Hepatitis C in US Correctional Facilities—
Making Molehills out of Mountains

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Acknowledgements/Potential COI

- National Science Foundation Grant: #1722906
- Past funding: Gilead, Abbvie, Merck—none currently

Objectives:

After attending, audience will be able to understand a mountain of information:

To explain the challenges that the US has with enumerating the cases of hepatitis C in its criminal justice (CJ) system

To outline several strategies for CJ systems to obtain medication at a reduced cost, below Average Manufacturer's Price.

To describe how the incarceration epidemic impedes hepatitis C elimination in the US

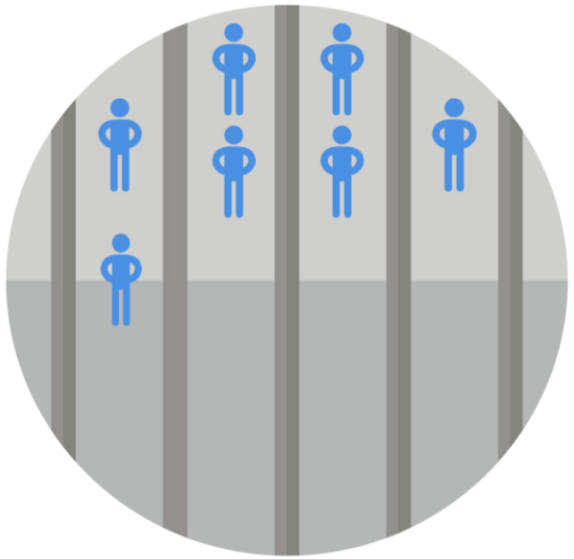
Surveillance

Challenges enumerating cases of hepatitis C in US criminal justice (CJ) system

Defining terms and assigning numbers: denominator

At a single point in time in the US

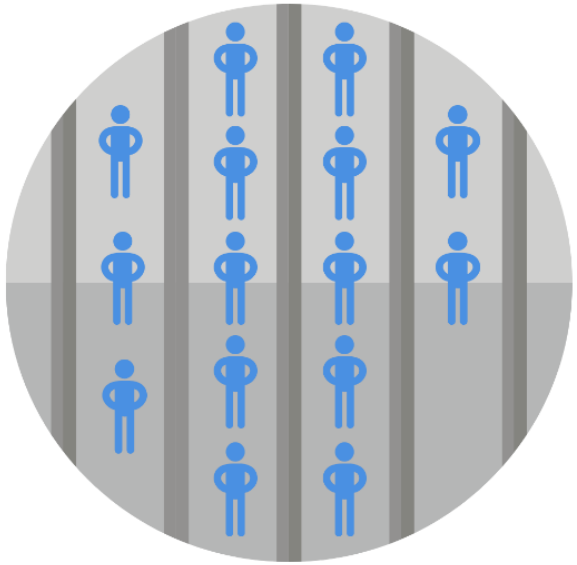
JAIL: Short stay



N= 0.7 Million

Approximately twice as many people are in prison than jail on any given day nationwide; ratio differs state by state

PRISON: Long stay



N= 1.5 Million

$$\sum = \quad 2.2 \text{ Million}$$

Source: Bureau of Justice Statistics (2016 data)

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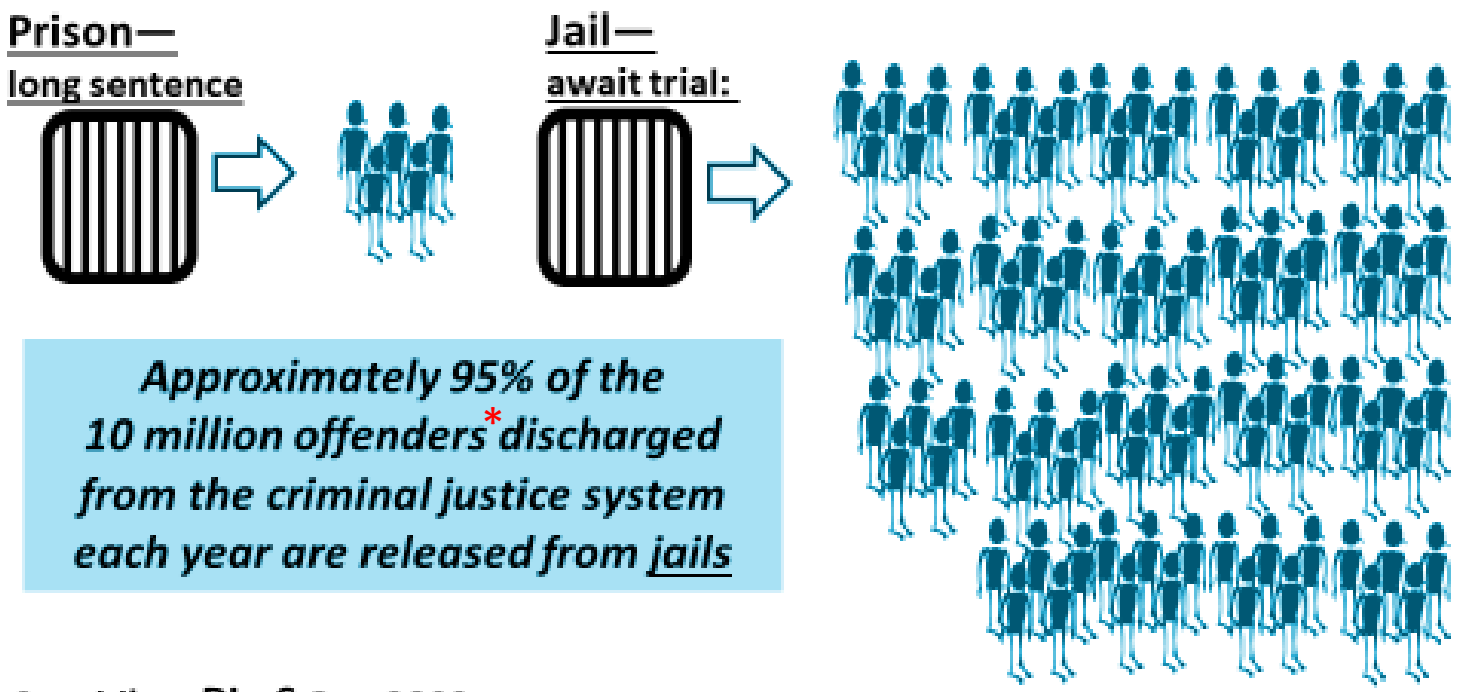
Contemplating flux

Number of individuals discharged from prisons and jails across 1 year



Approximately 95% of the 10 million offenders* discharged from the criminal justice system each year are released from jails

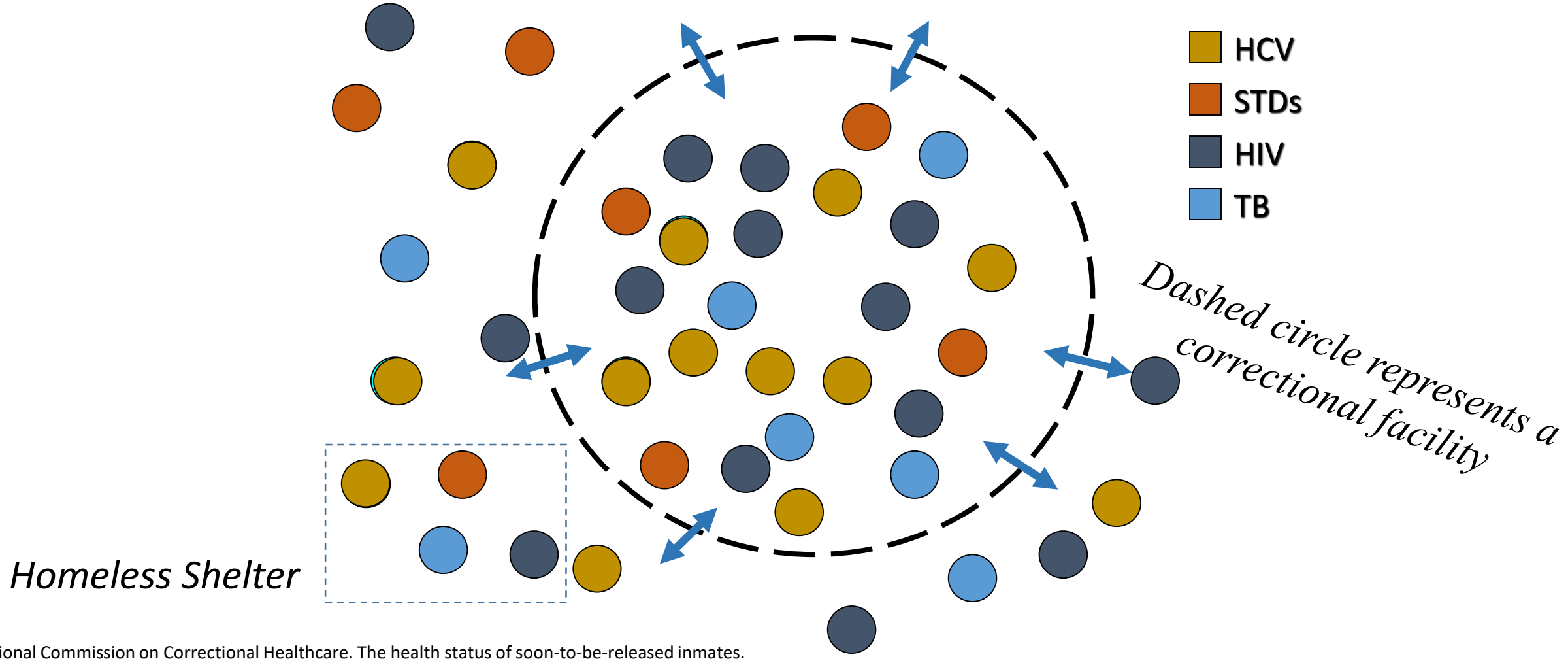
Source: Spaulding, PLoS One 2009

Jail: Median length of stay 2-5 days**, too short to complete HCV treatment during one stay.

**Spaulding AJPH

* Citation from old literature. Am using person first language going forward.

Community-Corrections Connection:
9-10 Million Incarcerated Persons Per Year Released to the Community



National Commission on Correctional Healthcare. The health status of soon-to-be-released inmates. A report to Congress. March 2002; Vol 1. http://www.ncchc.org/pubs/pubs_stbr.vol1.html. Accessed Jan 9, 2008.

Disincentive to screen in prisons…and jails

Estelle v. Gamble
USC 1976

- 8th amendment of the Constitution prohibits cruel and unusual punishment.
- USC ruled this meant: “deliberate indifference to health needs”

Disincentive to screen in prisons …and jails

Estelle v. Gamble USC 1976

- 8th amendment of the Constitution prohibits cruel and unusual punishment.
- USC ruled this meant: "deliberate indifference to health needs"
- ***"Liable …for denying humane conditions of confinement … [when] knows that inmates face a substantial risk of serious harm and disregards that risk by failing to take reasonable measures to abate it."*** **Farmer v. Brennan 1994**

Disincentive to screen in prisons…and jails

Newly identified medical issues → **Greater responsibility to treat.** → **Increased medical costs**

Unlike jails, prisons have adequate Length of Stay to treat HCV.

"Don't go lookin' for trouble"

- This becomes an issues with hepatitis C when prisons cannot afford costly DAAs

Cost-effectiveness in prisons: hepatitis C treatment

Who is paying?

Prisons bear up-front costs:

- Screening
- Counseling
- Drugs and medical care
- Connection to care after release

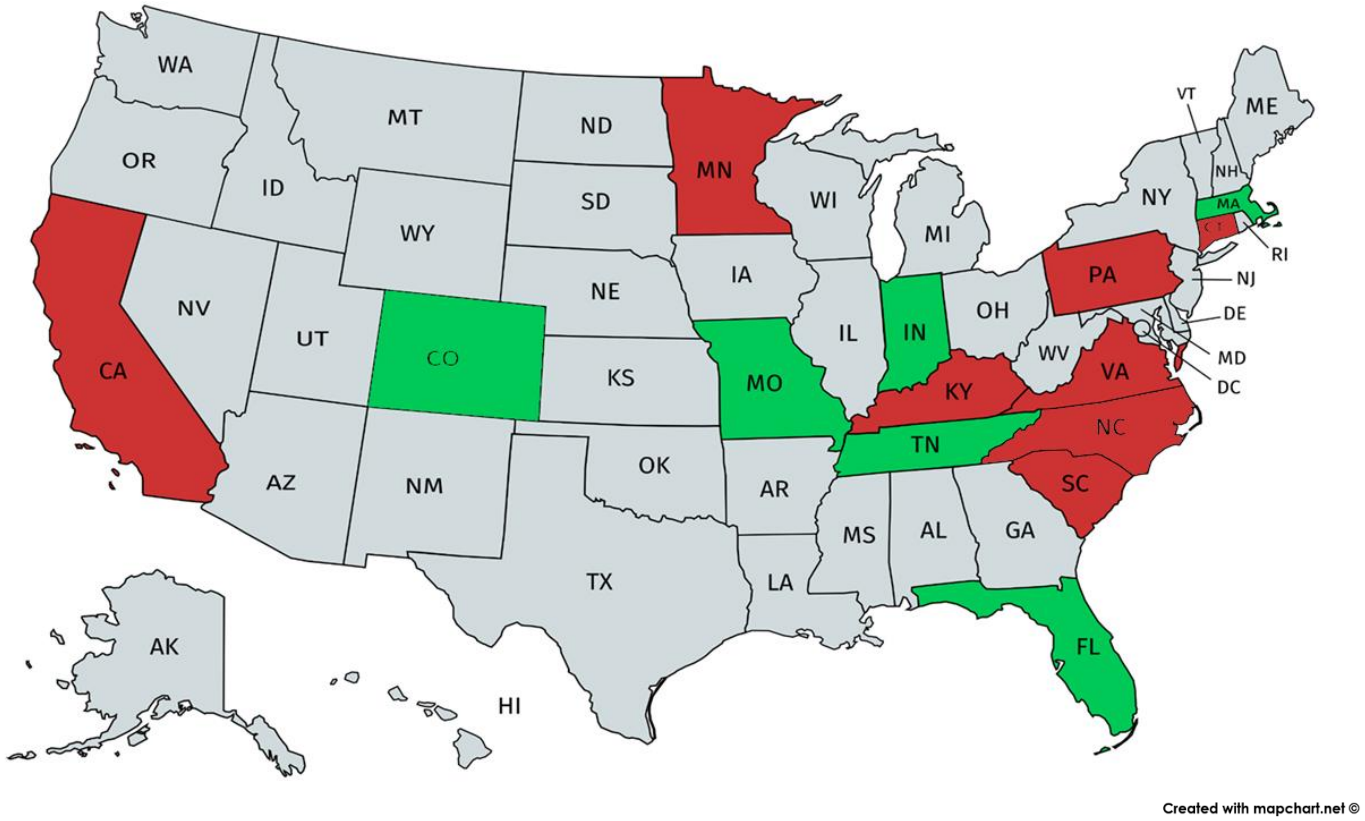
Society and individuals benefit:

- Gain life years
- Avert medical costs
- Prevent new infections

Need a true <u>societal/public health</u> perspective …but…

Cost-effectiveness from a societal perspective does not necessarily translate into cost-effectiveness for prisons budgets. If system not well funded, little incentive to find more persons who are potential treatment candidates.

HCV Treatment in Prisons: Court Cases



States where there are court orders or settlements are in green

Slide adopted (updated) from Erica Selig, JD, Florida Justice Institute. March 21, 2018, National Hepatitis Corrections Network. Houston TX. Used with permission.

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Lowering prices that US prison pay

Enumerating

Strategies for CJ to reduced cost, below Average Manufacturer’s Price.

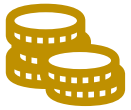
Ways of Decreasing Price

- Company can't just negotiate with a DOC to very low price
- Must give federal programs, such as Medicaid, the "best price"
- Negotiating too low with prison systems disrupts even bigger markets, such as Medicaid.

- A escape hatch from this:
  - **340 B program** exempts:
    - Safety net hospitals
    - Critical access hospitals
    - State STD clinics

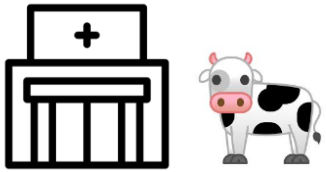
Ways To Decrease Prices for Prisons

Conservative | Daring | Pushing the envelope



Pooled procurement

340B Drug Pricing Program

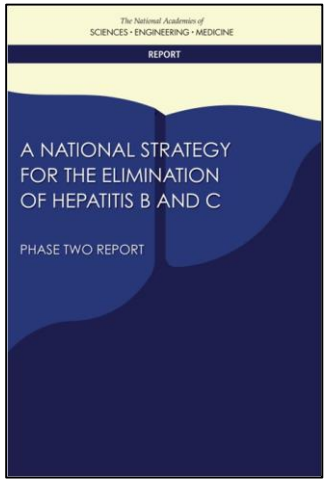


Partner with Critical Access Hospital

Nominal pricing

Government buys patent

Change best price rule statutorily



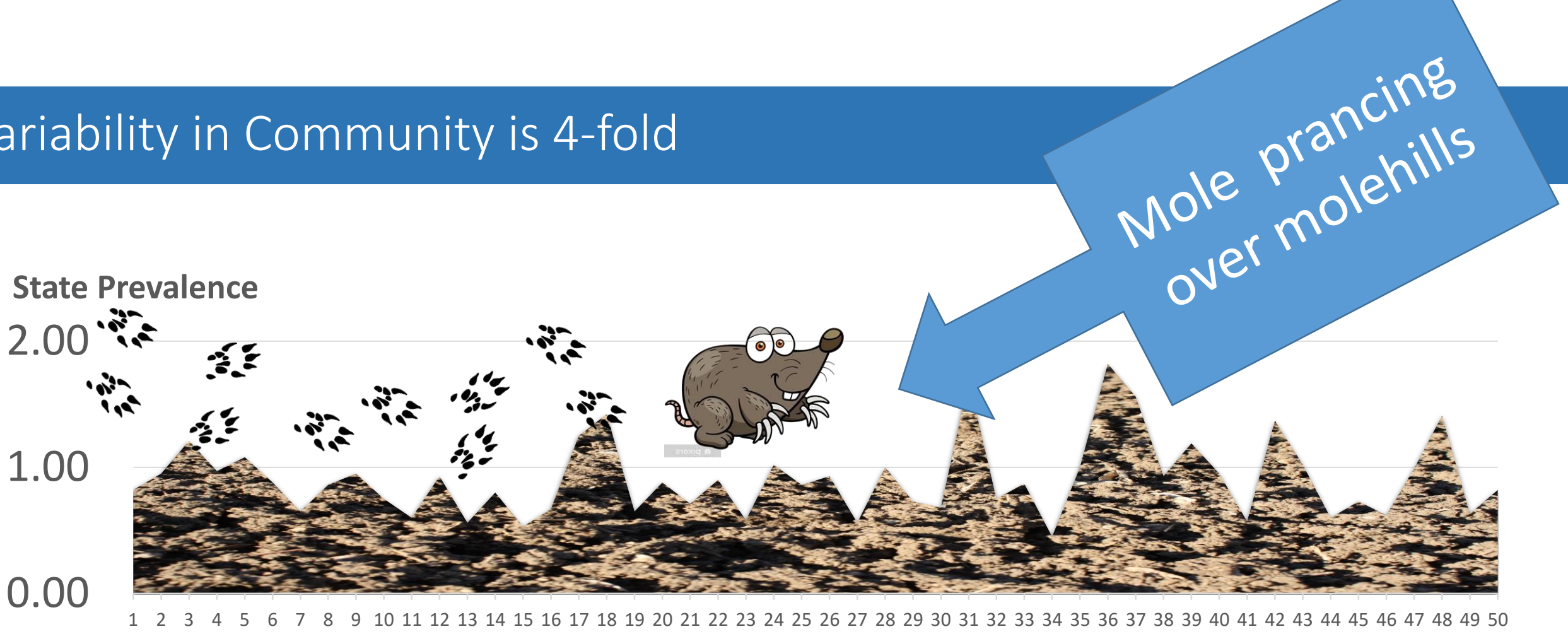
If you don't count cases, they are not on the map but ignored…

Enumerating

Paying

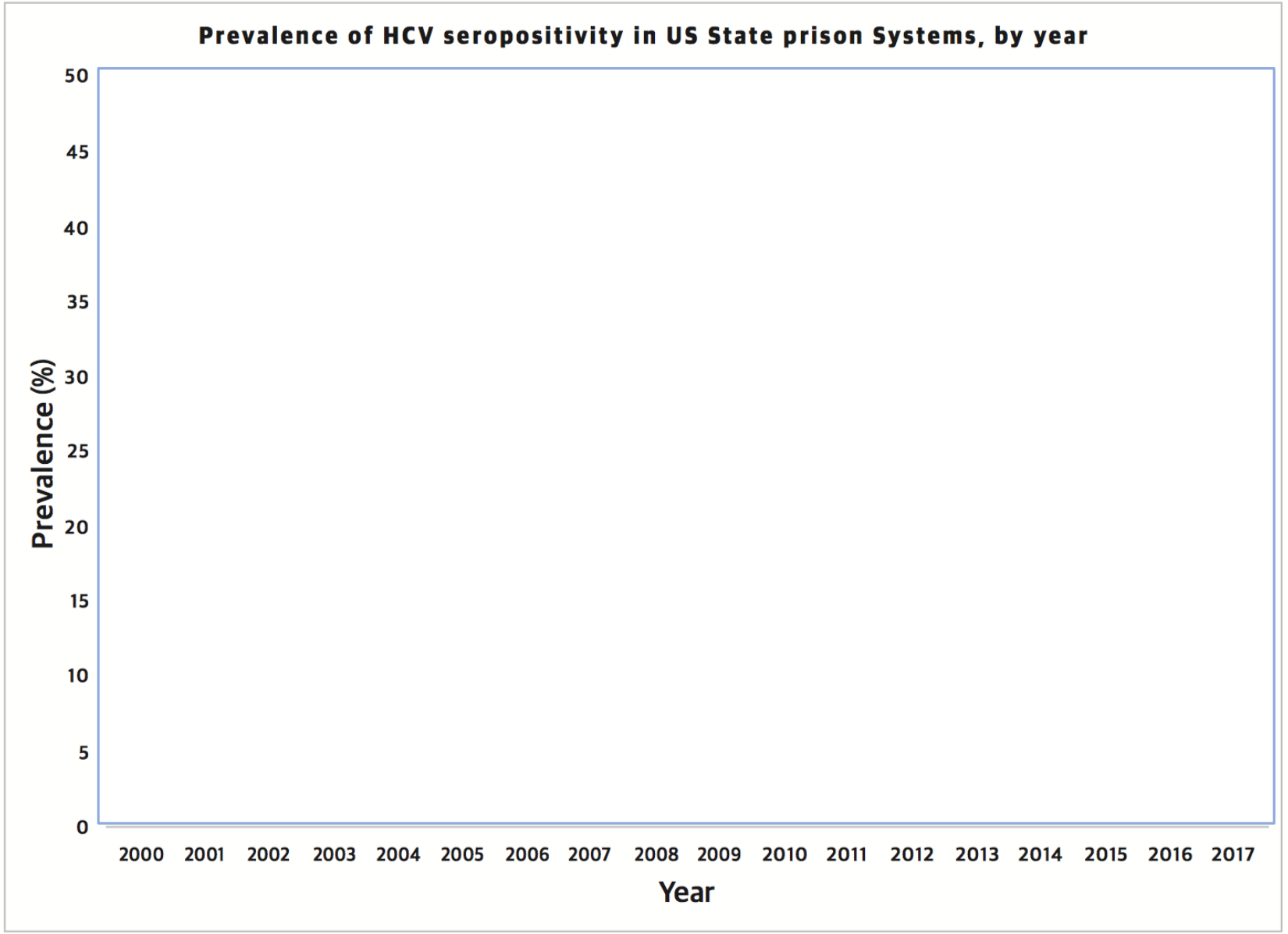
Not accounting for HCV epidemic in CJ system may impede hepatitis C elimination in the US

Variability in Community is 4-fold



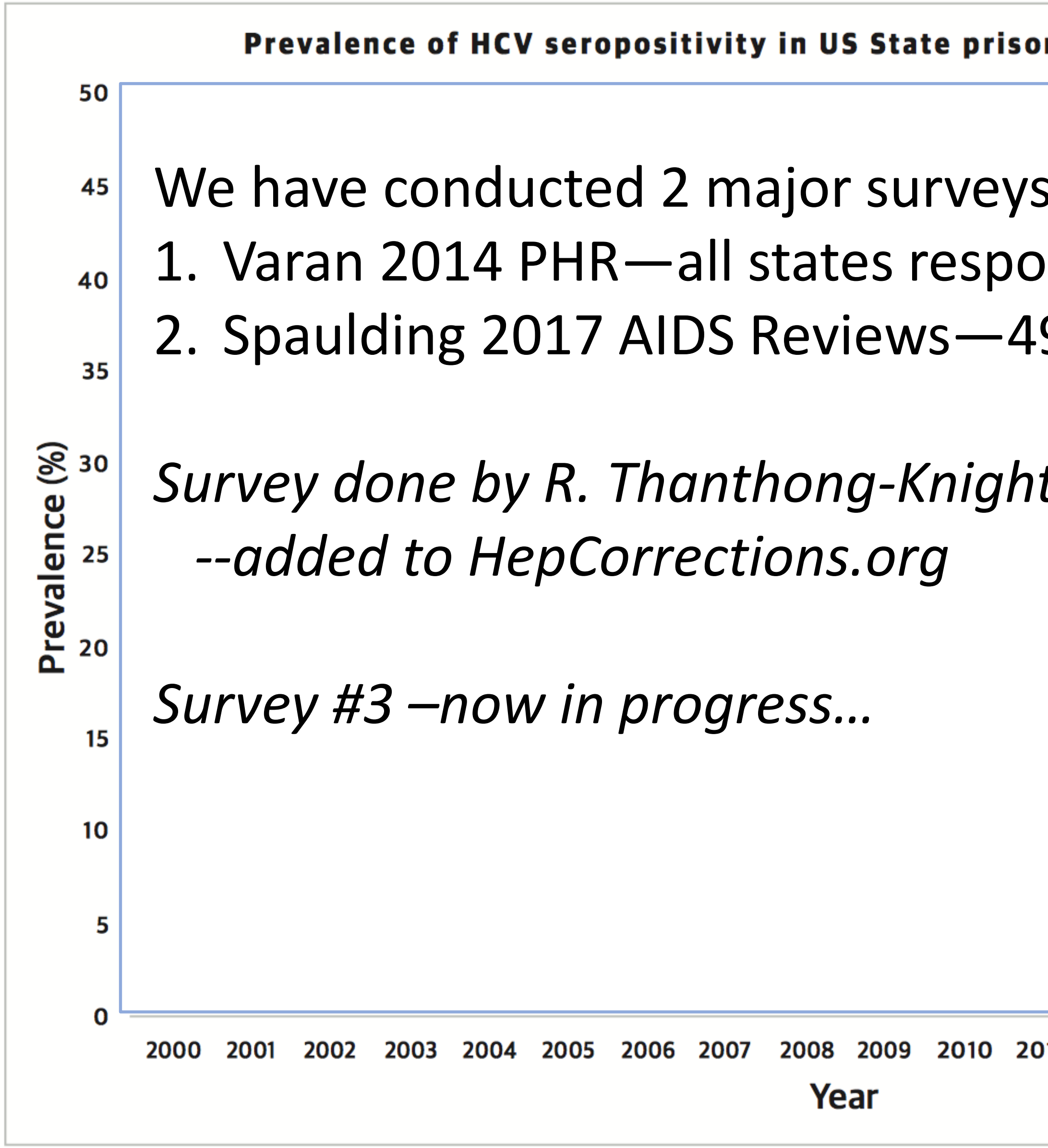
States: AL through WY

Surveys of State Departments of Corrections: Hepatitis C Antibody Prevalence



Source: Spaulding et al., AIDS Reviews 2017.

Surveys of State Departments of Corrections: Hepatitis C Antibody Prevalence

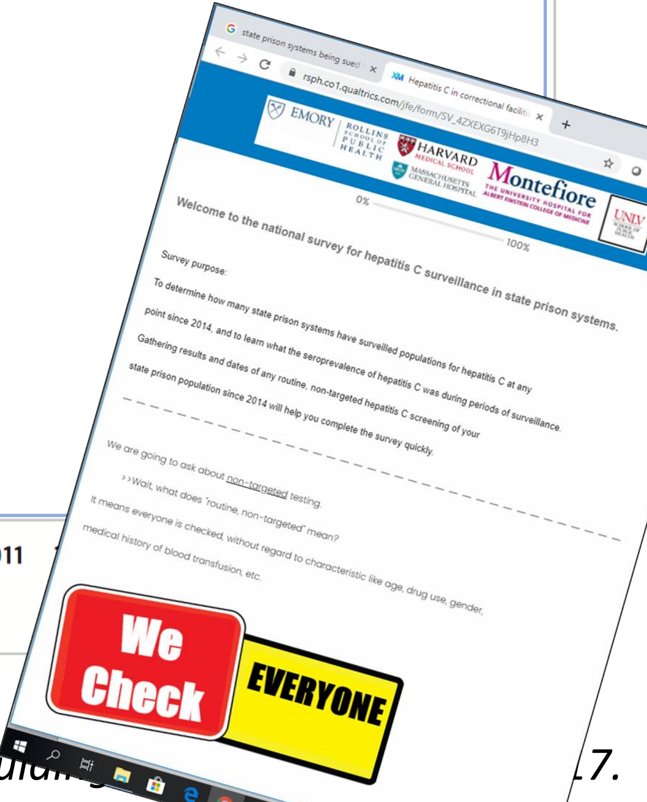


We have conducted 2 major surveys done to date

1. Varan 2014 PHR—all states responding
2. Spaulding 2017 AIDS Reviews—49 states responding

Survey done by R. Thanthong-Knight (Columbia)
--added to HepCorrections.org

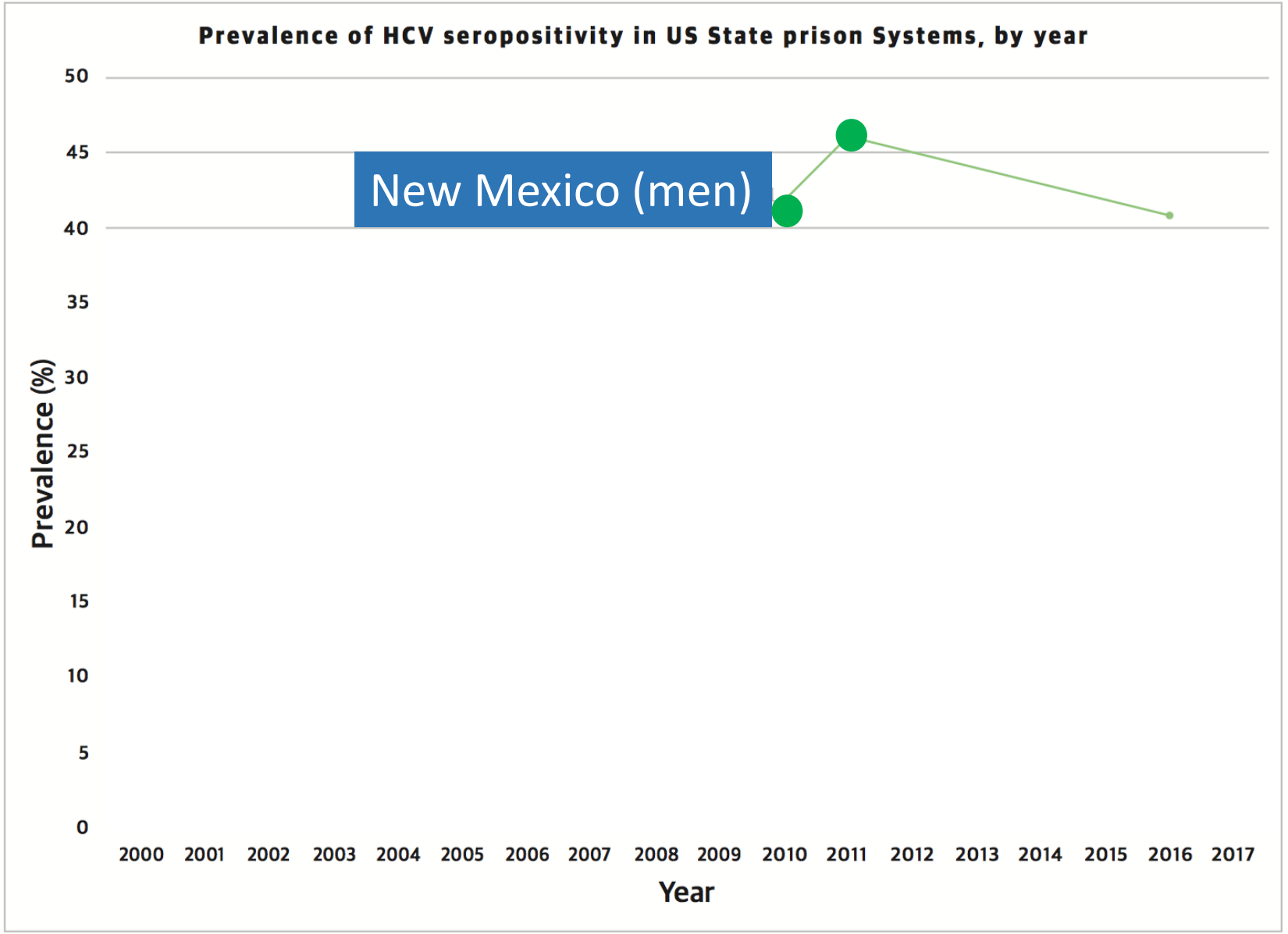
Survey #3 –now in progress…



Source: Spau[illegible] 7.

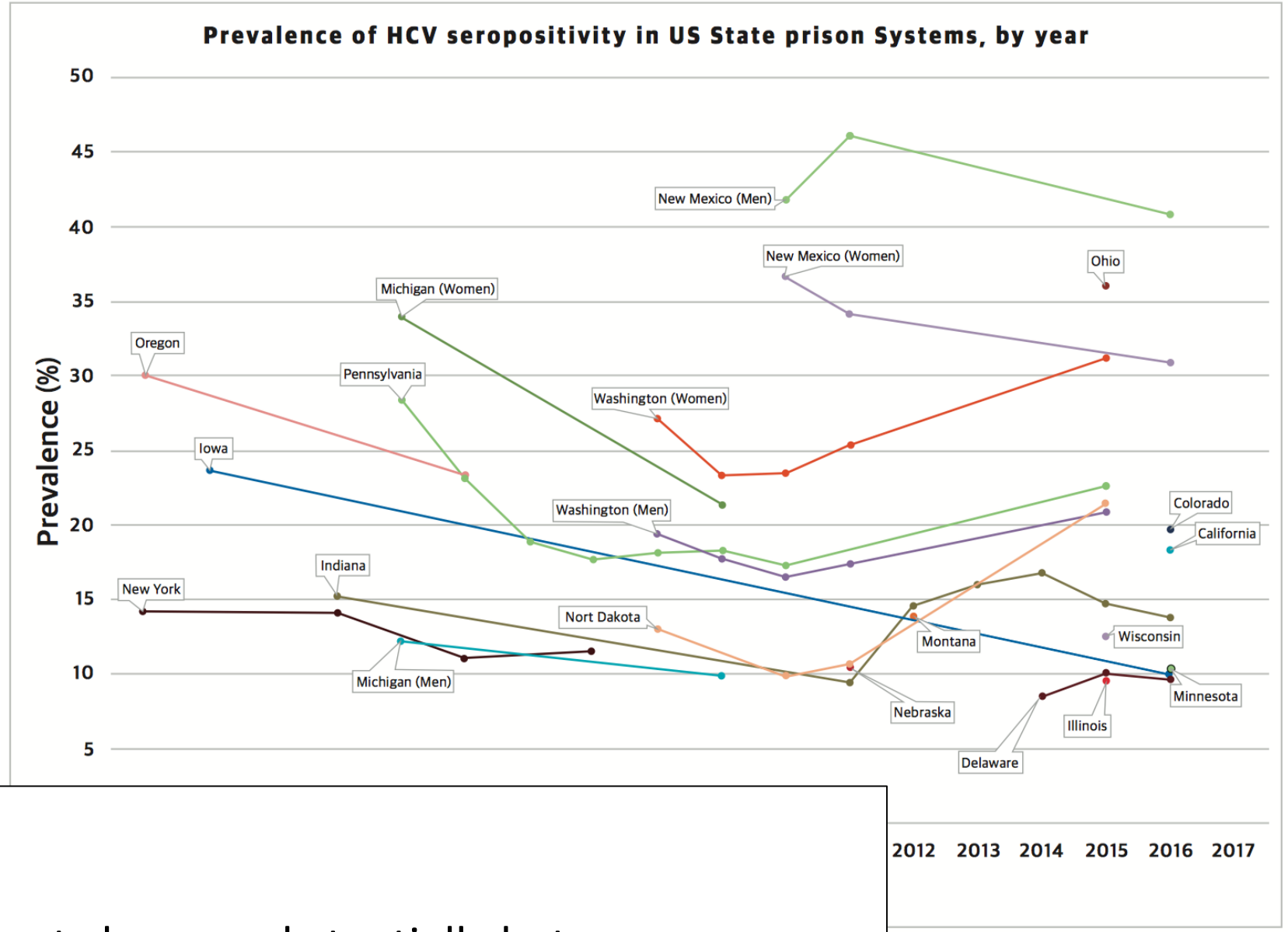
Survey on their infections:

State Departments of Corrections: Hepatitis C Antibody Prevalence



Source: Spaulding et al., AIDS Reviews 2017.

State Departments of Corrections: Hepatitis C Antibody Prevalence

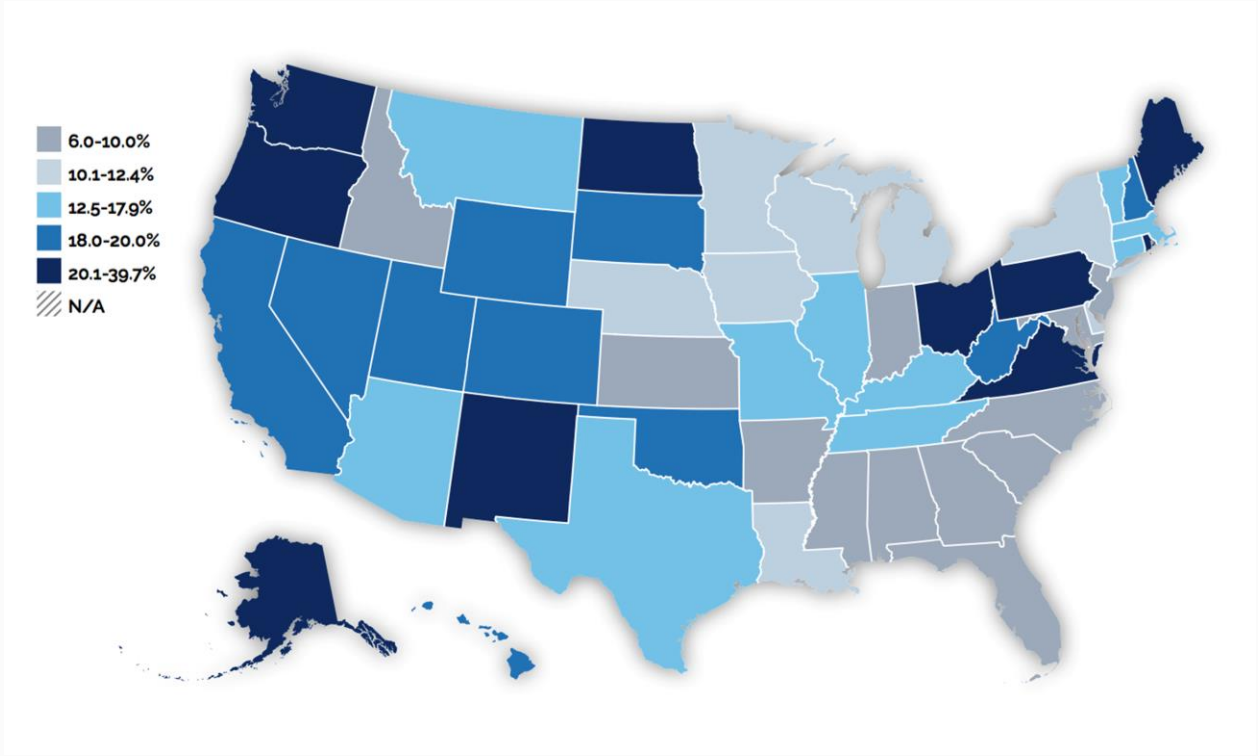


All surveys:

1. Marked heterogeneity
2. Ranking of states does not change substantially between surveys

Source: Spaulding et al., AIDS Reviews 2017.

Hepatitis C Ab Prevalence …varies by state



HepCorrections

Antibody:

- Range 5% - 48%
- Weighted mean: 18% (Varan 2014)

Viremia: when Ab+

- Range: 55% (California) – 78% (NM)
- Viremia prevalence: 4% -40%?

HEPATOLOGY

AASLD

HEPATOLOGY, VOL. 69, NO. 3, 2019

Estimating Pr
Virus Infectio
2013-2016

Used one value for prevalence of HCV in each state CJ system. Did not include published values for some states, e.g. NM Corrections Department

Megan G. Hofmeister,[1,2] Elizabeth M. Rose
Brian R. Edlin,[5] Jonathan Mermin,[5] John W. Ward,[1,6] and A. Blythe Ryerson[1]

Hepatitis C virus (HCV) infection is the most commonly reported bloodborne infection in the United States, causing substantial morbidity and mortality and costing billions of dollars annually. To update the estimated HCV prevalence among all adults aged ≥18 years in the United States, we analyzed 2013-2016 data from the National Health and Nutrition Examination Survey (NHANES) to estimate the prevalence of HCV in the noninstitutionalized civilian population and used a combination of literature reviews and population size estimation approaches to estimate the HCV prevalence and population sizes for four additional populations: incarcerated people, unsheltered homeless people, active-duty military personnel, and nursing home residents. We estimated that during 2013-2016 1.7% (95% confidence interval [CI], 1.4-2.0%) of all adults in the United States, approximately 4.1 (3.4-4.9) million persons,

Letter to the Editor: Disputed how HCV was estimated in CJ system

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Josiah D. Rich
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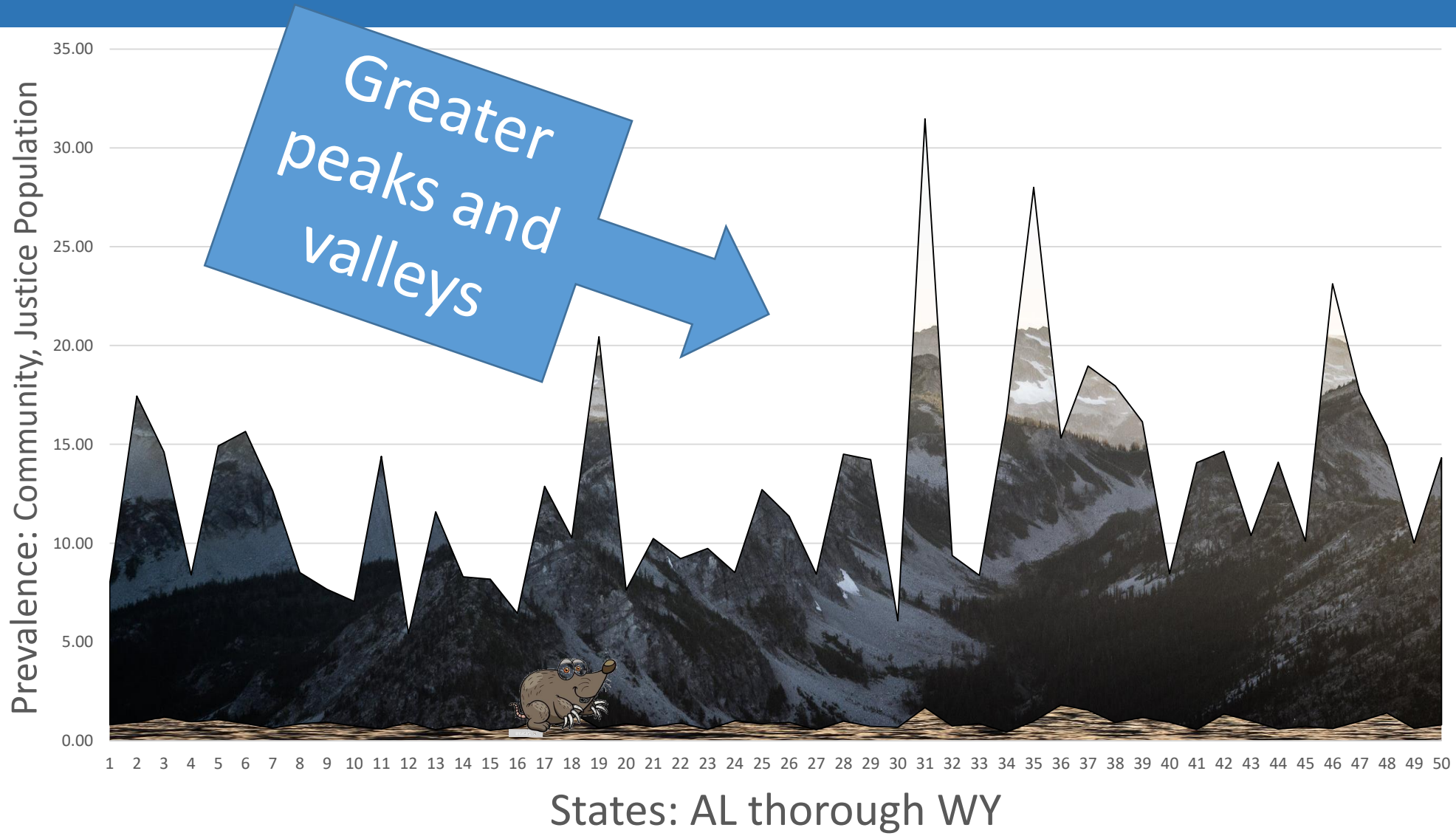
Stacey B. Trooskin
Philadelphia Fight

Ryan P. Westergaard
SoM&PH, University of Wisconsin

William J. Sabol
Georgia State University

Mountains vs Molehills: Prevalence of Viremia, CJ vs. Community

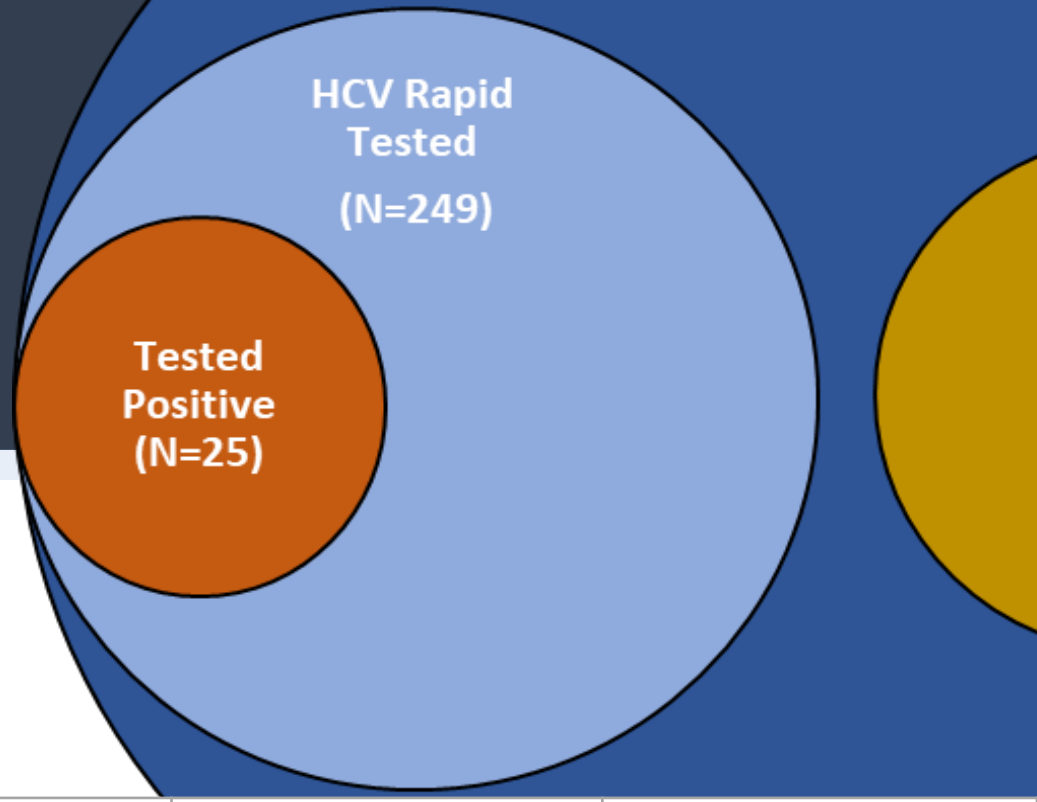


(Justifiable) criticism of prison methods of estimating prevalence

Inconsistent Definitions: Uncertainty over HCV prevalence, based on choice of numerator and denominator

Source: Beckwith et al., Journal of Public Health 2016, as published in AIDS Review 2017

Inconsistent Definitions: Uncertainty over HCV prevalence, based on choice of numerator and denominator

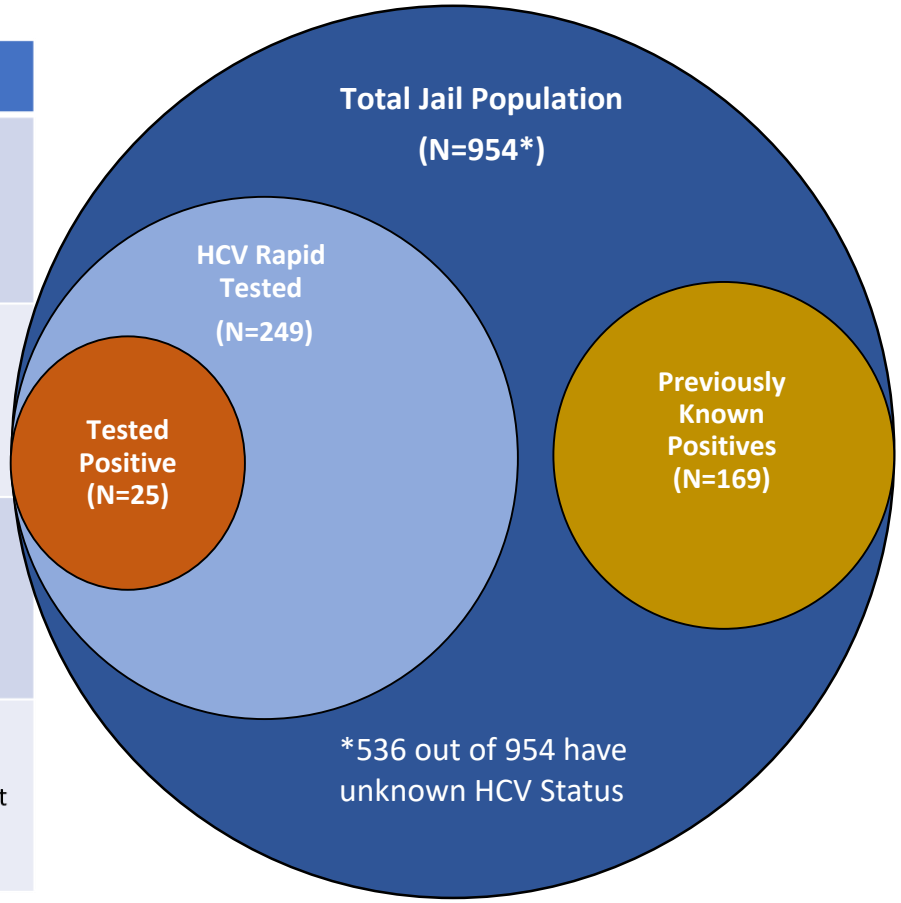


Inclusion Strategy	Tested + 25/249	Unknown N=536	Known + N=169	Calculation	Prevalence
New tests	25			25/249	10.0%

Source: Beckwith et al., Journal of Public Health 2016, as published in AIDS Review 2017

Estimating the Burden of Hepatitis C in Corrections

Inclusion Strategy	Calculation	Prevalence	Issues With this Strategy
$\frac{New\ Positives}{New\ Tests}$	$\frac{25}{249}$	10.0%	Ignores HCV positive who have been previously tested and unknowns.
$\frac{New\ Positives + Know\ Positives}{Total\ Jail\ Population}$	$\frac{25 + 169}{954}$	20.3%	Numerator does not include unknowns who may be positive.
$\frac{New\ Pos. + Known\ Pos. + 10\%\ of\ Unknown}{Total\ Jail\ Population}$	$\frac{25 + 169 + 54}{954}$	26.0%	Estimation, percentage of unknowns who are positive may vary from 10%.
$\frac{New\ Positives + Known\ Positives}{New\ Tests + Known\ Positives}$	$\frac{25 + 169}{169 + 249}$	46.4%	Ignores unknown, includes new negatives in denominator but not negatives from previous testing.



Spaulding et al. Infectious Disease Clinics of North America. 2018
Data from Beckwith et al., Journal of Public Health 2016, from modified analysis published in AIDS Review 2017.

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Original Investigation | Public Health

Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016

Eli S. Rosenberg, PhD; Elizabeth M. Rosenthal, MPH; Eric W. Hall, MPH; Laurie Barker, MSPH; Megan G. Hofmeister, MD, MPH; Patrick S. Sullivan, DVM, P
Patricia Dietz, DrPH; Jonathan Mermin, MD, MPH; A. Blythe Ryerson, PhD

Abstract

IMPORTANCE Infection with hepatitis C virus (HCV) is a major cause of morbidity and mortality in the United States, and incidence has increased rapidly in recent years, likely owing to increased injection drug use. Current estimates of prevalence at the state level are needed to guide prevention and care efforts but are not available through existing disease surveillance systems.

OBJECTIVE To estimate the prevalence of current HCV infection among adults in each US state and the District of Columbia during the years 2013 to 2016.

DESIGN, SETTING, AND PARTICIPANTS This survey study used a statistical model to allocate nationally representative HCV prevalence from the National Health and Nutrition Examination Survey (NHANES) according to the spatial demographics and distributions of HCV mortality and narcotic overdose mortality in all National Vital Statistics System death records from 1999 to 2016.

Key Points

Question During 2013 to
proportion of adults were
hepatitis C virus (HCV) infe
US state?

Findings In this survey st
national HCV prevalence c
2016 was 0.93% and varie
jurisdiction between 0.45
Three of the 10 states with
prevalence and 5 of the 9
highest number of HCV int
in the Appalachian region.

Used one CJ prevalence estimate from CDC's earlier paper: 10.7%.

Sensitivity analysis—consider having non-NHANES population reflect statewide epidemic: median difference in prevalence between methods 1 and 2 of 0.004% (relative multiplicative change of -0.5%).

DOI: 10.1111/jvh.13124

COMMENTARY

WILEY JVH

Comprehensive nationwide chronic hepatitis C surveillance is necessary for accurate state-level prevalence estimates

Miranda S. Moore[1] | Sharon K. Greene[2] | Angelica Bocour[1] | Catherine M. Brown[3] | Joseph R. Coyle[4] | Danica Kuncio[5] | Shauna Onofrey[6] | Megan T. Patel[7] | Ann Winters[1]

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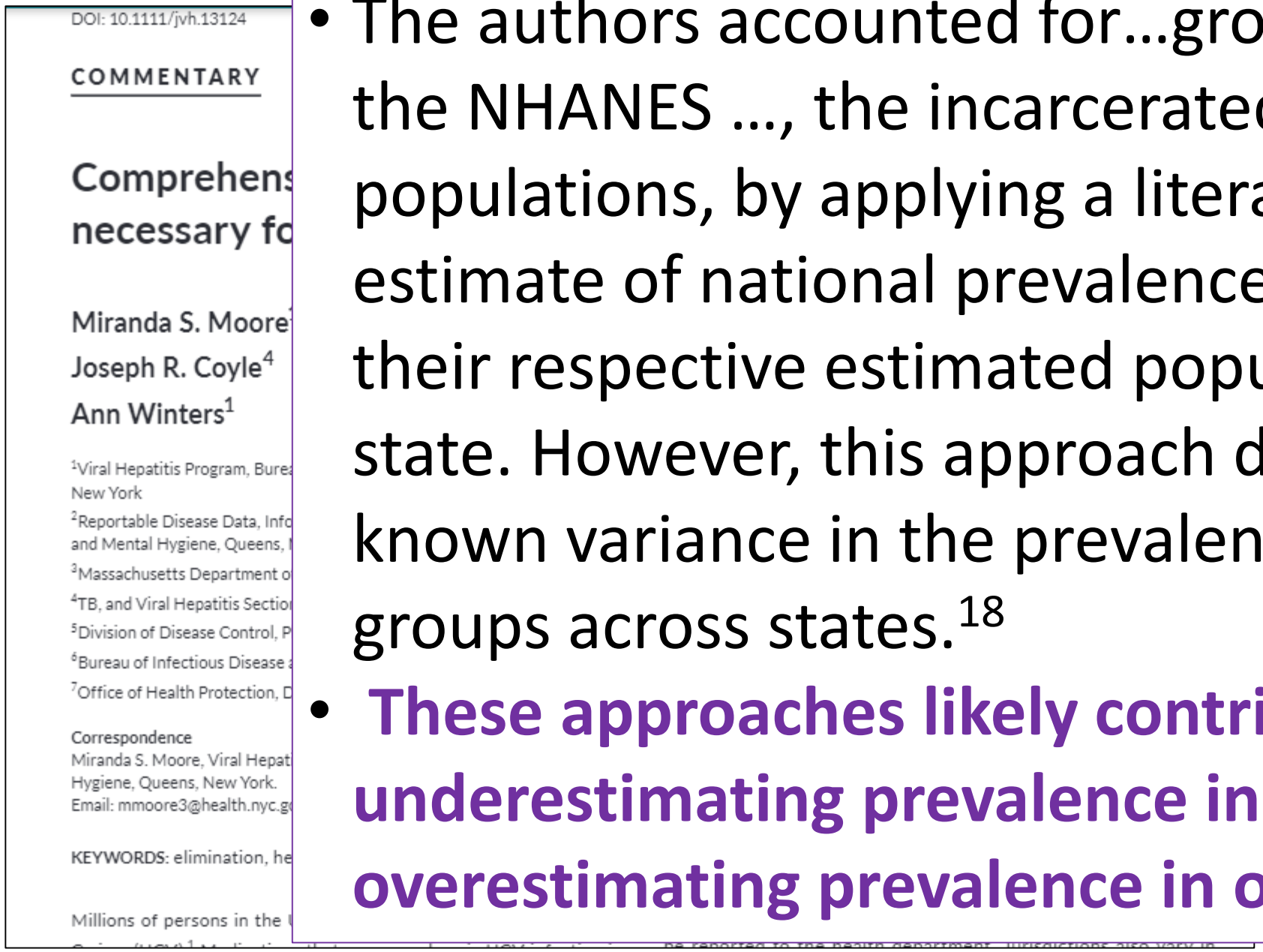
KEYWORDS: elimination, hepatitis C, pre

Millions of persons in the United State

A recent study by Rosenberg et al[3] presented state-level estimates of HCV prevalence in 2016 using indirect standardization of NHANES survey data and weighting based on HCV-related mortality data. However, we believe the accuracy of these prevalence estimates was likely affected by strong methodologic assumptions…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COMMENTARY

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- The authors accounted for…groups excluded from the NHANES …, the incarcerated and…homeless populations, by applying a literature-based estimate of national prevalence in each group to their respective estimated population size in each state. However, this approach did not account for known variance in the prevalence within these groups across states.[18]
- **These approaches likely contributed to underestimating prevalence in some states while overestimating prevalence in others**

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COMMENTARY

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necessary for ac

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Millions of persons in the United St

…Discrepancies such as these are **nontrivial**, as published prevalence estimates, like those presented by Rosenberg et al, are likely to be used for resource allocation and targets for elimination efforts.

Published: September 6, 2019

Using observed viremia prevalence in one high and one low prevalence state prison system as range of likely value for non-NHANES population: upper estimate for statewide prevalence is 1.8 times higher than lower estimate.

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Research Letter | Infectious Diseases

Assessment and Comparison of Hepatitis C Viremia in the Prison Systems of New Mexico and Georgia

Anne C. Spaulding, MD, MPH; Junyu Chen, MPH; Carolyn A. Mackey, MPH; Madeline G. Adee, MPH; Chava J. Bowden, BS; W. David Selvage, MHS, PA-C; Karla A. Thornton, MD, MPH

Introduction

Recently published estimates by Rosenberg et al[1] of hepatitis C virus (HCV)–infected persons by

Conclusions

1. **Prisons and Jails are reluctant to screen because can't afford therapy.**
2. **Strategies exist to lower cost of treatment.**

3. **Elimination of HCV depends on accurate portrayal of epidemic in CJ sector**

   —If you find it, elimination can come.

Any Questions?