

Administration (FDA)-cleared syphilis diagnostic tests or new investigational assays in the United States (US). Described here is a repository of residual syphilis serum specimens (N=464) that were tested and submitted by US state and local public health laboratories (PHL), with further evaluation performed at the CDC.

Methods Specimen submission criteria include de-identification of patient information, collection date, volume, storage conditions, freeze-thaw cycles, prior serology results, reported clinically diagnosed syphilis stage, treatment status, and demographics as available. Upon CDC receipt and assessment, 283/464 sera met the minimum 2 ml volume requirement for assay evaluation. Sex and age information were provided for all specimens, with some clinical data provided for reported (n=152) and unknown (n=131) syphilis stage. Previous test results were blinded and sera were tested using five FDA-cleared syphilis serological tests; nontreponemal Rapid Plasma Reagin (RPR), treponemal *Treponema pallidum* Particle Agglutination (TP-PA), Trep-Sure Enzyme Immunoassay (EIA), LIA-SON treponema screen (Chemiluminescence Immunoassay, CIA), and Syphilis Health Check (SHC). The investigational INNO-LIA Syphilis Score (Line Immunoassay, LIA) was also tested.

Results Of the five treponemal tests evaluated, overall sensitivity ranged from 76.3–100%, with EIA and SHC showing the highest and lowest sensitivity, respectively. The nontreponemal RPR demonstrated overall sensitivity between 63.2–100%. Concordance was high (84.2%) among the standard laboratory assays, RPR, EIA, CIA, and TP-PA. There was negligible variation in sensitivity based on reported syphilis stage for this panel.

Conclusion Laboratory generated data and limited reported clinical information associated with tested residual specimen panels may be of value for research and development of syphilis diagnostic tests. Repository growth is ongoing with active serum submissions from PHL.

Disclosure No significant relationships.

018.4 EVALUATION OF ROUTINIZED SYPHILIS SCREENING WITH HIV VIRAL LOADS AMONG MEN LIVING WITH HIV

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Background Frequent syphilis screening allows for early detection and treatment and decreased transmission. We conducted a clinic-based intervention incorporating opt-out syphilis testing into routine HIV viral loads. The primary objective was to determine the degree to which the intervention increased the detection rate of early syphilis.

Methods The Enhanced Syphilis Screening in HIV-positive Men (ESSAHM) Trial was a stepped wedge cluster-randomized controlled trial in 4 urban HIV clinics in Ontario, Canada from 01/02/2015 to 31/07/2017 (ClinicalTrials.gov: NCT02019043). Population: adult males. Intervention (I):

standing orders for syphilis serological testing with HIV viral loads. Control (C): maintenance of current, provider-initiated syphilis testing practice. Outcome: new diagnoses of early infectious syphilis. We obtained syphilis serologies via linkage with the centralized provincial laboratory and defined early syphilis cases using a standardized clinical worksheet and medical chart review. The trial was powered ($\geq 80\%$) to detect a $\geq 75\%$ increase in case detection rate, assuming 3 tests per patient per year. We employed a generalized linear mixed-effect model to estimate time- and age-adjusted rate ratios (aRR) comparing intervention to control periods.

Results 3,893 men were followed over 7,468 person-years (PY), and had a mean of 2 viral load tests per year. The mean number of syphilis tests per person per year increased from 0.65 in control to 1.44 in intervention periods. There were 217 new diagnoses of syphilis in total (C: 81; I: 136), for which 147 were cases of early syphilis (C:61; I:86). The detection rate increased from 1.51 per 100PY in control to 2.50 per 100PY in intervention periods, with a corresponding aRR = 1.28 (95%CI 0.73, 2.24; p = 0.40).

Conclusion The implementation of standing orders for syphilis serological testing with HIV viral loads resulted in a modest but statistically non-significant increase in detection of new cases of early infectious syphilis.

Disclosure No significant relationships.

018.6 PRENATAL CARE ENTRY AMONG PREGNANT WOMEN WITH SYPHILIS WHO USE METHAMPHETAMINES: A KEY TO CONGENITAL SYPHILIS PREVENTION

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Background In California, congenital syphilis (CS) increased for the fifth consecutive year in 2017, and contributed one third of CS cases in the United States. In response, state and local STD programs implemented CS prevention strategies. A CS Prevention Cascade monitors impact, assesses prenatal care (PNC) gaps, and estimates CS cases averted.

Methods This analysis used 2017 California Project Area surveillance data for women diagnosed with syphilis during pregnancy or at delivery. Cases were assessed for the following, each met ≥ 30 days prior to delivery: documented PNC, syphilis screening, treatment initiation, and treatment adequacy by stage. Data for each cascade bar included women counted in the preceding bar(s). The final bar represented the CS Prevention Ratio (CSPR) – the proportion of pregnant syphilis cases who did not deliver a CS infant. This cascade was then stratified by MU, defined as having either self-reported use upon interview or positive urine toxicology in pregnancy or at delivery. Three groups were identified: Non-MU (NMU); Positive-MU (PMU); Not interviewed (NI). A post-hoc stratified cascade included only pregnant syphilis cases with documented PNC, to explore how MU might impact CS case aversion once PNC is initiated.

Results 616 women were included; 239/118/259 were NMU/PMU/NI respectively. Within these groups 95%/86%/71% met PNC criteria, 89%/81%/66% received syphilis screening, 84%/75%/63% initiated treatment, 82%/73%/61% met treatment adequacy, and CSPR were 79%/69%/59% (p<0.001).

However, when considering only those with documented PNC (n=226/101/183): 94%/95%/94% received syphilis screening, 88%/88%/89% initiated treatment, 87%/85%/87% met treatment adequacy, and CSPR were 84%/81%/84% (p=0.84).

Conclusion Compared to NMU, PMU and NI were associated with a decreased CSPR. When considering only those with documented PNC, significant differences between groups were not observed, suggesting PNC entry may be a key intervention for CS prevention.

Disclosure No significant relationships.

019 – MODELS, NETWORKS AND TRANSMISSION DYNAMICS: NEW INSIGHTS FOR PROGRAMS

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1:45 PM – 3:15 PM

019.1 MODEL-BASED STUDY DESIGN FOR ESTIMATION OF ROUTE-SPECIFIC GONORRHEAL TRANSMISSION PROBABILITIES

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Background Gonorrheal infection occurs at multiple anatomical sites as a result of different types of sex. Assuming anal sex, oral sex, rimming, and kissing transmit infection leads to seven possible routes of transmission. Recent models of gonorrheal infection have shown that the route-specific transmission probabilities cannot be directly estimated from currently available data. Here, we have illustrated how theoretical models can be used to inform epidemiological study designs aimed at estimating these transmission probabilities. This methodology that we call ‘model-based study design’ informs 1) necessary sample sizes, 2) which variables need to be measured, and 3) how sensitive resulting estimates are to the analytical model misspecification.

Methods We simulated cohorts of high risk MSM over 2 years, where every three months, each man completes a sexual behavior questionnaire and has gonorrheal testing at all sites. Cohorts were simulated under many of conditions, such as measuring different variables, different levels of under and over reporting of sex acts, and different patterns of sexual behavior in the population. The simulated data were analyzed in a Bayesian framework where prior knowledge of the joint prevalence of single-site and multi-site gonorrheal infection was integrated into the analysis using the Stan programming language. Outcomes included coverage of true transmission probabilities, bias, and uncertainty in route-specific transmission probabilities.

Results Under ideal conditions, we have shown that route-specific gonorrheal transmission probabilities can be estimated from study designs similar to ongoing CDC projects.

However, we also found that failure to measure heterogeneity in sexual behavior, a high preponderance of very high-risk behavior, and systemic under-reporting of certain sex acts (but not random recall bias) significantly limit the power of cohort studies regardless of the design.

Conclusion Model-based study design provides a general method for the design, analysis, and evaluation of studies for complex parameters that cannot be estimated directly from available data.

Disclosure No significant relationships.

019.2 BRIDGING OF NEISSERIA GONORRHOEA ACROSS DIVERSE SEXUAL NETWORKS IN THE HIV PREP ERA

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Background Despite ‘best effort’ public health measures, the incidence of gonorrhoea is increasing in many countries. Recently, whole genome sequencing (WGS) has been used to investigate transmission of *Neisseria gonorrhoeae*, including antimicrobial-resistant (AMR) lineages, but to date, most studies have not combined genomic data with detailed patient-level information on sexual behaviour to define the extent of transmission across population subgroups (‘bridging’).

Methods We performed an observational study and undertook WGS and bioinformatic analysis on all cultured clinical isolates of *N. gonorrhoeae* in the state of Victoria, Australia, from January to December 2017. Antimicrobial susceptibility testing was performed on all isolates, and detailed epidemiological data was obtained, including data on sexual orientation, HIV status, use of HIV pre-exposure prophylaxis (PrEP), sex work, and overseas travel. Epidemiological associations were made with dominant genetic clusters of *N. gonorrhoeae*.

Results A total of 2,186 isolates were sequenced from 2,055 patients, 86.3% of whom were male. We identified eleven dominant genetic clusters, containing thirty or more patients, with the largest cluster comprising 181 patients. There was extensive bridging of clusters between men who have sex with men (MSM) and heterosexuals, with bisexual males identified in seven of the major clusters. Eight major clusters contained HIV-positive and HIV-negative patients (including individuals receiving PrEP). We also identified transmission of a novel azithromycin-resistant clone, associated with a mosaic *mtr* locus.

Conclusion To our knowledge, our study is the first to combine WGS with comprehensive individual-level behavioural risk data, providing verification for transmission of multiple gonococcal lineages within and across distinct sexual networks. Application of these methods in real-time will allow gonorrhoea transmission and antimicrobial resistance to be tracked, with ‘hotspots’ identified for interventions aimed at improving gonorrhoea control.

Disclosure No significant relationships.