healthcare facilities that are receiving contributed product; **R. Platt**, Clorox: Receipt of contributed product, Conducting clinical studies in which participating healthcare facilities are receiving contributed product; receive research funds from Clorox, but Clorox has no role in the design; Molnlycke: Receipt of contributed product, Conducting studies in healthcare facilities that are receiving contributed product; Sage Products: Receipt of contributed product, Conducting studies in healthcare facilities that are receiving contributed product; Xttrium: Receipt of contributed product, Conducting studies in healthcare facilities that are receiving contributed product

1001. A Single Dose Monoclonal Antibody (mAb) Immunoprophylaxis Strategy to Prevent RSV Disease in All Infants: Results of the First in Infant Study with MEDI8897

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Background. RSV is the most common cause of lower respiratory tract infection (LRTI) among infants making prevention of RSV disease a public health priority. A significant unmet need exists for RSV prevention in healthy infants. Our goal is to develop a mAb with an extended half-life ($t_{½}$) capable of protecting infants for an entire RSV season by using a single intramuscular (IM) dose. This study was conducted to evaluate the safety profile, pharmacokinetics (PK), RSV neutralizing antibody titers, and anti-drug antibody (ADA) responses for MEDI8897 in healthy preterm infants born between 32 and 35 weeks gestational age.

Methods. Infants were randomized 4:1 to receive a single IM injection of MEDI8897 10 mg (n = 8), 25 mg (n = 31), 50 mg (n = 32) or placebo (n = 18) and followed for 360 days. Enrollment occurred during the 2,015 RSV seasons in the US, South Africa, and Chile. Blood was collected at multiple timepoints. Infants who met criteria for a medically-attended (MA) LRTI had nasal swabs obtained for RSV testing by RT-PCR.

Results. A total of 85/89 (95.5%) infants completed the study. Adverse events (AEs) were reported in 17/18 (94.4%) placebo and 66/71 (93.0%) MEDI8897 recipients. Five serious AEs (three LRTIs, two febrile seizures) were reported in three MEDI8897 recipients. No events were consistent with hypersensitivity reactions. The estimated MEDI8897 serum $t_{½}$ ranged from 62.5 to 72.9 days. On day 151, 87% of the infants who received the 50 mg dose of MEDI8897 had serum concentrations above the target EC_{90} level of 6.8 µg/ml, and 93.3% showed a ≥3-fold rise from baseline in serum anti-RSV neutralizing antibody titers. ADA was detected in 28.2% of MEDI8897 recipients, but when present was not associated with any safety findings. ADA was detected at day 361 only in 26.5% of subjects. MA-LRTI was reported in 5 (7%) MEDI8897 recipients through 150 days after dosing. The one subject with an MA-LRTI caused by RSV had received a 10 mg dose of MEDI8897.

Conclusion. In healthy preterm infants, the safety profile of MEDI8897 was favorable. The extended $t_{½}$ of MEDI8897 with the corresponding increase in RSV neutralizing antibody levels was confirmed and supports protection from RSV disease during a typical 5-month season with a single 50 mg IM dose.

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1002. Respiratory Syncytial Virus bronchiolitis: Impact of second-hand smoke exposure on immune profiles

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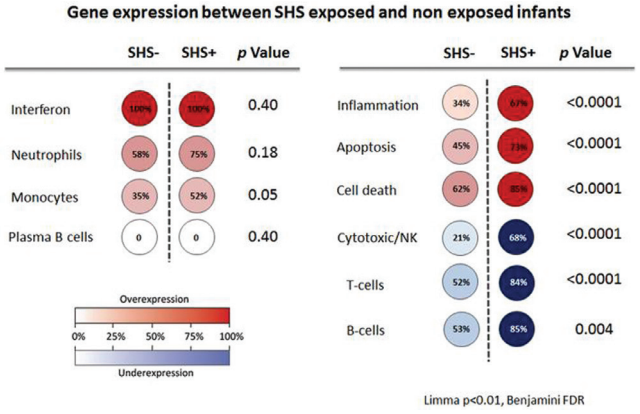
Background. RSV is the leading cause of hospitalization for bronchiolitis in infants and young children worldwide. Second-hand smoke (SHS) exposure has been associated with increased morbidity in children with respiratory infections. The objectives of this study were to explore the association between SHS measured by hair nicotine and disease severity in infants with RSV infection, and to define its impact on the blood transcriptional immune profiles.

Methods. Single-center, prospective study of previously healthy infants presenting to the Emergency Department with RSV bronchiolitis with and without SHS exposure assessed by hair nicotine levels. Exclusion criteria included: prematurity; chronic medical conditions, and insufficient hair. Clinical outcomes were assessed using a clinical disease severity score (CDSS; ranging from 0 to 15) and care provided (hospitalization and intensive care). Blood samples from patients and healthy controls were obtained at enrollment for gene expression profiling, and differences in profiles stratified by SHS exposure.

Results. A total of 70 infants with RSV were enrolled (median age 2.7 months; 44 (62.8%) males; 44 (62.8%) white). Hair nicotine was detected in 45 (64.2%) infants with RSV while 25 RSV+ infants had undetectable hair nicotine levels. Demographic variables were not significantly different between SHS exposed and nonexposed infants. Median nicotine concentrations in infants with severe (CDSS >10) vs. mild RSV disease (CDSS < 5) were 5.3 and 2.1 ng/mg (P = 0.49). In addition, blood transcriptional profiles in RSV infants exposed to SHS vs. nonexposed, were characterized by significantly greater overexpression of genes related to inflammation, apoptosis and cell death, and greater suppression of T and B cell-related genes (Figure 1).

Conclusion. In otherwise healthy infants with RSV infection exposure to SHS was associated with greater inflammation and blunted T and B cell responses. Although not statistically significant, hair nicotine levels were higher in patients with more severe RSV bronchiolitis.



Disclosures. **O. Ramilo**, Abbvie: Board Member, Consulting fee; Regeneron: Board Member, Consulting fee; Janssen: Board Member and Investigator, Consulting fee and Research grant; NIH: Grant Investigator, Research grant; **A. Mejias**, Janssen: Investigator and Scientific Advisor, Consulting fee and Research support; Abbvie: Consultant and Scientific Advisor, Speaker honorarium; Novartis: CME lecture, Speaker honorarium; NIH: Investigator, Research grant

1684. Obesity Following Antiretroviral Therapy (ART) Initiation is Common and Influenced by Both Traditional and HIV-/ART-Specific Risk Factors

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Session: 188. HIV: Modern ART
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Background. Weight gain commonly occurs among HIV-infected (HIV+) adults initiating modern ART regimens, and obesity is increasingly reported in this population. However, data regarding specific risk factors for obesity development after ART initiation are conflicting.

Methods. We retrospectively analyzed data from a cohort of HIV+ adults who initiated ART between January 1, 2000 and December 31, 2015 in Rio de Janeiro, Brazil. Body mass index (BMI) was assessed at ART initiation. Participants who were non-obese (BMI < 30 kg/m^2) at baseline and had ≥90 days of ART exposure were followed for development of obesity. Participants were censored at the time of obesity diagnosis or at end of follow-up (defined as death, loss to follow-up, end of study period or 2 years after their last weight measurement). Incidence rates were estimated using Poisson regression models and risk factor assessment was calculated using Cox regression models accounting for death and loss to follow-up as competing risks.

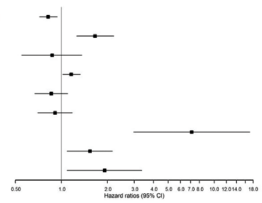
Results. Participants (n = 1,794) were 61.3% male, 48.3% white and had a median age of 36.3 years. At ART initiation, participants had a median BMI of 22.6 kg/m^2 and BMI category distribution was: underweight 14%, normal weight 56%, overweight 22% and obese 8%. Of the 1,567 non-obese participants followed after ART initiation, 76% gained weight, 44% increased their BMI category and 18% developed obesity. Median

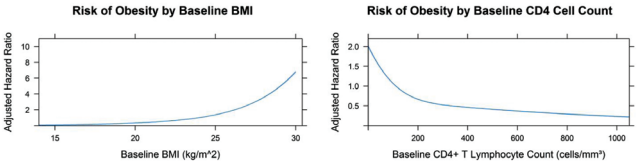
BMI at the end of follow-up was 24.7 kg/m^2 (0.4 kg/m^2 median annual change), the obesity incidence rate was 37.4 per 1000 person-years and the median time to obesity diagnosis was 1.9 years (vs. 4.7 years of follow-up for participants remaining non-obese). Factors associated with obesity after ART initiation included younger age at ART initiation, female sex, higher baseline BMI, lower baseline CD4$^+$ T lymphocyte count, higher baseline HIV-1 RNA, having an integrase inhibitor as the most-used ART core drug and having diagnoses of hypertension and diabetes mellitus (Figure).

Conclusion. Obesity following ART initiation is frequent among HIV+ adults, with rates increasing in recent years. Both traditional (female sex) and HIV-specific (more advanced HIV disease, integrase inhibitor use) risk factors contribute importantly to obesity incidence following ART initiation.

Figure. Factors Associated with Incident Obesity After Multivariate Analysis

	aHR	Lower CI	Upper CI
Age at ART Initiation (per 10 year increase)	0.82	0.72	0.94
Sex: Female (ref male)	1.66	1.26	2.20
Sex: Transgender Women	0.87	0.55	1.36
Baseline Viral Load (copies/mL) Log10	1.16	1.02	1.33
ART Backbone Drug: AZT (ref TDF)	0.86	0.67	1.10
ART Core Drug: PI (ref NNRTI)	0.91	0.70	1.18
ART Core Drug: INSTI	7.12	2.97	17.09
Baseline Diagnosis of Hypertension	1.54	1.09	2.16
Baseline Diagnosis of Diabetes Mellitus	1.92	1.09	3.36





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

Conclusion. For incarcerated PLH, both LTC and RIC as well as viral suppression are suboptimal after release. PLH who receive case management are more likely to have timely LTC. Targeted interventions and integrated programming aligning health and criminal justice goals may improve post-release HIV treatment outcomes.

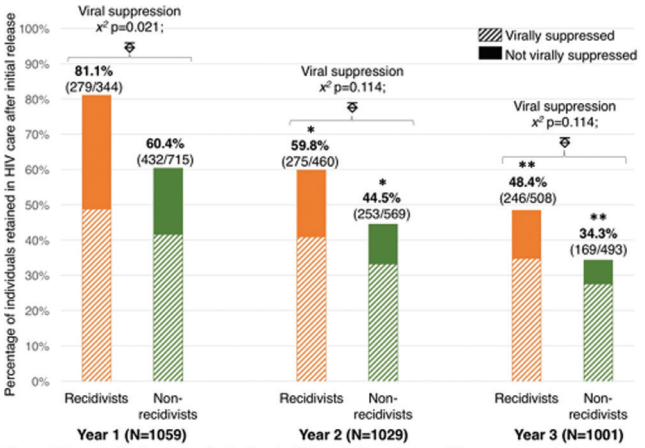


Figure 1. Longitudinal sustained retention in HIV care at one, two, and three years post-release, based on frequency of HIV-1 RNA viral testing, stratified by whether individuals were re-incarcerated at some point during the follow-up period. *statistically significant decline (McNemar's test p<0.0001) compared with initial one-year rates. **statistically significant decline (McNemar's test p<0.0001) compared with sustained two-year rates. ⊼statistically significant difference (x^2 p<0.0001) in retention rates between recidivists and non-recidivists across all time points. Among those retained, non-recidivists had higher viral suppression rates compared to recidivists at end of year 1 (p=0.021) and year 3 (p=0.048).

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

1685. Predictors of Linkage to and Retention in HIV Care Following Release from Connecticut Jails and Prisons

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Background. One in six people living with HIV (PLH) in the USA transition through prison or jail annually. During incarceration, people may engage in HIV care, but transition to the community remains challenging. Linkage to care (LTC) post-release and retention in care (RIC) are necessary to optimizing HIV outcomes, but have been incompletely assessed in prior observational studies.

Methods. We created a retrospective cohort of all PLH released from a Connecticut jail or prison (2007–2014) by linking Department of Correction demographic, pharmacy, and custody databases with Department of Public Health HIV surveillance monitoring and case management data. We assessed time to LTC, defined as time from release to first community HIV-1 RNA test, and viral suppression status at time of linkage. We used generalized estimating equations to identify correlates of LTC within 14 or 30 days after release. We also described RIC over three years following an initial release, comparing recidivists to non-recidivists.

Results. Among 3,302 incarceration periods from 1,350 unique PLH, 21% and 34% had LTC within 14 and 30 days, respectively, of which >25% had detectable viremia at time of linkage. Independent correlates of LTC at 14 days included incarceration periods >30 days (adjusted odds ratio [AOR] = 1.6; $P < 0.001$), higher medical comorbidity (AOR = 1.8; $P < 0.001$), antiretrovirals prescribed before release (AOR = 1.5; $P = 0.001$), transitional case management (AOR = 1.5; $P < 0.001$), re-incarceration (AOR = 0.7; $P = 0.002$) and conditional release (AOR = 0.6; $P < 0.001$). The 30-day model additionally included psychiatric comorbidity (AOR = 1.3; $P = 0.016$) and release on bond (AOR = 0.7; $P = 0.033$). Among 1,094 PLH eligible for 3-year follow-up, RIC after release declined over 1 year (67%), 2 years (51%) and 3 years (42%). Recidivists were more likely than nonrecidivists to have RIC but, among those retained, were less likely to be virally suppressed (Figure 1).

1686. Forty-eight-Week Safety and Efficacy On-Treatment Analysis of Ibalizumab in Patients with Multi-Drug Resistant HIV-1

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Background. Management of multi-drug-resistant (MDR) HIV-1 remains a challenge. The advent of antiretroviral (ARVs) with novel mechanisms of action are needed to expand therapeutic options for MDR patients. Ibalizumab (IBA) is a humanized monoclonal antibody with a unique binding specificity to the CD4 domain 2, allowing it to block viral entry into host cells without CD4 depletion. Patients completing the 24-week Phase 3 study (TMB-301) continued treatment in study TMB-311. Here, we report the durable efficacy and long-term safety of IBA with an optimized background regimen (OBR) through 48 weeks of treatment.

Methods. TMB-301 was an open-label study investigating the antiviral activity and safety of IBA plus OBR in highly treatment-experienced patients with MDR HIV-1. Patients received an intravenous loading dose of 2,000 mg followed by 800 mg doses every 2 weeks for 24 weeks. 7 days after loading dose, an OBR was added with at least 1 additional sensitive agent throughout the study. Following completion of the 24-week TMB-301 study, patients continued to receive IBA at 800 mg every 2 weeks under TMB-311 for up to 48 weeks. Safety and efficacy were assessed until 48 weeks.

Results. A total of 31 patients enrolled in TMB-301 completed the 24-week treatment period. Of 31 patients, 27 entered study TMB-311. These patients were highly resistant patients - 59% and 33% of patients had exhausted ≥3 and ≥4 ARV classes, respectively, and 7% of patients had HIV-1 resistant to all approved ARVs. IBA plus OBR was well tolerated. Of the 27 patients, 24 (89%) continued to receive treatment until Week 48. The three patients discontinued early due to non IBA-related reasons. No new or unexpected safety concerns emerged between Week 24 and 48. The potent suppression of viremia observed Week 24 was sustained through Week 48. Median viral load (VL) reduction from BL was 2.5 $\log_{10}$ at both Week 24 and 48. Of 27 patients (59%) 16 had VL <50 copies/ml and 17 (63%) patients had VL < 200 copies/ml. All 15 patients with VL < 50 copies/ml at Week 24 maintained viral suppression to Week 48.

Conclusion. IBA plus OBR continued to achieve high rates of virologic suppression through Week 48. The results support the durable efficacy and long-term safety