EZEKIEL FINK, MD

Dr. Ezekiel Fink is triple board certified in neurology, pain medicine, and brain injury medicine. After completing his neurology residency as a chief resident at Albert Einstein, he did two separate pain fellowship's at Harvard's Massachusetts General Hospital. After completing training, he joined the staff of the Department of Neurology at UCLA prior to joining the Methodist system as the System Director for Pain for the 7 hospital system in Houston, Texas.

He is widely published in the field of pain management and spends a substantial amount of time on policy work including extensive expert review/ educational work with the California Medical Board and Department of Justice.

Dr. Fink collaborates and partners extensively with clinical and public health entities including the Center for Disease Control (CDC), the Federation of State Medical Boards (FSMB), the National Security Council (NSC) on issues regarding the opioid epidemic and proper opioid prescribing.

Dr. Fink has no relevant financial relationships to disclose.

Texas Pain Society's 8th Annual Scientific Meeting on October 30, 2016

CDC OPIOID GUIDELINES Who? How? Why?

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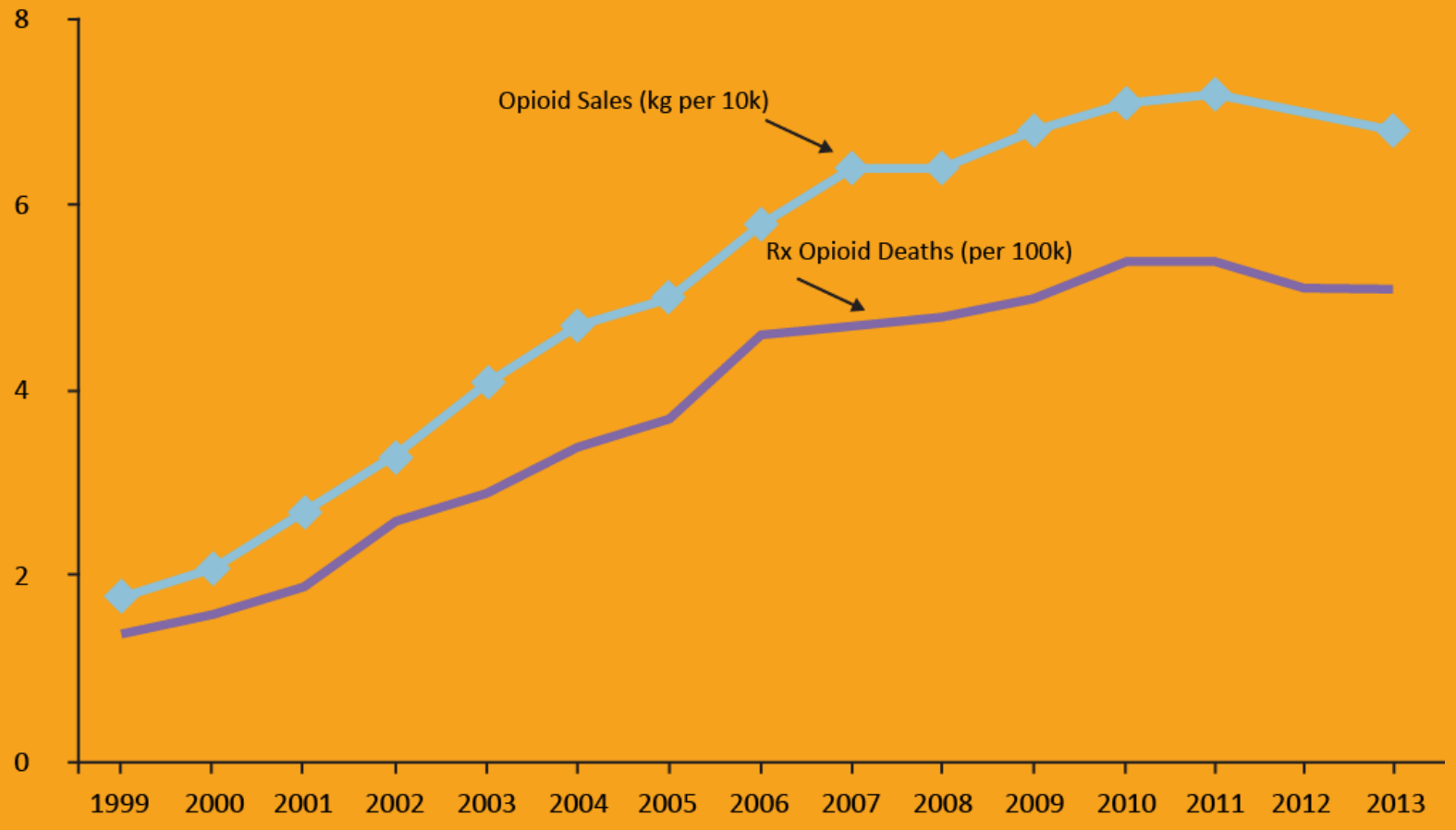
WHY?

THE U.S. OPIOID CRISIS:

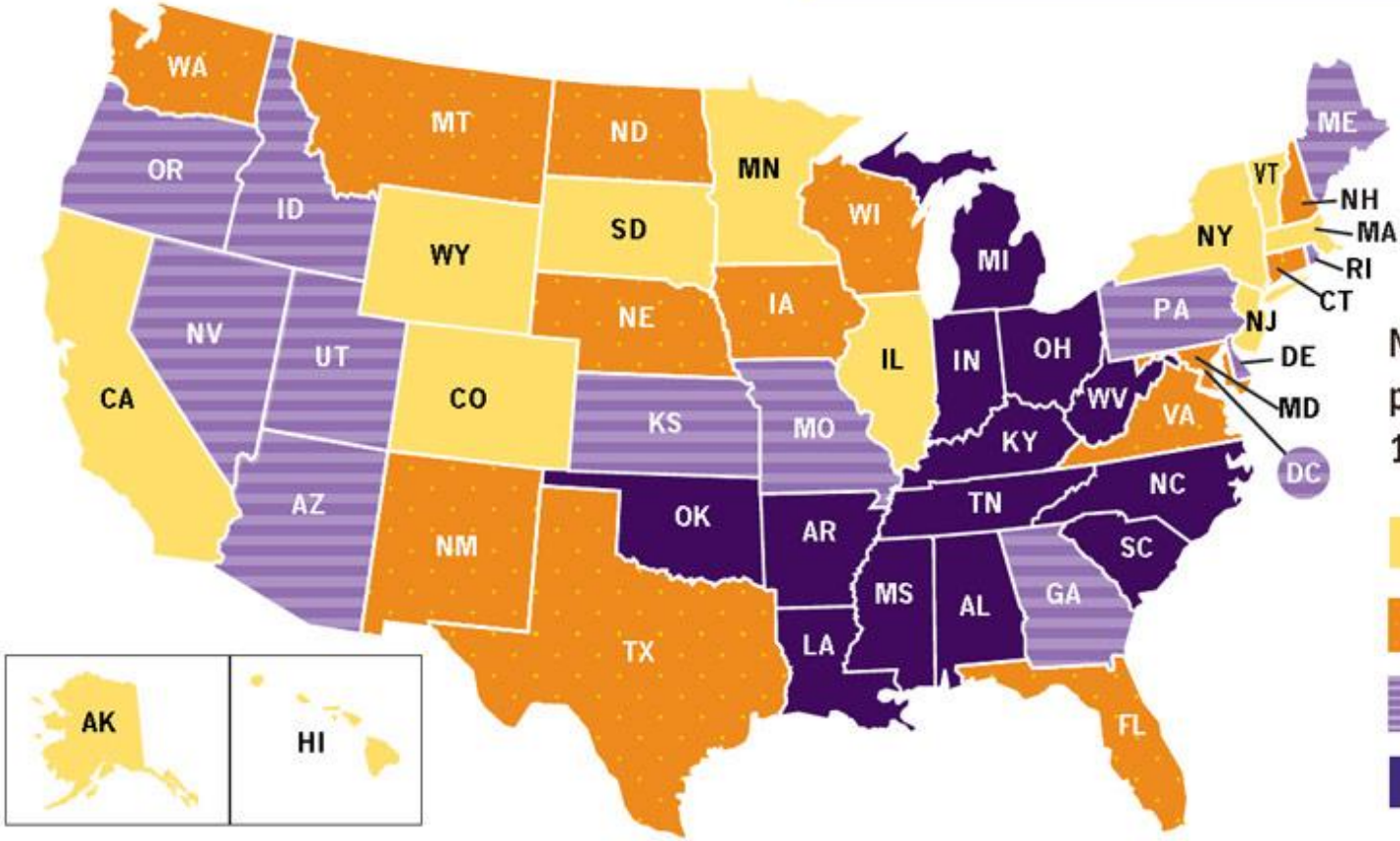
- In 2014, there was a record 18,893 deaths related to opioid overdose, including both medications and heroin
- In 2012, health care providers wrote 259 million prescriptions for opioid pain relievers
- Prescription opioid sales in the U.S. have increased by 300% since 1999
- Almost 2 million Americans, age 12 or older, either abused or were dependent on opioid pain relievers in 2013

WHAT IS RELATIONSHIP BETWEEN SHARP INCREASE IN OPIOID PRESCRIPTIONS AND INCREASE IN DEATHS ? CAUSATION?



National Vital Statistics System, DEA's Automation of Reports and Consolidated Orders System

Some states have more painkiller prescriptions per person than others.



SOURCE: IMS, National Prescription Audit (NPA™), 2012.

HOW DID WE GET HERE?

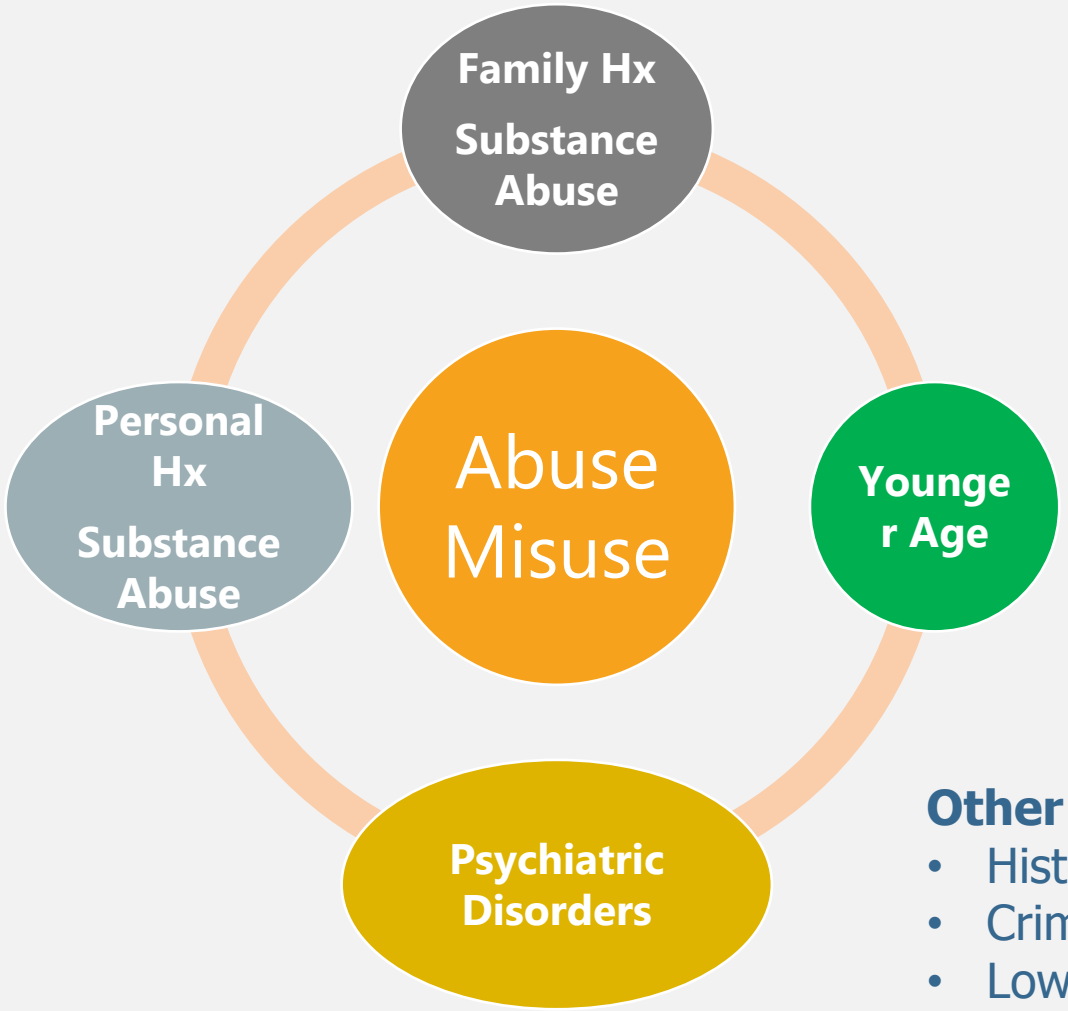
ONE MECHANISM:

- Underappreciation of risks of opioids/MD willingness to prescribe

- Unrealistic expectations by patients
- Under-identification of aberrant behaviors

- Adverse outcomes associated with the misuse, abuse and diversion of prescription opioids skyrocketing

RISK FACTORS FOR ABERRANT DRUG-RELATED BEHAVIORS



Other Factors:

- History of sexual abuse
- Criminal record
- Low reliability
- Lack of social support
- Smoking

Edlund MJ, et al. *Pain*. 2007;129(3):355-362.
Chou R, et al. *J Pain*. 2009;10(2):113-130.
Fishbain DA, et al. *Pain Med*. 2012;13(9):1212-1226.

STATE STRATEGIES +/-

- States are pursuing a variety of legislative strategies to address prescription drug abuse
  - Mandating a query to the state PDMP
  - Implementing Patient Review and Restriction programs ("lock-in" programs)
  - Requiring registration, certification and inspection of pain clinics ("Pill Mill" legislation)
  - Increasing access to opioid antagonists (Naloxone) and providing immunity to those that administer it
  - Mandating content-specific CME
  - Mandating drug testing in certain circumstances
  - Federation of State Medical Boards' *Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain*

PRESCRIPTION DRUG MONITORING PROGRAMS (PDMPS)

- 49 states, excluding Missouri and the District of Columbia, have implemented a PDMP (Missouri does not have PDMP legislation)
- 29 States – by statute, rule, or board policy – mandate that a prescriber or dispenser query the PDMP prior to prescription
- 35 states are engaged in Interstate Data Sharing*
- 9 States are implementing Interstate Data Sharing*
  - California, Texas, Washington, Montana, Georgia, Pennsylvania, New York, Connecticut, Massachusetts and Vermont

** Source: The **Prescription Drug Monitoring Program Training and Technical Assistance Center (PDMP TTAC)** at Brandeis University*

STATE LEGISLATION – IMPACT ON AUTONOMY

- 1,330 bills in the 2016 legislative session related to opioids, pain management, and controlled substances
- 300+ bills directly address opioid abuse, overdose, and prevention
  - Some states are mandating dosage (eg Maine – cap at 100 MME per day)
- 67 bills have been signed into law, such as:
  - **Hawaii SB 2392** authorizes health care professionals to prescribe an opioid antagonist directly to an at-risk individual, a person in a position to assist an at-risk individual, or an organization that provides services to at-risk individuals.
  - **Wisconsin AB 366** requires certification of a pain clinic in order for it to operate. Also requires a pain clinic to have a medical director who is a physician that practices in Wisconsin and requires a pain clinic to report annually to DHS certain information.
  - **Virginia HB 829** directs the Board of Medicine to require prescribers to complete two hours of continuing education in each biennium on topics related to pain management and addiction.

Making a Difference: State Successes

New York
75% ↓

2012 Action:

New York required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a 75% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

Florida
50% ↓

2010 Action:

Florida regulated pain clinics and stopped health care providers from dispensing prescription painkillers from their offices.

2012 Result:

Saw more than 50% **decrease in overdose deaths** from oxycodone.

Tennessee
36% ↓

2012 Action:

Tennessee required prescribers to check the state's prescription drug monitoring program before prescribing painkillers.

2013 Result:

Saw a 36% **drop in patients** who were seeing **multiple prescribers** to obtain the same drugs, which would put them at higher risk of overdose.

SOURCES: NY, TN: PDMP Center of Excellence at Brandeis University, 2014. FL: Vital Signs Morbidity and Mortality Weekly Report, July 1, 2014.

FSMB MODEL POLICY FOR THE USE OF OPIOIDS

- Update of model policy commenced in September 2016
- 16 State Medical Board pain management policies are the same or similar to the FSMB's most recent model policies, adopted in 2013
- Provides an updated guidelines for assessing a physician's management of pain
  - Is it medically appropriate?
  - Does it comply with applicable state and federal laws?

FEDERAL REGULATORY ACTIVITY +/-

- Multiple Congressional hearings focused on the opioid epidemic
- Addressing opioid abuse and the heroin epidemic are a priority for the Obama Administration. Strategies include but are not limited to --
  - Funding to Community Health Centers to increase treatment services
  - Increase the patient limit for qualified physicians who prescribe buprenorphine to treat opioid addiction
  - Support for the development of generic abuse-deterrent opioids
  - Funding opportunities for states to distribute nalaxone and expand medication-assisted treatment services
  - Request to medical schools to pledge to require students to enroll in courses that align with the CDC guidelines

FEDERAL REGULATORY ACTIVITY

- FDA's Advisory Committees held hearings on Risk Evaluation and Mitigation Strategies (REMS) for long acting/extended release opioids in May, 2016
  - Recommendations included --
    - Mandate content-specific CME for prescribers
    - Tie CME mandate to DEA registration
    - Expand REMS to shorter-acting opioids
    - Require manufacturers to follow strategies to ensure drug benefits>risks

HHS: NATIONAL PAIN STRATEGY

- HHS' Interagency Pain Research Coordinating Committee (IPRCC) published recommendations in March, 2016 – government's first coordinated plan for reducing the burden of chronic pain

- Makes recommendations for improving overall pain care in six key areas:

  - population research; prevention and care; disparities; service delivery and payment; professional education and training; and public education and communication.

- The Strategy calls for:

  - Developing methods and metrics to monitor and improve the prevention and management of pain

  - Taking steps to reduce barriers to pain care and improve the quality of pain care for vulnerable, stigmatized and underserved populations

  - **Increasing public awareness of pain, increasing patient knowledge of treatment options and risks,** and helping to develop a better informed health care workforce with regard to pain management

FEDERAL REGULATORY ACTIVITY

- U.S. Surgeon General Vivek Murthy, MD, MBA, launched an historic ***"Turn the Tide"*** campaign in August of 2016
  - Letters were sent to 2.3 million health care professionals seeking their commitment to combating opioid misuse by supporting
    - Enhanced education for treating pain
    - Screening patients for opioid use disorder
    - Leading a shift in the public perception of addiction so that it is treated as a chronic illness rather than a moral failing
- TurnTheTideRx.org

A KEY PAIN-RELATED FEDERAL LEGISLATIVE ACTIVITY

- *S. 524, The Comprehensive Addiction and Recovery Act (CARA)*
  - Authorizes the Attorney General to award grants to address the national epidemics of prescription opioid abuse and heroin use
  - Directs HHS to convene a Pain Management Best Practices Inter-Agency Task Force to develop: best practices for pain management and prescribing pain medication, and a strategy for disseminating such best practices
    - Includes developing a strategy for disseminating information about the best practices developed to prescribers, health professionals, pharmacists, State medical boards, and other parties
  - Signed into law by President Obama on July 22nd

GUIDELINE FOR PRESCRIBING OPIOIDS FOR CHRONIC PAIN

Purpose, Use, and Primary Audience

- **Primary Care Providers**
  - Family medicine, Internal medicine
  - Physicians, nurse practitioners, physician assistants
  - *Are specialists going to be held to this standard?*
- **Treating patients ≥18 years with chronic pain**
  - Pain longer than 3 months or past time of normal tissue healing
- **Outpatient settings**
- **Does have a lot in common with medical board chronic pain guidelines**
- **Does not include active cancer treatment, palliative care, and end-of-life care**

Clinical Evidence Summary

- *No long-term (≥ 1 year) outcomes in pain/function; most placebo-controlled trials ≤ 6 weeks*
- *Opioid dependence in primary care: 3%-26%*
- Dose-dependent association with risk of overdose/harms
- *Inconsistent results* for different dosing protocols; initiation with LA/ER increased risk of overdose
- Methadone associated with higher mortality risk
- No differences in pain/function with dose escalation
- Risk prediction instruments have insufficient accuracy for classification of patients
- Increased likelihood of long-term use when opioids used for acute pain

Contextual Evidence Summary

- Opioid-related overdose risk is dose-dependent
- Factors that increase risk for harm: pregnancy, older age, mental health disorder, substance use disorder, sleep-disordered breathing
- Providers lack confidence in ability to prescribe safely and are concerned about opioid use disorder
- Patients are ambivalent about risks/benefits and associate opioids with addiction

Organization of Recommendations

- **The 12 recommendations are grouped into three conceptual areas:**
  1. Determining when to initiate or continue opioids for chronic pain
  2. Opioid selection, dosage, duration, follow-up, and discontinuation
  3. Assessing risk and addressing harms of opioid use

DETERMINE WHEN TO INITIATE OR CONTINUE OPIOIDS FOR CHRONIC PAIN

Recommendation #1

- Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain.
- Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient.
- If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate.

(Recommendation category A: Evidence type: 3)

Recommendation #2

- Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks.
- Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

(Recommendation category A: Evidence type: 4)

Recommendation #3

- **Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy.**

(Recommendation category A: Evidence type: 3)

OPIOID SELECTION, DOSAGE, DURATION, FOLLOW-UP, AND DISCONTINUATION

Recommendation #4

- When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids.

(Recommendation category A: Evidence type: 4)

Recommendation #5

- When opioids are started, clinicians should prescribe the lowest effective dosage.
- Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.

(Recommendation category A: Evidence type: 3)

Recommendation #6

- Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.
- 3 days or less will often be sufficient; more than 7 days will rarely be needed.

(Recommendation category A: Evidence type: 4)

Recommendation #7

- Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation.
- Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently.
- If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.

(Recommendation category A: Evidence type: 4)

Follow-up

- **Re-evaluate patients**
  - within 1-4 weeks of starting long-term therapy or of dosage increase
  - at least every 3 months or more frequently.
- **At follow up, determine whether**
  - opioids continue to meet treatment goals
  - there are common or serious adverse events or early warning signs
  - benefits of opioids continue to outweigh risks
  - opioid dosage can be reduced or opioids can be discontinued.

Tapering Opioids

- **Work with patients to taper opioids down or off when**
  - no sustained clinically meaningful improvement in pain and function
  - opioid dosages ≥50 MME/day without evidence of benefit
  - concurrent benzodiazepines that can't be tapered off
  - patients request dosage reduction or discontinuation
  - patients experience overdose, other serious adverse events, warning signs.
- **Taper slowly enough to minimize opioid withdrawal**
  - A decrease of 10% per week is a reasonable starting point
- **Access appropriate expertise for tapering during pregnancy**
- **Optimize nonopioid pain management and psychosocial support**

ASSESSING RISK AND ADDRESSING HARMS OF OPIOID USE

Recommendation #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.

(Recommendation category A: Evidence type: 4)

Certain factors increase risks for opioid-associated harms

- **Avoid prescribing opioids to patients with moderate or severe sleep-disordered breathing when possible.**
- **During pregnancy, carefully weigh risks and benefits with patients.**
- **Use additional caution with renal or hepatic insufficiency, aged ≥65 years.**
- **Ensure treatment for depression is optimized.**
- **Consider offering naloxone when patients**
  - have a history of overdose
  - have a history of substance use disorder
  - are taking central nervous system depressants with opioids
  - are on higher dosages of opioids (≥ 50 MME/day).

Recommendation #9

- Clinicians should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him/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.**

(Recommendation category A: Evidence type: 4)

If prescriptions from multiple sources, high dosages, or dangerous combinations

- Discuss safety concerns with patient (and any other prescribers they may have), including increased risk for overdose.
- For patients receiving high total opioid dosages, consider tapering to a safer dosage, consider offering naloxone.
- Consider opioid use disorder and discuss concerns with your patient.
- If you suspect your patient might be sharing or selling opioids and not taking them, consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal.
- **Do not dismiss patients from care—use the opportunity to provide potentially lifesaving information and interventions.**

Recommendation #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.

(Recommendation category B: Evidence type: 4)

Use UDT to assess for prescribed opioids and other drugs that increase risk

- **Be familiar with urine drug testing panels and how to interpret results.**
- **Don’t test for substances that wouldn’t affect patient management.**
- **Before ordering urine drug testing**
  - explain to patients that testing is intended to improve their safety
  - explain expected results; and
  - ask patients whether there might be unexpected results.
- **Discuss unexpected results with local lab and patients.**
- **Verify unexpected, unexplained results using specific test.**
- **Do not dismiss patients from care based on a urine drug test result.**

Recommendation #11

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

(Recommendation category A: Evidence type: 3)

Avoid concurrent opioids and benzodiazepines whenever possible

- **Taper benzodiazepines gradually.**
- **Offer evidence-based psychotherapies for anxiety.**
  - cognitive behavioral therapy
  - specific anti-depressants approved for anxiety
  - other non-benzodiazepine medications approved for anxiety
- **Coordinate care with mental health professionals.**

Recommendation #12

- **Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.**

(Recommendation category A: Evidence type: 2)

If you suspect opioid use disorder (OUD)

- **Discuss with your patient and provide an opportunity to disclose concerns.**
- **Assess for OUD using DSM-5 criteria. If present, offer or arrange MAT.**
  - Buprenorphine through an office-based buprenorphine treatment provider or an opioid treatment program specialist
  - Methadone maintenance therapy from an opioid treatment program specialist
  - Oral or long-acting injectable formulations of naltrexone (for highly motivated non-pregnant adults)
- **Consider obtaining a waiver to prescribe buprenorphine for OUD** (see http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management)

CHALLENGES

- The next crisis is here – pain patients not getting care
- CDC Guidelines becoming a legal standard
  - **It was never intended to be**
- Doctors are scared
  - Regulation + punitive climate= opt out
  - Incentivize!!
- Providing timely access to care
  - Insurance must approve access to other treatment
- Coordinating efforts
  - Universal standards
- The “Arms Race”
- Changing public perception
  - Sustained educational campaign

QUESTIONS?

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