Pain Management in Individuals with Serious Illness and Co-morbid Substance Use Disorders
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Objectives
• Describe scope of substance abuse problem in the United States
• Discuss key components of a comprehensive pain and opioid risk assessment
• Describe universal precautions approach to opioid management
Prescription Drug Abuse

History and Update

Where are we now...

But this is not a new issue—circa 1900

As early as 1909, researchers began to report patients developing 'tolerance' to heroin. By 1912, heroin sales were accounting for roughly five percent of Bayer's net profits. French and American researchers were reporting cases of 'habit' and addiction.
Scope of Problem

Drug overdose deaths

- Overdose deaths quadrupled since 1999
- 1999-2014 - More than 165,000 died of prescription opioids
- Highest rate among ages 25-54
- Overdose deaths prescription drugs 2014 - 47,055
  - 61% of drug overdose deaths (28,647) involved pharmaceutical drugs
- Most common prescription opioids involved in overdose
  - methadone, oxycodone, hydrocodone

Opioid Overdose Deaths

National Opioid Overdose Deaths—Number of Deaths from Prescription Opioid Pain Relievers.

The figure above is a bar chart showing the total number of U.S. opioid overdose deaths involving opioid pain relievers from 2001 to 2014. The chart is overlaid by a line graph showing the number of deaths by females and males. From 2001 to 2014 there was a 4.4-fold increase in the total number of deaths.
Heroin- Emerging Concern

- Non medical use of prescription opioids risk factor for heroin use
- 145% increase in heroin use from 2007-2014
- Heroin overdose mortality
  - 2000: 1,842
  - 2014: 10,574
- BUT – No clear association of efforts to curb prescription drug abuse and increased heroin use
  - Increase started before changes in opioid policies

Synthetic Fentanyl Overdoses
- Emerging problem
- Increasing number of overdose deaths from synthetic fentanyl (carfentanil)
  - Deaths increased by 79% from 3105 in 2013 to 5544 in 2014
  - Eight high burden states (MA, ME, NH, OH, FL, KY, MD, NC)

Synthetic Fentanyl Overdose Deaths

Where Medications Obtained for Non-medical Use
2012-2013

*Other category includes the sources: "Home, Fake Prescription," "Street from Dispenser," "Other Store/Dispenser," "Pharmacy," and "Home, Other Misc."
Note: The percentages do not add to 100 percent due to rounding.
Scope of problem in palliative care and hospice

What we know or don’t know…

- Data about scope of problem palliative care/hospice limited
- Risks may be higher in home population than previously reported
  - Almost 70% of diverted prescription drugs obtained from family and friends\(^1\)
- Hospice home care
  - May be limited oversight
  - Large quantities of opioids may be in home to manage uncontrolled symptoms\(^2\)

\(^1\)Substance Abuse and Mental Health Services Administration. 2014. http://www.samhsa.gov/

What we know or don’t know…

- Training policies lacking for substance abuse and diversion issues within hospices (Virginia)\(^1\)
- Majority of palliative care programs surveyed
  - Did not have policies in place for addressing substance abuse or diversion issues
  - Were not consistently screening patients for the risk of substance use disorder\(^2\)
- Less than 50% palliative medicine fellows surveyed had received adequate training in addiction and managing opioid misuse
  - Majority did not feel prepared to treat pain in this population\(^3\)

Managing Pain in Serious Illness

Think about these patients...
• 50 y.o. woman with metastatic pancreatic cancer, neoplasm related pain, active cocaine abuse
• 68 y.o. woman with lung cancer, pain from tumor invasion, runs out of pills each week prior to visit. Family member reports son is taking medications
• 74 y.o. woman metastatic pancreatic cancer, severe pain, has received multiple prescriptions for opioids in the last few days, reports she has none left today – urine negative for opioids
• 26 y.o. with metastatic sarcoma found injecting crushed opioids in his hospital room

Pharmacologic Approaches
• Mainstay of treatment in serious illness
• WHO ladder approach to pain management
  • Oral
  • Around the clock
  • Individualized
• Use of multimodal analgesia
  • Non-opioids, adjuvant therapies provide analgesia and may be opioid sparing

Auret & Schug | Best Practice & Research Clinical Anaesthesiology | 2013:545-561
Multimodal analgesia is optimal, but opioids often become mainstay for severe pain toward the end of life – thus the focus for the rest of this presentation will be on safe opioid management.

Universal Precautions Approach to Pain Management

Universal precautions

• All patients treated as if they are at risk for addiction
• Originally developed for use in chronic pain management
• Effective strategy as clinicians may not always identify “at-risk” individual
• Reduces the stigma associated with labeling an individual as “at-risk”
Components of Universal Precautions

- Comprehensive pain assessment/Differential diagnosis for pain
- Opioid risk assessment
- Informed consent
- Clear documentation of the treatment plan, decision making, and goals for opioid therapy
- Ongoing reassessment of analgesia effect
- Use of urine drug screening

Pain Assessment

- Assessment should include
  - pain location(s)
  - duration/onset (is this acute or chronic?)
  - Characteristics - identify nociceptive versus neuropathic pain
  - aggravating factors such as wound care or activity
  - relieving factors such as medications, heat/ice or rest
  - Past pharmacologic and non-pharmacologic treatments and responses
  - associated symptoms such as depression, anxiety, or insomnia
  - adverse side-effects from analgesics such as sedation, nausea, constipation
  - risk for misuse if opioids are a consideration for treatment

Opioid Risk Evaluation

- Detailed history essential to assess for risk for abuse
- Many tools available, but have not been validated in population with serious illness
- Evaluation tools such as the Opioid Risk Tool (ORT), Revised Screener and Opioid Assessment for Patients with Pain (SOAPP-R) and the Diagnosis, Intractability, Risk, Efficacy (DIRE) have been recommended
Examples: Opioid Risk Screening Tools

<table>
<thead>
<tr>
<th>Opioid Risk Tool</th>
<th>Key Points</th>
<th>Sample form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid Risk Tool (ORT)</td>
<td>7 items</td>
<td>Patient interview</td>
</tr>
<tr>
<td>Write and Opioid Assessment for Patients with pain – Revised (SOAPP-R)</td>
<td>24 items</td>
<td>Self-administer</td>
</tr>
<tr>
<td>Diagnosis, risk, relapse, efficacy (DIRE)</td>
<td>7 items</td>
<td>Patient interview</td>
</tr>
<tr>
<td>Current Opioid Misuse Measure (COMM)</td>
<td>17 items</td>
<td>Self-administer</td>
</tr>
<tr>
<td>Pain Assessment and Documentation Tool (PADT)</td>
<td>41 items</td>
<td>Chart note Documentation</td>
</tr>
</tbody>
</table>

Ongoing Assessment Tools for patients on opioid therapy

Possible aberrant behaviors

- Medication issues
  - Self-escalating opioid doses
  - Recurrent prescription losses
  - Borrowing from family/friends
  - Pill count discrepancies
  - Multiple prescribers
- Changes in function (not related to disease)

Risk Stratification

- Establish level of risk based on clinical interview, history and results of opioid risk tools
- Level of risk determines frequency of follow-up, use of pill counts, frequency of random urine drug screens
- NO established guideline but multiple suggested strategies
Sample Risk Stratification

- **Low:**
  - Clinical assessment that the patient is likely to have “therapeutic” opioid behavior, AND
  - SOAPP-R score less than 9, AND
  - Morphine Equivalent Daily Dose (MEDD) <100 mg
- **Moderate risk:**
  - Clinical assessment that the patient is at increased risk for misuse of opioids OR
  - SOAPP-R score 10-21 OR
  - Morphine Equivalent Daily Dose (MEDD) >100 mg
- **High risk:**
  - Clinical assessment that the patient is at high risk for misuse of opioids, OR
  - SOAPP-R score 22 or higher

Dartmouth Hitchcock Palliative Care Opioid Prescribing Guidelines. 2016 (unpublished)

Example of Management

- All patients will have initial urine drug screen and sign patient-provider agreement
- Moderate to high risk patients will have increased frequency of visits (may be weekly), prescription drug monitoring program checked on each visit, pill counts, more frequent urine drug screens (frequency to be determined by prescriber)
- Moderate to high risk patients will complete Current Opioid Misuse Measure at every visit

Dartmouth Hitchcock Palliative Care Opioid Prescribing Guidelines. 2016 (unpublished)

Informed Consent

Patient/Prescriber Agreements

- Informed consent outlines the risk, benefits of opioid therapy
- Experts recommend the use of treatment agreements
  - Relatively weak evidence regarding the efficacy of agreement to reduce misuse and abuse
- Helpful education tool

Urine Drug Testing (UDT)

• Objective measure to see if the patient is taking what is being prescribed and to evaluate for the presence of illicit drugs or medications that have not been prescribed

• Although robust evidence for the use of UDT to prevent misuse is lacking experts recommend prior to initiation and periodically when patient is on chronic opioid therapy

• NB: Some insurances may not cover cost; hospice programs may need to absorb costs

Types of UDT

• Screening – Rapid turnaround
  • Immunoassay analyst
  • Low/no sensitivity synthetic or semisynthetic
  • Variable specificity

• Confirmatory – slower turnaround
  • Analyzed GC-MS
  • High sensitivity
  • Can detect individual drugs and their metabolites
  • Recommended for use in pain medicine
Prescription Drug Monitoring Programs (PDMP)

- Forty-nine states and one US territory had operational PDMP programs as of May 2016
- Programs state specific - differ in accessibility and functionality
  - Some programs have ability to check neighboring states
- Early data from PDMPs indicate programs may decrease abuse or misuse
- PDMP mandatory prior to prescribing opioids in some states
  - Early data showed changes in prescribing patterns in these states

PDMP and Electronic Prescribing

- Use of PDMPs may be useful in palliative care and hospice setting to track prescriptions
  - HOWEVER - Hospice prescribers may be exempt from reporting opioid dispensing or checking PDMPs
- Electronic prescribing of opioids
  - may improve opioid tracking
  - may decrease the risk of prescription forgery
  - mandated in certain states
  - use likely to increase over time

Opioids – General Guides

- Recent RCT – no significant differences in pain control/side effects/response comparison morphine, oxycodone, fentanyl, buprenorphine chronic cancer pain
- Substantial individual variation in the response to the agent, so rotation may be necessary
- Selection of one over another typically based on clinical judgement, formulary access, cost, or availability of a parenteral formulation

Opioid Selection

- Mu-agonist opioids trigger the ‘reward’ system
  - Produce euphoria through binding to GABAergic interneurons
  - Inhibit dopamine production
- Activation of reward system can trigger craving and possible misuse of opioids
- Immediate-release opioids (i.e.; oxycodone, hydromorphone)
  - Faster onset/increase of blood levels
  - Can trigger the ‘reward’ system
- Use of an extended release opioid (i.e. morphine ER, transdermal fentanyl) or a long acting formulation (i.e.; methadone)
  - Decrease ‘reward’ or ‘likeliness’ component of medication’s effect


Opioid Selection

- Consider use of abuse deterrent extended release opioids – but be aware may have problems with cost/authorizations1
- Minimize use of immediate release breakthrough medications2
- Be aware of certain formulations that are higher risk for diversion: e.g. Oxycodone IR 30 mg2
  - If concerned utilize opioids with ‘less likeability’
  - Morphine less likeability than oxycodone2
- Consider opioids with low street value and/or more difficult to abuse
  - Fentanyl patch
  - Morphine IR

2 Walsh & Broglio. NCNA. 2016;:51, 433-447.

Creating a Safe Treatment Plan

- Complete documentation of plan of care easily accessed by all team
- Specific instructions on the time of medication administration (i.e.; 800 a.m., 400 p.m.) versus every 8-hour dosing minimizes confusion
- For those with breakthrough pain who require the use of immediate release opioids
  - May be necessary to make medication time contingent or related to a painful activity versus relying on the pain severity as an indicator

Creating a Safe Treatment Plan

- Avoid prescribing high-street value medications
- Medications may vary according to the geographic location
- Individuals with repeated dose escalations should be reassessed for potential reasons
- Inefficacy of opioid or possibility of misuse or diversion
- Use of non-opioid adjuvants as part of the management plan
- Escalating doses of opioids may not always adequately address the pain
- In cases of cross-coverage, document detailed plan to ensure consistency


Follow-up visits

- Frequent visits to assess for appropriate use of prescribed medications, including urine drug screens when indicated
- For those individuals at very high risk for opioid misuse, consideration for daily visits,
- Fentanyl patches in the home or clinical setting, without dispensing a supply of oral pain medications


Follow-up visit

- Limited supply of opioids prescribed and dispensed especially for high-risk patients
- Family and/or friends (when appropriate) help ensure compliance
- Keep medications safely secured in lockboxes to prevent diversion or theft

Substance Abuse and Mental Health Services Administration. 2015/12/10. 2013
Follow-up Assessment

- Observe for signs of aberrant behavior
- Emergency room visits for pain without changes in pathology
- Unsanctioned dose escalations
- Early prescription refill requests
- Evidence of multiple prescribers - prescription drug monitoring program

Reassessment Tools

- Current Opioid Misuse Measure (COMM)\(^1\)
  - Useful to detect challenges with opioid use once patient started on opioids
- Pain Assessment Documentation Tool (PADT)\(^2\)
  - The 4 'A's – analgesia, activity, adverse side effects, aberrant behavior
- Use of these tools may detect changes in risk status and need for more frequent visits and monitoring

Other measures to consider

- Use of Pain Diary
  - Track self-reported use of medications
- Pill Counts
  - Ensure patient brings all medications in to each visit (may need to adjust if patient taking public transportation)
Medication Assisted Treatment

- Close collaboration with facility is essential for individuals utilizing methadone, buprenorphine or naltrexone for addiction
- Maintenance dose likely not sufficient to manage the pain (methadone, buprenorphine)
- Treatment program may continue the maintenance dose but another opioid or additional methadone in divided doses may be necessary
  - Ex: Methadone maintenance 40 mg daily plus methadone 15 mg in afternoon and night prescribed for pain
  - Methadone duration of pain relief 6-12 hours, reduces craving 24 hours


Opioid Reversal

- June 2016 all but three states (KS, WY, MT) legislation to improve naloxone access for laypersons
- Naloxone intramuscular and intranasal forms for laypersons available in many states
- Educate caregivers how to administer naloxone in event of overdose


Medication Disposal

- Educate about safe disposal of medications or the use of Drug Enforcement Agency (DEA) take back programs
- In hospice settings, policies for proper medication disposal
  - Rotation to another opioid before the previous opioid supply is finished
  - Upon patient’s death

Acute Care Setting

- Patient controlled analgesia (PCA) benefit through small incremental dosing preferable to intermittent clinician bolus dosing that may trigger the reward system
- Allows individual some control over the bolus dosing
- May reduce the perception there is ‘drug-seeking’
- Secured medication to minimize risk of tampering
- For those actively abusing drugs, extra precautions necessary
- Visitor restriction
- Searching of patient’s belongings


Conclusion

- Pain is prevalent in individuals with serious illness and requires a comprehensive assessment and treatment plan
- A comprehensive pain assessment includes risk assessment for misuse of opioid medications
- ‘Universal precautions’ should be utilized when designing an opioid pain management treatment protocol for all individuals
- Pain management in individuals with serious illness requires a unified interdisciplinary team approach

PCSS-O Colleague Support Program and Listserv

- PCSS-O Colleague Support Program is designed to offer general information to health professionals seeking guidance in their clinical practice in prescribing opioid medications.
- PCSS-O Colleague Support Program is a national network of trained providers with expertise in addiction medicine/psychiatry and pain management.
- Our mentoring approach allows every mentor/mentee relationship to be unique and catered to the specific needs of both parties.
- The mentoring program is available at no cost to providers.
- Listserv: A resource that provides an “Expert of the Month” who will answer questions about educational content that has been presented through PCSS-O project. To join, email pcss-o@aaap.org.

For more information on requesting or becoming a mentor visit: www.pcss-o.org/colleague-support
PCSS-O is a collaborative effort led by American Academy of Addiction Psychiatry (AAAP) in partnership with: Addiction Technology Transfer Center (ATTC), American Academy of Neurology (AAN), American Academy of Pain Medicine (AAPM), American Academy of Pediatrics (AAP), American Dental Association (ADA), American Medical Association (AMA), American Osteopathic Academy of Addiction Medicine (AOAAM), American Psychiatric Association (APA), American Society for Pain Management Nursing (ASPMN), International Nurses Society on Addictions (IntNSA), and Southeast Consortium for Substance Abuse Training (SECSAT).

For more information visit: www.pcss-o.org
For questions email: pcss-o@aaap.org

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