Pain Medicine

Have Opioids Outlived Their Usefulness for Chronic Pain

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I have no financial conflicts of interest.

OBJECTIVES

- RISKS AND BENEFITS OF OPIOID THERAPY
- STANDARD OF CARE FOR OPIOIDS
- OUTCOMES OF OPIOID THERAPY IN CHRONIC BENIGN PAIN PATIENTS

- Use dates back centuries (Opium) 3000 BC
- Modern use for Pain
  - Morphine 1806
    - used in Civil War; Soldiers Disease
  - Heroin 1898 synthesized from Morphine
    - Meant to be a Non-addictive Substitute for Morphine
  - 1950 Oxycodone
  - 1970 Controlled Substance Act (Schedule I-V)
  - 1978 Hydrocodone
- Categories
  - Opium Alkaloids (Morphine, Codeine)
  - Semisynthetic (Oxycodone, Hydrocodone)
  - Synthetic (Fentanyl, Methadone)

Mu_1: Euphoria, Supraspinal Analgesia, Confusion, Dizziness, Nausea, Low Addition Potential

Mu_2 Respiratory Depression, Cardiovascular and GI Effects (Naloxegol), Miosis, Urinary Retention

Delta: Spinal Analgesia, Cardiovascular Depression, Decreased Brain and Myocardial Oxygen Demand

Kappa: Spinal Analgesia, Dysphoria, Psychomimetic Effects, Feedback Inhibition of Endorphin System

TYPES

- SHORT-ACTING (SA)

  ORAL TYPICALLY 30MIN ONSET LASTING 4-6 HOURS

  SUBLINGUAL RAPID ONSET LASTING 2-4 HOURS

  SHORT ½ LIFE

- LONG-ACTING (LA)

  ORAL 8-24 HOURS; BUCCAL 12 HOURS
  TRANSCUTANEOUS 72 HOURS -7 DAYS

  LONGER ½ LIFE WITH PROLONGED ELIMINATION

  SUSTAINED RELIEF ONCE AT STEADY STATE

- ABUSE DETERRANT

  FORMS GEL, MATRIX, NALTRXONE/NALOXONE

SIDE EFFECTS

- ALTERED MENTAL STATUS / SEDATION
- NAUSEA
- URINE RETENTION
- ITCHING
- CONSTIPATION, CONSTIPATION, CONSTIPATION

COMPLICATIONS

- RESPIRATORY SUPPRESSION (DEATH)
- ADDICTION vs. DEPENDANCE
- HORMONAL DYSFUNCTION
  - DECREASED LIBIDO, MOOD DO, OSTEOPOROSIS
- DELAYED GASTRIC EMPTYING
- DYSTONIC REACTIONS
- CARDIAC (PROLONGED QT INTERVAL)
- SLEEP DISORDER
- HYPERALGESIA

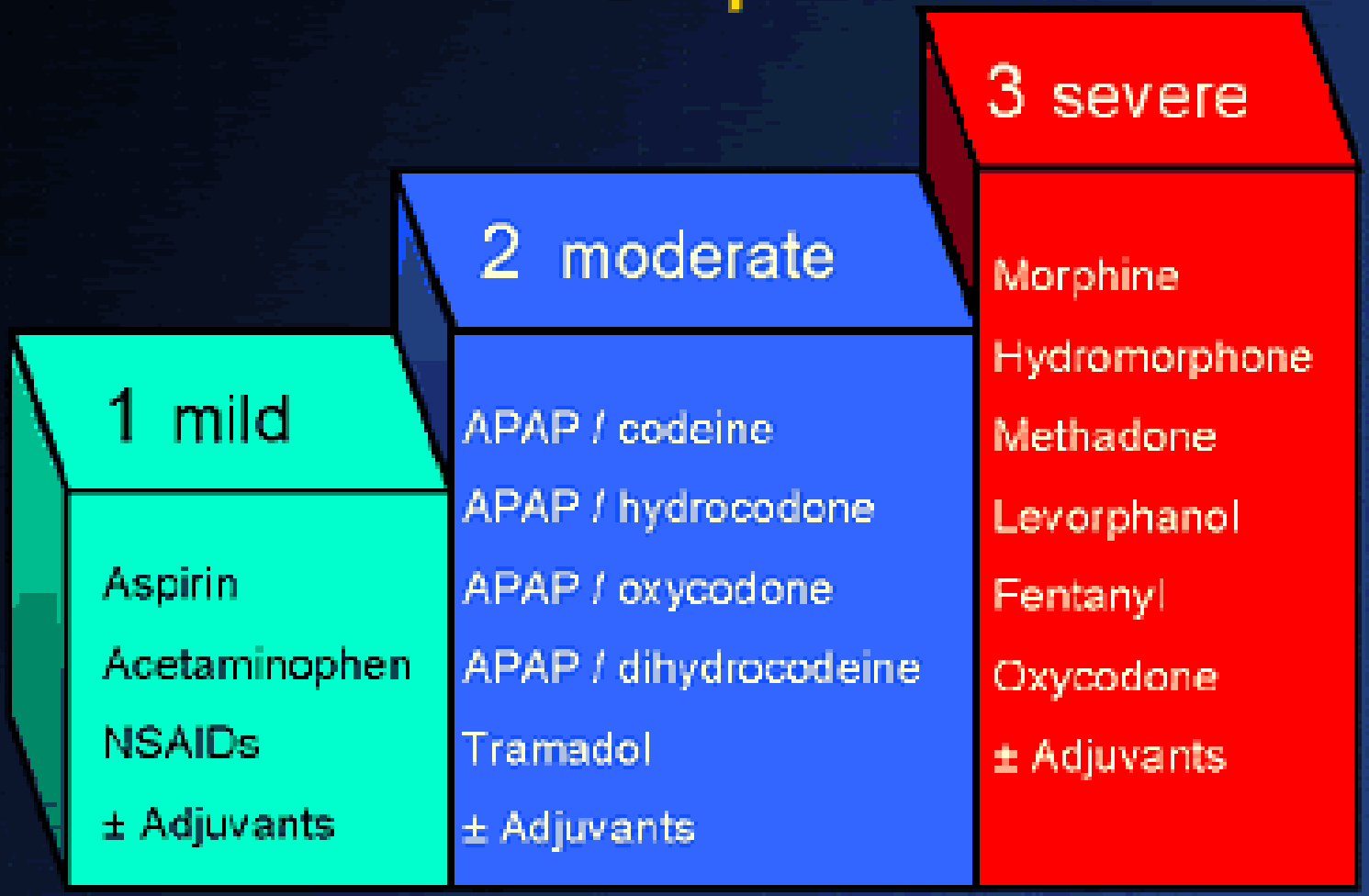
INDICATIONS

- ACUTE
  - TRAUMA (BURNS, FRACTURES, LACERATIONS)
  - OPERATIONS
  - KIDNEY STONES, GALLSTONES, MI, ETC…
- CHRONIC
  - BENIGN PAIN
  - CANCER PAIN (MOSTLY TERMINAL)
  - LA OPIOIDS
  - SA OPIOIDS (BREAKTHROUGH PAIN)

INDICATIONS FOR CHRONIC BENIGN PAIN

- MILD, MODERATE, SEVERE PAIN
- LACK OF ADEQUATE MEDICAL SCIENCE
  - NO LARGE MULTICENTER RCT
  - PRESCRIBING OPIOIDS 30 PLUS YEARS
  - MILLIONS OF PATIENTS
  - BILLIONS OF DOLLARS
- ANCEDOTAL EVIDENCE
- NO DOCUMENTED FUNCTIONAL IMPROVEMENT
- VAS 0-10
- BAD OUTCOMES

WHO 3-Step Ladder



World Health Organization. *Cancer Pain Relief, with a Guide to Opioid Availability*. 1996.

- USA 80% OF THE WORLDS OPIOIDS
- USA REPRESENT 5% OF WORLD POPULATION
- USA CONSUMES 99% OF HYDROCODONE
- 300 MILLION OPIOID PRESCRIPTIONS 2015
- $24 BILLION

CNBC: DINA GUSOVSKY

HYDROCODONE

- MOST COMMON OPIOID UNTIL 2014
- CHANGED TO SCHEDULE II IN OCTOBER 2014
- DECREASED 34% SINCE 2012
- REPORTS ATTRIBUTE TO OPIOID EPIDEMIC
- CONTROLS PLACED ON OPIOIDS
  - CAN NO LONGER CALL INTO PHARMACY
  - UPSURGE IN TRAMADOL PRESCRIPTIONS

MEDSCAPE; ROBERT LOWES MAY 4, 2017

CONTROLLED SUBSTANCE ACT (1970)

SCHEDULE I: HIGH ABUSE POTENTIAL, NO MEDICAL USE

LSD, HEROIN, MARIJUANA (EXTRACT?), ECSTASY

SCHEDULE II: HIGH ABUSE POTENTIAL, SEVERE DEPENDENCE

MORPHINE, OXYCODONE, HYDROCODONE, FENTANYL, METHADONE, OPIUM, AMPHETAMINES

SCHEDULE III: HIGH ABUSE POTENTIAL, LOW-MOD DEPENDENCE

BUTRANS, SUBOXONE, CODEINE <90MG, KETAMINE

SCHEDULE IV: LOWER ABUSE POTENTIAL

TRAMADOL, SOMA, BENZODIAZEPINES

SCHEDULE V: LOWEST ABUSE POTENTIAL

LYRICA, CODEINE 200MG

FEDERAL LAWS

SCHEDULE II

NO REFILLS

90 SUPPLY (2007); MULTIPLE PRESCRIPTIONS ALLOWED

PRESCRIPTIONS MUST HAVE REFILL TIME OR DATE

NO TIME LIMIT (expiration)

NO POSTDATED PRESCRIPTIONS

NO PILL LIMIT

FAX: LTCF, HOSPICE, DIRECTLY INTO PATIENT

SCHEDULE III, IV, V

MAY ISSUE FOR 6 MONTHS; ORIGINAL PLUS 5 REFILLS

WRITTEN, FAXED, CALLED

SOUTH CAROLINA LAW

- PRACTITIONER MUST REGISTER WITH DHEC
- UTILIZE SCRIPTS
- VALID PRACTITIONER-PATIENT RELATIONSHIP
- LEGITIMATE MEDICAL PURPOSE
- REQUIRES GOVERNMENT-ISSUED ID
- PRESCRIBING TO FAMILY MEMBERS IS A VERY BAD IDEA
- SCHEDULE II
  - NO REFILLS
  - MAY NOT EXCEED 31 DAY SUPPLY; EXCEPT PATCHES
  - PRESCRIPTION VALID FOR 90 DAYS
  - FAX FOR LTCF, HOSPICE, DIRECTLY INTO PATIENT (INTRATHECAL, IV)
- SCHEDULE III, IV, V
  - WRITTEN, FAXED, CALLED
  - REFILLED 5 TIMES IN 6 MONTH PERIOD
  - PRESCRIPTION VALID 6 MONTHS
  - MAY NOT EXCEED 90 DAY SUPPLY

Improvement Activities for Medicare

- STATE Prescription Drug Monitoring Program
- Not Federal Program
- State Level
  - Annual registration by eligible clinician or group in the prescription drug monitoring program of the state where they practice. Activities that simply involve registration are not sufficient. MIPS (MERIT BASED) eligible clinicians and groups must participate for a minimum of 6 months.

OPIOIDS

- TMTC articles in the Medical Journals on complications, lack of objective benefit and legal issues
- Resurgence of Heroin and new synthetic Fentanyl
- Opioid Epidemic???
- Big Pharma pushing opioid prescriptions
  - $$,$$$,$$$,$$$
- Pain Physicians being sued for overdose deaths
  - WHAT IS THE STANDARD OF CARE? (Legal Term)

OPIOID EPIDEMIC

- MEDIA (FOX NEWS COVERAGE)
- FEDERAL AND STATE GOVERNMENT INVESTIGATING
- GOVERNOR CHRISTIE LEADING FEDERAL TASK FORCE
- ATTACKING
  - PHARMACEUTICAL MANUFACTURERS
  - DISTRIBUTORS (CARDINAL, MCKESSON)
  - PHARMACIES (CVS, WALGREENS)
- WHO IS MISSING FROM THIS PROBLEM?

PHYSICIANS

- NO SHORTAGE OF PATIENTS
  - WAITING ROOMs LOOK LIKE METHADONE CLINIC
- GREAT SOURCE OF INCOME
- MONTHLY APPOINTMENTS
  - NP OR PA SEES PATIENTS
  - COPY AND PASTE NOTES
- FREQUENT URINE DRUG SCREENING
  - GOOD DOCTOR VS. GREEDY DOCTOR???
  - $200-$2000 PER UDS
  - RANDOM UDS EVERY 4-6 MONTHS & PRN
  - INSURANCE CONTRACT WITH OUTSIDE LAB

WHAT'S BEING DONE?

- NOT MUCH ABOUT PHYSICIANS
  - PAIN PRACTICES LOCAL, STATE, NATIONAL
  - UDS IS MAJOR SOURCE OF INCOME
  - LEGITIMATE MEDICAL NEED FOR OPIOIDS?
- NOBODY REALLY CARES?
  - STATE MEDICAL BOARDS (EXTREME CASES)
  - GOVERNMENT (BIG PHARMA LOBBYING)
  - MEDIA (GREAT STORY LAST WEEK)
- TOO MANY PLAYERS IN THIS GAME
- SOUTH CAROLINA GOVERNOR'S TASK FORCE
  - 2 HOUR CME EVERY 2 YEARS
  - UTILIZE SCRIPTS

- SCRIPTS
  - Georgia and Tennessee participate
  - No Reciprocal Relationship with North Carolina
  - Able to search back 4 years
- E-scripts to minimize illegal prescriptions
- Dosing 80-120 mg/day MED recommendation
  - MORPHINE IS THE STANDARD
  - CONVERT OTHER OPIOIDS TO DOSING EQUIVALENTS
  - FENTANYL IS THE EXCEPTION
  - HIGH DOSES LEAD TO HYPERALGESIA
- DEA, CDC, FDA, DHEC, State Medical Boards…

Washington State WC

- Specific criteria for prescribing opioids
- Expected outcomes (30% relief above baseline)
- Functional improvement (Work Conditioning or Vocational Rehabilitation)
- Monitoring
- Application Forms

  Clinically Meaningful Improvement in Function (CMIF)

Washington State Dept. of Labor & Industries

Department of Labor and Industries
PO Box 44291
Olympia WA 98504-4291

Opioids.Lni.wa.gov

CHRONIC OPIOID REQUEST FORM

Billing code 1078M

Worker's name _____ Claim number _____

Has the worker's opioid dose increased since last authorization? ☐ Yes ☐ No

Opioids must result in clinically meaningful improvement in function (CMIF) in acute or subacute phase and sustained CMIF during chronic phase. This means improvement of at least 30% as compared to baseline or in response to a dose change.

Function assessment

Current pain interference — This scale's examples of activities at different levels are not meant to be exclusive. In the last month, how much has pain interfered with the worker's daily activities and functions? Circle number.
0 — **No interference.** Goes to work each day, has a social life outside of work, takes an active part in family life.
1 — Can work/volunteer, be active eight hours daily, takes part in family life, has limited outside social activities.
2 — Can work/volunteer for at least six hours daily, has energy to make plans for one evening social activity during the week, is active on the weekends.
3 — Can work/volunteer for a few hours daily, is active at least five hours daily, does simple activities on the weekends.
4 — Can work/volunteer limited hours, has limited social activities on weekends.
5 — Not able to work/volunteer, struggles with home responsibilities and outside activities.
6 — Does simple chores around home, has minimal outside activities two days a week.
7 — Gets dressed in the morning, has minimal activities at home, has contact with friends via phone or email.
8 — Gets out of bed but doesn't get dressed, stays at home all day.
9 — Stays in bed at least half the day, has no contact with the outside world.
10 — **Unable to carry out any activities.** Stays in bed all day, feels helpless and hopeless about life.

Date of first function assessment or before a dose change (baseline): _____ Baseline function: _____

If an alternative function scale is used, indicate name of scale: _____ Current function: _____

Screening

For free, easy to use, and validated screening tools and opioid calculator, visit www.agencymeddirectors.wa.gov/opioiddosing.asp.

Have you documented in the medical records the following. . .		
1. Tried to manage the worker's pain with non-opioids?	Yes ☐	No ☐
2. Re-administered urine drug tests at frequency based on risk and verified the worker has no pattern of recurrent aberrant behaviors (e.g.presence of cocaine, amphetamine/methamphetamine, heroin, alcohol or non-prescribed drug; negative for prescribed opioids)? See instructions for how often to monitor.	Yes ☐	No ☐
3. Re-checked the state's prescription monitoring program at frequency based on risk and verified the worker has no pattern of recurrent aberrant behaviors (e.g. lost prescriptions, multiple prescribers, multiple early refills, unauthorized dose escalation)? See instructions for how often to monitor.	Yes ☐	No ☐
4. Signed a treatment agreement for chronic opioid therapy with the worker? Treatment agreement should be renewed yearly.	Yes ☐	No ☐
5. Re-assessed for potential contraindications to the use of opioids (e.g. substance use disorder excluding nicotine; history of opioid use disorder; confirmed presence of cocaine, heroin, alcohol, or amphetamine/methamphetamine)?	Yes ☐	No ☐
6. Verified the worker has no known evidence of or is not at high risk for serious adverse outcome from opioid use (e.g. COPD, asthma, sleep apnea, apparent intoxication)?	Yes ☐	No ☐
7. Obtained a pain management consult if opioid dose >120mg/d morphine equivalent dose (MED)? If consultation is exempted, explain in the medical records.	Yes ☐	No ☐

Dose

Current opioid	Dose (MED mg/d)
Current opioid	Dose (MED mg/d)
	Total MED

Sign

Provider name	L&I provider number/NPI	Phone number
Provider signature	Date	

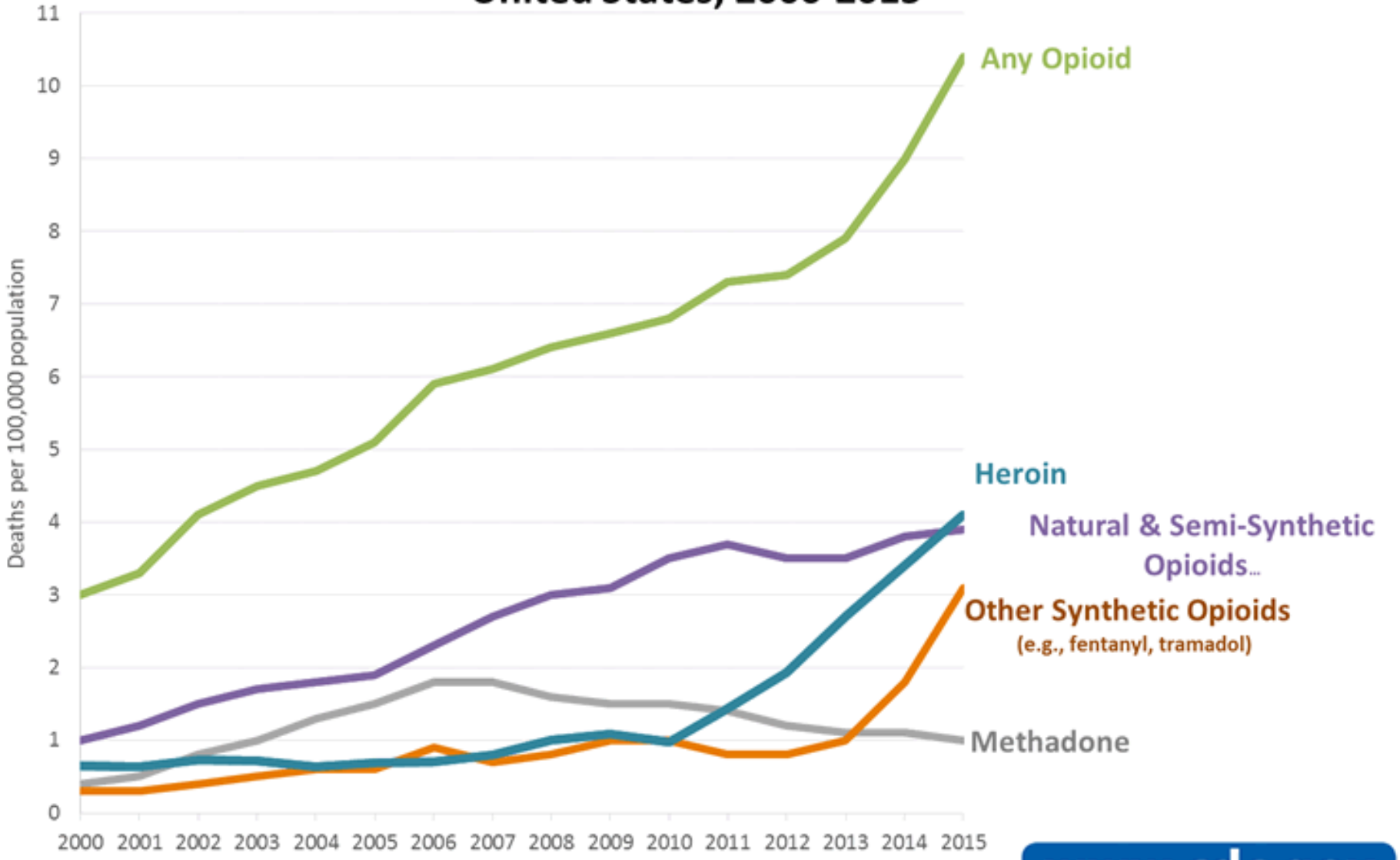
WORKERS COMPENSATION

- PHYSICIANS DISPENSING OUT OF OFFICE
- NOT USUALLY OPIOIDS
  - PAPERWORK / BUREAUCRACY
  - SECURITY
  - LEGAL ISSUES
- A LOT OF ADJUVANT MEDICATIONS
  - SLEEPING PILLS
  - BENZODIAZEPINES (ASSOCIATE W/ 30% OF ALL ODs)
  - MUSCLE RELAXANTS / ANTICONVULSANTS
  - NSAIDS
  - VITAMINS/FOOD SUPPLEMENTS
  - MOSTLY CNS DEPRESSANTS
- COSTLY TO INSURANCE COMPANIES
  - STOP ALLOWING DISPENSING IN OFFICE
  - DISPENSING PAYS PHYSICIAN WELL

In Office Prescriptions

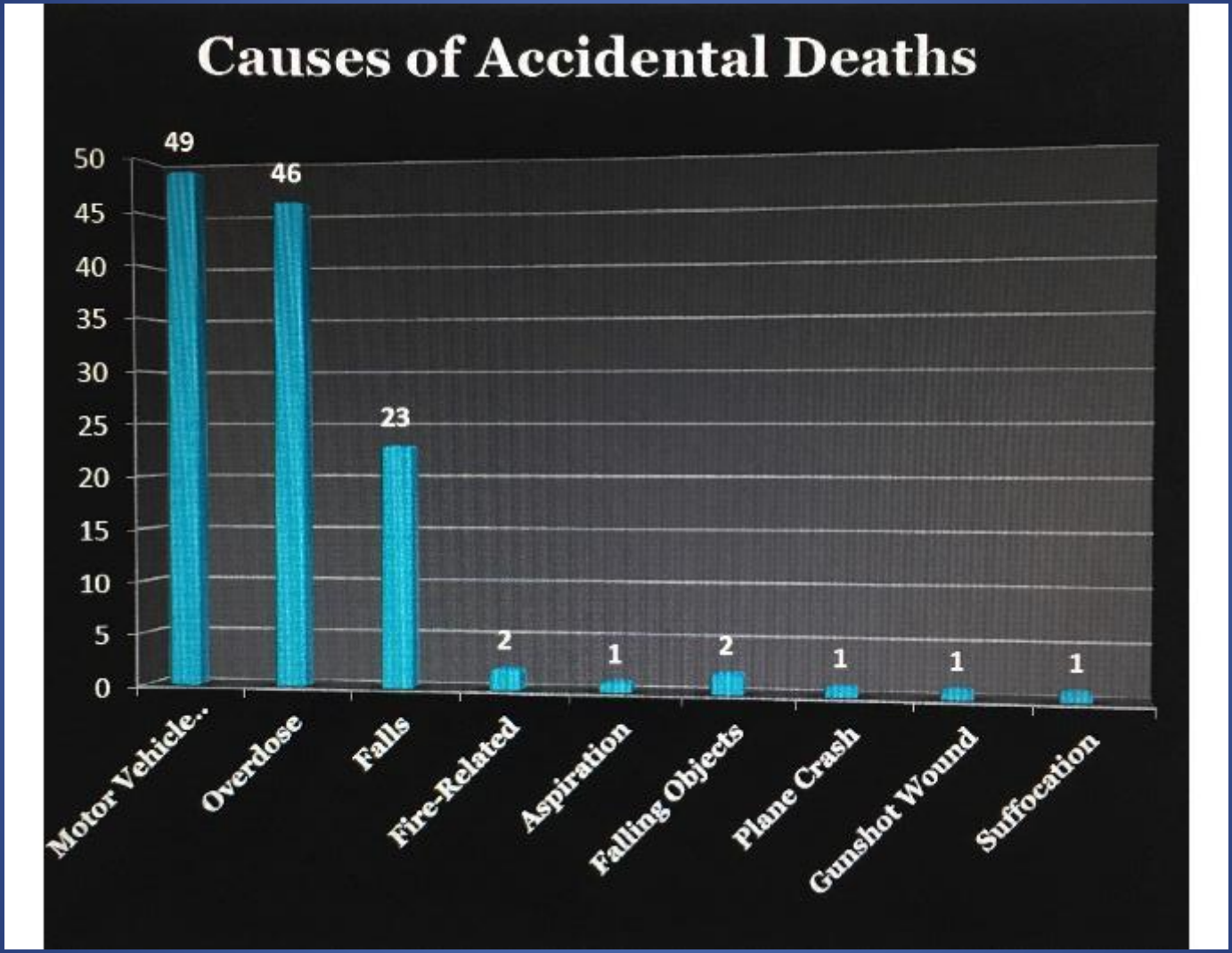
- Incentive to prescribe the highest reimbursed drug (SOMA)
- Alternative doses not available in the retail pharmacy (Ultram ER 150mg)
- Inexpensive OTC meds combined for higher cost (Capsaicin/Lidocaine/Menthol)
- Supplements (Theramine, Percura, Sentra…)
  - Limited and poor studies by the manufacturers
  - Only available in the physician's office?
  - FDA approved (Safety)

Overdose Deaths Involving Opioids, by Type of Opioid, United States, 2000-2015



SOURCE: CDC/NCHS, National Vital Statistics System, Mortality. CDC WONDER, Atlanta, GA: US Department of Health and Human Services, CDC; 2016. https://wonder.cdc.gov/.

www.cdc.gov
Your Source for Credible Health Information



Lexington County Coroner 2015

Prescription Opioid Overdose Data

Overdose deaths involving prescription opioids have quadrupled since 1999,[1,2] and so have sales of these prescription drugs.[3] From 1999 to 2015, more than 183,000 people have died in the U.S. from overdoses related to prescription opioids.[1,2]

Overdose Data

Opioid prescribing continues to fuel the epidemic. Today, nearly half of all U.S. opioid overdose deaths involve a prescription opioid.[1] In 2015, more than 15,000 people died from overdoses involving prescription opioids.

Most Commonly Overdosed Opioids

The most common drugs involved in prescription opioid overdose deaths include:

- Methadone
- Oxycodone (such as OxyContin®)
- Hydrocodone (such as Vicodin®)[4]

Overdose Deaths

Among those who died from prescription opioid overdose between 1999 and 2014:

- Overdose rates were highest among people aged 25 to 54 years.
- Overdose rates were higher among non-Hispanic whites and American Indian or Alaskan Natives, compared to non-Hispanic blacks and Hispanics.
- Men were more likely to die from overdose, but the mortality gap between men and women is closing.[5]

Additional Risks

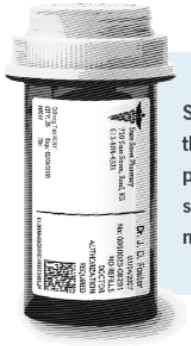
Overdose is not the only risk related to prescription opioids. Misuse, abuse, and opioid use disorder (addiction) are also potential dangers.

CDC OPIOID PRESCRIBING GUIDELINE MOBILE APP

Safer Opioid Prescribing at Your Fingertips

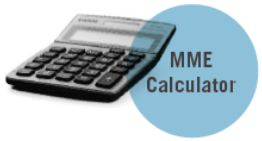
THE OPIOID GUIDELINE APP

Opioids can have serious risks and side effects, and CDC developed the CDC Guideline for Prescribing Opioids for Chronic Pain to encourage safer, more effective chronic pain management. CDC's new Opioid Guideline App makes it easier to apply the recommendations into clinical practice by putting the entire guideline, tools, and resources in the palm of your hand.



Since 1999, the amount of prescription opioids sold in the U.S. has nearly quadrupled.

FEATURES INCLUDE:



Patients prescribed higher opioid dosages are at higher risk of overdose death. Use the app to quickly calculate the total daily opioid dose (MME) to identify patients who may need closer monitoring, tapering, or other measures to reduce risk.

Access summaries of key recommendations or link to the full Guideline to make informed clinical decisions and protect your patients.

To provide safer, more effective pain management, talk to your patients about the risks and benefits of opioids and work together towards treatment goals. Use the interactive MI feature to practice effective communication skills and prescribe with confidence.

MANAGING CHRONIC PAIN IS COMPLEX, BUT ACCESSING PRESCRIBING GUIDANCE HAS NEVER BEEN EASIER.

Download the free Opioid Guideline App today!
https://www.cdc.gov/drugoverdose/prescribing/app.html.

Available on the App Store

ANDROID APP ON Google play

This App, including the calculator, is not intended to replace clinical judgment. Always consider the individual clinical circumstances of each patient.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

LEARN MORE | www.cdc.gov/drugoverdose/prescribing/guideline.html

RECENT CASE TO REVIEW

- Chronic Back and Leg pain (WC)
- Prior Lumbar Fusion
- Morphine SR 100 mg TID with Percocet 10 mg BID
- Neurontin, Ambien, Klonopin, Zanaflex, Mobic, Antidepressants, Food Supplements, Topicals
- VAS 5-7/10
- Permanent SCS (3 trials)
- Same Meds and VAS, No Functional Benefit after SCS
- No Improvement at a cost of +/- $60-80K for SCS

THANK YOU