

Discussion Panel: Self-Testing and Self-Collection for HIV and STIs

Moderator:

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Discussants:

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Barbara Van Der Pol, *PhD, American Sexually Transmitted Diseases Association (ASTDA)*

Evaluation of Self-Testing among MSM Project (eSTAMP)

Pollyanna Chavez, PhD

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and TB Prevention

Centers for Disease Control and Prevention

The findings and conclusions in this presentation are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

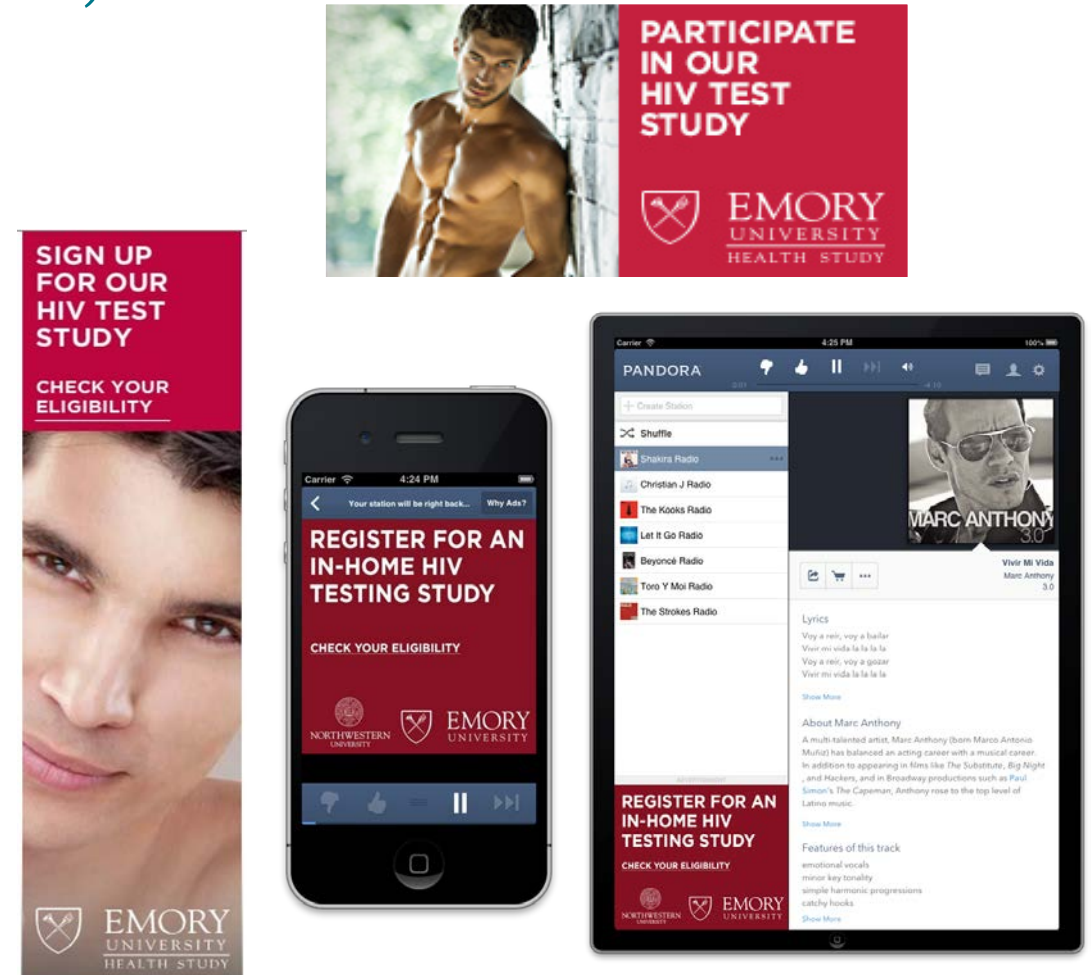
Tradenames are used for informational purposes and does not constitute an endorsement by CDC.



Evaluation of HIV Self-Testing Among Men who have sex with men Project (eSTAMP)

What is eSTAMP?

- Longitudinal 12-month randomized controlled trial (3/2015-12/2016)
- To evaluate the public health benefits of mailing free HIV self-tests to internet-recruited MSM in the U.S.
- RCT: HIV negative or unknown status



Randomized Control Trial (n=2665)

	Intervention Arm n=1325	Control Arm n=1340
Incentivized online surveys	Baseline, 3, 6, 9, 12 months	Baseline, 3, 6, 9, 12 months
First package mailed	2 OraQuick In Home HIV Test 2 Sure Check (under IDE)	
Additional self-tests	After completing survey, to replace self-tests used or distributed	

Survey participation: $\geq 54\%$ at each time point

	Intervention (n=1325)	Control (n=1340)
3 month survey	58%	54%
6 month survey	54%	56%
9 month survey	54%	62%
12 month survey	54%	61%
Participated in at least one follow-up survey	73%	71%

n=2665

	n	col %
Age		
18-29	1,527	57.3
30-39	692	26.0
40-49	293	11.0
50+	153	5.7
Race/Ethnicity		
Non-Hispanic white	1,540	57.8
Non-Hispanic black	261	9.8
Hispanic	620	23.3
Non-Hispanic, other race	244	9.2
Education		
High school diploma or less	436	16.4
Greater than high school education	2,222	83.4
Employment Status		
Unemployed	394	14.8
Employed	2,236	83.9

Most participants were young, non-Hispanic white, had received an education beyond high school, and were employed.

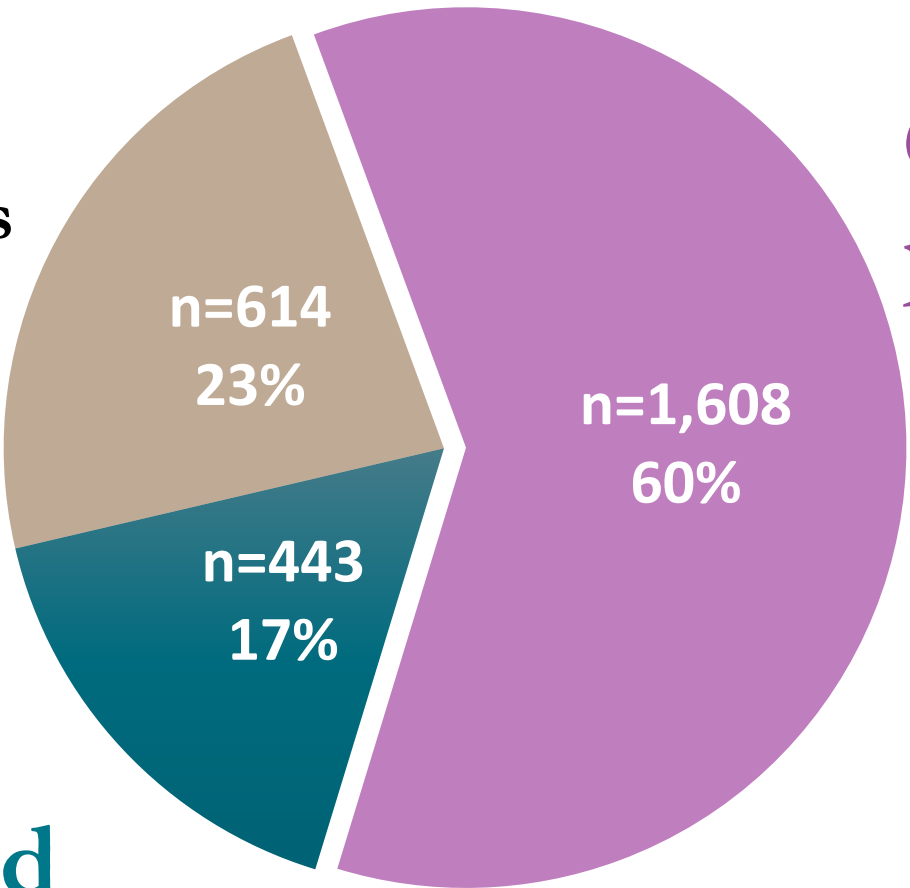
Baseline HIV testing history (n=2,665)

- Never tested
- Tested, not in the past 12 months
- Tested in the past 12 months

23% tested, not in the past 12 months

60% tested in the past 12 months

1 in 6
never tested



Intervention increased HIV testing and frequency of testing among internet-recruited MSM

MSM who completed ≥1 follow-up surveys (n= 1924)	Intervention (n=966)	Control (n=958)	p-value
Any HIV testing reported	937 (97%)	615 (64%)	<0.01
Tested ≥ 3 times during RCT	761 (79%)	214 (22%)	<0.01

Intervention increased frequency of HIV testing among MSM who were never testers at enrollment

MSM who completed ≥1 follow-up surveys (n= 293)	Intervention (n=157)	Control (n=136)	p-value
Tested ≥ 3 times during RCT	110 (70%)	10 (7%)	<0.01

There were more newly identified cases of HIV infection in the intervention arm

MSM who completed ≥1 follow-up surveys (n= 1924)	Intervention (n=966)	Control (n=958)	p-value
Newly identified cases of HIV infection*	22 (2.3%)	11 (1.1%)	0.03
Linked to care	16/22 (72.2%)	10/11 (90.9%)	0.38

**Previously undiagnosed and new cases based on preliminary positive or confirmed diagnoses.*

Condomless anal sex with male partners

**HIV
positive
partners**

	Intervention	Control
Baseline	5.8%	6.5%
3 months	5.1%	5.6%
6 months	6.4%	7.3%
9 months	6.5%	5.7%
12 months	5.6%	6.4%

**HIV
unknown
status
partners**

Baseline	31.0%	29.0%
3 months	17.1%	18.8%
6 months	18.4%	17.3%
9 months	16.3%	18.2%
12 months	16.6%	18.8%

**Providing HIV
self-tests was not
associated with
increased sexual
risk behaviors.**

No significant
differences
between arms.

Other testing outcomes

- Participants distributed the study HIV self-tests to members of their social/sexual networks.
- Participants reported back the results of the distributed tests.
- Potential for increasing the awareness of new infections.

Conclusion

The provision of free HIV self-tests:

- Increased the frequency of HIV screening among internet-recruited MSM.
- Increased awareness of HIV infection among participants and their sexual/social network associates.
- Not associated with increased sexual risk behaviors.

Thank you!

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Division of HIV/AIDS Prevention



HIV Testing and STI Screening in New York City

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New York City Department of Health and Mental Hygiene

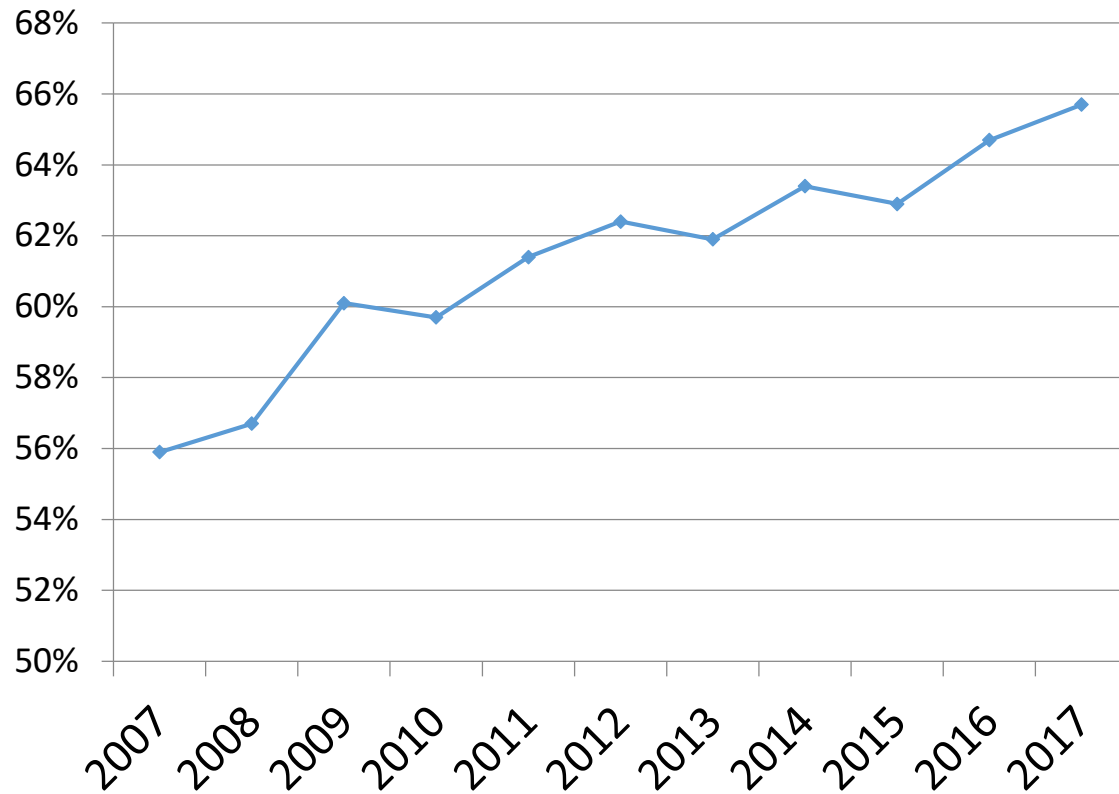
2019 HIV Diagnostics Conference

March 27, 2019

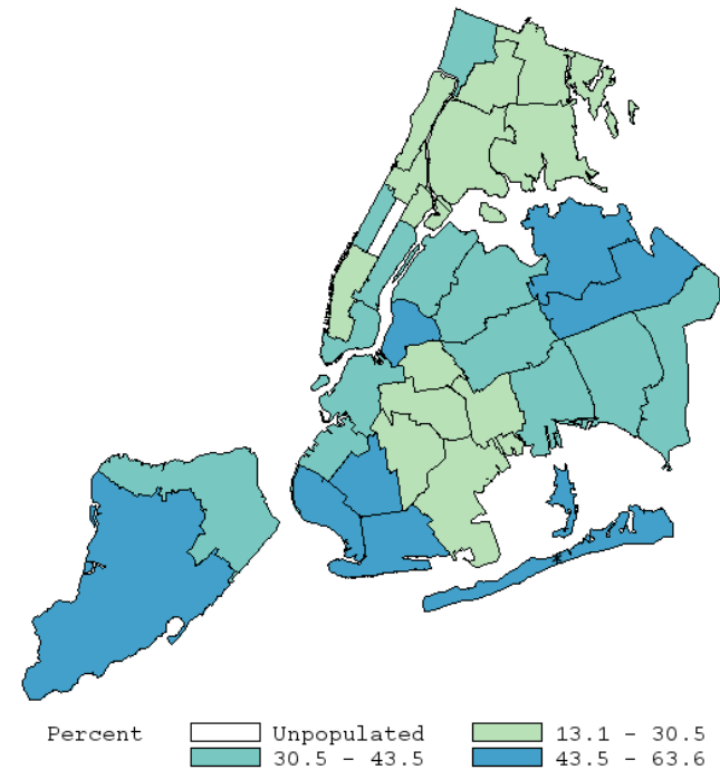
HIV Testing in New York City (NYC)

Community Health Survey

More New Yorkers Ever Tested for HIV, 2007-2017



Percent New Yorkers Never Tested, 2017



Disparities in testing still exist



NYC's Approach to HIV testing

- Two-tiered approach to HIV testing
 - Maximize access to testing to NYC residents
 - Enhance access to testing services for key populations
- Maximize use of available funds
 - Tier One: Routine HIV Testing
 - Tier Two: Prioritized HIV Testing

NYC's Two-Tiered Approach



Routine HIV Testing

- Normalizes HIV testing for all
- Leverages clinical settings already providing services to NYC residents
- Costs covered by many 3rd party payers
- Allows access to testing for persons of all risk levels who seeks medical care
- Allows key populations to test without disclosing to providers

Prioritized HIV Testing

- Extends testing to people not accessing medical services
- Provides access to testing to those who decline testing offer in clinical setting
- Provides testing to key populations in culturally acceptable settings by experienced providers
- In-home HIV tests provide additional access to HIV testing



ONLINE HIV TEST GIVEAWAY



DISTRIBUTION BY
COMMUNITY-BASED
ORGANIZATIONS (CBOS)



DISTRIBUTION BY DISEASE
INTERVENTION SPECIALISTS
TO PARTNERS OF HIV CASES

In-Home HIV Test Distribution



ONLINE HIV TEST GIVEAWAY

- Pilot online home test giveaway targeting men and transgender individuals who have sex with men in 2015
- Recruitment through social media
- Screening through online survey
 - Eligible participants receive discount code via email
- Manufacturer send package by mail
 - Package include additional NYC materials



Edelstein, National HIV Prevention Conference 2019, Abstract 5241

In-Home HIV Test Distribution



ONLINE HIV TEST GIVEAWAY

- Pilot online home test giveaway targeting men and transgender individuals who have sex with men in 2015
- Recruitment through social media
- Screening through online survey
 - Eligible participants receive discount code via email
- Manufacturer send package by mail
 - Package include additional NYC materials
- All eligible participants invited to follow-up survey
- Total 5 waves of giveaways
 - Over 12,000 tests sent
 - 16% reported never previously tested (range: 12%-22%)
 - Reported 0.6% new positivity (similar to other testing programs)

Edelstein, National HIV Prevention Conference 2019, Abstract 5241

In-Home HIV Test Distribution



DISTRIBUTION BY
COMMUNITY-BASED
ORGANIZATIONS (CBOS)

- Launched community home test giveaway, in collaboration with NYC CBOs, to reach key populations
- CBO partners distribute recruitment cards

AAXPL

Get a Free HIV Home Test Kit

NYC is giving away HIV home test kits.
Claim yours while supplies last!

Visit bit.ly/chtgiveaway and enter the code above
to see if you qualify for a free HIV home test.

Hubbard, National HIV Prevention Conference 2019, Abstract 5432

In-Home HIV Test Distribution



DISTRIBUTION BY
COMMUNITY-BASED
ORGANIZATIONS (CBOS)

- Launched community home test giveaway, in collaboration with NYC CBOs, to reach key populations
- CBO partners distribute recruitment cards
- Participants complete online eligibility survey
 - Eligible participants receive discount code via email
- Manufacturer send package by mail
- Participants can opt to pick up test kits at CBO
- Results, March 2017-January 2019
 - Over 22,000 recruitment cards distributed
 - 120 surveys completed with 100 eligible participants
 - 75 kits ordered
 - 35% eligible participants reported never tested for HIV

Hubbard, National HIV Prevention Conference 2019, Abstract 5432

In-Home HIV Test Distribution

Project THRIVE

Integrating STI Screening with HIV Testing

- CDC demonstration project to improve coordination of HIV prevention and care services for men who have sex with men (MSM) of color in Brooklyn
 - Lab-based 4th generation HIV testing by non-clinical CBOs
 - STI screening ,with client self-collection, by non-clinical CBOs
 - CBOs conducted some HIV testing and STI screening in the field
 - Clients navigated to prevention and care services, as appropriate
- STI screening integrated with HIV testing
 - STI screening allows CBOs to engage with MSM who have recently tested
 - STI screening allows CBOs to engage with persons living with HIV, including those who have never been in care or those currently not seeing medical provider



Project THRIVE

April 2017–December 2018

	Overall	MSM of Color	
		N	%
Enrolled	848	474	55.9%
Clients Tested for GC	249	134	53.8%
Tested Pos for GC	21	15	71.4%
% Tested Pos for GC	8.4%	11.2%	N/A
Clients Tested for CT	251	134	53.4%
Tested Pos for CT	11	5	45.5%
% Tested Pos for CT	4.4%	3.7%	N/A



Summary

- Self Testing for HIV and STI allows NYC Health Department to reach more persons from key populations
 - HIV self testing
 - Acceptable to persons in key populations
 - Reached people who have never tested for HIV
 - STI screening with self-collection
 - Allows CBOs to bring STI screening to non-clinical settings
 - Allows CBOs to engage key populations who are not interested in HIV testing to offer navigation to prevention and/or care services

Thank You



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Panel 4 Self-testing/Self-collection for HIV/STDs

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HIV/STIs Diagnostic Conference
March 25-28, 2019
Marriott Marquis, Atlanta GA

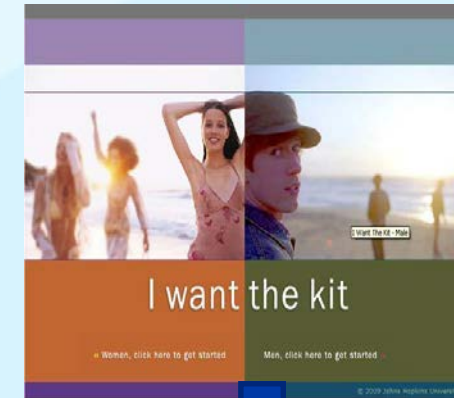


Internet Recruitment: iwantthekit.org

- **Methods**
 - Order a kit online
 - Kit mailed
 - Collect sample at home
 - Mail kit to lab
 - Receive results; Attend a clinic for Rx
- **New features 2013**
 - Secure password protected login
 - Selection of clinic before ordering kit
 - New instructions
 - Text/email to notify user that kit was mailed, received, and “results ready”
 - New information about STIs

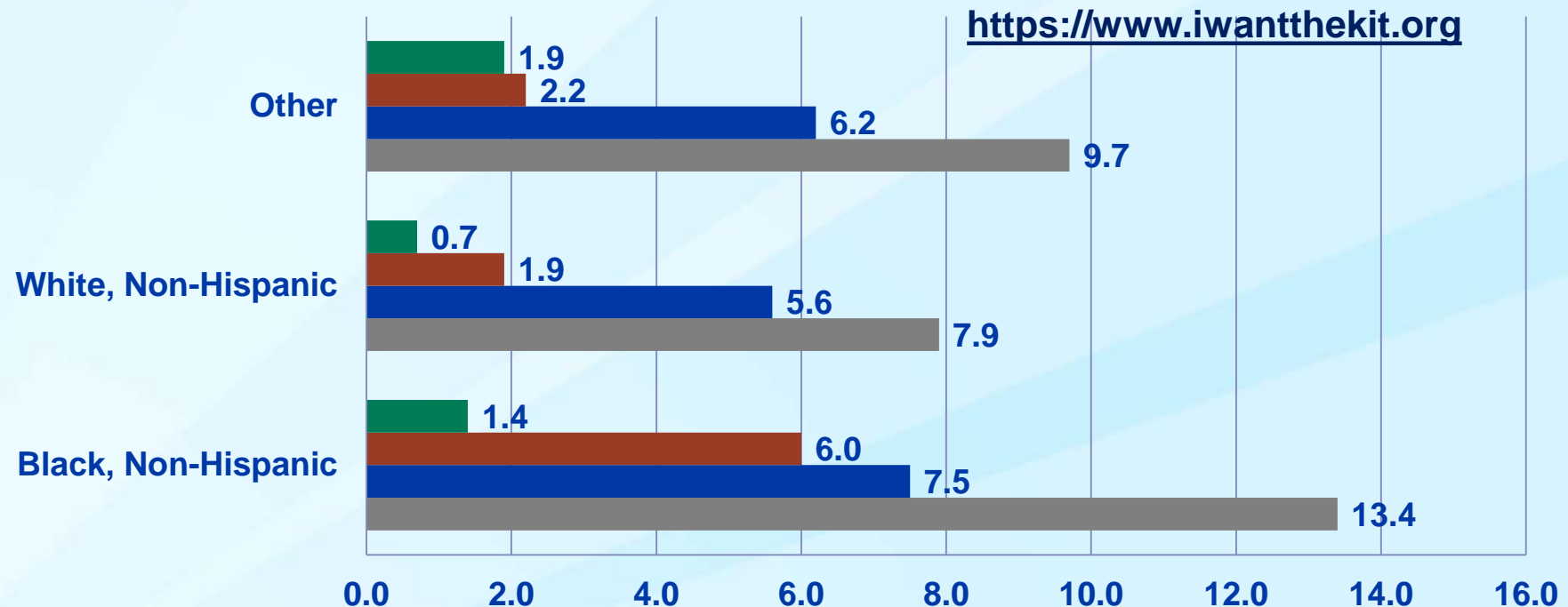


2004



2013

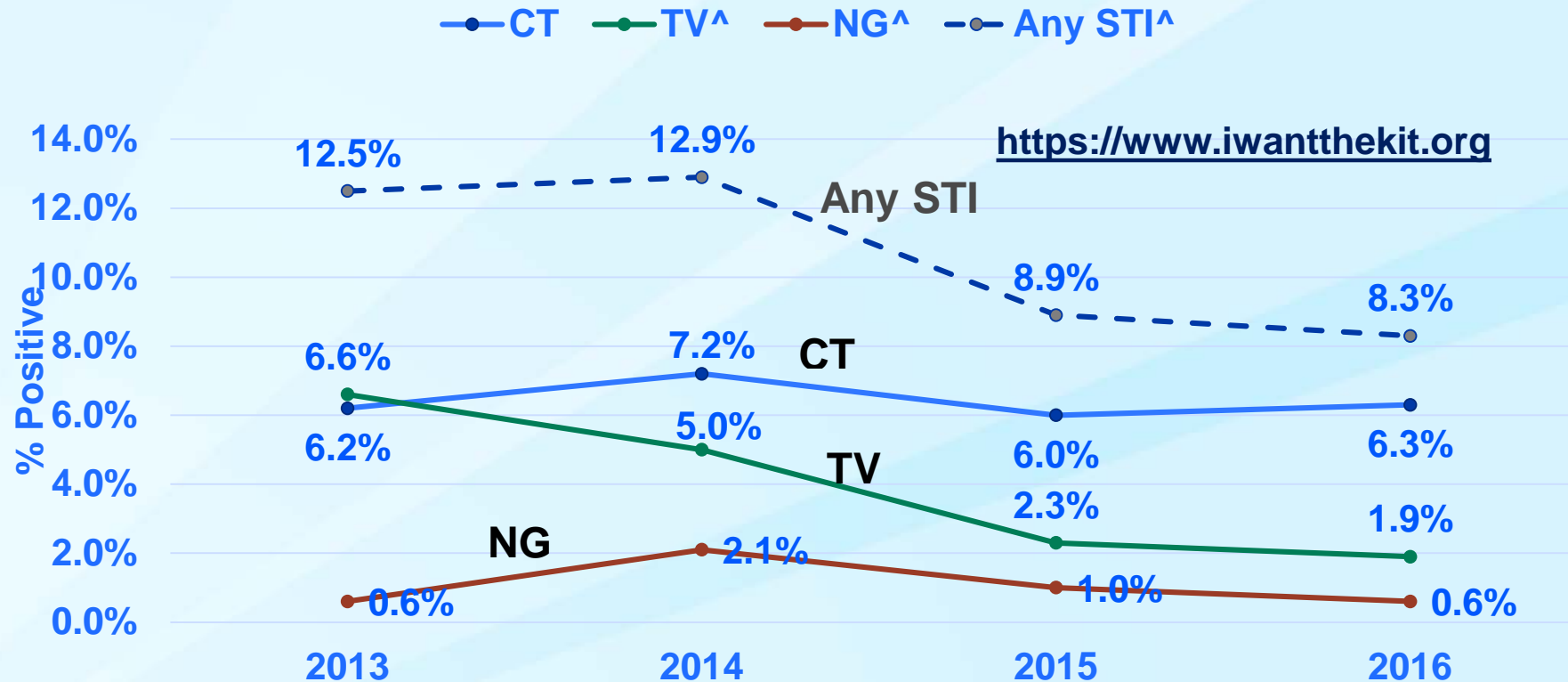
% Positive by Sexually Transmitted Infection (STI) and Race, IWTK 2013-2016



	Black, Non-Hispanic	White, Non-Hispanic	Other
■ Gonorrhea	1.4	0.7	1.9
■ Trichomoniasis [^]	6.0	1.9	2.2
■ Chlamydia	7.5	5.6	6.2
■ Any STI [^]	13.4	7.9	9.7

[^]Statistically significant differences (Pearson chi-square, $p < 0.01$)

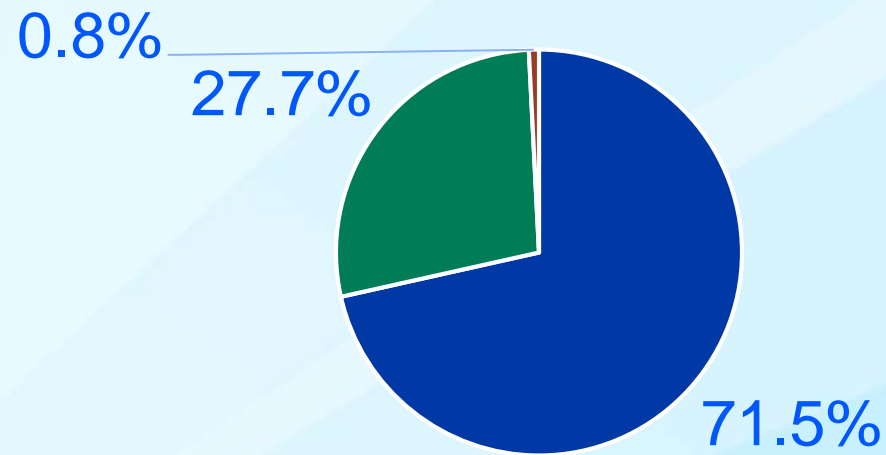
Sexually Transmitted Infection (STI) Trends, IWTK Specimens 2013-2016



CT = *Chlamydia trachomatis*, TV = *Trichomonas vaginalis*, NG = *Neisseria gonorrhoeae*

^Statistically significant differences (Pearson chi-square, $p < 0.01$)

IWTK Submissions by Anatomic Site Aug 2013-Dec 2016 (N=3,191)

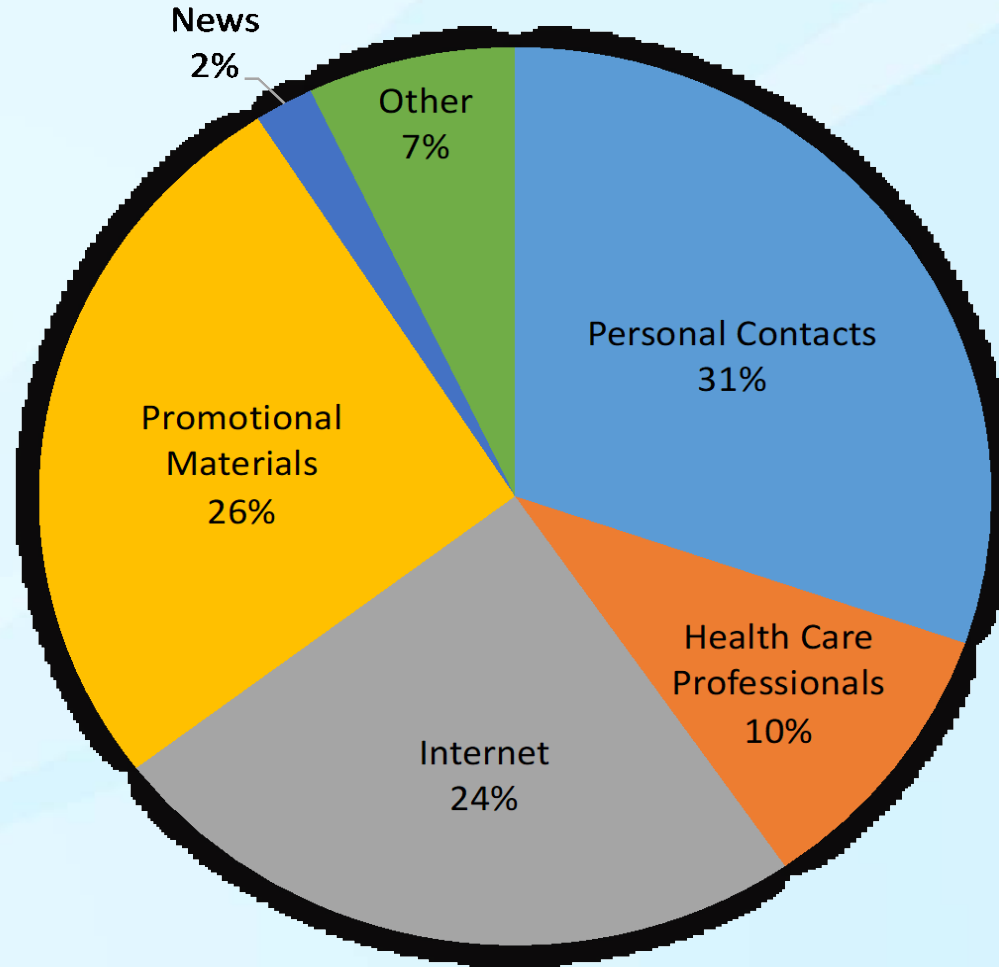


- % Urogenital Only
- % Urogenital and rectal
- % Rectal Only

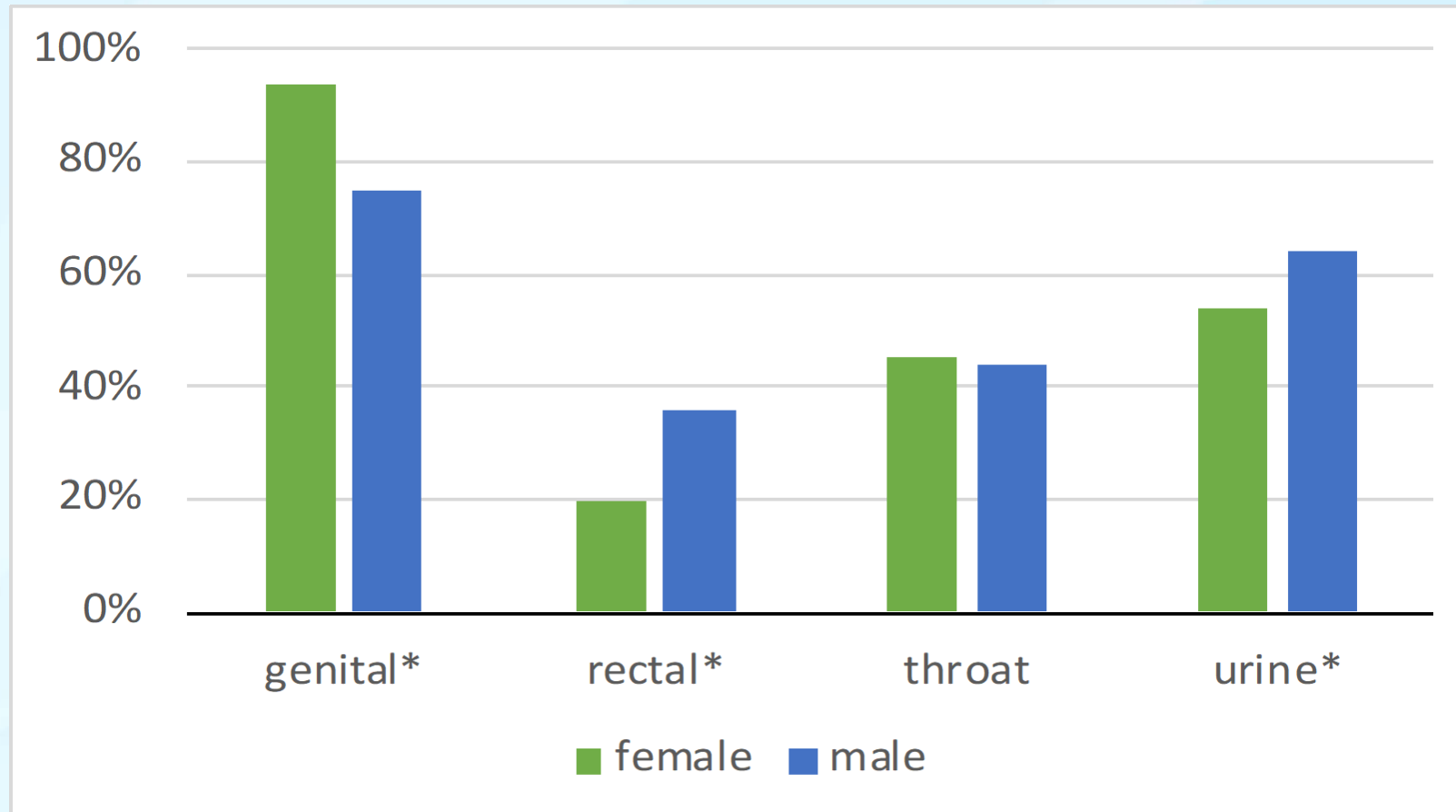
An Analysis of User Survey Data for an Internet Program for Testing for STI: I Want the Kit (IWTK) N=457

Demographic	n/N	%
Gender		
Male	168/457	36.8%
Female	284/457	62.1%
Genderqueer	3/457	0.7%
Trans male	1/457	0.2%
No response	1/457	0.2%

How Participants Learned about IWTK (N=457)



Percent preferring self-collection swab locations by gender (N=452)



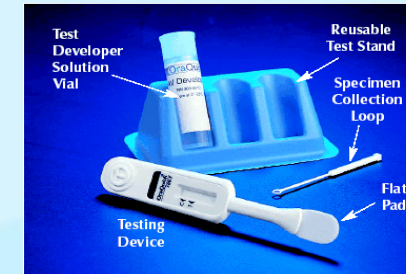
** Female/male preferences which have a significant difference in preference between genders*

HIV Home Test Progress



OraQuick HIV Self-testing Study – results from questionnaire (n=200)

easy to collect oral fluid	95.5%
easy to follow instructions	91.5%
easy to read and interpret results	96.5%
easy to perform test	97.0%
believe result is definitely correct	82.0%
or probably correct	18.0%
trust result very much	80.5%
or trust somewhat	19.5%
definitely recommend to a friend	94.5%
definitely test self again at home	83.5%
or probably test self again at home	14.5%



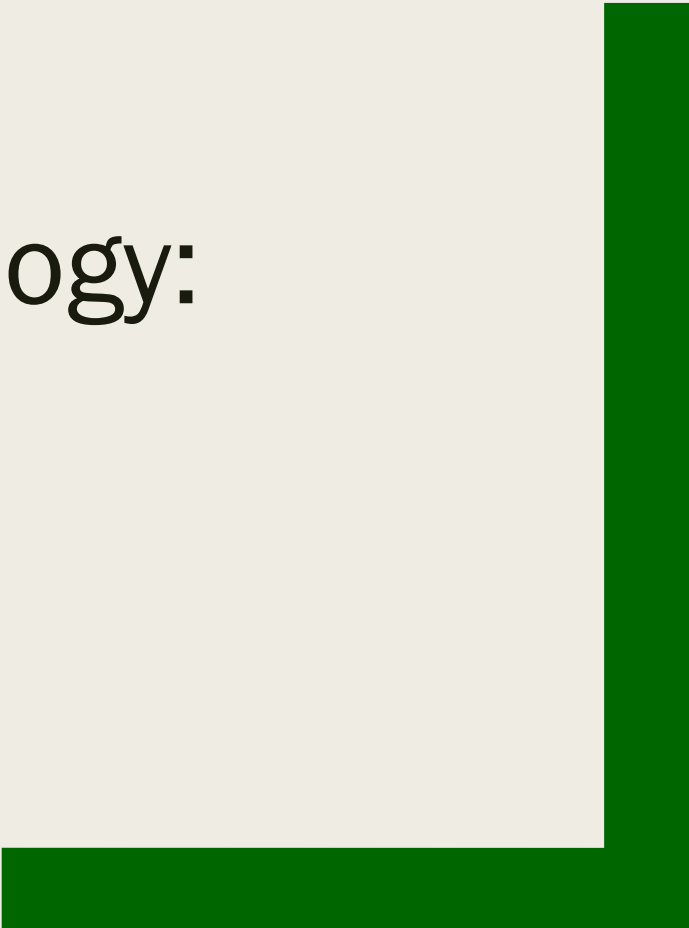
Maximum price pay to purchase OTC	\$10	24.0%	\$20	42.5%
	\$30	14.0%	\$40	16.0%

Earlier data: Of 83 who also tested for STIs, 16.9% w/ one STI



Applying New Technology: Intelligent Design

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Associate Professor of Medicine
University of Alabama at Birmingham
President, American STD Association



Disclosures

(Research Support, Consulting or Honorarium)

Research Grants to my Institution

- NIH
- CDC
- BD Diagnostics
- Binx Health
- Hologic
- Rheonix
- Roche Molecular
- SpeedX

Salary/Consulting Honoraria

- UAB
- NIH
- CDC
- FDA
- Abbott Molecular
- BD Diagnostics
- BioFire Diagnostics
- Roche Molecular

Rapid, Near-Patient, Point-of Care

- We must be clear in our terminology
- When is a rapid test not rapid?
 - *Consider the lowly RPR*
- Single versus multi-organism tests
- Do ALL tests need to be rapid or near-patient?
 - *Let's discuss HCV*

Home-Collection

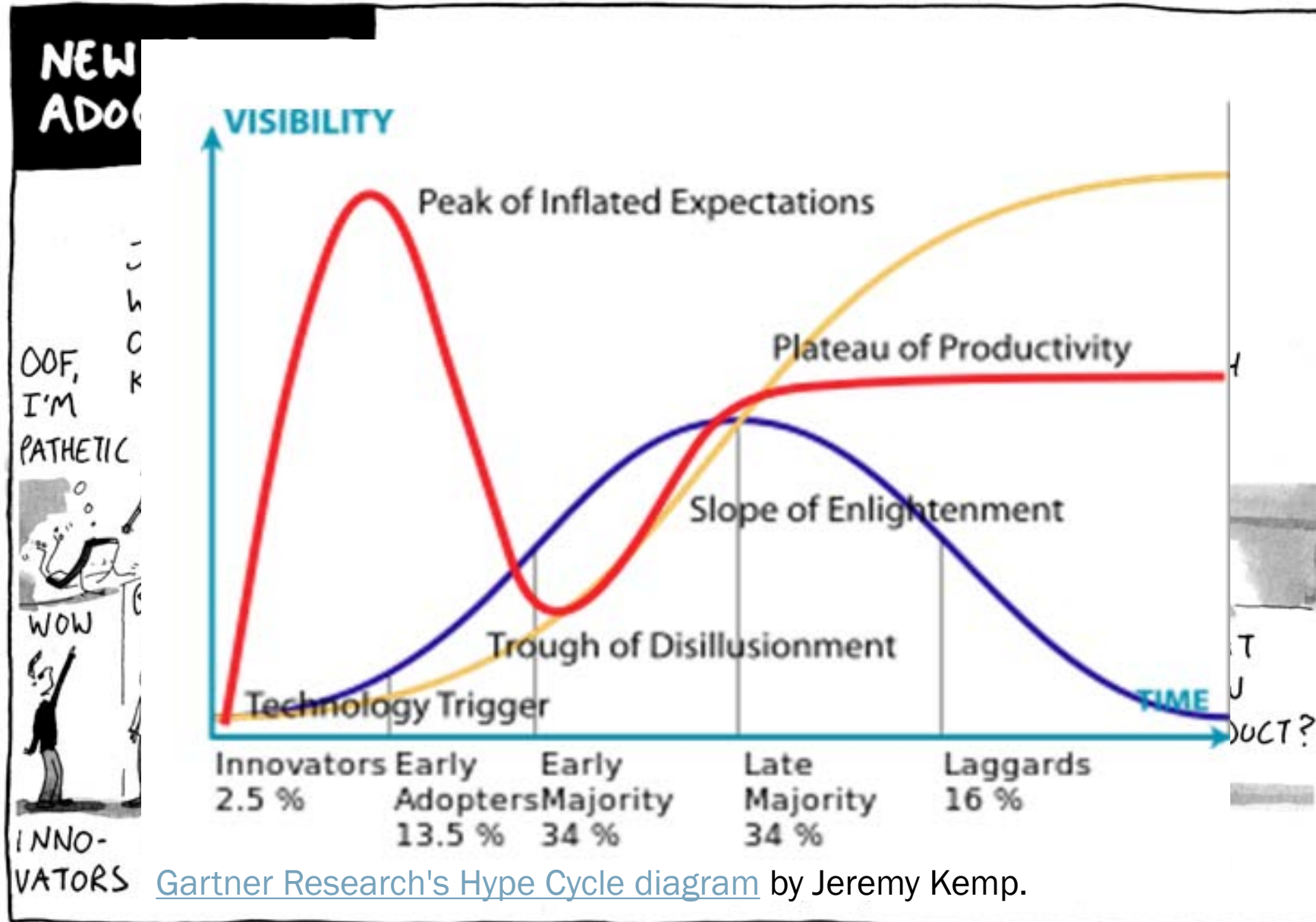
- How will intended use (related to samples) be managed?
 - *It won't – we need to let go*
- How will transport of samples be managed?
 - *This may be more critical – we need to develop solutions*
- How can we control what tests are ordered?
 - *Guidance needs to be put in place, but by whom?*

Self-Testing

- When to use tests
 - *Sexual remorse?*
 - *Symptoms?*
 - *Prior to sex?*
- Warm/hot-lines

Managing Identified Infections

- Will providers trust self-report?
 - *Repeat testing is notoriously unreliable*
 - *Confidence in tests and patient interpretation*
- Will other options be utilized?
- Is there a potential for co-infections?
- Partner management
- Surveillance

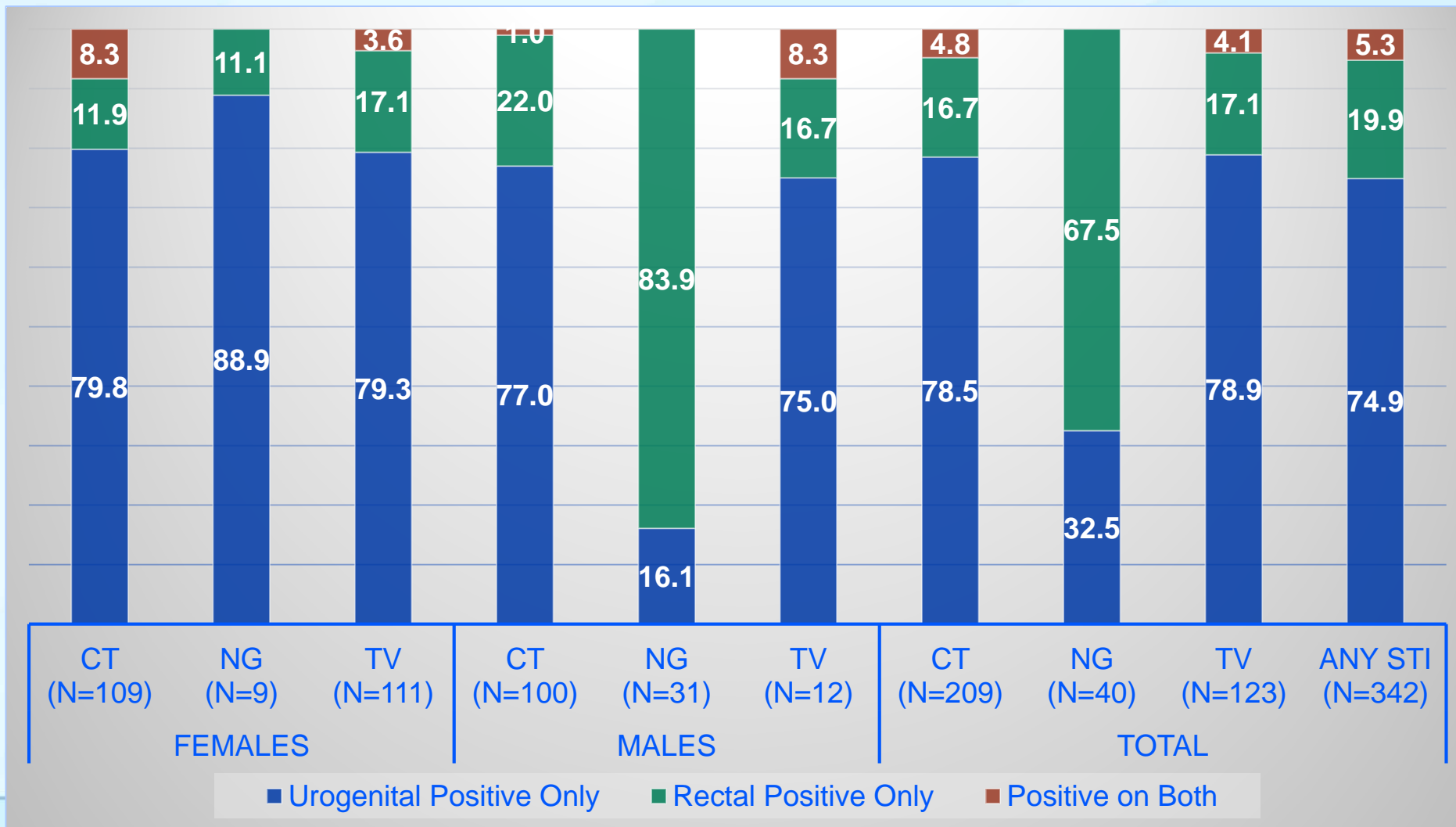


[Gartner Research's Hype Cycle diagram](#) by Jeremy Kemp.

IT'S TIME FOR *YOUR* THOUGHTS



Percent STI Positive by Sex, Specimen Type and Pathogen



Risk Analysis: Sexually Transmitted Infections

Risk Factor	%Positive	OR (95% CI)^	AOR (95%CI)^^
Male	11.4%	1.00	1.00
Female	9.8%	0.84 (0.67-1.06)	1.10 (0.87-1.40)
White, Non-Hispanic	7.9%	1.00	1.00
Black, Non-Hispanic	13.4%	1.81 (1.39-2.36)	1.67 (1.27-2.20)
Other Race	9.6%	1.24 (0.88-1.74)	1.15 (0.81-1.62)
Age (years)	--	0.96 (0.95-0.98)	0.97 (0.96-0.99)
2013	12.5%	1.00	1.00
2014	12.9%	1.04 (0.76-1.43)	1.14 (0.82-1.59)
2015	8.9%	0.68 (0.47-0.98)	0.78 (0.54-1.14)
2016	8.3%	0.64 (0.44-0.92)	0.72 (0.49-1.06)
Prior STI (Y:N)^γ	14.4%:9.9%	1.53 (1.18-1.99)	1.26 (0.96-1.66)
Rectal sex (Y:N)	14.8%:9.1%	1.73 (1.37-2.18)	1.81 (1.43-2.30)
IWTK Risk Score^μ	--	1.17 (1.10-1.25)	1.14 (1.07-1.22)
Used IWTK Before (Y:N)	9.8%:11.5%	0.84 (0.67-1.05)	0.79 (0.62-1.00)

*Findings in red were statistically significant at the <0.05 alpha level; see summary for interpretation; ^Odds Ratio (OR) estimates based on univariate logistic regression (N=3,191). ^^Adjusted Odds Ratio (AOR) estimates based on multivariate logistic regression with all risk factors listed included in the model (N=3,163); interactions between risk score and correlated covariates (Prior STI, or Rectal sex) were evaluated and removed from the model due to insignificance; the model fit was adequate (Hosmer and Lemeshow GOF, p=0.37); ^γPrior STI based on prior positives identified from IWTK testing where rescreening was completed. ^μRisk Score derived from IWTK Risk Quiz; risk estimated on a 10 point scale based on age, number of partners, history of STIs, condom use, and other risk factors

Specimen Positivity by Anatomic Site & Sex Aug 2013-Dec 2016

	Chlamydia [^]		Gonorrhea ^{^^}		Trichomonas		Any STI	
	Rectal N=907	Urogenital N=3,166	Rectal N=907	Urogenital N=3,165	Rectal N=908	Urogenital N=3,167	Rectal N=906	Urogenital N=3,166
Females	4.7	5.2	0.2	0.4	4.9	5.0	9.2	9.9
Males	5.2	5.9	5.9	0.4	0.7	0.8	9.8	7.0
Total	5.0%	5.5%	3.0%	0.4%	2.9%	3.2%	9.5%	8.7%

IWTK I WANT THE KIT

[ABOUT IWTK](#)

[WHAT IS AN STI?](#)

[TESTING](#)

[RESOURCES](#)

[RISK QUIZ](#)

[^]Excludes 1 urogenital and 1 rectal kit with missing results

^{^^}Excludes 2 urogenital and 1 rectal kit with missing results