

Health services evaluation of an emergency department HIV and syphilis testing program using rapid point-of-care diagnostic tests in Detroit, Michigan: 2015-2016

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March 24, 2016

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Division of HIV/AIDS Prevention



Background

- ❑ From 2010-2013 annual number of primary and secondary syphilis cases in Detroit increased 173%
 - 52% HIV co-infected
- ❑ Most (56%) syphilis cases were among black men who have sex with men (MSM) aged 34 years and younger
- ❑ In October 2013, the Herman Kiefer Health Complex was closed, which included Detroit's only STD clinic
 - Center of public health activities
 - Major HIV and STD testing site for the city
 - Served approximately 11,000 clients annually

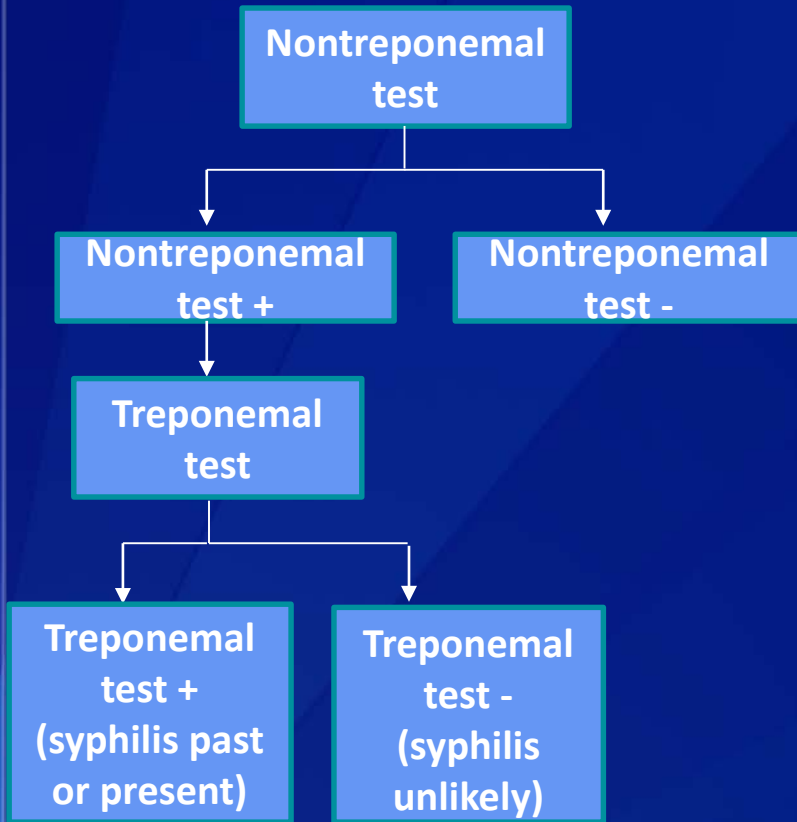
Background

- ❑ **Since 2013, there has been a gap in HIV and syphilis testing services in Detroit**
 - Need for novel HIV and syphilis testing models integrated into the healthcare operations of existing venues
 - Emergency departments (EDs) are healthcare venues that frequently serve at-risk populations
- ❑ **Henry Ford Hospital (HFH)**
 - Large tertiary care center in central Detroit
 - ED serves ~90,000 patients annually
 - Infectious disease (ID) clinic located in same facility

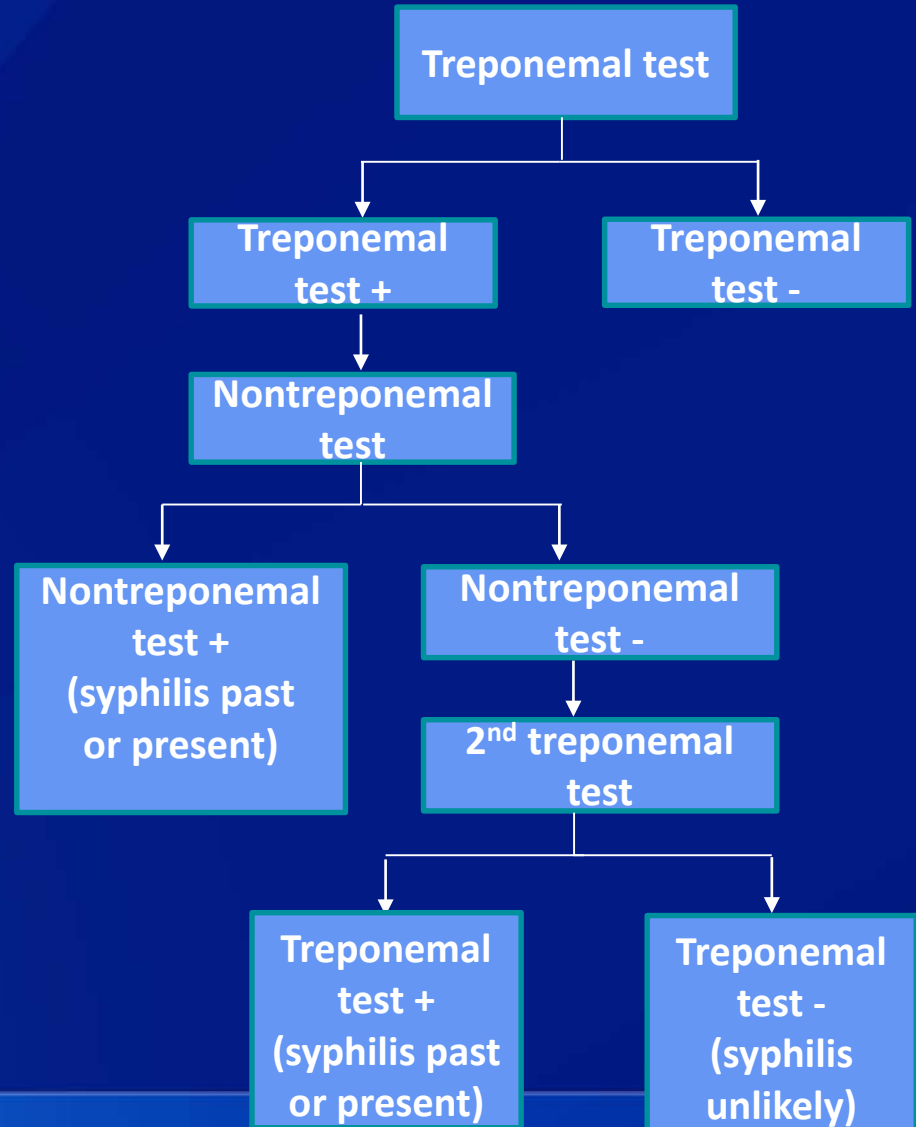


Syphilis

Traditional Algorithm



Reverse Algorithm



Objectives

- ❑ Implement a health services model in an urban ED using recently CLIA-waived rapid point-of-care (POC) tests for HIV and syphilis
- ❑ Assess the feasibility of the HIV and syphilis testing program
- ❑ Identify and link new HIV cases to care
- ❑ Identify and treat new syphilis cases
- ❑ Determine the prevalence of undiagnosed HIV and syphilis among young males in an ED to guide public health prevention efforts in Detroit

Methods

❑ Study population

- Target 1,000 Men aged 18-34 years
- Monday through Friday, 7:30am to 5pm
- Enrolled from 6/10/2015 to 1/15/2016 (n=690)

❑ Exclusion Criteria

- Previously tested for either syphilis or HIV during the study period
- Known HIV-positive patients
 - Tested for syphilis but not HIV
- Category I trauma patients

❑ Dedicated ID staff conducted counseling and testing

- Reduced ED staff burden
- Allow for immediate linkage to care (HIV) and treatment (syphilis)

Methods

❑ Rapid POC tests:

- Alere Determine HIV-1/2 Ag/Ab Combo test (Determine)
- Syphilis Health Check (SHC) treponemal test
- Both tests received CLIA waiver late 2014

❑ Lab-based testing for HIV

- HIV: Biorad HIV Combo Ag/Ab assay, Evolis platform
 - If reactive HIV Ag/Ab, confirmed by Multispot
 - If reactive Ag/Ab and non-reactive Multispot → RNA testing

❑ Lab-based testing for syphilis

- Rapid plasma reagin (RPR) (non-treponemal Ab)
PLUS
- Treponema pallidum particle agglutination assay (TPPA) (treponemal Ab)

Methods

❑ Study outcomes

- Number of new cases of HIV and syphilis identified
- Performance of rapid POC tests compared to lab based testing
 - Sensitivity (Sn), Specificity (Sp), Positive Predictive Value (PPV), Negative Predictive Value (NPV), Positive Concordance, and Negative Concordance
- Linkage to care for HIV cases
- Treatment in ED for syphilis cases

❑ Performance gold standards

- HIV: Biorad Ag/Ab assay confirmed by Multispot and RNA testing for discordant results
- Syphilis: laboratory confirmed syphilis cases-RPR confirmed by TPPA

Results

- ❑ From 6/10/2015 to 1/15/2016: 690 men aged 18-34 tested
- ❑ Demographics

Demographic Characteristic	All Participants (N=690)	HIV cases (n=5)	Syphilis Cases (n=4)
Age (mean, years)	26	22	26
Race/ethnicity			
Black (%)	87	100	100
White (%)	10	0	0
Hispanic/Latino (%)	5	0	0
MSM (%)	5	80	25

Concordance of Rapid Point of Care HIV Tests with Lab Based Confirmatory Testing

HIV Testing	Biorad Ag/Ab assay reactive	Biorad Ag/Ab assay non-reactive	Total
Determine Rapid HIV POC reactive	4 (Determine Ab +/Ag-)	1 (Determine Ab -/Ag+)	5
Determine Rapid HIV POC non-reactive	1 (Determine Ab -/Ag-)	667 (Determine Ab -/Ag-)	668
Total	5	668	673

Rapid HIV POC Test Performance

	HIV Determine rapid POC test compared to lab confirmed Biorad Ag/Ab assay (Gold Standard)
Sensitivity	80%, 95% CI [45%, 100%]
Specificity	99.9%, 95% CI [99%, 100%]
Positive Predictive Value	80%, 95% CI [45%, 100%]
Negative Predictive Value	99.9%, 95% CI [99%, 100%]
Positive Concordance	4/5 (80%)
Negative Concordance	667/668 (99.9%)

Comparison of Reactive SHC Specimens with Lab Based tests

Syphilis case	RPR	RPR Titer	TPPA
1: SHC reactive	Non-reactive	NA	Non-reactive
2: SHC reactive	Reactive	1:4	Reactive
3: SHC reactive	Non-reactive	NA	Reactive
4: SHC reactive	Reactive	1:16	Reactive
5: SHC reactive	Non-reactive	NA	Reactive
6: SHC reactive	Reactive	1:8	Reactive
7: SHC reactive	Non-reactive	NA	Reactive
8: SHC reactive	Reactive	1:4	Reactive

*All SHC non-reactive specimens (n=689) were RPR non-reactive

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Results

- ❑ Total of 5 new cases of HIV and 4 new active syphilis cases detected
- ❑ Confirmed HIV cases (n=4) or syphilis cases (n=4) was identified in 1.2% of participants using rapid POC tests
 - 0% co-infected
- ❑ Linkage and Treatment
 - All 5 newly diagnosed HIV patients linked to care at HFH ID clinic (n=4) or nearby ID clinic (n=1)
 - 50% (2/4) of true syphilis cases were treated in the ED

Limitations

- ❑ **Staff only available Monday - Friday 7:30am - 5pm**
 - ED operates 24/7
- ❑ **Insufficient statistical power to accurately estimate diagnostic test performance**
- ❑ **STAT RPRs were not available**
 - Diagnosis of syphilis could not be confirmed in ED

Conclusions

- ❑ **Rapid POC HIV and syphilis testing program was feasible in a busy ED**
 - Used dedicated non-ED staff reduces burden on ED staff
 - Allowed for easy linkage to care and treatment
- ❑ **Prevalence of HIV and syphilis exceeded expected rates**
 - Identified cases that might have otherwise been diagnosed late
- ❑ **Results highlight potential role for dual HIV and syphilis rapid testing in settings with at risk patients**
- ❑ **Testing for HIV with both rapid POC and lab-based Ag/Ab tests has dual benefits**
 - Provides immediate test results
 - Identifies acute infections

Conclusions

- ❑ SHC should be used in conjunction with an RPR to identify active syphilis
- ❑ Based on preliminary findings, when reactive the SHC was concordant with TPPA in 7/8 cases
- ❑ Non-reactive SHC useful for ruling out active syphilis infection

Future Analyses

- ❑ **Cost analysis**
- ❑ **Staff acceptability survey**
- ❑ **Evaluation of time to linkage to care and time to viral suppression**

Acknowledgements

Henry Ford Hospital

Norm Markowitz, MD

Kim Mumby, RN

Doreen Dankerlui, MPH

Jacob Manteuffel, MD

Michelle Slezak, MD

Alicia Golembieski, MS

Teresa Wiegand

MI Dept. of Health and Human Services

Karen Krzanowski, MA, MPH

Jim Kent, MS

CDC

Karen Hoover, MD, MPH

Phil Peters, MD

Yetty Fakile, PhD

Mary Kamb, MD, MPH

Alere

Trinity Biotech

Thanks!