

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

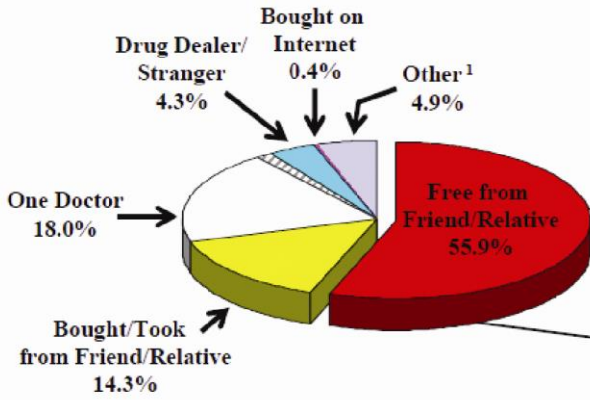
Physician Protect Thyself

- 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

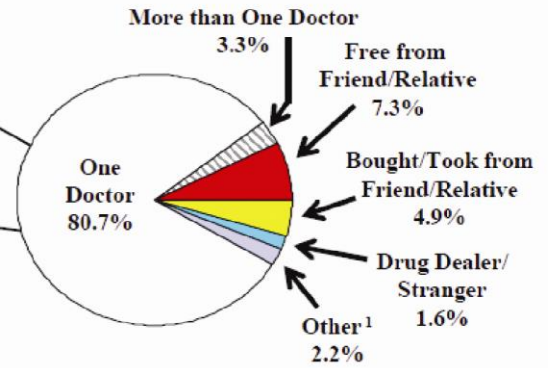
Prescription Monitoring Program

- 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

Source Where Respondent Obtained



Source Where Friend/Relative Obtained



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