Opioid Prescribing 2017: CDC Opioid Guidelines Turbulent Times

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Pain Management of Tulsa

Major Issues in 2017

- Major actions on a national level
- The epidemic of overprescribing
  - Expectations
  - Lack of convincing data
  - Conflicting guidelines
  - MED’s
  - Diversion and abuse

Oklahoma Issues

- Top 5 in prescribing
- Top 5 in deaths
- Major push for regulation and monitoring
- Required PMP checks
- Pill mills

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”

National Clinical Guidelines

- Federation of State Medical Boards
  - Approved by DEA
- American Pain Society
  - Consensus statement 2009
- ACOEM
  - Evidence based (but where is the evidence?)
- Occupational Disability Guidelines
  - Workers compensation and payer focused

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

Survey of Pain Patients by APS

- 90% felt more people would suffer
- 78% thought there would be more suicides
- 76% thought that doctors would prescribe less or not at all
- 60% felt that pain patients would obtain opioids through other sources
- 70% thought that heroin use would increase

FDA Opioid Action Plan 2016

- Expand use of advisory committees
- Develop warnings for IR opioids
- Strengthen post-market requirements
- Update REMS
- Expand access to abuse deterrent formulations
- Support better treatment
- Reassess risk-benefit of opioid use

Contributing Factors to Inadequate Treatment and Prescribing

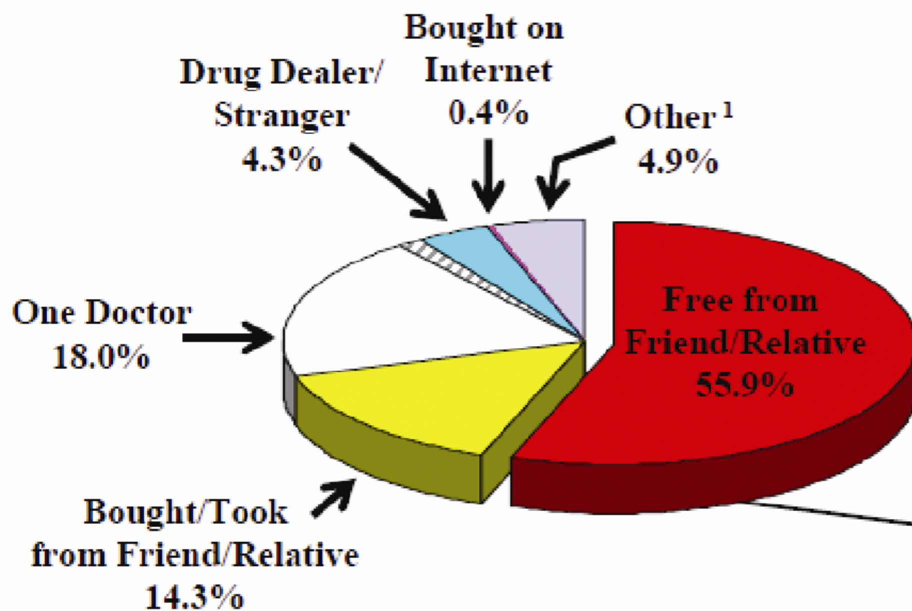
- Physician lack of knowledge in best clinical practice
- Inadequate research
- Conflicting clinical guidelines
- Physician misunderstanding of dependence/addiction
- Complete relief may not be an attainable goal

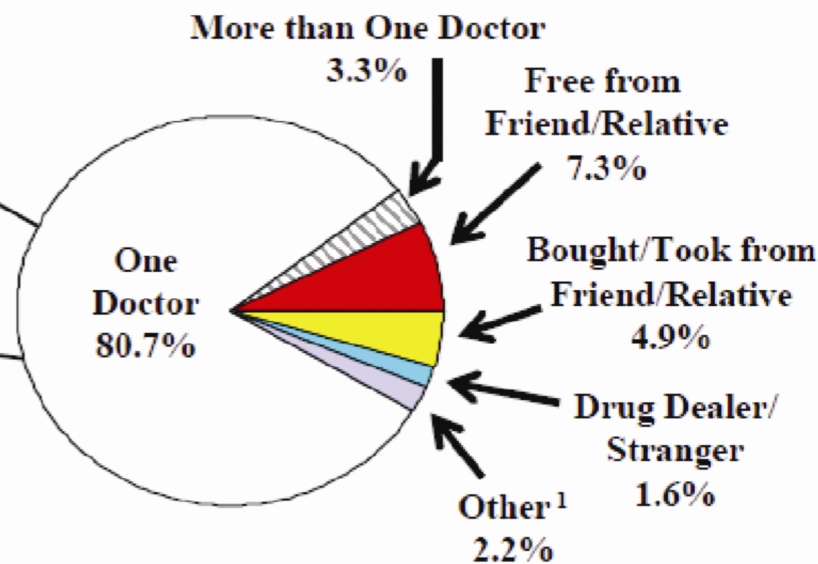
National Center on Addiction and Substance Abuse

- 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


Source Where Respondent Obtained
Bought on Internet 0.4%
Drug Dealer/ Stranger 4.3%
Other 1 4.9%
One Doctor 18.0%
Free from Friend/Relative 55.9%
Bought/Took from Friend/Relative 14.3%


Source Where Friend/Relative Obtained
More than One Doctor 3.3%
Free from Friend/Relative 7.3%
One Doctor 80.7%
Bought/Took from Friend/Relative 4.9%
Drug Dealer/ Stranger 1.6%
Other 1 2.2%

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

DEA Policy Statement

- Federal law states that controlled substances must be dispensed by physicians for a legitimate medical purpose in the usual course of professional practice
- DEA authority is not equivalent to that of a State medical board
- DEA will not provide medical training or issue guidelines as to the practice of medicine

REMS as of 2017

- White House recently unveiled a “multi-agency” plan to address the prescription drug epidemic
  - Physician education
  - Patient education
  - Expanding monitoring systems
  - Appropriate disposal of unused opioids
  - Focus on “pill mills”
- Still only addresses Schedule II medications with emphasis on long acting opioids

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

LTO Studies

- Short term studies show improvement
- Long term studies lacking
  - High abuse rates
  - High dropout rate
  - QOL measurements difficult
- Mono-therapy rarely effective
- More data shows improvement with decreased doses
- Controversy persists among groups

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

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

- 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

CDC Emphasis: Initiating Treatment

- Discussion of the risks and benefits
- Utilization of short acting opioid
- Avoidance of ER/LA opioids
- Initial one month trial
- More frequent follow up to assess benefits and harms
- Slow titration

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

Are Higher Dose Opioids Contraindicated?

- Not necessarily but….
- CDC: “The physician should carefully justify a decision prior to increasing doses above 90 MED’s”
- Consultation
- Closer follow up
- Understanding of the risks
- Informing the patient of potential risks
- Probably best to avoid in primary care setting

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

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 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

Why the Poor Response to COT?

- Think of the differential diagnosis
  - Patient selection
  - Pain syndrome
  - Unrealistic expectations
  - Abuse and diversion
  - Lack of multidimensional approach
  - Opioid induced hyperalgesia
- Perhaps the biggest mistake clinicians make is continued escalation of opioid doses

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

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

Urine Drug Screening

- All new patients and then random unless triggers seen
- Preliminary then confirmatory testing off site
- Insurance and Medicare 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

Common Mistakes

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

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

Addressing Obvious Abuse

- WEAN!
- Contact law enforcement agencies?
- Refer the patient for appropriate help
- Treat withdrawal if indicated
- Contact other physicians and pharmacies
- 30 day supply of opioids?
- Certain circumstances, consider referral
- "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