Three Site's a Charm: The Importance of Extragenital Testing for MSM

August 29, 2019

NCSD

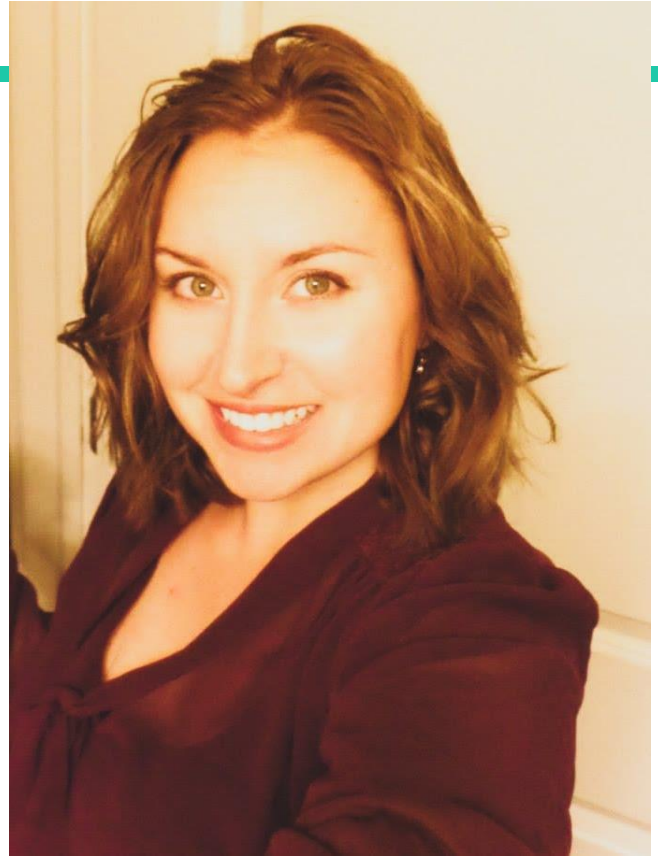
National Coalition of STD Directors

Logistics

This webinar is being recorded and will be shared with you.

Agenda

1. Overview of peer-reviewed on extragenital STD screening of MSM
   - *Kacie Taylor – Colorado*
2. Using comprehensive sexual histories to identify anatomical sites to be tested
   - *Dr. Ami Multani - Fenway Health; Boston*
3. Successfully incorporating self-collection of pharyngeal and rectal specimens for extragenital STD testing
   - *Rachel Howard - Maricopa County, AZ*
4. Successfully capturing anatomical site of reported chlamydia and gonorrhea cases through surveillance
   - *Daniel Daltry – Vermont*
5. Q&A



Kacie Taylor
Western Regional Consultant
Colorado Dept. of Public Health & Enviroment

EXTRAGENITAL TESTING WITHIN THE MSM POPULATION

Kacie Taylor, Western Regional Consultant

Colorado Dept. of Public Health & Environment

COLORADO
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WHAT IS EXTRAGENITAL TESTING?

- Nucleic acid amplification (NAAT)tests for detection of Neisseria gonorrhoeae and Chlamydia trachomatis from throat and rectal sites.

SCREENING RECOMMENDATIONS

CENTERS FOR DISEASE CONTROL AND PREVENTION

"The CDC recommends annual CT screening of all sexually active women aged <25 years."

"The guidelines also recommend screening sexually active MSM using NAATs from genital and extragenital sites for GC and CT, at annual or more frequent intervals as influenced by risk."[1]

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1. https://www.cdc.gov/std/tg2015/screening-recommendations.htm

The CDC recommends the following screening for MSM, regardless of condom use, using Nucleic Acid Amplification Tests (NAATs) as the preferred test:

- A test for urethral chlamydia or gonorrhea infection in men who had insertive intercourse in the past year.
- A test for rectal chlamydia or gonorrhea infection in men who had receptive anal intercourse in the past year.
- A test for pharyngeal gonorrhea infection in men who had receptive oral intercourse in the past year.

NOTE: CDC does not recommend testing for pharyngeal chlamydia infection, but most providers use combination tests for both chlamydia and gonorrhea.[2]

2. https://www.cdc.gov/std/tg2015/specialpops.htm#MSM

CENTERS FOR DISEASE CONTROL AND PREVENTION

COLORADO Department of Public Health & Environment

LABORATORY RECOMMENDATIONS

Centers for Disease Control and Prevention
MMWR
Recommendations and Reports / Vol. 63 / No. 2

NAAT is the recommended test method for both Chlamydia trachomatis and Neisseria gonorrhoeae in men and women.

The optimal specimen type to detect chlamydia or gonorrhea infection in men is a first-catch urine *which is equivalent to a urethral swab*.

NAAT is also the recommended test method for rectal and oropharyngeal specimens.[3]

3. https://www.cdc.gov/std/laboratory/2014labrec/2014-lab-rec.pdf

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STUDY: "Nucleic acid amplification tests in the diagnosis of chlamydial and gonococcal infections of the oropharynx and rectum in men who have sex with men."

Population Screened: 1,110 MSM clients

Location: San Francisco, CA city STD clinic

Data Reviewed: Sensitivity of Cultures vs NAATS in detecting CT/GC

https://www.ncbi.nlm.nih.gov/pubmed/18520976

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STUDY: "Nucleic acid amplification tests in the diagnosis of chlamydial and gonococcal infections of the oropharynx and rectum in men who have sex with men."

TABLE 1. Preliminary Performance Profile of Culture and NAATs for the Detection of *N. gonorrhoeae* and *C. trachomatis* in Oropharyngeal and Rectal Specimens (n = 205)

	Culture	SDA	AC2	PCR
Oropharyngeal				
GC sensitivity	60.0% (12/20)	75.0% (15/20)	95.0% (19/20)	60.0% (12/20)
GC specificity	100.0% (185/185)	99.5% (184/185)	100.0% (185/185)	78.9% (146/185)*
CT sensitivity	66.7% (2/3)	33.3% (1/3)	100.0% (3/3)	33.3% (1/3)
CT specificity	100.0% (200/200)	100.0% (200/200)	99.5% (199/200)	100.0% (200/200)
Rectal				
GC sensitivity	50.0% (9/18)	77.8% (14/18)	100.0% (18/18)	44.4% (8/18)
GC specificity	100.0% (187/187)	100.0% (187/187)	99.5% (186/187)	99.5% (186/187)
CT sensitivity	35.3% (6/17)	76.5% (13/17)	100.0% (17/17)	64.7% (11/17)
CT specificity	100.0% (186/186)	100.0% (186/186)	100.0% (186/186)	100.0% (186/186)

CT true positives defined as culture positive or 2 positive NAATs at that anatomic site or a single NAAT positive confirmed by an alternate NAAT assay. GC true positives defined as culture positive or AC2/PCR positive or AC2/SDA positive or a single NAAT positive confirmed by an alternate NAAT assay.

*$P < 0.05$ for comparison with culture.

https://www.ncbi.nlm.nih.gov/pubmed/18520976

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STUDY: "Extragenital Gonorrhea and Chlamydia Testing and Infection Among Men Who Have Sex With Men—STD Surveillance Network, United States, 2010–2012"

Population Screened: 21,994 MSM clients

Locations: 42 STD Clinics, 12 collaborating jurisdictions (7 state & 5 local health departments)

Timeframe Reviewed: 1 July2011 – 30 June 2012 and any visits within the 12 months prior

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4666527/

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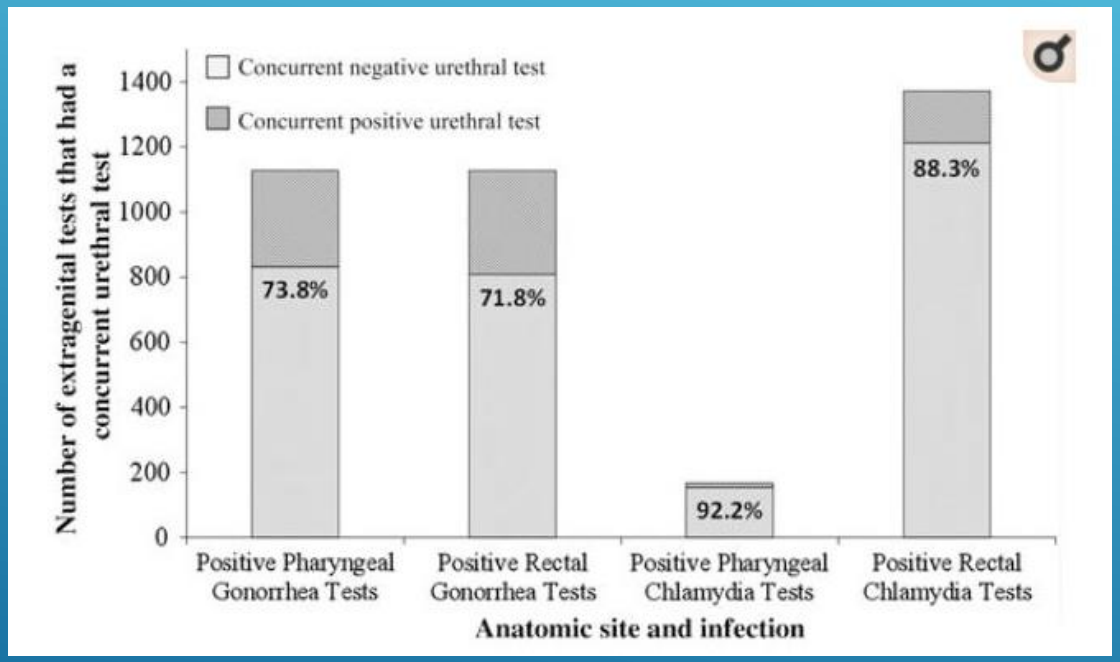
STUDY: "Extragenital Gonorrhea and Chlamydia Testing and Infection Among Men Who Have Sex With Men—STD Surveillance Network, United States, 2010–2012"



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4666527/

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May 23, 2019 - "FDA clears first diagnostic tests for extragenital testing for chlamydia and gonorrhea"

- cross-sectional, collaborative, multi-site clinical study
- 2,500+ patients
- Evaluation of the diagnostic accuracy of multiple commercially available nucleic acid amplification tests for detection of Neisseria gonorrhoeae and Chlamydia trachomatis from throat and rectal sites.
- Study results demonstrated two commercially available tests are safe and effective for extragenital testing for chlamydia and gonorrhea.

https://www.fda.gov/news-events/press-announcements/fda-clears-first-diagnostic-tests-extragenital-testing-chlamydia-and-gonorrhea

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BARRIERS TO EXTRAGENITAL TESTING

Provider Barriers

- Data
- Training
- Time-Management
- Discomfort

Client Barriers

- Discomfort
- Awareness
- Cost

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Ami Multani, MD
Physician & Medical Director of Infectious Disease
Fenway Health (Boston, MA)

FENWAY HEALTH

The Impact of Taking a Thorough Sexual History on STD testing

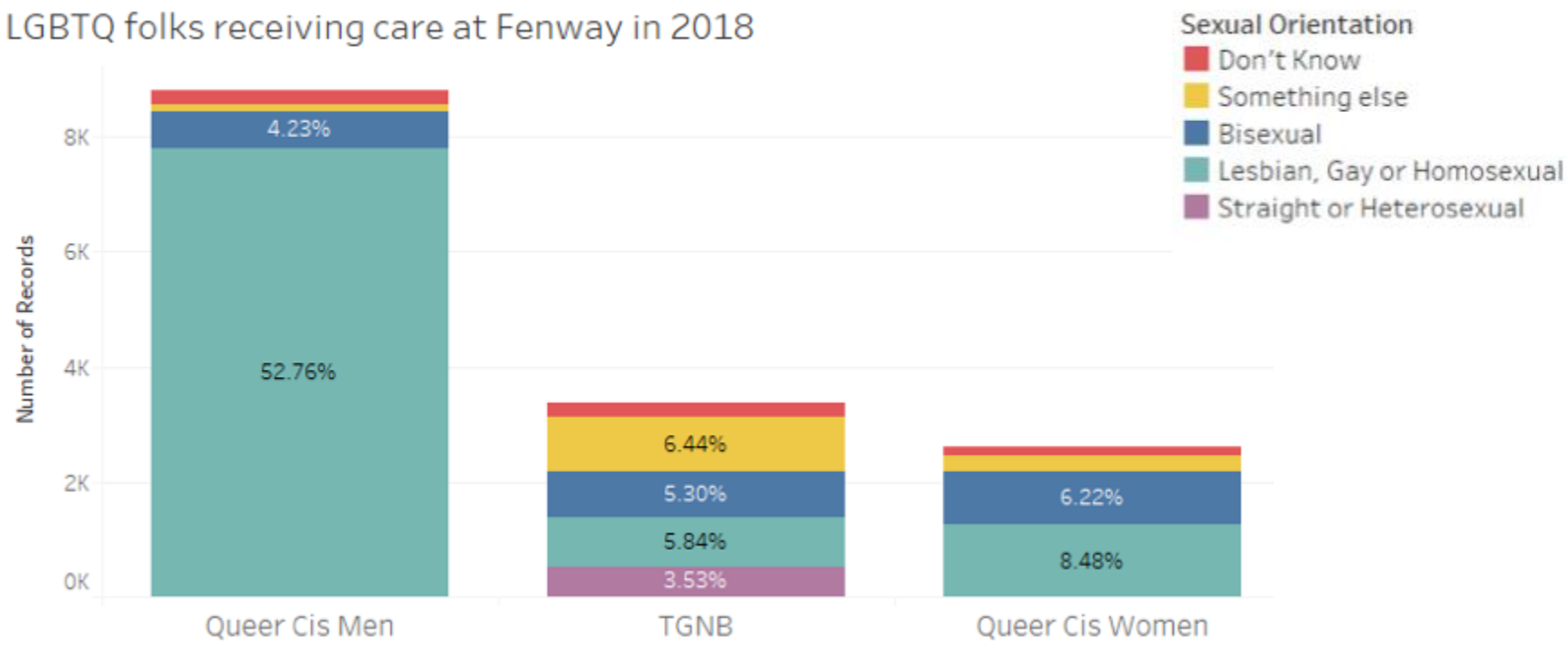
Ami Multani, MD
Medical Director of Infectious Disease
Fenway Health

fenwayhealth.org

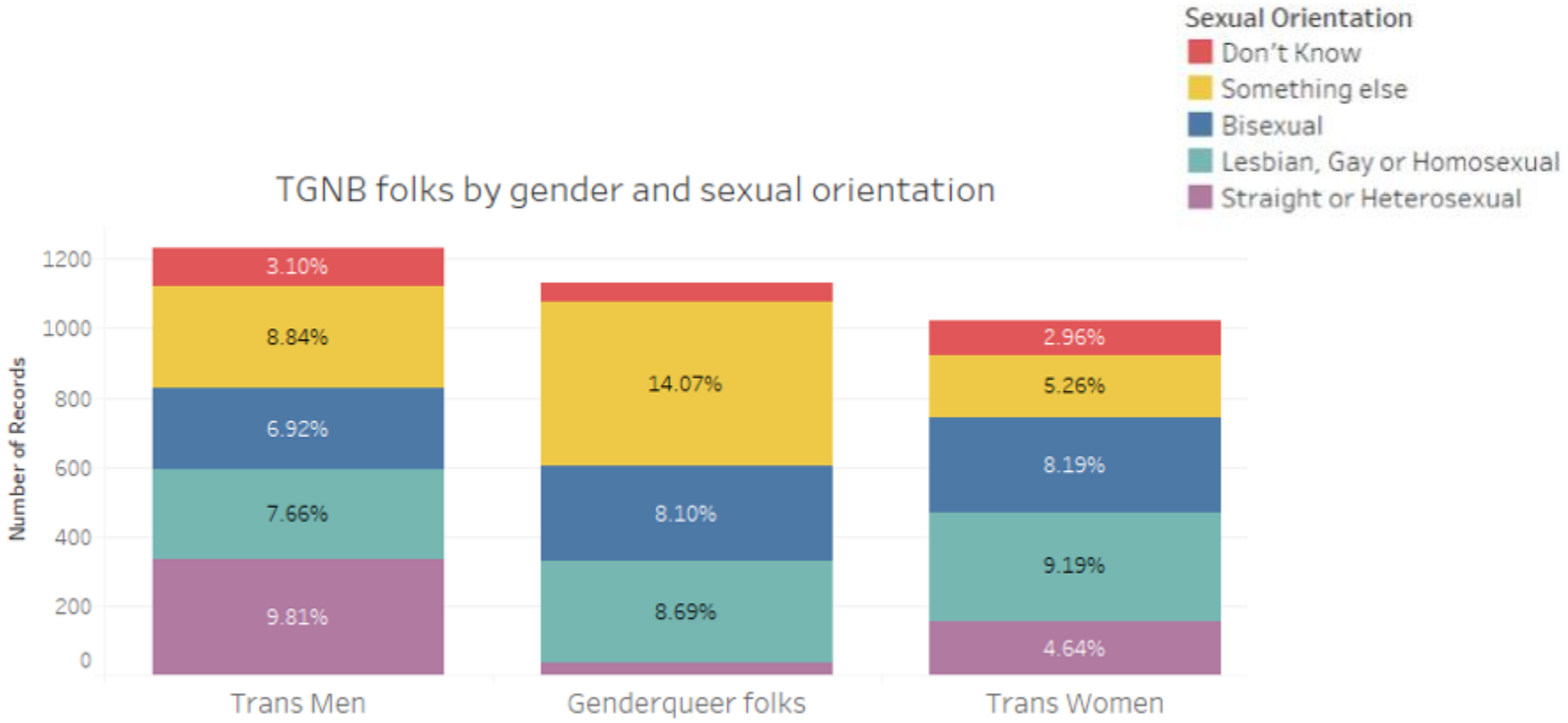
FENWAY HEALTH

- Federally qualified health center with 3 clinic sites in Boston, MA
- Established in 1971
- 34,000 patients / 122,000+ total visits in 2017
  - 50% are LGBTQ
  - 2200+ are PLWH
    - 94% male and MSM risk factor
  - 4000 are transgender
- NCQA Level 3 Prime Patient Centered Medical Home

LGBTQ PATIENTS RECEIVING CARE AT FENWAY HEALTH - 2018



TGNP PATIENTS BY GENDER AND SEXUAL ORIENTATION



SEX AND GENDER

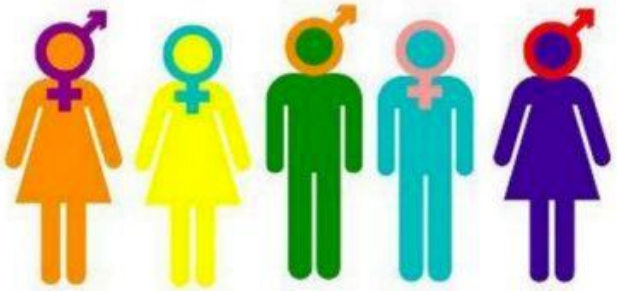
Sex and gender core determinants of health

Sex – biological differences

- Anatomy, chromosomes, hormones, genes, etc.

Gender – social and cultural distinctions

- Multidimensional
- Psychological, social, behavioral
- Gender identity, gender expression, gender roles



SEXUAL ORIENTATION AND GENDER IDENTITY ARE NOT THE SAME

- All people have a sexual orientation and gender identity
  - How people identify can change
  - Terminology varies

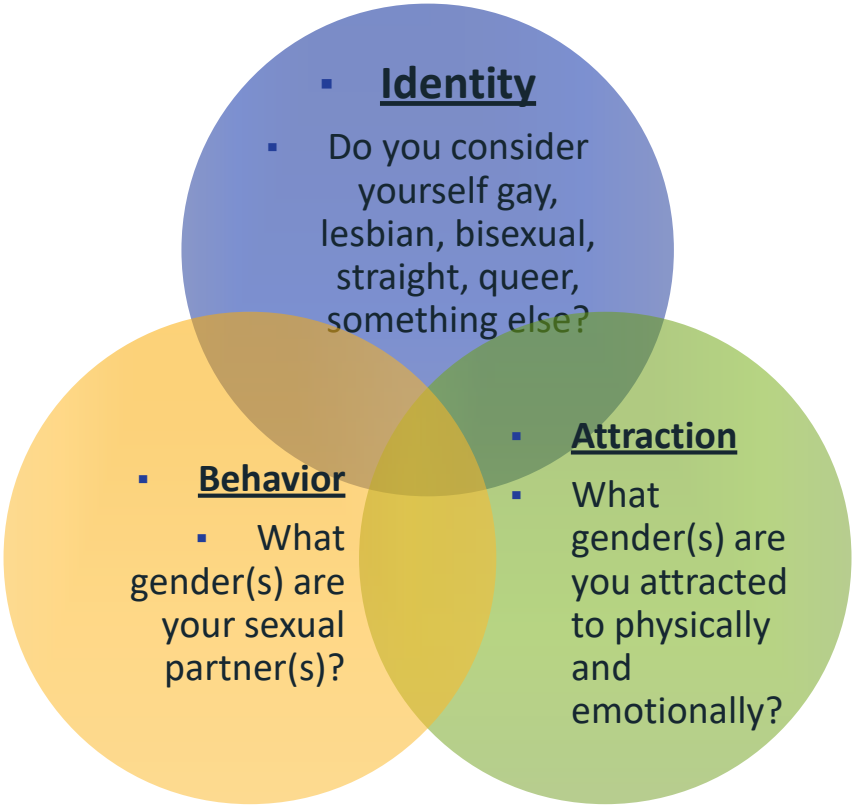
Gender Identity ≠ Sexual Orientation

SEXUAL ORIENTATION

Sexual orientation: how a person identifies their physical and emotional attraction to others

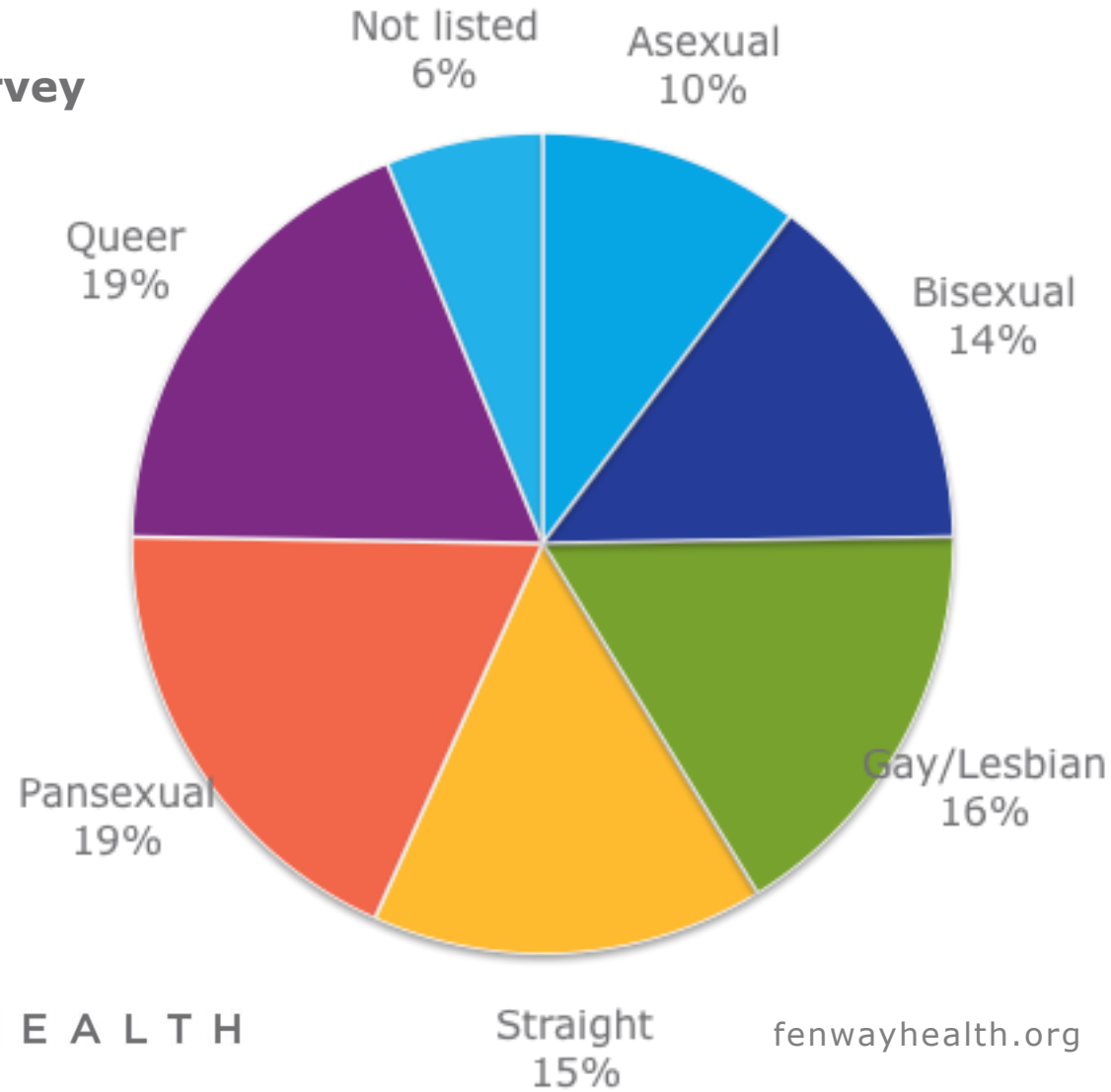
- Desire
- Behavior
  - Men who have sex with men- MSM (MSMW)
  - Women who have sex with women- WSW (WSWM)
- Identity
  - Straight, gay, lesbian, bisexual, queer, other

Dimensions of Sexual Orientation:



SEXUAL ORIENTATION OF GENDER DIVERSE INDIVIDUALS

2015 US Trans Survey



STD RISK FACTORS

- LGBT individuals face increased risk for HIV and STIs
  - Best documented for MSM - rates of HIV, syphilis, and gonorrhea exceed that of the general population
  - Transfeminine individuals face a 49x greater odds of HIV infection compared to all adults
  - Infection rates of STIs among lesbians, trans masculine, and non-binary folks remains unknown
    - 24% of trans masculine individuals report avoiding health care due to fear of discrimination and harassment

FENWAY HEALTH

1. Sexually Transmitted Disease Surveillance 2017. Centers for Disease Control and Prevention. 2018. Available at: https://www.cdc.gov/std/stats17/default.htm.
2. Baral SD, Poteat T, Stromdahl S, Wirtz AL, Guadamuz TE, Beyrer C. Worldwide burden of HIV in transgender women: a systematic review and meta-analysis. Lancet Infect Dis. 2013;13(3):214-222.

The New York Times

Gay and Transgender Patients to Doctors: We'll Tell. Just Ask.

By JAN HOFFMAN MAY 29, 2017

By knowing whether a patient is lesbian, gay, bisexual, transgender or straight, say public health experts, **clinicians can be more alert to a person's medical needs and more thoughtful in interactions**. If hospitals report statistics on all patients, health care disparities among L.G.B.T. patients can be identified and redressed more effectively.

But **most doctors and nurses** are in no rush to comply. In several studies, they have said they **feel uneasy about asking** because they don't want to make patients uncomfortable.

Research now suggests those assumptions may be wrong.

A new study of both patients and providers in the journal JAMA Internal Medicine looked at the feasibility of gathering such information in emergency departments. Nearly 80 percent of providers surveyed believed that patients would refuse to disclose their sexual orientation.

By contrast, **only 10 percent of patients from a randomized, national sample of lesbian, gay, bisexual and heterosexual subjects said they would refuse**. (Those who said they would decline were more likely to be bisexual.)

The New York Times

Gay and Transgender Patients to Doctors: We'll Tell. Just Ask.

By JAN HOFFMAN MAY 29, 2017

The signature message from the study, added Dr. Haider, the director of the hospital's Center for Surgery and Public Health, is that "patients are saying that **you'll make us feel more comfortable if you ask — and ask everyone, so that normalizes the questions.**"

JAMA Network

JAMA Internal Medicine

View Article

JAMA Intern Med. 2017 Jun; 177(6): 819–828.
Published online 2017 Apr 24. doi: 10.1001/jamainternmed.2017.0906

PMCID: PMC5818827
PMID: 28437523

Emergency Department Query for Patient-Centered Approaches to Sexual Orientation and Gender Identity

The EQUALITY Study

Adil H. Haider, MD, MPH,[1,2] Eric B. Schneider, PhD,[1,2] Lisa M. Kodadek, MD,[3] Rachel R. Adler, ScD, RD,[1,2] Anju Ranjit, MD, MPH,[1,2] Maya Torain, BA,[4] Ryan Y. Shields, MD,[5] Claire Snyder, PhD,[6,7] Jeremiah D. Schuur, MD,[8] Laura Vail, MS,[6] Danielle German, PhD,[9] Susan Peterson, MD,[10,11] and Brandyn D. Lau, MPH, CPH[3,7,11,12]

FENWAY HEA

WHY TALK ABOUT SEXUAL HEALTH?

- It is integral to a person's general health
- It is associated with happiness, well-being, and longevity
- Sexual function is lifelong and evolves over the lifespan
- It may be associated with Morbidity and Mortality
- There is a high prevalence of sexual dysfunction (or mis-function or misunderstanding!)
- Sexual history and current function may indicate
  - psychiatric and/or other medical disorders
  - may explain current health problems (e.g abuse and violence, prior STDs)
  - may determine the need for primary prevention (e.g immunizations, contraception, PEP, PrEP, etc.)

Nussbaum and Hamilton, "The Proactive Sexual Health History", 2002

SEXUAL HISTORY

- Sexual health history is an important part of a routine medical exam or physical history for ALL patients, **regardless** of gender identity or sexual orientation

- Important factors:
    1. Heterogeneity of sexual identities
    2. Diverse sexual partnerships & practices
    3. Sensitivity to language

TALKING ABOUT SEX

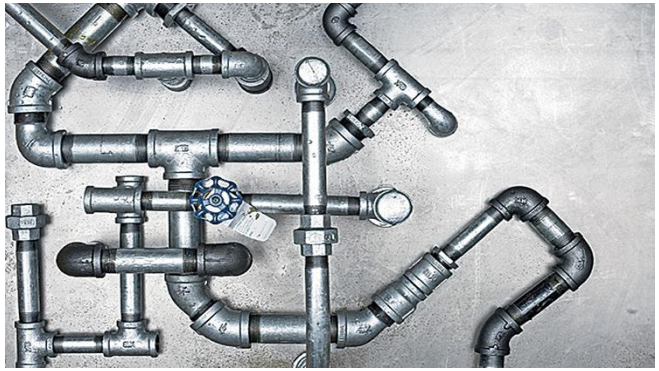
- Introductory language
  - Acknowledge and affirm differences in identity, language use, and sexual practices
  - **Take an Anatomic Inventory!**

    "Have you had any body modification surgeries?"
  - Establish from the beginning what words you and the patient will use

    "When referring to your genitals, are there specific terms that you use?"

    "I typically stick with medical terms, but if there is language or words you prefer, please let me know!"
    - Check in to make certain that the both you and the patient have the same understanding of these terms

Clitoris, phallus, dick, penis
Vagina, genital canal, front hole
Penetrative sex, vaginal sex, frontal sex
Anus/anal, back hole, butt, plumbing



TALKING ABOUT SEX

- Ask questions to capture diverse sexual behaviors
  - Validate all sexual practices by asking about both high & low risk activities … and PLEASURES!
  - Don't assume people are limited to certain kinds of sex based on gender (i.e., include questions about insertive sex)

- Ask open ended questions
  - Who are you having sex with?
  - What kinds of sex are you engaging in
    - "which body parts of yours touch which body parts of your partner"
  - Are you engaging in sex for pleasure or do you feel forced in any way?
    - Are you engaging in sex for money, housing, drugs, or any other service
  - Do you feel safe in your current relationship? Do you feel empowered to tell your partner to use condoms?
  - Are you using any prosthesis or toys for sex? Are you sharing these?

EXPLORING RELATIONSHIPS

- Basic forms: monogamy, open relationships, polyamory, BDSM, kink, etc
- Sexual activities: oral, vaginal, anal sex … and beyond!
- Gender presentation and disclosure
- Survival sex
- Transitioning within an established relationship
- Safe spaces
- The decision to be sexual

CLINICAL INTERVIEW: THE 8 "P"S

The CDC's 5 "P"s

1. Partners
2. Practices
3. Protection for STDs
4. Past history of STDs
5. Prevention of pregnancy

The 8 "P"s

1. **Preferences**
2. Partners
3. Practices
4. Protection for STIs
5. Past history of STIs
6. Pregnancy
7. **Pleasure**
8. **Partner Violence**

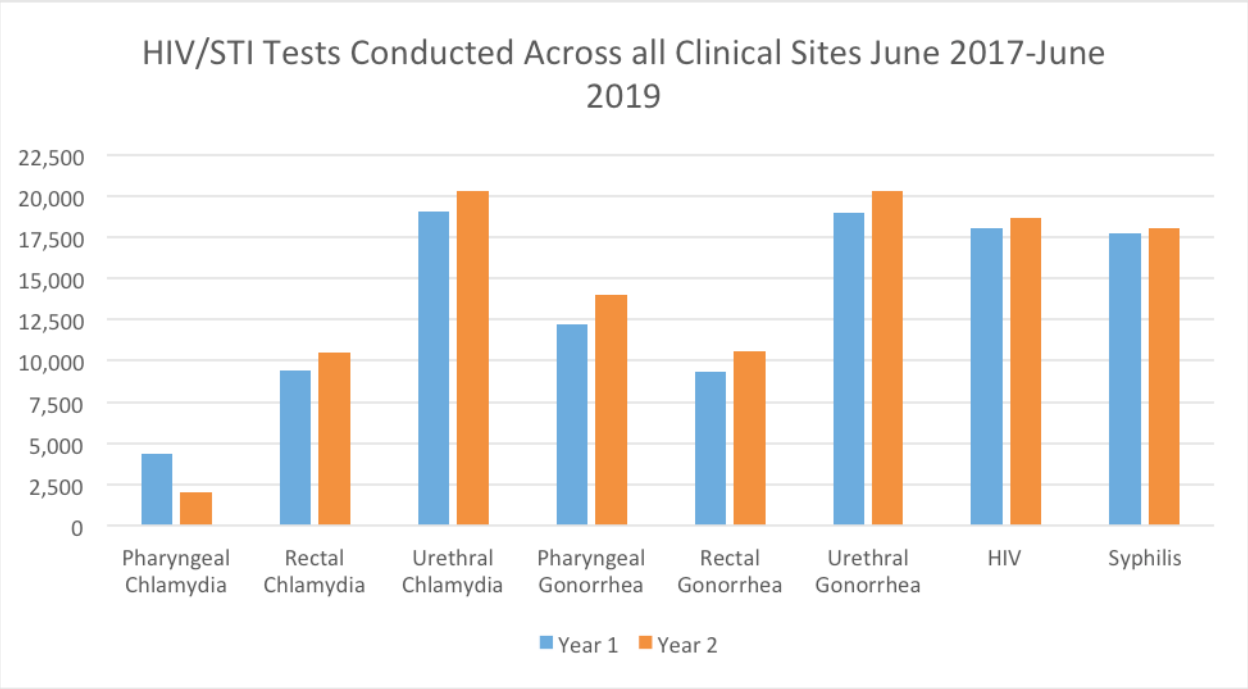
CLINICAL INTERVIEW: THE 8 "P"S

	"P"	Example Questions
1	Preferences	• Do you have preferred language that you use to refer to your body (i.e., genitals)? • Are you currently sexually active? • What kinds of sex do you engage in?
2	Partners	• Are you sexually active with one partner or more than one? • Are you dating anyone or sexually active? • Do you have any outside partners? • How would your partners identify themselves in terms of gender?
3	Practices	• Do you use toys inside your [insert preferred language for genitals] or anus, or do you use them on your partners? • Do you have any other types of sex that hasn't been asked about?
4	Protection from STIs	• Are there some kinds of sex where you do not use barriers? Why?
5	Past history of STIs	• If yes… Do you remember the site?

CLINICAL INTERVIEW: THE 8"P"S

	"P"	Example Questions
6	Pregnancy	• Have you considered fertility preservation/banking gametes? • Have you thought about having your own biological children, or carrying a pregnancy? • When you are having sex, is there any exposure to sperm or chance of pregnancy? • Have you considered contraceptive options?
7	Pleasure	• Do you feel you are able to become physically aroused during sex? • How satisfied are you with your ability to achieve orgasm? • Do you have any pain or discomfort during or after orgasm? • Is sex fun? • Are you having sex for pleasure or are these other reasons (survival sex/transactional sex)
8	Partner Abuse	• Has anyone ever forced or compelled you to do anything sexually that you did not want to do? • Is there any violence in any of your relationships? Do you feel safe at home?

HIV/STD TESTS CONDUCTED AT FENWAY HEALTH



POSITIVITY RATE OF HIV/STIS AT FENWAY HEALTH

Positivity Rate for HIV/STIs at all Clinical Sites		
	Year 1	Year 2
Pharyngeal Chlamydia*	1.14%	2.39%
Rectal Chlamydia	9.14%	8.62%
Urethral Chlamydia	2.28%	2.19%
Pharyngeal Gonorrhea	3.91%	4.73%
Rectal Gonorrhea	5.79%	5.30%
Urethral Gonorrhea	1.34%	1.35%
HIV**	0.88%	0.91%
Syphilis	10.05%	9.50%

Rachel Howard, MPH
STD Epidemiologist
Maricopa County Dept. of Public Health (Phoenix, AZ)

Successful Extragenital Testing Integration in Maricopa County, AZ

Rachel Howard, MPH

MCDPH STD Epidemiologist

NCSD Three Site's a Charm: The Importance of Extragenital Testing for MSM

August 29th, 2019

Maricopa County Department of Public Health STD Clinic

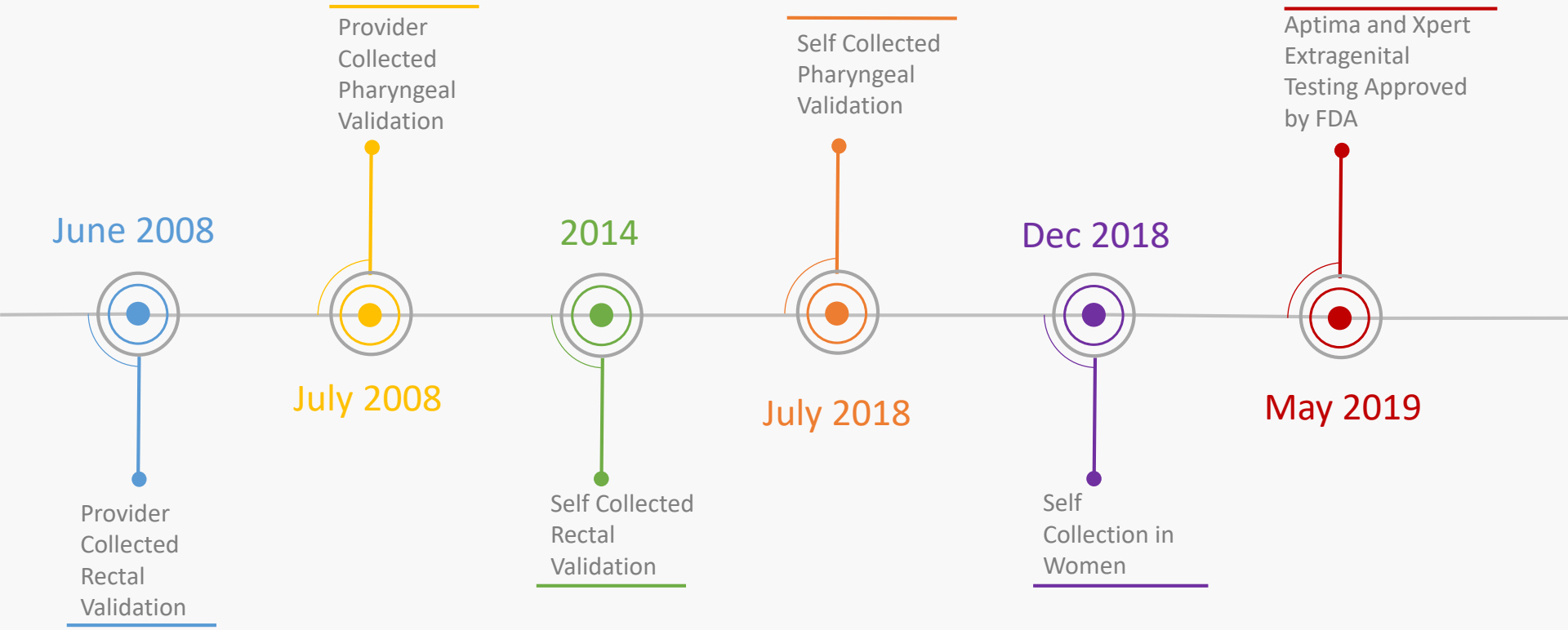
Express Testing

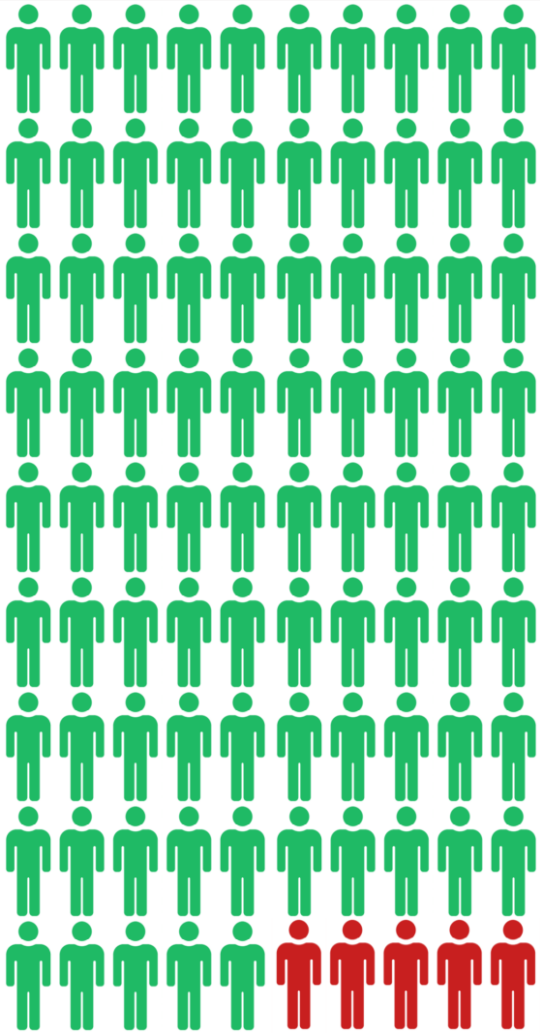
- Chlamydia, Gonorrhea, Syphilis, and HIV Testing
- “Worried by Well”
- 18,801 Visits in 2018

Provider Visits

- Chlamydia, Gonorrhea, Syphilis, and HIV Testing
- Chlamydia, Gonorrhea, and Syphilis Treatment
- Symptom Evaluation
- 11,852 Visits in 2018

MCDPH Extragential Testing Timeline

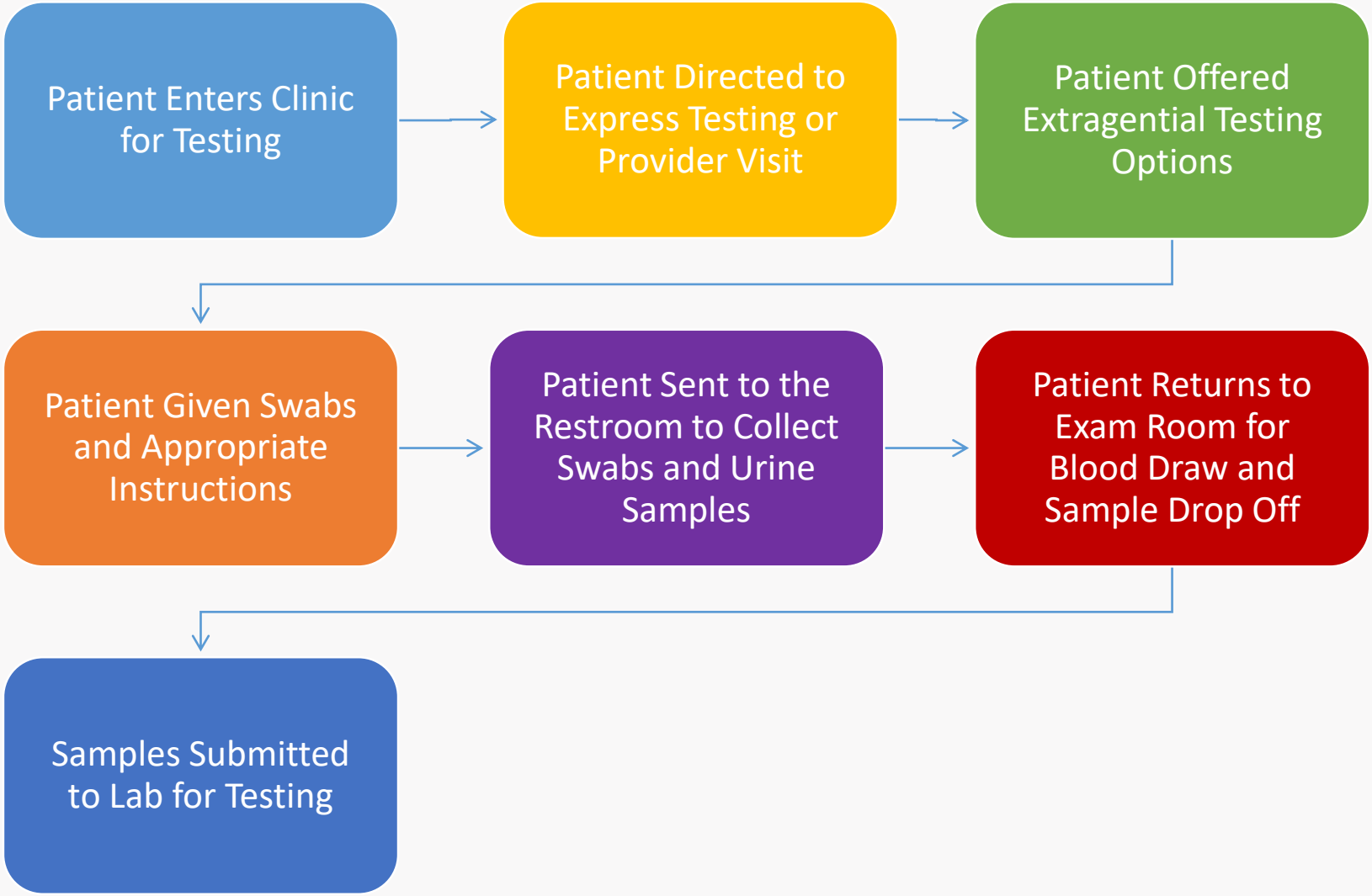




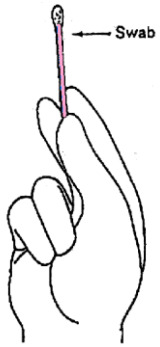
Validation Design

- Self Collected Swabs:
  - 100 provider collected swabs, 100 self collected swabs
  - 95% agreement to validate
  - Saw very high test result correlation between provider and self collected swabs
  - Saw a slightly higher positivity rate in self collected group

Extragenital Testing Clinic Flow

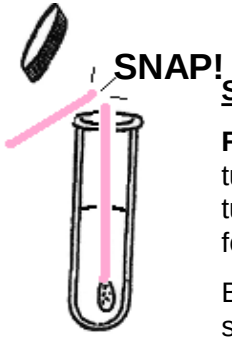


MCDPH Rectal Self Collection Instructions



Step 1.

Open kit and remove tube and package with green writing. Remove the PINK swab with the shaft. **USE PINK SHAFT SWAB ONLY.**



Step 3.

Remove cap from test tube. Place swab in test tube. Do not puncture the foil cap.

Break swab shaft at the score mark.

Step 2.

Insert swab 1 inch into the anus and turn for 5 – 10 seconds.

If needed, before inserting swab, wet swab with water or saline solution.

Step 4.

Put cap back tightly on test tube to prevent any leaking. Try not to splash the liquid out of the tube.

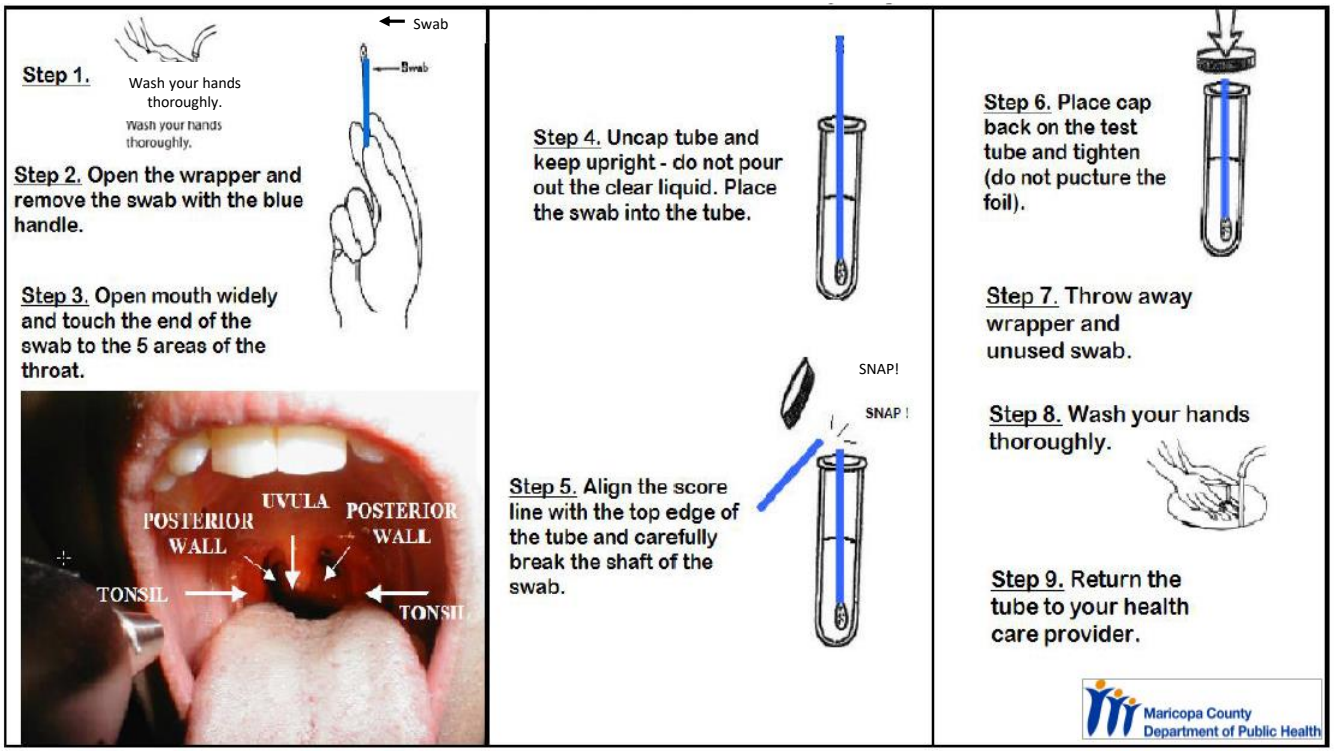
Step 5.

Discard wrapper and unused swab. **Wash your hands.** Return the tube to the health worker.

Maricopa County
Department of Public Health

Public Health Clinical Services-STD Clinic

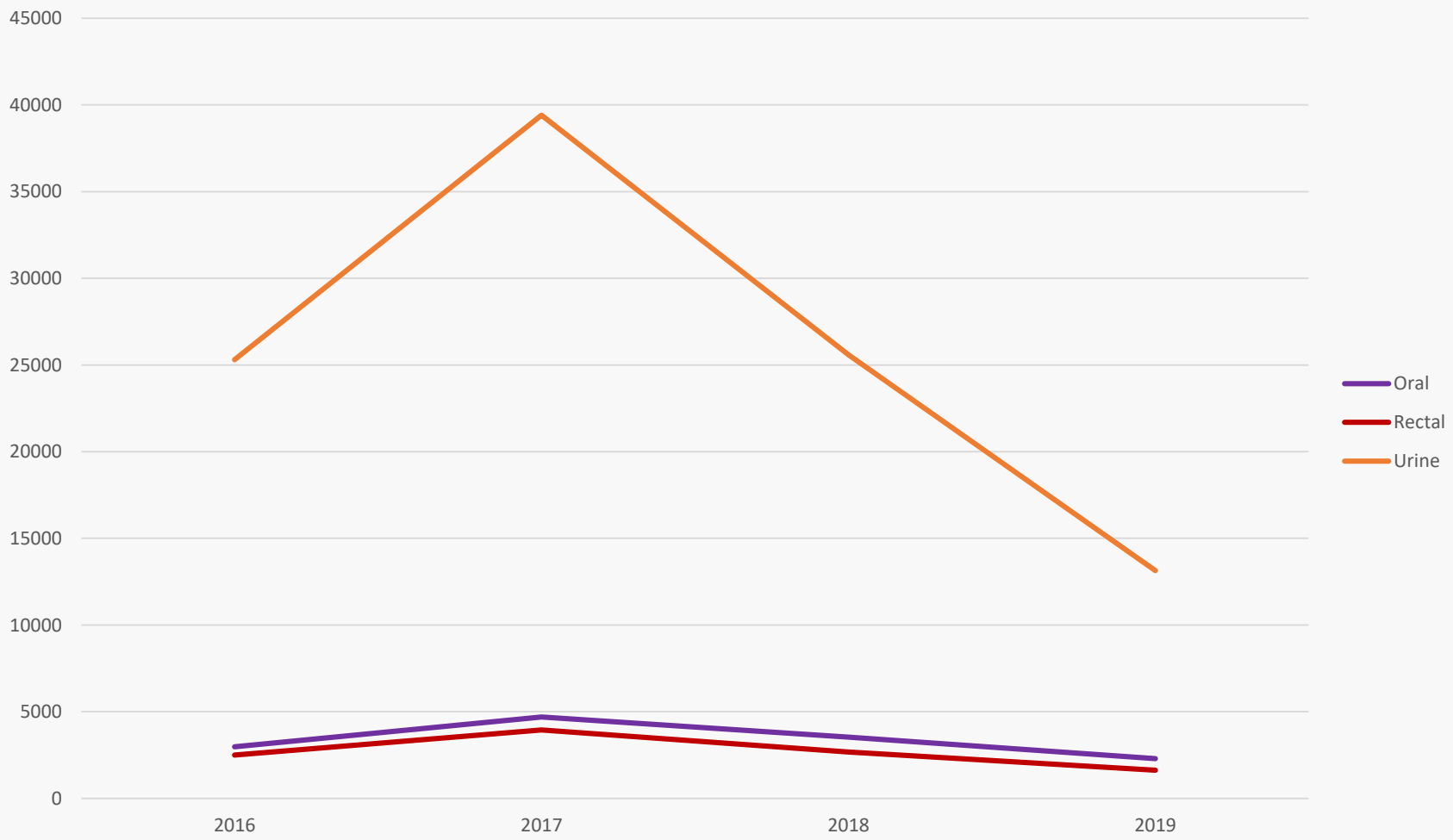
MCDPH Pharyngeal Self Collection Instructions



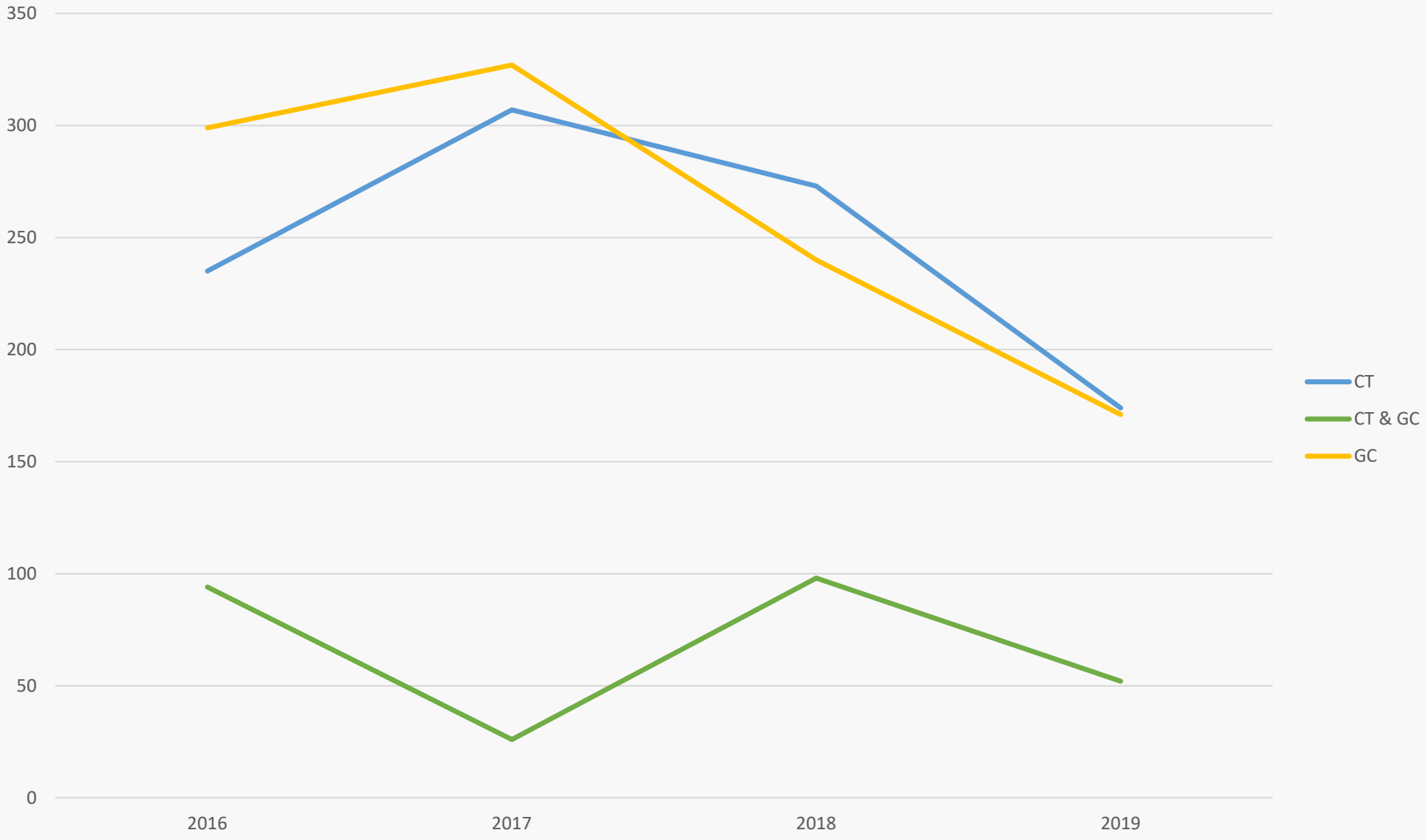
Maricopa County Department of Public Health

Public Health Clinical Services-STD Clinic

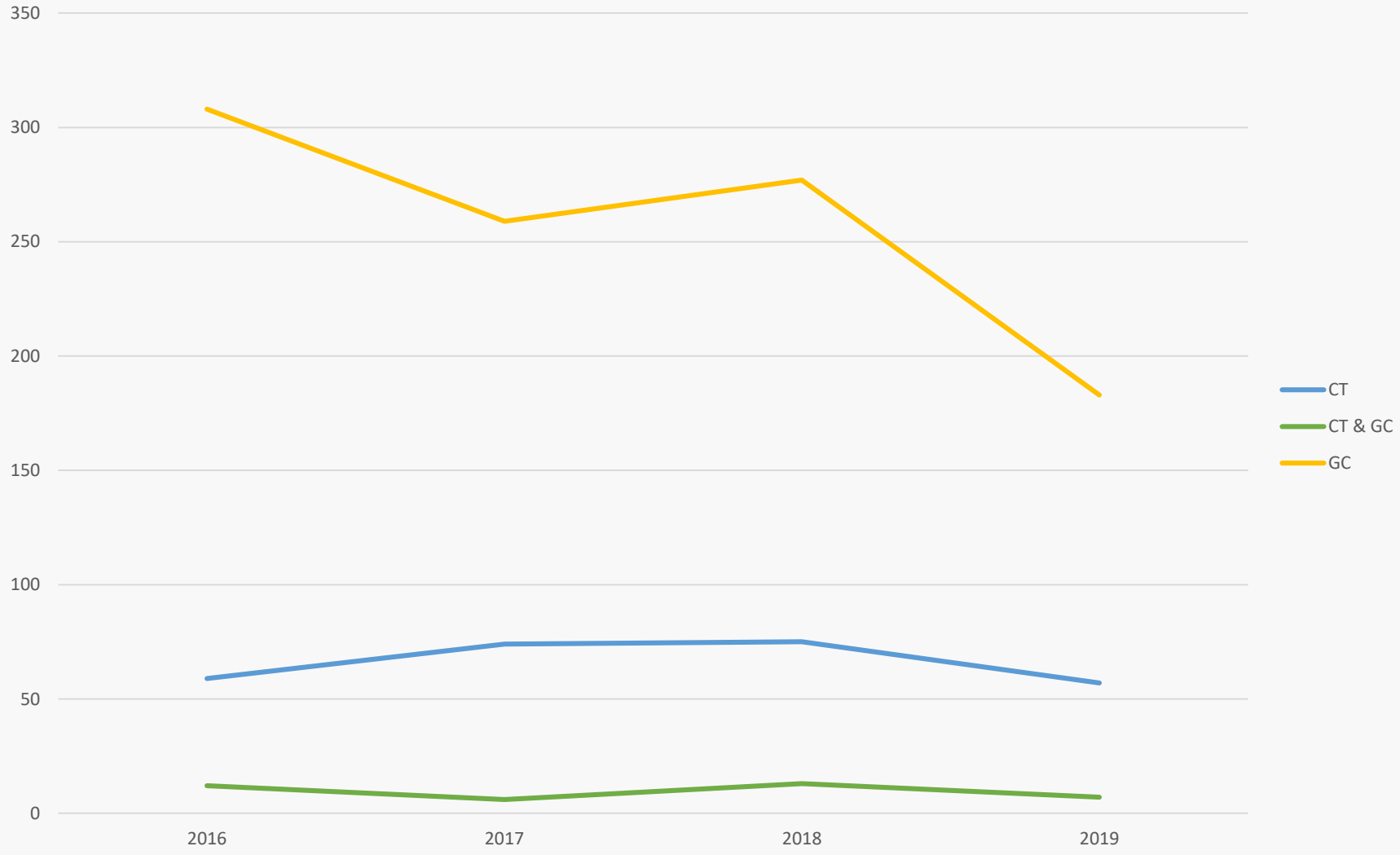
In 2018, 19% of Aptima testing was performed on extragenital sites.



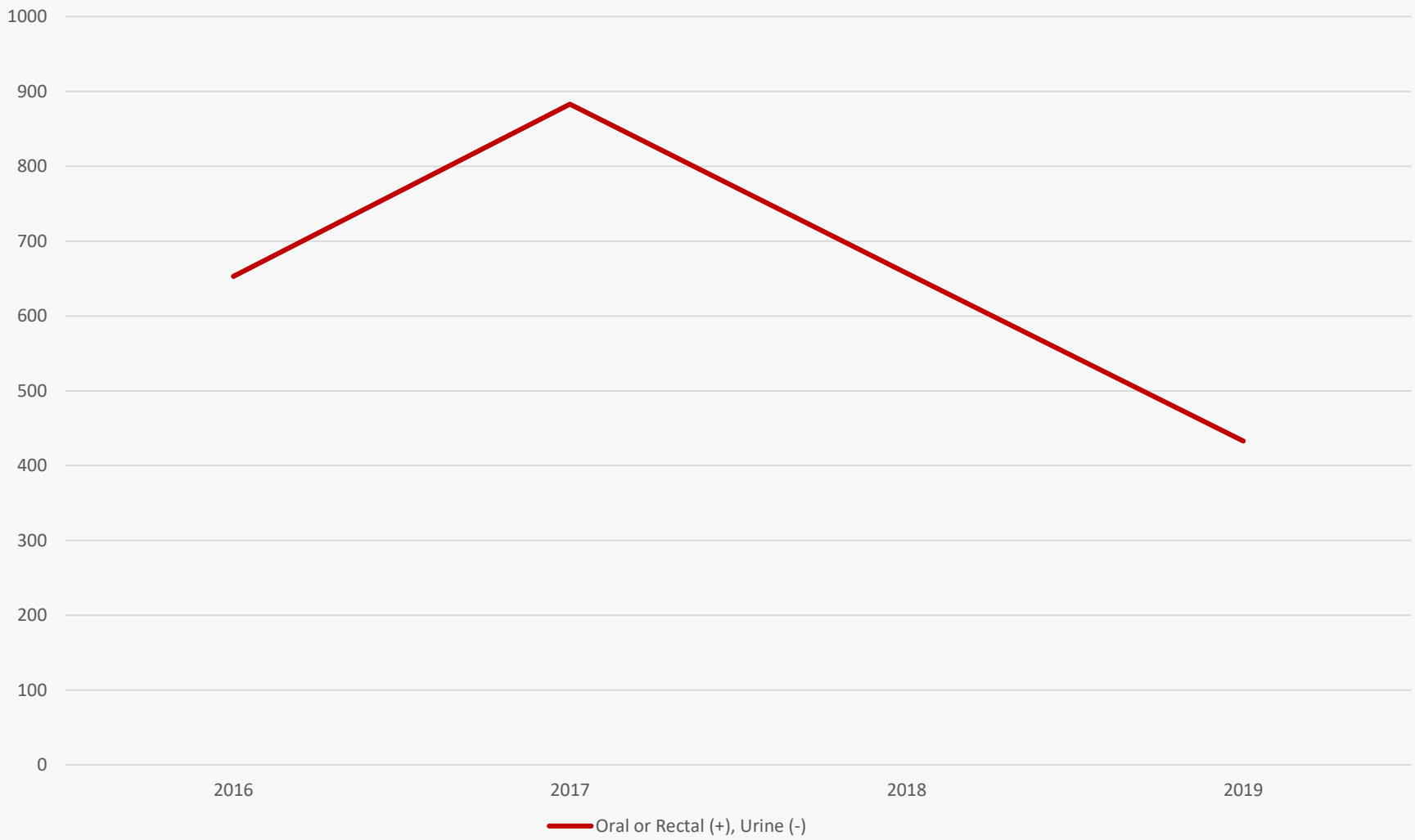
In 2018, 7.7% of chlamydia only and 16.5% of gonorrhea only infections were detected through rectal testing.



In 2018, 2.1% of chlamydia only and 19.0% of gonorrhea only infections were detected through pharyngeal testing.



Since 2016, 2,262 individuals had a negative urine test, but tested positive for CT and/or GC via an extragenital test.



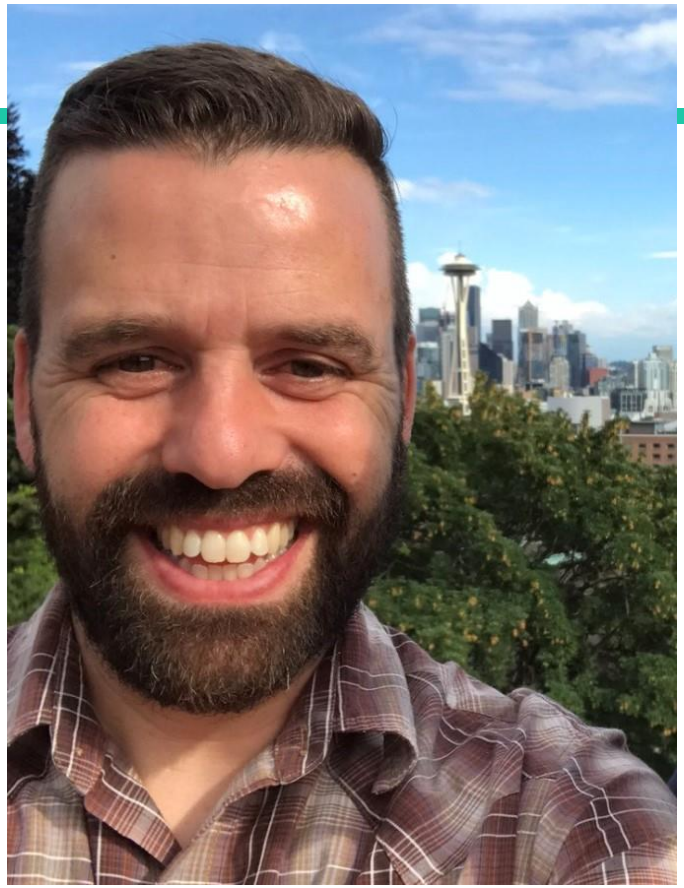
Challenges

- Designing the executing the initial validation
- Finding best practice model for the time period
- Staffing outreach events with providers prior to self collection validation
- Ensuring proper communication of directions for self collected samples
- Ensuring correct labeling of samples

Successes

- Simple transition for our lab
- Provides patients with customizable testing options based on potential exposure
- No longer missing infections isolated to an extragenital site
- Better understanding of population
- Provides more complete context of infection patterns for potential intervention efforts

Questions?



Daniel Daltry, MSW
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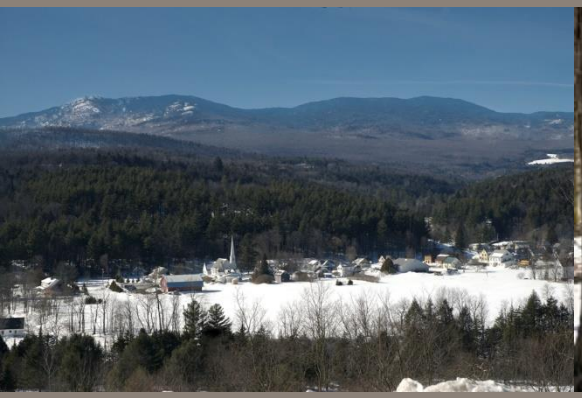
Vermont Dept. of Health




Three Sites a Charm: The Importance of Extragenital Testing for MSM Confirmation

VERMONT
DEPARTMENT OF HEALTH

An exploratory of the Vermont Experience

Moment for Concern

"About one in ten gay and bisexual men with syphilis or rectal gonorrhea acquire HIV within one year of their STI diagnosis."

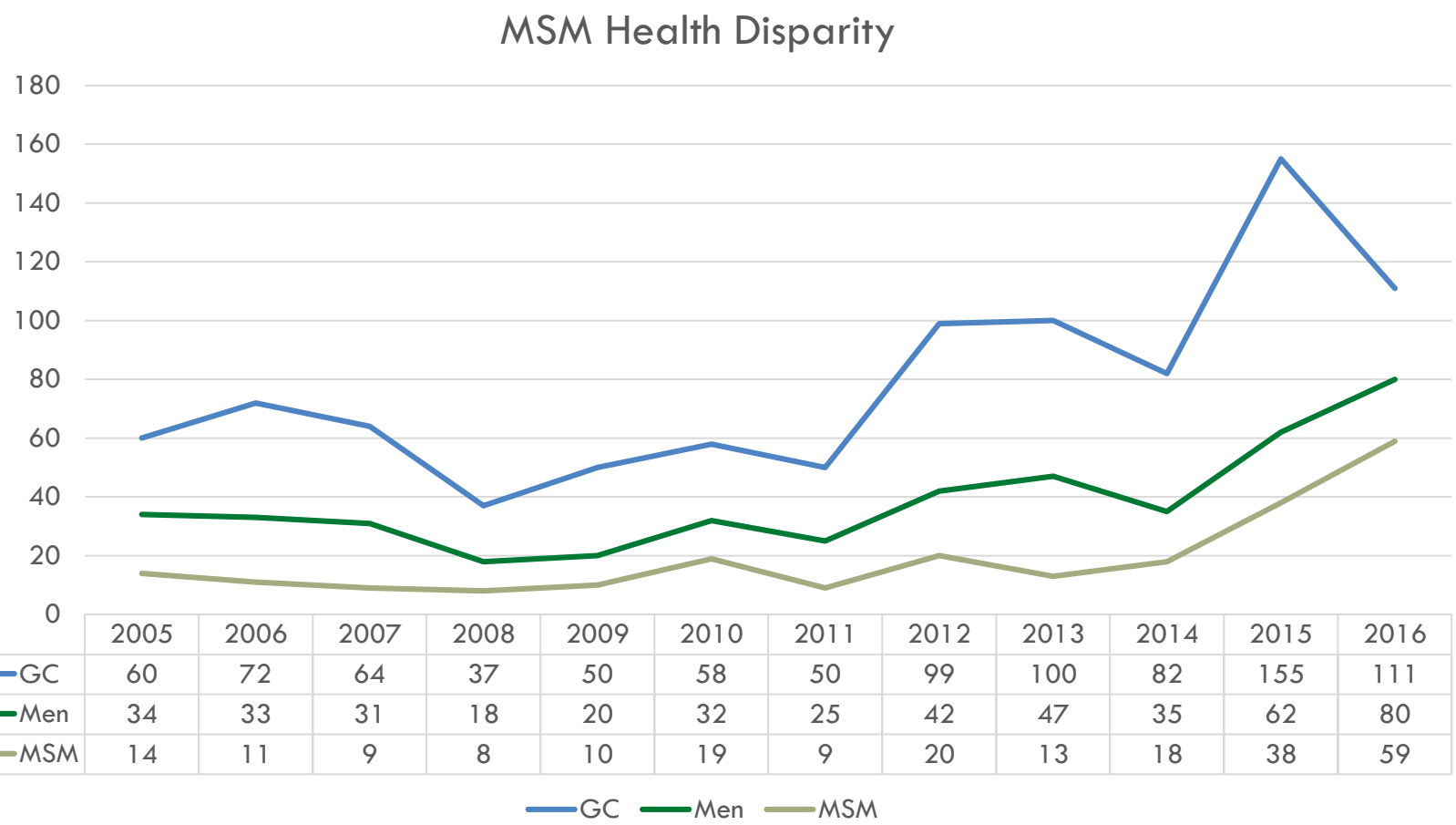
- U.S. Preventive Services Task Force. Final recommendation statement: human immunodeficiency virus (HIV) infection: screening. December 2014.

Current Policy

- It is well established urine screening only for CT and GC misses most infections in MSM.
- CDC recommends at least annual screening for MSM via urine and extra genital testing.
- Self- collected NAAT based testing have not been cleared by the FDA for dx of extra genital testing.
- NAAT is superior to culture.

Time to Focus

Gonorrhea Trend in Vermont



	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
GC	60	72	64	37	50	58	50	99	100	82	155	111
Men	34	33	31	18	20	32	25	42	47	35	62	80
MSM	14	11	9	8	10	19	9	20	13	18	38	59

Vermont Department of Health

Vermont we have a problem

There is a health inequity at play here!!!

2016 Data Points: MSM and GC

- 53% of the total gonorrhea cases were MSM
- 61% of the cases at risk for being the one in 10 individuals nationally that will contract HIV within the course of one year
- 36% of the cases on PrEP (ahead of the national recommendation for now)
- Six of these cases are co-infected with HIV

The ideal screening

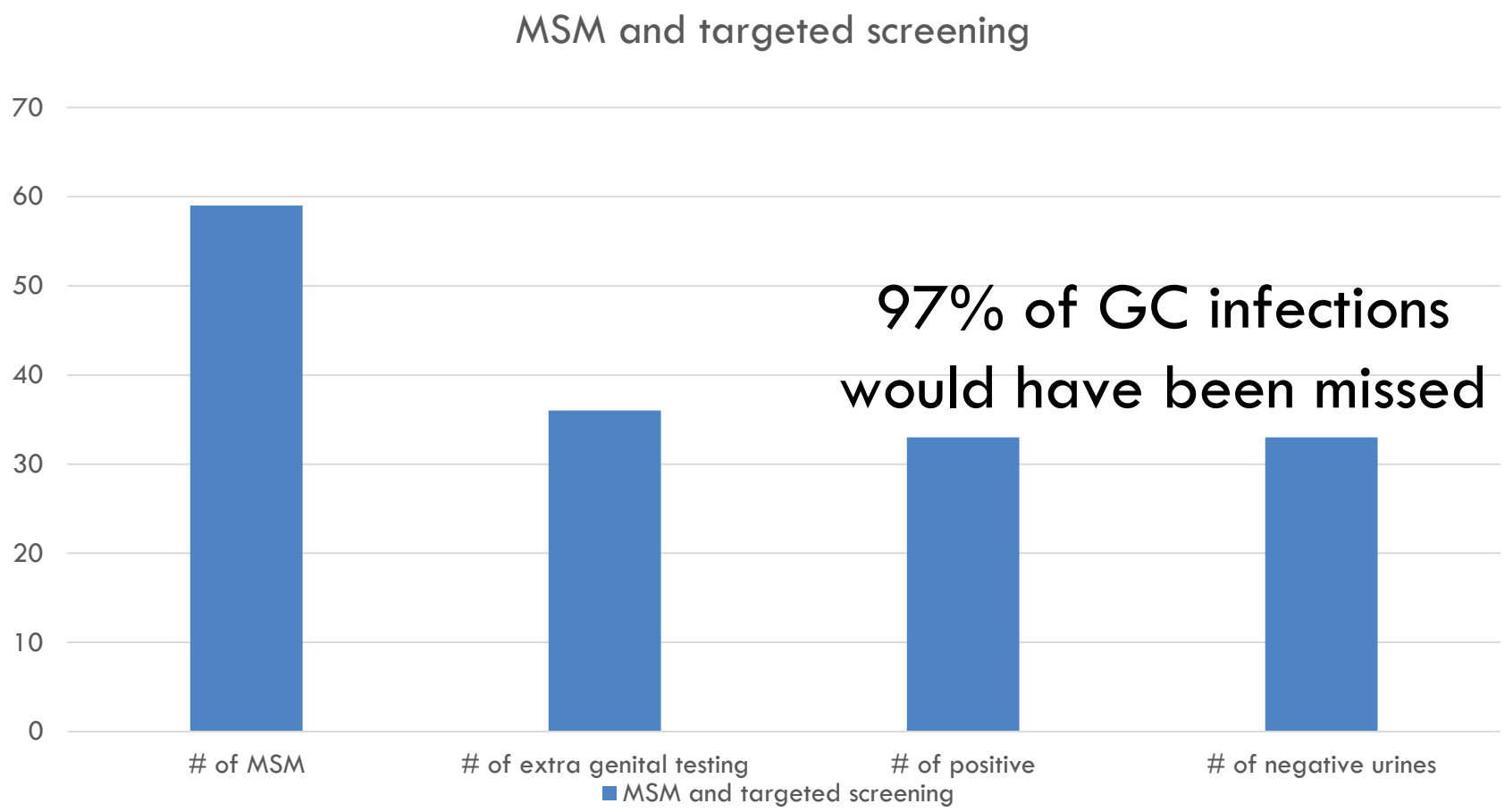
Don't forget the "triple dip" for MSM

- HIV/Syphilis/ HepC Serologies
- Pharyngeal GC NAAT*
- Urine GC/CT NAAT
- Rectal GC/CT NAAT*

National Network of STD HIV Prevention Training Centers

*Off-label use. Not FDA-approved for testing at extragenital sites, but many reference labs have validated the assay for use.

Screen comprehensively/ appropriately



Take home messages

- Triple Dip: Just Do It, your morbidity is counting on it
- Gonorrhea Control Plan:
  - Test and Treat Patients (Ensure Access to Care)
  - Targeted Screening (Based on Local EPI)
  - Treat Sex Partners
  - Engage Communities
  - Involve Medical Providers
  - Promote Safe Sex

Gonorrhea Control is not an all or nothing proposition

Thank you and Contact information

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Questions

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- The webinar recording and slides will be shared with those who registered and will be available on the NCSD website.
- Please complete the webinar evaluation once the webinar ends.