




Diagnostics for Curable Sexually Transmitted Infections

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Disclosures

(Research Support, Consulting or Honorarium)

Research Grants to my Institution

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

Salary/Consulting Honoraria

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

Topics

- STIs and the *other* sexually transmitted infection
- What's out there / What's on the way
- Remaining gaps

STI AND HIV



STIs in the Age of PrEP

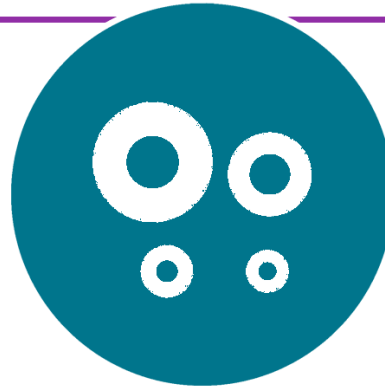
- Rates are on the rise (globally)
- STIs are a strong indicator of HIV risk
 - *10% of incident HIV cases in MSM are attributable to chlamydia/gonorrhea [Jones et al, STI, 2019]*
- Diagnostics are moving away from specialty care
- Are STIs a reasonable cost of reducing HIV risk???

The STATE of STDs in the United States



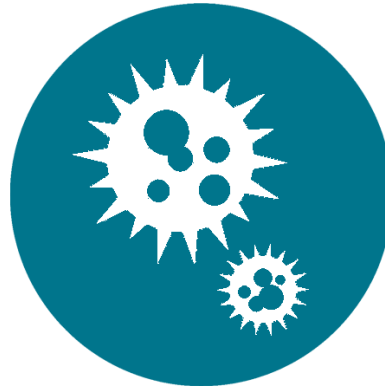
in 2017

THE NATION EXPERIENCES
STEEP AND SUSTAINED STD
INCREASES.



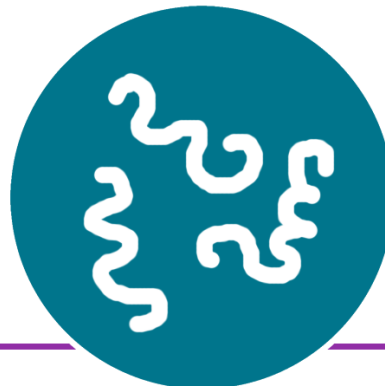
1.7 million
CASES OF CHLAMYDIA

22% increase since 2013



555,608
CASES OF GONORRHEA

67% increase since 2013



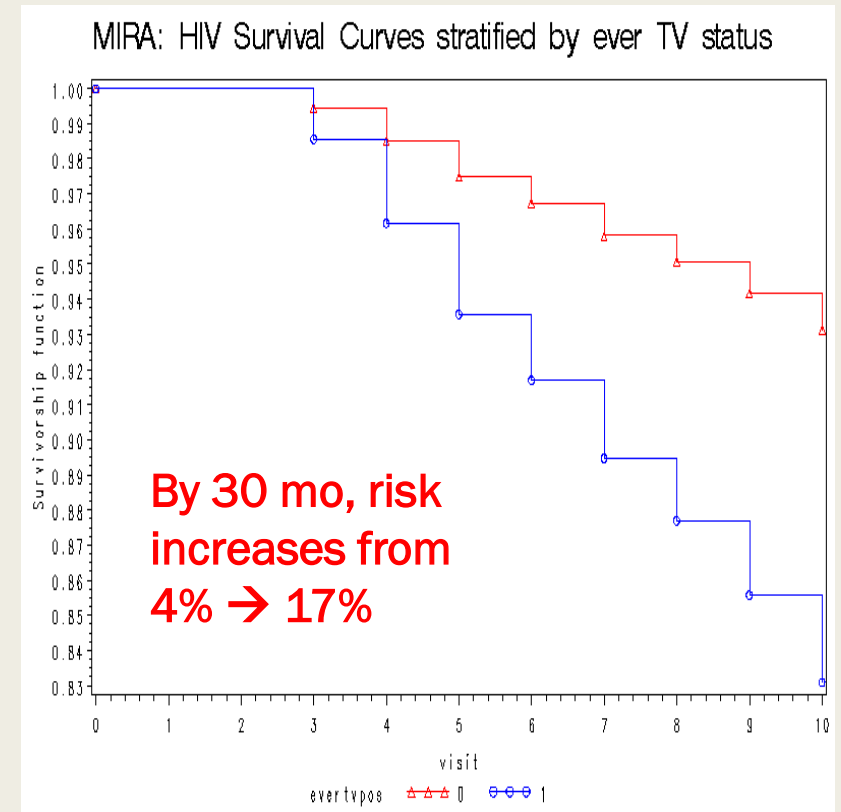
30,644
CASES OF SYPHILIS

76% increase since 2013

LEARN MORE AT: www.cdc.gov/std/

Trichomonas vaginalis

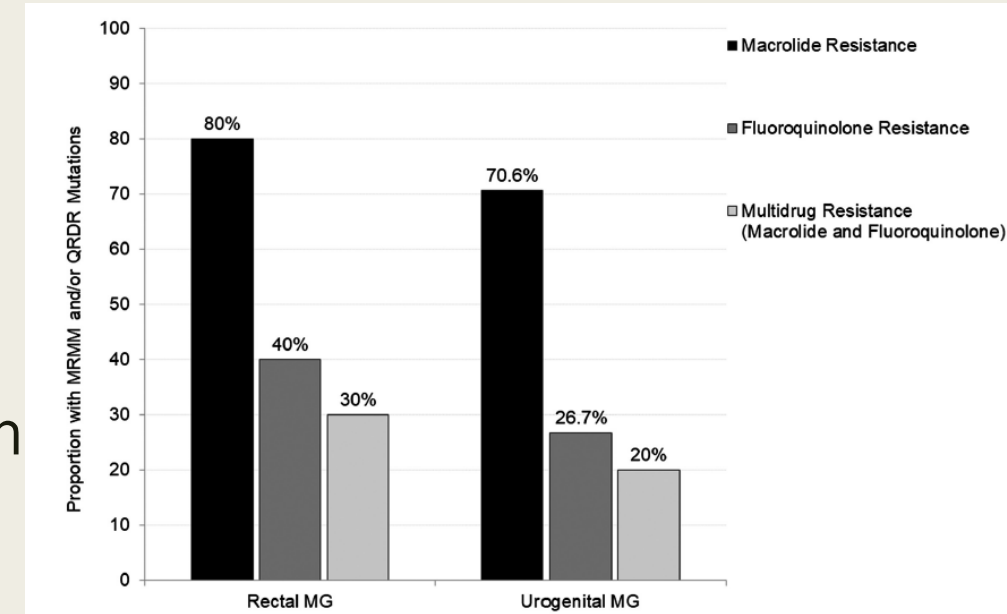
- WHO estimates ~143 million new infections each year (Feb 2019)
 - 131 million chlamydial infections
 - 78 million gonococcal infections
- Trichomonas is a key player in HIV transmission



Mavedzenge et al, 2011

Mycoplasma genitalium

- Evidence of a role in non-gonococcal urethritis
- Rectal infection is common
- Adverse reproductive outcomes in women *may be associated* with MG infection
- Antimicrobial resistance is COMMON (40-80%)



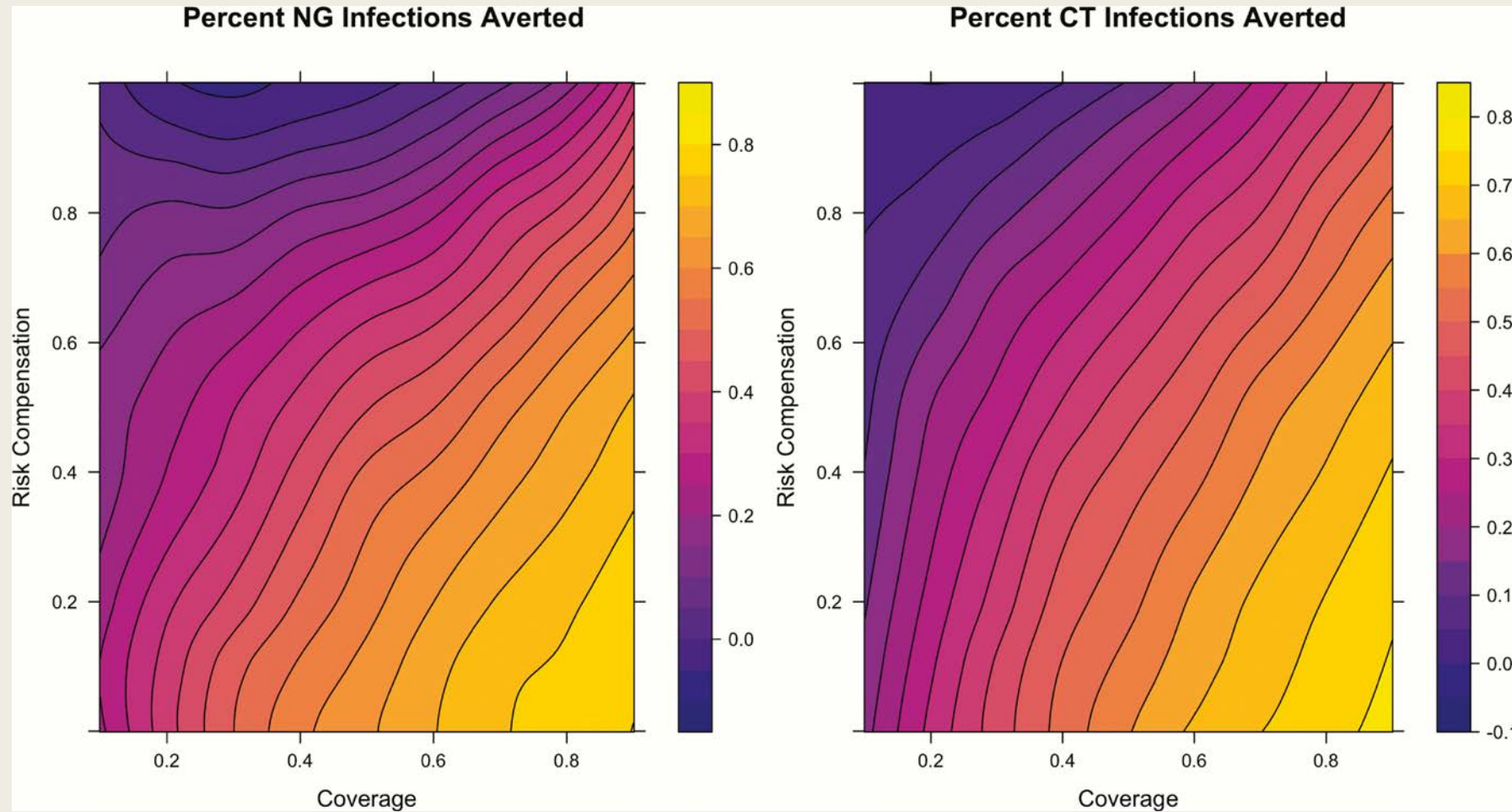
Dionne-Odom, et al. 2018 STD

PrEP is an STI Control OPPORTUNITY

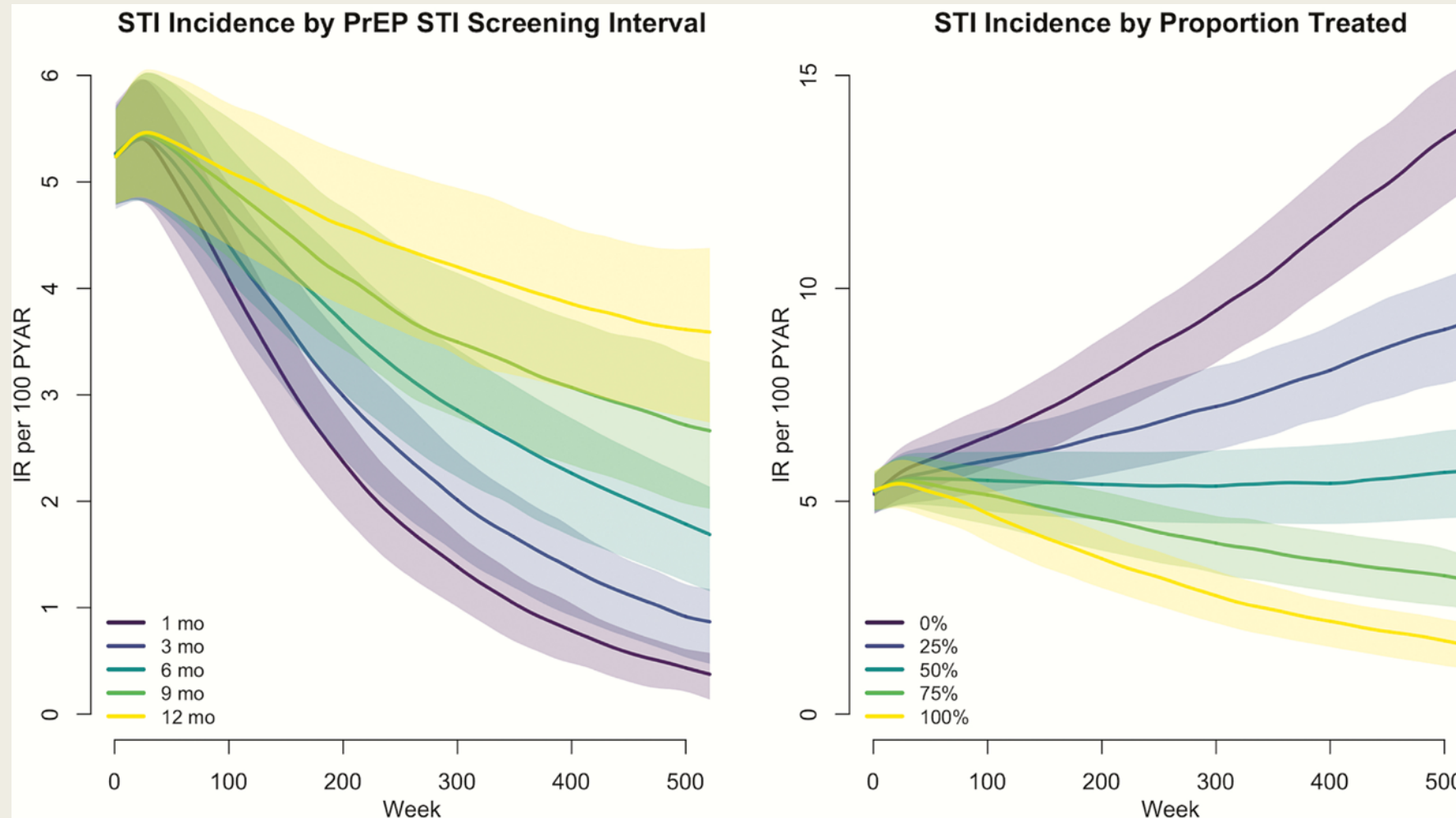
- Numerous studies have reported increased STI rates in populations on PrEP
- Few have controlled for increasing rates in populations NOT on PrEP

	Immediate	Deferred	Unadjusted odds ratio	Adjusted odds ratio (90% CI)*	p value
Any	152/265 (57%)	124/247 (50%)	1.33	1.07 (0.78–1.46)	0.74
Gonorrhoea†	103/261 (39%)	89/242 (37%)	1.12	0.86 (0.62–1.20)	0.46
Chlamydia†	77/261 (30%)	54/242 (22%)	1.46	1.27 (0.89–1.80)	0.27
Syphilis	30/263 (11%)	22/247 (9%)	1.32	1.29 (0.79–2.10)	0.39
Rectal gonorrhoea or chlamydia	93/258 (36%)	77/238 (32%)	1.18	1.00 (0.72–1.38)	0.99

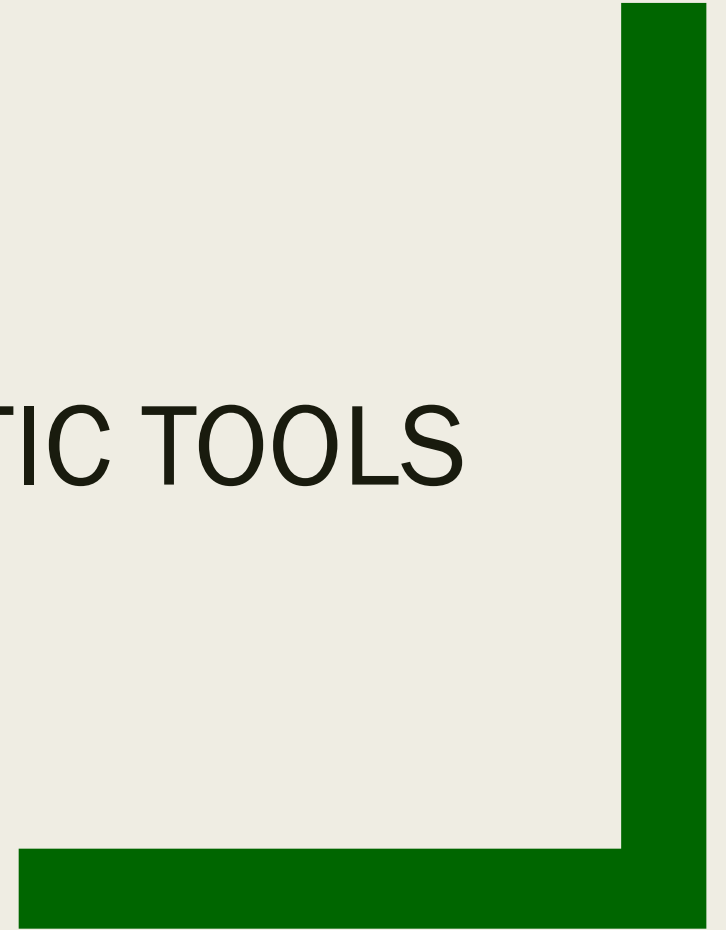
Modeling the impact of STI screening (I)



Modeling the impact of STI screening (II)



DIAGNOSTIC TOOLS



Chlamydia/Gonorrhea/Trichomonas/Mycoplasma

- New generation assays
 - Multiple pathogens
 - Expanded sample types
 - Throughput
 - Lab efficiencies
- Novel diagnostic technologies
 - Speed
 - Near-patient

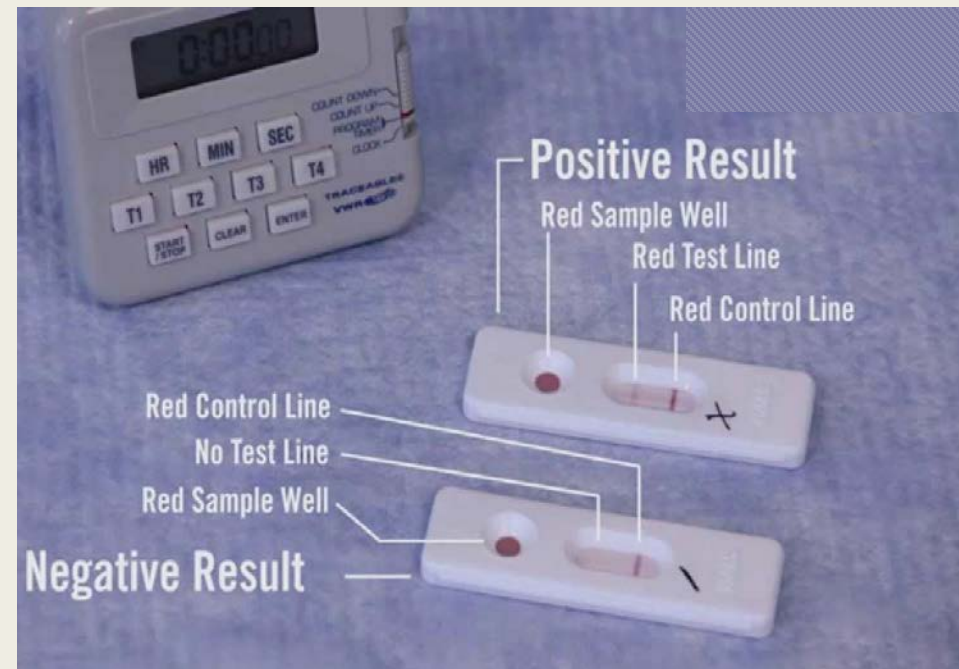


Syphilis Serology

- Lab-based
 - *Reverse algorithm [works well for blood screening]*
 - *Automated testing*
- On site testing
 - *RPR & confirmation*
- Field-based testing
 - *Can reduce time-to-treatment by a week! [Obafemi, STI, 2019]*

An Available Rapid Syphilis Test

- Whole blood, serum or finger stick
- ~10 minutes
- ***Similar*** to an HIV test
- Do you want this?
 - *In what settings / circumstances?*



Rapid Syphilis Testing in the Community

- Target population: People at risk who might not otherwise be screened
- Becoming common with HIV CBOs both in the US and globally
- STD control programs are using this to expand their reach
- Data from the 2016 CDC STD Prevention Conference:
 - LA: 54/1234 (4.4%) *30/54 (55.6%) confirmed*
 - PA: 29/698 (4.1%) *15/29 (51.7%) confirmed*

Consumer Driven Options

- Internet-based test requests
- Home collection
- Non-clinical collection venues
- Self-testing (OTC)

REMAINING GAPS



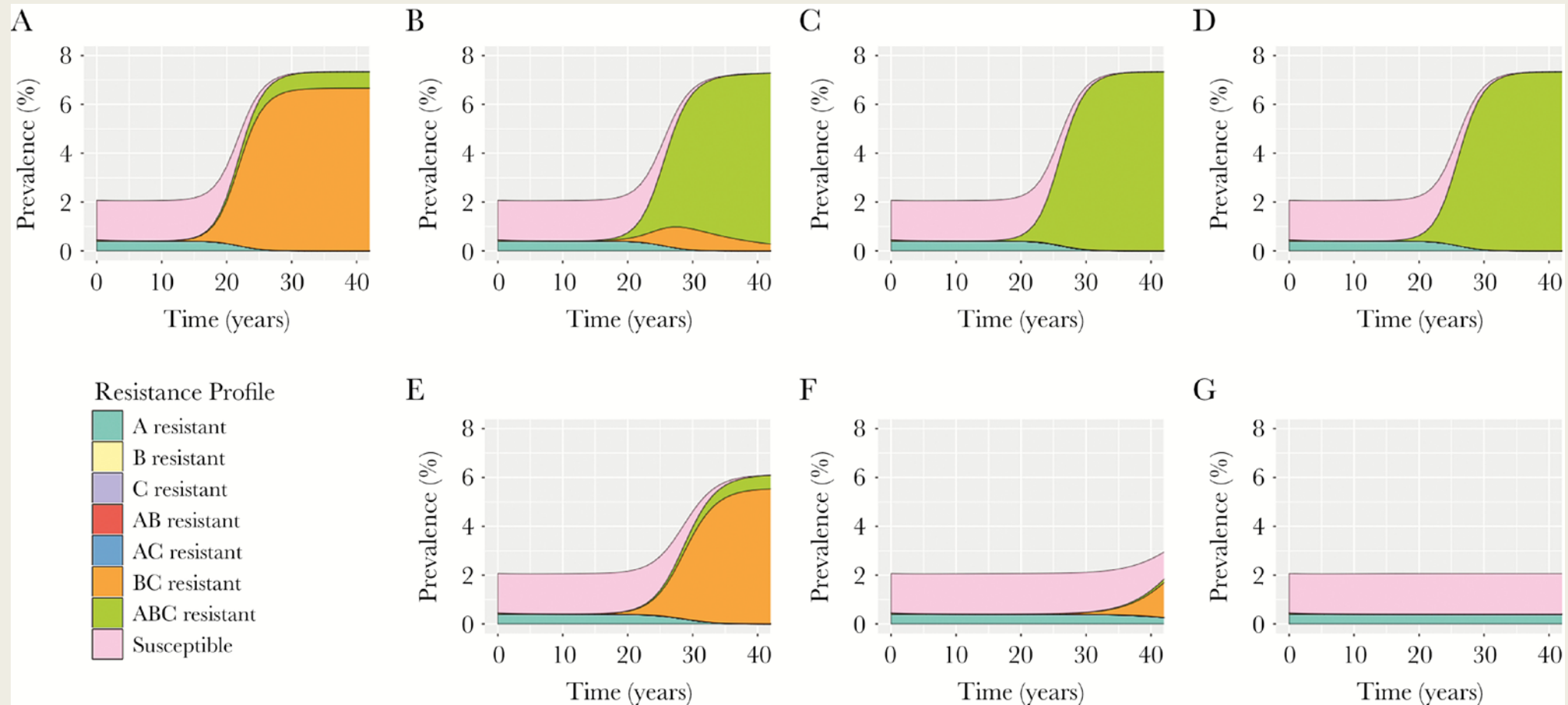
Gonorrhea Resistance

What *strategy* for testing do we need?

- Lab or clinic based?
- Reflex or in parallel?
- Testing to rule in treatment or rule out treatment?

Gonorrhea Resistance

What types of tests do we need?

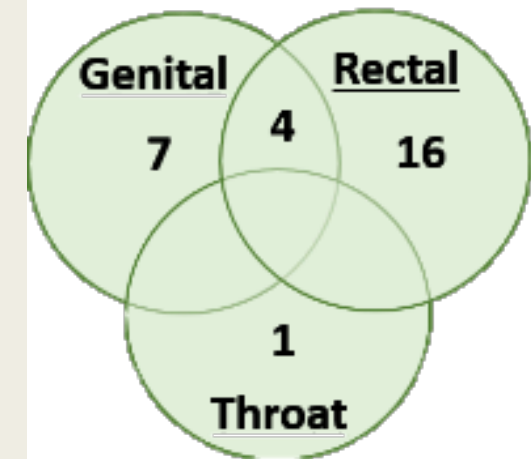


Non-clinical collection (& testing?) venues *(this will be important for PrEP)*

- Internet based ordering
- Pharmacies and other health service venues
- Community-based Outreach
 - *Re-integration of STI & HIV services*

Table 1	MSM	MSW
N	104	61
Any STI	N=20	N=12
CT	13	11
GC	8	2
TV	1	0
Syphilis	3	0
HIV	1	0

Personal
Communication,
Birmingham AIDS
Outreach



Surveillance

- How best to capture data from rapid tests in non-clinical settings
- How to deal with OTC test results
- The time to prepare is NOW!

Quality of Results for non-Traditional Testing

- Who will provide training and oversight?
- Who will be performing tests
 - *Online vendors (Gaydos 2009)*
 - *HCP*
 - *Outreach workers*
- Will tests be performed as optimized?
 - *Sample collection*
 - *Timing*
 - *Interpretation of results*

Summary

- Technology continues to improve our capacity to detect organisms
 - *Sequencing technology also continues to give us new targets to consider as potential causes of disease*
- Regulatory pathways need to be considered
 - *Many labs doing what needs to be done rather than what is cleared*
 - *Many rapid options only available Ex-US*
- One-size NEVER fits all