Opioid Prescribing 2018: The Impact of SB1446

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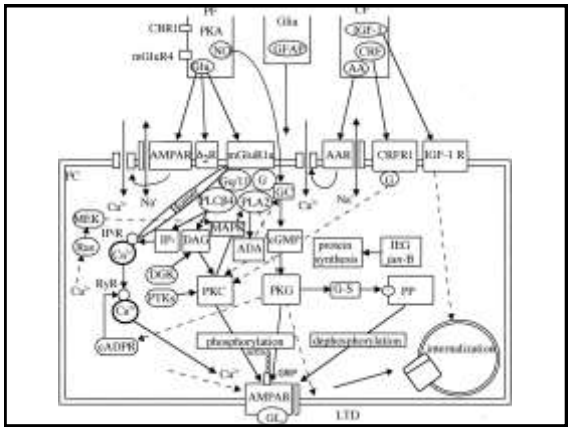


Opioid Prescribing:

- Chronic pain is highly complex
- Opioids alone are often inadequate
  - 25-50% improvement in pain scales
- Opioid therapy can be highly beneficial in select patients who demonstrate compliance and function
- Often the only remaining option for some patients
- Nationwide reduction of opioid prescriptions from peak in 2010
- Oklahoma has had roughly 20% reduction in opioids

National Issues

- CMS actions with a "hard stop" at 90 MME's in 2019?
- DEA reducing manufacturing of opioids 25% in 2017 and a further 20% in 2018 and more in 2019
- Pharmacy chains and insurance payors with varying policies
- Numerous states capping at <90-100 MME's
- Numerous laws regarding initial prescriptions
- Oregon initiative
- Increased investigations of providers and pharmacies

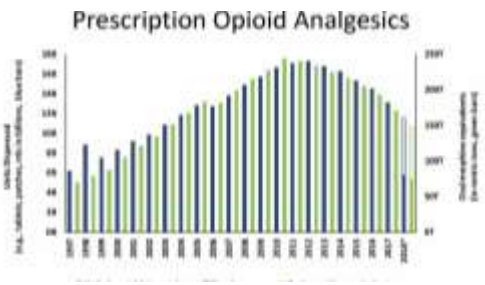
Opioid Deaths

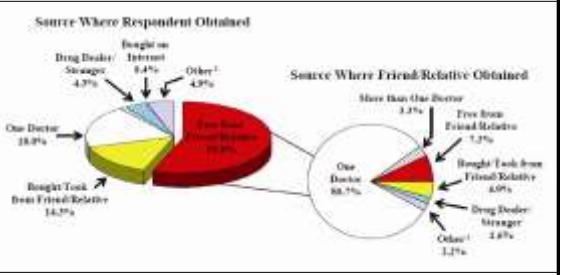
- Major reason for CDC, national and state legislative involvement
- 72,000 overdose deaths in 2017
- Significant escalation in illicit opioids
- Diversion: most deaths are from "non-prescribed" opioids
- Lethal combinations especially with benzodiazepines
- Illegal opioids outpacing prescribed opioids
- Without question the number one reason for governmental intrusion

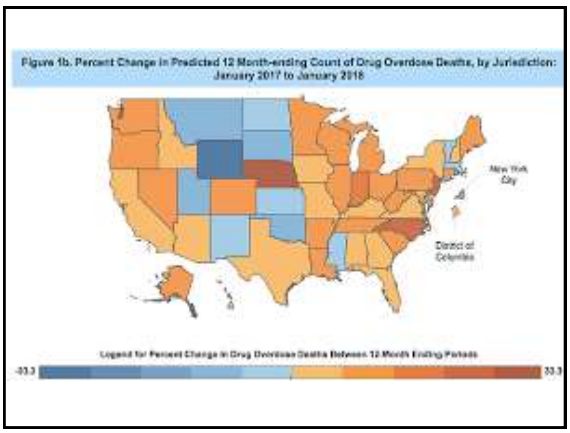
CDC Enhanced Opioid Overdose Surveillance 2017

- 11 states participated including Oklahoma
- 59% of deaths due to illicit opioids
- 18.5% combined prescription and illicit opioids
- 18% positive for only prescription opioids
  - 50% of these deaths also positive for benzodiazepine
  - "Findings indicate that illicit opioids were a major driver of deaths… and were detected in approximately three of four deaths"

Prescription Opioid Reduction







Are Opioids Efficacious for Chronic Pain?

- Long term outcome studies are lacking but also lacking for most all pain therapies
- Insight based on available evidence
  - Opioid use may be the most important factor impeding recovery of function
  - Opioids may not consistently and reliably relieve pain and can decrease quality of life
  - The routine use of opioids cannot be recommended
- Appropriate only for selected patients with moderate-severe pain that significantly affects quality of life

First Line Approach

- Important issue in SB1446
- Non-pharmacological approach
- Non-opioid approach
- Emphasis on
  - Behavioral therapies
  - Functional therapies
  - Adjunctive medications
  - Opioids are a "last resort" option

Chronic Opioid Therapy (COT)

- Consensus agreement that it can be useful in carefully selected patients with moderate to severe pain
- SB1446 demands constant attention to attempts at lowering doses
- Absolutely demands:
  - Compliance: As with any medical problem
  - Documentation
  - Vigilant monitoring for abuse and diversion
  - Assessment of opioid related side effects
  - Understanding of opioid use in chronic pain

Patient Selection and Risk Stratification

- History, physical examination and diagnostic testing
- Psychosocial risk assessment
- Expectations: physician and patient
- Risk assessment is an underdeveloped skill for most clinicians
- SB1446 requires vigilant monitoring of abuse and addiction
- SB1446 emphasizes documentation of the progress of the patient to the treatment objectives

The "Ideal" Patient

- Well defined pathology
- Good insight and desire to improve
- Willing to "work hard" to improve
- Interested in other modalities and work-up
- Not focused on opioids but desire to improve
- Good understanding that opioids will provide "some" relief to help them improve
- Examples

The "Wrong" Patient

- Diffuse and poorly localized pain
- No interest in work-up or other modalities
- Focus is on opioids alone
- Poor insight and unrealistic expectations
- Poorly motivated with no desire to "work hard"
- Poor functionality
- Examples

Patients at Risk

- Psychosocial issues
- History of addiction
  - Risk of relapse, harm and treatment failure
- Adverse Childhood Experience (ACE)
  - Abuse, neglect, household dysfunction and traumatic stressors
- Poor motivation and lack of insight
- Disability, Medicaid and even prior criminal activity
- Unrealistic expectations
- Prior overdose

Opioid Use Disorder

- 3-26% incidence
- Significant impairment or distress
- Poor insight and social support
- Inability to reduce opioids
- Inability to control use
- Decreased function
- Social function reduced
- Failure to fulfill work, home or school obligations
- Commonly referred to as “abuse” in the literature

Medication Assisted Treatment

- Emphasized with patients who display OUD
- Buprenorphine: Partial agonist
- Methadone
- Behavioral therapies
  - Help maintain retention
  - Help reduce relapse rate
- CDC emphasis on:
  - Availability
  - Cost

Opioid Induced Hyperalgesia

- Increased sensitivity to noxious or non-noxious stimuli
- Sensitization of pro-nociceptive mechanisms
- Hypersensitivity and allodynia
- Confused with tolerance
- Caused with rapid escalation and high dose therapy?
- Activity at the NMDA receptor in dorsal horn
- Novel medications now and future

"Forced" Dose Reductions

- There is really no evidence on this approach
- A vulnerable population of patients
- Does this lead to more harm?
- Rupture of patient-physician relationship
- Increased disability
- Risk of illicit drug use
- Suicide
- Consider referral

SB1446: Major Points of Emphasis

- Addiction and abuse
- Dose reduction and cessation
- Emphasis on lower MME's
- Alternative therapies
- Strong focus decreasing the risks of acute pain leading to chronic opioid therapy
- ***Strong language for assessing, documenting and specifying your care of the opioid patient***

Required CME

- One hour per year
- Pain management and opioid use or
- Addiction medicine

Initial 7 Day Prescription

- Acute pain in an opioid naïve patient
- Acute pain episode due to surgery or new condition in a patient on opioids. Examples:
  - Dental procedure
  - Renal stone
  - ER visit for unrelated pain complain
- Shall be for the lowest effective dose
- Must check PMP
- Failure to check PMP shall be grounds for discipline

Initial 7 Day Prescription

- Take and ***document*** a thorough medical history
- Including experience of the patient with non-opioid medication and non-pharmacological pain management
- Screen for substance abuse and addiction
- Conduct and ***document*** a physical examination
- PPA required for under 18 and pregnancy

Prior to Issuing an Initial Prescription

- Practitioner shall discuss and ***document*** with a note in medical record of the risks not limited to
  - Risks of addiction and overdose and risks of combining alcohol and or benzodiazepines
  - The reasons why the prescription is necessary
  - Alternative treatments that may be available
  - Risks associated with the drug being prescribed such as physical and psychological dependence, that "opioids are highly addictive" and overutilization can lead to death

Subsequent 7 Day Prescription

- Practitioner determines that the prescription is necessary
- ***Document*** rational for subsequent prescription
- Practitioner determines the the subsequent script does not present a risk of abuse, addiction or diversion and ***documents*** in the chart
- Refills? 14 day supply at initial prescription?
- Sequential prescriptions?
- In office visit with the practitioner?

Prior to Issuing a 3rd Prescription

- Similar to issuing the initial prescription
- Practitioner shall discuss and ***document*** with a note in medical record of the risks not limited to
  - Risks of addiction and overdose and risks of combining alcohol and or benzodiazepines
  - The reasons why the prescription is necessary
  - Alternative treatments that may be available
  - Risks associated with the drug being prescribed such as physical and psychological dependence, that "opioids are highly addictive" and overutilization can lead to death

Patient-Provider Agreement

- Provides informed consent
- Essentially an opioid "contract"
- Needed before the 3rd prescription and for chronic pain treatment
- Needed at initial prescription for under 18 and pregnancy
- The Boards will provide an approved agreement for use

Patient-Provider Agreement

- Explain the possible risks
- Document the understanding of patient and physician
- Establish the rights and obligations of the patient
- Storage of opioids
- Establish specific medications and other treatments
- Specify the measures used by the physician to monitor the patient
- Delineate the process for termination of agreement
- Compliance shall constitute valid informed consent

Issuance of a 3rd Prescription

- The practitioner shall enter into a patient-provider agreement (PPA)
- The practitioner shall include a note in the medical record that the patient has discussed with the practitioner the risks of developing physical or psychological dependence
- Alternative therapies that may be available and…
- ***Document in the medical record***
- Remember…
  - PPA needed initially for under 18 and pregnancy

Chronic Utilization of Opioids

- When an opioid is continuously prescribed for 3 months or more the practitioner shall
  - Assess patient prior to every renewal to determine if the patient is experiencing problems with physical or psychological dependence *and* ***document*** the results of that assessment
    - What constitutes assessment?
    - In office? By phone? Telemedicine?
    - Refills of Schedule III?
    - Mid level providers?
    - "The" practitioner

Chronic Utilization of Opioids

- Review at a minimum every 3 months
  - The course of treatment
  - Any new information about the etiology of the pain
  - Progress of the patient toward treatment objectives
  - Monitor the compliance with the pain management agreement and any recommendations that the patient seek a referral
  - Check PMP (and save in the chart?)
  - ***Document the results***

Chronic Utilization of Opioids

- Periodically make reasonable efforts*, "unless clinically contraindicated"*, to
  - Stop use of controlled substance
  - Attempts to decrease the dosage
  - Try other medications and treatment modalities in an effort to reduce the potential for abuse or development of physical or psychological dependence
  - DOCUMENT and SPECIFY the efforts undertaken

Further Requirements

- "Any provider authorized to prescribe opioids shall adopt and maintain a written policy or policies that include execution of a written agreement to engage in an informed consent process between the prescribing provider and "qualifying opioid therapy patient".
- PPA in combination with written policy

Qualifying Opioid Therapy Patient

- ***A patient requiring opioid treatment for more than 3 months***
  - Does not matter if low dose or high dose
- ***A patient who is prescribed a benzodiazepine and opioid together***
  - What about different doctors prescribing each?
  - Psychiatrist and PCP
- ***A patient prescribed a dose of opioids over 100 MME's***

The OBNDD is Authorized To….

- Provide unsolicited notification to the licensing board
  - If a patient has received one or more prescriptions for CDS in quantities or frequency inconsistent with recognized standards or safe practice
  - If a practitioner has exhibited prescriptive behavior indicating potentially problematic prescribing patterns
  - Failure to check PMP as required under law shall be grounds for licensing board to take disciplinary action

OBNDD Shall Report:

- Registration of prescribers and dispensers in the central repository (PMP)
- Data regarding the checking and using of the PMP
- Data from boards regarding continuing education
- Effects on the prescriber work force
- Changes in the number of patients taking more than 100 MME's
- Data regarding quantity of opioid medications prescribed in MME's

Further Points

- Shall not apply to patients with active cancer pain, end of life, palliative, hospice care or long term care facility
- Shall not apply to medications for the treatment of substance abuse or opioid dependence
- "The provider shall be held harmless from civil litigation for failure to treat pain if the event occurs because of the non-adherence by the patient with any of the provisions in the patient-provider agreement".

Conclusion: Key Points

- SB1446 has stringent documentation requirements
- Much emphasis placed on addiction and abuse
- Focus on alternatives to opioids
- Consider weaning or decreasing dosages even in well functioning patients
- Attempts to decrease acute pain episodes leading to chronic opioid therapy
- Many unanswered questions