Reducing Opioid Prescribing through Education and Support (ROPES-2)

FMSRE 2018 Project

PI: Zsolt Nagykaldi, PhD

Student: Peyton Weaver

Presentation Objectives

- Identify the problem and specific gaps addressed by the study
- Describe the study design and methods to address the gap
- Explain where the researchers are in the process of completing this study
- Lay out the goals for this summer and steps required to attain these goals

Background and Rationale

- Problem: For years, evidence has shown that long-term, over-prescription of opioids to patients with non-cancer chronic pain (NCCP) can lead to many undesired outcome both at the individual and population levels (e.g., opiate-addiction, morbidity and mortality, and a high societal cost). However, despite a body of in-depth knowledge and the availability of national guidelines, opioid over-prescribing in NCCP continues to be several times of that in 2000.
- Our research: This study specifically aims to observe the impact of educating and resourcing family practitioners regarding how to improve their patient conversations about reducing or ceasing opioid use in NCCP.

The Epidemiology of Opioid Misuse

Why is the high opioid prescription rate a problem?

1 Increase in opioid-related deaths

Opioids are the most common drug class associated with accidental overdose deaths in OK.

Overall prescribing rate of opioids in the U.S. in 2016 was 66.5 per 100 people.

2 Increase in illicit opioid drug use

Most common source of prescription opioids is from family/friends.

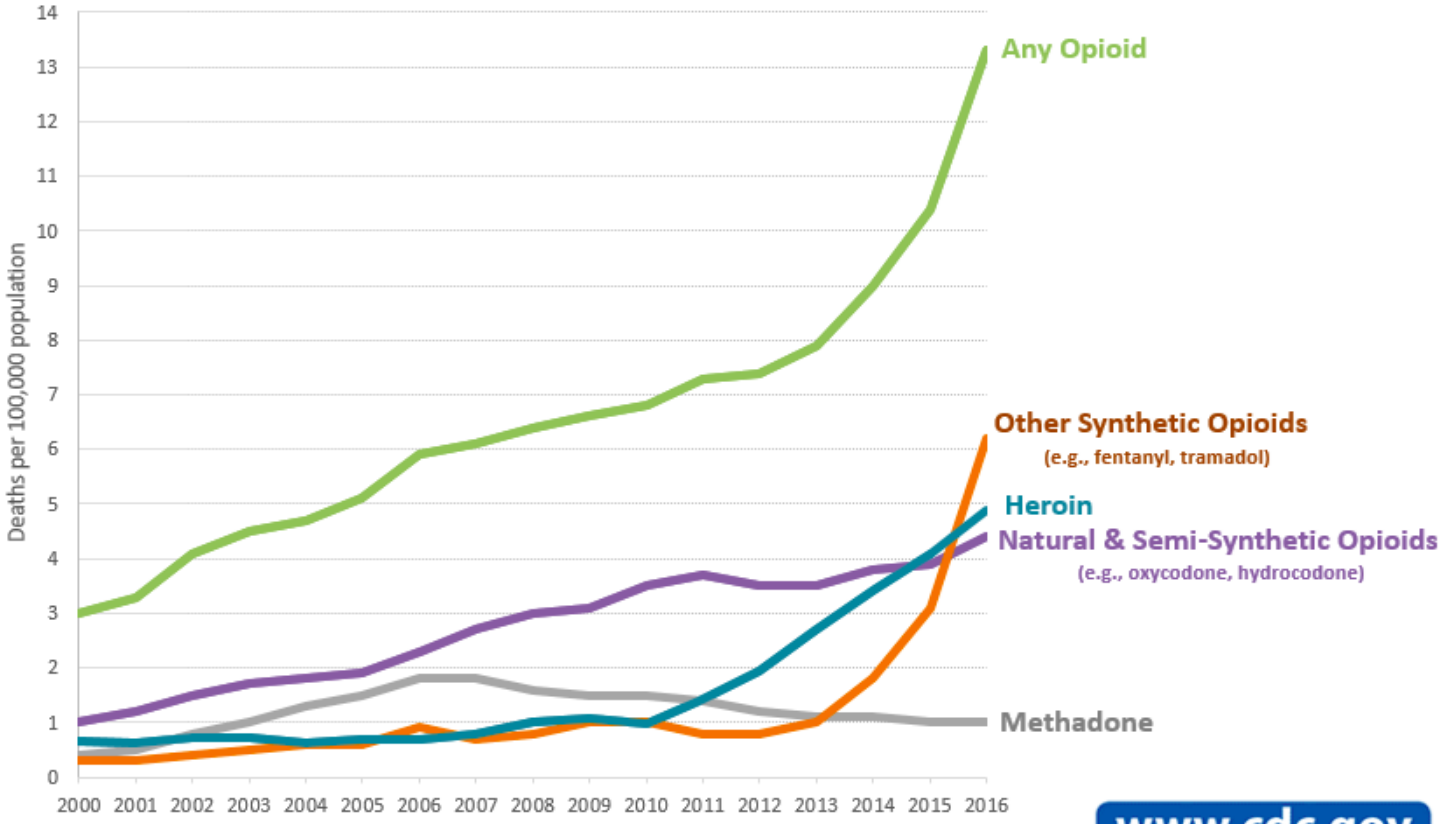
Once reliant on prescription opioids, people may switch to or add illicit opioids (such as heroin and fentanyl).

3 Adverse side effects

Sedation/drowsiness, decreased concentration, altered mood, constipation, dry mouth, abdominal pain, sexual dysfunction, osteopenia, falls (esp. in the elderly), etc.

Based on public CDC and OSDH data

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2016



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Ser vices, CDC; 2017. https://wonder.cdc.gov/.

www.cdc.gov
Your Source for Credible Health Information

What the Evidence Says about Opioid Tx

- A Cochrane review (Noble et al, 2010) demonstrated weak evidence for opioids in a minority of patients who stayed on the treatment and high rates of discontinuation of opioids in patients treated for NCCP
- In a systematic review of 21 studies, Manchikanti et al (2011) found “fair” evidence for Tramadol in managing osteoarthritis and poor evidence for all other drugs and conditions
- Another Cochrane review (Chaparro et al, 2013) showed that there are no placebo-controlled RCTs supporting the effectiveness and safety of long-term opioid therapy for treatment of chronic low back pain. Few trials compared opioids to NSAIDS or anti-depressants for chronic low back pain

What We Have Learned From ROPES-1

(Study by Dr. Colin Bradley from Ireland; August, 2017 – January 2018)

- Identify and review a list of patients on opiates for NCCP: generate an "opiate registry"
- Target patients on high-risk opioid doses first (>90 morphine milligram equivalents - MMEs)
- Discuss effectiveness vs. risk concerns regarding long term opioid therapy
- Re-evaluate chronic pain in terms of nature, severity, and putative cause
- Evaluate risk factors for substance misuse and mental health and manage or refer, as appropriate
- Ascertain current reported benefit from opioid treatment – in terms of pain relief and improved function
- Reported ongoing high level of pain and/or impaired function suggests opioid treatment is ineffective and should be discontinued
- Offer and initiate an opioid tapering regimen and alternative therapies

Research Questions

1. Can we develop a relatively simple, toolkit-based approach to help clinicians improve their conversations about opioid therapy in NCCP patients?
2. What educational content and resources should a toolkit contain, so it is effective, while the intervention remains low intensity?
3. Can recording and analyzing toolkit-enhanced patient encounters help us further improve the intervention and our resources?

Study Methods

1. Advise selected physicians (~5) on which patients (~25) may be candidiates for this intervention
2. Provide an academic detailing (AD) session for these physicians:
    a. Information on how opioids in NCCP are generally ineffective and often unsafe
    b. Strategies for how to facilitate conversations centered on reducing/ceasing opioid use
    c. Methods for determining patient total opioid dose (Morphine Milligram Equivalents)
3. Evaluate medical charts to determine the list of patients who meet inclusion criteria (patients with non-cancer chronic pain who are prescribed opioids) and ask the clinicians to review the list
4. Obtain pre-study verbal consent through a phone call by the Research assistant (me!), followed by complete informed consent at the patient's scheduled appointment

Methods (continued)

5. Audio-record patient office visits with his/her physician

6. Analyze recordings using Conversation Analysis techniques (Pomerantz and Fehr, 1997), focusing on segments that relate to pain management and opioid therapy:

    a. Discussion content and the mode of verbal delivery
    b. Type of talk (change, advice, education, and prescription)
    c. Turns analysis (who speaks, when, for how long, and the dynamics of the converstaion)

7. Conduct follow-up interviews with family practitioners 4-6 weeks later to evaluate the effectiveness of the intervention and to improve it, as well as the toolkit resources

8. Review patient charts to identify any potential changes in opioid management

What's in the Toolkit?

The SEA Protocol for a Safer and Better Therapy In Non-Cancer Chronic Pain

Safety

1) Deliver a facilitated message on the serious safety risks of opioids:
   a) Ice-breaker info graph on risk increase
   b) Dr. Criswell's risk assessment tool with recommendations & naloxone Rx and handout in mid to high-risk groups
   c) CDC/OSDH patient handout on general risk of opioids

Effectiveness

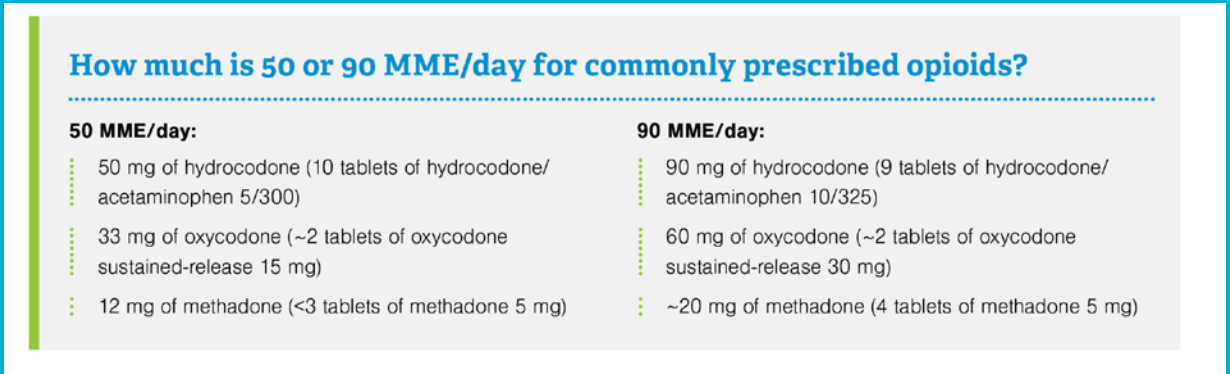
2) Assess the opioid's effectiveness to improve pain and functional status:
   a) The 3-question PEG tool

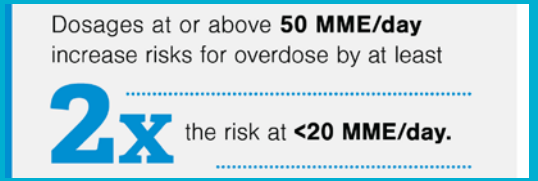
Alternatives

3) Explore safer and more effective alternatives:
   a) CDC/OSDH patient handout on non-opioid treatments
   b) Discussion of most suitable alternatives for patient

Tools to Help Calculate Morphine Milligram Equivalents (MMEs)

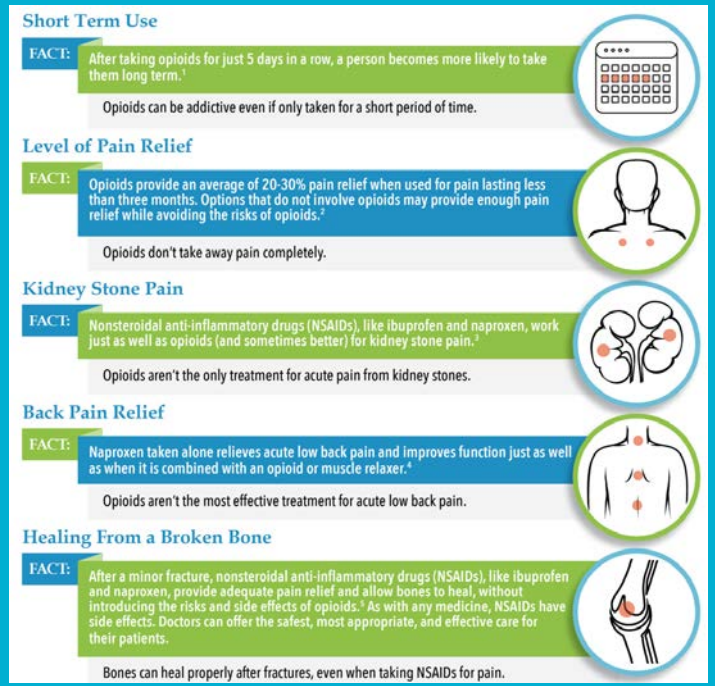
From: poison.health.ok.gov
“CALCULATING TOTAL DAILY DOSE OF OPIOIDS FOR SAFER DOSAGE”





Patient Education Materials on Opioids

"PAIN & PRESCRIPTION OPIOIDS: WHAT YOU NEED TO KNOW"
From: poison.health.ok.gov



Short Term Use

FACT: After taking opioids for just 5 days in a row, a person becomes more likely to take them long term.[1]

Opioids can be addictive even if only taken for a short period of time.

Level of Pain Relief

FACT: Opioids provide an average of 20-30% pain relief when used for pain lasting less than three months. Options that do not involve opioids may provide enough pain relief while avoiding the risks of opioids.[2]

Opioids don't take away pain completely.

Kidney Stone Pain

FACT: Nonsteroidal anti-inflammatory drugs (NSAIDs), like ibuprofen and naproxen, work just as well as opioids (and sometimes better) for kidney stone pain.[3]

Opioids aren't the only treatment for acute pain from kidney stones.

Back Pain Relief

FACT: Naproxen taken alone relieves acute low back pain and improves function just as well as when it is combined with an opioid or muscle relaxer.[4]

Opioids aren't the most effective treatment for acute low back pain.

Healing From a Broken Bone

FACT: After a minor fracture, nonsteroidal anti-inflammatory drugs (NSAIDs), like ibuprofen and naproxen, provide adequate pain relief and allow bones to heal, without introducing the risks and side effects of opioids.[5] As with any medicine, NSAIDs have side effects. Doctors can offer the safest, most appropriate, and effective care for their patients.

Bones can heal properly after fractures, even when taking NSAIDs for pain.

NON-OPIOID PAIN TREATMENTS HAVE FEWER RISKS

For pain that will likely be gone in a week or two, it is always best to start with non-opioid pain treatments. Opioids may help control pain at first, but they are usually not necessary.

Consider other options that may work just as well or better, but have far fewer risks.

- Over-the-counter pain relievers
- Physical therapy
- Exercise
- Professional help coping with the emotional effects of pain

OPIOIDS ARE STRONG PRESCRIPTION MEDICATIONS

Opioids can be the right choice for treating severe pain, such as from cancer or immediately after major surgery. However, medications such as these are very powerful and can be deadly. **Even if you take them as directed, ALL opioids have serious side effects such as addiction and overdose.**

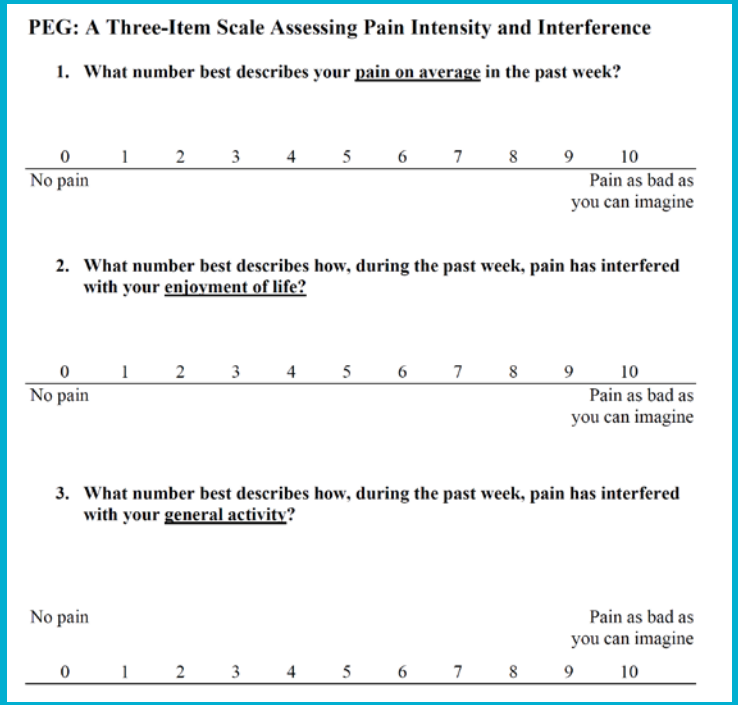
OPIOIDS ARE CHEMICAL COUSINS OF HEROIN AND ARE HIGHLY ADDICTIVE

You can build up a tolerance to opioids over time, so you need to take more and more to get the same relief. The higher the dose, the more dangerous opioids are. You can even become addicted after a short time.

RISKS ARE GREATER WITH

- Pregnancy
- Older age (65 years or older)
- Sleep apnea
- Mental health conditions (such as depression or anxiety)
- History of drug misuse, substance use disorder, or overdose

PEG Tool to (Re)Evaluate Chronic Pain and Its Effect on Functioning



PEG: A Three-Item Scale Assessing Pain Intensity and Interference

1. **What number best describes your pain on average in the past week?**

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

2. **What number best describes how, during the past week, pain has interfered with your enjoyment of life?**

0 1 2 3 4 5 6 7 8 9 10

No pain — Pain as bad as you can imagine

3. **What number best describes how, during the past week, pain has interfered with your general activity?**

No pain — Pain as bad as you can imagine

0 1 2 3 4 5 6 7 8 9 10

The brief Pain, Enjoyment, General Activity (PEG) Scale (Krebs et al., 2009)

Computing the PEG Score:
Add the responses to the three questions, then divide by three to get a mean score (out of 10) on overall impact of points.

Using the PEG Score:
The score is best used to track an individual's changes over time. The initiation or change in therapy should result in the individual's score decreasing over time.

Where are We Now?

- We are still in the process of obtaining our IRB approval
  - Recent update: non-federally funded research collecting highly sensitive information may be required by an IRB to obtain a Certificate of Confidentiality from the NIH
- Five physicians in the surrounding OKC area have agreed to participate (several in the OUFMC clinics)
- A patient packet has been compiled from evidence-based and good practice resources to be used during office visits to guide the conversation about reducing/ceasing opioids, including patient handouts and work-sheets for assessing their level of current risk, their pain, and physical functioning

Our Goals For This Summer

- Obtain IRB approval
- Gain informed consent from about 5 physicians and about 25 patients
- Educate and resource physicians via the academic detailing visit
- Audio record office visits with enrolled patients
- Analyze the recordings
- Potential activities (~1.5 months beyond the main study):
  - Review patient medical records for potential changes in opioid therapy
  - Meet with participating physicians to discuss their experience and suggestions

Questions?