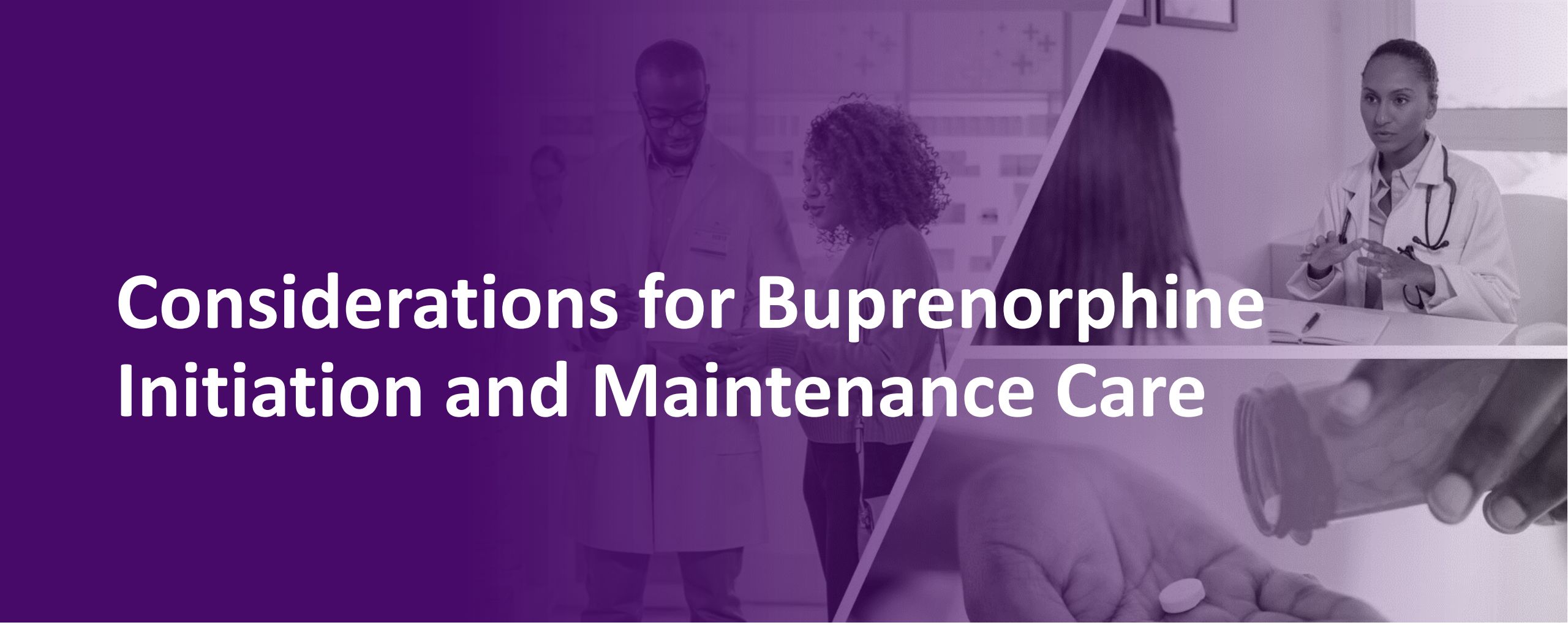

Considerations for Buprenorphine Initiation and Maintenance Care

The meeting will begin shortly

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Housekeeping

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Due to the meeting size, your microphone and video will remain off during the meeting.

This public meeting is being recorded. The slides, transcript, and video recording will be available on the FDA Foundation website after the meeting.

While we won't have time to directly address audience questions during today's meeting, you may use the Zoom chat function for comments.

Today's Agenda (Eastern Time)

REAGAN-UDALL FOUNDATION FOR THE FDA

1 p.m.	Opening Remarks and Recap of Day 1
1:05 p.m.	Session 5: Promoting Access to Buprenorphine in the Real-World Setting
2:05 p.m.	Session 6: Opportunities to Address Treatment Needs through Product Development
3:20 p.m.	Break
3:30 p.m.	Session 7: Future Directions
4:30 p.m.	Adjourn

Session 5: Promoting Access to Buprenorphine in the Real-World Setting

Presenter:

- **Barbara Andraka-Christou, PhD, JD,** University of Central Florida

Panelists:

- **Dwayne Dean, RCPF, CPRS, RPS,** Peer Recovery Training and Support Services
- **Tom Menighan, MBA, ScD, FAPhA,** American Pharmacists Association
- **Matthew Strait, MS,** Drug Enforcement Administration
- **Robert Baillieu, MD, MPH, FAAFP,** Substance Abuse and Mental Health Services Administration

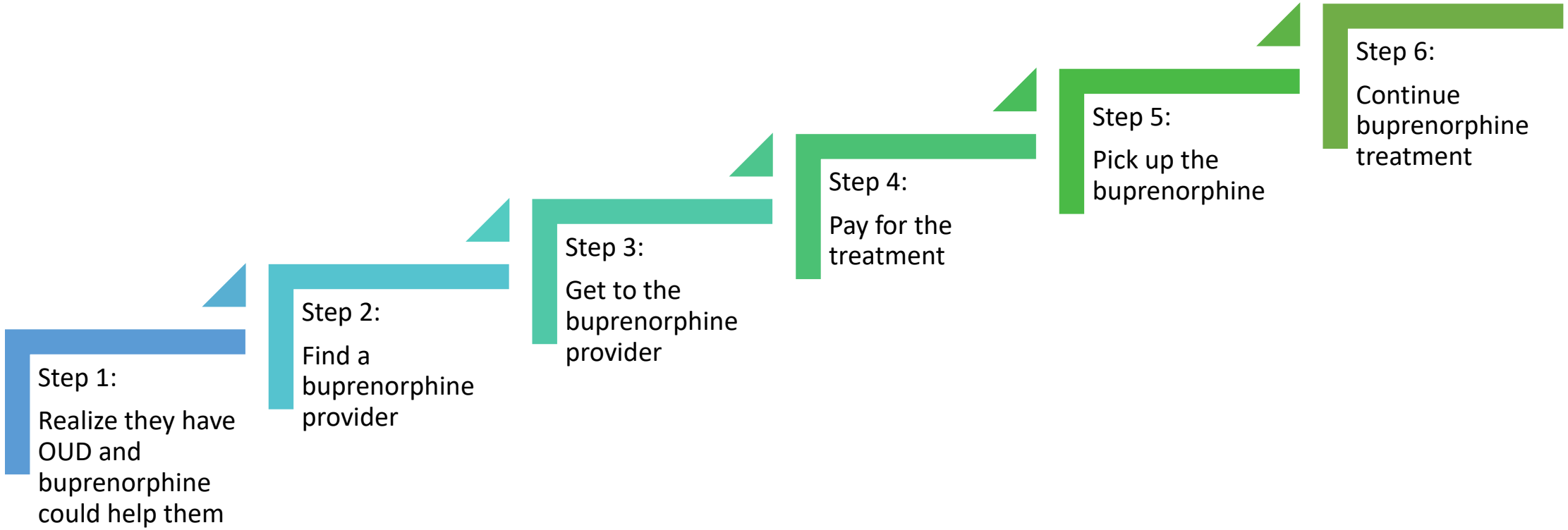
Promoting Access to Buprenorphine in the Real-World Setting

Barbara “Basia” Andraka-Christou, JD, PhD

Associate Professor, University of Central Florida

School of Global Health Management & Informatics

Steps for patients accessing buprenorphine



Step 1: Realize they have OUD and buprenorphine could help them

- Barriers:
  - OUD is very stigmatized[1]
  - Misconceptions about buprenorphine[2,3]
- Addressing barriers through policy:
  - PSA framing OUD as a health condition[4]
  - PSA about benefits of buprenorphine
  - Decriminalization of opioid[5] possession

Step 2: Find a buprenorphine provider

- Barriers:
  - Public provider lists are inaccurate[6]
  - Buprenorphine providers may not be accepting new patients or prescribing to very few patients[7]
  - Few providers in general[8], but especially in rural areas[9] & communities of color[10]
  - Limited MOUD provision in EDs[11], SUD facilities[12], & the justice system[13]
  - State restrictions on advanced practice clinician prescribing[23]
  - State-imposed buprenorphine prescribing barriers[14]
- Addressing barriers through policy:
  - Require buprenorphine education in medical schools, PA schools, and nursing schools as condition of funding
  - Expand student loan forgiveness and stipends to treat OUD in underserved areas
  - Clarify legal standard of care for OUD
  - Eliminate state-imposed prescribing buprenorphine prescribing barriers
  - States expand independence of advanced practice clinicians, including clinical pharmacist practitioners[22]
  - State laws mandating ED initiation of buprenorphine or warm-hand off[15], requiring licensed SUD facilities to provide or connect patients to buprenorphine[15], mandating justice institutions allowing buprenorphine[16]

Step 3: Get to the buprenorphine provider

- Barriers:
  - Transportation[17,18]
  - State-mandated frequency of visits[14]
  - Lack of reliable Internet access for telehealth[19]
- Addressing barriers through policy:
  - Maintain pandemic-era telehealth flexibilities
  - Improve WIFI access in rural areas and communities of color
  - Eliminate visit frequency mandates (beside basic refill restrictions for Sch. III CS)

Step 4: Pay for the treatment

- Barriers:
  - Providers only accepting cash[6]
  - Providers not accepting Medicaid[6]
  - Providers accepting Medicaid, but patient lives in non-expansion state
  - Low coverage of and prior auth requirements for XR formulation[20]
- Addressing barriers through policy:
  - State law mandate coverage of buprenorphine, including XR[21]
  - State law prohibit prior authorization for buprenorphine[21]
  - All states expand Medicaid
  - Higher reimbursement in Medicaid

Step 5: Pick up the buprenorphine treatment

- Barriers:
  - Limited supply of buprenorphine in community pharmacies[24] and hospitals[25]
  - Stigmatization of buprenorphine patients[16]
- Addressing barriers through policy:
  - Mandatory buprenorphine education in pharmacy schools
  - Clarify standard of care for stocking buprenorphine
  - Policies for expanding access to XR formulations

Step 6: Continue buprenorphine treatment

- Barriers:
  - All the barriers previously mentioned
  - Housing instability[27]
  - Misconception that short-term buprenorphine is better than long-term[26]
  - “High threshold” treatment
  - Sober living homes requiring cessation
- Addressing barriers through policy:
  - PSA about long-term buprenorphine effectiveness
  - Increase housing access for low-income populations
  - State laws mandating sober living homes accepting people using buprenorphine[15]

Imagine if these barriers existed to lifesaving treatment for other deadly health conditions (e.g., diabetes)

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Session 5: Promoting Access to Buprenorphine in the Real-World Setting

Presenter:

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Panelists:

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- **Tom Menighan, MBA, ScD, FAPhA,** American Pharmacists Association
- **Matthew Strait, MS,** Drug Enforcement Administration
- **Robert Baillieu, MD, MPH, FAAFP,** Substance Abuse and Mental Health Services Administration

Session 6: Opportunities to Address Treatment Needs through Product Development

Presenter:

- **Kelly Dunn, PhD, MBA, MS,** John Hopkins University

Panelists:

- **Pouya Azar, MD,** Vancouver General Hospital
- Harm Reduction Michigan
- **Bartholt Bloomfield-Clagett, MD,** U.S. Food and Drug Administration
- **Jody Green, PhD, MA,** Uprise Health
- **Iván Montoya, MD, MPH,** National Institute on Drug Abuse
- **Michelle Winberg,** Harm Reduction Michigan

Opportunities to Address Treatment Needs Through Product Development

Kelly Dunn, Ph.D., MBA
Johns Hopkins University School of Medicine

Disclosures past 3 years: Consulted for Cessation Therapeutics; DemeRx; Mind Med, Inc.

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Current Epidemiological Trends

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- Unprecedented rates of drug poisonings

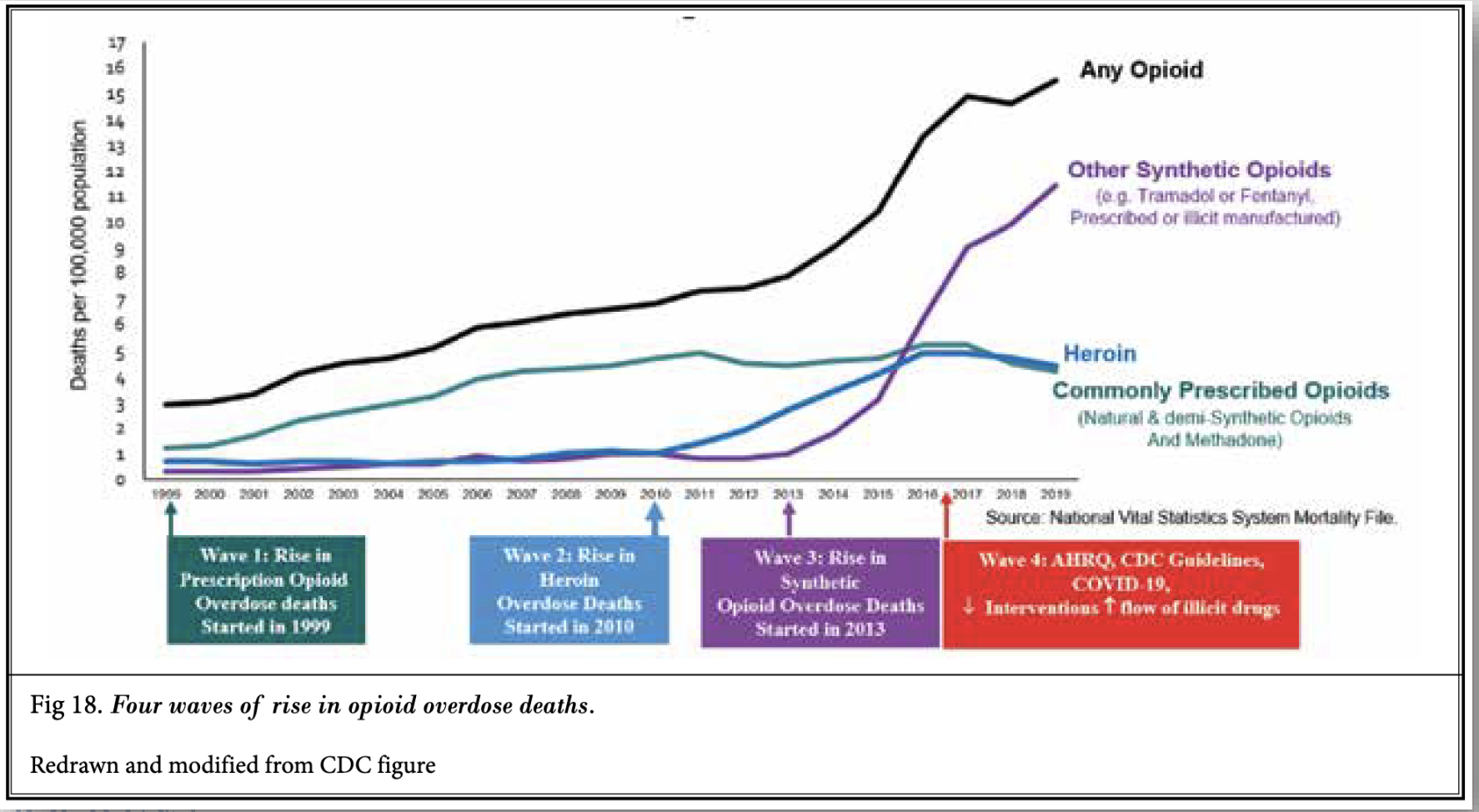

Fig 18. *Four waves of rise in opioid overdose deaths.*

Redrawn and modified from CDC figure

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Manchikanti et al., 2022, Pain Physician

Current Epidemiological Trends

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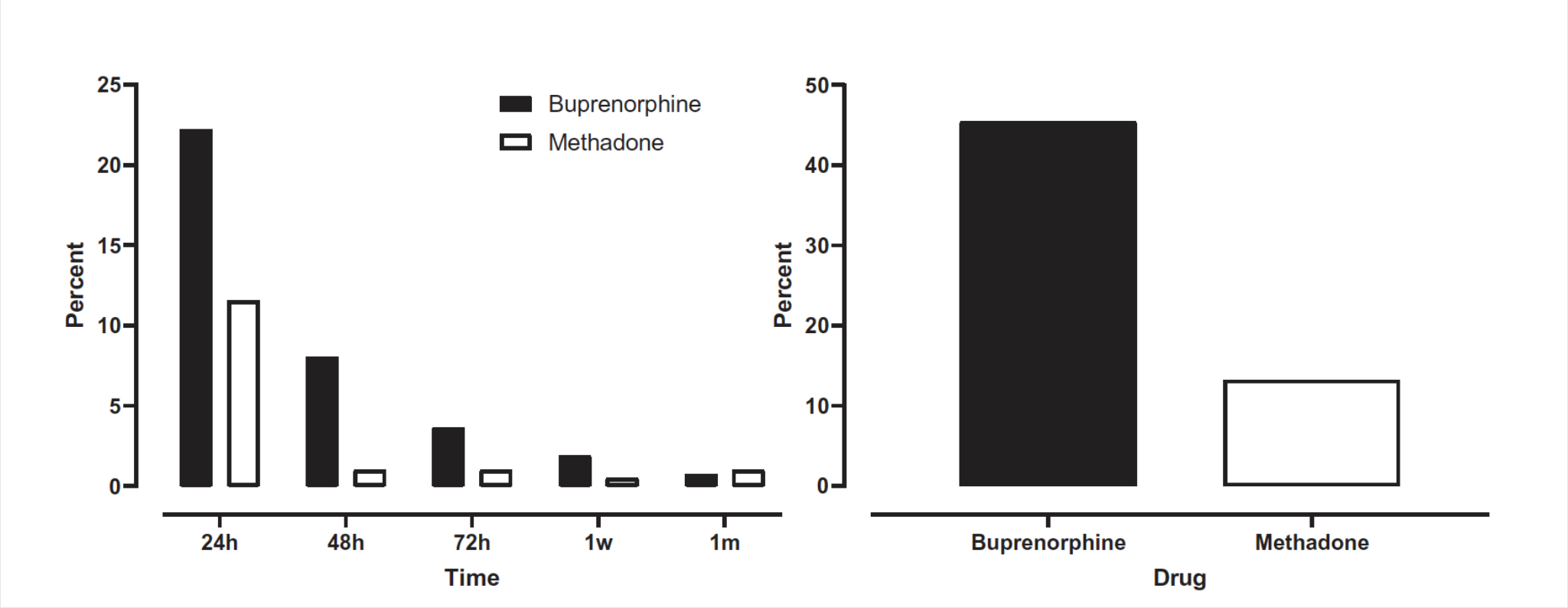
- Buprenorphine is likely interacting with illicit fentanyl and causing precipitated withdrawal



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Varshneya et al.., 2022, J Addiction Medicine

Current Epidemiological Trends

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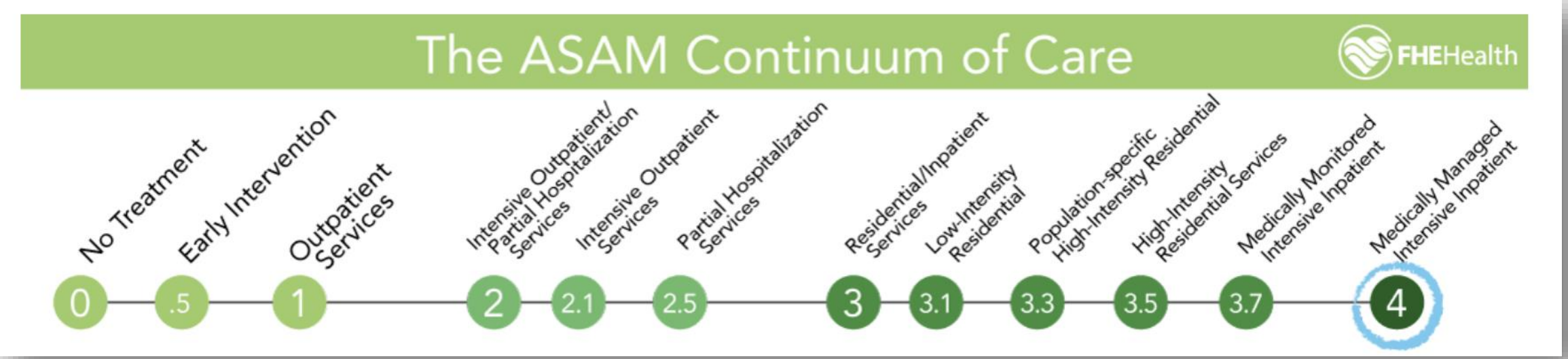
- There is a robust treatment continuum and existing medications for OUD…



…but we lack good outcomes assessments, ability to match to treatment intensity, and/ability to predict relapse/success

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Where can innovation help most?

Current Unmet Need

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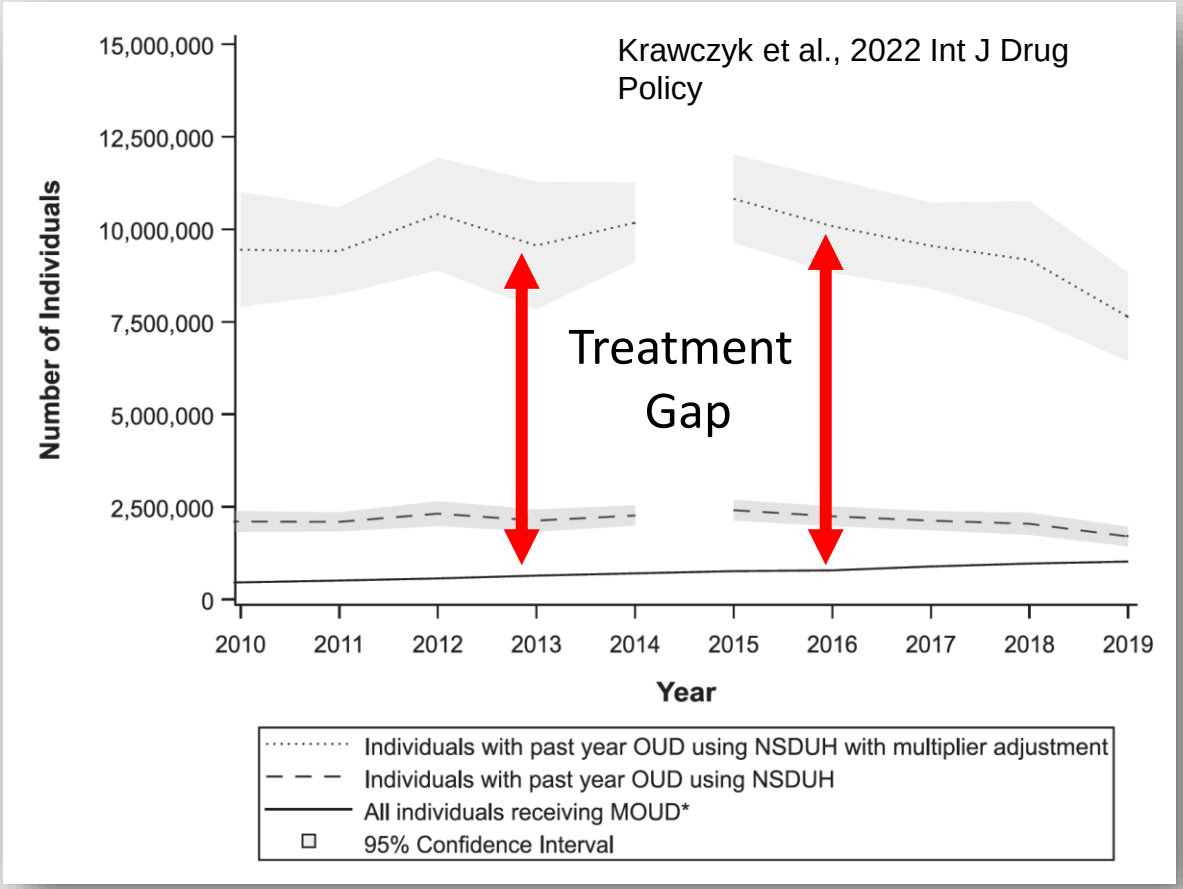
Buprenorphine is our most scalable treatment model

Current Provider Barriers :

- Lack of time to take on new patients
- Concern about precipitating withdrawal
- Concerns about diversion



Huhn & Dunn, 2017, JSAT

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Current Unmet Need

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1. We need novel strategies to support comfortable induction onto buprenorphine (especially following fentanyl)

Low Dose Strategy
- Need doses <2mg
- Transdermal or buccal dosing?

High Dose Strategy
- Mono-products?
- High doses?

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2. Precipitated Withdrawal Management

- Short-acting opioids as a bridge (?)
- Opioid-like medications that have lower potency (tramadol? Kratom?)
- Non-opioid adjunctive/support medications (ketamine?)

- Induction protocols
- Structured provider training and/or mentoring (ECHOs, hub-and-spoke models?)

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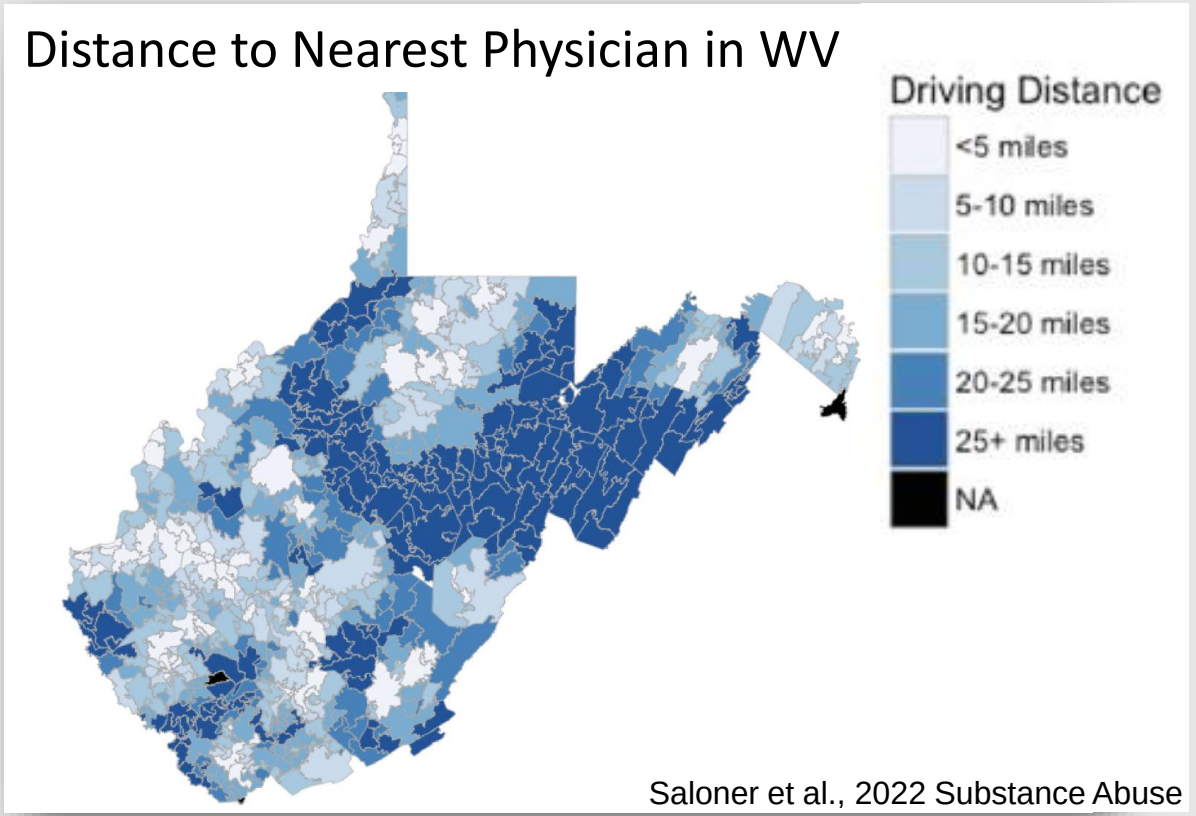
3. Increase treatment access in rural settings, support remote medication management

- Opioid problems further exacerbated by high rates of comorbid mental illness, chronic pain
- Women less likely than men to enter treatment



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4. Expansion might be addressable with extended-release formulations

Buprenorphine is available in ER weekly or monthly formulations

However…

- Induction and eligibility for treatment can be challenging
- Distribution may require specialty pharmacies
- Complex payer structures
- Physician and patient adoption currently low

Current Unmet Need

MOR

5. Increase provider confidence by reducing diversion risk

- Novel packaging or monitoring can provide secure and remote medication management

Emocha

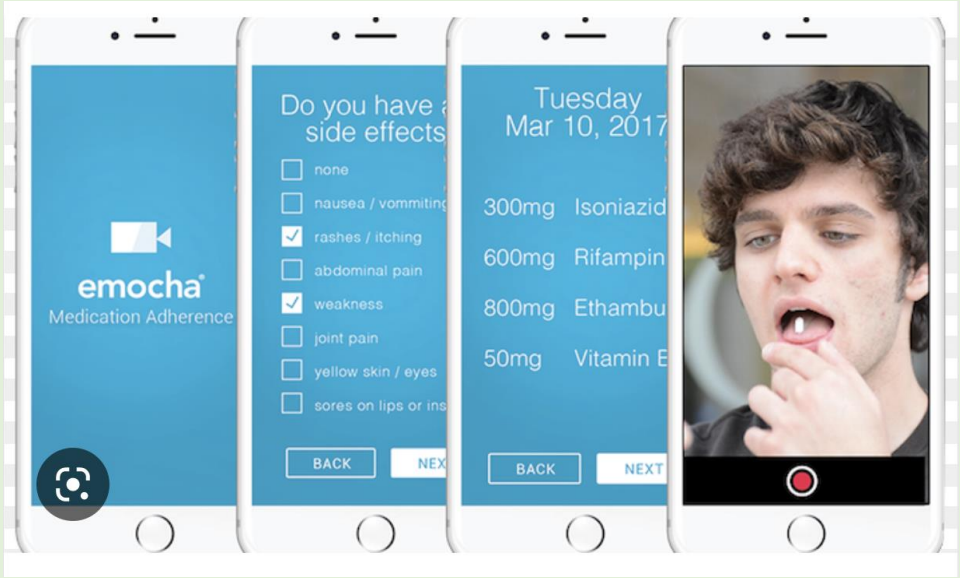

Image from mobihealthnews.com

MedMinder

Image from MedMinder

Pippa Tipper Dispenser

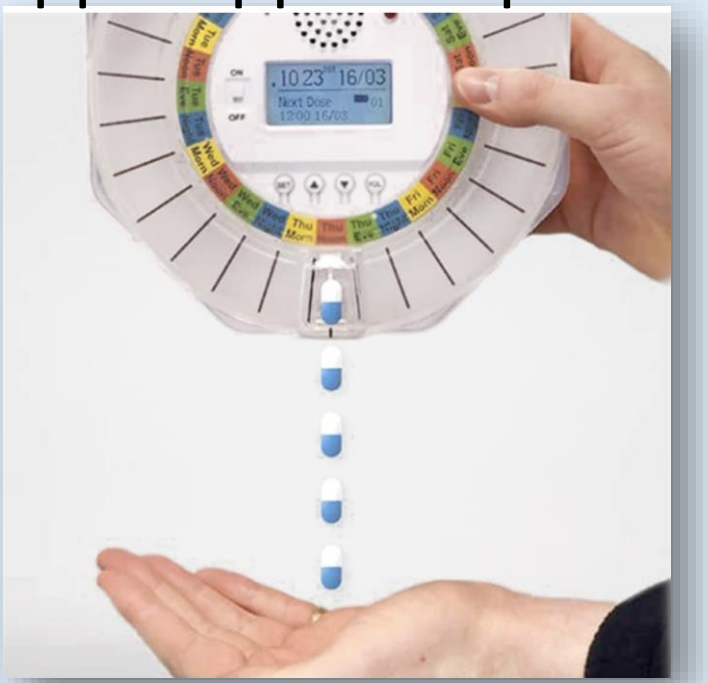

Image from The Alzheimer's Store

6. Treat complex clinical presentations

- We need treatments for polysubstance (stimulant) use
  - Novel medications and/or expanded access to behavioral strategies such as contingency management
- Expand access to psychosocial counseling
  - Digital therapeutics?
  - Telemedicine expansion?
- Comorbid chronic pain
- Manage cravings

DEA, SAMHSA Extend COVID-19 Telemedicine Flexibilities for Prescribing Controlled Medications for Six Months While Considering Comments from the Public

Tuesday, May 9, 2023

Examples of Innovation

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Innovative approaches currently being studied:

- Biosensors to detect craving, withdrawal, overdose
- The “naloxone parachute” to administer naloxone automatically
- Pivoting devices from analgesia to opioid use (e.g., Percutaneous nerve field stimulators for opioid withdrawal and/or pain)
- Psychedelic treatment of OUD
- Predictive algorithms to match patients to treatment intensity
- Digital therapeutic products
- Chat-bot based counseling
- Virtual reality based interventions

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Conclusions

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We cannot adequately solve our current substance use crises by employing the same existing strategies

We need new ideas and big thinkers who can introduce new approaches and ways of thinking

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Conclusions

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Kelly E. Dunn: kdunn9@jhmi.edu ,
www.MarylandOpioidResearch.com

Also visit Innovations for Substance Use Disorder (I4SUD): NIDA-funded entrepreneurial training program: www.i4sud.com

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Session 6: Opportunities to Address Treatment Needs through Product Development

Presenter:

- **Kelly Dunn, PhD, MBA, MS,** John Hopkins University

Panelists:

- **Pouya Azar, MD,** Vancouver General Hospital
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- **Bartholt Bloomfield-Clagett, MD,** U.S. Food and Drug Administration
- **Jody Green, PhD, MA,** Uprise Health
- **Iván Montoya, MD, MPH,** National Institute on Drug Abuse
- **Michelle Winberg,** Harm Reduction Michigan

We are taking a short break

The meeting will resume at 3:30 pm ET

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Session 7: Future Directions

Panelists:

- **Brian Clear, MD,** Bicycle Health
- **Michelle Lofwall, MD, DFAPA, DFASAM,** University of Kentucky
- **Yngvild K. Olsen, MD, MPH,** Substance Abuse and Mental Health Services Administration
- **Marta Sokolowska, PhD,** U.S. Food and Drug Administration
- **Nora Volkow, MD,** National Institute on Drug Abuse

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