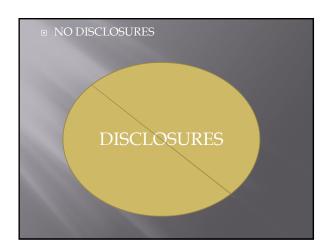
# THE OPIOID CRISIS: PRESCRIBING IN THE MIDST OF AN EPIDEMIC Abraham Kabazie, MD System Director Division of Pain Medicine Vice Chairman, Department of Anesthesiology Allegheny Health Network Clinical Assistant Professor Temple University School of Medicine

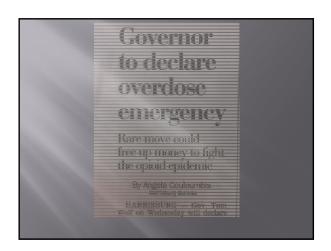


# Sledge – Hammer to Pain " Among the remedies which it has pleased the Almighty God to give to man to relieve his sufferings, none is so universal and so efficacious as opium." Dr. Thomas Sydenham (1624 – 1689)

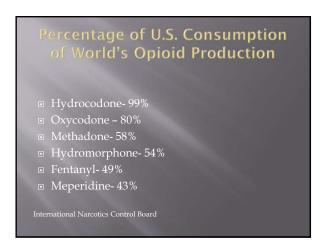
# "OH, JAB ME WITH YOUR NEEDLE A HUNDRED TIMES AND A HUNDRED TIMES I WILL THANK YOU, SAINT MORPHINE." Jules Verne (1828-1905)

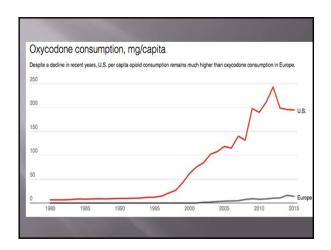
# The Crisis

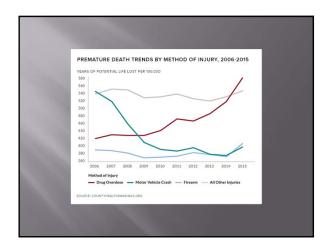
- The United States is in the midst of a severe epidemic of opioid addiction and overdose deaths. Drug overdose deaths, once rare, have increased sharply over the past 20 years and have surpassed car crashes as the leading cause of accidental death. Between 1999 to 2013, more than 220,000 American lives were lost to opioid related overdoses.
- 175,000 from prescription opioids and 45,000 from heroin

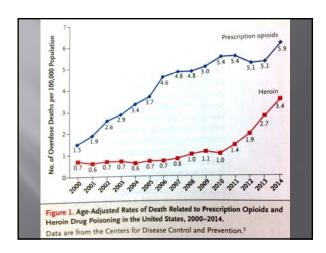


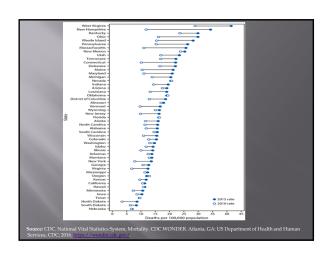


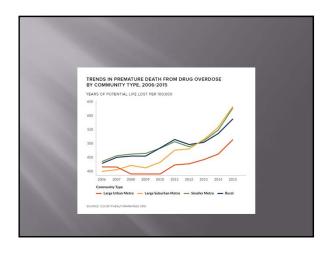


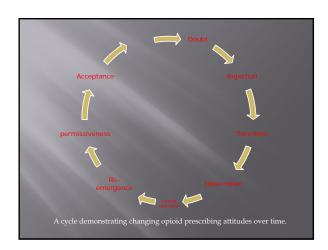












# Permissiveness, Acceptance, Doubt, Rejection, Sanctions

- 1860's-Civil War 400,000 with "soldiers disease".
- 1920's-"Nearly 80% of the morphine addicts have acquired the habit from legitimate medications."
  - Dr. Alexander Lambert, AMA President
- 1930-1950's- Opioids illegal, "unnecessary, dangerous.

# Hibernation, Re-emergence

- "Use of narcotics in terminal cases is to be condemned...Dominant on the list of these unfortunate effects is addiction."
  - American Medical Association Consensus Paper 1940
- 1960's 1970's-Hospice Movement: Death with dignity
  • 1967-first living will
  • 1969-Kubler-Ross, On Death and Dying
  • 1973-Patient Bill of Rights

## Opioid Maintenance Therapy for Non-Malignant Pain

- Retrospectively evaluated for safety and efficacy.
   19 > 4 years, 6 > 7 years.
- 24 patients-partial or fully adequate relief.
- Few substantial gains in employment or function.
- Conclusion of study- Opioid maintenance therapy can be a safe, salutary and a more humane alternative to surgery or no treatment with intractable NM pain.

- Adverse effects of long term use are
- Systemic toxicity is negligible.
- Development of tolerance is minimal.
- Pain control, addiction and withdrawal do not
- Their use should not be unduly limited by unfounded fears.

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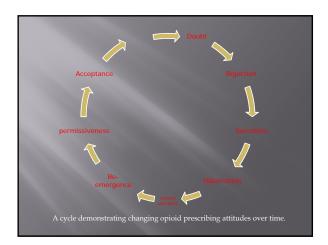
# Opioids and Chronic Pain (Acceptance)

- 1996- Purdue launches Oxycontin
- 1999 JCAHO released pain management standards as part of the accreditation standards for hospitals and other health care settings. *Pain as the "5<sup>th</sup> vital sign"*.
- 2000 Congress passed into law a provision that declared the ten year period beginning January 1, 2001 as the "Decade of Pain Control and Research."

# The Prescription Opioid Epidemic (Doubt)

- Opioids are the most commonly prescribed class of medications in the U. S.
- 245,000,000 opioid prescriptions written in 2014
- In 2014 10.3 million persons reported using prescription opioids not prescribed for them or for euphoria

Volkow ND, McLellan AT. Opioid Abuse in Chronic Pain-Misconceptions and Mitigation Strategies. NEJM. 2016;374: 1253-1263.



# Differing Viewpoints

- "there is no evidence that opioids are effective in chronic pain conditions and significant evidence that they cause harm," and urged that they be used as a "last resort."\*
- Federal policy has "disproportionately focused on reducing opioid use rather than increasing pain relief" and that "excessive concerns" about opioids could "virtually eliminate" opioids as an option for chronic pain.\*\*

Schneiderhan J, et al. Primary care of patients with chronic pain. JAMA. 2017;317(23):2367-2368\*
Kroehke k, et al. Management of chronic pain in the aftermath of the opioid backlash. JAMA. 2017;317(23):2365-2366\*\*

# P.R.O.P.

- Physicians for Responsible Opioid Prescribing
  - Strike word "moderate" from CNMP opioid treatment and limit use solely to treat "severe" pain
  - Allow no more than a maximum of 90 days of
  - Allow no more than the equivalent of 100mg of morphine daily (MED).

# Physicians for Responsible Opioid Prescribing (PROP)

- August 31, 2017- a petition was signed by the Association of State and Territorial Health Officials, Physicians for Responsible Opioid Prescribing, the National Safety Council and the American College of Medical toxicology.
- Petition asked the FDA to ban opioid pills that when taken as directed would add up to a daily dose of more than 90 morphine

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# P.R.O.P.

- "The existence of these products implies that they are safe. They aren't".
- The petitioners claim toddlers and preschoolers who get their hands on the pills and teenagers who experiment with drugs would be less likely to overdose and die if the high dose pills were off the market.

Dr. Andrew Kolodny, Founder Physicians for Responsible Opioid Prescribing

# Prescription Opioid Abuse

- Among persons aged 12 years of age or older who were abusing opioids, 53% reported receiving them for free from a friend or relative.\*
- Survey: 80% of 125,000 individuals recently initiating heroin use reported that their opioid use began with nonmedical use of prescription opioids\*\*

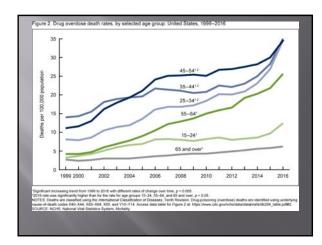
Substance Abuse and Mental Health Services Administration National survey 2013\* Muhuri P, et al. Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States. CBHSQ Data Review. August 2013\*\*

# Deaths from Prescription Opioid Overdose (1999-2013)

- Most were ages 25 to 54
- Overdose rate for adults aged 55-64 increased more than seven fold
- The large majority were non-Hispanic whites
- Age adjusted rates among:
  - Non-Hispanic white persons increased 4.3 times
  - Non-Hispanic black persons increased 2.8 times
  - Hispanic persons increased 1.5 times
  - American Indian or Alaska Natives increased almost 4 times

Centers for Disease Control and Prevention

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# **Drug Overdose Deaths**

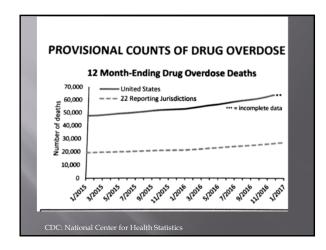
- Deaths involving prescription opioids continue to rise
- Leading cause of death for Americans under 50 years of age
- Roughly 52,000 people in U.S. in 2015, and 64,000 in 2016- a 22% increase.

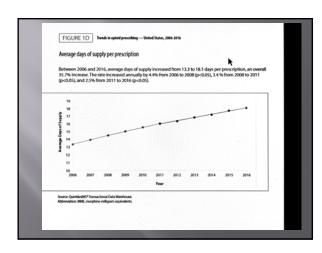
CDC: National Center for Health Statistics

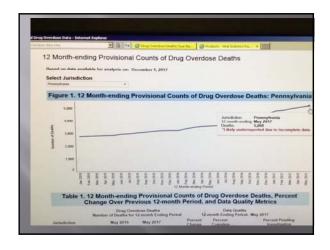
# Prescription Opioid Overdose, Abuse, and Dependence

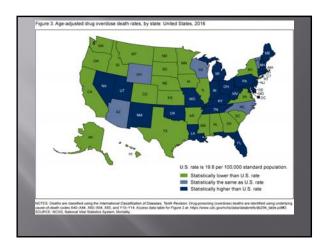
- United States 2013
  - Total economic burden estimated to be \$78.5 Billion
  - Approximately one third (\$28.9 Billion) due to increased health care and substance abuse treatment
  - Approximately one quarter of the cost is borne by the public sector in health care, substance abuse treatment and criminal justice costs.

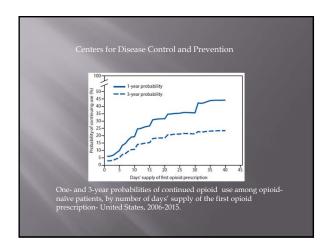
Florence CS, et al: The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. Medical Care 54(10) 901-906, 2016











"I just minimized or dismissed the issues...of abuse, addiction and diversion...

...Ten years later, and we recognize that was a big error...we need to talk about the use of opioids and other prescription drugs from the perspective of two skill sets...how to prescribe, but at the same time, (doctors) have to have a skill set in addiction medicine, how to assess the risk of abuse and diversion and addiction...or they shouldn't use them."

# A Perfect Storm

- Fragmentation of Care Difficulty assessing prior use or dependency
- Recognition of Pain as an important factor in the management of patients
- Time Pressures Medication related management versus counseling or other techniques
- Commercial Pressures Marketing of Pain Medications and New Formulations
- $\ {\color{red} \blacksquare}$  Governmental Mandates in Both Directions Treat pain adequately versus limit prescriptions

# **Concepts and Definitions**

- Substance use disorder
   A cluster of cognitive, behavioral and psychological symptoms indicating that an individual continues to use a substance despite significant substance related problems. A diagnosis based on pathological pattern of behaviors related to the use of the substance.
   Tolerance
   A state in which markedly increased drug doses are required to achieve desired effect or exposure results in diminution of 1 or more opioid effects over time
   Physical dependence
   A state of adaptations manifested by a drug class specific withdrawal syndrome that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level the drug, and/or administration of antagonist

# **Concepts and Definitions**

- - reasons other than prescribed. Misuse can be willful or unintentional use of a substance in a manner not consistent with legal or medical guidelines, such as altering dosing or sharing medicines, which has harmful or potentially harmful consequences. It does not refer to use for mind altering purposes.

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# **Concepts and Definitions**

Misuse with consequences. The use of a substance to modify or control mood or state of mind in a manner that is illegal or harmful to oneself or others. Potentially harmful consequences include accidents or injuries, blackouts, legal problems, and sexual behavior that increases the risk.

# **Concepts and Definitions**

a primary, chronic, neuro biologic disease with genetic, psychosocial, and environmental factors influence thing its development and manifestations.
 It is characterized by behaviors that include one or more of the following: impaired control over drug use, compulsive use, continued use despite harm, and craving. This term is no longer applied as a diagnostic term.

# **Concepts and Definitions**

• The intentional transfer of a controlled substance from legitimate distribution and dispensing channels into illegal channels or obtaining a controlled substance by any legal method.

A syndrome occurring when blood or tissue concentrations of the substance decline in someone who had maintained prolonged heavy use resulting in withdrawal symptoms that may vary greatly across the classes of substances.

# Opioids in the Primary Care Setting

- Survey of 1,000 U.S. primary care physicians
- 85%- opioids are overused in clinical practice
- 55%- very concerned about addiction
- 48%-concerned about death
- 44%-motor vehicle crashes
- 62% believed that tolerance occurs often
- 56% believed that physical dependence occurs often

"Prescription Drug abuse: a National survey of Primary Care Physicians" Catherine S. Hwang, et al. Johns Hopkins Bloomberg School of Public Health

# Opioids in the Primary Care Setting

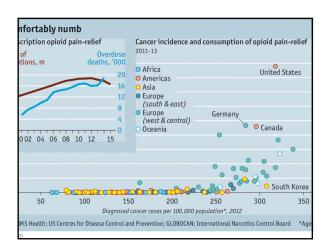
- 88% expressed confidence in their ability to prescribe appropriately
- May reflect the fact that doctors tend to perceive their own clinical judgement superior to that of their peers.
- "Ego bias. "

"Prescription Drug Abuse: a National survey of primary Care Physicians" Catherine S. Hwang et al. Johns Hopkins Bloomberg School of Public Health.

# Cancer Patients and Substance Abuse: Epidemiology

- Substance abuse is prevalent in the general population
- ☐ There is no compelling reason to think that age corrected substance abuse rates would be lower in people with cancer then rates in the normal population (ie, having cancer does not some how protect against substance abuse).

Passik SD, et al. Prevalence of substance abuse disorders in cancer patients. Psychiatric Times. http://www.psychiatrictimes.com



# Cancer Patients and Substance Abuse: Epidemiology

■ The relatively low prevalence of substance abuse among cancer patients treated in tertiary care hospitals may reflect institutional biases or a tendency for patient under reporting in the setting.

 $Passik SD, et al. \ Prevalence \ of substance \ abuse \ disorders \ in \ cancer \ patients \ Psychiatric Times. \ http://www.psychiatrictimes.com$ 

# Cancer patients and Substance Abuse

- ☐ A retrospectively chart review on patient's with cancer seen in the University of Virginia Palliative Care Clinic during 1 month in 2012.
- Evaluated Opioid Risk Tool (ORT) variables and total scores, insurance status and urine drug screens.

Barclay JS, et al. Screening for substance abuse risk in cancer patients using the Opioid Risk Tool in urine drug screen. Support Care Cancer. 2014 Jul;22(7): 1883-8

# Cancer Patients and Substance Abuse

- 114 cancer patients seen. The mean Opioid Risk Tool score was 3.7, with 43% of patients found to be at medium to high risk.
- Age (16-45 years old, 23%) and a personal history of alcohol (23%) or illicit drugs (21%) were the most common risk factors identified.
- Urine drug screens were performed on 40% of the patients with abnormal findings in 45.65% the patients.

Barclay JS, et al. Screening for substance abuse risk in cancer patients using the Opioid Risk Tool in urine drug screen. Support Care Cancer. 2014 Jul;22(7): 1883-8

# Strategies for Addressing the **Opioid Epidemic**

- - Take back programs/ disposal boxes
- Change/influence prescribing practices
  - Education-medical school, residency
  - Prescription drug monitoring programs
     Mandatory vs voluntary
     Insurance based policies

National Academies of Science Engineering, Medicine Consensus Study Report, July 2017 Pain Management and the Opioid Epidemic

# Strategies for Addressing the **Opioid Epidemic**

- Reduce demand
  - Educate public/patientsRisks and benefits
- Reduce harm
- FDA oversight/monitoring
  - Systems approach versus product specific approach
- Research

National Academies of Science .Engineering .Medicine Consensus Study Report . July 2017

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# **Opioid Prescribing Guidelines**

- National Institutes of Health
- American Pain Society
- American Academy of Pain Medicine
- American Academy of Pain Management
- American Society of Addiction Medicine
- Federal Guidelines
- State Guidelines
- Professional Society Guidelines

 □ Centers for Disease Control and Prevention Recommendations for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative Care, and End of Life Care.

Dowell D, Haegerich TM, Chou R. CDC guidelines for prescribing opioids for chronic pain-United States, 2016. JAMA. 2016;315(15):1624-1645.

# CDC Guidelines...

- Determining when to initiate or continue opioids for chronic pain.
  - non pharmacologic and non opioid pharmacologic therapy is preferred
  - before starting opioids established treatment goals and consider exit strategies if needed in the event risks outweigh benefits
  - periodically ongoing opioid therapy should be reevaluated regarding risks, realistic benefits and patient and clinician responsibilities.

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# CDC Guidelines.....

- Opioid selection, dosage, duration, follow-up,
  - Start with immediate release opioids instead of extended release opioids.

  - Reassess if increasing to 50 MME a day
    Avoid increasing to 90 MME a day or carefully justify why
  - Re-evaluate every 3 months for benefit/harm.

# CDC Guidelines....

- Assessing risk and addressing harms of opioid
  - Before starting and periodically during continuation of opioid therapy perform a risk assessment screen(s)
    DI.R.E., O.R.T., C.O.M.M.
    Check PDMP.
    Use urine drug screens

  - Avoid opioids and benzodiazepines concurrently where ever possible
     Offer or arrange evidence based treatment for patients with opioid use disorder

Pennsylvania Department of Health Prescription Drug **Monitoring Program** 

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# **PAPDMP**

- □ There are NO exceptions to registering- by law, every physician licensed to practice in Pennsylvania must register.
  - "a prescriber who does not prescribe controlled substances still needs to register for the system and is required to query the system if they believe or have reason to believe, using sound clinical judgement that a patient may be Abusing or diverting drugs."

# When to Query

- When first prescribing any schedule II through V controlled substance for the purposes of establishing a baseline,
- Or, suspicion of abuse or diversion of any schedule II through V controlled substance.

- Patient populations most at risk include those with:

  - A family history of opioid dependence or other substance abuse
    Continued need for opioid analgesics despite resolution of pain
    Psychiatric disorders (depression, anxiety disorder, bipolar disorder)
    Human immunodeficiency virus (HIV)

  - Hepatitis C virus (HCV)A history of recreational drug use
  - Easy access to prescription drugs from healthcare professionals

# Pain and Opioid Dependence and Tolerance

- Clinically not unrelated phenomena\*
- Presence of one condition seems to influence the expression of the other.
- The presence of addictive disease seems to worsen the experience of pain.\*\*

\*\* Savage SR. Pharm Therapies Drug and Alcohol Addictions. New York: Dekker; 1995. pp373-409

# **Considerations When Prescribing** Opioids

- Long term and short term side effects
   Tolerance and dependence
   Opioid hyperalgesia
   Opioid induced endocrine dysfunction
- Patient selection

  - Pain generatorAbuse, diversion, addiction potential
- Safety issues- Risk of falls, driving, misuse
- Medical/Legal issues- Over, under prescribing.
- DOCUMENTATION

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