

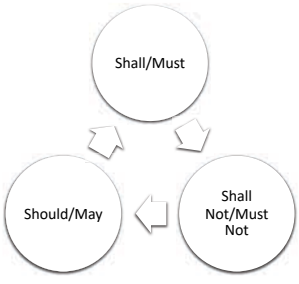
START HERE →Ask yourself these questions (and more)



Step 1 – Select Three Charts to Review

New Patient	Established Patient – High Risk	Established Patient – Using opioids >3 years

Step 2 – Make a List of Licensing Board and Professional Standards "Directives"



INDIANA RULE – EVALUATION AND RISK STRATIFICATION

844 IAC 5-6-4 Evaluation and risk stratification by physician

Authority: *IC 25-22.5-2-7; IC 25-22.5-13-2*
Affected: IC 25-1-9; IC 25-22.5

Sec. 4. (a) The physician shall do the physician's own evaluation and risk stratification of the patient by doing the following in the initial evaluation of the patient:

(1) Performing an appropriately focused history and physical exam and obtain or order appropriate tests, as indicated.

(2) Making a diligent effort to obtain and review records from previous health care providers to supplement the physician's understanding of the patient's chronic pain problem, including past treatments, and documenting this effort.

(3) Asking the patient to complete an objective pain assessment tool to document and better understand the patient's specific pain concerns.

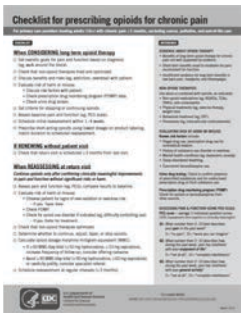
(4) Assessing both the patient's mental health status and risk for substance abuse using available validated screening tools.

(5) After completing the initial evaluation, establishing a working diagnosis and tailoring a treatment plan to meaningful and functional goals with the patient reviewing them from time to time.

(b) Where medically appropriate, the physician shall utilize nonopioid options instead of or in addition to prescribing opioids.

(Medical Licensing Board of Indiana; 844 IAC 5-6-4; filed Oct 7, 2014, 12:27 p.m.: 20141105-IR-844140289FRA, eff Nov 1, 2014 [IC 4-22-2-36 suspends the effectiveness of a rule document for 30 days after filing with the Publisher. LSA Document #14-289 was filed Oct 7, 2014.])

CDC Opioid Prescribing Guidelines - Checklist



Step 3 –
Review Charts with Directives List in Mind;

Ask: Where am I vulnerable?

Risk Evaluation and Risk Management

Turn your weaknesses into strengths and change the conversation with the patient

RISK DOMAINS CHECKLIST – FROM Argoff, et al

Rational Urine Drug Monitoring in Patients Receiving Opioids for Chronic Pain: Consensus Recommendations, by Charles E. Argoff, MD,* Daniel P. Alford, MD, MPH,† Jeffrey Fudin, PharmD, DAIPM, FCCP, FASHP,‡ et al., *Pain Medicine* 2017; 0: 1–21

Risk of Overdose – No Universal Standard yet, but SAMHSA and CDC, and Ohio

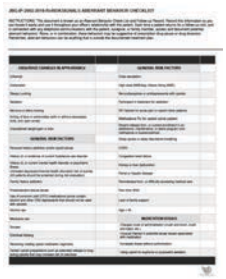
EVALUATING RISK OF HARM OR MISUSE

Known risk factors include:

- Illegal drug use; prescription drug use for nonmedical reasons.
- History of substance use disorder or overdose.
- Mental health conditions (eg, depression, anxiety).
- Sleep-disordered breathing.
- Concurrent benzodiazepine use.

RISK-Behavior Tracking Form Ideas

You cannot effectively talk with a patient about risk issues, if you do not have an overall understanding of the patient's behavioral patterns.



Proper Timing and Use of UDT Results (with or without Aberrant Behaviors)

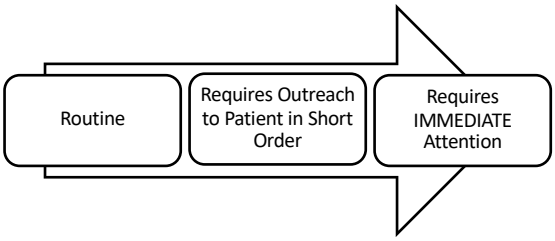
Addressing the Weaknesses

REPRISE:

Now, how do you handle Jane Doe's UDT report?

INITIAL OFFICE VISIT and RELEVANT RX	UDT ORDERED	DATE ON LAB REPORT	Date EMR Shows Review	RESULTS	Aberrant?
1/24/15 RX after OV = OXYCODONE Patient had prior Rx Tylenol #3	Yes	1/28/15	**2/24/15**	Gabapentin+ TCA+	Yes, Gabapentin not disclosed, but is Rx from another doctor. Oxycodone Rx given.
2/24/15 Rx is OXYCODONE, Morphine added	Yes	3/1/15	**3/24/15**	Gabapentin+ Oxycodone - TCA+ Dextromethorphan+	Yes, Dextromethorphan; Missing Rx Opioid (Oxy)
3/24/15 Rxs for Oxycodone, Morphine, Gabapentin	Yes	4/2/15	**4/24/15**	Morphine + Gabapentin+ Oxycodone +	Yes, Morphine+ **but 6-MAM-NEG** Oxycodone+
4/24/15 Rxs for Oxycodone, Morphine, Gabapentin	Yes	5/26/1	**Reviewed after Patient's death.**	Morphine+ 6-MAM+ FENTANYL+ Oxycodone+	Patient overdosed and died.

UDT TRIAGE PROTOCOL

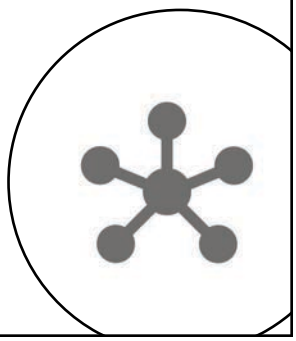


Sample Treatment Decisions following Risky Behaviors and Aberrant UDT Results

Risk Responses- Possibilities (some work, some do not – keep the patient at the center and document rationale)		
Discussed the behavior/result	Require more frequent visits	Require increased PDMP database checks
Require increased UDT* with caution and selectively if known risks	Implement opioid supply controls (fewer dosage units in more frequently issued prescriptions)	Propose a change of medication, dosing, formulation, etc.
Refer for substance abuse treatment	Refer for mental health evaluation	Refer to specialty service
Plan reduction in opioid dose and taper off of medication (Terminate the medication)	Buprenorphine	Withdrawal from care* (serious step and requires its own lecture)
Educate	Give more strikes (wait and see)	Other

Addressing the Weaknesses

Coordination of Care



Uncertainty in Dx | Specialized Tx | Unable to Achieve Goals | Discomfort with Opioid Therapy

Hx of SUD or Substance Abuse | Evidence Suggests Misuse/Abuse | Run out of Ideas - Several Treatments tried without success

Consultations and Referrals – COORDINATION OF CARE - "As Necessary" (Do your charts show you've considered coordination and consults/referrals?)

REPRISE:
Now, how do you handle John Smith's report?

"My primary care physician is out of town and I'm afraid I will get sick if I have to wait for him to return to get my _____[Opioid or Benzodiazepine or other]."

"I am not sleeping well and not dealing with the increased pain I am having because you reduced my opioids last time. I am seeing a psychiatrist to help me cope with the pain, and he told me that I should go back up on my dose of _____ to help me deal with increased pain and anxiety."

Critical Coordination of Care Issue – I'm out of my Benzodiazepines

"My primary care physician is out of town and I'm afraid I will get sick if I have to wait for him to return to get my _____[Opioid or Benzodiazepine or other]."

PDMP Check Shows Last Rx was indeed by the name "other" prescriber and about 30 days ago. Patient seems like he's due for a refill and not prescribing may cause seizures or withdrawal.

WHAT IF TIME:

1. What if the patient's "other" prescriber switched their benzodiazepine from Alprazolam to Clonazepam at the last visit, and patient is now out of Alprazolam and tells you his provider is out of town and he needs his Alprazolam?

2. What if the patient's BP during the office visit with you this same day is 80/60?

3. What if the patient tells you that he is having trouble sleeping and thinks he has sleep apnea?

4. What if the patient tells you he is using alcohol?

What do you do? What do you document? How do you handle the patient's request for the BZO?

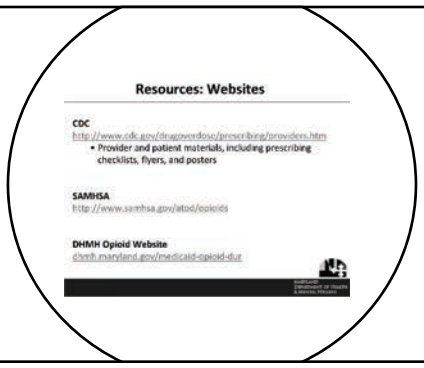
Patient Risk Mitigation & Risk Education

Overdose Events (Fatal or Non-Fatal):

Steps you can take to mitigate against them AND Steps you can take when they do happen

EDUCATE PATIENTS AND STAFF MEMBERS

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



Step 4A - Create a risk triage plan

Learn of Event
(see Step 4B)

Preserve Chart and Understand Events Regarding Specific Patient

Obtain Legal Input Regarding Status of Specific Patient and Practice Improvements
(see Step 4C)

Internal Education to Staff and Necessary Practice Updates

External Education to Patients and Family Members

Ongoing Monitoring with Legal Counsel

Step 4B – Identify Patients That May be at risk for Overdose Event (Fatal or Non-Fatal) and Review their Charts

Other Topic Areas for Consideration:

- Naloxone and MME
- Patient Education; **Follow-up on Naloxone Availability**
- Decisions when Patient Does not Fill Naloxone Prescription
- How you learned about the Overdose Event (Non-Fatal)
- How you learned about the Overdose Event (Fatal)
- Internal and External Responses
- Legal Issues

Step 4C - Follow through with your plan and update it periodically

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

Checklists

Licensing Board Directives	Professional Society and Basic Regulatory Guidance on Chronic Opioid Therapy	Risk Assessment Tools, Stratification, and Monitoring	Internal Education	Patient and Family Member Education
History and Physical Examination	American Academy of Pain Medicine	Risk of Abuse/Addiction	Current State Requirements	Risks of Opioid Use
Risk Evaluation	American Association for Clinical Chemistry	Risk of Diversion	CDC and Academy Positions	Informed Consent Process
Treatment Plan	Federation of State Medical Boards	Risk of Overdose	Interaction with Pharmacists	Consequences if Treatment Agreement Violation
Informed Consent	Medicare Guidance	Other Behavioral Risks	PDMP Use	Safe Use
Treatment Agreement	CDC Guidelines	Protocols for Scoring and Overall Assessment of Risk and Stratification	Drug Testing	Safe Storage
Periodic Review	SAMHSA Materials	Protocols for Monitoring tied to Risk Stratification	Opioid Trials and Exit Strategies	Safe Disposal
Consultations and Referrals	Other	Protocols for Coordination of Care	Business Relationships	Naloxone
Documentation Requirements		Referral Plan and Overdose Event Plan	Self-Audit	Exit Strategies and Boundaries

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Thank you!