

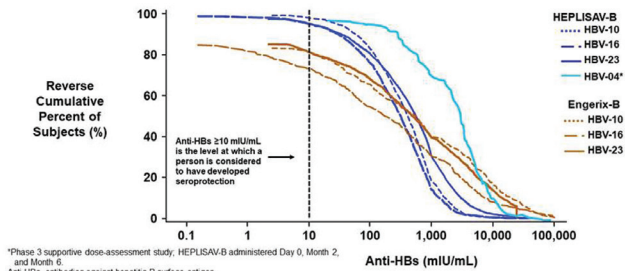
Background. HEPLISAV-B[®] [hepatitis B vaccine (recombinant), adjuvanted] uses a cytidine phospho-guanosine (CpG) oligonucleotide or “1018,” a Toll-like receptor 9 agonist, as an adjuvant. Engerix-B [hepatitis B vaccine (recombinant)], as well as other hepatitis B vaccines, use alum. HEPLISAV-B, a 2-dose vaccine given at Weeks 0 and 4, was recently approved for use in adults ≥18 years for the prevention of hepatitis B. Approval of HEPLISAV-B was based on three pivotal phase 3 noninferiority trials, comparing it with Engerix-B, a 3-dose vaccine given at Day 0, Day 30, and 6 months. Immunogenicity and safety results for these trials, HBV-10, HBV-16 and HBV-23, have been published previously; the safety of HEPLISAV-B was generally similar to Engerix-B.

Methods. The 3 randomized trials were observer-blinded and collectively included subjects aged 18–70 years. Immunogenicity analysis based on antibody against hepatitis B surface antigen (anti-HBs) levels were based on the per-protocol analysis. Presented here are reverse cumulative frequency plots of anti-HBs serum concentrations for the 3 trials.

Results. Across the trials, reverse cumulative frequency plots of anti-HBs concentrations showed a higher proportion (>90%) of HEPLISAV-B subjects developed a seroprotective antibody level (anti-HBs levels ≥10 mIU/mL) compared with Engerix-B subjects (80% to ~90%). A higher proportion of HEPLISAV-B subjects had anti-HBs levels between 10 mIU/mL and 1,000 mIU/mL. While a higher proportion of Engerix-B subjects had anti-HBs levels >1,000 mIU/mL, a significantly higher proportion of Engerix-B subjects did not develop seroprotective antibody levels. The response curves indicate a more consistent immune response with a higher percentage of subjects achieving seroprotection with less variability for HEPLISAV-B compared with Engerix-B, which showed a more variable response and fewer subjects achieving seroprotection.

Conclusion. HEPLISAV-B, using a CpG adjuvant, results in a higher percentage of persons achieving seroprotection and produces a more uniform and consistent induction of protective antibody levels than Engerix-B, an alum-adjuvanted vaccine.

Reverse Cumulative Frequency Plot of Anti-HBs Concentration for HEPLISAV-B Week 24 and Engerix-B Week 28 in HBV-10, HBV-16, and HBV-23 (Per-Protocol Populations)



Disclosures. R. N. Hyer, Dynavax Technologies Corporation: Employee and Shareholder, Salary and Stock options. R. Janssen, Dynavax Technologies Corporation: Employee and Shareholder, Salary and Stock options.

2288. Adherence to Hepatitis B Screening and Treatment Guidelines in Oncology Patients Starting Anti-CD20 Therapy

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Session: 244. Miscellaneous Vaccines
Saturday, October 6, 2018: 12:30 PM

Background. Hepatitis B virus (HBV) reactivation is a common complication in the treatment of oncology patients when using anti-CD20 monoclonal antibodies (MABs) such as rituximab, obinituzumab, and ofatumumab. In such patients, the reaction of HBV is seen in up to 70% who are HBV DNA positive. Antiviral therapy in high-risk patients has been shown to improve outcomes.

Methods. This retrospective review evaluated patients at Thomas Jefferson University Hospital who received rituximab, obinituzumab, or ofatumumab as a component of hematologic malignancy therapy between 2013 and 2016. We determined the number of patients who had appropriate HBV testing prior to therapy, the number who received appropriate antiviral therapy, and the number who developed reactivation of HBV and their outcomes.

Results. 402 patients received one of the above anti-CD20 MABs between November 2013 and December 2016. Of these 402 patients, 52 (13.4%) did not have either HBsAg or HBeAb performed prior to anti-CD20 therapy. 39 (9.7%) patients had positive HBsAg or HBeAb prior to therapy. Of these 39 highrisk patients, only 16/39 (41.3%) were placed on appropriate antiviral therapy. Two of the 39 high-risk patients (5.1%), who were not started on antiviral therapy, developed HBV reactivation as a complication of anti-CD20 MAB therapy.

Conclusion. A significant number of patients were not appropriately screened with HBV markers prior to anti-CD20 therapy for hematologic malignancies at our institution. In addition, less than half of highrisk HBV patients received appropriate

antiviral therapy. System-wide changes are anticipated to improve this process at our institution.

Disclosures. All authors: No reported disclosures.

2289. Accuracy of a Rapid Multiplex PCR Plus a Chromogenic Phenotypic Test Algorithm for the Detection of ESBL and Carbapenemase-Producing Gram Negatives Directly From Blood Cultures

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Session: 245. Molecular & Sequence Based Diagnostics
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Background. We studied the multiplex PCR panel (BioFire Blood Culture ID panel, “BCID”) with phenotypic testing using the Rosco Diagnostic Rapid ESBL Screen kit 98022 (RE) and the Neo-Rapid CARB kit 98024 (RC) for extended-spectrum β-lactamase (ESBL)/carbapenemase producing Gram negative bacilli (CPGNB) detection directly from blood culture bottles, in patients with Gram negative bacteremia.

Methods. The RE and RC kits were evaluated in a verification phase with 98 blood cultures, comprising 43 spiked with GNB: 23 *Escherichia coli*, 9 *Klebsiella pneumoniae*, 7 *Enterobacter cloacae*, 2 *Serratia marcescens*, one *Pseudomonas aeruginosa*, one *Acinetobacter baumannii* complex with varying resistance genotypes (11 CTX-M-15, 5 CTX-M9, one SHV-18, one SHV-3, one TEM-10, 3 IMI, 4 IMP, 4 KPC, 2 NDM, one OXA-23+OXA-51-like, 3 OXA-232, one OXA-48, one SME-1, 2 VIM-1, 2 AmpC from reference and clinical isolate banks, and ATCC 25922), and 54 clinical blood cultures with GNB (5 phenotypic ESBL-positive, one KPC, 48 no known β-lactamase). In a prospective phase, a further 123 clinical blood cultures positive for GNB were tested simultaneously with the BCID, RE and RC kits.

Results. In the verification phase, the RE kit detected 24/25 of ESBL-positive samples (sensitivity 96%, specificity 99%). The RE kit did not detect the 2 AmpC-producers, and was positive for a *K. oxytoca* isolate, which are known to produce chromosomally encoded β-lactamases. The RC kit detected 11/22 of CPGNB (sensitivity 50%, specificity 100%). It missed IMI, OXA-23+OXA-51-like, OXA-232, OXA-48, SME-1 and VIM CPGNB (weak carbapenemases), but detected NDM, KPC, IMP. In the prospective phase, the RE kit detected 20/20 ESBL-positive blood culture samples (sensitivity 100%). The single OXA-48 positive sample was detected by both the RE and RC kits. The 123 blood cultures had a total of 125 panel-represented targets detectable by BCID. The BCID detected 124 /125 (missed one *K. pneumoniae* in a polymicrobial bacteremia), and there were 2 *Proteus* false-positives (sensitivity 99%, specificity 98%). No KPC-positive samples were detected by BCID.

Conclusion. An algorithm comprising the BCID and the RE/RC kits applied to positive blood cultures allows both rapid and accurate pathogen identification and detection of ESBLs and some carbapenemases (e.g., KPC, NDM, IMP). This may allow the institution of timelier, directed therapy.

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2290. Identification of Pathogens in Synovial Fluid Samples With an Automated Multiplexed Molecular Detection System

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