Background. Bezlotoxumab (BEZ) was approved in 2017 for prevention of recurrent C. difficile infection (CDI), with a number needed to treat (NNT) of 10 reported in the registration trials. Little information is available on its effectiveness in high-risk populations. BEZ was added to the institutional outpatient formulary in 2017 for use in patients with CDI at high-risk for recurrent CDI (rCDI), i.e., history of solid organ (SOT) or hematopoietic stem cell (HCT) transplantation, active malignancy, chronic steroid (prednisone equivalent 20 mg/day), and failed fecal microbiome transplant (FMT). Patients that met criteria were referred by the antimicrobial stewardship team to the infectious disease clinic for BEZ insurance approval and administration. The goal of this study was to evaluate the effectiveness and safety of BEZ in this high-risk population.

Methods. The cohort of patients referred for BEZ were compared by those who received BEZ vs. those who did not receive BEZ (standard of care, SOC). The primary endpoint was rCDI at ≤100 days of BEZ infusion or end-of-treatment (EOT). Secondary endpoints were time to rCDI and insurance status. Safety of BEZ was evaluated as infusion reaction ≤24 hours and death ≤100 days.

Results. Twenty-nine patients were referred for BEZ; 14 (48%) received BEZ. Characteristics in Table 1. rCDI at 100 days occurred in 14.3% BEZ vs. 28.6% SOC (P = 0.3654) with an NNT of 7. Average time to rCDI was longer in the BEZ group vs. SOC (49 vs. 27 days). No infusion reactions or death were noted in the BEZ group. Insurance approval for BEZ was denied in 26.7%. Medicaid coverage was common in SOC (46.7% vs. 7.1%; P = 0.0191) and Medicare coverage was more common in BEZ group (71.4% vs. 33.3%; P = 0.0438).

Conclusion. Early experience with BEZ appears promising in a high-risk, pre-dominantly immunocompromised population. The NNT to prevent rCDI was 7. Larger cost–benefit studies in immunocompromised and transplant populations are warranted.

Table 1: Characteristics of BEZ and SOC Patients

| Variable         | BEZ (N = 14) | SOC (N = 15) | P-value |
|------------------|--------------|--------------|---------|
| Age ≥60          | 57.1%        | 26.7%        | 0.1027  |
| ≥1 prior CDI episodes | 50%          | 26.7%        | 0.2042  |
| Average no. of prior CDI episodes | 2           | 2           |         |
| Immuno compromised | 78.6%        | 86.7%        | 0.5704  |
| SOT recipient    | 42.8%        | 33.3%        |         |
| HCT recipient    | 21.4%        | 13.3%        |         |
| Active cancer    | 29.6%        | 26.7%        |         |
| Failed FMT       | 7.1%         | 6.7%         | 0.9667  |

Disclosures. All authors: No reported disclosures.

506. The Impact of Bowel Management System (BMS) on the Incidence of Hospital-Onset (HO) C. difficile Infection Laboratory-ID Events Despite Diagnostic Stewardship

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Session: 59. Healthcare Epidemiology: Updates in C. difficile Thursday, October 4, 2018: 12:30 PM

Background. C. difficile infection (CDI) Laboratory identified events are reportable to CMS through the CDCs NHISN. Diagnostic stewardship has been shown to decrease the incidence by decreasing false-positive incidental C. difficile-associated laboratory systems (BMS) have been associated with transient loss of tone of anal spincter muscles that result in diarrhea. These episodes of diarrhea may be misdiagnosed as CDI due to a false-positive test result. The objective of this study was to determine whether the use of BMS has resulted in false-positive CDI Lab-ID events.

Methods. We performed a retrospective review of all HO-CDI Lab ID events from October 1, 2016 to December 31, 2017 in a 1,157-bed tertiary academic medical center. Since 2013, several interventions were implemented to decrease the incidence of CDI Lab-ID events. These interventions have included: (i) enhanced environmental cleaning, (ii) CDI testing algorithm, (iii) use of hydrogen peroxide terminal cleaning of high-risk units, and (iv) computer-assisted decision support diagnostic stewardship. Poisson regression analysis was performed to compare incidence rates. P-value of ≤0.05 was considered significant.

Results. A sustained low and decreasing HO-CDI incidence was observed from 2013 to 2017 (7.9, 6.0, 7.1, 6.5 and 5.2 CDI/10,000 patient days; P = 0.01). An incremental decrease was observed when comparing the annual incidence in 2016 to the YTD incidence in 2017 (6.5 vs. 5.2 CDI/10,000 patient days; P = 0.001). Comparing the five quarters before diagnostic stewardship was implemented to post implementation, the CDI incidence decreased from 6.7 to 5.2 CDI events/10,000 patient days (P = 0.009). Of the 180 HO-CDI Lab ID events that occurred post-implementation of the diagnostic stewardship, 31 (17%) were in cases in which the computer-assisted alerts were overridden and may have been false positives. An additional 12 (6.7%) cases occurred in patients who had BMS in place within 48 hours and 22 (12%) had BMS in place within 1 week.

Conclusion. Diagnostic stewardship through computer-assisted decision support is an effective method of reducing false-positive CDI Lab-ID events. We found that an additional 12% of the HO-CDI are potentially false positives as these were observed from patients who had BMS in place immediately before the positive test results.

Disclosures. All authors: No reported disclosures.