The Difficult Patient:
Risk Mitigation Strategies

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Opioid “Backlash”

• “National emergency”
• “Opioids not indicated for chronic pain”
• Forces pushing for reduction of opioid use
• CDC guidelines and the fallout
• Recent FDA actions
• White House and congressional actions
The Perfect Storm

- Press to manage pain better
- Federal changes to better address pain
- Linking pain to outcome scores
- The “fifth vital sign”
- Introduction of extended release opioids
- Proliferation of “pain management”
- Internet reviews
CDC Guidelines

• Released March 2016
• Opioid overdoses and deaths
• Emphasis on high dose opioids
• First governmental guidelines
• Voluntary
• Reducing opioid consumption
• Access to treatment
Fallout From CDC Guidelines

- National press response
- “Doctor driven”
- Physician fear of prescribing
- Patient fears of decreased access
- Will it become mandatory
- How will payors respond
- May mirror the ODG effect on workers compensation
Contributing Factors to Inadequate Treatment and Prescribing

- Physician lack of knowledge in best clinical practice
- Inadequate research
- Poor understanding of risk mitigation
- Poor utilization of PMP and UDS
- Conflicting clinical guidelines
- Physician misunderstanding of dependence/addiction
- Complete relief may not be an attainable goal
National Center on Addiction and Substance Abuse

• 15.2 million abuse prescription drugs (2.5 X increase in 10 years)
• 20% of patients obtaining opioids for chronic pain abuse the medication
• 10-20% of these patients abuse illicit drugs
• Increased prescribing of opioids linked to misuse, abuse and deaths
• Absolute link between increased prescribing and availability for abuse
Epidemic of Medical Prescription Drug Abuse

• Supply
  • Explosion in the use of prescription opioids in response to the “under treatment” of pain
  • Retail grams of opioids sold show significant increase
  • Number of prescriptions for controlled substances nearly doubled in last 10 years
  • Since 2004 risk has escalated without increased evidence of benefit

• Sources of opioids
  • Number one source is from family and friends
  • The medicine cabinet is our greatest threat
Opioid Deaths

• Major reason for CDC involvement
• Significant escalation
• Diversion: most deaths are from “non-prescribed” opioids
• Lethal combinations especially with benzodiazepines
• Good data to support dose linked relationship
• Without question the number one reason for governmental intrusion
CDC Emphasis

• Directed at primary care physicians
• Opioids not recommended for routine use
• Does not include end of life, cancer pain and palliative pain care
• Management of pain is a multidisciplinary problem requiring numerous modalities to address physical and psychosocial aspects
Opioid Prescribing

- Chronic pain is complex
- Opioids alone are typically inadequate
  - 25-50% improvement in pain scales
- Opioids are beneficial in small subset of patients
  - Many patients would do well with discontinuation or reduction of opioids and pursue adjunctive therapies with psychological support
- No “universal” efficacy with opioids
CDC Emphasis: First Line Approach

- Non-pharmacological approach
- Non-opioid approach
- Emphasis on
  - Behavioral therapies
  - Functional therapies
  - Adjunctive medications
  - Patient and provider expectation
  - Opioids are a “last resort” option
Are Opioids Efficacious for Chronic Pain?

• Evidence is scant
• CDC insights
  • Opioid use may be the most important factor impeding recovery of function
  • Opioids do 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
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
• COT should be viewed as a treatment of last resort
  • Consider all other modalities prior to initiation
  • Use opioids in addition to a multidisciplinary approach to pain
Chronic Opioid Therapy (COT)

• Consensus agreement that it is may be useful in carefully selected patients with severe pain

• Demands
  • Compliant patient
  • Documentation
  • Close monitoring through follow up
  • Vigilant monitoring for abuse and diversion
  • Assessment of opioid related side effects
  • Understanding of opioid use in chronic pain
Chronic Opioid Therapy

• Informed consent and discussion of risk vs. benefit
• Therapeutic trial of 4-6 weeks
• Exhaustion of other modalities
• Insufficient data on starting dose
  • “Start low go slow”
  • Conversion tables
• Ongoing monitoring and assessment of benefit vs. risk, expectations and alternative modalities
• Consider a taper or wean even in functional patients
Success

- Compliant patient who understands the concept of the therapy and importance of close observation
- Rare dose increases
- Often dose decreases
- Honest and straightforward when problems arise
- ADL’s improve
- Understands the goal of therapy
- Realistic expectations
Drug Seeking?

• Even a skilled physician can be “duped”
• Common scenarios patient request for opioids or opioid increase
  • Progression of disease
  • New painful diagnosis
  • Psychological issues
  • Poor understanding of pain
  • Failure to use adjunctives or other therapies
  • Abuse or diversion
Difficulties: Why?

• Patient selection
• Pain syndrome
• Expectations
• High dose opioid therapy
• Opioid Use Disorder
• Opioid induced hyperalgesia
• Reliance only on opioids
• Abuse and diversion
Expectations

• Patient and physician usually have a different view
• Perhaps the best way to avoid problems
• Explain:
  • Your expectations
  • Listen to the patients expectations
  • Come to a middle ground of understanding
  • Develop a “trust”
  • Explain the rationale for your decision
  • Have available a print out of the CDC guidelines
Common Difficulties

- Benzodiazepine and other sedatives
- Previous non-fatal overdose
- Oxygen dependency
- Sleep apnea
- Renal or hepatic disease
- Age >65
- Be sure and document the rationale for opioid use
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
Opioid Use Disorder

• Significant impairment or distress
• 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
Risk Factors for OUD

• Younger age
• Previous substance abuse
• Back pain, headache and non-specific pain
• Co-existing depression and anxiety
• Greater than 90 MED’s a day
CDC Emphasis:

- IR vs. ER/LA opioid therapies
  - Little mention of abuse deterrent medications
- Benzodiazepine use with opioids
  - Significant increase in deaths and ER visits
- Acute pain leading to chronic therapy
- Methadone
- Offering naloxone to patients at risk
- High dose opioids
Morphine Equivalent Doses

• MED’s are the major topic of most consensus statements and a focus of research
• Generally 120mg but growing support for less
• Very good data supports risks with MED of greater than 50-120mg
• Increased rates of side effects, poor function and death
• Must be a “point of pause” for physicians and requires EXTREME caution
High Dose Opioid Therapy

- Data is proving more reliable
- Defined as 100-160mg morphine or equivalent a day
  - Continues to decline
- Opioid rotation vs. weaning?
  - Opioid rotation linked to increased death
- Strong evidence linked with poor outcome
- 9x increase in deaths with 100mg or higher MED
- Remember, existence of persisting pain does NOT constitute evidence of undertreatment
CDC Emphasis: High Dose Opioids

- Providers should prescribe lowest possible dose
- Additional precautions at > 50 MED’s
- Should avoid > 90 MED’s
- Risks of overdose still double at 50 MED’s
- Demands documented increase in function and no adverse side effects
- Recommend consultation over 90 MED’s
  - Closer follow-up
  - Consideration of other risk factors
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
Prescription Drug Monitoring

- The “4 A’s” is a useful tool
- Ongoing dialogue with patients
- Regular monitoring is critical as risks and benefits do not remain static
  - Changes in the pain condition
  - Presence of co-existing disease
  - Changes in psychological or social factors
Physician Protect Thyself

• Pay attention to a pattern of activity that suggests abuse and address
• Monitor closely through follow up and documentation
• Use available tools:
  • PMP website
  • UDS and pill counts
  • Pharmacies
• Obligated to protect yourself, your patient and society from opioid abuse and diversion
Prescription Monitoring Program

• Powerful tool
• Mandated in Oklahoma first visit and every 180 days
• Physician and staff friendly
• Helps with determining MED’s
• Helpful to determine other scheduled drugs like benzodiazepines
• Good “teaching moment” with the patient
Urine Drug Screening

• All new patients and then random unless triggers seen
• Becoming standard of care
• An excellent education tool for the physician
• Insurance driven limitations
• Triggers for UDS
• Need for confirmatory testing
• Is the prescribed drug in the system
• Are there illicit drugs or non-prescribed opioids in the urine
Pill Counts

- Appropriate disposal of unused meds
- Where is the medication if not in the urine?
- On-site or at a local pharmacy
- Ideally within 24 hours
- When switching opioids
- In circumstances of signs of diversion
- Lockbox or safe
Don’t Forget Documentation

• A patient problem requires a documented response and action
• Something occurred so it requires a note
  • UDS result
  • PMP result
  • Non-fatal overdose
  • Lost or stolen prescription
  • Phone calls
Difficult Situations

• Pain is subjective
• Physicians are care givers not law enforcement officers
• A lost or stolen prescription?
• Abnormal UDS
• Illicit drugs
• Pattern of abuse demands a response
• Counseling of patient
  • Some better off opioids
  • Poor insight, unrealistic expectations
  • Discussion of alternative treatment modalities
Common Mistakes

• Continued escalation of opioids despite no evidence of improvement
  • Why? Think of the differential diagnosis
• Opioids used in pain syndromes known to be poorly responsive
• Failure to document
• Not addressing psychosocial issues
• Lenient with abuse behaviors
• Failure to use monitoring systems
Common Difficulties

- Overuse of a prescription
- Illegal drug in the system
- Nonprescribed drug in the system
- Abuse or honest mistake?
- Manipulative and argumentative
- Bargaining and anger
- Is there a pattern here?
Difficult Conversations

- “I think you might have OIH”
- “You don’t seem to be better on opioids”
- “You seem sedated”
- “Maybe we need to decrease your dose to <90 MEDS”
- “Your urine shows an illegal drug”
- “I wonder if you might have an opioid use disorder”
- “We received a phone call...”
My Personal Views

• Try not to “kick the can down the road”
• Rarely fire a patient with opioid or illicit drug problems
• Often push for counseling or treatment
• Continue to provide care with adjunctives unless behavior cannot be tolerated
• I do not tolerate threats to staff or myself
• Most chronic pain patients fire themselves
• Close contact with referring doctor
Addressing Obvious Abuse and Diversion

- Don’t “play the game”
- Contact law enforcement agencies?
- Refer the patient for appropriate help
- Treat withdrawal if indicated
- Contact other physicians and pharmacies
- 30 day supply of opioids?
- Consider referral for treatment
- “Under no circumstances may a physician dispense with the knowledge the drug will be abused or diverted” (DEA 2006)
A Final Caution: What the Boards View as Inappropriate

• Inadequate attention
• Inadequate monitoring
• Inadequate patient education and consent
• Unjustified dose escalations
• Excessive opioid dosing
• Not using tools for risk mitigation
Conclusion: Key Points

• Thoroughly evaluate the pain complaint
• Consider psychological issues
• Consider opioids as a treatment of last resort
• Use a contract and informed consent
• Patients should demonstrate a high level of responsibility
• An accountability system must be in place