Narcotic Addiction in Patients with Chronic Pain

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Addiction Psychiatrist
### Exhibit 1-1 Statistics on Substance Use and Chronic Pain in the United States

<table>
<thead>
<tr>
<th>Category</th>
<th>Statistic</th>
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</thead>
<tbody>
<tr>
<td>Chronic pain patients who may have addictive disorders</td>
<td>32% (Chelminski et al., 2005)</td>
</tr>
<tr>
<td>People ages 20 and older who report pain that lasted more than 3 months</td>
<td>56% (National Center for Health Statistics, 2006)</td>
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<tr>
<td>People experiencing disabling pain in the previous year</td>
<td>36% (Portenoy, Ugarte, Fuller, &amp; Haas, 2004)</td>
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<tr>
<td>People ages 65 and older who experience pain that has lasted more than 12 months</td>
<td>57% (National Center for Health Statistics, 2006)</td>
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<tr>
<td>Civilian, noninstitutionalized U.S. residents ages 12 and older who report nonmedical use* of pain relievers in past year</td>
<td>5% (Substance Abuse and Mental Health Services Administration [SAMHSA], 2007)</td>
</tr>
<tr>
<td>People ages 12 and older who report that they initiated illegal drug use with pain relievers</td>
<td>19% (SAMHSA, 2008)</td>
</tr>
<tr>
<td>People with opioid addiction who report chronic pain</td>
<td>29–60% (Peles, Schreiber, Gordon, &amp; Adelson, 2005; Potter, Shiffman, &amp; Weiss, 2008; Rosenblum et al., 2003; Sheu et al., 2008)</td>
</tr>
</tbody>
</table>

*Nonmedical use is use for purposes other than that for which the medication was prescribed.*
ASAM defines SUD as primary chronic brain disorder with genetic, psychosocial and environmental factors influencing its course.

Chronic relapsing disease characterized by impaired control, preoccupation with use, use despite adverse consequences, and distorted thinking, most notably denial.
Relapse and Conditioning

- Repeated alcohol use has caused "conditioning" to occur in related circuits.
- Now "cues" associated with alcohol use can activate the reward and withdrawal circuit.
- This can evoke anticipation of alcohol or feelings similar to withdrawal that can precipitate relapse in an abstinence patient.

Pseudo-addiction

A controversial term coined to describe aberrant drug-related behaviors (e.g., clock watching, drug seeking), that resemble those of patients with addiction but that actually result from inadequate treatment of pain (Weissman & Haddox, 1989).
Acute Pain

- Time limited - hours to weeks
- Related to damage
- “response to injury system”
- Damage heals and pain subsides
- Computer functions properly
Chronic Pain Syndrome

- Pain > 6 months
- Depression, anxiety, anger, fear
- Restriction in daily activities
- Excessive use of medications and medical services
- Multiple, *non-productive* tests, treatment, surgeries
- No clear relationship to organic disorder
Chronic Pain

- The original signs of injury may disappear or resolve to some minimal scar.
- There is a mismatch between the amount of pain and the amount of injury.
- Relatives and doctors begin to express their frustration.
Central Pain

- Sensitization of the brain and nervous system
- May effect nociceptors, spinal column, thought-processing centers
- Misunderstood- felt to be less than real
- Associated with emotional and psychological suffering – depression, anger, fear, frustration, hopelessness
- Real as any other chronic pain – not imagined
How does acute pain become chronic pain?

- Surgery or injury causes inflammation
- Peripheral Nociceptive Fibers
  - Transient Activation
  - Sustained currents
- Peripheral Nociceptive Fibers
  - Sustained Activation
- CNS Neuroplasticity
  - Hyperactivity
- CHRONIC PAIN

5 Key Facts About Chronic Pain:

- All pain is real.
- Emotions drive the experience of pain.
- Opioids often make pain worse.
- Treat to improve function.
- Expectations influence outcomes.
- A medical condition or syndrome in its own right
Biomedical Model

- Pain is entirely biological in origin
- Most effective treatment is medical in nature
- Real pain is “physical”
- Emotions discounted – psychosomatic, hypochondriacs, malingerers, addicts
- Emotional experience of pain determines perception of pain and suffering
Pain Management

Medically based

Surgery

Medications

Physical Therapy

Spinal Stimulator

Morphine Pump
Initial Evaluation Regarding Pain

- H and P
- Obtain and review previous records
- Assess risk for current and past SUD - UDS
- Controlled substance abuse monitoring program
- Assess pain level
- Assess level of functioning
- Assess for depression
Initial Evaluation Regarding Pain

- Discuss realistic goals and length of treatment
- Patient contract
- UDS
- Non-opiod options first
- Discuss risk of cross addiction and relapse
- Consider methadone or buprenorphine
Universal Precautions in Pain Medicine

- Reassessment of pain score and level of functioning
- Regularly assess the “Four As” of pain medicine: Analgesia, Activity, Adverse reactions, Aberrant behavior
- Periodically review pain diagnosis and co-morbid conditions, including addictive disorders
- Documentation
Pain Assessment and Documentation Tool (PADT)

- Areas covered:
  - Analgesia
  - Activities of daily living
  - Adverse events
  - Aberrant drug-related behavior
Pain Assessment

- Patients may be describing suffering in addition to pain intensity
- Physicians tend to believe pain is lower than patient reports
- Physicians especially more likely to underestimate pain in women, elderly, minorities, low economic status, SUD’s
Pain Assessment Scale

Clinical definition of pain:
“Whatever the patient states it is unless proven otherwise.”

<table>
<thead>
<tr>
<th>No Pain</th>
<th>Moderate Pain</th>
<th>Worst Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1 2 3 4 5 6 7 8 9 10</td>
<td></td>
</tr>
</tbody>
</table>
Pain Scale

- **0**- Pain free
- **1**- Very minor annoyance, minor twinges
- **2**- Minor annoyance, brief strong twinges
- **3**- Annoying enough to be distracting
- **4**- Can be ignored if involved in work
- **5**- Can’t be ignored more than 30 minutes
Pain Scale

- 6- Can’t be ignored but still go to work and social activities
- 7- difficult to concentrate, interferes with sleep, can function with effort
- 8- Physical activity severely limited, can read and converse with effort
- 9- unable to speak, crying or moaning
- 10- Unconscious
Assessment in SUD

- Patient may over report pain secondary to fear of being under-treated
- May underreport pain to avoid medications that may cause relapse
- May exaggerate to obtain opiate pain medications for other reasons
Pain Management Summary

- Opiate addicts will have a high tolerance and require higher doses for adequate control.
- Use standing doses and avoid prn schedule.
- Consider anticonvulsants and SNRI’s.
- Prescribe small number of tablets.
- Controlled substance query.
- Acetaminophen may be used in patients with liver disease as long as they are not drinking (<2 grm/day).
- Methadone clinic.
- Suboxone.
- Hyperalgesia.
- CBT, massage.
Pain Management in SUD

- More frequent visits
- Recommend a lock box
- Have family hold and administer medication
- UDS
- State prescription monitoring program
Active Addiction

- Successful treatment in a primary care setting is improbable
- Refer to formal addiction treatment program
- If patient refuses treatment, do not prescribe chronic opioid medications and use as leverage to move patient into treatment
- Motivational Interviewing
Hx of SUD Other Than Opiods

- Discuss cross addiction and risk of relapse with primary substance and obtain UDS
- Encourage non-opiod options
- Consider low dose suboxone
- Inpatient - Treat as normal with adequate pain control – do not undertreat
- Discharge with low number of pills
- Have family manage medication
- Refer patient to SUD therapist or Addiction MD
Hx of SUD including opioids

- Discuss high risk of relapse and need for support
- Assess for Hx of IV use
- Non-opioid options if possible
- Inpatient – Standard pain management but expect probable tolerance to typical doses – Do not under treat
- Discharge with low quantity, fentanyl patch, suboxone, tramadol
Acute Pain Episodes

- Non-pharmacological modalities
- Change to long acting medications as soon as possible
- Bolster recovery support
- Maintain patients on agonist therapy and supplement with additional medications
- Patient controlled analgesia
- Do not detox from benzodiazepines for acute pain treatment
- Prescribe small number of pills with more frequent refills if needed
Adjuvants To Somatic Pain

Non-pharmacologic:
- Ice, heat
- Physical therapy
- Chiropractic/osteopathic manipulations
- Massage
- Acupuncture
- Yoga
- Topical agents (Ben Gay/Icy Hot – with menthol, salicylates, Capsaicin)
- Local injections (steroids, lidocaine)
- Glucosamine
- SAM-e

Pharmacologic:
- NSAIDs
- Cox 2 inhibitors
- Steroids
- Muscle relaxants
- Anticonvulsants
- TCA’s/SNRI’s
Pharmacologic Non-Opioid

- NSAID’S, COX 2 inhibitors, acetaminophen
- Tricyclics – amitriptyline, nortriptyline - Remeron
- SNRI’s - Effexor, Cymbalta, Pristiq, Savella Fetzima
- Anticonvulsants – Neurontin, Lyrica, Topamax
- Muscle Relaxants— (AVOID SOMA/carisoprodol) Consider baclofen
Patients and Providers Need Reasonable Expectations

- Opiates can be expected to work in about 40% of patients
- Opiates may lower pain by about 30-35%
- 40-50% of patients will drop out on their own
- If no response after 3 months, further treatment unlikely to be helpful
Opiate Induced Hyperalgesia

- Long-term use of opioids may also be associated with the development of abnormal sensitivity to pain, and both preclinical and clinical studies suggest that opioid-induced abnormal pain sensitivity has much in common with the cellular mechanisms of neuropathic pain.

- Opioid induced abnormal pain sensitivity has been observed in patients treated for both pain and addiction.
Opioid Hyperalgesia

- How can you differentiate from tolerance?
  - Increasing the opioid dose should improve pain control in the tolerant patient, but may have no effect or worsen pain in the hyperalgesic patient

- What to do for hyperalgesia?
  - Opioid reduction/discontinuation
  - Opioid rotation
Ideal Opioid Prescribing

- Discuss risks/benefits with patient
- Set goals for therapy and time limit of trial
- Use an initial screening tool (SOAPP, ORT) to determine if patient is likely to be at high risk for abuse
- Perform informed consent/sign contract
- Use moderate dose opioids, generally <100 mg/day and max 180 mg/day morphine equivalents
- Monitor frequently with a follow up tool (PADT, COMM), urine toxicology screening, and PDMP
- Titrate off therapy if poor response or major misuse/abuse
Prior to Initiation of Therapy: Tools to Predict Opiate Abuse

- Opioid Risk Tool (ORT)
- SOAPP and SOAPP-R
- Studied in small, selected groups only
- Results have not been validated in larger studies
- Modest positive and negative likelihood ratios
Contributing Factors

- Onset of drug abuse or addiction to other substances usually precedes abuse of prescription medication
- Drug Characteristics - rapidity of onset, route of administration, purity, brand name
- Hydrocodone abused far in excess of other opioids
Patient Characteristics

- Past or current SUD
- Use of meds in non-prescribed doses or routes of administration
- Use of meds for reasons other than indicated
- Younger age
- Health care workers
- Psychiatric dual-diagnosis
- Family history of SUD
Clinician Characteristics

- Difficulty identifying high risk patient
- Dated clinical knowledge
- Deceived
- Distracted
- Defiant
- Disabled
- Dishonest
- Discomfort
Practice Characteristics

- Prescribing prior to obtaining complete clinical data (medical records, PE, SBIRT)
- Prescribing multiple controlled substances
- Prescribing for extended periods without reevaluating
- Lack of monitoring (UDS, prescription monitoring program)
- Failure to obtain consults
- Prescribing despite aberrant patient behavior
Opioid Contracts

- No prospective studies to support their use
- Are commonly used in specialty pain clinics
- Opinion differs slightly on when to use:
  - Some recommend these for all patients on chronic therapy, others only for patients felt to be at high risk for abuse or with relative contraindications to opioids
Opioid Contracts

- Typically address the following areas:
  - Effects and side effects of narcotics, including probability of physical dependence and consequences of withdrawal
  - Compliance with dosing regimen
  - Compliance with follow up, specialty appts
  - Monitoring for substance abuse
  - Need to get all meds from single doctor and pharmacy
  - Need to meet with physician before any dose changes or before taking any new medicines
  - Consequences of failure to meet the stipulations
Ongoing Monitoring

- Monitoring for efficacy
  - PADT

- Monitoring for abuse
  - PADT
  - Current Opioid Misuse Measure (COMM)
  - Addiction Behaviors Checklist (ABC)
Urine Drug Screen

- Urine drug screens typically check for evidence of opiate, alcohol, benzodiazepine, cocaine, marijuana, amphetamine and barbiturate use.
- Some opiates may need to be specifically requested such as oxycodone, fentanyl, methadone, and buprenorphine.
Length of Time Drugs of Abuse Can Be Detected in Urine

- Alcohol: 7-12 hours
- Amphetamine: 48 hours
- Barbiturate: 24 hours to 3 weeks
- Benzodiazepines: 3 days to 1 month
- Cocaine: 3 days
- Marijuana: 3 days to over 1 month
- Opioids: 48 hours to 4 days
## Urine Drug Screens

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Diluted</th>
<th>Adulterated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Creatinine</td>
<td>Less than 20</td>
<td></td>
</tr>
<tr>
<td>ph</td>
<td>Less than 3</td>
<td>Greater than 11</td>
</tr>
<tr>
<td>s.g.</td>
<td>Less than 1.003</td>
<td></td>
</tr>
<tr>
<td>nitrite</td>
<td>Greater than 500</td>
<td></td>
</tr>
</tbody>
</table>
Benefit of Urine Toxicology?

- What are we using it for?
  - To detect the presence of prescribed opioids?
  - To detect other opioids or illicit drugs?
Pill Counting

- No studies demonstrating accuracy or effectiveness of pill counts in reducing aberrant behaviors
- Labor intensive
Criteria for Problematic Opioid Use

- Overwhelming focus on opiate issues during visits that impede progress with other issues (>3 visits into care) especially immediate release or brand name
- ≥3 early refills or escalating use in absence of change in medical condition
- Multiple calls or visits associated with pain Rx's
- Prescription problems including lost, spilled, or stolen meds
- Supplemental sources of opiates (multiple providers, ER’s, or illegal sources)
Approach to the Patient with High Opioid Risk

- Be nonjudgmental in all interactions
- Take a risk vs. benefit approach in explanations for further treatment options
- Show a commitment to continue to work with the patient for pain control whether opioids are used or a non-opioid approach will be taken
- Make appropriate referrals and schedule careful follow-up
Relapse

- Minor relapses with quick stabilization – may refer to addiction counselor
- Closely monitor opioids
- Short interval dosing
- Major relapse – refer to methadone maintenance program or consider Suboxone
- Discontinue if patient harm and public safety outweigh benefits
- Offer to treat with other modalities – don’t fire the patient
Deciding Whether to Maintain or Terminate Opioid Treatment

- What are the criteria for success or failure?
  - Pain relief
  - Sense of well-being
  - Improved function
  - Improved quality of life

- Any of these may be considered reasonable goals; failure to reach any or deterioration in the physician-patient relationship

- Have an exit strategy
How to Switch to Methadone

- Probably reasonable to use a ratio of 5:1 morphine equivalents in patients on low-moderate doses
  - Example: MS Contin 120 mg/day would convert to 24 mg methadone ≈ 20 mg starting dose

- Use 10:1 ratio for morphine doses ≥ 180 mg/day

- Increase by no more than 25% of total dose every 5-7 days

- Prescribe TID for pain

- Refer to methadone clinic
Buprenorphine for CNTP: The Future for High-risk Patients

- Partial $\mu$-agonist, $\kappa$-antagonist (buprenorphine)
  - Minimal respiratory depression
  - Ceiling effect

- Combined with naloxone to prevent using a different route of administration

- High receptor affinity; prevents the high from other opiates
Buprenorphine

- Suboxone film - buprenorphine plus naloxone
  - 2/0.5, 4/1, 8/2, 12/3
- Zubsolve SL tablet – buprenorphine/naloxone
  - 1.4/0.36, 5.7/1.4
- Subutex – buprenorphine 2, 8
- Butrans Transdermal – 5,10,15,20 mcg/hr patch q 7 days
Buprenorphine for CNTP

- DEA Schedule III; CSAT waiver required to prescribe for opiate addiction
- Waiver NOT required to prescribe off-label for pain
  - Write “for chronic pain” or “off-label use”
- Good for moderately severe pain
- Dosed up to 32 mg/day divided TID/QID
Can One Use S/L Buprenorphine with or without Naloxone for Pain Management?

◆ The off-label use of the sublingual formulations of buprenorphine (Suboxone®/Subutex®) for the treatment of pain is *not* prohibited under DEA regulations.

➢ One does *not* need a waiver from CSAT but a valid registration to prescribe a Schedule III controlled substance

- Under these circumstances one does *not* place an X before one’s DEA number
- Personally, I recommend writing on prescription: “Pain patient, off label use”

Heit HA, Covington E, Good PA
(Former Chief Liaison and Policy Section Office of Diversion Control):
Dear DEA,
S/L Buprenorphine and the Treatment of Pain

- Effective analgesia is achieved at relatively low μ receptor occupancy
  - 5-10 %
- Degree of analgesia is *not* related to plasma concentration of the drug
  - The dissociation from the μ receptor site will lag behind plasma concentration
- 0.4 mg of buprenorphine = 10-12 mg of morphine
  - At least 30 times more potent than morphine
- Analgesic effects – 0.1-8 mg

S/L Buprenorphine

◆ Chronic pain management
  - 6-8 hour analgesic duration
    - As with methadone
  - tid or qid dosing
    - Always follow "Universal Precautions in Pain Medicine" in all cases of pain management

◆ OAT
  - Stabilizing drug
  - Long duration of action ( >24 h)
  - qd dosing

D Gourtay, HA Heit, A Almahrezi

HA Heit, DL Gourtay.
Buprenorphine in Pain and Addiction.
S/L Buprenorphine and the Treatment of Pain

- Elective procedure/surgery (mild-to-moderate pain and not NPO)
  - S/L Buprenorphine with or without naloxone
  - Take the total qd dose of buprenorphine
    - Give the total dose divided in tid or qid doses
- Titrate to effect with a maximum dose around 8 mg/dose
  - If breakthrough medication is needed, use one with high receptor site affinity and potency
    - Oral transmucosal fentanyl lozenges/tablets
    - Hydromorphone
    - PCA

S/L Buprenorphine and the Treatment of Pain

- Elective procedure/surgery (NPO)
  - Discontinue S/L buprenorphine
  - PCA with full \( \mu \) agonist
    - Titrate to effect to prevent withdrawal
    - Then treat the pain with an opioid with high receptor site affinity and potency
      - Fentanyl
      - Hydromorphone
        » Second choice
      - Avoid meperidine

HA Heit, DL Gourlay
Buprenorphine in Pain and Addiction.
S/L Buprenorphine and the Treatment of Pain

- Acute pain patient on buprenorphine agonist therapy (mild-to-moderate pain and not NPO)
  - Divide S/L buprenorphine dose to tid or qid schedule
  - Titrate to effect
    - Up to 8 mg tid to qid of buprenorphine
    - Limit of dose for pain?

- Alternative is to discontinue S/L buprenorphine
  - Switch to full μ agonist if time permits
    - Titrate the μ agonist to limit withdrawal
    - Titrate to effect to treat the pain

HA Heit, DL Gourlay
Buprenorphine in Pain and Addiction.
In H Smith and SD Passik (eds). Pain and Chemical Dependency.
S/L Buprenorphine and the Treatment of Pain (Mild-to-Moderate Pain)

◆ Acute pain superimposed on chronic pain
  ➢ Assumes S/L buprenorphine in divided doses was controlling pain
    – Add IR/RO opioid with high receptor site affinity and potency
      – Hydromorphone
      – Oral transmucosal fentanyl lozenges/tablets
  ➢ Titrate to effect

References:
SUD patients maintained on ORT

- Methadone – consider TID dosing and contact methadone clinic
- Use non-opiod options
- Inpatient – Continue methadone maintenance dose and use high affinity short acting pain meds (be aware of tolerance) Do not under treat
- Outpatient – Limit quantity and have family manage medications
- Do not use buprenorphine – will induce withdrawal
Naltrexone (Vivitrol)

- Naltrexone decanoate injection
- u opioid antagonist
- IM q 4 weeks
- Non-opiod options
- Nerve block
- Over ride blockade under supervision
- Consult anesthesia
Psychology of Pain

- Pain is variable
- Pain is modifiable
- Pain differs from person to person
- Pain differs from culture to culture
- Pain is a highly personal experience
- Pain cannot be defined simply in terms of particular kinds of pain
Mood Affects Pain

- Depression
- Chronic pain - >30% have depression
- Depression – 75% may have pain
- Increase in depression results in increase in pain – need to treat both
Emotions

- Negative emotions increase pain
- Positive emotions decrease pain
- Resisting pain increases pain
- Relaxing into pain and less resistance decreases pain
Emotions and Thoughts

- Need to pay attention to thoughts and emotions to eventually modify them
- Patients may be initially resistant (it’s all in my head)
- Majority of pain experience and ability to reduce pain lies with thoughts and emotions
- Need to address the suffering in addition to the sensation
- Secondary gain?
Cycle of Uncontrolled Pain and Fear

- Pain
- Avoidance Behaviors
- Decreased Mobility
- Social Limitations
- Diminished Self-Efficacy
- Altered Functional Status
Reversal of Cycle of Fear and Pain

- Pain
- Exercise
- Increased Mobility
- Improved Function
- Enhanced Self-Efficacy
- Less Pain
Treatment Implications

- Surrender
- Utilize body awareness
- Develop “relaxed attention”
- Involved with others
- Pain Recovery – Develop Balance
Pain Recovery – Develop Balance

• Mental
• Emotional
• Physical
• Spiritual

RESULTING CHANGES

– Relationships
– Positive actions and behaviors
A TREATMENT IMPROVEMENT PROTOCOL
Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders

TIP 54

Substance Abuse and Mental Health Services Administration
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-7277)