Cancer Pain Control During an Opioid Epidemic

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ELNEC Webinar
October 15, 2019
Objectives

• Review the scope and impact of the United States opioid crisis and the necessity for careful prescription of opioid medications.
• Describe the necessity of opioid medications for pain management in patients with cancer and survivors, and discuss strategies to ensure that patients have access to medications necessary for managing pain.
• Define strategies to maintain patient safety and minimize the risks of opioid misuse and abuse during chronic opioid use.
Unintended Consequences

• Unrelieved pain is a public health crisis
• Opioid misuse and overdose deaths are emergencies
• Unintended consequences of efforts to reduce opioid overdoses include further stigma and unrelieved pain
• Simple solutions helped create the current crisis
• Comprehensive, complex solutions are needed to resolve these two public health crises
Cholangiocarcinoma, IVC stent, Y-90 left hepatic artery radioembolization
7 day supply opioid
“per CDC guidelines”
Metastatic prostate cancer
Difficulty filling opioids at retail pharmacies
Metastatic NSCLC, severe pain, dehydration, hypokalemia
MRI in ED: No IV opioid due to nationwide shortage
# Opioids and Cancer Pain: Patient Needs and Access Challenges

In 2016, ASCO issued a policy statement on the need to balance public health concerns about opioid abuse with ensuring access to opioids as a component of appropriate pain management for patients and survivors of cancer. Recent evidence suggests that access challenges are growing.

### Opioids Are Frequently Needed to Effectively Manage Cancer Pain.

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Survivors</th>
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</thead>
<tbody>
<tr>
<td>Experience Chronic Cancer-Related Pain</td>
<td>55%</td>
<td>40%</td>
</tr>
<tr>
<td>Use Opioids to Manage Their Pain</td>
<td>43%</td>
<td>10%</td>
</tr>
</tbody>
</table>

8 Out of 10 patients with advanced cancer have moderate to severe pain.

### In the Wake of Policies Intended to Address the Opioid Crisis, It Has Become Harder for Cancer Patients to Access the Pain Treatment They Need.

40% of U.S. oncology practices say their patients had trouble filling opioid prescriptions. Barriers included:

- 69% Prior Authorization and/or Precertification Required
- 61% Limits on Number of Pills per Prescription
- 44% Caps on Maximum Dosage
- 37% Medication Unavailable at Local Pharmacy
- 34% Patients Often Need Hard Copy of Prescription
- 28% Inability to E-Prescribe These Drugs in Some States

Growing barriers to access:

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insurance Coverage Denied</td>
<td>11%</td>
<td>14%</td>
</tr>
<tr>
<td>Refills Required at a Single Pharmacy</td>
<td>30%</td>
<td>32%</td>
</tr>
<tr>
<td>Limited Number of Refills</td>
<td>36%</td>
<td>21%</td>
</tr>
</tbody>
</table>
OPIOIDS AND CANCER PAIN:
PATIENT NEEDS AND ACCESS CHALLENGES

In 2016, ASCO issued a policy statement on the need to balance public health concerns about opioid abuse with ensuring access to opioids as a component of appropriate pain management for patients and survivors of cancer. Recent evidence suggests that access challenges are growing.

92% of U.S. oncology practices are concerned that restrictions on opioid prescribing will result in undertreating cancer pain.¹

Filling opioid prescriptions. Barriers included:³

- 44% MEDICATION UNAVAILABLE AT LOCAL PHARMACY
- 37% PATIENTS OFTEN NEED HARD COPY OF PRESCRIPTION
- 34% INABILITY TO E-PRESCRIBE THESE DRUGS IN SOME STATES
- 11% INSURANCE COVERAGE DENIED
- 14% REFILLS REQUIRED AT A SINGLE PHARMACY
- 21% LIMITED NUMBER OF REFILLS

¹²³⁴

Cancer Prevalence

• In 2012, new cancer cases worldwide – 14.1 million, 8.2 million deaths, $32.6\text{ million people living with cancer}$
• By 2030, 21.7 million new cases, 13 million cancer deaths, $52.2\text{ million survivors}$

Global Cancer Facts & Figures, 3rd Edition, 2015, American Cancer Society (ACS) and International Agency for Research on Cancer (IARC)
Good News/Bad News

• Good news – more treatments are leading to better survival from a variety of serious illnesses
• Bad news – more persistent pain syndromes
• More bad news – opioid abuse epidemic
How the Epidemic of Drug Overdose Deaths Ripples Across America

By HAIEYOUN PARK and MATTHEW BLOCH  JAN. 18, 2016

The New York Times
The number who die each year from...

- Drug overdoses: 52,404
- Car accidents: 37,757
- Guns: 35,763
- H.I.V.: 6,465
Figure 1. National Drug Overdose Deaths Number Among All Ages, by Gender, 1999-2017

Source: Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018
3 Waves of the Rise in Opioid Overdose Deaths

Wave 1: Rise in Prescription Opioid Overdose Deaths
Wave 2: Rise in Heroin Overdose Deaths
Wave 3: Rise in Synthetic Opioids (like fentanyl)


https://www.cdc.gov/drugoverdose/epidemic/index.html
CDC Guideline for Prescribing Opioids for Chronic Pain

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.

CDC developed and published the CDC Guideline for Prescribing Opioids for Chronic Pain to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings.

Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.
5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to 50 morphine milligram equivalents (MME) or more per day, and should avoid increasing dosage to 90 MME or more per day or carefully justify a decision to titrate dosage to 90 MME or more per day.

6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed.
Payers
Industry
Distributers
Joint Commission
Doctors
Government
Patients
How Do We Achieve Balance?

Pain Control

Opioid Misuse Epidemic
Substance Use Disorder

• Addiction: “chronic disease of brain reward, motivation, memory, and related circuitry,” characterized by “an individual pathologically pursuing reward and/or relief by substance use and other behaviors”

• Addiction is not a choice or a moral failure

• Stigma
  - “Abuser”
  - “Frequent flyer”

• Leads to judgment, punitive beliefs rather than compassion

Substance Use Disorders are Chronic Medical Illnesses

• Drug/alcohol continuous abstinence 1 year post discharge ~40-60%
• Optimal adherence to treatment
  – Diabetes < 60%
  – Hypertension < 40%
  – Adult onset asthma < 40%
• Proportion of patients requiring medical care to re-establish control
  – Adults with type 1 diabetes 30-50%
  – Adults with hypertension or asthma 50-70%

Review

Addiction to opioids in chronic pain patients: A literature review

Jette Højsted *, Per Sjøgren

Multidisciplinary Pain Centre, University Hospital of Copenhagen, Rigshospitalet, Blegdamsvej 9, 2100 Copenhagen, Denmark

Received 20 February 2006; received in revised form 28 August 2006; accepted 30 August 2006
Available online 27 October 2006

Abstract

Opioids have proven very useful for treatment of acute pain and cancer pain, and in the developed countries opioids are increasingly used for treatment of chronic non-malignant pain patients as well. This literature review aims at giving an overview of definitions, mechanisms, diagnostic criteria, incidence and prevalence of addiction in opioid treated pain patients, screening tools for assessing opioid addiction in chronic pain patients and recommendations regarding addiction problems in national and international guidelines for opioid treatment in cancer patients and chronic non-malignant pain patients.

The review indicates that the prevalence of addiction varied from 0% up to 50% in chronic non-malignant pain patients, and from 0% to 7.7% in cancer patients depending of the subpopulation studied and the criteria used. The risk of addiction has to be considered when initiating long-term opioid treatment as addiction may result in poor pain control. Several screening tools were identified, but only a few were thoroughly validated with respect to validity and reliability.

Most of the identified guidelines mention addiction as a potential problem. The guidelines in cancer pain management are concerned with the fact that pain may be under treated because of fear of addiction, and the guidelines in management of non-malignant pain patients include warnings of addiction. According to the literature, it seems appropriate and necessary to be aware of the problems associated with addiction during long-term opioid treatment, and specialised treatment facilities for pain management or addiction medicine should be consulted in these cases.

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Keywords: Addiction; Chronic pain; Screening tools; Questionnaires; Incidence; Prevalence
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Keywords: Addiction; Chronic pain; Screening tools; Questionnaires; Incidence; Prevalence
Similar histories of cancer and SUD (stigma, fear, blame)

DEA reduced opioid manufacturing 25% in 2017; 20% in 2018; 10% in 2019 (of 6 frequently abused opioids)

444 bills proposed 2018
- Enhanced education, develop guidelines
- Limit opioids to certain groups, time limits (3-7 day supply, maximum dosage (100 mg OME/day)
- Some exempt hospice/palliative care, few exempt cancer
Review Article

Cancer Pain Management and the Opioid Crisis in America: How to Preserve Hard-Earned Gains in Improving the Quality of Cancer Pain Management

Judith A. Paice, PhD, RN

Cancer 2018;124:2491-2497.
**Barriers Related to Patients and Family Members**

- **Reluctance to Report Pain**
  - Anxiety regarding meaning of pain
  - Fear presence of pain will limit treatment options
  - Concerns of being "a bother" to the oncology team
  - Assumptions that pain is to be expected, that team knows they have pain

- **Fear of Addiction**
  - Enhanced by media attention to opioid misuse epidemic and celebrity deaths

- **Inadequate Training in Use of Pain Medications**
  - Reduced adherence due to misunderstandings regarding opioid use and "prn" administration

- **Socioeconomic Limitations to Accessing Treatment**
  - Support to get to clinic for reassessment, cost of transportation, families taking off work

- **Cognitive and Affective Factors**


**Barriers Related to Health Care Professionals**

- **Inadequate Knowledge**

- **Insufficient Pain Assessment Due to Inadequate Knowledge, Competing Priorities, Time Limitations**

- **Lack of Awareness of the Biopsychosocial and Spiritual Components of Pain**

- **Reluctance to Prescribe Opioids**
  - Concerns about adverse effects, addiction, tolerance
  - Belief that opioids are to be used only during terminal phase
  - Worry about payment, need for prior authorization, delays in access
  - Fear of regulatory oversight, loss of license

**Barriers Related to Health Care Systems**

- **Inadequate Time**

- **Limited Access to Pain Specialty Care**

- **Limited Reimbursement for Opioid and Non-Opioid Therapies**

- **Limited Payment for and/or Access to Non-Pharmacologic Therapies (e.g., PT/OT, Mental Health, Counseling, integrative therapies)**

- **Limited Formularies**

- **Shortages of Opioids in Retail and Hospital Pharmacies**
Educate patients and family members regarding:

- Importance of reporting and treating pain in oncology
- Their individual risk for addiction based upon risk assessment along with strategies that will be employed to prevent misuse
- Appropriate use of ATC and prn opioids and need to follow directions carefully
- Need to use opioids for pain relief only, not to treat anxiety or sadness, or to enhance sleep
- Need to have one prescriber (may be one team in oncology) provide prescriptions
- Safe storage and disposal of medications

Oncology professionals will obtain education regarding:

- Comprehensive pain and addiction risk assessment
- Tolerance, physical dependence, addiction
- Universal precautions
- Regulatory and licensing statues that guide clinical practice and opioid prescribing in their state

Health systems and oncology practices will provide access to:

- Prescription drug monitoring data within the electronic health record
- Laboratory services that provide rapid urine toxicology results
- Pain and palliative care specialists
- Adequate opioid and other pharmacological formularies
- Mental health counseling
- Non-pharmacological and integrative pain therapies
- Addiction resources
Management of Chronic Pain in Survivors of Adult Cancers: American Society of Clinical Oncology Clinical Practice Guideline

Judith A. Paice, Russell Portenoy, Christina Lacchetti, Toby Campbell, Andrea Cheville, Marc Citron, Louis S. Constine, Andrea Cooper, Paul Glare, Frank Keefe, Lakshmi Koyyalagunta, Michael Levy, Christine Miaoiski, Shirley Otis-Green, Paul Sloan, and Eduardo Bruera
What is a Cancer Survivor?

National Coalition for Cancer Survivorship
• Survivor - from the moment of diagnosis through the rest of their life

National Cancer Institute’s Office of Cancer Survivorship
• Survivor is a person with a history of cancer who is beyond the acute diagnosis and treatment phase

• 14 million in the United States
• 2/3 living 5 years or longer
• Prevalence of pain 40% or higher

https://www.canceradvocacy.org/
https://cancercontrol.cancer.gov/ocs/
Key Recommendations

• Screening and Comprehensive Assessment (cancer treatment syndromes)
• Treatment and Care Options
• Risk Assessment, Mitigation and Universal Precautions
### Chronic Pain Syndromes Associated with Cancer Treatment

**Chemotherapy-related pain syndromes**
- Bony complications of long-term corticosteroids
- Avascular necrosis
  - Vertebal compression fractures
  - Carpal tunnel syndrome
- Chemotherapy-induced peripheral neuropathy
- Raynaud’s syndrome

**Hormonal therapy-related pain syndromes**
- Arthralgias
- Dyspareunia
- Gynecomastia
- Myalgias
- Osteoporotic compression fractures

**Radiation-related pain syndromes**
- Chest wall syndrome
- Cystitis
- Enteritis and proctitis
- Fistula formation
- Lymphedema
- Myelopathy
- Osteoporosis
- Osteoradionecrosis and fractures
- Painful secondary malignancies
- Peripheral mononeuropathies
- Plexopathies: brachial, sacral

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Evaluate for recurrent disease*

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Chronic Pain Syndromes Associated with Cancer Treatment

Nonpharmacologic Interventions

Table 4. Disciplines and Interventions for Chronic Pain

<table>
<thead>
<tr>
<th>Disciplines</th>
<th>Examples of Possible Interventions</th>
<th>Strength of Evidence and Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical medicine and rehabilitation</td>
<td>Physical therapy, occupational therapy, recreational therapy, individualized exercise program, orthotics, ultrasound, heat/cold</td>
<td>Evidence-based; benefits outweigh harms; evidence quality: intermediate; strength of recommendation: moderate</td>
</tr>
<tr>
<td>Integrative therapies</td>
<td>Massage, acupuncture, music</td>
<td>Evidence-based; benefits outweigh harms; evidence quality: low; strength of recommendation: weak</td>
</tr>
<tr>
<td>Interventional therapies</td>
<td>Nerve blocks, neuraxial infusion (epidural/intrathecal), vertebroplasty/kyphoplasty</td>
<td>Evidence-based; benefits outweigh harms; evidence quality: intermediate; strength of recommendation: moderate</td>
</tr>
<tr>
<td>Psychological approaches</td>
<td>Cognitive behavioral therapy, distraction, mindfulness, relaxation, guided imagery</td>
<td>Evidence-based; benefits outweigh harms; evidence quality: intermediate; strength of recommendation: moderate</td>
</tr>
<tr>
<td>Neurostimulatory therapies</td>
<td>TENS, spinal cord stimulation, peripheral nerve stimulation, transcranial stimulation</td>
<td>Evidence-based; benefits outweigh harms; evidence quality: low; strength of recommendation: weak</td>
</tr>
</tbody>
</table>

Abbreviation: TENS, transcutaneous electrical nerve stimulation.
### Adverse Effects Associated with Long-Term Opioid Use

<table>
<thead>
<tr>
<th>Persistent common adverse effects</th>
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<tbody>
<tr>
<td>Constipation</td>
</tr>
<tr>
<td>Mental clouding</td>
</tr>
<tr>
<td>Upper GI symptoms (pyrosis, nausea, bloating)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Endocrinopathy (hypogonadism/hyperprolactinemia)</th>
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<tbody>
<tr>
<td>Fatigue</td>
</tr>
<tr>
<td>Infertility</td>
</tr>
<tr>
<td>Osteoporosis/osteopenia</td>
</tr>
<tr>
<td>Reduced libido</td>
</tr>
<tr>
<td>Reduced frequency/duration or absence of menses</td>
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<table>
<thead>
<tr>
<th>Neurotoxicity</th>
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</thead>
<tbody>
<tr>
<td>Myoclonus</td>
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Other changes in mental status (including mood effects, memory problems, increased risk of falls in the elderly)

Risk of opioid-induced hyperalgesia (incidence and phenomenology uncertain, but escalating pain in tandem with dose escalation raises concern)

<table>
<thead>
<tr>
<th>Sleep-disordered breathing</th>
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</thead>
<tbody>
<tr>
<td>Increased risk of concurrent benzodiazepine in patients predisposed to sleep apnea</td>
</tr>
<tr>
<td>New-onset sleep apnea</td>
</tr>
<tr>
<td>Worsening of sleep apnea syndromes</td>
</tr>
</tbody>
</table>

Risk Assessment

- Pain
- Function
- Misuse/abuse of drugs
  - Current/past misuse of prescription or illicit drugs
  - Alcohol, smoking, gambling
- Environmental/genetic exposure
  - Family, friends with substance misuse disorder
- Sexual abuse, PTSD

Table 3. Risk Factors for Substance Use Disorders

<table>
<thead>
<tr>
<th>Risk Factor</th>
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<tbody>
<tr>
<td>Smoking history</td>
</tr>
<tr>
<td>Past or current alcohol use disorder; risky alcohol intake (eg, binge drinking)</td>
</tr>
<tr>
<td>Past or current use of recreational substances</td>
</tr>
<tr>
<td>First use of substances at an early age (eg, 15 years of age or younger)</td>
</tr>
<tr>
<td>Family history of alcohol abuse or substance use disorder</td>
</tr>
<tr>
<td>Trauma (eg, sexual abuse, posttraumatic stress disorder)</td>
</tr>
<tr>
<td>Legal problems, history of incarceration, other issues</td>
</tr>
</tbody>
</table>

Paice JA. Managing cancer pain during an opioid epidemic. *Oncology* 2018; 32(8)
THE SILENCE: THE LEGACY OF CHILDHOOD TRAUMA

I never got any help, any kind of therapy. I never told anyone.

By Junot Díaz
Universal Precautions

- Prescription Drug Monitoring Programs
- Urine toxicology
- Agreements/contracts

Assess and stratify risk of opioid misuse

Decide whether or not to prescribe

Minimize risk

Monitor drug-related behaviors

Respond to aberrant behaviors

Table 4. Universal Precautions for Opioid Use in Chronic Cancer Pain Management

1. Assess pain and risk of opioid misuse.
   - Assess pain and risk for substance use disorder.
   - Conduct examination and review medical record.
   - Review prescription drug monitoring program.
   - Conduct urine drug screening.

2. Decide whether or not to prescribe.
   - Stratify risk of diversion and abuse.

   - Optimize adjuvant analgesics.
   - Use multimodal pain therapy.
   - Obtain treatment for psychiatric illness, including anxiety, depression, and sleep disorders.

   - Evaluate effectiveness (decreased intensity and improved function).
   - Review and treat adverse effects.
   - Monitor adherence.

5. Respond to aberrant behaviors.
   - Assess for behaviors that may indicate uncontrolled pain, compulsive use, use to treat other conditions (anxiety, depression, sleep), or diversion.
   - Intervene by prescribing small amounts at shorter intervals, using pill counts, and using drug screening more frequently.
   - Consult psychiatric and/or addiction specialists.

Structure Based Upon Risk

Minimal Structure

- Annual urine toxicology
- Review of PDMP every 3 months
- Clinic appointments every 3 months
- Prescriptions provided for 30 day supply – may provide 3 prescriptions (e.g. “may fill on or after June 1, 2019”)

Higher Structure

- Frequent urine toxicology
- Review of PDMP with each refill
- Reassess pain, function, aberrant behaviors frequently; reconsider need
- Prescriptions provided for 1-2 week supply
- Engage family
- Taper when indicated
- Refer to addiction specialist


Paice JA. Risk assessment and monitoring of patients with cancer receiving opioid therapy. *The Oncologist* 2019; 24: 1-5
When Opioids are No Longer Beneficial: Weaning

- Slow downward titration – 10% reduction/week
- Offer psychosocial support
- Optimize nonopioids and adjuvant analgesics
- Use antidepressants rather than benzodiazepines to treat irritability and sleep disturbances
- Provide a clear verbal and written plan

Safe Storage & Disposal

• Educate patients/families regarding safe medication practices
  – Don’t leave medications out, medicine cabinet
  – Lock boxes

• Safe disposal
  – Take back programs – pharmacies, police depts
  – Mix drug in wet coffee grounds or kitty litter until dissolved, then dispose in garbage – do not flush down toilet (FDA recommends flushing opioids)

National Take Back Day
October 26, 2019

www.deadiversion.usdoj.gov
Educational Tools

https://www.cancer.net/sites/cancer.net/files/asco_answers_safe_storage_and_disposal.pdf
Solutions

- Research
- Education
- Evidence based guidelines for managing pain in those with current/past history of SUD
- Access to care – pain, addiction, mental health counseling, PT/OT
- Partnerships
- Be aware of implicit bias
- Advocate!
DRUG DEALER, MD
How Doctors Were Duped, Patients Got Hooked and Why It's So Hard to Stop
Anna Lembke, MD

DREAMLAND
The True Tale of America's Opiate Epidemic
Sam Quinones

DOPESICK
Dealers, Doctors and the Drug Company That Addicted America
Beth Macy
To the Editor:
Your editorial about the opioid crisis brought to mind the words of the great American journalist H. L. Mencken: “For every complex problem there is an answer that is clear, simple and wrong.” Ignoring the social determinants that drive drug use and minimizing the critical medical roles of pain assessment and opioids, as your editorial does, are a disservice to those struggling with opioid dependence and those suffering from pain.

A few scientific facts: Heroin is now the most frequent opioid of first illicit use, not legally prescribed opioids. Heroin and synthetic fentanyl account for most opioid-related deaths, and their use is rising. Concurrently, 100 million Americans experience pain that impairs their ability to work, delays surgical recovery, causes depression and reduces life expectancy.

We do not minimize the contributions of drug advertising and inappropriate prescribing on the opioid epidemic. We do not disagree that we need better education in pain management, prescription monitoring systems and nonopioid treatments.

But unless we meaningfully address the complex problems of poverty and lack of gainful employment, mental illness and social isolation, we are creating a solution that is not only wrong but will also lead to unnecessary suffering for millions.

R. SEAN MORRISON
JAMES CLEARY, NEW YORK
“Never doubt that a small group of thoughtful, committed citizens can change the world. Indeed, it is the only thing that ever has”.

Margaret Mead