honorarium. MSD: Consultant and Speaker's Bureau, Consulting fee and Speaker honorarium. ViiV: Consultant and Speaker's Bureau, Consulting fee and Speaker honorarium. **A. Clarke**, GSK: Scientific Advisor, Consulting fee. Gilead: Conference attendence, Scientific Advisor and Speaker's Bureau, Conference attendance support, Consulting fee and Speaker honorarium. BMS: Conference attendence, Conference attendance support. Janssen: Conference attendence, Conference attendance support. **M. Thompson**, Bristol Myers Squibb: Research Contractor, Research support. ViiV Healthcare: Research Contractor, Research support. **C. Brinson**, Gilead: Investigator, Scientific Advisor and Speaker's Bureau, Research support and Speaker honorarium. Theratech: Investigator, Research support. BMS: Investigator, Research support. SlieaGen: Investigator, Research support. GSK ViiV: Consultant, Investigator and Scientific Advisor, Consulting fee, Research support and Speaker honorarium. Daiichi Sankyo: Sub Investigator, Research support. Novo Nordisk: Investigator, Research support. Sanofi: Investigator, Research support. Watson: Investigator, Research support. Salix: Investigator, Research support. Janssen: Investigator, Research support. Roche: Investigator, Research support. Colucid: Investigator, Research support. Eisai: Investigator, Research support. Shionogi: Investigator, Research support. Elcelyx: Investigator, Research support. Sangamo: Sub Investigator, Research support. **D. Hagins**, GlaxoSmithKline: Scientific Advisor and Speaker's Bureau, Honoraria and Speaker honorarium. ViiV Healthcare: Scientific Advisor and Speaker's Bureau, Honoraria and Speaker honorarium. Gilead: Scientific Advisor, Honoraria and Speaker honorarium. Bristol-Myers Squibb: Scientific Advisor and Speaker's Bureau, Honoraria and Speaker honorarium. **M. Ramgopal**, Gilead: Grant Investigator, Research grant.**A. Antinori**, AbbVie: Consultant, Consulting fee. BMS: Consultant and Grant Investigator, Consulting fee and Research grant. Gilead: Consultant and Grant Investigator, Consulting fee and Research grant. Janssen-Cilag: Consultant and Grant Investigator, Consulting fee and Research grant. Merck: Consultant, Consulting fee. ViiV Healthcare: Consultant and Grant Investigator, Consulting fee and Research grant. **X. Wei**, Gilead: Shareholder, Salary and Stock. **K. White**, Gilead: Employee and Shareholder, Salary and Stock. **S. Collins**, Gilead: Employee and Shareholder, Salary and Stock. **A. Cheng**, Gilead: Employee and Shareholder, Salary and Stock. **E. Quirk**, Gilead: Employee and Shareholder, Salary and Stock. **H. Martin**, Gilead: Employee and Shareholder, Salary and Stock.

LB5. Safety of In Utero Antiretroviral (ARV) Exposure: Neurologic Outcomes in HIV-Exposed, Uninfected Children

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Background. Antiretroviral therapy for pregnant women with HIV has dramatically decreased perinatal transmission of HIV, but concerns remain regarding adverse neurologic outcomes from possible mitochondrial dysfunction or other mechanisms in children exposed in utero to antiretroviral (ARV) medications.

Method. We evaluated HIV-exposed uninfected (HEU) children enrolled in the Surveillance Monitoring for ART Toxicities (SMARTT) study, a longitudinal observational cohort study conducted by the Pediatric HIV/AIDS Cohort Study (PHACS) network. The primary outcome of interest was a "neurologic case" (microcephaly, febrile seizures, seizure disorders, ophthalmologic disorders, other neurologic conditions) as determined by clinical review blinded to ARV exposure. Log-binomial regression analysis was used to obtain adjusted relative risks (aRRs) for associations between in utero ARV exposure and neurologic case status, accounting for potential confounders including Hispanic ethnicity, tobacco use during pregnancy, and birth cohort (2011–2014 and 2015–2017 vs. <2011). To account for variable person-time follow-up within the cohort, Poisson regression models for adjusted incidence rate ratios (aIRRs) were also fitted.

Result. Among 3,747 eligible HEU children enrolled in SMARTT (52% male, 68% Black and 31% Hispanic), 237 were diagnosed with neurologic conditions, yielding an event rate of 6.3% (95% CI: 5.6%, 7.2%). Tobacco and alcohol use during pregnancy were common (17% and 8%, respectively). The majority of children had in utero ARV exposure (87%); 60% to PI-based regimens, 16% to NNRTI-based regimens and 7% to PI + NNRTI-based regimens. In adjusted models, there was a trend towards an association between efavirenz exposure (EFV) and neurologic case status (aRR: 1.60, 95% CI: 0.99, 2.58). This association was statistically significant in sensitivity analyses restricted to children enrolled prior to or shortly after birth (aRR: 1.80, 95% CI: 1.06, 3.05), excluding children with confirmed congenital anomalies (aRR: 1.66, 95% CI: 1.02, 2.64), and accounting for person-time follow-up (aIRR: 1.55, 95% CI: 1.00, 2.76).

Conclusion. EFV exposure during pregnancy was associated with a higher risk of neurologic abnormalities in infancy and childhood.

Disclosures. **R. Van Dyke**, Giliad Sciences: Grant Investigator, Research grant. **E. G. Chadwick**, Abbott Labs: Shareholder, stock dividends. AbbVie: Shareholder, stock dividends.

LB6. Oral Lefamulin Is Safe and Effective in the Treatment of Adults With Community-Acquired Bacterial Pneumonia (CABP): Results of Lefamulin Evaluation Against Pneumonia (LEAP 2) Study

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Background. Lefamulin, a first in class pleuromutilin, is being developed as an IV and oral formulation for treating CABP. The second of 2 phase 3 Lefamulin Evaluation Against Pneumonia studies, LEAP 2 (NCT02813694; EudraCT 2015-004782-92) evaluating an oral 5-day regimen, is presented here. LEAP 2 complements the positive results from LEAP 1, an IV-to-oral switch study in patients with PORT Risk Class III-V.

Methods. In this multicenter, randomized, double-blind, double dummy study, patients with CABP were randomized to oral lefamulin 600 mg q12h for 5 days or moxifloxacin 400 mg q24h for 7 days. Adults with PORT Risk Class II–IV were eligible (≥50% were to have PORT Risk Class III or IV). The US FDA primary endpoint was early clinical response (ECR) (96 ± 24 h after first dose) in the intent-to-treat (ITT) population. The EMA coprimary endpoints (FDA secondary endpoints) were investigator assessment of clinical response (IACR) at test of cure (TOC) (5–10 days after last dose) in the modified ITT (mITT) and clinically evaluable (CE) TOC populations. For FDA and EMA endpoints, noninferiority was concluded if the lower limit of the two-sided 95% CI was greater than −10% (Figure 1).

Results. A total of 738 patients were randomized (n = 370 lefamulin, n = 368 moxifloxacin). Five days of lefamulin was noninferior to 7 days of moxifloxacin for both FDA and EMA primary endpoints (Figure 2). Lefamulin was efficacious regardless of PORT Risk Class (ECR responder rates for PORT II, III, and IV: 91.8% [168/183], 91.0% [132/145], and 85.0% [34/40] for lefamulin; 93.1% [176/189], 90.2% [120/133], and 85.7% [36/42] for moxifloxacin, respectively). Both agents demonstrated similar ECR responder and IACR success rates across baseline CABP pathogens. Rates of serious adverse events (AEs) and AEs leading to discontinuation were low and similar between groups. Most frequently reported AEs were gastrointestinal, the majority of mild severity with few discontinuations.

Conclusion. Five-day oral lefamulin demonstrated noninferiority for both FDA and EMA efficacy endpoints vs. 7-day oral moxifloxacin. Both agents were safe and generally well tolerated. Lefamulin shows promise as an oral monotherapy with a complete spectrum of antibacterial activity against CABP pathogens.

Figure 1. LEAP 2 Phase 3 Trial Design, Oral Administration

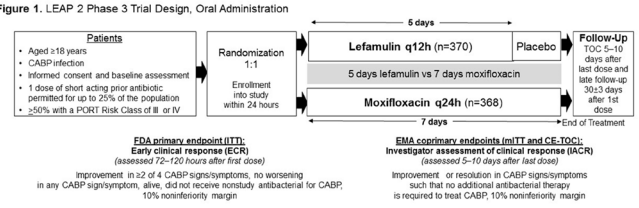
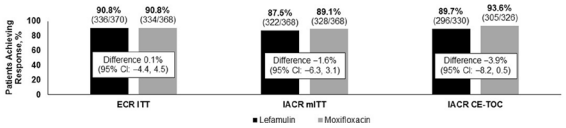


Figure 2. FDA (ECR) and EMA (IACR) Primary Endpoints



Disclosures. **E. Alexander**, Nabriva: Employee and Shareholder, Salary and Stock Options. **L. Goldberg**, Nabriva: Employee, Employee Stock Options and Salary. **A. Das**, Achaogen: Consultant, Consulting fee. Cempra: Consultant, Consulting fee. Contrafect: Consultant, Consulting fee. Paratek: Consultant, Consulting fee. Tetraphase: Consultant, Consulting fee. Wockhardt: Consultant, Consulting fee. Theravance: Consultant, Consulting fee. Zavante: Consultant, Consulting fee. Utility: Consultant, Consulting fee. Former Employee of Nabriva: Employee, Salary. Nabriva: Consultant, Consulting fee. **G. J. Moran**, Nabriva: Scientific Advisor, Consulting fee. **C. Sandrock**, Nabriva: Consultant, Consulting fee. **L. B. Gasink**, Former Employee of Nabriva: Employee, Salary. **P. Spera**, Nabriva: Employee and Shareholder, Salary. **C. Sweeney**, Nabriva: Employee, Employee Stock Options and Salary. **S. Paukner**, Nabriva: Employee and Shareholder, Salary. **W. W. Wicha**, Nabriva: Employee and Shareholder, Salary. **J. Schranz**, Nabriva: Employee and Shareholder, Salary.

LB7. Contract Tracing Investigation Following First Case of Andes Virus in the United States

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Background. In January 2018, a patient admitted to a Delaware hospital tested positive for New World hantavirus by IgM and IgG ELISA. Subsequent testing by CDC's Viral Special Pathogens Branch (VSPB) confirmed Andes virus (ANDV) by reverse transcription polymerase chain reaction (RT-PCR) and sequencing. ANDV is transmitted to humans through contact with long-tailed rice rats endemic to Argentina and Chile. Unlike other hantavirus species, ANDV can be transmitted person to person, but transmission is typically limited to close contacts of ill persons. Because of this risk, a contact tracing investigation was initiated by CDC, state and county health departments.

Method. A suspect case was defined as a person with close contact with the traveler who became ill within the maximum incubation period (42 days) following last contact. A high-risk contact was defined as a person with exposure to the traveler's body fluids. A low-risk contact was defined as a person who had provided care or in-flight service to, or was seated near the traveler for at least 1 hour, in the absence of exposure to body fluids. All contacts were advised to self-monitor their temperature daily for 42 days from last contact, and to seek medical care for any of the specified symptoms. Contacts that developed symptoms were tested for ANDV by RT-PCR and serology by VSPB.

Result. Fifty-three contacts were identified in six states; 51 were successfully reached. Of these, 28 were healthcare workers, 15 were airline contacts, seven were acquaintances of the traveler, and one was a hospital roommate. Two high-risk contacts were identified, both of whom remained asymptomatic. Six low-risk contacts reported influenza-like illness, diarrhea, or mild rhinitis during the incubation period. All six symptomatic low-risk contacts tested negative for ANDV by PCR, IgM, and IgG. The remaining low-risk contacts remained asymptomatic.

Conclusion. Hospitalized patients with ANDV should be managed with standard, contact, and droplet precautions. While the risk of human-to-human transmission is low, contact tracing should be considered to identify potential cases and limit additional exposures. Health providers should consider ANDV in returning travelers with a nonspecific febrile or acute respiratory illness who have traveled to the Andes region of Argentina or Chile in the preceding 6 weeks.

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

LB8. Outbreak of Enterovirus A71 Neurologic Disease in Children—Colorado, 2018

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Background. In May 2018, an outbreak of enterovirus A71 (EV-A71) neurologic disease was detected at Children's Hospital Colorado (CHCO) prompting a public health investigation. We characterized clinical, laboratory, and radiologic findings during this outbreak.

Methods. A case was defined as meningitis, encephalitis, or acute flaccid myelitis with EV-A71 identified from a biologic specimen in a child examined at CHCO after March 1, 2018. Biologic specimens from children with neurologic disease and EV identified by clinical reverse-transcription polymerase chain reaction (RT-PCR) were typed by VP1 sequencing at CDC.

Results. As of July 20, 2018, 28 cases of EV-A71 neurologic disease were identified. This report describes the clinical, laboratory, and radiologic findings for the first 13 children identified with EV-A71 neurologic disease, for whom complete information is available. The median age was 13 months (range = 10 days–35 months) and 11 (85%) were male. Neurologic presentations included 12 (92%) with meningitis, 9 (69%) with encephalitis, and 3 (23%) with acute flaccid myelitis (AFM). All 13 children had fever and irritability; 3 (23%) had hand, foot, and mouth disease. Neurologic signs included encephalopathy (n = 7, 54%), ataxia (n = 7, 54%), myoclonus (n = 6, 46%), limb weakness (n = 4, 31%), cranial nerve deficits (n = 2, 15%), and seizures (n = 1, 8%). Nine (90%) of 10 children with cerebrospinal fluid (CSF) specimen analyzed had a pleocytosis (>5 white blood cells/uL); 6 of 8 (75%) children who had brain imaging showed abnormalities, with 5 (63%) in the brainstem, 3 (38%) in the cerebellum, and 3 (38%) in the spinal cord. All 13 children had EV-A71 identified in nasopharyngeal, pharyngeal, or fecal specimens; only 2 of 11 (18%) tested had EV identified in CSF. All 13 children were hospitalized and 4 (31%) required intensive care. The 3 (23%) children with AFM had residual limb weakness at time of discharge. All children survived.

Conclusion. EV-A71 should be considered when children present with myoclonus, ataxia, or limb weakness in the setting of a febrile illness. Testing of nonsterile sites (respiratory, pharyngeal, or fecal) should be considered when CNS disease associated with EV is suspected and initial CSF testing is negative.

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LB9. Rising High Rate of Invasive Group A *Streptococcus* Infections Among Persons Experiencing Homelessness in San Francisco, 2010–2017

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Background. Rates of invasive group A *Streptococcus* (iGAS) disease in the United States have risen since 2014; reasons remain unclear. Outbreaks of iGAS infection among persons experiencing homelessness (PEH) and persons who inject drugs in Europe, Canada, and the United States have been described. Using active, population-based surveillance data from California's Emerging Infections Program, we describe incidence trends and characteristics of iGAS infection among PEH and persons not experiencing homelessness (PNEH) in San Francisco (SF) County during 2010–2017.

Methods. We defined an iGAS case as infection with GAS isolated from a normally sterile site (e.g., blood) in an SF resident. We calculated annual iGAS disease incidence rates (cases per 100,000 population) for PEH and PNEH using denominators from SF's Department of Homelessness and Supportive Housing and the State of California Department of Finance. Demographic, clinical, and exposure characteristics of PEH and PNEH were compared by chi-square or t-test.

Results. We identified 673 iGAS cases in SF during 2010–2017. Among these, 34% (229/673) were among PEH. Annual iGAS incidence among PEH rose from ~300 (2010–2014) to 547 (95% CI: 379–714) per 100,000 in 2017 (P < 0.001, Cochran-Armitage trend test); rates peaked at 758 (95% CI: 561–955) in 2016. Annual iGAS incidence in PNEH rose from a mean of 5 in 2010–2013 to 9.3 (95% CI: 7.3–11.4) per 100,000 in 2017 (P < 0.001). Annual iGAS incidence in PEH was 42–72 times that in PNEH. PEH with iGAS infections were significantly younger and more likely to be male, white, and uninsured or enrolled in Medicaid (P < 0.05 for each) compared with PNEH with iGAS disease. Case fatality ratios, ICU admission, infection type, and length of hospital stay did not differ significantly. Smoking, current injection drug use, current alcohol abuse, and AIDS diagnosis were significantly more common among PEH with iGAS. Obesity, diabetes, and cancer were significantly more common among PNEH with iGAS.

Conclusion. In San Francisco, iGAS rates among both PEH and PNEH have risen significantly. Incidence of iGAS is strikingly higher in PEH than in PNEH and exposures differed between PEH and PNEH with iGAS. This information could inform development of disease control and prevention strategies.

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LB10. Changing Epidemiology of Hepatitis A Virus Infections–– United States, 2007–2017

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Background. Hepatitis A virus (HAV) is primarily spread fecal-orally and causes acute illness including fever, jaundice, and diarrhea. After introduction and widespread use of the hepatitis A vaccine in the United States, infection with HAV decreased and outbreaks typically associated with a common-source were uncommon.

Method. CDC receives reports of hepatitis A infections from states through the National Notifiable Disease Surveillance System (NNDSS) and/or directly to the viral hepatitis outbreak response team. We analyzed NNDSS hepatitis A data for 2007–2016, and a combination of NNDSS data and cases directly reported to the CDC hepatitis A outbreak response team during 2017; excluding 2017 NNDSS data from the four states that directly reported outbreaks to the outbreak response team to eliminate the potential for double-counting cases.

Result. During 2007–2011, a total of 10,619 hepatitis A cases were reported; 521 (5%) were associated with outbreaks. Of the 274 outbreak-associated cases for whom clinical data were reported, 102 (37%) were hospitalized and one (0.3%) died. Of the 407 outbreak-associated cases for whom risk exposure data were reported, 210 (52%) were associated with a common source. Comparatively, during 2012–2017, a total of 11,483 hepatitis A cases were reported; 2,323 (20%) were associated with outbreaks. Of the outbreak-associated cases for whom clinical data were reported, 1,306/2,162 (60%) were hospitalized and 43/2,178 (2%) died. Of the outbreak-associated cases for whom risk exposure data were reported, 379/2,188 (17%) were associated with a common source.

Conclusion. In the United States, outbreaks of hepatitis A infections in the decade prior to 2017 were infrequent and typically associated with a common source. Reported cases associated with hepatitis A outbreaks are increasing, along with concurrent increases in hospitalizations and deaths among persons with outbreak-associated infections. Recent outbreaks indicate a decrease in cases associated with a common-source exposure. Decreasing the susceptible population through adherence