

compared with 31.4% of placebo ($P = 0.29$), while the proportion among non-MV patients was 45.0% vs. 31.0% (difference -14.0%, $P = 0.15$), respectively. Time to CSS in the non-MV stratum was shorter in DAS181-treated patients (figure). Median change in nasopharyngeal PIV viral load by Day 10 and median hospitalization days were -1.44 vs. -0.68 \log_{10} ($P = 0.51$) and 13.5 vs. 21 days ($P = 0.10$) for DAS181 and placebo, respectively. Mean absolute increase from baseline FEV1% predicted was 16.82 for DAS181 vs. 2.02 for placebo ($P = 0.001$). Post-hoc analysis on the probability to return to room air (RTRA) suggested that DAS181 reduced SO need in the non-MV stratum after Day 21 ($P = 0.09$). HCT recipients within 360 days from transplant had a 40.8% treatment effect on RTRA at Day 28 ($P = 0.04$) and 36.7% on mortality at Day 45 when compared with placebo ($P = 0.06$). The rate of adverse events was similar in both treatment groups. Day 45 all-cause mortality was comparable in both groups (32.4% DAS181 vs. 31.4% placebo).

Conclusion. DAS181 was well tolerated and showed a signal for clinical efficacy in IC patients with PIV LRTI. DAS181 was granted Breakthrough Therapy Designation for the treatment of PIV LRTI in IC patients and a phase 3 trial is being planned.

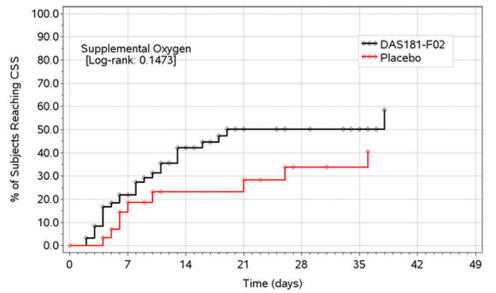


Figure. Time to Clinical Stability Survival Kaplan Meier Plot

Disclosures. R. F. Chemaly, Ansun Biopharma: Consultant and Investigator, Consulting fee and Research grant. R. Moss, Ansun Biopharma: Employee, Salary. F. M. Marty, Ansun Biopharma: Investigator, Research grant. C. R. Wolfe, Ansun Biopharma: Investigator, Research grant. S. J. Lawrence, Ansun Biopharma: Investigator, Research grant. S. Dadwal, Ansun Biopharma: Investigator, Research grant. R. Soave, Ansun Biopharma: Investigator, Research grant. J. Hwang, Ansun Biopharma: Employee, Salary. S. Hawley, Ansun Biopharma: Employee, Salary. R. Routh, Ansun Biopharma: Employee, Salary. J. Ho, Ansun Biopharma: Employee, Salary. G. Wang, Ansun Biopharma: Employee, Salary. N. Chang, Ansun Biopharma: Employee, Salary. M. Boeckh, Ansun Biopharma: Consultant and Investigator, Consulting fee and Research support.

1716. Results of the Respiratory Protection Effectiveness Clinical Trial (ResPECT) Lewis Radonovich, MD¹, Michael S. Simberkoff, MD, FIDSA,² Mary Bessesen, MD², Alexandria C Brown, PhD³, Derek Cummings, PhD⁵, Charlotte Gaydos, DrPH, FIDSA⁶, Jenna Los, MLA⁷, Amanda Krosche, BS⁸, Cynthia Gibert, MD, MSc⁹, Geoffrey Gorse, MD¹⁰, Ann-Christine Nyquist, MD, MSPH, FPIDS¹¹, Nicholas Reich, PhD, Maria Rodriguez-Barradas, MD, FIDSA¹⁴, Connie Price, MD¹⁵ and Trish Perl, MD, MSc, FIDSA, FSHEA¹⁶, ¹National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Pittsburgh, Pennsylvania, ²VA New York Harbor Healthcare System, New York, New York, ³VA Eastern Colorado Healthcare System, Denver, Colorado ⁴University of Massachusetts Amherst, Amherst, Massachusetts, ⁵Department of Biology and Emerging Pathogens Institute, University of Florida, Gainesville, Florida, ⁶Division of Infectious Diseases, Department of Medicine, Johns Hopkins University, Baltimore, Maryland, ⁷Medicine, Johns Hopkins University, Baltimore, Maryland, ⁸College of Medicine, Weill Cornell Medicine, New York, New York, ⁹FIDSA, Washington, DC, VAMC, Washington, DC, ¹⁰FIDSA, VA St. Louis Healthcare System, St. Louis, Missouri, ¹¹University of Colorado School of Medicine/Children's Hospital Colorado, Aurora, Colorado, ¹³Department of Biostatistics and Epidemiology, School of Public Health, University of Massachusetts Amherst, Amherst, Massachusetts, ¹⁴Department of Medicine, Michael E. DeBakey VA Medical Center, Houston, Texas, ¹⁵Infectious Diseases, University of Colorado School of Medicine/ Denver Health and Hospital, Denver, Colorado, and ¹⁶Division of Infectious Diseases Department of Medicine, University of Texas Southwestern Medical Center, Dallas, Texas

Session: 199. Clinical Trials that May Change Your Practice
Saturday, October 6, 2018: 8:45 AM

Results of the Respiratory Protection Effectiveness Clinical Trial (ResPECT)

Background. Respiratory protection (RP) for healthcare personnel (HCP) is controversial and clinical studies are inconclusive about the effectiveness of N95 respirators (N95) and medical masks (MM) for protecting HCP from workplace viral respiratory infections and illnesses (VRII).

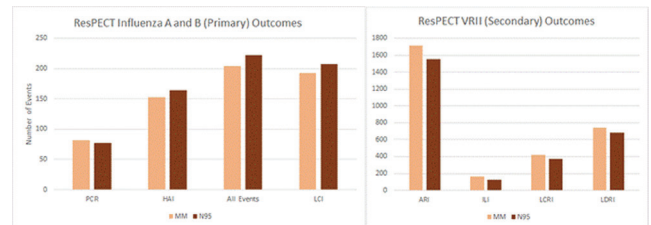
Methods. We conducted a cluster-randomized, investigator-blinded, multisite effectiveness study comparing N95 to MM in geographically diverse, high exposure

outpatient settings between 2011 and 2016. Each year during VRII season, participants were assigned devices when within 6 feet of patients with known or suspected respiratory illness. Respiratory swabs were collected from symptomatic and asymptomatic participants. Diaries detailed VRII exposures, influenza vaccination, adherence to RP and hand hygiene, and manifestations of illness. The primary and secondary outcomes were the incidence of laboratory-confirmed influenza (LCI) using polymerase chain reaction (PCR) and hemagglutinin inhibition assays (HAI), and acute respiratory illness (ARI), influenza-like illness (ILI), laboratory-confirmed respiratory illness (LCRI), and laboratory-detected respiratory infection (LDRI) (figure). Intervention protective effects were estimated using unadjusted odds and incidence rate ratios.

Results. 5,180 HCP seasons enrolled and randomized (2,243 to N95 and 2,446 to MM), with 4,689 (91%) completing the study. In the intention-to-treat cohort (ITT), among participants in the N95 and MM groups, respectively, 207 (8.2%) and 193 (7.2%) were diagnosed with LCI (odds ratio [OR] 1.14, 95% confidence interval [CI] 0.93-1.40); 1,556 (61.9%) and 1711 (64.1%) were diagnosed with ARI (relative risk [RR] 0.99, CI 0.92-1.06); 128 (5.1%) and 166 (6.2%) were diagnosed with ILI (RR 0.87, CI 0.68-1.10), 371 (14.8%) and 417 (15.6%) were diagnosed with LCRI (RR 0.97, CI 0.84-1.12); and 679 (27.0%) and 745 (27.9%) were diagnosed with LDRI (RR 0.99, CI 0.89-1.09). The adjusted ITT and per-protocol analyses yielded similar results.

Conclusion. In this outpatient-based, cluster-randomized, controlled trial, neither N95 nor MM resulted in superior protection from LCI or VRII.

Figure: ResPECT Outcomes. (A) Influenza Incidence and Primary Outcomes Panel. (B) Secondary Outcomes



Disclosures. C. Gaydos, BioFire: Consultant, Consulting fee. Cepheid: Speaker's Bureau, Speaker honorarium. Becton Dickinson: Speaker's Bureau, Speaker honorarium.

1717. The Impact of Routine Molecular Point-of-care Testing for Gastrointestinal Pathogens in Adults Hospitalized With Suspected Gastroenteritis: Results of a Pragmatic Randomized Controlled Trial (GastroPOC)

Ahalya Malachira, MD¹; Kate Beard, MD²; Nathan Brendish, MD² and Tristan Clark, BM MRCP DTM&H MD³, ¹Infection, University Hospital Southampton Foundation NHS Trust, Southampton, UK, ²University of Southampton, Southampton, UK and ³Clinical and Experimental Sciences, University of Southampton, Southampton, UK

Session: 199. Clinical Trials that May Change Your Practice
Saturday, October 6, 2018: 8:45 AM

Background. Adults hospitalised with diarrhoea are routinely isolated as an infection control measure, but many have non-infectious etiology. Side room facilities are a limited resource in hospitals. Routine laboratory testing takes several days to generate results but rapid molecular platforms can test comprehensively for GI pathogens and generate a result in 1 hour, making them deployable as point-of-care tests (POCT). POCT could reduce unnecessary isolation facility use in addition to other benefits.

Methods. In this pragmatic, pilot randomised controlled trial, adults hospitalised with suspected gastroenteritis were recruited and randomised 1:1 to receive either POCT (using the FilmArray GI panel) or routine clinical care. Results of POCT were communicated directly to clinical and infection control teams. The primary outcome was duration of time in a side room and secondary outcomes included turnaround time, proportion of patients with a pathogen detected, proportion of patients correctly de-isolated, time to de-isolation, antibiotic use and length of hospital stay.

Results. 140 patients were recruited. Groups ($n = 70$) were well matched in terms of baseline characteristics. The median [IQR] turnaround time for results was 1.7 [1.6-2.3] hours in the POCT group and 61 [49-84] hours in the control group, $P < 0.0001$. Pathogens were detected in 44% of patients in the POCT group and 23% in the control group; $P = 0.012$. Overall the duration of side room isolation was 1.9 [1.0-2.9] days in the POCT group compared with 2.7 [1.8-5.1] days in the control group; $P = 0.001$. For those testing negative for pathogens this was 1.3 [0.8-2.5] days in the POCT group versus 2.7 [1.8-5.0] days in the control group, $P < 0.0001$. 63% of pathogen-negative patients were correctly de-isolated in the POCT group versus 28% in the control group, $P = 0.0012$. Antibiotic use and length of stay data will be available subsequently.

Conclusion. POCT using the FilmArray GI panel resulted in a substantially reduced turnaround time for results and an increase in the proportion of patients with pathogens correctly detected. POCT was associated with a reduction in the duration of unnecessary side room use. If these benefits are confirmed in further studies and cost effectiveness is demonstrated, molecular POCT for GI pathogens should replace current diagnostic pathways.

Disclosures. T. Clark, BioFire LLC: Collaborator, Research support and Speaker honorarium. NIHR: Grant Investigator, Grant recipient.