

# PainWeek®

## 2+2 Before: Using “New Math” to Calculate Opioid Risk

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# Disclosure

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- Nothing to Disclose

# Learning Objectives

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- Describe opioid risk
- Summarize how different types of opioid risk have varying levels of clinical impact
- Describe the term “unhealthy use” of licit and illicit substances
- Identify how current forces challenge us to implement a different methodology for risk/analysis determination when opioid analgesics are determined to be an appropriate component of pain treatment

# PainWeek®

## What *is* Opioid Risk?

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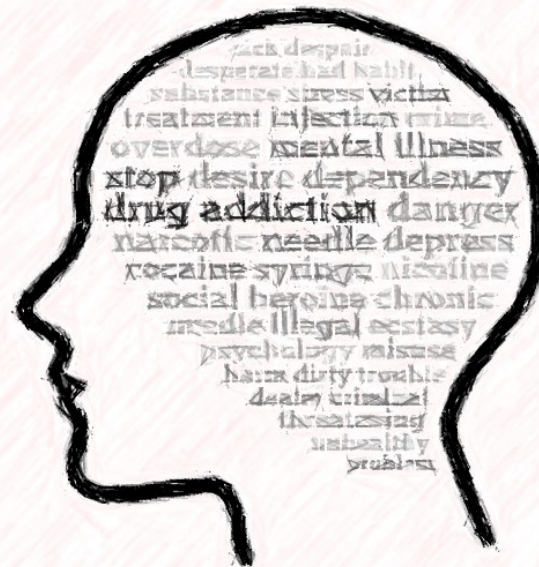
It depends who you ask...

Risk defined: The possibility of something bad happening



# Opioid Risk...

- What comes to mind?
  - Adverse effects?
  - “Unhealthy use” or aberrant drug-related behaviors?
  - The Opioid Overdose Epidemic?
  - What influences what comes to your mind?





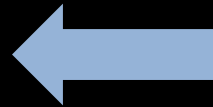
# Different Types of Opioid Risk

- Adverse effects
- Are these really risks?
  - Tolerance
  - Physical/Physiologic dependence
- “Unhealthy use”
  - Will define later...
- Risk of aberrant drug-related behavior
  - The opioid epidemic
- Regulatory risk
- Other risk(s)



# Opioid Risk – Adverse Effects

- Constipation
- Nausea/Vomiting
- Dry mouth
- Itching
- Sweating
- Endocrinopathy/hormonal axis imbalance
- Immunosuppression
- Sleep disturbances
- Other side effects
- RESPIRATORY DEPRESSION



# Risk Factors for Potential Opioid-Related Adverse Effects Have Been Identified

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- Prior history of:
  - Nausea/Vomiting with opioid therapy
  - Chronic constipation
  - Itching/flushing/histamine release
  - Obstructive sleep apnea
  - Morbid obesity
  - Chronic obstructive pulmonary disease
  - Being co-prescribed other central nervous system depressants
  - Etc.





# Opioid Risk vs Complication vs Adaptation

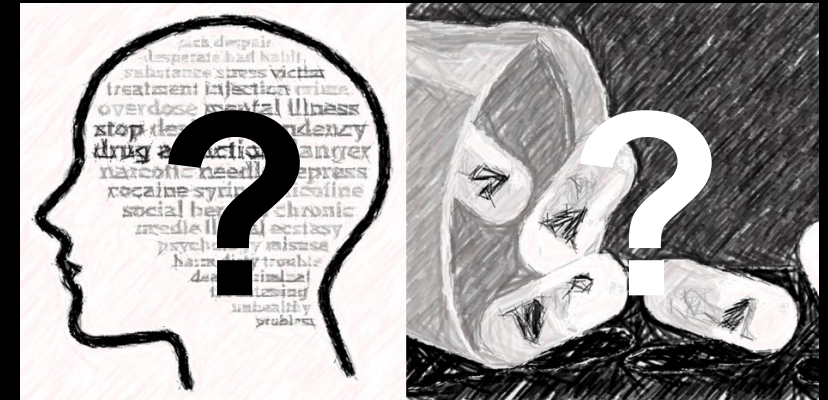
## ■ Tolerance

–A state of adaptation in which longer-term exposure leads to diminished analgesic effect requiring higher doses to achieve therapeutic goals

## ■ Physical/Physiologic dependence

–A state of adaptation in which longer-term exposure leads to the manifestation of withdrawal symptoms or syndrome when there is:

- Abrupt cessation
- Rapid dose reduction
- Administration of an agonist



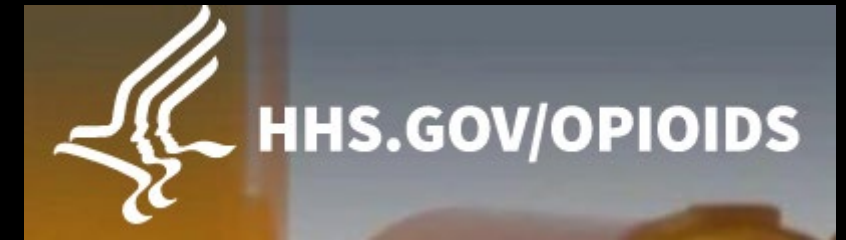
# Opioid Risk – “Unhealthy Use?”

- Definitions for the purposes of this talk and past contextual references:
- Misuse
  - Use of a medication (for a medical purpose) other than as directed or indicated, whether willful or unintentional, and whether harm results or not
- Abuse
  - Any use of an illegal drug or the intentional self-administration of a medication for a nonmedical purpose such as altering one’s state of consciousness, for example, getting high
- Addiction
  - A primary, chronic disease involving brain reward, motivation, memory, and related circuitry that can lead to relapse and progressive development, and that is potentially fatal if left untreated; markers include craving and continued use despite adverse outcomes



# The Opioid Epidemic According to Department of Health and Human Services (HHS)

- What *is* the U.S. opioid epidemic?
  - “In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to opioid pain relievers and healthcare providers began to prescribe them at greater rates”
  - “Increased prescription of opioid medications led to widespread misuse of both prescription and non-prescription opioids before it became clear that these medications could indeed be highly addictive”
  - “In 2017 HHS declared a public health emergency and announced a 5-Point Strategy To Combat the Opioid Crisis”



## THE OPIOID EPIDEMIC BY THE NUMBERS



**70,630**

people died from drug overdose in 2019<sup>2</sup>



**10.1 million**

people misused prescription opioids in the past year<sup>1</sup>



**1.6 million**

people had an opioid use disorder in the past year<sup>1</sup>



**2 million**

people used methamphetamine in the past year<sup>1</sup>



**745,000**

people used heroin in the past year<sup>1</sup>



**50,000**

people used heroin for the first time<sup>1</sup>



**1.6 million**

people misused prescription pain relievers for the first time<sup>1</sup>



**14,480**

deaths attributed to overdosing on heroin (in 12-month period ending June 2020)<sup>3</sup>



**48,006**

deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending June 2020)<sup>3</sup>

### SOURCES

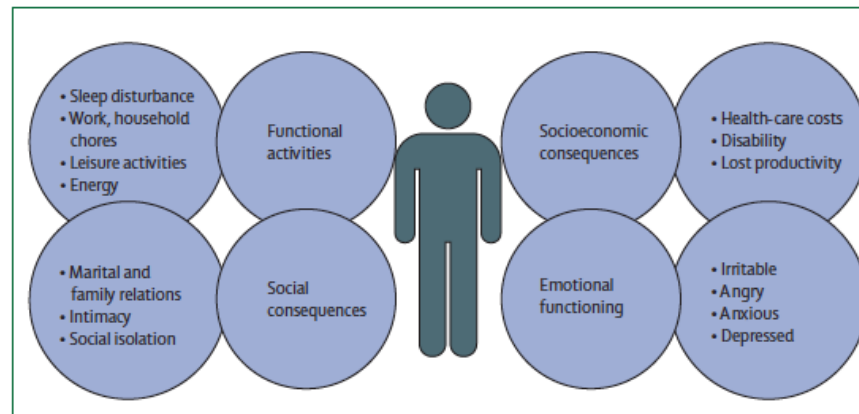
1. 2019 National Survey on Drug Use and Health, 2020.

2. NCHS Data Brief No. 394, December 2020.

3. NCHS, National Vital Statistics System. Provisional drug overdose death counts.

# “Unhealthy Use” of Opioids vs Undertreated Pain: Do Both Situations Carry Risk?

- The Substance Abuse and Mental Health Services Administration’s (SAMHSA) National Survey of Drug Use and Health<sup>1</sup> has shown that most people who use prescription analgesics “nonmedically” obtain them from friends or family most often from a valid prescription
  - Large sample sizes provide this data
- Some of the immediate consequences of untreated or undertreated pain include:
  - Reduced quality of life
  - Impaired physical function
  - Economic burden
  - Physical disability
  - Fear/Anger
  - Depression/Anxiety
  - Reduced social capacity



**Figure 1: The effect and burden of chronic pain**

Chronic pain affects every aspect of a patient's life, contributing to a loss of both physical and emotional function, affecting a patient's levels of activity (ability to work at home and job and engage in social and recreational pursuits); additionally, there are often serious economic consequences as a result of health-care bills and potential loss or decrease in financial income.

Turk DC, Wilson HD, Cahana A. Treatment of chronic non-cancer pain. The Lancet. 2011; 377(9784): 2226—2235.

**SAMHSA**  
Substance Abuse and Mental Health  
Services Administration

# Where Opioids Were Obtained for Most Recent “Unhealthy Use” Among Past Year Misusers Aged 12 or Older, by Age Group:

Source for Most Recent Misuse among Past Year Misusers of Pain Reliever	Aged 12+ (2015)	Aged 12+ (2016)	Aged 12-17 (2015)	Aged 12-17 (2016)	Aged 18+ (2015)	Aged 18+ (2016)	Aged 18-25 (2015)	Aged 18-25 (2016)	Aged 26+ (2015)	Aged 26+ (2016)
<b>GOT THROUGH PRESCRIPTION(S) OR STOLE FROM A HEALTH CARE PROVIDER</b>	4,354	4,124	228	205	4,126	3,919	764	665	3,361	3,254
Prescription from One Doctor	4,066	3,895	193	165	3,874	3,730	719	605	3,155	3,124
Prescriptions from More Than One Doctor	206	156	14	28	191	128	25	34	167	95
Stole from Doctor's Office, Clinic, Hospital, or Pharmacy	82	73	21	12	60	61	20	26	40	35
<b>GIVEN BY, BOUGHT FROM, OR TOOK FROM A FRIEND OR RELATIVE</b>	6,422 <sup>a</sup>	5,831	469	449	5,953 <sup>a</sup>	5,382	1,717 <sup>b</sup>	1,432	4,236	3,951
From Friend or Relative for Free	4,843	4,446	312	303	4,531	4,143	1,225 <sup>a</sup>	1,009	3,307	3,133
Bought from Friend or Relative	1,128	979	81	71	1,047	908	393 <sup>a</sup>	273	655	635
Took from Friend or Relative without Asking	451	406	77	74	375	331	100	149	274	182
<b>BOUGHT FROM DRUG DEALER OR OTHER STRANGER</b>	586	665	42	73	543	592	240	170	303	422
<b>SOME OTHER WAY<sup>1</sup></b>	588 <sup>b</sup>	374	96 <sup>a</sup>	54	492 <sup>a</sup>	320	163 <sup>b</sup>	75	329	245

Numbers in Thousands, 2015 and 2016



# Risk Factors for Potential “Unhealthy Use” of Opioids Have Been Identified

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- Younger age
- Pain-related disability
- Catastrophizing
- Fear related to unknown etiology of pain
- Low level of social support systems
- Personal or family history of substance abuse
  - Past or present
- Psychological history
  - Trauma
  - Stress
- Etc.



# Another Consideration of Risk



# Unhealthy Use

JAMA | US Preventive Services Task Force | **RECOMMENDATION STATEMENT**

## Screening for Unhealthy Drug Use

### US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

JAMA. 2020;323(22):2301-2309

#### ▪ Defined as:

- The use of substances (not including alcohol or tobacco products) that are illegally obtained or the nonmedical use of prescription psychoactive medications
- The use of medications for reasons, for duration, in amounts, or with frequency other than prescribed or by persons other than the prescribed individual
- These substances are:
  - Ingested
  - Inhaled
  - Injected
  - Administered using other methods
- In order to:
  - Affect cognition, affect, or other mental processes (i.e., to “get high”)
  - Achieve some other nonmedical goal(s)

# Screening for Unhealthy Drug Use

JAMA | US Preventive Services Task Force | RECOMMENDATION STATEMENT

## Screening for Unhealthy Drug Use

### US Preventive Services Task Force Recommendation Statement

US Preventive Services Task Force

JAMA. 2020;323(22):2301-2309

- Task Force Recommendation:
  - Screen by asking questions about unhealthy drug use in all adults 18 years or older
    - Asking questions – *not* testing biological specimens
    - Regardless of risk factors
- Rationale
  - Detection
  - Benefit in early detection, intervention, and treatment

# The “Old Math” – Patient-Level Risk

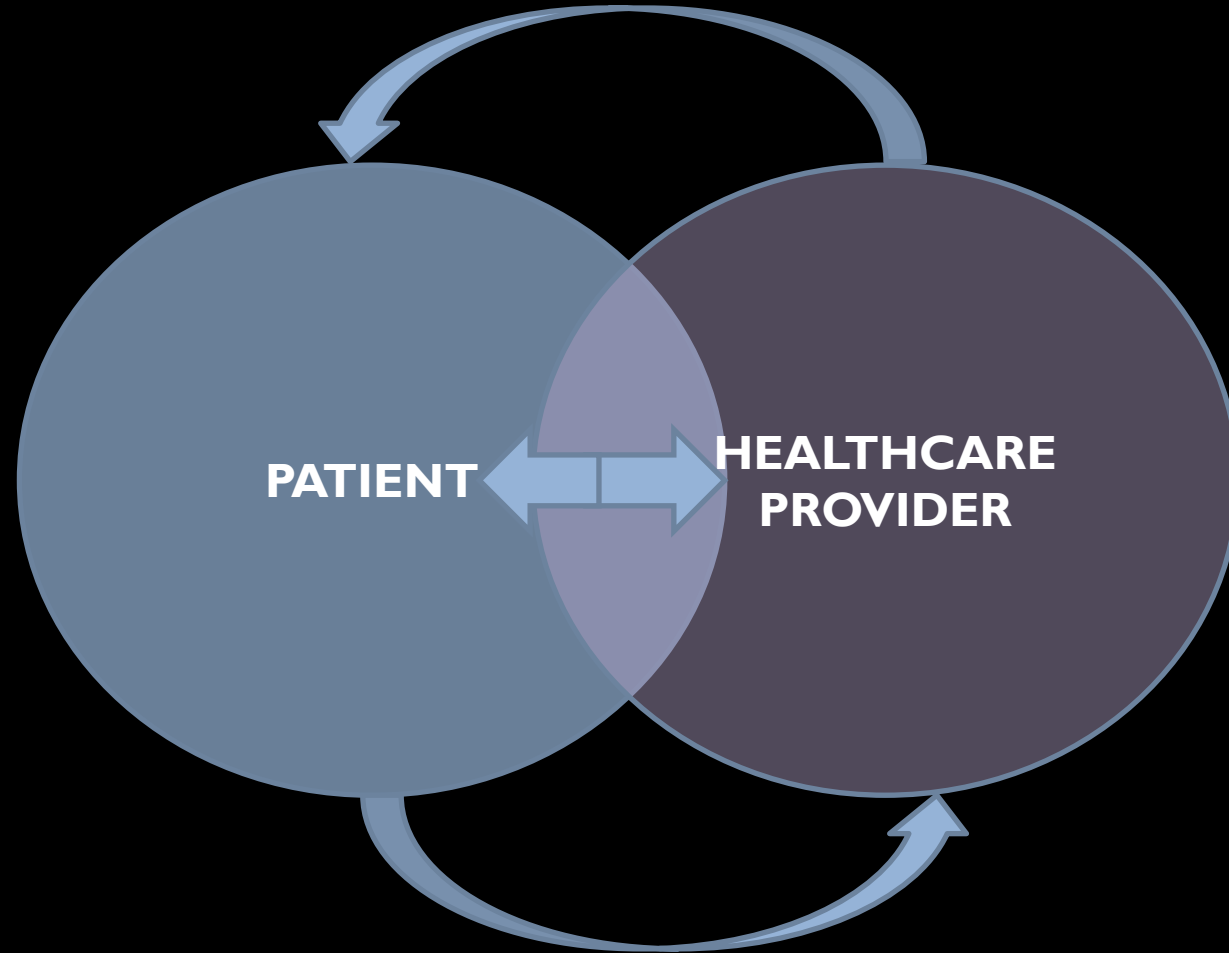
- Our natural inclination is to think about:
  - Things that can happen to patients directly as a result of risk of adverse effects of a medication-based treatment
    - Think warfarin analogy
  - Possible “complications”
    - Allergic reactions
    - Physiologic sequelae
    - Fall risk
    - Cognitive impairment
    - Etc.
  - Restrictions





# Patient-Level Opioid Risk

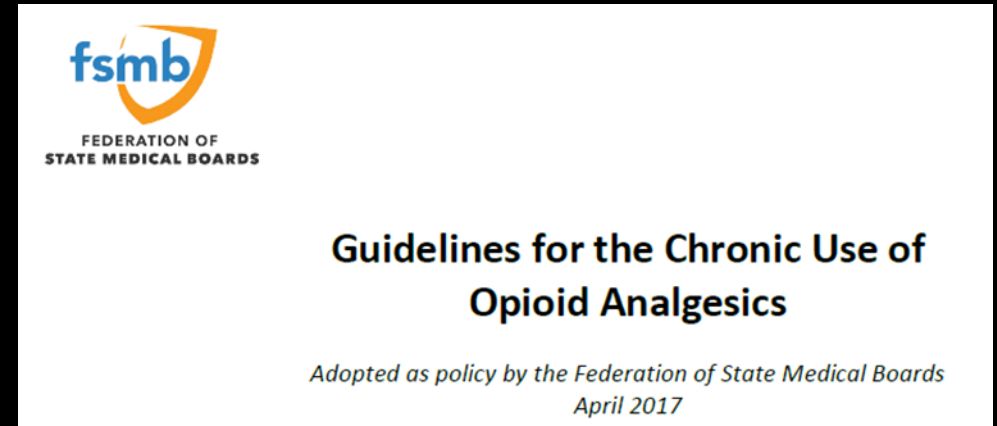
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# Mitigating Patient-Level Opioid Risk

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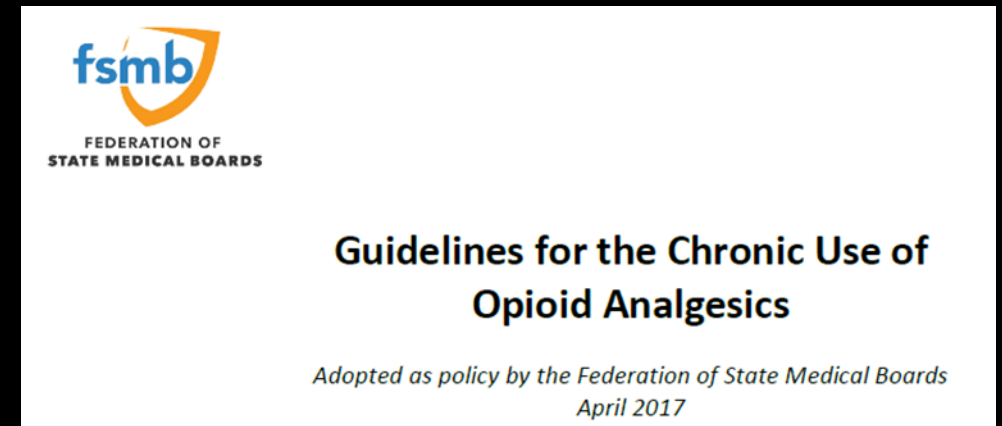
- Adequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain
  - Benefits should outweigh the risks
- Screening for unhealthy use
- Adequate monitoring for aberrant behaviors should be employed
  - Some patients might benefit from:
    - Opioid rotation
    - Dose reduction/tapering
    - Discontinuation
- Adequate attention to patient education
  - Shared decision-making
  - \*\*\*Safe storage and disposal\*\*\*



# Mitigating Patient-Level Opioid Risk

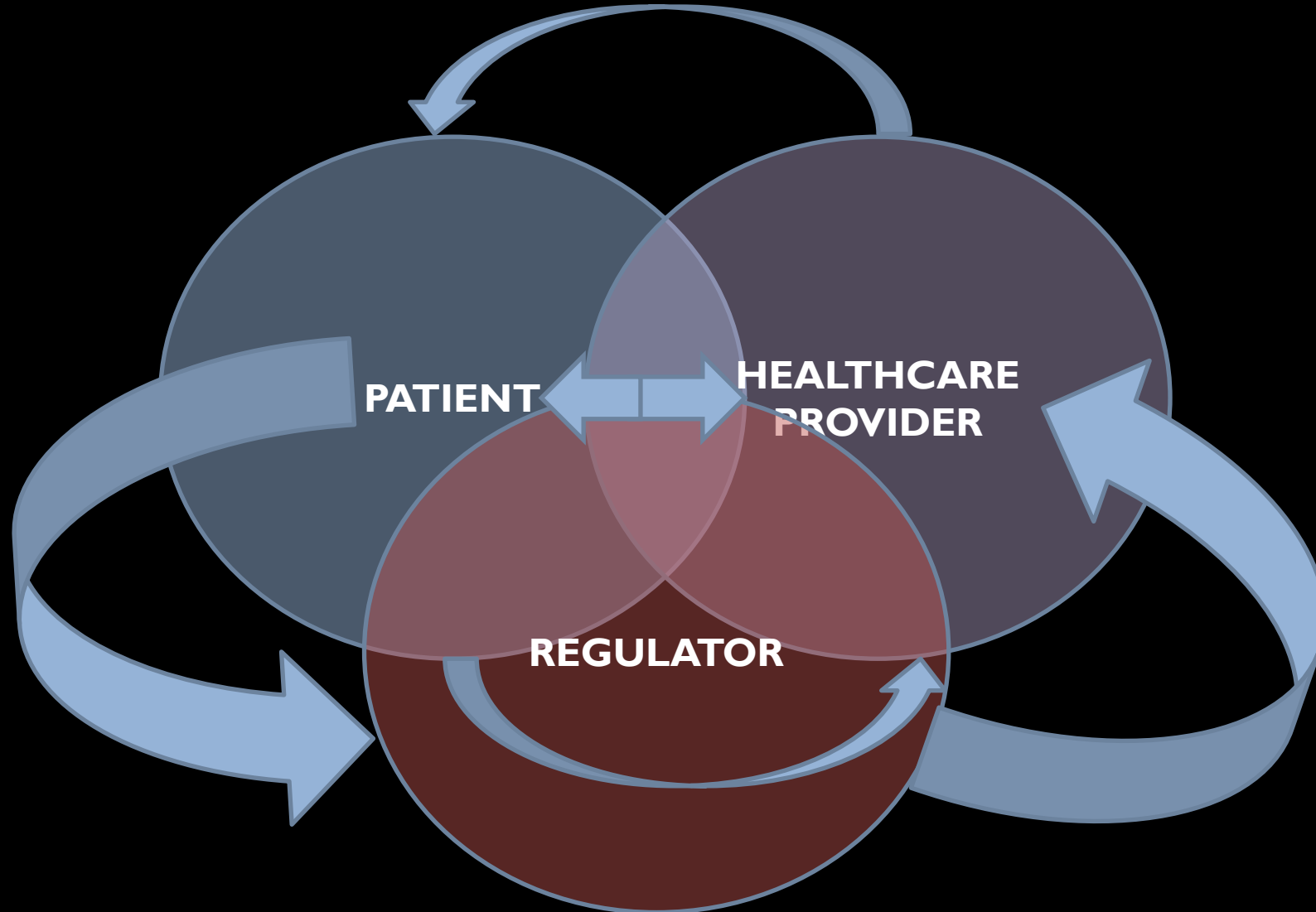
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- Adequate attention to informed consent
  - Clear and demonstrated patient understanding of:
    - The clinical basis for the use of opioid analgesics
    - Risks (expected and potential)
    - Benefits (expected and potential)
      - Aligned with mutually discussed goals and expectations of pain treatment
    - Alternatives to opioid therapy
    - Safe storage and disposal
    - Hazards associated with co-administration of other substances
- Opioid Agreement
  - NOT informed consent
  - Delegation of responsibilities
- Identify presence of risk predictors



# Another Dimension of Opioid Risk

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# Regulatory Opioid Risk?

- Adherence to Drug Enforcement Agency (DEA) rules and regulations regarding prescribing a controlled substance
- Adherence to local state medical board rules and regulations
  - Check prescription drug monitoring program (PDMP) database
  - Electronic prescribing
- “Appropriate” prescribing of opioids as per the FSMB
- Intersection of the CDC Guidelines<sup>1</sup> and local clinical practice recommendations





# Opioid-Related Regulatory Risk

- Considers opioid treatment “inappropriate” including but not limited to:
  - Inadequate attention paid to:
    - Initial pain assessment
    - Risk determination (of aberrant drug-related behavior)
  - Inadequate monitoring of potential for aberrant drug-related behaviors and use of available tools
  - Inadequate attention to patient education and informed consent
  - Unjustified dose escalation
  - Excessive reliance on opioid analgesics (particularly high doses)



## Guidelines for the Chronic Use of Opioid Analgesics

*Adopted as policy by the Federation of State Medical Boards  
April 2017*



# Opioid-Related Regulatory Risk



- Investigators are going back *three years to identify any doctors who may have prescribed the drugs inappropriately when someone dies of an overdose death*, even if it was not the fatal dose, and send them letters
- A physician in San Francisco was sent a letter explaining that a patient he had treated died in 2012 from taking a toxic cocktail of methadone and Benadryl — and he was the doctor who wrote the patient's last prescription for methadone
  - He had *two weeks to respond to the letter* with a written summary of the care he had provided, *and* a certified copy of the patient's medical record facing fines of \$1,000 per day if he didn't comply

## TREATMENTS

### California Doctors Alarmed As State Links Their Opioid Prescriptions to Deaths

January 23, 2019 · 2:28 PM ET  
Heard on *All Things Considered*

APRIL DEMBOSKY

FROM KQED



# Opioid-Related Regulatory Risk

MEDPAGE TODAY®

Pain Management > Opioids

## Four Nurse Practitioners Accused in Calif. Death Certificate Project

— One surrendered license; another accused of coming to work "wobbly," "drugged," and "under the influence"

by Cheryl Clark, Contributing Writer, MedPage Today

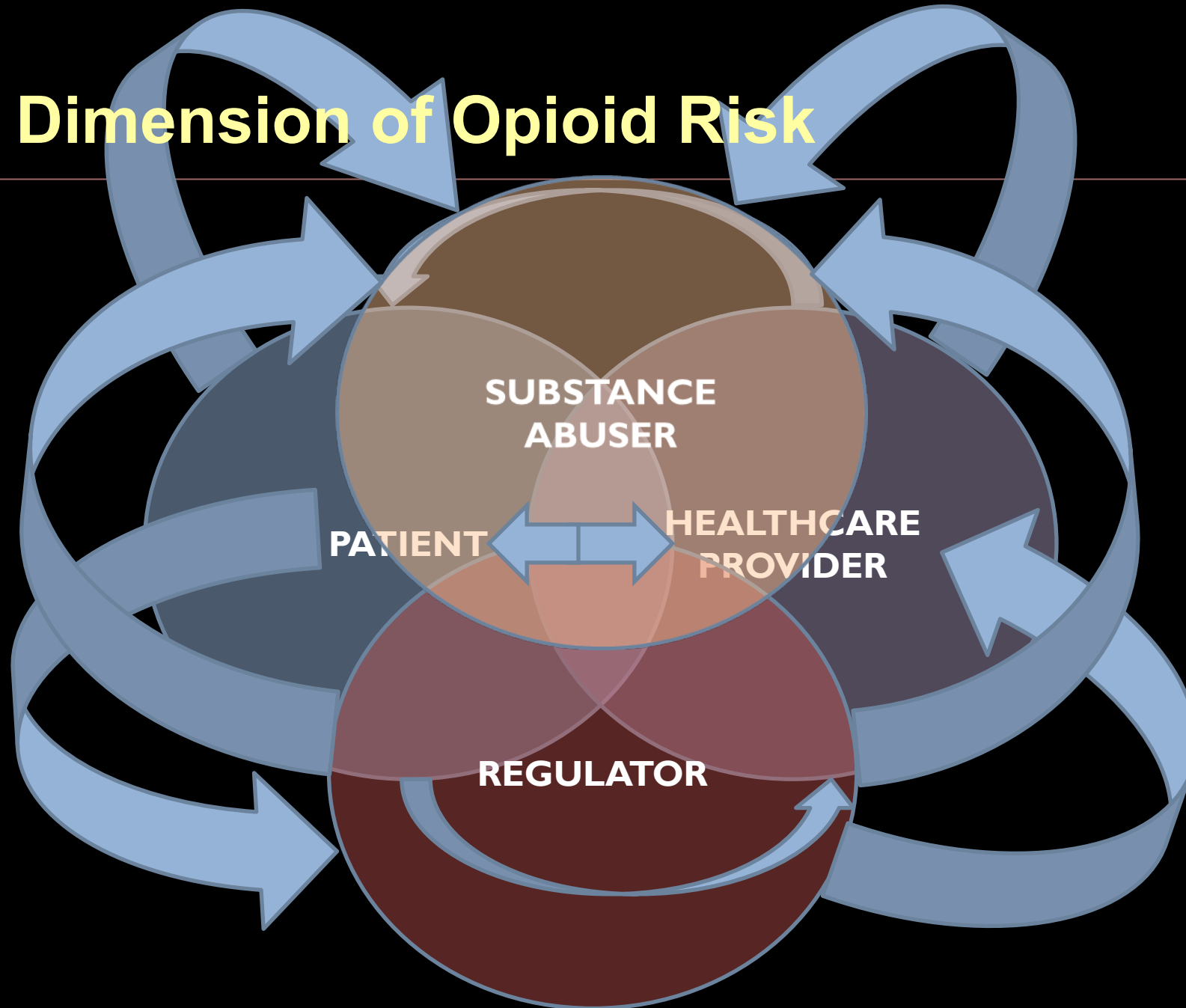
September 11, 2019



- Physicians and nurse practitioners are not the only healthcare professionals under investigation in California for involvement in patients' overdoses
- The Osteopathic Medical Board of California is investigating two cases but has not yet filed any accusations
- The Medical Board of California has also overseen investigations of 31 physician assistants; all but one of those cases are now closed.

# Another Dimension of Opioid Risk

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# Substance Use-Related Opioid Risk

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least **3** other drugs.

**Heroin** is a highly addictive opioid drug with a high risk of overdose and **death** for users.

People who are addicted to...



ALCOHOL

are

**2x**



MARIJUANA

are

**3x**



COCAINE

are

**15x**



Rx OPIOID PAINKILLERS

are

**40x**

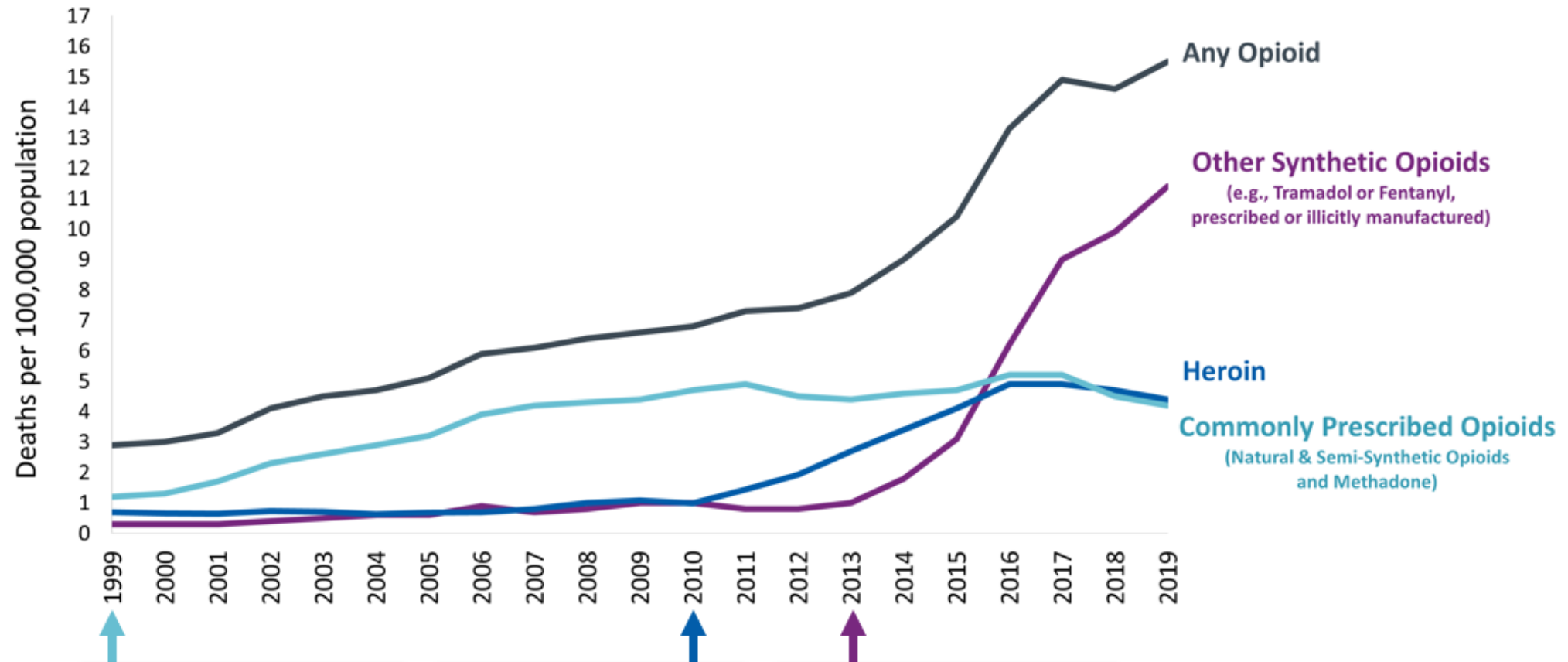
...more likely to be addicted to heroin.

SOURCE: National Survey on Drug Use and Health (NSDUH), 2011-2013.



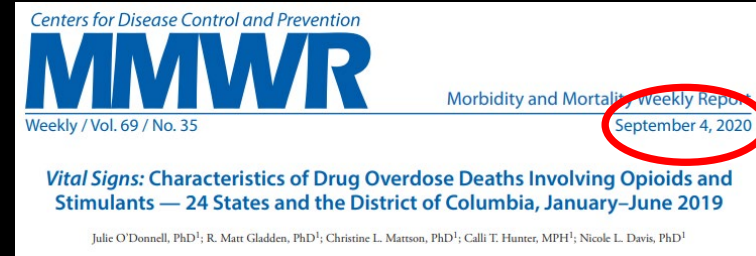
# Substance Use-Related Opioid Risk

## Three Waves of the Rise in Opioid Overdose Deaths



1. Mattson CL, Tanz LJ, Quinn K, Kariisa M, Patel P, Davis NL. Trends and Geographic Patterns in Drug and Synthetic Opioid Overdose Deaths — United States, 2013–2019. *MMWR Morb Mortal Wkly Rep* 2021;70:202–207.
2. Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers—United States, 1999–2008. *MMWR Morb Mortal Wkly Rep*. 2011 Nov 4; 60(43):1487–1492.

# Substance Use-Related Opioid Risk



- After decreasing from 2017 to 2018, provisional data indicate that drug overdose deaths **increased in 2019**, driven by opioid-involved and stimulant-involved overdose deaths
- **Illicitly manufactured fentanyls (IMFs), heroin, cocaine, or methamphetamine** (alone or in combination) were involved in **83.8% of overdose deaths during January–June 2019**; at least one potential opportunity for intervention was identified in 62.7% of overdose deaths
- Targeting crucial opportunities for intervention with evidence-based overdose prevention programs can help reverse increases in drug overdose deaths. Interventions to reduce overdose deaths involving **illicit opioids and stimulants, particularly IMFs**, are needed and should be complemented by efforts to prevent initiation of prescription drug misuse and illicit drug use.

# Substance Use-Related Opioid Risk



## Issue brief: Drug overdose epidemic worsened during COVID pandemic

**\*Updated June 1, 2021**

The nation's COVID pandemic made the nation's drug overdose epidemic worse. This issue brief highlights media and other reports showing increases in drug overdose mortality and other concerns relating to access to evidence-based care for substance use disorders, patients with pain as well as harm reduction services. The reports below cite data from multiple and varied sources, including national, state and local public health agencies, law enforcement, emergency medical services, hospitals, treatment centers, research journals and others. Every state has reported a spike or increase in overdose deaths or other problems during the COVID pandemic.

# Substance Use-Related Opioid Risk

- The most populous state, California, saw an increase in fatalities of 45.9 percent from December 2019 to December 2020, according to the new data. In Vermont, deaths rose by 57.6 percent, the largest increase in the country, followed closely by Kentucky at 53.7 percent
- Nationally, the number of overdose deaths was more than double the estimated number of motor vehicle fatalities
- *"I'm just heartbroken," National Institutes of Health Director Francis Collins said in an interview. "We have another public health crisis, of major proportions. It's not infectious, but is spreading across our county and taking far too many lives."*

## Drug overdose deaths soared to a record 93,000 last year



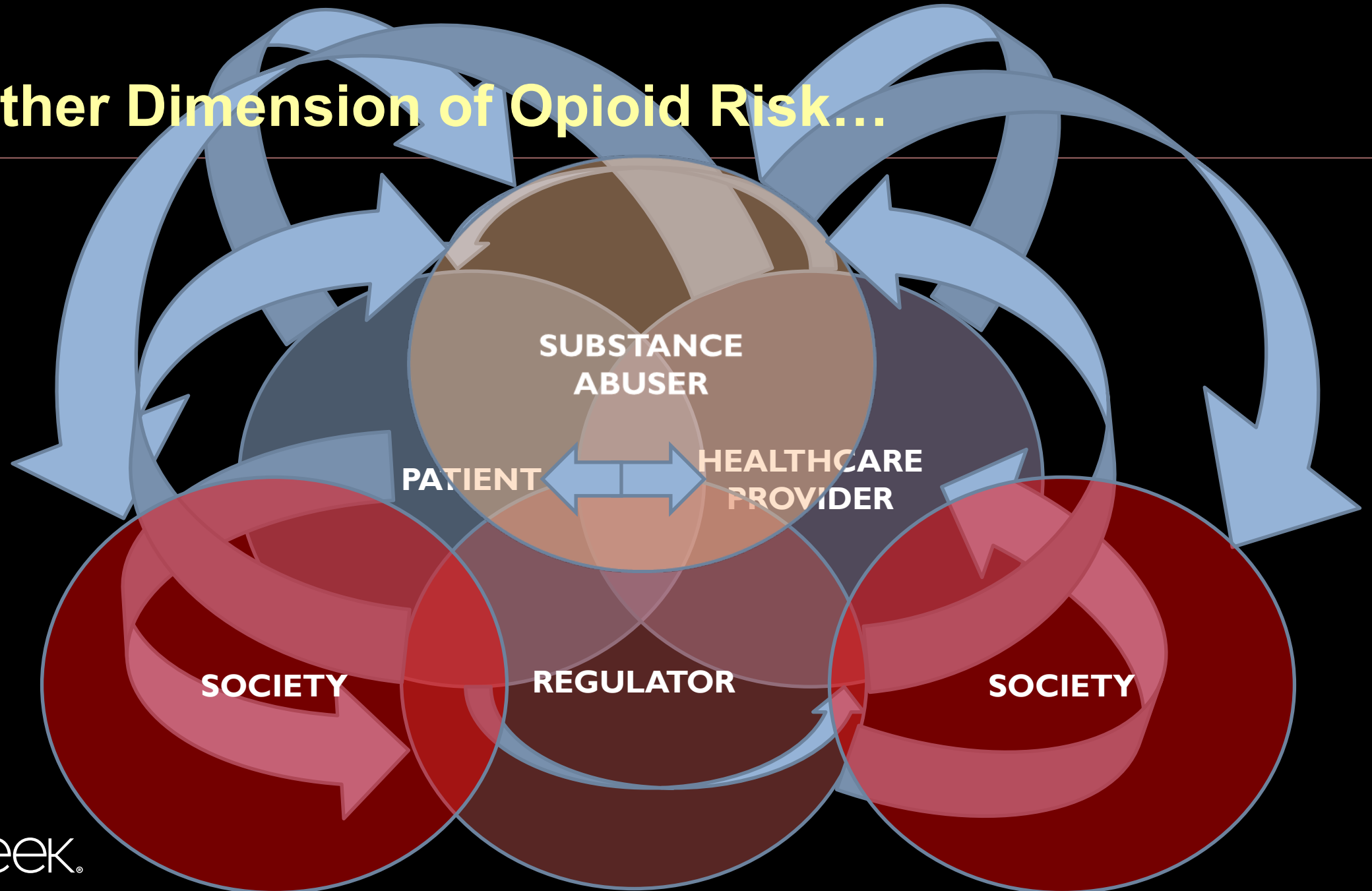
Anne Emerson, who is in recovery and a counselor for the Recovery Advocacy Project, holds a photograph of her late fiancé, who died of a fentanyl overdose, in Coon Rapids, Minn., on June 9. (Ben Brewer/Bloomberg News)

By Lenny Bernstein and Joel Achenbach

July 14, 2021 | Updated today at 3:26 p.m. EDT



# Another Dimension of Opioid Risk...



Original Investigation | Substance Use and Addiction

# Association of Opioids Prescribed to Family Members With Opioid Overdose Among Adolescents and Young Adults

Anh P. Nguyen, PhD; Jason M. Glanz, PhD; Komal J. Narwaney, PhD; Ingrid A. Binswanger, MD

## Another Dimension of Risk – Societal Opioid Risk



# Societal Opioid Risk

- Evidence suggests that the family plays an important role in the spread and consumption of prescription opioid analgesics
- Consider two distinct but linked sources of exposure and potential overdose risk:
  - Opioids prescribed to youth
  - Opioids prescribed to other family members in the household
- This study looked at 72,040 adolescents and young adults aged 11 to 26 years
- Findings:
  - Exposure to family members with opioid prescriptions in the past month increased risk of pharmaceutical overdose
    - Independent of youth being prescribed opioids

# Societal Opioid Risk

## ■ Findings (Cont'd)

- Possibly having opioids in the house provided ready access
- Family use of opioids may reflect familial modes of behavior, attitudes, and norms regarding medical and nonmedical use of opioids
- Family exposure may be a marker of problems related to parental use of opioids including:
  - Aberrant behaviors
  - Intermittent oversedation
  - Development of opioid use disorders
  - Increased levels of stress and instability

# Societal Opioid Risk

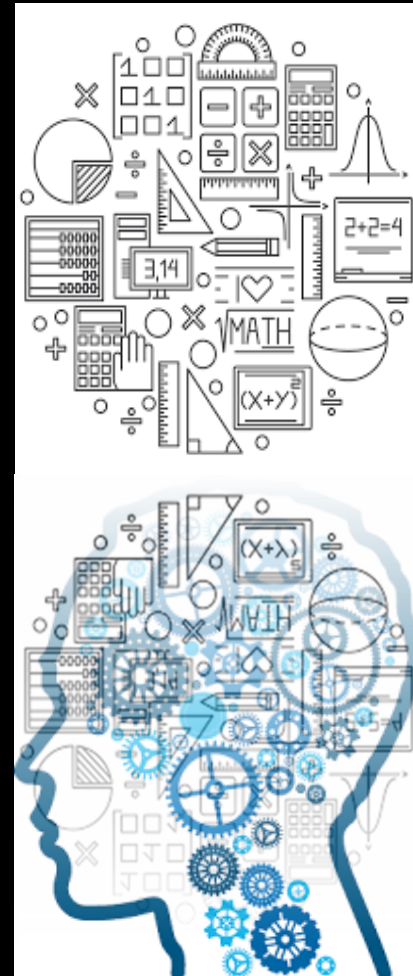
## ■ Conclusions:

- Suggestive that prescribing opioid analgesics in adult medicine practice should include:
  - Counseling patients about the risks of opioids to youth members of the household
- While reducing opioid prescriptions has been a focus of recent prevention efforts, such as the Centers for Disease Control and Prevention 2016 opioid guidelines, limiting access should be carefully balanced against the risk of:
  - Complications resulting from “volatile dosing”
  - Undertreatment of pain
- Safe storage and disposal make sense but may have unintended consequences:
  - A change in access could lead to illicit source-seeking
- Bottom line:
  - Exposure to young adult members in the household setting is **COMMON**

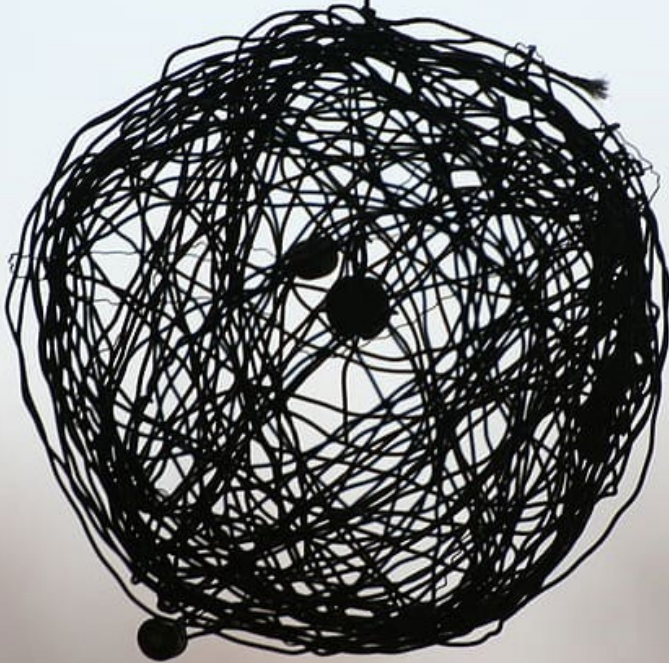


# Clinical Considerations and Implications

- The “**New Math**” for determining opioid risk/benefit analysis:
  - Much more consideration than just patient-level risk
  - Risk/Benefit analysis must consider risk to others
    - Should be included in the informed consent process
  - Should be related to whether naloxone is introduced into the household setting
    - What impact does that have on the clinical interaction?
      - COMMUNICATION
- The key things to keep in mind:
  - Context
  - The outcome of the expanded analysis calculation
  - What “Plan B” is...



# Because Here's What we Don't Want



## PATIENTS WITH CHRONIC PAIN FEEL CAUGHT IN AN OPIOID-PRESCRIBING DEBATE

ANALYSIS | BY [KAISER HEALTH NEWS](#) | AUGUST 01, 2018

Faced with skyrocketing drug overdoses, states are cracking down on opioid prescribing. Some patients with chronic pain say they are becoming collateral damage.

*This article first appeared August 01, 2018 on [Kaiser Health News](#).*

By [Will Stone, KJZZ](#)

*"What they are doing is not working. They are having no effect on the guy who is on the street shooting heroin and is really in danger of overdosing." she said. "Instead, they are hurting people that are actually helped by the drugs."*

# Questions?

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**Thank You!**