

Prescription Drug Abuse

- Prescription drug abuse is a serious US public health problem
- National Survey of Drug Use and Health in 2002 prevalence of lifetime non-medical pain reliever use ages 18-25
 - Increased from 2001 (19.4%) to 2002 (22.1%) following trend from 1992 (6.8%)
- National Institute Drug Abuse survey in 2003 of 12th graders reporting non-medical use of medications
 - 10.5% used Vicodin
 - 4.5% used OxyContin

PLAINTIFFS TRIAL
EXHIBIT

P-29624_00001

Morrison Exhibit

No. 24

12/16/2021 It

Chronic Pain: Prevalence and Impact

- 35% of Americans have chronic pain
- > 50 million Americans are partially or totally disabled by chronic pain
- 50 million lost workdays per year
- \$65 to \$75 billion per year cost to society in lost productivity and medical costs

National Pain Survey, Conducted for Ortho-McNeil Pharmaceutical, 1999.

Cost of Pain To Employers

American Productivity Audit¹

- 28,902 adults surveyed by phone
- 13% with less productivity due to pain over 2 week period
 - Headache, back pain, arthritis pain, and other musculoskeletal pain
- 76.6% of productivity loss was on job, not absences
- Lost productive time mean of 4.6 h/wk
- Total annual cost of pain related lost productivity and absences: \$61.2 Billion

1. Stewart et al JAMA, November 2003

Pseudoaddiction

- Behaviors that may occur when pain is undertreated
- Patients may become focused on obtaining medications
- May seem to be medication-seeking
- Behaviors resolve when pain is appropriately treated

AAPM, APS, ASAM. Definitions Related to the Use of Opioids for the Treatment of Pain. [consensus document] 2001.

Physical Dependence

- Abstinence syndrome caused by dose reduction or administration of an antagonist
- Abstinence symptoms can often be avoided with careful tapering and monitoring for the withdrawal symptoms
- May exist after few days of regular opioid dosing but onset is highly variable
- Does not independently cause or define addiction

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Tolerance

- Increasing dose required to maintain the same effect
- May develop at different rates for different effects
 - Tolerance to sedation and nausea occur relatively rapidly
 - Tolerance to constipation may not occur at all
- Tolerance to analgesia is seldom a clinical problem
 - Tolerance rarely “drives” dose escalation
 - Tolerance does not cause addiction
- “Pseudotolerance”: worsening disease leads to increased dose requirement

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Diversion

- The use of a legitimately prescribed medication for illicit, illegitimate purposes, perhaps with the intent to sell or distribute
- Examples
 - Stolen, altered or forged prescriptions
 - Trading for profit on medication from others
 - Scams

Risk Factors to Opioid Abuse

- Age
- Family History of Abuse
- Personal History of Abuse
- Personality factors including psychiatric disease
- Family dynamics and social factors

Monitoring Patients for Aberrant Behaviors

- Degree of monitoring based on perceived risk
- The higher the risk the more controls, for example:
 - Regular urine drug screens
 - Medications prescribed for limited periods (i.e. every 2 weeks)
 - Pill counts
- Family members should be interviewed
- May require consultation with:
 - Addiction medicine specialist
 - Psychiatrist or psychologist
- May need to discontinue opioid therapy.

Opioid Agreements Advantages

- Written documentation of informed consent
 - Forms basis for patient-physician discussion
- Clear definitions of patient and provider responsibilities
 - Sets boundaries
 - Enforces consequences
 - Encourages patients to take responsibility
- Protection of high risk patients
 - Supports patients most vulnerable to abuse
 - Aids early diagnosis of addiction and substance abuse relapse
- Facilitates treatment plan modification for noncompliance
- Anticipation of potential medical legal problems

Opioid Agreement Limitations

- Efficacy in ensuring compliance not yet established
 - One small (n=20), retrospective study showed that signed agreement did not predict compliance
 - Need for prospective, large, multicenter outcomes studies
- Agreements may reinforce stigma of opioid abuse if not based on thoughtful relationship of trust and honesty
- Not a substitute for vigilance (avoid false sense of security)
- Require physicians to follow their responsibilities to avoid legal liability

Opioid Agreement Content

Common elements

- Goals of therapy: monitor pain, function, side effects
- Single provider: one physician and pharmacy
- Informed consent on all opioid risks
- Definitions of addiction, tolerance and physical dependence
- Patient discloses: substance abuse history, current medications
- Need for complete, honest self-report

Who Should Sign Opioid Agreements?

- AAPM and APS: an option any chronic pain patient managed with opioids
- US FSMB: recommended for “high risk” patients
- Some authors argue for individual physician discretion
- Others argue for all chronic noncancer pain patients
 - Becomes “office policy” for all patients
 - No patients singled out or discriminated against
- Some pain specialist have PCP’s also sign the agreement

Aberrant Behaviors Less Predictive Abuse

- Aggressive complaining
- Drug hoarding when symptoms milder
- Requesting specific drugs
- Acquisition of drugs from other medical sources
- Unsanctioned dose escalation once or twice
- Unapproved use of the drug to treat another symptom
- Reporting psychic effects not intended by the clinician
- Occasional impairment

(Passik et al, 1998)

Aberrant Behaviors More Predictive Abuse

- Selling prescription drugs
- Prescription forgery
- Stealing or “borrowing” drug from another person
- Injecting oral formulation
- Obtaining prescription drugs from non-medical source
- Multiple episodes of prescription “loss”
- Concurrent abuse of related illicit drugs
- Multiple dose escalations despite warnings
- Repeated episodes of gross impairment or dishevelment

(Passik et al, 1998)

Prescription monitoring

- Several states have programs
 - KASPER (Kentucky All Schedules Prescription Electronic Reporting)
 - CURES (California Utilization Review and Evaluation Systems)
- Insurance company or Medicaid reports
- Limitations
 - Problems with patient identification
 - Neighboring states may not have programs
 - Need for national program (NASPER)

FSMB Model Prescribing Guidelines

1. Diagnosis supported by a history, physical, and appropriate tests before prescribing
2. Treatment plan contained in the records includes the use of appropriate non-addictive modalities and includes referrals to appropriate specialists
3. Decide whether "non-narcotic" modalities are appropriate; would help from a chronic pain clinic, a psychological evaluation, or perhaps even from surgery be helpful