

was 4.0% (296/7404) while the prevalence of LC HIV infection was 3.6% (129/3559). Among PEH with LC HIV results, gender (male, transgender), year of screening (2008–2010, 2011–2013) and location of screening (onsite) were independently associated with higher HIV prevalence ($p < 0.05$). Adjusted analysis showed statistically significant interaction between gender and age [Adjusted prevalence ratio for men vs. women: young PEH (0–29 years) 8.47 (5.13, 14.00), $p < 0.0001$]. Year of screening and shelter of residence also remained significant in the adjusted model.

Conclusion: The prevalence of HIV among PEH in Atlanta is more than four times higher than the prevalence in the general Atlanta population (0.86%). In addition to essential TB control measures needed in congregate settings like homeless shelters, strong efforts to concurrently increase access to HIV prevention and care at homeless shelters may also help reduce both HIV transmission and TB acquisition in this at-risk population in the South and move the South closer to achieving the US End TB and Ending the HIV Epidemic goals.

Disclosures: All Authors: No reported disclosures

115. Opioid Continuum of Care for Persons Living with HIV: The First 8 Months
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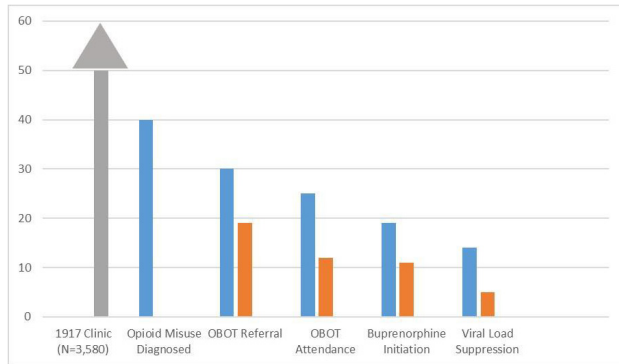
Session: O-22. HIV in Special Populations

Background: Approximately 15% of persons with HIV (PWH) have opioid use disorder (OUD) over their lifetime. Due to substance use-related behaviors, untreated OUD is an obstacle to ending the HIV epidemic, especially in rural states with limited treatment options. In November, 2019, The UAB 1917 HIV Clinic opened an outpatient based opioid treatment (OBOT) clinic one half day a week. The objective of this study is to evaluate clinical outcomes and utilization over 8 months. We hypothesized that approximately 200 PWD would have OUD, many with comorbid stimulant use, and that new referrals would increase over time.

Methods: This is a retrospective study PWH at the 1917 clinic from OBOT start until June 2020. Opioid misuse was identified by patient reported illicit use using validated tools and/or ICD9 code in the last 12 months. We stratified PWH to determine the OUD continuum of care for all versus those with comorbid stimulant disorder: OBOT referral, attendance, buprenorphine initiation, and HIV suppression (viral load < 20). We explored changes in clinic utilization following COVID19.

Results: A total of 3,580 patients receive care in the UAB 1917 HIV clinic of whom 40 were identified as having opioid misuse (Fig 1, blue). Overall, 30 patients were referred to OBOT, 25 attended any OBOT visit, 19 were initiated on buprenorphine and 14 (74%) had a VL < 20 in the last 3 months. Over half of patients had comorbid stimulant use disorder (orange). Patients received an average of 3.7 visits (range 1–10) over the study period. Although the number of new referrals did not increase (average 3.8 per month), the overall number of OBOT appointments increased from an average of 12 per month before COVID to 26 per month after March 1.

Figure 1. The Opioid Continuum of Care for PWH at the UAB Outpatient Opioid Treatment Clinic (blue) including those with comorbid Stimulant Use Disorder (orange)



Conclusion: A surprisingly low percentage of patients report opioid misuse, which likely underestimates the true OUD burden in the Deep South. Stimulant Use Disorder affects over half: an added barrier to HIV suppression. In this small and early assessment, there are multiple missed opportunities for progress along the OUD continuum starting with diagnosis and referral. Yet, even this small clinic has rapidly reached clinical capacity (1/2 day weekly) accelerated by psychosocial needs in the context of COVID19.

Disclosures: All Authors: No reported disclosures

116. Antiviral Activity and Safety of Long-acting Cabotegravir (CAB LA) Plus Long-acting Rilpivirine (RPV LA), Administered Every 2 Months (Q2M), in HIV-positive Subjects: Results from the POLAR Study

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Session: O-23. Hot Clinical Trials

Background: Long-acting (LA) cabotegravir (CAB) and rilpivirine (RPV) injectable suspensions have demonstrated efficacy in phase III studies. POLAR assessed antiviral activity and safety of CAB LA+RPV LA, administered every 2 mos (Q2M), in HIV-1 infected, antiretroviral therapy-experienced adults who completed LATTE and received once-daily oral CAB30mg+RPV25mg treatment.

Methods: POLAR is a phase IIb, multicenter, open-label, rollover study in 97 virologically suppressed, HIV-infected adults. LATTE participants who completed ≥312 weeks on study, with plasma HIV-1 RNA < 50c/mL at screening, were eligible for POLAR and offered the option to switch to CAB LA+RPV LA Q2M or to the oral fixed dose combination of dolutegravir (DTG)/rilpivirine (RPV) once daily, for continued maintenance of HIV-1 RNA suppression. 90 participants chose CAB LA+RPV LA and 7 participants chose oral DTG/RPV. The primary outcome measure was proportion of participants with plasma HIV-1 RNA ≥ 50c/mL after 12 mos (M12) of therapy. Safety and laboratory measures were assessed throughout the study. Participants selecting LA treatment completed satisfaction and quality-of-life questionnaires at Day 1, M6, and M12.

Results: At M12, no participant had HIV-1 RNA ≥ 50c/mL or protocol defined virologic failure (confirmed plasma HIV-1 RNA > 200c/mL). Excluding injection-site reactions (ISRs), nasopharyngitis (11%), upper respiratory tract infection (11%), diarrhea (10%), and pyrexia (10%) were the most commonly reported adverse events (AEs) in the Q2M arm. 10% (9/90) of Q2M participants reported AEs ≥ grade 3; 0 were drug related. 2% (2/90) of Q2M participants had AEs leading to withdrawal. 6% (5/90) of participants reported serious AEs (1 considered drug-related). Over 12 mo, 1534 injections were administered; 463 ISRs were reported (30%; all grade 1/2 [84%/16%]); resolution of ISRs occurred after a median of 3 days. Minimal changes in lab parameters were observed in participants across 12 mo. 88% of participants who received LA therapy preferred CAB LA+RPV LA vs oral therapy.

Table 1

Month 12 Snapshot Study Outcomes	Q2M (N=90) n (%)	DTG + RPV (N=7) n (%)
HIV-1 RNA <50 c/mL	88 (97.8)	7 (100.0)
HIV-1 RNA ≥50 c/mL	0	0
Data in window not below threshold	0	0
Discontinued for lack of efficacy	0	0
Discontinued for other reason while not below threshold	0	0
Change in background therapy	0	0
No virologic data	2 (2.2)	0
Discontinued study due to AE or death ^a	1 (1.1)	0
Discontinued study for other reasons ^b	1 (1.1)	0

a. Drug-related AE of depression
b. lost to follow-up.

Table 2

Overall Summary of Adverse Events	Q2M (N=90) n (%)	DTG + RPV (N=7) n (%)
Any AE	86 (96)	3 (43)
Any Drug-related AEs	65 (72)	1 (14)
Any Grade 3-5 AEs	9 (10)	0
Drug-related Grade 3/4 AEs	0	0
Adverse Events Leading to Withdrawal/Permanent Discontinuation of Study Treatment ^a	1 (1)	0
Drug-related AEs leading to Withdrawal/Permanent Discontinuation of Study Treatment ^a	1 (1)	0
Any SAE	5 (6)	0
Drug-related SAEs ^b	1 (1)	0
Fatal SAEs	0	0
Drug-related fatal SAEs	0	0

Note: AEs in this table include ISRs.
a. Drug-related AE of depression.
b. Drug related SAE of injection site extravasation.

Conclusion: CAB LA+RPV LA, administered Q2M, resulted in durable virologic suppression, an acceptable tolerability profile, and high levels of participant satisfaction over the first 12 mo of treatment in POLAR.

Disclosures: Anthony Mills, MD, Gilead (Grant/Research Support, Advisor or Review Panel member) Janssen Pharmaceutica (Grant/Research Support, Advisor or Review Panel member) Merck (Grant/Research Support, Advisor or Review Panel member) Shionogi (Grant/Research Support) ViiV Healthcare (Grant/Research Support, Advisor or Review Panel member) Gary J. Richmond, MD, FACP, FCCP, Gilead (Scientific Research Study Investigator) TaiMed (Scientific Research Study Investigator) Viv (Scientific Research Study Investigator) Cheryl Newman, MD, Gilead (Grant/Research Support) GlaxoSmithKline (Grant/Research Support, Speaker's Bureau) ViiV Healthcare (Research Grant or Support, Speaker's Bureau) Olayemi Osiyemi, M.D., GlaxoSmithKline (Advisor or Review Panel member, Speaker's Bureau) ViiV Healthcare (Advisor or Review Panel member, Speaker's Bureau) Jerry

Cade, MD, Gilead (Consultant, Research Grant or Support, Speaker's Bureau) Janssen Pharmaceutica (Consultant) Merck (Consultant, Research Grant or Support, Speaker's Bureau) ViiV Healthcare (Consultant, Research Grant or Support) Cynthia Brinson, MD, Gilead (Advisor or Review Panel member, Speaker's Bureau) ViiV Healthcare (Advisor or Review Panel member, Speaker's Bureau) Nisha Andany, MD, MPH, FRCP, Gilead Sciences (Scientific Research Study Investigator) GlaxoSmithKline (Scientific Research Study Investigator) Janssen (Scientific Research Study Investigator) David Margolis, MD, MPH, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Kenneth Sutton, MA, GlaxoSmithKline (Shareholder) ViiV Healthcare (Employee) Viviana Wilches, HBS, MBIotech, GlaxoSmithKline (Employee, Shareholder) Jeremy Roberts, MSc, GSK (Employee) Cynthia C. McCoig, MD, ViiV Healthcare (Employee) Kati Vandermeulen, MSc, Janssen Pharmaceutica (Employee, Shareholder) William Spren, PharmD, ViiV Healthcare (Employee, Shareholder)

117. Adjunctive Daptomycin in the Treatment of staphylococcus Aureus Bacteremia

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Session: O-23. Hot Clinical Trials

Background: Bloodstream infections (BSI) caused by methicillin-susceptible *Staphylococcus aureus* (MSSA) are associated with significant morbidity and mortality. The objective of our study was to determine whether daptomycin given in combination with an anti-staphylococcal beta-lactam improved outcomes in MSSA BSI.

Methods: A randomized, double blind, placebo-controlled trial was performed at two academic hospitals in Montreal, Canada. Patients ≥ 18 years of age with MSSA BSI receiving either cefazolin or cloxacillin monotherapy were considered for inclusion. In addition to the standard of care treatment, participants received a 5-day course of adjunctive daptomycin or placebo. The primary outcome was the duration of MSSA BSI in days.

Results: Of 318 participants screened, 115 were enrolled and 104 were included in the intention to treat analysis (median age 67 years; 34.5% female). The median duration of bacteremia was 2.04 days among patients who received daptomycin versus 1.65 days in those who received placebo (absolute difference 0.39 days, $p=0.40$). A modified intention to treat analysis involving participants who remained bacteremic at the time of enrollment found a median duration of bacteremia of 3.06 days among patients who received daptomycin versus 3.0 days in those who received placebo (absolute difference 0.06 days, $p=0.77$). Ninety-day mortality in the daptomycin arm was 18.9% vs. 17.7% in the placebo arm ($p=1.0$). There were no significant differences in the proportion of patients who developed renal failure, hepatotoxicity, or rhabdomyolysis between groups.

Conclusion: Among patients with MSSA BSI, the administration of adjunctive daptomycin therapy to standard of care treatment did not shorten the duration of bacteremia.

Disclosures: All Authors: No reported disclosures

118. Eliminating Blood Culture Contamination with an Initial-specimen Diversion Device

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Session: O-23. Hot Clinical Trials

Background: Blood samples obtained via traditional venipuncture can become contaminated by superficial and deeply embedded skin flora. We evaluated the hospital-wide use of an initial-specimen diversion device (ISDD) designed to shunt these microorganisms away from the culture bottle to reduce blood culture contamination (BCC) and sequelae: false-positive central line-associated bloodstream infections (CLABSIs), repeat blood culture draws, inappropriate antibiotic usage, increased patient length-of-stay and misdiagnosis. The study aimed to show the proportion of blood cultures containing contaminants drawn by phlebotomy staff using the ISDD versus those drawn using traditional methods. Nursing staff continued to use traditional methods to draw blood cultures in the emergency department (ED) and from inpatients.

Methods: Over a four-month trial at Stanford Health Care (SHC), 4,462 blood cultures were drawn by phlebotomy staff using the ISDD (Steripath Gen2, Magnolia Medical Technologies) in the ED and from inpatients; 922 blood cultures were obtained by phlebotomy staff using standard methods. Additionally, 1,413 blood cultures were drawn by nursing staff using standard methods. The number of matched sets (2 bottles [aerobic/anaerobic] plus 2 bottles [aerobic/anaerobic], with total volume 40 ml) obtained through traditional methods and by the ISDD were recorded. Contaminants

were defined by the National Healthcare Safety Network (NHSN). In addition, sets in which 1 out of 4 bottles contained vancomycin-resistant *Enterococcus* (VRE) or *Candida* sp. were also recorded, even though these are not considered contaminants by the NHSN.

Results: Of 4,462 blood cultures obtained using the ISDD there were zero contaminants found (BCC rate 0%) versus 29 contaminated sets using traditional methods (BCC rate 3.15%). Twenty-eight contaminants were observed from nursing staff blood culture draws (BCC rate 1.98%). Zero false-positive CLABSIs were associated with use of the ISDD for the trial period. No matched sets containing 1 of 4 bottles with VRE or *Candida* sp. were observed.

Table: Stanford Health Care blood culture collection methods and contamination events (March 15, 2019 - July 21, 2019)

	Matched Sets	Contaminated Sets	Contamination Rate	False-Positive CLABSIs
Standard Method (Nursing Staff)	1,413	28	1.98%	0
Standard Method (Phlebotomy)	922	29	3.15%	1
Standard Method (Combined)	2,335	57	2.44%	1
ISDD (Phlebotomy)	4,462	0	0.00%	0

Conclusion: The trial results encourage adoption of the ISDD as standard practice for blood culture at SHC.

Disclosures: All Authors: No reported disclosures

119. A Respiratory Syncytial Virus Prefusion F Protein (RSVPref3) Candidate Vaccine Administered in Older Adults in a Phase I/II Randomized Clinical Trial Is Well Tolerated

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Session: O-23. Hot Clinical Trials

Background: RSV is a common cause of respiratory acute illness in older adults (OA). We evaluated safety and reactogenicity of RSVPref3 candidate vaccine in young adults (YA) and OA.

Methods: In this phase I/II, placebo-controlled, multi-country trial (NCT03814590), YA aged 18–40 years were randomized 1:1:1:1 and received 2 doses of Low-, Medium- or High-dose of RSVPref3 non-adjuncted vaccine, or placebo, 2 months apart. Following favorable safety evaluation, a staggered enrolment with 2 steps followed in OA aged 60–80 years, who were randomized 1:1:1:1:1:1:1:1 to receive 1 of the 9 RSV vaccine formulations containing Low-, Medium- or High-dose of RSVPref3 non-adjuncted or adjuncted with AS01_A or AS01_B, or placebo (same schedule). Safety/reactogenicity up to 1 month post-dose 1 are reported here.

Results: Exposed set was comprised of 48 YA and 1005 OA. Within 7 days post-dose 1, any solicited/unsolicited adverse event (AE) ranged from 58.3% to 83.3% across YA vaccinees (placebo YA: 58.3%) and from 29.9% to 84.2% across OA vaccinees (placebo OA: 33.7%) (Fig 1). Pain was the most common solicited local AE, being reported in $\leq 58.3\%$ of YA (placebo YA: 0.0%) and at higher rates in the adjuncted groups ($\leq 75.7\%$) vs non-adjuncted groups of OA ($\leq 14.1\%$) and placebo OA (4.1%) (Fig 2A). Of solicited general AEs, fatigue (YA: $\leq 41.7\%$ in vaccinees vs 50.0% in placebo; OA: $\leq 48.5\%$ in vaccinees vs 16.3% in placebo) and headache (YA: $\leq 33.3\%$ in vaccinees vs 16.7% in placebo; OA: $\leq 27.7\%$ in vaccinees vs 8.2% in placebo) were most commonly reported (Fig 2B), while fever $\geq 38.0^\circ\text{C}$ was observed in $\leq 3.0\%$ of OA vaccinees (placebo OA: 0.0%). Grade 3 solicited local and general AEs were observed in OA only, with erythema ($\leq 4.9\%$ in vaccinees vs 0.0% in placebo) and fatigue ($\leq 2.0\%$ in vaccinees vs 1.0% in placebo) being most common (Fig 2). No serious AEs (SAEs) were reported in YA. A number of 11 OA reported a SAE within 1 month post-dose 1, but none was fatal or assessed as vaccine-related. No clinically significant abnormalities occurred in hematological/biochemical parameters in any group.

Figure 1. Percentage of participants presenting at least one type of solicited/unsolicited adverse event (AE) within 7 days post-dose 1

