Opioid Safe Prescribing and the CDC Guidelines

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System Medical Director, Hospice and Palliative Medicine, Wellmont Health System
• 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 the Guidelines
• 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.

**Purpose of this Review**
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 and interdisciplinary process
  - Many non-opioid modalities
    - Physical therapy
    - Psychology
    - Non opioid medications
      - Steroids
      - Anticonvulsants
      - Antidepressants
      - SNRI
• In 2011, TN was second in the country for opioid scrips
• 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

Why Is This Necessary?
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
ADDICTION RARE IN PATIENTS TREATED WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,852 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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17,000 U per square meter daily). Patients who had complete remissions (except for three over 60 years of age) received central-nervous-system therapy (2400 rads to the skull, with five intrathecal injections of methotrexate or arabinosyl cytosine, or both). During complete remission, they were given 6-mercaptopurine (70 mg per square meter daily), methotrexate (25 mg per square meter each week), and courses of vincristine and prednisone every three to four months.

Results are shown in Table 1. They do not support the suggestion by Dr. Bitran that in adults with acute lymphoblastic anemia, T-cell leukemia has a poorer prognosis than B-cell disease. However, because of the limited number of cases and the short follow-up, the present data are far from definitive. More information on this point is needed. The identification of prognostic factors in acute lymphoblastic anemia in adults is critical, not only for the choice of induction therapy but also because young adults with an established poor prognosis could profit from allogeneic-marrow transplantation during the first remission. Therefore, we suggest that for the time being it may be wiser to base prognosis on more established criteria, such as age and blast-cell count in the blood.

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Dollars Spent Marketing OxyContin (1996-2001)

Figure 1: Promotional Spending for Three Opioid Analgesics in First 6 Years of Sales

Absolute dollars in millions

“C’mon, c’mon – it’s either one or the other.”
Total Sales & Prescriptions for OxyContin (1996-2002)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales</th>
<th>Percentage increase</th>
<th>Number of prescriptions</th>
<th>Percentage increase</th>
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</thead>
<tbody>
<tr>
<td>1996</td>
<td>$44,790,000</td>
<td>N/A</td>
<td>316,786</td>
<td>N/A</td>
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<tr>
<td>1997</td>
<td>125,464,000</td>
<td>180</td>
<td>924,375</td>
<td>192</td>
</tr>
<tr>
<td>1998</td>
<td>286,486,000</td>
<td>128</td>
<td>1,910,944</td>
<td>107</td>
</tr>
<tr>
<td>1999</td>
<td>555,239,000</td>
<td>94</td>
<td>3,504,827</td>
<td>83</td>
</tr>
<tr>
<td>2000</td>
<td>981,643,000</td>
<td>77</td>
<td>5,932,981</td>
<td>69</td>
</tr>
<tr>
<td>2001</td>
<td>1,354,717,000</td>
<td>38</td>
<td>7,183,327</td>
<td>21</td>
</tr>
<tr>
<td>2002</td>
<td>1,536,816,000</td>
<td>13</td>
<td>7,234,204</td>
<td>7</td>
</tr>
</tbody>
</table>

• 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

Source: National Vital Statistics System
Rate of Rx Painkiller Sales, Deaths and Substance Abuse Treatment Admissions (1999-2010)

Source: National Vital Statistics System
Painkiller drugs sales spike over last decade

Sales of the nation's two most popular prescription painkillers, oxycodone and hydrocodone, have exploded across the U.S. in the last decade, according to an Associated Press analysis of data provided by the Drug Enforcement Administration. Oxycodone is the key ingredient in OxyContin, Percodan and Percocet while hydrocodone is the key ingredient in Vicodin, Norco and Lortab. Both medicines are highly addictive and frequently abused.

Percent change for drug sales per capita, 2000-2010

- < 0
- 0% - 99%
- 100% - 199%
- 200% - 299%
- 300% - 399%
- 400% - 499%
- > 500%
• 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...
Long Term Goals of Pain Management

• Improve Symptoms
• Improve Functioning
• Improve Quality of Life
• Minimize adverse effects, including death
• Minimize addiction
• Will be finalized in January 2016
• Intended to help providers safely treat pain while minimizing adverse outcomes

CDC Guidelines
• 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
• Providers should discuss the risks, benefits, and alternatives to continuing therapy periodically during 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
• 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
• 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
Reassess

• 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.
• 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 Assessment Tools

• **DIRE**
  • Diagnosis, Intractability, Risk, Efficacy Score
    • Numerical Score
    • Categorizes patients into “Not suitable” vs “Good candidate”
- **SOAPP-R**
  - Screener and Opioid Assessment for Patients With Pain-Revised
    - 24 item, patient completed
    - Widely used
    - Impulsivity, legal, PHx, past sexual abuse (risk factor)
    - Classifies Low and High Risk
• 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)
• Prescription monitoring system assists in
  • Research
  • Statistical analysis
  • Criminal investigation
  • Enforcement of state laws
  • Education of health care practitioners
• Collects and maintains data regarding controlled substances
  • Schedule II, III, IV
    • And some Schedule V
• Submitted every 7 days
• Prescriber, patient, and prescription information
• 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

Registration (TN SPECIFIC)
Requirements to Use CSMD

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

**CSMD Alerts**
• 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)
• 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

* No other drugs were involved.

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

** Stratified by Age **

<table>
<thead>
<tr>
<th>Drug combination</th>
<th>Aged 12 to 34</th>
<th>Aged 35 to 44</th>
<th>Aged 45 to 64</th>
<th>Aged 65 or older</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzodiazepines alone</td>
<td>28%</td>
<td>30%</td>
<td>37%</td>
<td>39%</td>
</tr>
<tr>
<td>Benzodiazepines and opioids</td>
<td>37%</td>
<td>43%</td>
<td>47%</td>
<td>59%</td>
</tr>
<tr>
<td>Benzodiazepines and alcohol</td>
<td>35%</td>
<td>43%</td>
<td>51%</td>
<td>55%</td>
</tr>
<tr>
<td>Benzodiazepines, opioids, and alcohol</td>
<td>39%</td>
<td>47%</td>
<td>57%</td>
<td>70%</td>
</tr>
</tbody>
</table>

* All estimated risks are statistically significantly greater than 20% at the .05 level.
** No other drugs were involved.
Providers should offer/arrange *evidence based treatment*
- Usually opioid agonist therapy
  - Combined with behavioral therapy
Not in the CDC Guidelines

Or TN State Specific
Screening for Mental Health

- Consider screening for
  - Depression
  - Anxiety
  - Current or past substance abuse
- Address these in the treatment plan
**PATIENT HEALTH QUESTIONNAIRE-9 (PHQ-9)**

Over the last 2 weeks, how often have you been bothered by any of the following problems? (Use *X* to indicate your answer)

<table>
<thead>
<tr>
<th></th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

For scoring: 0 + ______ + ______ + ______ + ______ = Total score: ______

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

<table>
<thead>
<tr>
<th>Not difficult at all</th>
<th>Somewhat difficult</th>
<th>Very difficult</th>
<th>Extremely difficult</th>
</tr>
</thead>
</table>

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.
Scoring the PHQ-9

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

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
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
• 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
• 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 Law
• If detected, provider must report to law enforcement
  • Form is located at:
    • http://bit.ly/1bPjSiT
  • 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”
PRACTITIONER REPORT OF POTENTIAL DOCTOR SHOPPER TO LAW ENFORCEMENT

To: Local law enforcement agency (Sheriff’s Office, Police Department, Judicial District Drug Task Force, or TennCare Investigations):

From: (Practitioner’s name)
Office address:
Phone number:
Date: (Must be within 8 business days of incident)

Re: Controlled Substance Report / as required by Tenn. Code Ann. §53-11-309(a)

The above-named physician, dentist, optometrist, podiatrist, veterinarian, pharmacist, advanced practice nurse with a certificate of fitness issued under title 63, chapter 7, or physician assistant has actual knowledge that on , the following person:

(insert date)

Patient’s Name:
Patient’s Address:
Driver’s License Number & State:
Patient’s DOB:

knowingly, willfully and with intent to deceive, obtained or attempted to obtain controlled substances by deceit or failing to disclose that he/she has received the same controlled substance or one of similar therapeutic use, or a prescription for the same controlled substance or one of similar therapeutic use, from another practitioner within the previous 30 days.

For Department Use Only

<table>
<thead>
<tr>
<th>Date Received</th>
<th>Approved</th>
<th>Disapproved</th>
<th>Director or Designee Signature</th>
<th>Date of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/24/10</td>
<td></td>
<td></td>
<td></td>
<td>RDA 15140</td>
</tr>
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</table>
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
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
Tailor treatment to patient

- No “one size fits all” regimens
  - This is a red flag to the DEA
- Use the minimum amount needed to accomplish adequate symptom management
- Reassess frequently
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 \(\approx\) 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