Statistical questions, and challenges, for estimating the effect of opioid-related policies and programs

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Acknowledgments

- Bloomberg American Health Initiative
- Bloomberg Opioid Initiative and partners (Pew Charitable Trusts, Vital Strategies, CDC Foundation)
- JHSPH colleagues (Brendan Saloner, Beth McGinty, Colleen Barry, Lainie Rutkow, Sachini Bandara, etc.)
- National Institute of Drug Abuse (NIDA)
- NOTE: WORK IN PROGRESS!!!

Outline

- What is the current state of the crisis?
- Project 1: State policy evaluation
- Project 2: Focused initiatives in specific states
- Conclusions/points of consideration

The Opioid Epidemic Is Hard to Miss

The New York Times

The Class of 2000 'Could Have Been Anything'

The high school yearbook is a staple of teenage life. But for some, it reflects the devastating toll of the opioid crisis.

SAN DIEGO LOCAL WEATHER INVESTIGATIONS SPORTSWRAP THE SCENE ENTERTAINMENT

San Diego Walgreens Contributed to Opioid Crisis: DEA

Around the height of the opioid epidemic in 2009, drug giant Walgreens handled nearly 1 in 5 oxycodone and hydrocodone pills

25°

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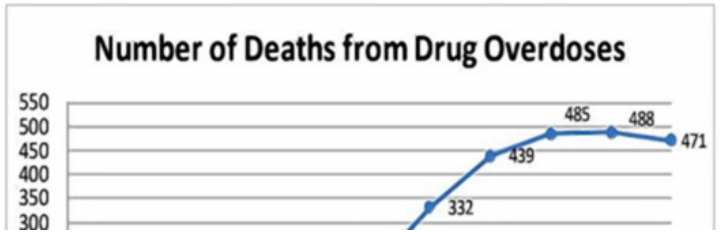
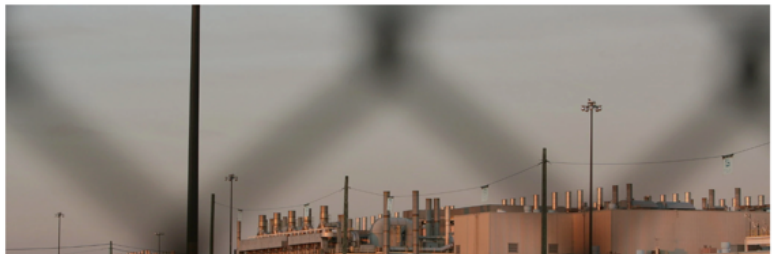
Toxic cocktail: Overdose deaths from mixing fentanyl with other drugs on the rise in N.H.



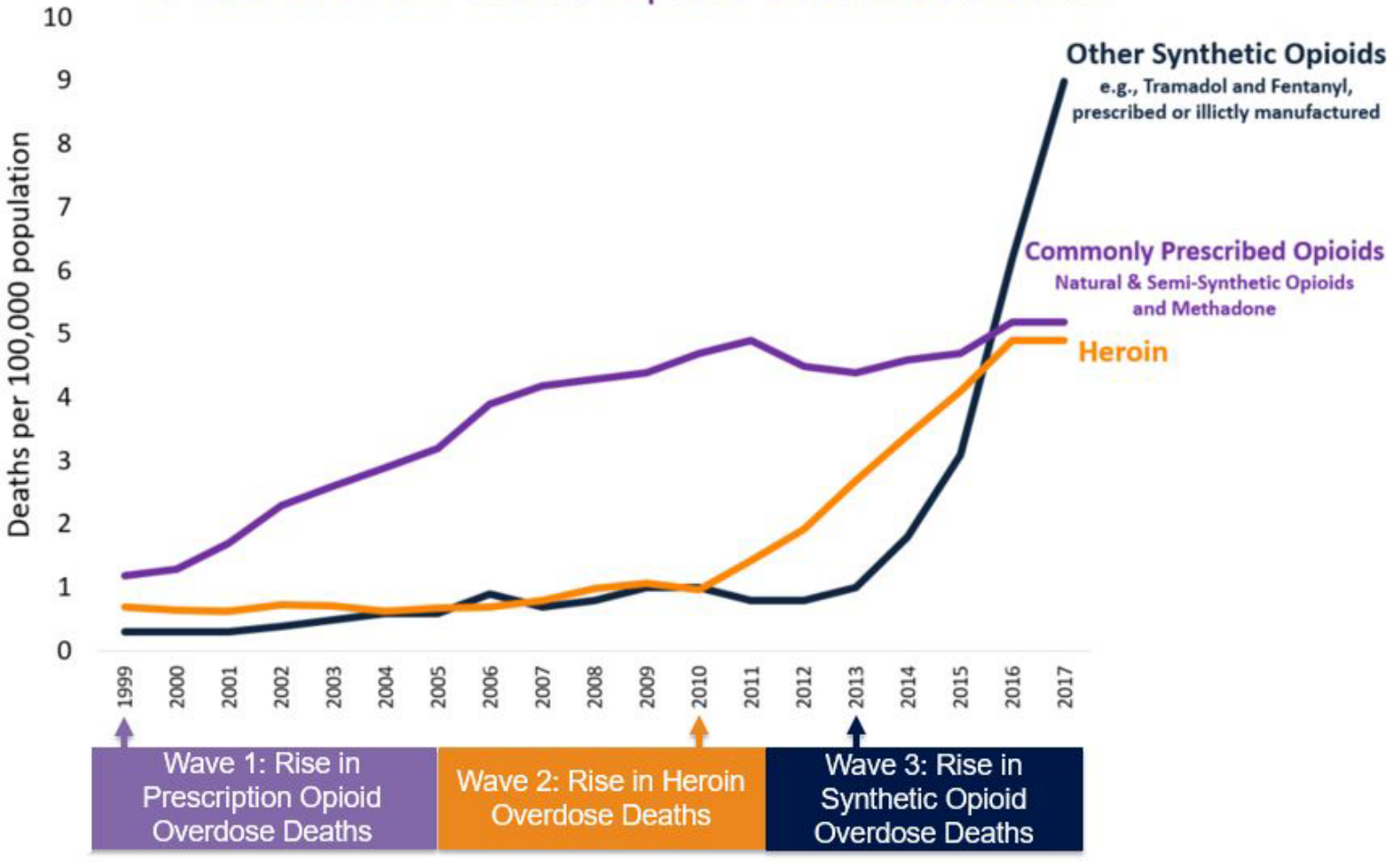
The New York Times

Opioid Deaths Rise When Auto Plants Close, Study Shows

Research found 85 percent more deaths among those of prime working age in places where car factories closed compared with where they stayed open.



3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

Major Barriers to Combat Epidemic

1. High rates of stigma
2. Lack of understanding that opioid addiction is a chronic, relapsing illness, but responsive to evidence-based medication treatment
3. Poor access to medication treatment in most communities in America
4. The epidemic is evolving

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State opioid prescribing laws

- Many states have implemented policies that aim to limit inappropriate opioid prescribing

- Four main types:
  - Mandatory enrollment in Prescription Drug Monitoring Programs (PDMP): 22 states
  - Mandatory PDMP query laws: 33 states
  - Pill mill laws, to regulate pain clinics and prevent rogue clinics: 11 states
  - Opioid prescribing caps laws, which limit prescriptions: 35 states

- Aim to reduce inappropriate prescribing but concerns also about whether will restrict access to opioids for those who need them (e.g., chronic pain)

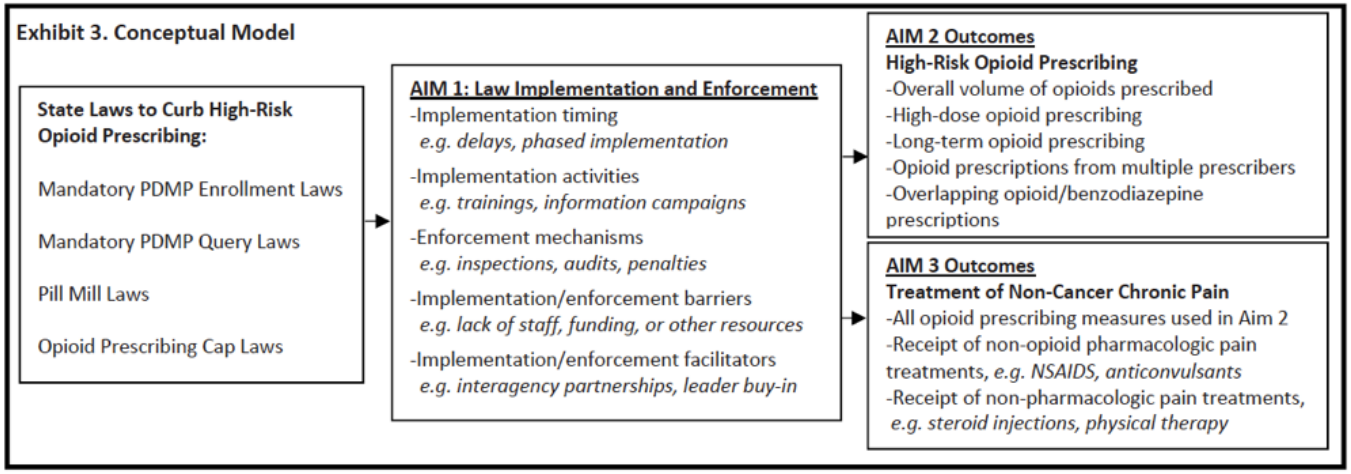
Study aims (PI's: Beth McGinty, Lainie Rutkow, JHSPH)

1. Characterize the implementation and enforcement of these laws
    1. Qualitative interviews in 16 treatment states
    2. Little examination so far of how implementation and enforcement varies (but likely varies quite a bit)

2. Study the effects of these laws on opioid prescribing patterns
    1. Will use information from Aim 1 on implementation and enforcement to understand whether effects vary by enforcement levels

3. Study the effects of these laws on treatment of non-cancer chronic pain
    1. 3 conditions: lower back pain, headache, fibromyalgia
    2. Clinical guidelines have concluded opioid risks often outweigh benefits for these conditions
    3. Expect reductions in opioid prescriptions and increases in non-opioid pharmacologic and non-pharmacologic treatments (steroid injections, physical therapy)

Some of the challenges/opportunities…



- Prior studies haven't looked at implementation
- Some states implement multiple laws around the same time, or over time, but so then have different policy environments/combinations of laws

Data available

- Qualitative interviews (Aim 1)
- QuintilesIMS LifeLink LRx/Dx prescription and outpatient claims data (Aims 2 and 3)
  - 88% of all US retail prescriptions
  - Linked to patients and prescribers over time; uses a patented algorithm to link prescriptions to patients
  - Includes diagnosis codes
  - Claims-level data
- Data will be analyzed at the state-month level
  - e.g., overall volume of opioid prescribing (MME) per patient, indicators of dangerously high daily dose, long-term prescriptions, prescriptions from multiple providers
- 16 total “treatment” states

Statistical methods

- Synthetic control
  - Goal: Find a weighted combination of other states that matches the pre-law outcomes and covariates in each of the treated states
  - Weights formed to minimize the mean squared prediction error between pre-law trends in treatment and (weighted) comparison states
  - Note: Will likely evolve and use methods that also combine an outcome model with this

- For each "treatment" state that implemented one of the 4 laws of interest:
  - Ensure 2 years "pre" and 2 years "post" data
  - Ensure no no other state laws that could influence opioid prescribing during that window
  - Find all potential comparison states with the same opioid prescribing laws as the treatment state for the entire study period (except the law of interest)

- Will generate 16 state-specific effect estimates
  - Small samples, but correlate law implementation with impacts
  - Although this may be a bad idea/ particularly challenging!

Challenges/complications

- Small samples (N=16 states)
  - How can we best capitalize on the qualitative data?
  - How to make this truly “mixed methods”?
- Lots of questions about how to construct the synthetic control
  - Which covariates
  - How to weight covariates vs. outcomes in the MSPE calculation
  - How to best combine weighting approach with outcome model
  - See my talk tomorrow!!
- Best time-scale to use?
  - Monthly? Quarterly? Annual? Daily???

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Bloomberg Opioids Initiative

Deep Focus States

- November 30th: At Bloomberg American Health Summit, Mike announced along with Governor Wolf that Pennsylvania will be first state to join our opioid program and will receive $10 million in support

- March 14th: Mike announces along with Governor Whitmer that Michigan will be the second state selected to join our opioid program and will also receive $10 million in support

Technical Support States

- District of Columbia (March 2019)
- New Jersey (June 2019)
- West Virginia (August 2019)
- New Mexico (November 2019)

What is the Hopkins evaluation role?

- Program evaluation
- NOT “is this initiative working overall?”
  - That would be very challenging given the multitude of programs and policies happening in states across the country, and various new federal funding sources
- RATHER: “What are some generalizable lessons we can obtain from pieces of the initiative to help other localities?”

So how are we doing that?

- LOTS of phone calls….
- Even when you're "on the ground" from Day 1, program and policy implementation is challenging
  - Lots of time for partners (Vital Strategies, Pew) to work with state partners to develop promising and appropriate programs
- Data hard to come by
  - Some resources: e.g., Alleghany County has a great data linkage system, Medicaid claims data may be available
  - But often little data available on the outcomes being targeted (e.g., transitions from correctional facilities out, ensuring continuity of care, harm reduction strategies including naloxone distribution)

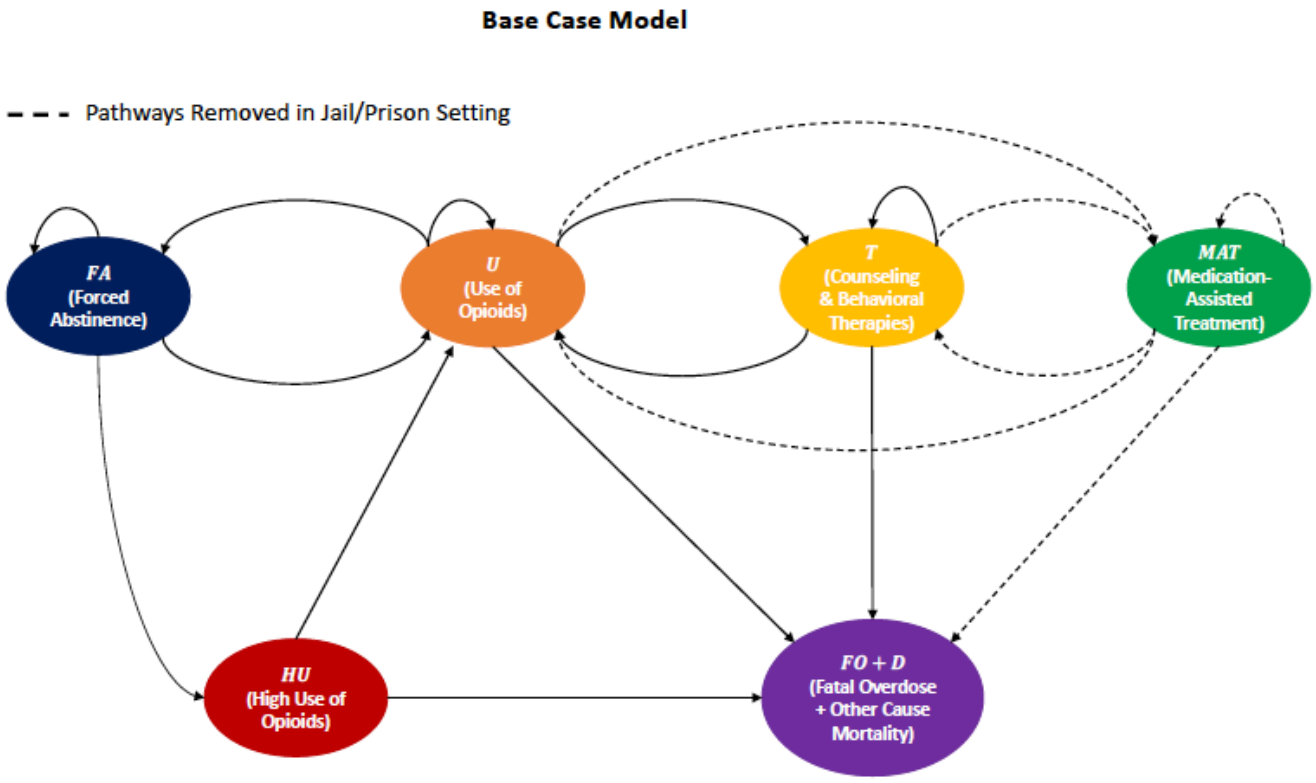
What does this look like so far?

- Lots of qualitative work
  - e.g., qualitative interviews to understand implementation of buprenorphine treatment in PA emergency departments
  - e.g., qualitative interviews to understand roll-out of buprenorphine treatment by EMT's in ambulances in Camden, NJ
- Hopefully some capture-recapture based approaches to study hard to reach populations in specific areas, to study harm reduction strategies such as safe consumption sites
- Some use of large-scale national datasets to understand trends
  - e.g., using national data on substance use treatment facilities to understand treatment capacity
  - e.g., looking at use of medication for opioid use disorder among Native American populations

An aside: “Evaluation”

- One challenge has been different use of the term “evaluation”
- For some, descriptive data on whether programs being implemented
- For others, deep process evaluation, including qualitative interviews, investigation
- For others (us?!), impact evaluation aiming to really understand the effects of some program or policy

Systems model of medication treatment in criminal justice settings



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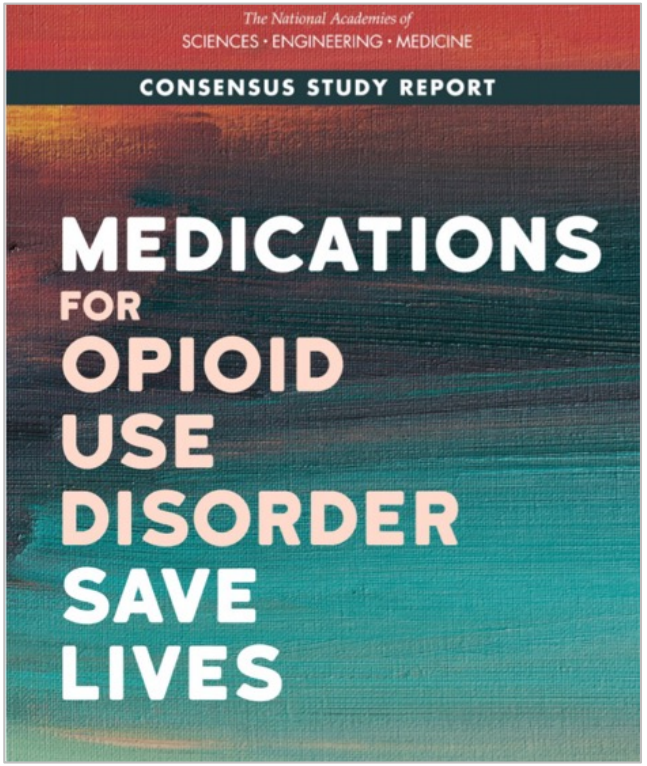
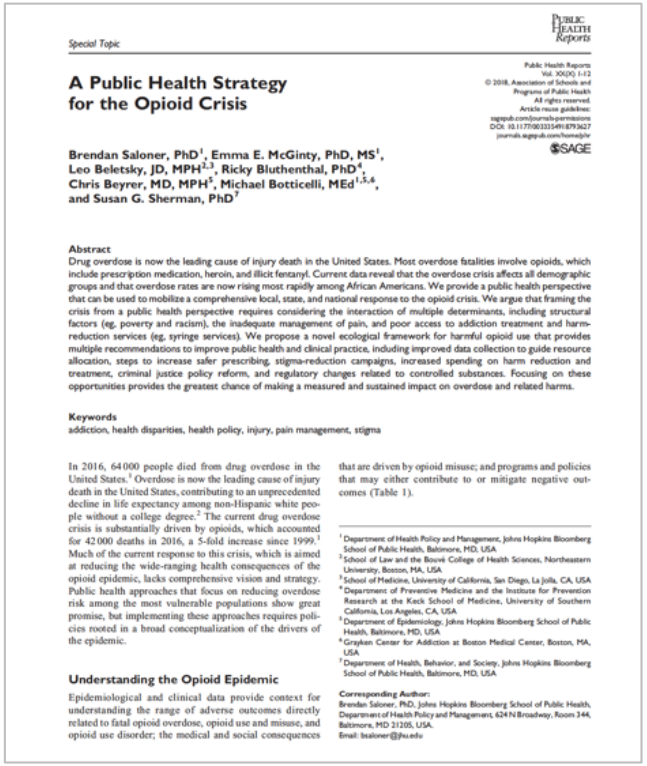
What is the role of statisticians?

- Advocate for rigorous data collection
- Advocate for thoughtful program implementation, when possible
  - e.g., randomize sites to get program first
- Most needs are fairly basic statistical approaches!
  - How do we balance desire for rigorous and innovative methods with the state of where the current state of the science is?
- But mostly, patience…
  - Not sure why, but we are often viewed with skepticism and nervousness
  - (I think that we will come in and say “you have to randomize, and give us all your data” and then walk away)

To learn more…





Special Topic

Public Health Reports

A Public Health Strategy for the Opioid Crisis

Public Health Reports
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Abstract

Drug overdose is now the leading cause of injury death in the United States. Most overdose fatalities involve opioids, which include prescription medication, heroin, and illicit fentanyl. Current data reveal that the overdose crisis affects all demographic groups and that overdose rates are now rising most rapidly among African Americans. We provide a public health perspective that can be used to mobilize a comprehensive local, state, and national response to the opioid crisis. We argue that framing the crisis from a public health perspective requires considering the interaction of multiple determinants, including structural factors (eg, poverty and racism), the inadequate management of pain, and poor access to addiction treatment and harm-reduction services (eg, syringe services). We propose a novel ecological framework for harmful opioid use that provides multiple recommendations to improve public health and clinical practice, including improved data collection to guide resource allocation, steps to increase safer prescribing, stigma-reduction campaigns, increased spending on harm reduction and treatment, criminal justice policy reform, and regulatory changes related to controlled substances. Focusing on these opportunities provides the greatest chance of making a measured and sustained impact on overdose and related harms.

Keywords

addiction, health disparities, health policy, injury, pain management, stigma

In 2016, 64 000 people died from drug overdose in the United States.[1] Overdose is now the leading cause of injury death in the United States, contributing to an unprecedented decline in life expectancy among non-Hispanic white people without a college degree.[2] The current drug overdose crisis is substantially driven by opioids, which accounted for 42 000 deaths in 2016, a 5-fold increase since 1999.[1] Much of the current response to this crisis, which is aimed at reducing the wide-ranging health consequences of the opioid epidemic, lacks comprehensive vision and strategy. Public health approaches that focus on reducing overdose risk among the most vulnerable populations show great promise, but implementing these approaches requires policies rooted in a broad conceptualization of the drivers of the epidemic.

Understanding the Opioid Epidemic

Epidemiological and clinical data provide context for understanding the range of adverse outcomes directly related to fatal opioid overdose, opioid use and misuse, and opioid use disorder; the medical and social consequences that are driven by opioid misuse; and programs and policies that may either contribute to or mitigate negative outcomes (Table 1).

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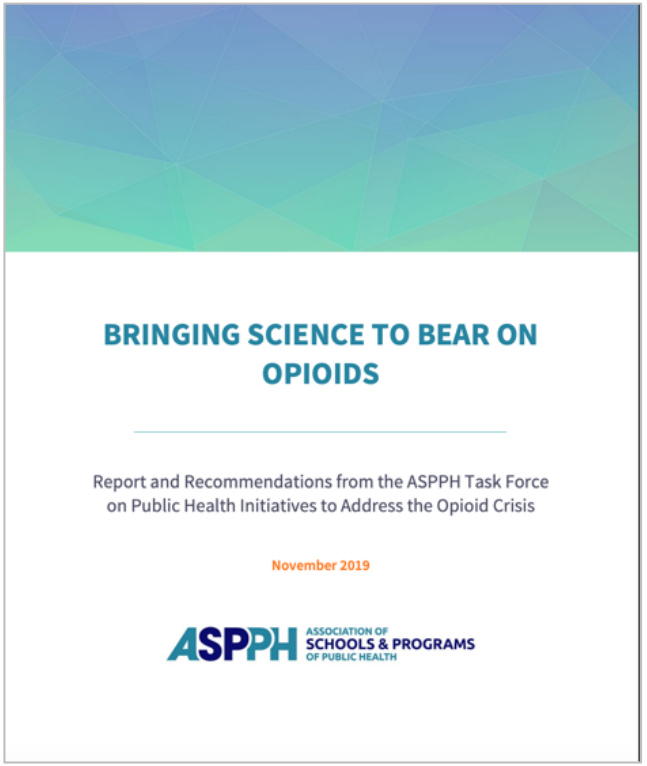
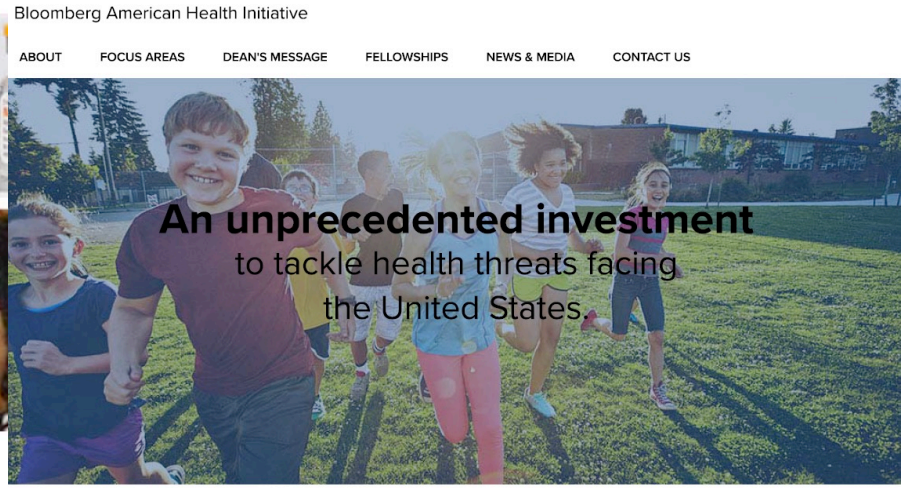


And to talk up work and opportunities at Hopkins…post-doc openings currently too!

Reach out @lizstuartdc, estuart@jhu.edu

Center for Mental Health and Addiction Policy Research



https://www.jhsph.edu/about/bloomberg-american-health-initiative/index.html

https://www.jhsph.edu/research/centers-and-institutes/center-for-mental-health-and-addiction-policy-research/index.html

Public health is rising to the challenge… again.