THE OPIOID EPIDEMIC:

How it Happened and
What Alternatives Are Best for Our Pain Patients?

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OBJECTIVES

-Recognize the roll that prescription opioids have contributed to the Opioid Epidemic

Investigate the Opioid Epidemic timeline and Introduce the players in this scenario

-Review both pharmacologic and non-pharmacologic treatment modalities for pain

-Assess treatment goals for any patient in pain

-Identify high-risk patient populations

-Define the ALTO concept and Recommend specific options for pain relief in selected conditions

Definition of Opioids

- Natural (Opiates)
  - Heroin, Morphine, Codeine
- Semi-synthetic
  - Hydrocodone, Oxycodone, Hydromorphone, Oxymorphone
- Synthetic
  - Methadone, Fentanyl, Tramadol, Meperidine, Propoxyphene

The Many Ps of the Epidemic

- Papaver somniferum
- Pfizer
- Product Promotions/Publications
- Purdue Pharma
- Porter & Jick
- Portenoy
- Patents
- Pseudoaddiction

HYDROCODONE

- Schedule III to Schedule II
- Most common Rx in the US
- US consumes 99% of world's supply*

*UN Report

More Ps of the Epidemic

- Pain Pills
- Pain as the 5th Vital Sign
- Pain Academy, Association, Foundation, Society
- Press Ganey
- Purging of medical opioids
- Pain Clinics/Pill Mills
- Pike Co, KY
- Proliferation of Heroin & Fentanyl

TIMELINE

- 5000 BC: Opium utilized in the Mediterranean region
  - Papaver somniferum
- 1804: Morphine isolated from Opium by Friedrich
- 1853: Hypodermic syringe invented
- 1874: Dr A Wright synthesizes diacetylmorphine
- 1898: Bayer reproduces Wright's drug—calls it Heroin
- 1914: Congress passes the Harrison Narcotics Tax Act

TIMELINE

- 1951: Arthur Sackler revolutionizes drug advertising
  - Promotes Pfizer's Terramycin
- 1952: Sackler family buys Purdue Frederick
- 1959: Discovered that MD Publications paid Henry Welch (Chief of FDA Abx Division) $300,000 to promote certain drugs
- 1960: Sackler's campaign for Valium makes it Pharma's first $1 million drug
- 1967: Sacklers found Mundipharma in Germany

TIMELINE

- 1979: Porter & Jick, Boston U School of Medicine
  - Dr Hershel Jick, Medical Researcher
  - Jane Porter, grad student assistant, helped with calculations
- 1980: 1 paragraph letter to the editor*
  - Reviewed 12,000 hospitalized Pts who received opioids and concluded addiction was rare
- Praised later as "extensive research" by *Time*
- WHO declares Morphine as "essential drug"
  - States "freedom from pain is an essential human right"

*NEJM. 1980Jan 10;302(2):123.;25(2):171-86.

TIMELINE

- 1984: Purdue Pharma releases MS Contin
  - Marketed for Ca Pts
  - Biggest seller in Purdue's Hx
  - Patent to expire in late 1980s
- 1986: * Russell Portenoy "opioid maintenance can be used safely and effectively without fear of addiction in patients with non-malignant pain"
  - Study based on 38 cases
  - No Hx of drug abuse

*Pain. 1986May;25(2):171-86.

TIMELINE

- 1989:Article in *Pain* by Dr David Haddox coining the term "Pseudoaddiction"
- 1990: *Scientific American* cites Porter & Jick as "a landmark study"
- 1992: Agency for Health Care Policy and Research "pain should be assessed"
- 1993: Portenoy speaks of "Opiophobia" and that opioid addiction & abuse are "medical myths"

TIMELINE

- 1995: Purdue reformulates oxycodone into a long acting form and OxyContin is patented
- FDA allows Purdue to claim OxyContin has lower abuse potential than other Oxy products due to its timed-release formula
  - But also placed warning "not to crush the tabs"
- FDA Examiner Dr Curtis Wright oversees the process

TIMELINE

- 1996: Purdue markets OxyContin for chronic pain
- President of the American Pain Society urges Drs to treat Pain as a 5th Vital Sign
- 1997: Purdue funds pain organizations who publish joint statement touting the use of opioids for chronic pain
  - American Chronic Pain Association
  - American Academy of Pain Medicine
- Consensus statement is written by Dr David Haddox He Chairs the committee that developed the report

TIMELINE

- 1998: VA and JCAHO adopt "Pain as the 5th Vital Sign"
- FSMBs policy change, reassuring Drs about Rx pain meds
- OxyCodone Rxs: Q 8 h now more common then Q 12 h
- 2000: Congress passes a bill (signed by President Clinton) declaring the 2000's the decade of pain control and research
- The Joint Commission sets standards re: assessment and management of pain
  - Widespread use of "Pain is the 5th Vital Sign"
  - Publishes a guide "no evidence that addiction is a significant issue"

TIMELINE

- 1999-2010: OxyContin sales rose 9-fold during this time, now up to $3 billion/yr
- 2001: Purdue pays >$40 million in bonuses to its reps, who already make hundreds of thousands of $ in commissions
- WA State Workers' Comp Pts start dying of opioid ODs
- 2003: US GAO Report requested by Congress finds FDA "didn't realize the drug could be mixed in H_2O & injected"
- 2004: OxyContin becomes most prevalent abused Rx opioid
- 2006-2015: Purdue & their nonprofits spend $900 million on lobbying & other political contributions

TIMELINE

- 2007: OD deaths now surpass MVC deaths
- Purdue pleads guilty to a felony count of OxyContin "misbranding" & fined $635 million
- 3 Purdue execs (CEO, CMO, Gen Council) plead guilty to criminal misdemeanor charges of fraud & false branding of OxyContin, fined $35 million, probation for 3 yrs, & ordered to perform 400 hrs of community service
- KY State Attorney General Greg Stumbo files wrongful death cases in Pike County vs Purdue

TIMELINE

- 2010: New OxyContin released w/ subtlety different formulation and receives new patent
- Prior to this new patent, Purdue denies old product was easy to abuse; however, now with new patent, asks FDA not to allow generic versions because they are unsafe. The FDA obliged.
- Mundipharma continues to sell old formulation in Canada, England, Latin America, Middle East, & Asia

TIMELINE

- 2010: WA State legislature mandates Rx guidelines
- 2011: IOM issues report on relieving pain in America "Moral imperative to treat pain"
- 2012: The American Pain Foundation disbands after a US Senate Finance Committee announced its investigation in OxyContin promos
- Dr Portenoy has "second thoughts" *Wall Street Journal*
  - "Overestimation of benefits, understatement of risks"
- 2014: FDA reclassifies Hydrocodone to Schedule II

TIMELINE

- 2015: WA State updates Rx guidelines
- All states (except MO) have PDMPs
- > 42,000 deaths in US from opioids
- Purdue has now earned >$35 billion from OxyContin
- 2016: CDC declares Opioids as epidemic and publishes opioid Rx guidelines
- 44% of Americans know a pain pill addict*
- Both AMA and AAFP pass resolutions to drop "pain as the 5th VS"

*Kaiser Study

TIMELINE

- 2017: > 72,000 deaths in US from Opioids
- 50% of men in the labor force are taking an opioid*
- "Opioids have reduced life-expectancy in US" (CDC)
- 2/3 of opioid misusers are working endangering themselves or others**
- More and more teens present to EDs addicted to opioids***
- 41 state attorneys general investigate opioid manufactures

*Brookings Institute **SAMHSA ***Allareddy

TIMELINE

- 2017: President Trump declares the Opioid Epidemic a "Public Health Emergency"
- 2018: Billionaire Richard Sackler is granted patent on a new formulation of buprenorphine. The patent acknowledges:
  - that opioids may "display an addictive potential"
  - the threat poised by the opioid crisis
  - the need for abuse-resistant form of Buprenorphine

DEFINITION of PAIN

- Unpleasant sensory and emotional experience associated with actual or potential tissue damage*
- From the Latin *poene*, meaning penalty
- Pain is always subjective

*International Association for the Study of Pain

PAIN'S PURPOSE

- Protective mechanism
- Can we decrease pain to "0" ?
- Primary goal is to return the Pt to a normal, functional life ASAP
- "My job is to manage your pain at the same time I manage the potential of some medications to harm you"

TREATING CHRONIC PAIN

- More medication is <u>not</u> necessarily better
- High doses = danger
- Concurrent medication risks

ISSUES

- Physical, Psychological, Social, Spiritual needs
- Chronic pain and mental illness
- Psychological/Psychiatric illness and opioids
- Pts with pain are perceived & judged in certain ways--often negatively
- Pt screening
- Short term benefit vs long term risk

ISSUES

- Of Pts who use opioids for at least 90 days, > 60% more likely to still be on chronic opioids in 5 yrs
- Uncertain long-term efficacy, clear evidence of harm
  - Long-term opioid use leads to new onset depression (Scherr, 2016)
  - SPACE Study in JAMA 2018

PROGRESS

- Integrated care/care coordination/health homes
- Training & education of providers, staff, leadership teams, administration
- State Guidelines
- CDC Guidelines

HCAHPS Questionnaire

- Hospital Consumer Assessment of Healthcare Providers and Systems
- Press Ganey
- "During this hospital stay, did you need medicine for pain?"
- "During this hospital stay, how often did the hospital staff do *everything* they could to help with your pain?"

PATIENT NEEDS

- High utilizers of health care
  - Frequent office, ED visits
  - Too many interventions
- Often difficult to treat
- Needs may not line up with options
- Pt expectations do not equal best Tx
- Unmet needs
  - Misunderstanding
  - Dissatisfaction
  - Poor or inadequate Tx
  - Poor outcomes

SUPPORT

- Significant formal and/or informal support
  - Family
  - Friends
  - Providers
  - Nurses
  - Non-clinical staff
  - Pharmacy
  - Behavioral health

TREATMENT GOALS

- Utilize non-opioids as 1st line
- Utilize Opioids as 2nd line Tx
- Discuss realistic pain management goals w/ all Pts
- Discuss addiction potential and side effects w/ those using Opioids

LIFESTYLE CHANGES

- Exercise
- Weight Loss
- Meditation
- Smoking Cessation

NON-OPIOIDS

Oral Meds

- NSAIDs
- Acetaminophen
- Haloperidol
- Dicyclomine
- Gabapentin
- TCAs
- Triptans

NON-OPIOIDS

- Topicals
  - Lidocaine
  - MethylSalicylates
  - NSAID's
  - Capsaicin

NON-OPIOIDS

- Parenterals
  - Ketorolac
  - Acetaminophen
  - Lidocaine
  - Diphenhydramine
  - Metoclopramide
  - Droperidol
  - Dexamethasone
  - Ketamine

MISC

- Cannabis
- N_2O

NON-PHARMACOLOGY

- Trigger Point Injections
- Nerve Blocks
- OMM
- Acupuncture
- TENS
- Nerve Stims
- PT
- Massage
- Yoga

ALTO Alternatives To Opioids

- Acute on Chronic Back Pain
- Opioid-naïve M/S Pain
- Migraine or Recurrent Primary Headache
- Extremity Fx or Dislocation
- Gastroparesis or Chronic Functional Abd Pain
- Renal Colic

ALTO PATHWAYS

- Opioid-tolerant Chronic Back Pain/Radicular Pain
  - APAP, NSAIDs, steroids, topicals, trigger-point inj
- Migraine or Recurrent Primary HA
  - Antiemetics, NSAIDs, steroids, Valproic acid, Mg++, triptans, cervical trigger-point inj
  - Tension component: muscle relaxant
  - Neuropathic component: Gabapentin

ALTO PATHWAYS

- Extremity Fx or Dislocation
  - N_2O, Lidocaine regional anesthesia, low dose Ketamine
- Arthropathy or Tendon Pain
  - Intra-articular steroid/anesthetic injection
- Gastroparesis or Chronic Functional Abd Pain
  - Typical antiemetics, Haloperidol, Diphenhydramine, Dicylomine, Lidocaine infusion
- Renal Colic
  - APAP, Ketoralac, Lidocaine infusion, NS bolus

MEDICAL RECS

- Avoid Opioids whenever possible
- Perform a risk assessment screen
- Consider potential drug interactions
- Rx lowest possible dose, shortest appropriate duration
- Avoid "Long Acting" or "Extended Release" opioids for acute pain

HIGH-RISK CRITERIA

- Personal or family Hx of substance abuse
- Age 16-45 yrs
- Mental Health/Psych Hx
- Hx Sexual abuse
- Current other controlled drugs

HIGH-RISK COMORBIDITIES

- Pulmonary (COPD, Sleep Apnea)
- Cardiac (CHF)
- Organ Dysfunction (Renal or Hepatic Dysfunction)
- Pregnancy
- Geriatric
- Peds

PRACTICE RECS

- Always Consult PDMP
- Groups should share their tracking, collecting, and sharing individual Rx patterns
- Chronic Pain Pts receive opioids from only 1 practice
- Pts receiving controlled med Rxns must have appropriate ID
- Refuse to refill "lost" or "stolen" opioid Rx's
- Counsel Pts on risks, proper storage, disposal

POLICY RECS

- Colorado PDMP should develop an automated query system
- Pain Control should be removed from Pt Satisfaction Surveys

SUMMARY

- Pain treatment does not = Pain Pill
- "Pill for every Ill" is not appropriate
- Don't treat the Pain Score… Treat the Patient