Opioid Safe Prescribing and the CDC Guidelines

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Purpose of the Guidelines

• CDC partnered with:
  • National Institute on Drug Abuse (NIDA),
  • Substance Abuse and Mental Health Services Administration (SAMHSA)
  • Office of the National Coordinator for Health Information Technology (ONC)
  • to review existing opioid prescribing guidelines for chronic pain and identify common elements.

Purpose of this Review

• This review is intended to enhance the use of evidence-based guidelines by:
  • Informing agencies, providers, and medical/professional organizations about evidence-based practices that can improve patient outcomes.
  • Providing states, federal agencies, and other organizations with a review of recommendations so that they can better develop implementation tools for providers, such as clinical decision support in electronic health records.
**Some Baseline Information**

- MEDD
  - PO “Morphine Equivalent Daily Dose”
- CSMD
  - “Controlled Substances Monitoring Database”

**Chronic Pain**

- Defined as pain lasting longer than 90 days
- Requires an interdisciplinary process
  - Many non-opioid modalities
    - Physical therapy
    - Psychology
    - Non-opioid medications
      - Steroids
      - Anticonvulsants
      - Antidepressants
      - SNRI

**Why Is This Necessary?**

- In 2011, TN was second in the country for opioid scripts
- Unintentional overdose
  - Increased 250% from 2001 to 2011
  - Eclipsed MVA, Homicide, Suicide in 2010
- Neonatal Abstinence Syndrome grew 10-fold 2001-2011
- Five-fold increase in Worker’s Comp cases for opioid abuse
- Chronic pain still needs treatment
  - 116 million US adults suffer from chronic pain
  
  - Reference: Tennessee Clinical Practice Guidelines for Outpatient Management of Chronic Non-Malignant Pain
Pain

• Acute and chronic pain
• Among the most common reasons
  • For physician visits
  • For taking medication
  • For work disability
• Affects
  • Physical and mental functioning
  • Quality of life
  • Productivity

Porter and Jick Letter

Dollars Spent Marketing OxyContin (1996-2001)

Figure 1: Promotional Spending for Three Opioid Analgesics in First 5 Years of Sales

Source: United States General Accounting Office, Dec. 2003, "OxyContin Abuse and Diversion and Efforts to Address the Problem."
Opioid Addiction is “rare in pain patients”
Physicians allow patients to suffer needlessly because of “opiophobia”
Opioids are safe and effective for chronic pain
Opioid therapy can be easily discontinued

Industry Influenced “Education”
Figure 1: Rate of unintentional drug overdose death in the United States, 1970-2007

Rate of Rx Painkiller Sales, Deaths and Substance Abuse Treatment Admissions (1999-2010)

Source: National Vital Statistics System
• Top 1% of States that sell prescription pain medications
• Top 10 for deaths by overdose
• Unintentional Drug overdose
  • Number one cause of death in TN
  • Over motor vehicle accidents, homicides
  • Peak age 40-49
• Providers prescribed 17 opioid scrips per capita
  • National average=12
  • Source: Prescription Drug Abuse: Strategies to Stop the Epidemic.
  • Healthyamericans.org

**TN Ranks Highly in...**

• Improve Symptoms
• Improve Functioning
• Improve Quality of Life
• Minimize adverse effects, including death
• Minimize addiction

**Long Term Goals of Pain Management**

• Will be finalized in January 2016
• Intended to help providers safely treat pain while minimizing adverse outcomes

**CDC Guidelines**
Initiating Opioid Therapy

- Non opioid pharmacologic therapies are preferred for chronic pain
- Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh the risks

Before Starting long-term opioid therapy

- Establish treatment goals
  - Realistic goals for pain and function
  - Continue opioid therapy only if there is clinically meaningful improvement
    - Pain
    - Function
    - Outweighs patient risk

Periodically During Therapy

- Providers should discuss the risks, benefits, and alternatives to continuing therapy
Risks of continuing therapy

• Generally, short-acting pain medications are started first
• Long acting pain medications are initiated only when patient is fully tolerant to short-acting medications
  • AND if tangible benefits are seen in function

Intiating therapy

• Patient on Lortab 10/325 q4h prn
• Takes 4-6/day
• ~40-60mg PO morphine equivalents
• Candidate for starting long-acting pain medication
  • E.g., MSContin 15 PO BID
• Can often decrease short-acting medications when long-acting are started
  • E.g., Lortab 10/325 q6-8h prn

Example
• When Opioids are started providers should prescribe the lowest possible effective dosage
• Implement additional precautions when increasing dosage to 50mg+ MEDD
• Avoid increasing dose to 90+ MEDD for chronic non-malignant pain

What dose?

• When prescribing for acute pain
  • Lowest effective dose of SHORT ACTING opioid
  • Prescribe only enough needed for the expected duration of pain severe enough to require opioids
  • Three or fewer days are usually sufficient for pain not related to major surgery
  • In TN, providers may write 7 days, non-refillable to avoid having to check the CSMD or comply with other regulations (if any).
  • Long Term opioid use often begins with treatment for acute pain

Acute Pain

• Reevaluate patients within 1-4 weeks of starting long-term opioid therapy
  • Assess benefits and harms of continued therapy
  • Evaluate chronic therapy patients no less than every 3 months
  • Work to reduce opioid dosage over time whenever possible.

Reassess
• Before starting opioid therapy:
  • Evaluate risk factors for opioid related harm
    • Pathologic Use
    • Overdose
    • Risk to fetus
  • Incorporate strategies to mitigate risk
    • Including offering Naloxone when increased risk is present

Risk for Pathologic use

Risk Assessment Tools

• DIRE
  • Diagnosis, Intractability, Risk, Efficacy Score
    • Numerical Score
    • Categorizes patients into “Not suitable” vs “Good candidate”

Risk Assessment Tools

• SOAPP-R
  • Screener and Opioid Assessment for Patients With Pain-Revised
    • 24 item, patient completed
    • Widely used
    • Impulsivity, legal, PIs, past sexual abuse (risk factor)
    • Classifies Low and High Risk
Pain Medications and Pregnancy

- Women of child-bearing age and reproductive capacity
  - Should be asked about the possibility of pregnancy at each visit
  - Use of contraception should be discussed
  - Referral to high risk OBGYN considered
  - (We’ll cover “Women’s Issues” later in the 2 hrs)

CSMD

- Prescription monitoring system assists in
  - Research
  - Statistical analysis
  - Criminal investigation
  - Enforcement of state laws
  - Education of health care practitioners

CSMD Data

- Collects and maintains data regarding controlled substances
  - Schedule II, III, IV
  - And some Schedule V
  - Submitted every 7 days
  - Prescriber, patient, and prescription information
Registration (TN SPECIFIC)

• All prescribers of controlled substances MUST register
  • Go to http://tnsmd.com and click “Register”
  • May allow licensed and up to two unlicensed extenders per location
  • Staff login and create a separate account
  • Provider then must approve their access

Requirements to Use CSMD

• On initiation of any new regimen of controlled substances
  • Every 6 months thereafter

CSMD Alerts

• Number of Pharmacies
  • RED: 5 within 90 days
  • YELLOW: 4 within 90 days
• Number of Prescribers
  • RED: 5 within 90 days
  • YELLOW: 4 within 90 days
• MEDD
  • RED ≥ 120 MEDD
  • YELLOW ≥ 90 MEDD but <120 MEDD
Reassessment

• Providers must continually monitor patients for signs of
  • Abuse
  • Misuse
  • Diversion
  • Improvement of underlying condition
• Document improvement in
  • Physical Functioning
  • Psychosocial Functioning
• Drug Screening should be done twice a year (minimum)

REMEMBER

• If recent UDS shows no opioids in system weaning is not necessary
• If drug diversion is suspected, further prescribing is not indicated.
• If any circumstance is thought to constitute more risk to the patient or community than the potential for withdrawal, no additional opiates should be prescribed.

Benzodiazepines and Opioids

• Benzodiazepines depress central nervous system (CNS) activity
• When combined with other drugs that depress CNS activity they may present serious or even life-threatening problems.
ER Visits Involving Benzos

Stratified by Age

Table 2: Predicted risk (in percent) of a more serious outcome among emergency department patients involving benzodiazepines alone or in combination with opioids or other drugs, by age and drug combination (patients aged 12 or older)

<table>
<thead>
<tr>
<th>Drug combination</th>
<th>19 to 34</th>
<th>35 to 44</th>
<th>45 to 54</th>
<th>55 to 64</th>
<th>65 or older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzodiazepines alone</td>
<td>25%</td>
<td>30%</td>
<td>37%</td>
<td>50%</td>
<td>55%</td>
</tr>
<tr>
<td>Benzodiazepines and opioids</td>
<td>35%</td>
<td>43%</td>
<td>47%</td>
<td>50%</td>
<td>55%</td>
</tr>
<tr>
<td>Benzodiazepines and alcohol</td>
<td>35%</td>
<td>43%</td>
<td>51%</td>
<td>51%</td>
<td>53%</td>
</tr>
</tbody>
</table>

“More Serious Outcome” was defined as admitted, transferred, or death

Opioid use Disorder

- Providers should offer/arrange evidence based treatment
- Usually opioid agonist therapy
  - Combined with behavioral therapy
Not in the CDC Guidelines
Or TN State Specific

- Consider screening for
  - Depression
  - Anxiety
  - Current or past substance abuse
  - Address these in the treatment plan

Screening for Mental Health
• Scoring: Count the points and total the score.
  • The possible range is 0-27.
  • Minimal depression 0-4 may not need depression treatment
  • Mild depression 5-9 Physician uses clinical judgment
  • Moderate depression 10-14 Physician uses clinical judgment
  • Moderately severe depression 15-19
  • Severe depression 20-27 Warrants treatment for depression, using antidepressant, psychotherapy and/or a combination of treatment.

**Scoring the PHQ-9**

• Review of prior records DIRECTLY RELATED to patient's CHRONIC PAIN CONDITION
  • Just saying “I have arthritis” is not sufficient
  • Prescribers have had difficulty justifying some diagnoses before the BME
    • “Well, they TOLD me they had cancer.”
  • Remember, another prescriber writing pain medications is not in itself justification to continue them

**Records Review**

• “There shall be the establishment of a current diagnosis that justifies a need for opioid medications.”

**Establish a Diagnosis**
Initiating Opioids
For Management of Chronic Non-Malignant Pain

Basics of Opioid Therapy

- Short acting
  - Incident pain
  - Acute pain
  - Short-term treatment
  - Mild pain
- Long acting
  - Less of a peak effect
  - Chronic pain requiring round the clock dosing
  - ONE long-acting, ONE short-acting
  - Short-acting MEDD should never be more than 50-100% of the long-acting.

Upon Initiating Opioids

- Initiation should be presented as a therapeutic trial
- Opioid naïve?
  - Use lowest dose and titrate to effect
- INFORMED CONSENT must be obtained
  - See sample informed consent
  - Risks, alternatives and benefits
  - Likelihood of dependence, risk of oversedation
  - Pregnancy
  - Risk of impaired motor skills, addiction and death
- Written treatment agreement
• Reasons for discontinuation of controlled substances
• Practice policy on “early refills”
• Policy on lost prescriptions
• Use of one pharmacy
• Periodic drug testing
• Female patients will tell the provider if they want to avoid unintended pregnancy and if they become pregnant

Written Treatment Agreement

• “The provider should discuss methods to prevent unintended pregnancy...”
• Signed informed consent stating a woman has been educated about the risks of opioid treatment during pregnancy
• Pregnancy test prior to initiation should be done in all at-risk women
• Ask about pregnancy at each visit
• Consider long-acting reversible contraceptive
• Consider referral to high risk OBGYN if appropriate

Women’s Health

• State recommends that patients on >100 MEDD should be referred to a pain specialist
• Consultation vs management
• If not done, document why
• Monitor patients for abuse
• UDS at least twice a year
• Document pill counts
• Check the CSMD
• Ongoing risk assessment
• Stop opioid therapy if the risks outweigh the benefits
• Taper if indicated

Ongoing Therapy
Tapering Protocol

- Any time the risks outweigh the benefits therapy should be discontinued
- Discontinuation poses risk for withdrawal
  - Nausea, vomiting, piloerection, diaphoresis, myalgia
    - Acute post withdrawal syndrome
  - Depression, malaise, fatigue, lasting up to two YEARS
- Benzodiazepine withdrawal can be fatal
- Low dose opioids → low risk for withdrawal
- Responsibility of the current provider to address this issue

Weaning Opioids

- Conservative:
  - 10% reduction per week
- Moderate
  - 25% reduction every 4 days
- Aggressive
  - 25-50% reduction daily
- TN Dept of Health does not recommend any specific protocol
- Adjuvant medication
  - Clonidine 0.1mg q6h or 0.1mg TD q24h
    - Hypotension and anticholinergic effects

Doctor Shopping Law

- TN Code 53-11-309
  - “Any physician…who has actual knowledge that a person has knowingly, willfully and with intent to deceive, obtained or attempted to obtain controlled substances in a manner prohibited [by the law] shall cause a report to be submitted…within five business days of obtaining such knowledge.”
  - Exemption if treating a mental illness
Doctor Shopping

- If detected, provider must report to law enforcement
  - Form is located at:
    - Fax directly to 423 267 8983
    - Or scan and email to: kim.litman@tn.gov
  - Simply starts a process
  - Enters patient into a database looking for other “red flags”

Whither Suboxone?

- Buprenorphine/naloxone (naloxone discourages misuse)
- Initially designed to allow opiate addiction treatment in the PCP office
- Requires an “X” DEA certificate
- Frequently done in “Suboxone Clinics”
- Drug of choice for outpatient opiate detoxification
- Initiation/Maintenance/Taper
• Pill counts
• Symptoms/indications
• Response to treatment
• Titrations or weaning/rationale
• UDS
• Discussion of risks/benefits/Alternatives

**Document! Document! Document!**

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• If you had 10/10 pain and were given Tylenol #3, what might you do?
  • Complain
  • Ask for stronger narcotics
  • Ask for early refills/take more than prescribed
  • Switch doctors/get multiple scrips
  • Act out
• Increasing dose: Counterintuitive
  • Pseudoaddicts will complain less
  • No effect on drug seekers

**Pseudoaddiction**

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• No “one size fits all” regimens
  • This is a red flag to the DEA
  • Use the minimum amount needed to accomplish adquate symptom management
  • Reassess frequently

**Tailor treatment to patient**

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**A Few Clinical Pearls**

- NEVER use transdermal fentanyl for:
  - Acute pain
  - Opioid naïve elderly patients
- ALWAYS convert to Transdermal Fentanyl using the chart in the PDR
  - Shown to avoid adverse events
- Adjust breakthrough dose to long-acting dose
  - LA 24h dose — SA 24h dose at maximum use
  - E.g., 120mg LA, 10-20mg SA q4hr prn
- ONE long acting, ONE short acting

**Resources for further learning**

- PainEdu.Org
- PainMed.Org
- NCPCO.Org
  - (Hospice and Palliative Medicine)
- Dr Baumrucker
  - hospicedoc@charter.net