

# CDC/HRSA (CHAC) Workforce Workgroup

April 19, 2023

## **CHAC Workforce Workgroup Members:**

Vincent Guilamo-Ramos (Chair)

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# Workforce Workgroup Activities

This term of the workgroup was from Nov 2022 – April 2023

- Met twice in December and March

DFOs:

- Shalonda Collins, MPH, CHES
- Marah Condit, MS

# Presentation Overview

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**1 Scope of the Workforce Workgroup's Work**

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**2 Setting the Context: Workforce Challenges and  
Priorities**

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**3 Discussion**

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# Scope of Work

**The workforce working group was tasked with developing the evidence base on priority issues for the HIV workforce, including aligning HIV workforce regulation and funding through:**

- **Incentivizing programs that create pathways for more diversity in professional careers for HIV treatment and prevention services**
- **Investing in workforce infrastructure for the delivery of decentralized, differentiated status-neutral HIV services to promote a shift toward a comprehensive, whole-person, interdisciplinary, and team-based model of HIV service delivery.**

# HIV Workforce Priority Challenges and Potential Strategies

## Challenges



**Insufficient trainees entering HIV specialties**

*Sub-Challenge:  
Diversifying the HIV Workforce*



**Aging HIV workforce**



**Diversion of HIV providers to other infectious disease areas**

## Potential Strategies



**Recruit:**

Create pathways to increase the recruitment of a diverse cohort of HIV-specialty trainees



**Retain:**

Maintain the current HIV workforce through educational, financial, work environment, and policy incentives



**Reimagine:**

Develop infrastructure for a new model of HIV service delivery and workforce configuration

# HIV Workforce Priority Challenges



## Insufficient trainees entering HIV specialties

*Sub-Challenge:  
Diversifying the HIV Workforce*

- Available HIV-specialty programs are limited in number and geographically clustered
- Trainee exposure to HIV-specific education and clinical context is inconsistent

Source: Institute of Medicine. 2011. *HIV Screening and Access to Care: Health Care System Capacity for Increased HIV Testing and Provision of Care*. Washington, DC: The National Academies Press,



## Aging HIV workforce

- Increasing numbers of HIV clinicians are reaching retirement age
- 68.2% of HIV Clinicians are  $\geq 45$  years old

Gilman et al. The HIV Clinician Workforce in the United States. *HIV Specialist*. Retrieved from: <https://aidsetc.org/resource/first-look-hrsa-hiv-workforce-study>; HIV Specialists: 2015 estimates, HRSA, HIV Specialist; ; U.S. Bureau of Labor Statistics, Occupational Employment and Wage Statistics, 2020: HIV.gov U.S. Statistics, 2022



## Diversion of HIV providers to other infectious disease areas

- e.g. COVID-19 response directly impacted HIV and infectious disease specialty workforce by siphoning specialists and funding

Giovanni G, Milic J, Martinez E, et al. Human Immunodeficiency Virus (HIV) Care Models During the Corona Virus Disease 2019 (COVID-19) Era, *Clinical Infectious Diseases*. 2021. 73(5);1222-1227.

# Strategy #1: Increased Recruitment Efforts



## **Recruit:**

Create pathways to increase the recruitment of a diverse cohort of HIV-specialty trainees

## Potential mechanisms for consideration:

### **Pathway Programs for HIV-Specialization**

Further development and expansion of HIV-specialist **pathway programs**, including the integration of HIV-specialist training in **GME** and **GNE**

### ***Why specialize in HIV?: Elevating the Benefits of HIV-Specialization***

HIV epidemic response continues to serve as an **exemplar for health activism**, calling attention to **health inequities** and **challenging the current paradigm** of healthcare

### **Financial Incentives for HIV-Specialist Trainees**

Examples: **Loan repayment** options and funding streams such as **HRSA primary care grants**, **HRSA Bio-preparedness Workforce Pilot Program**

# Strategy #2: Retaining the Current HIV Workforce



## **Retain:**

Maintain the current HIV workforce through educational, financial, work environment, and policy incentives

## **Potential mechanisms for consideration:**

### **Innovative Payment Structures for Reimbursement of HIV Services**

Examples: Increased **Medicaid and Medicare reimbursement rates** for HIV-specialists providing primary care, **risk-adjusted provider reimbursement, reimbursement for alternative models** of service delivery

### **Regulatory Barriers Limiting Providers from Practicing to Highest Level of Training/Licensure**

i.e. Nurse practitioner- and physician assistant-delivered primary care results in comparable patient outcomes to physicians.

### **Work Environment Considerations**

Ensure viable pathways for continued **education and training, career advancement**, and adequate **compensation**

# Strategy #3: Reimagining the Model for HIV Service Delivery



## Reimagine:

Develop infrastructure for a new model of HIV service delivery and workforce configuration

## Potential mechanisms for consideration:

**Policy and infrastructure levers for delivering decentralized, differentiated HIV prevention and care**

Example: **COVID-19 PHE flexibilities** allowed healthcare workforce to provide responsive infectious disease prevention and treatment at a large-scale

**Redefine the HIV workforce for comprehensive health and social service provision**

Involve **PLWHIV, Primary Care Providers, RNs, LPNs, Pharmacists, Dentists, Social Workers, Behavioral/Mental Health Professionals, Community Health Workers**, etc.

**Expand and maximize the existing HIV workforce to include entire available, qualified workforce**

Examples: **Practice transformation** demonstrations (e.g. “share-the-care” and increased care coordination) to maximize the existing workforce

# Discussion

- 1. Infrastructure development for delivery of decentralized, differentiated HIV prevention and care (e.g., telehealth, community-based delivery of services, etc.)**
- 2. Integration of all team members (e.g. CHWs, RNs, LPNs, Social Workers, Pharmacists, Behavioral/Mental Health Professionals) into the HIV workforce in partnership with other care providers and address appropriate training standards, compensation, and paths for promotion**
- 3. Removal of regulatory barriers that place restrictions on practice at the highest level of training and licensure (e.g., for nurse practitioners, PAs, medical technicians, pharmacists, etc.)**
- 4. Incentivization of programs that create pathways for more diversity in professional careers beyond CHR (e.g. fellowship programs) of the workforce with current and emerging needs and challenges of PLWHIV communities**

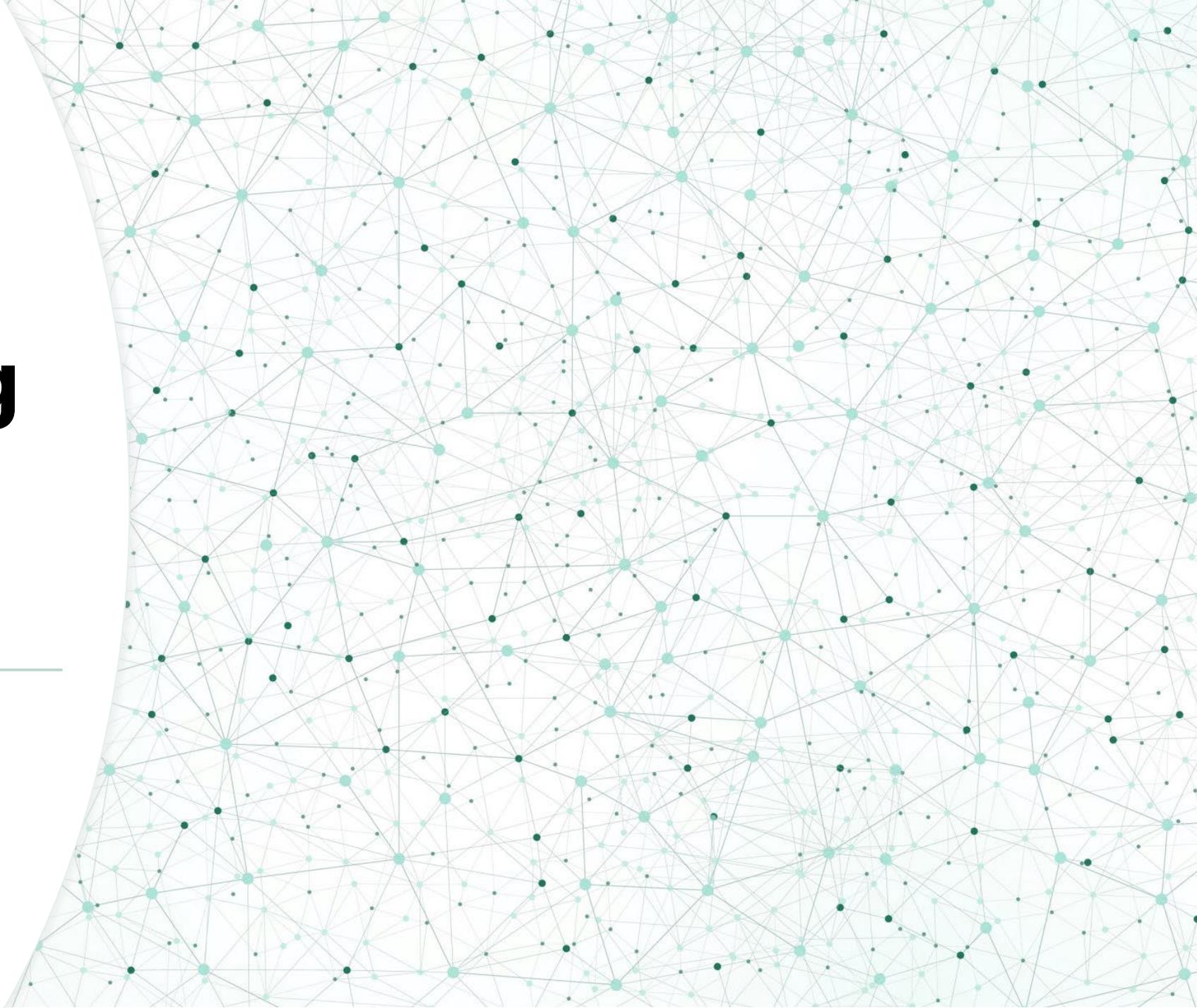


# CHAC STI Self-Testing Workgroup Report

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CHAC Atlanta Meeting

April 19, 2023

A complex network diagram background consisting of numerous small, interconnected nodes and lines, primarily in shades of teal and black, creating a dense, web-like structure that fills the right side of the page.

# Workgroup Meetings and Membership

- Workgroup Term: November 2022 – April 2023
  - Meetings were held in January, February and April 2023
  - Invited two guest speakers:
    - Dr. Ellen Kersh, Branch Chief, CDC Division of STD Prevention Laboratory
    - Dr. Barbara Van Der Pol, Professor of Medicine & Public Health, STI Laboratory Director, University of Alabama at Birmingham

## Workgroup Members:

- Jodie Dionne (Chair)
- Johanne Morne
- Shannon Dowler
- Shruti Mehta
- Christine Markham

## Designated Federal Officials:

- Marah Condit, MS
- Shalonda Collins, MPH, CHES

# Focus Areas

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01

Knowledge gaps in the development of high quality STI diagnostic testing with self-collected samples (CT/NG/syphilis)

02

Regulatory barriers to the approval of self-collected swabs for STI diagnostic testing within and **outside** the clinical setting

03

How to improve access to and uptake of affordable, available STI testing for adolescents and adults who need it.

# Definitions

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**STI self collection** can occur in a clinical or non-clinical setting.

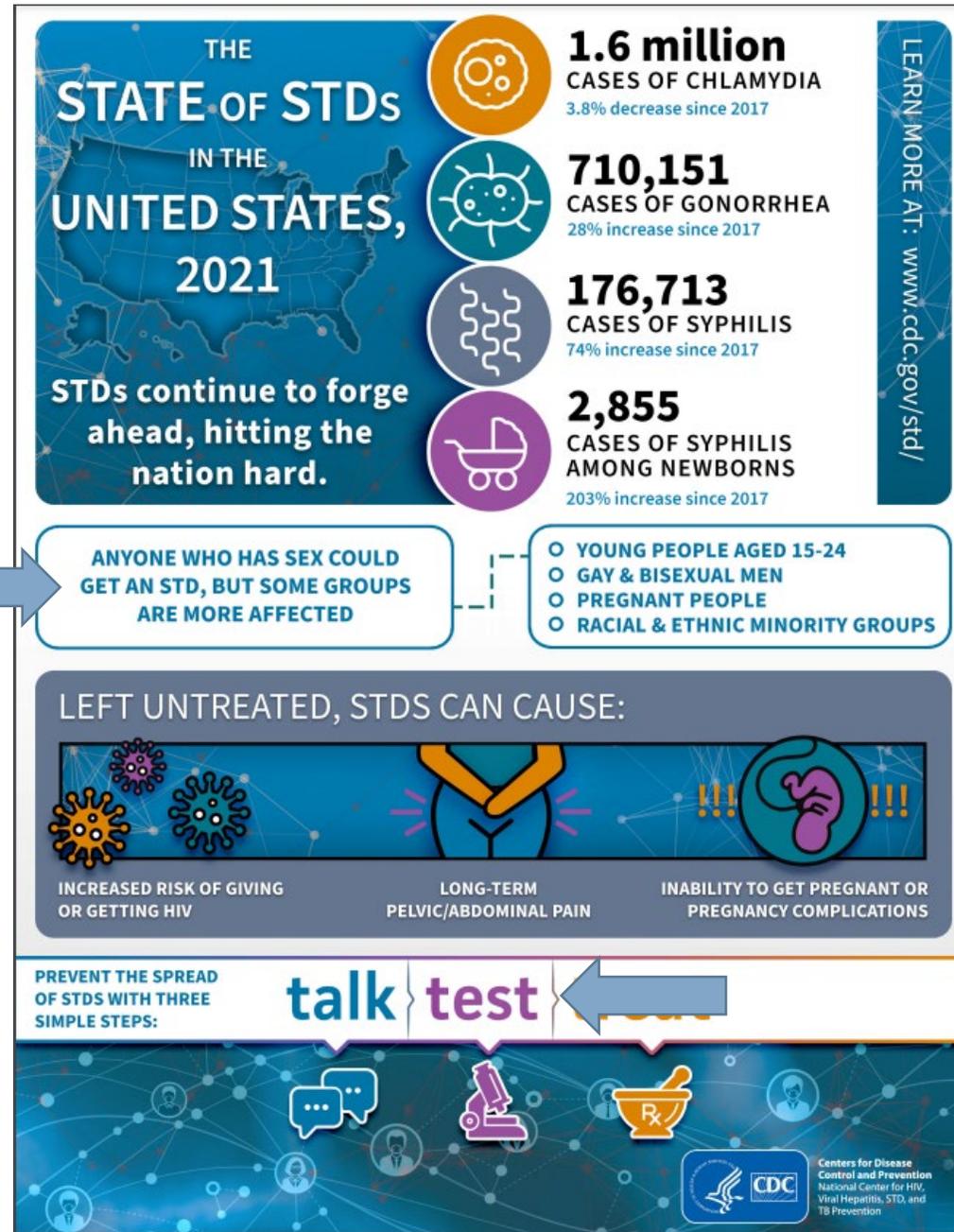
CT/NG samples are genital or extragenital.

**STI self-testing** is collected, performed, and interpreted by the user (at point of care [POC]) without input from a provider (i.e. CLIA waived urine pregnancy test)

**Direct to consumer (OTC) testing** can be ordered by the user (often online) without input from a provider

# 2021 CDC STI Surveillance

Released 11 April 2023



# WHO 2019 Recommendations

## Recommendation on self-collection of samples for STI testing

### GC/CT

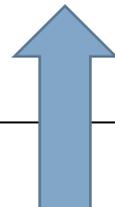
Self-collection of samples for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* **should be made available** as an additional approach to deliver STI testing services for individuals using STI testing services. *(strong recommendation, moderate-certainty evidence)*

### Syphilis

Self-collection of samples for *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* **may be considered** as an additional approach to deliver STI testing services for individuals using STI testing services. *(conditional recommendation, low-certainty evidence)*

## WHO Consolidated Guideline on Self-Care Interventions for Health

Sexual and Reproductive Health and Rights



Systematic review of 11 studies 1998-2018\*:  
RR for STI uptake 2.9 (95% CI 1.2-7.3)  
RR for STI case finding 2.2 (95% CI 1.0-4.5)  
(compared to clinician collected or no testing)

\*11 in HIC, 6 in US

## SELF-COLLECTION BENEFITS

- Person-centered
- Can reduce barriers to STI testing (privacy, stigma)
- Complementary to existing programs and approaches
- Benefit measured in terms of improved outcomes for the individual and at the population level

## SELF-COLLECTION RISKS

- Exposure to buffer
- Harm with self-swab
- Lack of stability data - NAAT performance if samples are heated or testing delay

## Home-based versus clinic-based specimen collection in the management of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections

Luisa Fajardo-Bernal <sup>1</sup>, Johanna Aponte-Gonzalez, Patrick Vigil, Edith Angel-Müller, Carlos Rincon, Hernando G Gaitán, Nicola Low

- **Objective:** To assess the **effectiveness and safety of home-based specimen collection** as part of the management strategy for CT and GC infections compared to clinic-based
- 10 randomized controlled trials (RCTs) published 1998-2013
- Selection criteria: sexually active, persons engaged in higher risk behavior (MSM and sex workers), symptomatic or asymptomatic
- Results:
  - In 8/10 studies more home-collected specimens were tested compared to clinic based
  - 9/10 studies showed lower proportion of positive results in home-based collection
  - 96% of women found self collection comfortable and easy

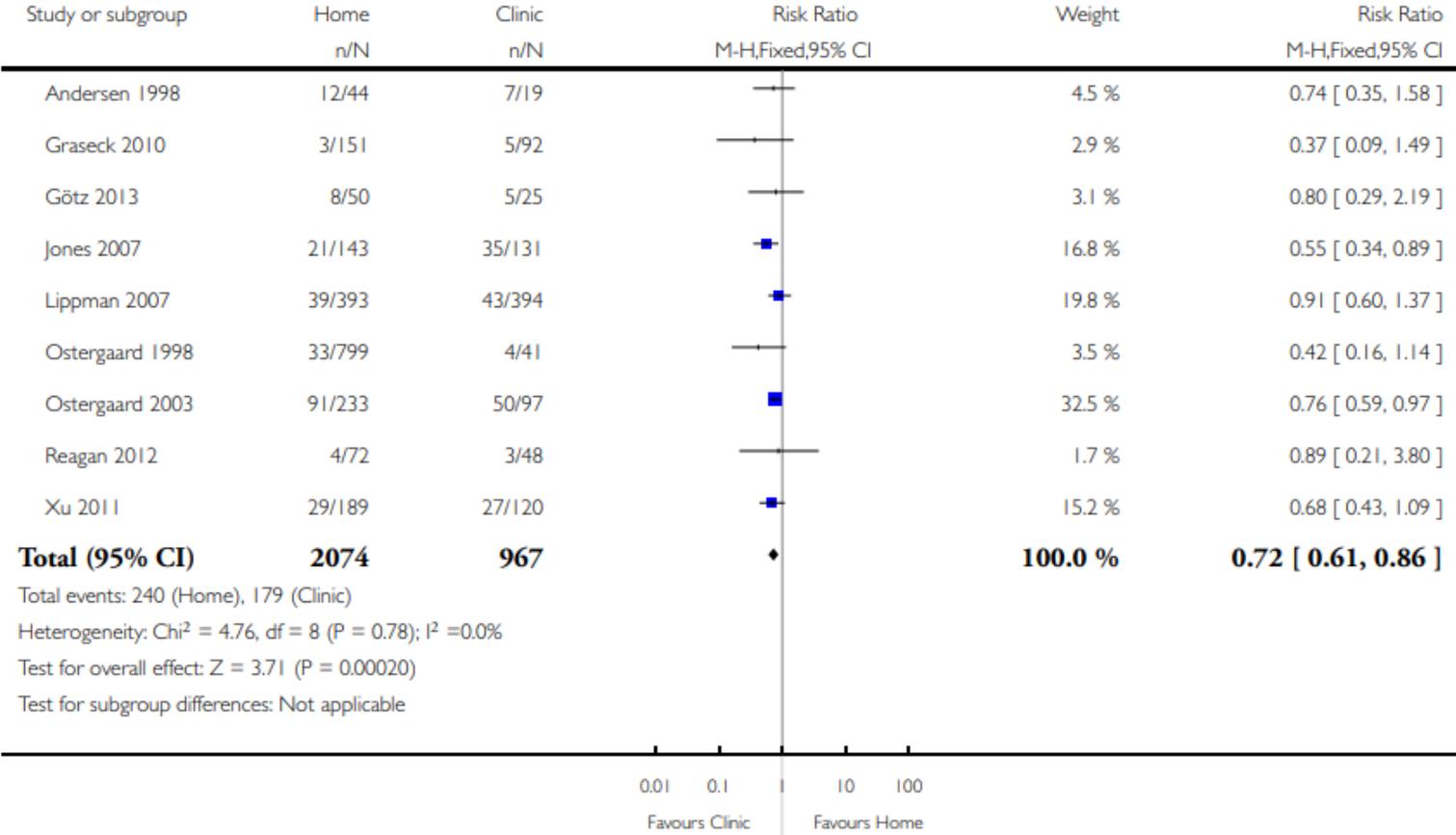
# Lower proportion of positive tests in the home collection group

## Analysis 1.7. Comparison 1 Home-based vs clinic-based specimen collection for CT and NG, Outcome 7 Positive test prevalence.

Review: Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections

Comparison: 1 Home-based vs clinic-based specimen collection for CT and NG

Outcome: 7 Positive test prevalence



# Current Landscape for STI Self-Testing

- Published data shows efficacy and cost-effectiveness of CT/NG NAAT self-testing in a variety of populations.
  - 14-19 million CT/NG NAAT performed each year in the US.
- COVID self-testing outside the clinical setting suggested a path for FDA approval (EUA).
- In many clinics, genital CT/NG self-collection (vaginal swabs in women, first-catch urine in men as preferred specimens) is **standard of care**.
  - Self-testing for urogenital CT/NG has been recommended by CDC since 2014 due to equivalent test performance and higher patient acceptability compared to clinician-collected samples.

# Current Landscape for STI Self-Testing

- **Barrier:** FDA has not approved any STI self-collection testing for use in a non-clinical setting. Labs are out of compliance if they perform validation procedures on swabs collected in the non-clinical setting.
- CDC Division of STD Prevention is working to publish a systematic review on the efficacy and acceptability of self-collected STI testing
- ASTDA recently published a position statement about the pitfalls and opportunities with the rapid spread of direct to consumer STI testing.
  - \$280 for CT/NG/TV/Mycoplasma testing. Some testing has poor sens/spec.



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# Challenges

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- Regulatory barriers have prevented FDA licensure of CT/NG self-collection outside of the clinical setting.
- Manufacturer Perspective
  - FDA submission requirements for self-collect indication (\$\$\$\$)
  - Complex, poorly defined requirements (STI reporting, treatment, linkage to care)
- Self-collection of extra-genital CT/NG NAAT specimens in the non-clinical setting requires instruction. (readily available)
- Syphilis testing requires blood sampling – more complex than CT/NG
  - Dried blood spots for treponemal antibody testing
  - Microtainers (1 mL) can allow for non-treponemal testing



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# Regulatory Solutions

- Formal FDA guidance and a streamlined process to allow assay claims to include CT/NG sample self-collection in non-clinical settings.

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- Define acceptable performance loss in terms of test sensitivity for CT/NG testing outside the clinical setting.
  - Oraquick POC HIV test was approved by FDA at 92% sensitivity.
- Allow laboratories to perform validation procedures on self-collected swabs.
  - Specify transport conditions.
  - Address safety concerns.
- Regulations for quality control for CT/NG testing by all vendors.

## **IWTK** I WANT THE KIT

Take Control, Know Your Status

In partnership with MD  
Dept of Health, Baltimore  
City HD, NIH, Tribal Health  
Boards

- “I want the kit” CT/NG home test kit from Johns Hopkins is free for residents of Maryland, Alaska, Oklahoma, Kansas, New Mexico, Utah, Nevada, Arizona.

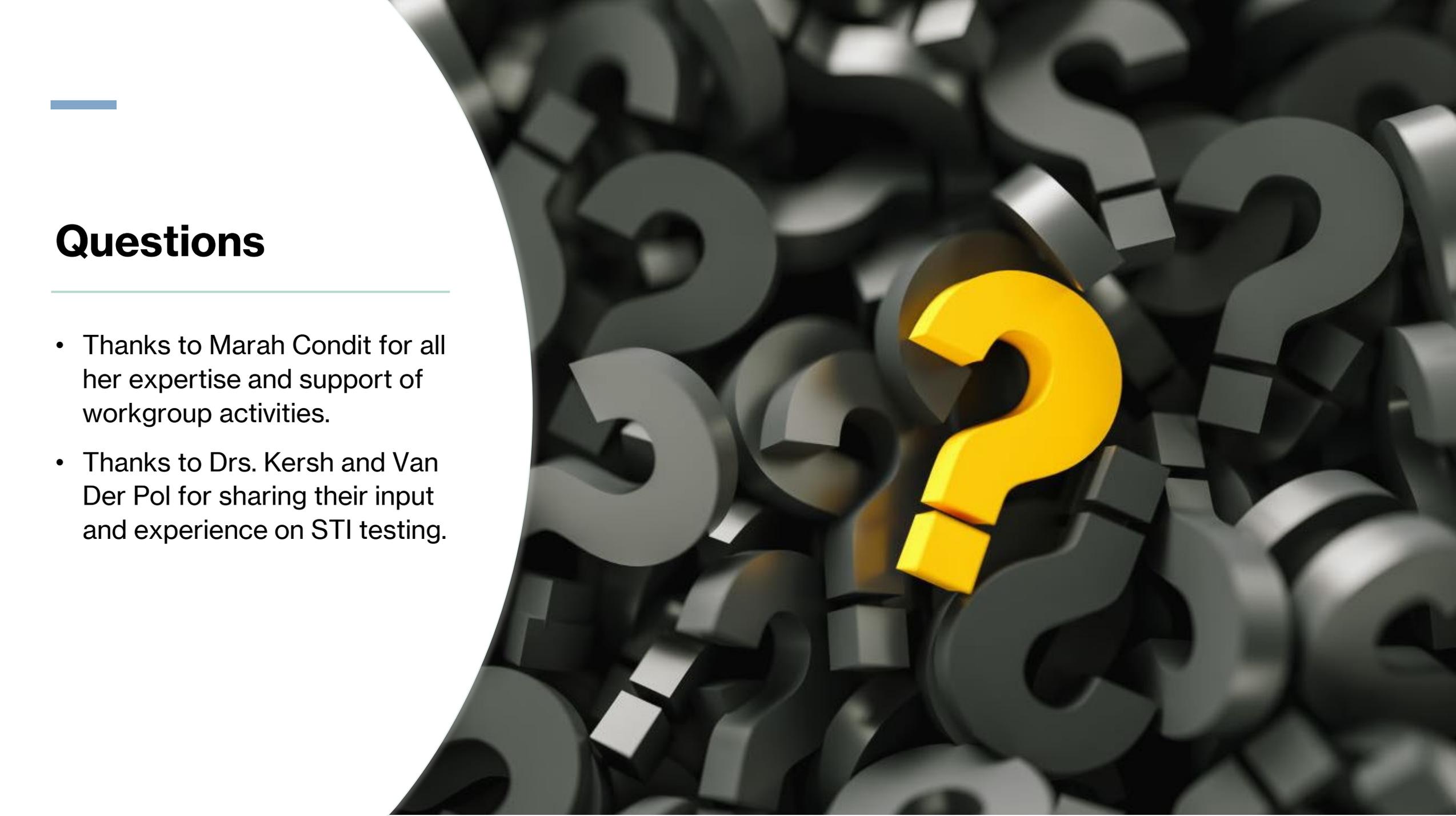
# Other Solutions and Knowledge Gaps

- Partnership with public health can help ensure that STI reporting, treatment, and partner notification is connected to testing outside clinical settings. Linkage to care based on test results is critical to improving STI outcomes.
  - CDC STI Lab is working to develop self-collection guidelines
- Novel approaches to improving access: vending machines, telehealth
- Standardized aligned STI reporting mechanisms are needed (i.e. COVID-19)
- STI diagnosis as a sentinel event: opportunity to link to HIV PrEP and doxy PEP
- Research Needs:
  - Improve high quality CT/NG/syphilis POC testing and comparative performance
  - Cost-effectiveness analyses to compare performance characteristics and case finding
  - Increase access to affordable STI testing especially in populations with existing barriers

# Conclusions



- Rates of curable CT/NG/syphilis in the US are rising with 15 million NAAT tests performed each year.
  - There is high demand for STI testing online - quality and cost varies.
- Published data suggests that STI self-collection in the non-clinical setting is feasible and highly acceptable. Test sensitivity is lower than in clinic.
- One regulatory barrier to improving access to STI testing is the current FDA requirement for sample collection in the clinical setting.
- CDC, FDA, local public health officials, and frontline providers are committed to improving access to high-quality STI diagnosis. The best programs ensure high treatment rates, linkage to care, and timely reporting.



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## Questions

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- Thanks to Marah Condit for all her expertise and support of workgroup activities.
- Thanks to Drs. Kersh and Van Der Pol for sharing their input and experience on STI testing.