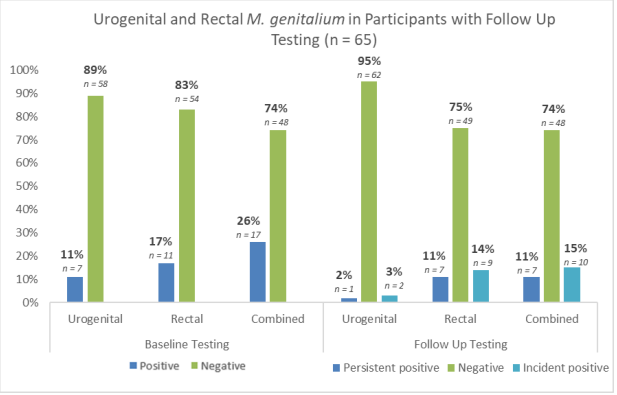
Figure 2. Detection of urogenital and rectal M. genitalium among participants with baseline and follow up testing



Conclusion. In this cohort of MSM with a recent diagnosis of a bacterial STI, routine testing identified urogenital or rectal *M. gen* in 24% of participants at baseline and 31% at either baseline or follow-up. The association of persistent *M. gen* with the risk for subsequent symptomatic infection and drug resistance merits further investigation.

Disclosures. **Emma D. Bainbridge, MD, MPH**, **Hologic** (Grant/Research Support) **Olusegun O. Soge, PhD**, **Hologic Inc.** (Grant/Research Support)**SpeeDx Inc.** (Grant/Research Support) **Annie Luetkemeyer, MD**, **Cepheid** (Grant/Research Support)**Hologic** (Grant/Research Support)**Mayne Pharma** (Grant/Research Support)

164. Antimicrobial Susceptibility of Urogenital and Extragenital *Neisseria gonorrhoeae* Isolates Among Men Who Have Sex with Men – SURRG and eGISP, 2018–2019

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Session: O-33. STIs and Enteric Infections

Background. Extragenital gonococcal infections are common among men who have sex with men (MSM); however, data comparing antimicrobial susceptibilities of urogenital and extragenital *Neisseria gonorrhoeae* isolates are limited. We investigated differences in gonococcal antimicrobial susceptibility by anatomic site among cisgender MSM using specimens collected through CDC's enhanced Gonococcal Isolate Surveillance Project (eGISP) and Strengthening the U.S. Response to Resistant Gonorrhea (SURRG).

Methods. During January 1, 2018–December 31, 2019, 12 eGISP and 8 SURRG sites collected urogenital, pharyngeal, and rectal isolates from cisgender MSM in STD clinics. Gonococcal isolates were sent to regional laboratories for antimicrobial susceptibility testing by agar dilution. To account for correlated observations, linear mixed-effects models were used to calculate geometric mean minimum inhibitory concentrations (MICs) and mixed-effects logistic regression models were used to calculate the proportion of isolates with elevated or resistant MICs; comparisons were made across anatomic sites.

Results. Participating clinics collected 3,974 urethral, 1,553 rectal, and 1,049 pharyngeal isolates from 5,456 unique cisgender MSM. There were no significant differences in the geometric mean MICs for azithromycin, ciprofloxacin, penicillin, and tetracycline by anatomic site. For cefixime and ceftriaxone, geometric mean MICs for pharyngeal isolates were higher compared to anogenital isolates ($p< 0.05$). The proportion of isolates with elevated ceftriaxone MICs (≥ 0.125 µg/ml) at the pharynx (0.67%) was higher than at rectal (0.13%) and urethral (0.18%) sites ($p< 0.05$).

Table 1. Comparison* of antimicrobial susceptibility distribution by antimicrobial and anatomic site of gonococcal infection among men who have sex with men — eGISP and SURRG, 2018–2019

Antimicrobial and measured parameter**	Pharyngeal (n=1,049)	Rectal (n=1,553)	Urethral (n=3,974)	P-value
Azithromycin				
Geometric mean MIC (95% CI)	0.32 (95% CI: 0.30-0.34)	0.31 (95% CI: 0.29-0.33)	0.30 (95% CI: 0.29-0.31)	0.27
Number (%; 95% CI) with elevated MIC	124/1,049 (11.2%; 95% CI: 9.4-13.3)	182/1,553 (11.3%; 95% CI: 9.8-13.1)	420/3,974 (10.2%; 95% CI: 9.3-11.3)	0.38
Cefixime				
Geometric mean MIC (95% CI)	0.0192 (95% CI: 0.0185-0.020)	0.0181 (95% CI: 0.0175-0.0187)	0.0176 (95% CI: 0.0173-0.018)	**<0.001**
Number (%; 95% CI) with elevated MIC	3/1,049 (0.29%; 95% CI: 0.09-0.88)	8/1,553 (0.52%; 95% CI: 0.26-1.0)	11/3,974 (0.28%; 95% CI: 0.15-0.50)	0.41
Ceftriaxone				
Geometric mean MIC (95% CI)	0.0108 (95% CI: 0.0103-0.0113)	0.00987 (95% CI: 0.0095-0.0102)	0.0098 (95% CI: 0.0096-0.0101)	**<0.001**
Number (%; 95% CI) with elevated MIC	7/1,049 (0.67%; 95% CI: 0.32-1.4)	2/1,553 (0.13%; 95% CI: 0.03-0.51)	7/3,974 (0.18%; 95% CI: 0.08-0.37)	**0.03**
Ciprofloxacin				
Geometric mean MIC (95% CI)	0.12 (95% CI: 0.10-0.15)	0.11 (95% CI: 0.09-0.13)	0.12 (95% CI: 0.10-0.13)	0.50
Number (%; 95% CI) with resistant MIC	450/1,049 (42.7%; 95% CI: 39.5-46.0)	649/1,553 (41.6%; 95% CI: 38.9-44.2)	1701/3,974 (42.6%; 95% CI: 40.9-44.3)	0.77
Penicillin				
Geometric mean MIC (95% CI)	0.63 (95% CI: 0.58-0.68)	0.60 (95% CI: 0.57-0.65)	0.66 (95% CI: 0.63-0.69)	0.08
Number (%; 95% CI) with resistant MIC	140/1,049 (13.0%; 95% CI: 11.0-15.2)	200/1,553 (12.6%; 95% CI: 11.0-14.4)	603/3,974 (14.8%; 95% CI: 13.7-16.0)	0.06
Tetracycline				
Geometric mean MIC (95% CI)	1.55 (95% CI: 1.44-1.68)	1.48 (95% CI: 1.39-1.58)	1.47 (95% CI: 1.40-1.53)	0.45
Number (%; 95% CI) with resistant MIC	377/1,049 (35.7%; 95% CI: 32.7-38.8)	512/1,553 (32.9%; 95% CI: 30.5-35.4)	1377/3,974 (34.5%; 95% CI: 32.9-36.1)	0.31

Abbreviations: eGISP= enhanced Gonococcal Isolate Surveillance Project; SURRG= Strengthening the U.S. Response to Resistant Gonorrhea; MIC= minimum inhibitory concentration; CI= Confidence interval

*We fitted overall models with and without "anatomic sites" and compared the two models to get the overall p-value; if the overall p-value was statistically significant (<0.05), we conducted post-hoc testing to adjust for multiple tests using the Holm adjustment. Linear mixed-effects model was used for geometric mean MICs and mixed-effects logistic regression model was used for the proportion of isolates with elevated or resistant MICs across anatomic sites, respectively, to account for the multiple isolates provided by the same patients.

**Clinical and Laboratory Standards Institute (CLSI) has not established criteria for resistance to azithromycin, cefixime, and ceftriaxone; breakpoints used to define "elevated MIC" for these antimicrobials include: azithromycin MIC of ≥2.0 µg/ml, cefixime MIC of ≥0.25 µg/ml, and ceftriaxone MIC of ≥0.125 µg/ml. Antimicrobial susceptibility testing results were interpreted according to criteria recommended by CLSI for penicillin resistance (MIC ≥ 2 µg/ml or β-lactamase positive), ciprofloxacin resistance (MIC ≥1.0 µg/ml), and tetracycline resistance (MIC ≥2.0 µg/ml). Tested ranges for antimicrobials (µg/ml): azithromycin (0.008–16), cefixime (0.002–1), ceftriaxone (0.001–1), ciprofloxacin (0.001–32), penicillin (0.008–64), tetracycline (0.06–64).

Conclusion. Based on data collected from multi-jurisdictional sentinel surveillance projects, antimicrobial susceptibility patterns of *N. gonorrhoeae* isolates may differ among MSM at extragenital sites, particularly at the pharynx. Continued investigation into gonococcal susceptibility patterns by anatomic site may be an important strategy to monitor and detect the emergence of antimicrobial resistant gonorrhea over time.

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165. Emergence of Extensively Drug-Resistant *Salmonella enterica* Serotype Typhi Infections—United States, 2008–2020

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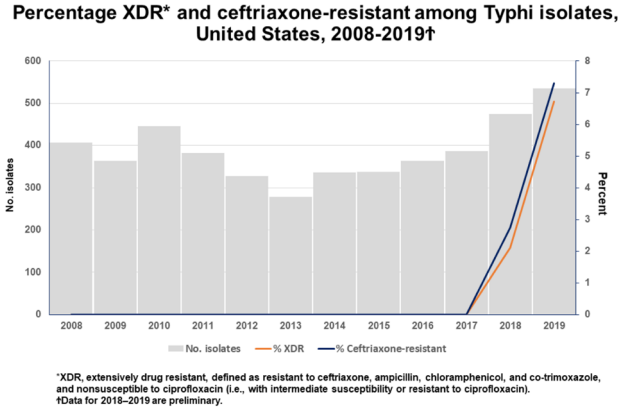
Session: O-33. STIs and Enteric Infections

Background. Typhoid fever, caused by *Salmonella* Typhi, is fatal in 12%–30% of patients not treated with appropriate antibiotics. In 2016, a large outbreak of extensively drug-resistant (XDR) Typhi infections began in Pakistan with cases reported globally, including the United States. In 2021, the Centers for Disease Control and Prevention (CDC) issued a health advisory on XDR infections among U.S. residents without international travel. We describe resistance of Typhi infections diagnosed in the United States to help guide treatment decisions.

Methods. Typhoid fever is a nationally notifiable disease. Health departments report cases to CDC through the National Typhoid and Paratyphoid Fever Surveillance system. Isolates are submitted to the National Antimicrobial Resistance Monitoring System for antimicrobial susceptibility testing (AST) using broth microdilution. AST results are categorized by Clinical and Laboratory Standards Institute criteria. We defined XDR as resistant to ceftriaxone, ampicillin, chloramphenicol, and co-trimoxazole, and nonsusceptible to ciprofloxacin.

Results. During 2008–2019, of 4,637 Typhi isolates, 52 (1%) were ceftriaxone resistant (axo-R); 71% were ciprofloxacin nonsusceptible, 1 azithromycin resistant (azm-R), and none meropenem resistant. XDR was first detected in 2018, in 2% of 474 isolates and increased to 7% of 535 in 2019. Of the 52 axo-R isolates, 46 were XDR, of which 45 were from travelers to Pakistan, and one from a non-traveler; 6 were not XDR, of which 4 were linked to travel to Iraq. In preliminary 2020 reports, 23 isolates were XDR; 14 were from travelers to Pakistan, 8 from non-travelers, and 1 from someone with unknown travel status. Among those with XDR infection, median age was 11 years (range 1–62), 54% were female, and 62% were from 6 states.

Conclusion. Ceftriaxone-resistant Typhi infections, mostly XDR, are increasing. Clinicians should ask patients with suspected Typhi infections about travel and adjust treatment based on susceptibility results. Carbapenem, azithromycin, or both may be considered for empiric therapy of typhoid fever among travelers to Pakistan or Iraq and in uncommon instances when persons report no international travel. Ceftriaxone is an empiric therapy option for travelers to countries other than Pakistan and Iraq.



Disclosures. **All Authors**: No reported disclosures

166. Congenital Syphilis in Minnesota, 2016-2020

Nicholas Lehnertz, MD, MPH, MHS[1]; Khalid Bo-Subait, MPH[1]; Candy Hadsall, RN, MA[1]; Cheryl Barber, MS, MPH[1]; Allison LaPointe, MPH[1]; Cindy Lind Livingston, n/a[1]; Karmen Dippmann, n/a[1]; Marcie Babcock, n/a[1]; Brian Kendrick, n/a[1]; Jayne Griffith, MA, MPH[1]; Gina Liverseed, DNP, APRN, WHNP[1]; Peggy Darrett-Brewer, n/a[1]; Christine L. Jones, MSW[2]; [1]Minnesota Department of Health, St. Paul, Minnesota; [2]MN Department of Health, St. Paul, Minnesota

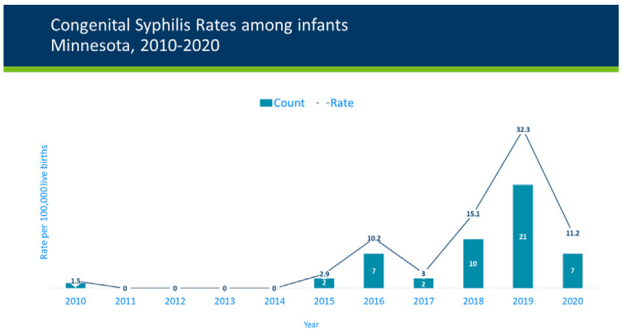
Session: O-33. STIs and Enteric Infections

Background. Nationally, cases of congenital syphilis (CS) have increased over the past 5 years. We reviewed CS cases in Minnesota from 2016-2020.

Methods. All cases of syphilis, including CS, are reported to the Minnesota Department of Health (MDH), including accompanying data on maternal age, baby's sex, race, test results, maternal stage and treatment of mother and child. Medical records and case interviews were reviewed; the 2018 national case definition was used to classify cases.

Results. During 2016-2020, there were 47 CS cases from 45 mothers, peaking in 2020 at a rate of 3.2/10,000 live births. 43 (91.5%) cases of CS had no clinical signs, 1 (2.1%) CS case was inadequately treated, and there were 2 deaths.

The median maternal age was 28 (IQR 9, range 18-38). 13 (28.9%) identified as Black, non-Hispanic, 13 (28.9%) as American Indian/Alaska Native (AI/AN), 9 (20.0%) as White, non-Hispanic, 3 (6.7%) as Hispanic, 2 (4.4%) as Asian/Pacific Islander, and 5 (11.1%) Other/Unknown. Twenty-four (51.1%) cases occurred in the Minneapolis/St. Paul metropolitan area. 2 (4.4%) cases were primary, 1 (2.2%) was secondary, while 18 (40.0%) maternal cases were staged as early non-primary, non-secondary (ENPNS) and 24 (53.3%) were late unknown duration. 14 (31.1%) of mothers had their initial prenatal visit in the first trimester, 6 (13.3%) in the 2nd trimester, 11 (24.4%) in the 3rd, and 14 (31.1%) unknown. None of the maternal cases were HIV+, 2 were identified as positive for hepatitis C. 18 (40.0%) mothers had no or limited prenatal care, 21 (46.7%) had inadequate treatment for syphilis, and 18 (40.0%) had inadequate maternal testing. No cases reported substance use, but one case had a positive substance screen at delivery, and case interviews also documented a role of substance use and home instability in several other cases.



Conclusion. Case rates of CS are the highest ever seen in MN. There is disproportionate impact in persons of color and indigenous Minnesotans. Lack of access to prenatal care, missed opportunities for testing, and incomplete or insufficient treatment were found in maternal cases. More work needs to be done with communities at risk and with prenatal care providers to ensure adequate testing, identification and treatment for syphilis in women of child-bearing age.

Disclosures. **All Authors**: No reported disclosures

167. Efficacy of Investigational Microbiota-Based Live Biotherapeutic RBX2660 in Individuals with Recurrent *Clostridioides difficile* Infection: Data from Five Prospective Clinical Studies

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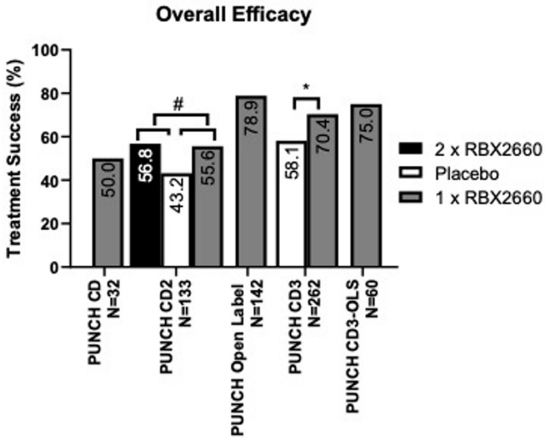
Session: O-33. STIs and Enteric Infections

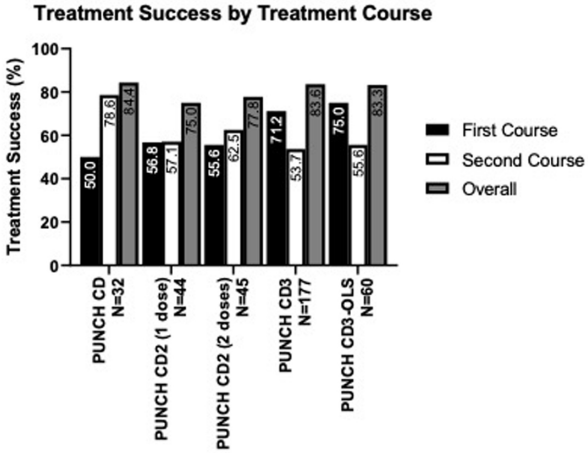
Background. Microbiota-based treatments have shown promise to reduce recurrence, morbidity, and mortality for recurrent *Clostridioides difficile* infections (rCDI), but consistent and reliable clinical efficacy data are needed to support regulatory approvals that broaden patient access. Here we provide cumulative data from 5 prospective clinical studies evaluating RBX2660—a standardized, microbiota-based investigational live biotherapeutic—for reducing rCDI recurrence.

Methods. This analysis included three phase 2 (PUNCH CD, PUNCH CD2, PUNCH CD Open Label) and two phase 3 trials (PUNCH CD3, PUNCH CD3-OLS *ad hoc* analysis). All participants were ≥18 years old with documented rCDI who completed standard-of-care (SOC) oral antibiotic therapy prior to treatment with RBX2660. Depending on the trial, assigned study treatment was 1 or 2 doses of RBX2660 or placebo, with Treatment Success (TS) defined as remaining recurrence-free for 8 weeks after treatment. Treatment responders were monitored for additional recurrence through at least 6 months after receiving the last RBX2660 dose. Treatment non-responders were administered SOC antibiotic treatment and/or additional RBX2660 treatment and monitored for recurrence for 8 weeks after the last received RBX2660 treatment.

Results. Among the 5 trials with a total of 629 participants, RBX2660 consistently reduced the recurrence of rCDI, with TS rates ranging from 50 to 78.9% (Figure 1). Among primary non-responders, additional RBX2660 treatments further reduced recurrence and overall rates of TS ranged from 75.0% to 84.4% (Figure 2). Among CD, CD3, and CD3-OLS, a majority of primary responders remained CDI-free to 6 and up to 24 months with success rates ranging from 74.4% to 92.1%.



*, Bayesian hierarchical model; 98.6% (0.986) probability of superiority, which exceeded the predefined 0.975 success threshold.
#, Chi-square test; p>0.05.
PUNCH CD3-OLS: enrolled subjects with IBD, IBS, Immunocompromised Conditions; Ongoing, *ad hoc* analysis.



PUNCH CD3-OLS: enrolled subjects with IBD, IBS, Immunocompromised Conditions; Ongoing, *ad hoc* analysis.

Conclusion. Among 5 trials with consistent investigational product and clinical endpoints, RBX2660 consistently reduced rCDI recurrence, with a majority of treatment responders remaining CDI-free for at least 6 and up to 24 months. Further, initial lack of response to RBX2660 did not preclude clinical benefit of additional RBX2660