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Opioids & Pain Medications
What OTs need to know
Barbara L. Kornblau

Learning Objectives
- At the end of this session, attendee will be able to
  1. Explain different medications used to treat pain and the benefits and risks of each
  2. Describe 3 factors that contributed to the opioid crisis
  3. Explain 3 strategies in use to combat opioid abuse
  4. List 2 problems created by limited access to prescription medications
  5. Describe OTs role in helping patients who take prescribed opioids to manage their pain

Pain as a Public Health Issue
- Pain is a universal experience.
- Chronic pain conditions affect at least 116 million U.S. adults. (almost 1/3 or all adults)
  - It cost of $560–635 billion annually in direct medical treatment costs and lost productivity.
- Pain’s occurrence, severity, duration, response to treatment, and disabling consequences vary from person to person because pain, like other severe chronic conditions,
  - is much more than a biological phenomenon and has profound emotional and cognitive effects.
Incidence of Chronic Pain

<table>
<thead>
<tr>
<th>Condition</th>
<th>Number of Sufferers</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Pain</td>
<td>116 million Americans</td>
<td>Institute of Medicine of The National Academies</td>
</tr>
<tr>
<td>Diabetes</td>
<td>25.8 million Americans (diagnosed and undiagnosed)</td>
<td>American Diabetes Association</td>
</tr>
<tr>
<td>Coronary Heart Disease (heart attack and chest pain) Stroke</td>
<td>16.3 million Americans</td>
<td>American Heart Association</td>
</tr>
<tr>
<td>Cancer</td>
<td>11.9 million Americans</td>
<td>American Cancer Society</td>
</tr>
</tbody>
</table>

(AAPM, n.d.)

Pain Treatment

- Pain is treated with over the counter medications such as acetaminophen, ibuprofen (Advil or Motrin), naproxen (Aleve) OTC
- Acetaminophen (Tylenol) is just a pain reliever – not an anti-inflammatory OTC
- Opioids – controlled substance

OTC Pain Meds

- Acetaminophen: causes liver toxicity when you take 4,000 milligrams in a day
  - This is 8, 500 mg tablets – which is the dose for Extra Strength Tylenol
- Often included in other over-the-counter meds like cold med or in prescription drugs like Vicodin or Percocet creating increased danger of accidental overdose

NSAIDS

- Long-term NSAID therapy increases the risk of gastrointestinal bleeding 10- to 30-fold.2 (dose dependent)
- Acetaminophen doesn’t but it can cause liver damage at therapeutic doses in some circumstances & worse w/alcohol users
- Genetics also plays a role

Abbott & Fraser, 1998

What are Opioids?

- Opioids are medications that relieve pain.
  - They reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus.
  - Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs.

(NIH, 2014)

What are Opioids Used For?

- Hydrocodone products are the most commonly prescribed for a variety of painful conditions, including dental and injury-related pain.
- Morphine is often used before & after surgical procedures for severe pain.
- Codeine is often prescribed for mild pain.
- Some of these drugs—codeine and diphenoxylate (Lomotil) for example—can be used to relieve cough and severe diarrhea.

(NIH, 2014)
Side Effects of Opioids

- Respiratory suppression
- Constipation
- Drowsiness
- Nausea
- Risk for dependence or addiction if not taken properly
- [Genetics may affect opioid dosing via the cytochrome P450 (CYP450) enzyme system that metabolizes drugs]

What does this mean in OT?

- Don’t have the patient do anything with mechanical equipment.
- Watch for unusual reactions or behavior
- Document pain and reactions to medications
- Be aware of safety concerns

Dependence vs Addiction

- “Physical dependence occurs because of normal adaptations to chronic exposure to a drug”
- “Addiction, which can include physical dependence, is distinguished by compulsive drug seeking and use despite sometimes devastating consequences.”
- “Dependence is often accompanied by tolerance, or the need to take higher doses of a medication to get the same effect.”
  (NIH, 2014)
The Opioid Crisis Is Not New

Brief History of Opioid Use

- There was a stigma to taking opioids
- Starting about 20 years ago, physicians began to prescribe opioids for non-cancer pain conditions.
  - Before this, opioids were used mainly for palliative care
- Fear of addiction with opioid use

- 1980 study of 11,882 hospital patients treated with painkillers, only 4 became addicted because of their treatment. (Porter & Jick, 1982)
- 1982 survey of 151 burn facilities. Out of 10,000 hospitalized burn patients who received opioids to treat their burn pain, responders reported no cases of addiction. (Perry & Heidrich 1982)
In 1987, the New York Times reported the results of a survey that showed that "65 percent of the hospital patients who were in pain were under-treated for it" - Stigma (Goleman, 1987)

1996: the Project on Legal Constraints on Access to Effective Pain Relief (PLCAEPR) developed a Model Pain Relief Act to encourage states to adopt laws to decrease barriers to treatment of intractable pain
- States began to adopt the Model Pain Relief Act to decrease barriers to necessary drug therapy for patients suffering from chronic or intractable pain
  - (PLCAEPR, 1996)

Model pain acts were supposed to protect prescribers
- 1998, the Federation of State Medical Boards' (FSMB) adopted its Model Policy for the Use of Controlled Substances for the Treatment of Pain as policy
  - to assist state medical boards and other health care regulatory boards to promote the appropriate use of controlled substances in the management of chronic cancer and non-cancer pain (FSMB, 1998)
Joint Commission program starts 2001
  - Endorsed by 21 organizations representing the health care community and law enforcement, including the DEA
  - The consensus statement laid out a pain policy that recognized the under-treatment of pain, and emphasized the need to treat pain aggressively with opioids if indicated, while recognizing the potential for abuse.
  - FSMB adopts this in 2004

Several things happened as opioid prescribing became more acceptable
1. More prescribers
2. More prescription drugs out there
3. More diversion of prescription drugs
4. Addiction to prescription drugs

Working with providers, pain policy researcher etc, the DEA put guidance on its website in the form of FAQ’s on August 11, 2004. Two months later they took down the guidance, eliminating guidance for prescribers.
  - Warned opioid prescribers of the threat of investigation they face.
DEA starts going after doctors

- Looks at practices that prescribe a lot of opioids and go after them
- Many of them are pain practice physicians
- Looking at deaths

Deaths Involving Opioid Analgesics in the United States

Methadone catch 22

- Methadone is a synthetic opioid used as a substitute for heroine
  - This use requires special additional certification of prescribers
- Methadone is also used to treat moderate-to-severe chronic pain
  - Special certification not required
Methadone catch 22

- Methadone has a very long half-life
- Prescribers underestimate the risks

The Opioid Crisis

- In 2007, Purdue Pharma pleaded guilty in the United States for misleading doctors about OxyContin, a felony accompanied by a $634 million fine – (Meier, 2007)
- Several high paid doctors promoted wide use of opioids, claiming it was not addictive and high doses were needed by some to treat chronic pain

Opioid Crisis

- In 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and Senior Committee Member Chuck Grassley (R-Iowa), started a big investigation
  - the crisis stems from the significant influence of drug manufacturers on the messaging of
  - pain-related non-profit organizations, professional societies,
  - individuals leaders in the field and
  - their collaboration and financial influences

(United States Senate Finance Committee, 2012)
Actions to Control Abuse & Limit Access

- Changes in practice: Medication Agreements
- Changes in law
  - State laws that regulate several aspects of practice and opioid use
  - Federal Laws REMS and TIRF Rems
- Medication reversal
  - Suboxone
  - Naloxone

Medication Agreements

- Patient agrees to abide by opioid safety rules to avoid abuse and diversion
- Sample provisions:
  - “I will give my doctor an accurate history of the intensity of my pain, the effect of the pain on my daily life, and how well the medicine is helping to relieve the pain.”
  - I will not get drugs from any other sources – no street drugs – no pot – no illegal drugs
- I will not share, sell or trade my medication with anyone.
- I will take the meds the way the doctor told me to
- If I have side effects, I will report them to my doctor
- I will use only one pharmacy. This one _____
- I will designate one person to pick up my prescriptions if I can’t
- I agree to random drug tests and forfeit meds if I fail
- I know I cannot get early refills
I won’t drive or operate equipment
I will keep my medications safe – theft and loss procedures
I will inform my doctor if I need treatment for a new condition that causes pain. (dental work)
I will follow through on treatment plan
If I do not follow through on treatment plan – no meds – Conditions under which my doctor will stop prescribing

I know I must stop treatment if it doesn’t work
I realize the state may have access to my electronic health records
I give my permission to contact other providers and pharmacies And State databases
I realize it is dangerous for me to get pregnant while on opioids
I realize opioids cause a decrease in testosterone level
I will bring all unused pain medicine to every office visit.
I will contact my doctor for Emergencies, ER visits, or Hospital Admissions
I agree to follow these guidelines that have been fully explained to me. All of my questions and concerns regarding treatment have been adequately answered. A copy of this document has been given to me. (informed consent)
I realize my pain doctor will only prescribe pain meds

However…….

There is no evidence that medication agreements work
“Our systematic review reveals that weak evidence supports the use of opioid treatment agreements and urine drug testing to reduce opioid misuse, despite the theoretical benefits of these strategies.”

(Starrels et. al., 2010)
So… OTs can help

- Taking medication is an IADL
- Help patients comply with medication agreements by working on for ex:
  - Proper storage of the opioids
  - Maintaining a list of all medications, and supplements
  - Maintaining a medication diary of symptoms and side effects to report to prescriber

State Laws

- Laws Requiring a Physical Examination before Prescribing
- Laws Requiring Tamper-Resistant Prescription Forms
- Laws Regulating Pain Clinics
- Laws Setting Prescription Drug Limits
  - How often you can renew
  - How many can be dispense or prescribe at a time
  - Prescription Drug Monitoring Programs

State Laws

- Laws Prohibiting “Doctor Shopping”/Fraud
  - Only certain types of providers can prescribe
  - Prescription Drug Monitoring Programs
- Laws Requiring Patient Identification before Dispensing
  - Must show a driver’s license
- Laws Providing Immunity from Prosecution/Mitigation at Sentencing for Individuals Seeking Assistance During an Overdose
  - To encourage rehab and save lives
- Laws requiring courses like this one

Cumulative number of states authorizing prescription drug abuse-related laws by type of law, United States, 1970-2010

http://www.cdc.gov/HomeandRecreationalSafety/Poisoning/laws/index.html

REMS Program

- Risk Evaluation & Mitigation Strategies
- REMS are required risk management plans that use risk minimization strategies to ensure the benefits of certain prescription drugs outweigh their risks. 2007 FDAA
  - Required to be dispensed with the drug
  - Written in non-technical language
  - Standardized format (font size, headers, etc.)

TIRF REMS

- The Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) program is an FDA-required program to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines.
  - The purpose of the TIRF REMS Access program is to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines.
  - Must enroll in the program to prescribe, dispense, or distribute TIRF medicines.
TIRF REMS

- Federal government program that apply to providers, prescribers, distributors pharmacists.
- Retrain everyone but what about the patient?
- OT can help patients with their responsibilities in the medication relationship

Drug Treatment As Treatment

- Suboxone (buprenorphine)- an opioid that only activates about 40 percent of opioid receptors in the brain and prevents them from accepting any more. (sublingual)
  - suppresses withdrawal symptoms and cravings for opioids – no euphoria
  - When it is in the brain for 24 hours, the brain can’t accept anymore opioids
  
  (Stuckert, 2011)

Drug Treatment as Treatment

- Naloxone is an strong, fast, opioid antagonist
  - It is included in Suboxone, in case the pill is crushed and snorted or injected. It will quickly go to the brain and block the opioid receptors
  - Available for drug oversdose rescue as an inhaler or an injector with instructions that walk you though using it. Saves lives.

  (Stuckert, 2011)
Results of Limited Access

- Prescription drugs were easy to get. Now that they have made them more difficult to get we have a new problem: Heroin

Side Effects of Limited Access

- More people looking to Heroin:
  - “What started as an OxyContin and prescription-drug-addiction problem in Vermont has now grown into a full-blown heroin crisis.”
    - Peter Shumlin, Governor of Vermont, (Amsden, 2014)

- A lot of the drug overdoses occur in rural areas where there are no detox facilities or practitioners trained in Suboxone
Side Effects of Limited Access

- People with legitimate pain conditions are having difficulty getting their medications
- This may affect OT.
- Patients will not perform well if they are in pain
- Pain may further limit them
- May be referred to OT because of pain

What Do We Really Know About Opioids?

- “Evidence on long-term opioid therapy for chronic pain is very limited, but suggests an increased risk of serious harm that appears to be dose-dependent.”
- “…most clinical and policy decisions regarding use of long-term opioid therapy must necessarily still be made on the basis of weak or insufficient evidence.”

Chou, et. al. 2014

What Do We Really Know About Opioids?

- “More research is needed to understand long-term benefits, risk of abuse and related outcomes, and effectiveness of different opioid prescribing methods and risk mitigation strategies.”

Chou, et. al. 2014
References


