640. Development of a Laboratory Verification Protocol for Concurrent Detection of Bacterial, Fungal, and Antimicrobial Resistance Genes in a Multiplex Syndromic Joint Infection Panel

Monica Cronin, MS[1]; Taylor K. Fadgen, Bachelor of Science[1]; Lisa Ogden, BS[1]; Jeremy P. Green, BS[1]; Stephanie A. Thatcher, MS[1]; Rebecca C. Young, MS[1]; Brandon Hoelcle, BS[2]; [1]BioFire Diagnostics, LLC, Salt Lake City, Utah; [2]ZeptoMetrix, LLC, Buffalo, New York

Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Verification is a critical component of implementing a diagnostic test in a clinical lab and can be time consuming and costly. A verification protocol and organism panel were developed in collaboration with ZeptoMetrix®, LLC to verify all analyte detections for the BioFire® Joint Infection (JI) Panel*. The BioFire JI Panel detects 31 pathogens and 8 antimicrobial resistance (AMR) genes associated with joint infections from synovial fluid specimens.

Methods. A protocol was developed using prototype NATtrol™ controls from ZeptoMetrix®, synovial fluid, and the BioFire® FilmArray® 2.0 and the BioFire® FilmArray® Torch Systems. Control materials were tested in the presence of synovial fluid from pooled human donors. The 32 targets required for all analyte detections were divided into 5 pools of 6-7 analytes and then tested over multiple days on several systems.

Results. Preliminary outcomes were good with a cumulative positive detection rate of 100% (310/310) and expected negative detections of 99.3% (1182/1190) from 50 prototype BioFire JI Panel test runs. AMRs were correctly identified in 50/50 (100%) replicates when a correlated bacterium was present. Unexpected detections of *Streptococcus* spp. (7/50) and *Staphylococcus lugdunensis* (1/50) were likely due to contaminants in the synovial fluid; *Streptococcus* spp. was confirmed by testing the synovial fluid in isolation.

Conclusion. Efficient performance verification may be achieved by combining 32 organisms/8 AMR into 5 pools and can be completed with 20 test runs in 4 days. The pooling scheme provides multiple positive/negative detections per analyte and accurately detects AMR. The protocol and controls serve as a useful tool for providing reliable detections of targets over multiple days, operators and systems and offers a flexible solution for supporting verification needs.

**The BioFire® Joint Infection Panel is currently pending US FDA De Novo review. This product has not been evaluated by other global regulatory agencies for in vitro diagnostic use.* Not available for sale. Panel menu subject to change.

Disclosures. **Monica Cronin, MS**, **BioFire Diagnostics, LLC** (Employee) **Taylor K. Fadgen, Bachelor of Science**, **BioFire Diagnostics, LLC** (Employee) **Lisa Ogden, BS**, **BioFire Diagnostics, LLC** (Employee) **Jeremy P. Green, BS**, **BioFire Diagnostics, LLC** (Employee, Shareholder) **Stephanie A. Thatcher, MS**, **BioFire Diagnostics** (Employee) **Rebecca C. Young, MS**, **BioFire Diagnostics, LLC** (Employee) **Brandon Hoelcle, BS**, **ZeptoMetrix, LLC** (Employee)

641. Clinical Predictors of Hospital-Acquired Bloodstream Infections

Radhika Sheth, MD[1]; Mehakmeet Bhatia, DO[1]; Vivek Kak, MD[1]; [1]Henry Ford Allegiance Health, Jackson, Michigan

Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Hospital-acquired bloodstream infections (HABSI) are associated with increased mortality and decreased hospital quality metrics. This has led to an increased focus on blood culture stewardship. Little data exists regarding predictive factors of bacteremia in hospitalized patients. We aim to determine what clinical characteristics in patients were predictive of HABSI.

Methods. This is a retrospective case-control study of 540 patients with positive blood cultures admitted to our health system between September 1, 2017, to April 1, 2020. Electronic medical records of patients with positive blood cultures were independently reviewed to determine contamination versus true bacteremia. We looked at different clinical parameters and laboratory investigations within 24 hours of drawing blood cultures. Clinical variables were age ≥ 60 years, heart rate ≥ 90/minute, systolic blood pressure ≤ 90 mmHg or use of a vasopressor, oral temperature > 38°Celsius (100.4°Fahrenheit), white blood cells (WBC) count ≥12,000/µL, lymphocytes ≤ 1000/mm3, platelets < 150,000 /µL, and creatinine >2.0 mg/dL. Stepwise logistic regression analysis was used for predictive statistical model development.

Results. In a cohort of 481 patients with hospital-acquired bacteremia, 350 cases had true bacteremia and 131 cases were contaminated blood cultures. Stepwise regression analysis showed that white blood cell (WBC) count ≥ 12,000 cells/µL, lymphocyte count ≤ 1000/mm^3, creatinine > 2.0 mg/dL, and oral temperature > 38°C (100.4°F) were associated with HABSI (R-square= 0.06, p value= 0.002).

Conclusion. Our findings suggest that WBC count, lymphocyte count, creatinine, and oral temperature together can be used to develop appropriate blood culture stewardship models in the inpatient setting. This may help minimize unnecessary blood cultures.

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642. Facility Reported vs. CLSI MIC Breakpoint Comparison of Carbapenem Non-susceptible (Carb-NS) Enterobacteriaceae (ENT) from 2016-2019: A Multicenter Evaluation

Vikas Gupta, PharmD, BCPS[1]; Kalvin Yu, MD[1]; Jason M Pogue, PharmD, BCPS, BCIDP[2]; Janet Weeks, PhD[1]; Cornelius J. Clancy, MD[3]; [1]Becton, Dickinson and Company, Franklin Lakes, NJ; [2]College of Pharmacy, University of Michigan, Ann Arbor, MI; [3]University of Pittsburgh, Pittsburgh, PA

Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Carbapenem (Carb) minimum inhibitory concentration (MIC) breakpoints were lowered by CLSI in 2010 and recognized by FDA in 2012. Adoption of revised breakpoints is often slow, which may lead to under-reporting of Carb non-susceptibility (NS) by facilities. We compare facility-reported rates of Carb-NS ENT to the CLSI MIC breakpoints for a large nationwide collection of isolates in the United States (US) from 2016-2019.

Ertapenem ENT interpretation (evaluable isolates)			
Interpretation (MIC; µg/mL)	**Facility Reported: n (%)**	**Revised per CLSI: n (%)**	**Underreporting by Facility vs. Revised per CLSI (%)**
I (1)	1,835 (0.2%)	2,420 (0.26%)	24.2%
R (>=2)	4,749 (0.51%)	5,684 (0.61%)	16.4%
S (<=0.5)	931,342 (99.30%)	929,822 (99.13)	
Total	**937,926**	**937,926**	

IPM/MEM/DOR ENT interpretation (evaluable isolates)			
Interpretation (MIC)	**Facility Reported: n (%)**	**Revised per CLSI: n (%)**	**Underreporting by Facility vs. Revised per CLSI (%)**
I (2)	10,338 (0.48%)	15,043 (0.70%)	31.3%
R (>=4)	14,547 (0.67%)	18,815 (0.87%)	22.7%
S (<=1)	2,132,900 (98.85%)	2,123,927 (98.43%)	
Total	**2,157,785**	**2,157,785**	

Methods. All adults with a positive non-contaminant ENT culture (first isolate of a species per 30-day period from blood, respiratory, urine, skin/wound, intra-abdominal, or other) in ambulatory/inpatient settings from up to 300 US hospitals from 2016-2019 were evaluated (BD Insights Research Database). Facility-reported Carb-NS was defined as: susceptible (S), intermediate (I) or R to ertapenem (ETP), imipenem (IPM), meropenem (MEM) and/or doripenem (DOR) per commercial panels. Where available, MICs were interpreted using CLSI 2010 MIC breakpoints (µg/ml): ≤ 0.5 (S), 1 (I), ≥ 2 (R) for ETP and ≤1 (S), 2 (I), and ≥ 4 (R) for IPM/MEM/DOR. For evaluable ENT isolates we compared susceptibility results as reported by the facility to CLSI MIC breakpoints.

Results. Overall, 77.4% (937,926/1,211,845) and 90.6% (2,157,785/2,381,824) non-duplicate ENT isolates with facility-reported susceptibility results also had interpretable MIC results for ETP and IPM/MEM/DOR, respectively (Tables). ETP S rates were 99.3% and 99.1% as reported by facilities and using CLSI criteria, respectively. S rates of other Carbs were 98.9% and 98.4% by facility reporting and CLSI criteria, respectively. Systematic application of CLSI breakpoints under-reported EPT-I and –R isolates by 24.2% and 16.4%, respectively, and identification of IPM/MEM/DOR-I and –R isolates by 31.3% and 22.7%, respectively.

Conclusion. Systematic application of CLSI breakpoints in 2016-19 would have had minimal impact on ENT S rates in the US. However, facility reporting failed to identify 18.8% of ETP I or R and 26.5% of IPM/MEM/DOR I or R isolates. The clinical implications of this observation are unknown. Facilities should know their local epidemiology, decide if under-reporting might be an issue, and assess if there is any impact on their patients.

Disclosures. **Vikas Gupta, PharmD, BCPS**, **Becton, Dickinson and Company** (Employee, Shareholder) **Kalvin Yu, MD**, **BD** (Employee) **Jason M Pogue, PharmD, BCPS, BCIDP**, **Merck** (Consultant)**QPex** (Consultant)**Shionogi** (Consultant)**Utility Therapeutics** (Consultant)**VenatoRX** (Consultant) **Janet Weeks, PhD**, **Becton, Dickinson and Company** (Employee) **Cornelius J. Clancy, MD**, **Merck** (Grant/Research Support)

643. Evaluation of Rapid Blood Pathogen Identification Along with Antimicrobial Stewardship at an Academic Teaching Institution

Sharon Blum, PharmD[1]; Terrence McSweeney, PharmD[2]; Samad Tirmizi, PharmD, BCIDP[3]; brian Auditore, PharmD[4]; Diane Johnson, MD[1]; Brian Malone, RPh[4]; [1]NYU Langone - Long Island, Mineola, NY; [2]Yale New Haven Hospital, New Haven, CT; [3]Yale New Haven Hospital, New Haven, CT; [4]NYU Langone Long Island, Mineola, New York

Session: P-29. Diagnostics: Bacteriology/mycobacteriology

Background. Bloodstream infections are a major cause of morbidity and mortality in hospitalized patients. Prompt initiation of effective antimicrobials are essential to optimize patient outcomes. New diagnostic technologies rapidly identifying bacteria, viruses, fungi, and parasites in infections of various body sites. There is a paucity of literature determining if stewardship programs run by one trained pharmacist with rapid diagnostics decreases time to optimal antimicrobial therapy.

Methods. This was a retrospective chart review of positive bloodstream infections identified via rapid diagnostic technologies. The EHR of admitted adult patients