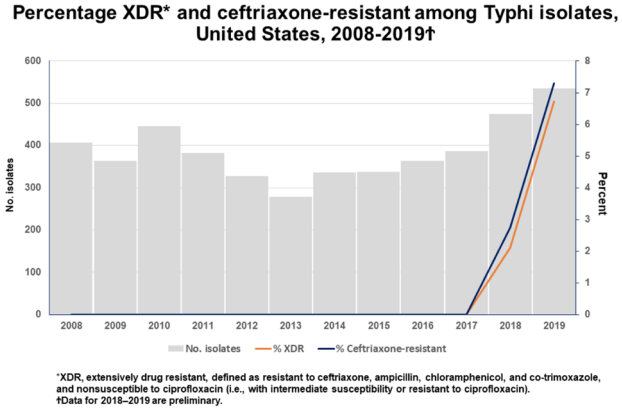

Disclosures. **All Authors**: No reported disclosures

166. Congenital Syphilis in Minnesota, 2016-2020

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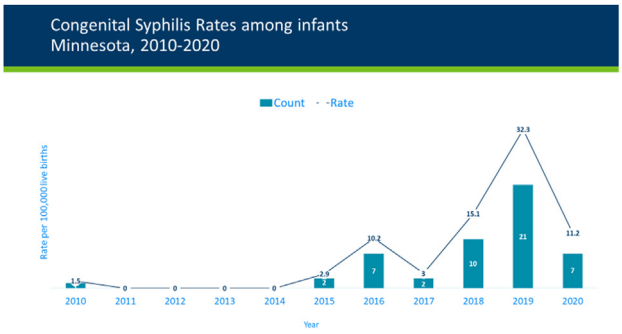
Session: O-33. STIs and Enteric Infections

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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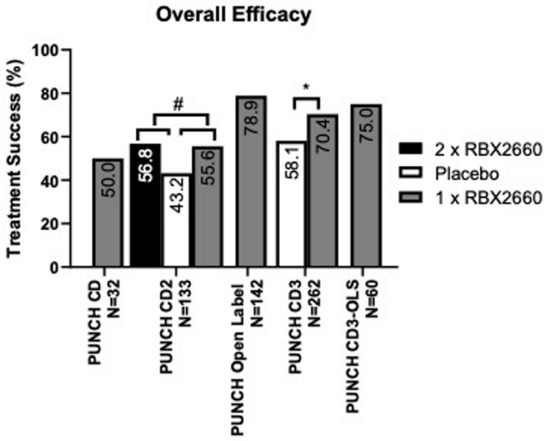
Session: O-33. STIs and Enteric Infections

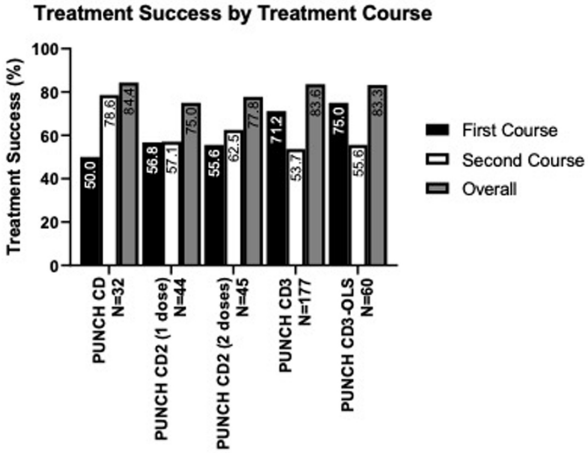
Background. Microbiota-based treatments have shown promise to reduce recurrence, morbidity, and mortality for recurrent *Clostridioides difficile* infections (rCDI), but consistent and reliable clinical efficacy data are needed to support regulatory approvals that broaden patient access. Here we provide 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