

# Specimen Self-collection for HIV/STI Testing and PrEP Adherence Monitoring among MSM

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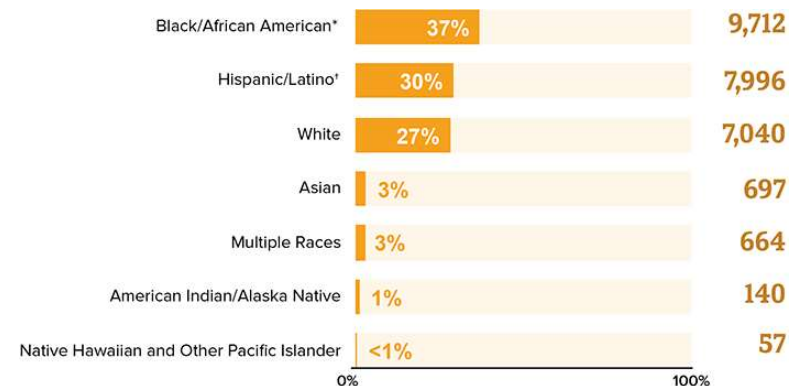
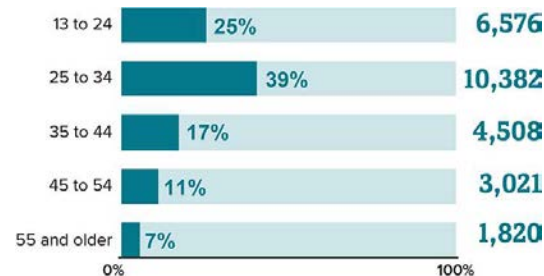
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# MSM and HIV

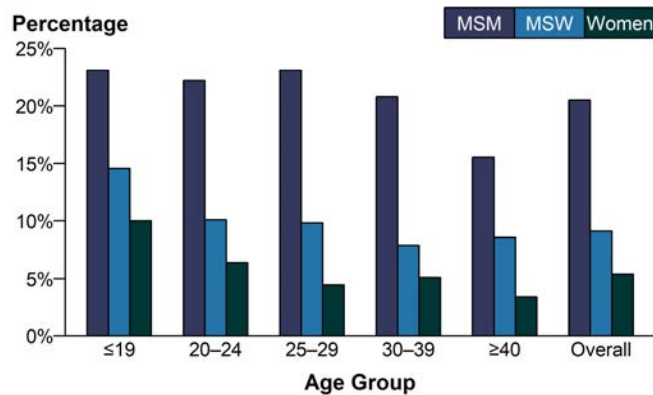
- Gay, bisexual and other men who have sex with men (MSM) in the US are disproportionately affected by HIV<sup>1</sup>



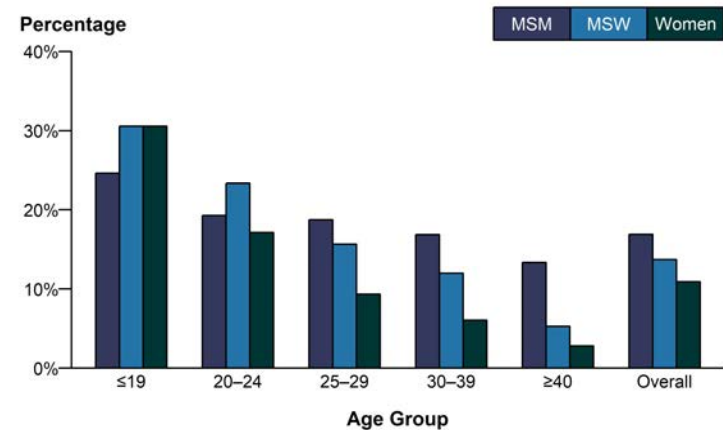
# MSM and other STIs

- MSM also experience a high burden of other STIs<sup>2</sup>, which can increase the risk of HIV acquisition or transmission<sup>3,4</sup>

**Figure** Gonorrhea — Proportion of STD Clinic Patients\* Testing Positive by Age Group and Sex and Sex of Sex Partners, STD Surveillance Network (SSuN), 2018

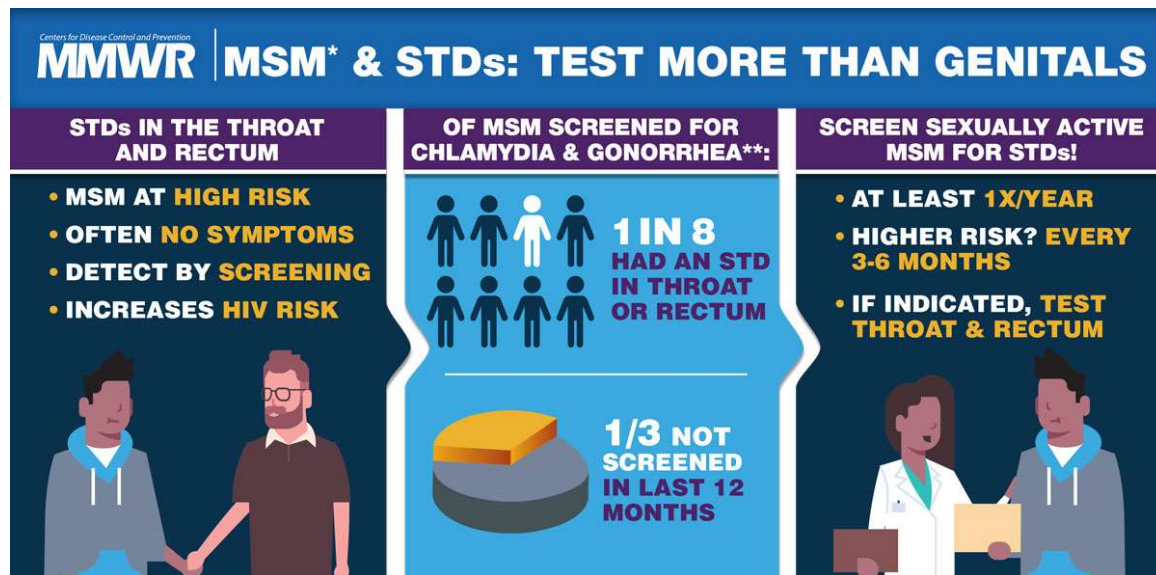


**Figure** Chlamydia — Proportion of STD Clinic Patients Testing Positive\* by Age Group and Sex and Sex of Sex Partners, STD Surveillance Network (SSuN), 2018



# MSM and other STIs

- Extragenital STIs, i.e. gonorrhea or chlamydia in the throat or rectum are often asymptomatic, but are prevalent among MSM<sup>5</sup>



# Screening for HIV and other STIs

- CDC recommends that all sexually active MSM should be tested for HIV, gonorrhea and chlamydia at least once a year<sup>6,7</sup>

## TAKE CHARGE: GET SCREENED

Screening **at least** annually for sexually active gay men/MSM at sites of exposure regardless of condom use.

- Every 3 to 6 months if at increased risk
- Every 3 months if on PrEP


A line drawing of a male figure from the waist up, facing forward. Three arrows point to specific areas: 'ORAL' points to the mouth, 'RECTAL' points to the anus, and 'GENITAL' points to the penis.

Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2015.

NASTAD National Coalition of STD Directors

# PrEP for HIV Prevention

- Testing for HIV is the first step in offering pre-exposure prophylaxis (PrEP) to those who test negative, or initiating treatment for those who test positive

	Population	Effectiveness Estimate	Source	Interpretation
	<i>"Optimal or Consistent Use"<sup>a</sup> (Taking PrEP daily or at least 4 times per week)</i>			
	Men who have sex with men (MSM)	~99%	Grant, 2014 Liu, 2015 McCormack, 2015 Volk, 2015 Marcus, 2017	When taking PrEP daily or consistently ( <i>at least 4 times per week</i> ), the risk of acquiring HIV is reduced by about 99% among MSM. While daily use is recommended in the U.S., taking PrEP consistently ( <i>at least 4 times per week</i> ) appears to provide similar levels of protection among MSM. The effectiveness of oral PrEP is highly dependent on PrEP adherence. When taking oral PrEP daily or consistently, HIV acquisition is extremely rare and has not been observed in any of the studies described below. In clinical practice, a few cases of new HIV infections have been confirmed while HIV-negative individuals were on PrEP with verified adherence.

# Specimen Self-collection

- Self-collection of specimens (finger-stick blood, urine, throat swab, rectal swab) at home and their return by mail for laboratory testing has the potential to reduce personal and logistical barriers to regular HIV/STI screening faced by MSM<sup>8</sup>
- Self-collection of hair and its return by mail might facilitate remote PrEP adherence monitoring, and allow for the identification of MSM facing adherence difficulties

**Which kinds of specimens will MSM be willing to self-collect and return by mail, and will the specimens be adequate for laboratory testing?**

# Project Caboodle!



- Objective – Explore the acceptability and feasibility of self-collecting and returning by mail a bundle of 5 different specimens for HIV, gonorrhea and chlamydia testing, as well as PrEP adherence monitoring, among MSM aged 18 to 34 years



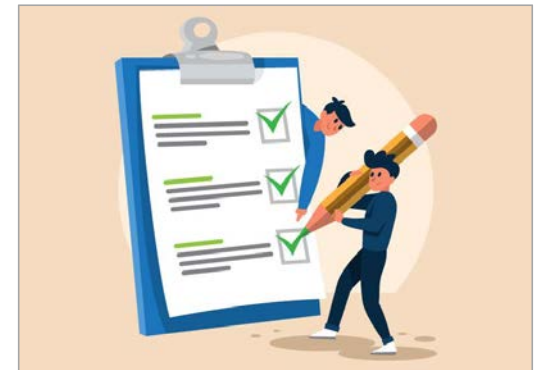
# Project Caboodle! Recruitment

- 101 sexually active MSM were recruited using racially and ethnically diverse advertising on a social networking website (Facebook) and a mobile gay dating app (Grindr)



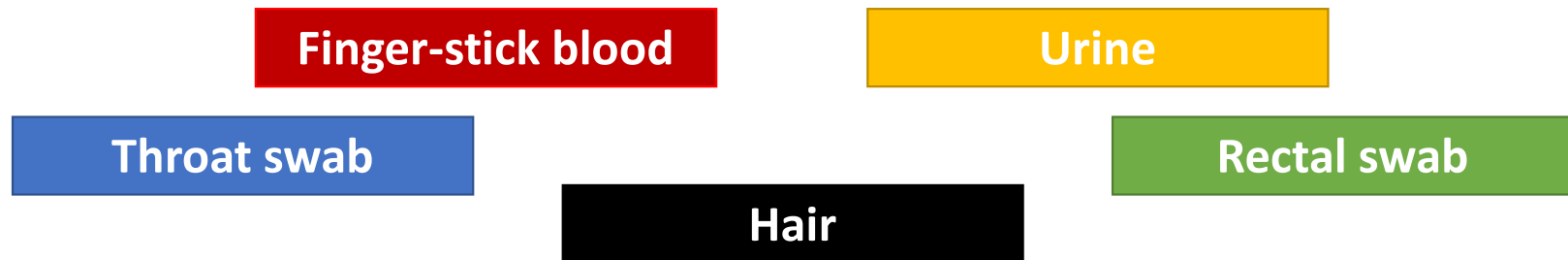
# Project Caboodle! Recruitment

- Eligibility criteria
  - Cisgender male
  - 18 to 34 years of age
  - Currently reside in the US or dependent areas
  - Report an HIV-negative or unknown status
  - Had  $\geq 2$  male sex partners in the past 3 months
  - Willing to receive a box containing instructions and materials for specimen self-collection and return
- Eligible men were asked to provide their full name, an email address, a mobile phone number, and a preferred mailing address



# Project Caboodle! Phase 1 Procedures

- Participants were first emailed a link to our Web-based survey, programmed in Qualtrics
- Survey completers were provided an incentive of US \$40 in the form of an Amazon gift card
- Participants were then shipped a box containing instructions and materials for self-collecting and potentially returning 5 specimens



# Project Caboodle! Phase 1 Procedures



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- Specimen return was completely voluntary, and no incentives were provided to participants for completing this step
- Lab results were returned to our study staff through password-protected files shared over Box, a secure cloud storage and collaboration platform



# Project Caboodle! Phase 1 Procedures

- HIV, gonorrhea, and chlamydia test results were delivered back to participants by our trained counselor over the phone



- Anyone with a positive test result was emailed a list of local healthcare providers within 24 hours, and contacted again after 2 weeks to assess linkage to care

# Project Caboodle! Phase 1 Preliminary Results

- Mean age = 26 years
- Race/ethnicity
  - 38 (37.6%) were non-Hispanic white
  - 17 (16.8%) were non-Hispanic black
  - 29 (28.7%) were Hispanic
  - 17 (16.8%) were of some other race/ethnicity
- Educational level
  - 59 (58.4%) had a Bachelor's degree or higher
  - 33 (32.7%) had an Associate's/Technical degree or some college education
  - 9 (8.9%) had a high school diploma or GED

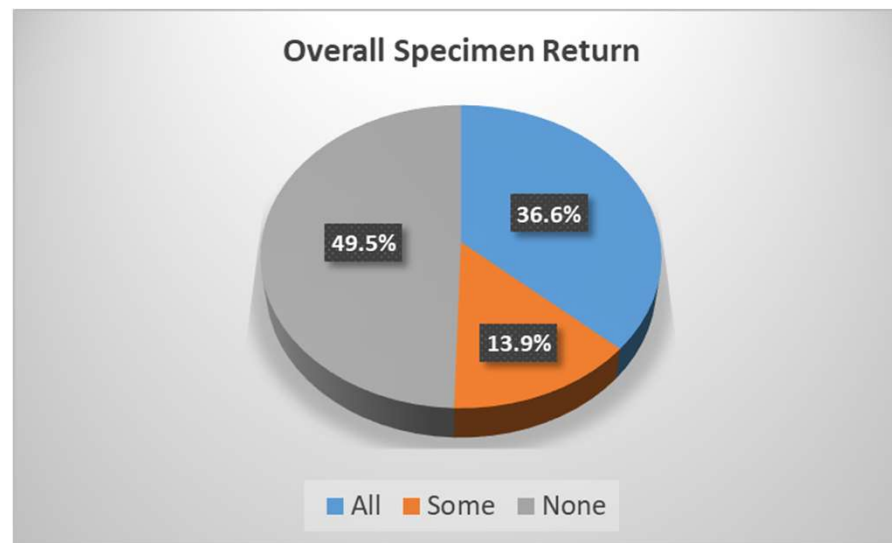
# Project Caboodle! Phase 1 Preliminary Results

- Sexual orientation
  - 87 (86.1%) identified as gay
  - 7 (6.9%) identified as bisexual
  - 7 (6.9%) identified as queer, questioning, pansexual, straight
- Relationship status
  - 68 (67.3%) were single
  - 33 (32.7%) were partnered
- Sex with  $\geq 2$  men in the past 3 months
  - 55 (54.5%) had engaged in condomless anal sex
  - 70 (69.3%) had engaged in condomless oral sex



# Project Caboodle! Phase 1 Preliminary Results

- 37 returned all specimens, 14 returned some specimens, and 50 returned no specimens



# Project Caboodle! Phase 1 Preliminary Results

	+ for HIV	+ for gonorrhea	+ for chlamydia	✓ for PrEP adherence monitoring
Finger-stick blood (n=44)	0 (0.0%)	-	-	-
Urine (n=47)	-	0 (0.0%)	1 (2.1%)	-
Throat swab (n=48)	-	0 (0.0%)	0 (0.0%)	-
Rectal swab (n=46)	-	1 (2.2%)	2 (4.3%)	-
Hair (n=46)	-	-	-	36 (78.3%)

# Project Caboodle! Phase 2 Procedures

- In-depth interviews were conducted with a subset of 24 participants (10 who returned all specimens, 7 who returned some specimens, 7 who returned no specimens) via videoconferencing



- Interviewees were provided an incentive of US \$40 in the form of an Amazon gift card

# Project Caboodle! Phase 2 Preliminary Results

- Finger-stick blood
  - *“I just think of fear. You know the pain is coming.”* – 27 years, Asian
  - *“I initially thought I was gonna send it, but then I said, I really dislike the finger-prick.”* – 30 years, non-Hispanic white
- Urine
  - *“I just felt like things would get messy. Like, say if it broke mid-ship... I wouldn't wanna deal with that.”* – 22 years, non-Hispanic white
- Throat swab
  - *“I don't even like doing that when I go to the clinic, 'cause it's like a gag reflex.”* – 32 years, non-Hispanic black

# Project Caboodle! Phase 2 Preliminary Results

- Rectal swab
  - *“To be very blunt, I just don't like things going up my ass.”* – 22 years, non-Hispanic white
  - *“Uncomfortable. I thought that was weird and inappropriate.”* – 27 years, non-Hispanic black
- Hair
  - *“I think this one said that you either had to pluck or cut a tuft of hair, and that seemed a little intense... And also it was, this is the one you had to send to a different place.”* – 30 years, non-Hispanic white
  - *“The thing is that actually I'm bald, so I don't have hair, basically.”* – 29 years, Hispanic

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