2022 URBAN ARCH ANNUAL MEETING

Uganda Russia Boston Alcohol Network for
Alcohol Research Collaboration on HIV/AIDS

Program Booklet

May 10, 2022

Table of Contents

Annual Meeting Agenda 3-4
Early Career Investigator Oral/Poster Abstract Presentations 5-9
Annual Meeting Attendees 10-16
International URBAN ARCH Center Program Advisory Committee (PAC) 17
A Tribute to Richard Saitz 18-19
URBAN ARCH Consortium
- URBAN ARCH Grants 2011-2016 20
- URBAN ARCH Grants 2016-2021 21
- URBAN ARCH Affiliated Studies 22-23
- URBAN ARCH Data Collected at Baseline (2016-2021) 24
- URBAN ARCH Clinical Values & Samples Collected (2016-2021) 25-26
- URBAN ARCH Baseline Demographics (2016-2021) 27
- URBAN ARCH Repository Overview and Content 28-29
- URBAN ARCH Publication Guidelines 30-31
- URBAN ARCH Publications (2012-2022) 32-43

Beyond the URBAN ARCH Consortium
- International URBAN ARCH Center Overview 44
- Addressing Related Comorbidities for HIV by Employing Remote technologies (ARCHER) Overview 45
- Microbiome, mETabolites, and Alcohol in HIV to reduce CVD (META HIV CVD) Overview 46

Alcohol, Gut-Dysbiosis, Inflammation, and Non-AIDS Diseases among People with HIV – Satellite Meeting at RSA 47-48
Information on the Inter-CFAR Substance Use Research Community (I-SURC) 49

2022 URBAN ARCH Annual Meeting
Tuesday, May 10th, 2022

The objectives of the 2022 URBAN ARCH Annual Meeting are to bring together URBAN ARCH teams and collaborators to do the following:

- Discuss the findings, accomplishments, legacy, and continuation of the URBAN ARCH Consortium
- Introduce the International URBAN ARCH Center and other 2nd generation URBAN ARCH P01 Centers
- Examine collaboration opportunities across HIV/alcohol P01 Centers
- Engage trainees in HIV and alcohol research domestically and internationally
- Update the Program Advisory Committee and receive feedback on progress and challenges of the International URBAN ARCH Center

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JOIN VIA ZOOM

8:30 – 8:35 Welcome, introductions, and orientation to the day *(Jeffrey Samet)*

8:35 – 8:45 A tribute to Dr. Rich Saitz *(opportunity for attendees to share)*

8:45 – 9:00 NIAAA HIV/alcohol priorities *(Kendall Bryant)*

9:00 – 10:45 URBAN ARCH Consortium – What We Learned and What We Still Can Learn

- 9:00 – 9:35 Uganda ARCH
- 9:35 – 10:10 Russia ARCH
- 10:10 – 10:45 Boston ARCH

10:45 – 11:00 Break

11:00 – 11:45 International URBAN ARCH Center Mission and Overview

- 11:00 – 11:15 Theme, Organization, Cores, Training and Mentoring *(Jeffrey Samet & Debbie Cheng)*
- 11:15 – 11:30 TRAC study *(Judy Hahn)*
- 11:30 –11:45 SPIRIT study *(Kaku So-Armah)*

11:45 – 12:30 Break

12:30 – 1:10 2nd Generation URBAN ARCH P01 Centers Overview and Trainee Opportunities

- 12:30 – 12:50 ARCHER *(Michael Stein)*
- 12:50 – 1:10 META HIV CVD *(Matthew Freiberg)*

1:10 – 1:55 Discussion of collaborative opportunities

2:00 – 2:45 Early Career Investigator Oral/Poster Abstract Presentations

2:00 – 2:15 (Choose between breakout room A or B)

A. Alcohol use is associated with increased Pre-exposure Prophylaxis (PrEP) continuation and adherence among pregnant and post-partum women in South Africa (*Amanda Miller*)

B. ART suppressed HIV patients with opioid use disorder show a block in latency reversal (*Binita Basukala*)

2:15 – 2:30 (Choose between breakout room A or B)

A. The effect of heavy alcohol consumption on plasma TMAO levels: A repeated cross-sectional study (*Samuel O Mensah*)

B. The prevalence and correlates of alcohol use and alcohol use disorders among young people (15 – 24 years) and adults in Eswatini, Malawi and Zambia (*Zethu Msibi*)

2:30 – 2:45 (Choose between breakout room A or B)

A. Effect of alcohol consumption on CD4 recovery after antiretroviral therapy initiation *(Angela McLaughlin)*

B. Associations between alcohol use and antiretroviral therapy uptake among people living with HIV in rural Uganda *(Adriane Wynn)*

2:45 Adjourn/Transition to Closed Meeting for International URBAN ARCH Center and Program Advisory Committee

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Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

Early Career Investigator Oral/Poster Abstract Presentations

Alcohol use is associated with increased Pre-exposure Prophylaxis (PrEP) continuation and adherence among pregnant and post-partum women in South Africa

Presented by Amanda Miller, PhD

Department of Epidemiology, Fielding School of Public Health, University of California, Los Angeles, CA, USA

Background: South African (SA) women experience exceedingly high levels of alcohol use and incident HIV infection prior to and during pregnancy and postpartum periods, underscoring the need to address these issues in this population. When used consistently, oral pre-exposure prophylaxis (PrEP) is highly effective at reducing risk of HIV acquisition. There is evidence that alcohol use may be a barrier to optimal PrEP outcomes, but this relationship has not been explored among pregnant and breast-feeding women at high risk of HIV infection. To characterize the relationship between alcohol use and PrEP continuation and adherence in this population, we analyzed data from a prospective observational cohort of 1200 HIV-negative pregnant women enrolled at first antenatal care visit and followed through 12 months postpartum in Cape Town, SA.

Methods: We examined associations between report of any and hazardous alcohol use (measured using the AUDIT-C (cutoff of ≥3)) in the past year prior to pregnancy and PrEP continuation (ongoing receipt of PrEP prescription at 3 months) and adherence at 3-month follow-up using both self-reported (missing <2 doses in past 7 days) and biomarker-confirmed (presence of any tenofovir in blood) adherence measures. The analytic sample comprised of pregnant women who initiated PrEP at baseline and had not been censored at 3-month follow-up (n=943).

Results: Median participant baseline age was 26 years [IQR 22-31]; median gestation age was 22 weeks [IQR 15-31]. At 3-month follow-up, 41% were still pregnant. After adjusting for age, education, residence and current relationship, hazardous alcohol use was associated with increased odds of continuing PrEP (aOR 1.55, 95% CI: 1.17-2.06) and self-reported (aOR 1.41, 95% CI: 1.07, 1.86) and biomarker-confirmed (aOR 1.36, 95% CI: 0.99-1.88) adherence. The same trend was observed when looking at associations between any alcohol use and PrEP continuation and adherence.

Conclusions: While existing literature suggests alcohol use can serve as a barrier to PrEP care and adherence, among pregnant and postpartum women in SA who initiated PrEP, recent alcohol use and hazardous drinking were associated with higher odds of PrEP continuation and adherence. These findings suggest PrEP is an acceptable HIV prevention strategy in this high-risk population.

To be presented at 2:00pm (Presentation A)

ART suppressed HIV patients with opioid use disorder show a block in latency reversal

Presented by Binita Basukala

Department of Biology, Boston University, Boston, MA

Of the 12 million people who inject drugs worldwide, 13% live with HIV. Chronic opioid use affects host immune system and increases an individual's susceptibility to HIV infection. However, it is unclear how opioid use changes the course of HIV pathogenesis. Particularly, there is a gap in understanding how opioids impact HIV latency. Latency results in a reservoir of infected quiescent cells that evade antiviral immune responses, are not targeted by ART, and allow HIV viremia to rebound upon treatment interruption. In vitro studies show that opioids modulate activity of transcription factors involved in T cell activation and HIV transcription. We hypothesize that chronic opioid use shapes HIV reservoir towards persistently infected cells that are resistant to reactivation. We utilized PBMCs from People living with HIV (PLWH) with/without recent opioid use or opioid use disorder (OUD) who were enrolled in the St. PETER and LINC-II studies conducted in Russia. Intact proviral DNA ddPCR assays were performed on peripheral blood mononuclear cells from ART treated PLWH with (n=8) or without (n=13) OUD to quantify intact and defective proviral genome. Samples from ART treated PLWH with OUD compared to those without OUD had similar ratios of intact and defective proviruses. To evaluate latency reversal, we activated PBMCs from ART treated PLWH with/without OUD with □CD3/28 beads and performed RT-ddPCR assays for HIV RNA. We saw variable response in PLWH without OUD where half of the samples showed an increase in HIV RNA upon activation. Interestingly, only 1 of 8 samples from PLWH with OUD showed an increase in HIV transcription. We failed to observe suppression of HIV reactivation in vitro from latent cells generated using a primary CD4+ T cell latency model. We show that PLWH with OUD have a pool of persistent HIV proviruses that are refractive to reactivation although opioids did not affect HIV replication and latency reactivation in vitro. The discrepancy in our in vitro and in vivo results suggests that while opioids may not directly impact HIV replication, latency and reactivation in CD4+ cells, opioids may indirectly shape the HIV reservoir in vivo by modulating anti-HIV immune functions.

To be presented at 2:00pm (Presentation B)

The effect of heavy alcohol consumption on plasma TMAO levels: A repeated cross-sectional study

Presented by Samuel Mensah, MD, MPH

Department of Medicine, Boston Medical Center, Boston, MA, USA

Background: Heavy alcohol consumption is associated with increased risk of cardiovascular disease. Alcohol-related alterations in the intestinal microbiome may be a novel mechanism for this association. Trimethylamine n-oxide (TMAO) is an intestinal microbiome-dependent metabolite that is associated with increased risk of cardiovascular disease. We hypothesized that heavier alcohol consumption is associated with increased TMAO levels.

Methods: Participants were recruited from the St PETER HIV study, a clinical trial to reduce alcohol and smoking among persons living with HIV (PLWH) in Russia. Eligibility for the trial included at least five heavy drinking days in the 30 days prior to baseline, as assessed by the Timeline Follow Back (TLFB) method. Heavy drinking was defined as intake of greater than three standard drinks for women or greater than four standard drinks for men. Number of days on which heavy drinking occurred in the prior month, the main exposure, was measured at baseline and at 3-months. Plasma TMAO level, the outcome, was natural log transformed to approximate a normal distribution. Results were back transformed for ease of interpretation. A general additive model analysis was performed as the first step. In the absence of nonlinear association, a multiple linear regression estimated the association between number of heavy drinking days and plasma TMAO levels adjusting for age, gender, BMI, renal function, HIV viral load and recent seafood consumption.

Results: Participants (N=400) had the following characteristics at baseline: mean age 38 +6 years, 34% female. The median (interquartile range) number of heavy drinking days in the past month was 8 (6,10) days. The median (interquartile range) plasma TMAO was 4.0 (2.3, 6.0) µM. The general additive model suggested a linear relationship between number of heavy drinking days and log plasma TMAO. In the multivariable regression analysis, we did not detect a significant association between heavy drinking days and plasma TMAO after adjusting for confounders (beta = 1.00, 95% CI: 0.99, 1.01, p=0.53).
Conclusion: We did not detect an association between heavy drinking days and TMAO levels in this sample of PLWH with heavy alcohol use. Future work should consider using blood-based biomarkers of alcohol consumption, phosphatidylethanol (PEth).

To be presented at 2:15pm (Presentation A)

The prevalence and correlates of alcohol use and alcohol use disorders among young people (15 – 24 years) and adults in Eswatini, Malawi and Zambia

Presented by Zethu Msibi, MS

Division of Epidemiology and Biostatistics, School of Public Health, University of the Witwatersrand

Background: Excessive alcohol use is a remarkable trouble in public health worldwide. It is escalating in Sub-Saharan Africa due to marketing aggressively and lack of individual and policy level interventions. We used the national representative population-based HIV Impact Assessment (PHIA) data to determine the prevalence and correlates of alcohol use (AU) and alcohol use disorders (AUD) in young people and adults in Eswatini, Malawi and Zambia.
Methods: PHIA surveys 2015 – 2017data was analyzed. The surveys employed multistage sampling strategy to recruit study participants at household level. The sample in each country dataset were as follows Eswatini(n=9885) Malawi(n=19405), and Zambia(n=27,382). The analysis utilized multivariable models of logistic regression models that identify the correlates of AU and AUD. Analyses was adjusted for weights, stratification, and clustering using the survey platform analysis in Stata version 15. P-value of <0.05 was considered statistically significant.
Results: AU prevalence in young people and adults was 17.9% and 23.3% in Eswatini, 10.9% and 22.1% in Malawi, and 14.6% and 32.4% in Zambia. The prevalence of AUD in young people and adults was 9.1% and 14.2% in Eswatini, 3.5% and 11.2% in Malawi, and 7.6% and 20.6% in Zambia. The correlates of AU and AUD encompass being male (aOR: 4.62 (95% CI: 3.35 -5.79), age group, higher education level (aOR: 1.70, 95% CI: 1.16 -2.48), divorced or separated or widowed in all 3 countries (aOR: 1.96, 95% CI: 1.55 -2.48), HIV positive status in Zambia (aOR: 1.49, 95% CI: 1.12 -1.99), multiple sexual partners in Malawi (aOR: 11.90, 95% CI: 6.76 -20.93), employed class in Zambia (aOR: 2.06, 95% CI: 1.64 -2.59) and engaging in commercial sexual relations in Malawi.
Conclusion: The reported AU and AUD are common in youth and adults in Eswatini, Malawi and Zambia. Both AU and AUD are related with being male, age group 20 – 24 years old, educational level (higher), HIV status, transactional sex and multiple sexual partners, widowed or separated and HIV status and risky sexual behaviours in the three countries. There is an urgent need for targeted alcohol interventions and such interventions could be integrated with sexual and reproductive health programs.

To be presented at 2:15pm (Presentation B)

Effect of alcohol consumption on CD4 recovery after antiretroviral therapy initiation

Presented by Angela McLaughlin, MD, MPH

Section of Infectious Diseases, Department of Medicine, Boston Medical Center, Boston, Massachusetts, USA

Background: Alcohol is immunomodulatory and widely consumed by people with HIV. Slowed CD4 recovery after initiating antiretroviral therapy (ART) is associated with worse HIV outcomes, so understanding alcohol's effect on this process has high clinical relevance. We hypothesized that alcohol consumption at ART initiation is associated with slower CD4 recovery.

Methods: We retrospectively analyzed two pooled longitudinal alcohol/HIV cohorts (2014-2019) in St. Petersburg, Russia. Eligible participants were ART naïve at enrollment, initiated ART during the study, and self-reported adherence ≥80%. We assessed alcohol consumption by the validated blood biomarker phosphatidylethanol (PEth) and categorized as low, moderate, and high based on median PEth 80 ng/mL (<8, 8-80, and >80 ng/mL, respectively). Our secondary alcohol measure was self-reported number of prior-month heavy drinking days (>4 drinks/day for males and >3 drinks/day for females). We used random effects piecewise linear regression to estimate the mean CD4 count at ART initiation and the slope of CD4 recovery by alcohol group.

Results: Of 54 eligible participants, average age was 35 years and 27% were female. Mean pre-ART alcohol consumption in the low, moderate, and high drinking groups were PEth 1, 30, and 339 ng/mL and monthly heavy drinking days 2.3, 4.8, and 7.4, respectively. Corresponding CD4 counts at ART initiation were 487, 433, and 393 cells/mm3. After starting ART, CD4 count increased monthly by 13.6 cells/mm3 (95% CI 0.33, 26.9) with low alcohol consumption, 1.37 cells/mm3 (95% CI -5.62, 8.35) with moderate consumption, and 2.52 cells/mm3 (95% CI -3.98, 9.02) with high consumption (Figure).

Conclusions: Among Russians with HIV, we observed faster CD4 recovery after ART initiation in those with low compared to moderate and high alcohol consumption. Future studies will use continuous alcohol measures to assess the threshold above which CD4 recovery slows and will evaluate associations between alcohol and other cell counts and presence of clinical infections.

To be presented at 2:30pm (Presentation A)

Associations between alcohol use and antiretroviral therapy uptake among people living with HIV in rural Uganda

Presented by Adriane Wynn, PhD

Division of Infectious Diseases and Global Public Health, University of California, San Diego, La Jolla, CA, USA

Background: Alcohol use among people living with HIV (PLHIV) is common and associated with negative impacts on the HIV care cascade. In 2017, Uganda implemented the universal test-and-treat (UTT) strategy, which expanded access to antiretroviral therapy (ART) to all PLHIV. However, gaps in ART coverage persist in certain populations. We evaluated the relationship between alcohol and ART uptake among PLHIV and linked to care in Uganda. We also assessed ART adherence among a sub-sample of participants.

Methods: PATH/Ekkubo is a cluster-randomized trial evaluating a linkage to HIV care intervention in four rural Ugandan districts, Nov 2017-Sept 2021. Our sample included: 1) baseline data from individuals not enrolled in the trial (previously diagnosed HIV+ and linked to care); and 12-month follow-up data from those enrolled in the control group (previously diagnosed, but not linked to care, or newly diagnosed HIV+ at enrollment). Alcohol use was measured as any current (AUDIT-C>0), harmful (AUDIT-C women ≥3, men 4≥), and binge use (≥6 drinks on one occasion). ART use was assessed with, "Are you taking ARVs?" ART and alcohol use were examined using logistic regressions adjusting for age, gender,

marriage, education, religion, wealth, depression, and baseline or control group. We assessed ART adherence among the control group, dichotomized as any versus no missed doses in the past four days.
Results: Among 931 HIV+ adults, 40% reported current alcohol (32% of women, 61% of men); 21% reported harmful (19% of women, 28% of men); and 18% reported binge use (14% of women, 29% of men). In multivariable models, those with current (adjusted Odds Ratio [aOR] 0.46; 95% CI: 0.30-0.72), harmful (aOR 0.32; 95% CI: 0.20-0.51), and binge use (aOR 0.32; 95% CI: 0.19-0.51) were significantly less likely to be on ART. In the sub-analysis, current (aOR 5.25; 95% CI: 1.69-16.33) and binge use (aOR 5.16; 95% CI: 1.45-18.35) were associated with increased odds of missed ART doses.
Conclusions: Any current, harmful, and binge alcohol use were associated with lower uptake of ART and adherence. Tailored interventions for individuals who use alcohol may be needed to optimize the benefits of the UTT strategy.

To be presented at 2:30pm (Presentation B)

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In memory of our dear colleague, Dr. Rich Saitz (1963 – 2022)

For Richard Saitz (1963-2022)

In September 2020, my friend and Boston University colleague Dr. Rich Saitz wrote to me: “I have the bad luck of having been diagnosed with an inoperable pancreatic adenocarcinoma. I have a P01 application in the works and I wondered if you might be willing and interested in taking it over?” Because Rich had work for me to do, I was among the first to know this terrible news. I was undone; the grant was due in eight weeks. I accepted the next day, and Rich and I become multiple PIs for the proposal.

As Rich began chemotherapy, he was hopeful that we could pull off the application and that he would be in better shape when we were eventually funded. I enjoined the wonderful senior investigators who now constitute the leadership of the ARCHER grant, who traced out the ideas you will read in this newsletter. We wrote fast, with Rich pitching his thoughts about the Aims from his sick bed. He was the Rich I had always known: a scold for clear thinking, an empirical stickler. He had strong opinions, but not inflexible ones. He wanted us to play to BU’s strengths and past work, and also to be innovative. Because we were in the middle of the COVID-19 pandemic, our projects would live in the new world of telehealth.

For decades, Rich had been an influential writer and editor around the primary issues of clinical alcohol research, a mentor to many, a miner of good ideas, a keeper of common sense. He had directed Boston ARCH, the Boston Alcohol Research Collaboration on HIV/AIDS, which gave birth to ARCHER. So he was there from the beginning of this vein of work. His spirit, his direction and high standards, will be there until the end.

–Michael Stein

Uganda Russia Boston Alcohol Network for
Alcohol Research Collaboration on HIV/AIDS

ARCH I Main Grants: Initial funding period (2011–2016)

The **U**ganda **R**ussia **B**oston **A**lcohol **N**etwork for **A**lcohol **R**esearch **C**ollaboration on **H**IV/AIDS (URBAN ARCH) Consortium was funded by NIAAA in September 2011 to carry out cohort and intervention studies to address gaps in our understanding about HIV and alcohol. The central goal of the URBAN ARCH Consortium is to examine the consequences of alcohol on HIV disease and to mitigate its harmful effects. The Consortium studies build upon three existing cohorts of people with HIV (PWH) from Boston, Uganda, and Russia with distinctive strengths and well-characterized alcohol consumption patterns. The three cohorts are integrated in terms of characteristics and common measures, which will allow evolution of cross-cohort studies. Moreover, samples collected from all three cohorts are stored in a centralized repository for future use.

Administrative Coordinating Core – URBAN ARCH Consortium U24AA020778 (JH Samet)
The Administrative Coordinating Core ensured that the scientific and programmatic goals of the URBAN ARCH Consortium were achieved with high quality and timeliness. The Admin Core oversaw the data and sample repository and encouraged collaboration with investigators within and outside the Consortium.

Biostatistics and Data Management (BDM) Core – URBAN ARCH Consortium U24AA020779 (DM Cheng)
The principal objectives of the Biostatistics and Data Management Core were to provide active statistical collaboration in the design and analysis of each individual study and to develop and maintain an integrated, centralized data management system that may be used by all studies within the URBAN ARCH Consortium.

Impact of Heavy Alcohol Use on Pre-ART HIV Disease – Uganda ARCH Cohort U01AA020776 (JA Hahn)
This was a 484-person prospective cohort study to determine the effect of heavy alcohol consumption (self-report and PEth) on HIV disease progression (i.e., CD4) prior to the start of antiretroviral therapy in Mbarara, Uganda.

Alcohol and Zinc Impact on Inflammatory Markers in HIV Disease – Russia ARCH Cohort U01AA020780 (JH Samet)
The Russia ARCH Cohort examined a cohort of 400 Russian ART-naive PWH with a spectrum of alcohol use to determine alcohol's impact on biomarkers reflecting microbial translocation.

Zinc for HIV Disease among Alcohol Users – An RCT in the Russia ARCH Cohort U01AA021989 (MS Freiberg/JH Samet)
This double-blinded randomized controlled trial assessed the efficacy of zinc supplementation vs. placebo on improving markers of mortality, HIV disease progression, acute MI risk, microbial translocation, and inflammation among 250 Russian PWH, who were ART-naïve at enrollment and had a recent history of heavy drinking.

Addressing Alcohol/HIV Consequences in Substance Dependence – Boston ARCH Cohort U01AA020784 (R Saitz)
The Boston ARCH Cohort (n=250) aimed to accurately characterize alcohol use and consequences in people with HIV infection affected by multiple substances and looked prospectively at impact on bone health.

Uganda Russia Boston Alcohol Network for
Alcohol Research Collaboration on HIV/AIDS

ARCH II Main Grants: 2nd funding period (2016–2021)

The **U**ganda **R**ussia **B**oston **A**lcohol **N**etwork for **A**lcohol **R**esearch **C**ollaboration on **H**IV/AIDS (URBAN ARCH) Consortium was initially funded by NIAAA in September 2011 to carry out cohort and intervention studies to address gaps in our understanding about HIV and alcohol. The central goal of the URBAN ARCH Consortium is to examine the consequences of alcohol use on comorbidities among people living with HIV, including tuberculosis (TB), cardiovascular disease, and falls so as to increase availability of treatments and improve outcomes. The Consortium studies build upon three existing cohorts of people with HIV from Boston, Uganda, and Russia with distinctive strengths and well-characterized alcohol consumption patterns. The three cohorts are integrated in terms of characteristics and common measures, which has allowed for the evolution of cross-cohort studies. Moreover, samples collected from all three cohorts are stored in a centralized repository for future use.

Administrative Coordinating (Admin) Core – URBAN ARCH Consortium U24AA020778 (JH Samet)
The Administrative Coordinating Core ensures that the scientific and programmatic goals of the URBAN ARCH Consortium are achieved with high quality and timeliness. The Admin Core oversees the data and sample repository and encourages collaboration with investigators within and outside the Consortium.

Biostatistics and Data Management (BDM) Core – URBAN ARCH Consortium U24AA020779 (DM Cheng)
The principal objectives of the Biostatistics and Data Management Core are to provide active statistical collaboration in the design and analysis of each individual study and to develop and maintain an integrated, centralized data management system that may be used by all studies within the URBAN ARCH Consortium.

Uganda Cohort – TB Preventive Therapy for HIV-infected Alcohol Users in Uganda: An Evaluation of Safety, Tolerability, and Adherence U01AA020776 (JA Hahn)
Alcohol **D**rinkers' **E**xposure to **P**reventive **T**herapy for **T**B (ADEPTT) will examine the safety and tolerability of tuberculosis (TB) preventive therapy for HIV-infected drinkers. The study (n=300) will also estimate the level of adherence to TB preventive therapy overall, by month on therapy and by drinking level, and determine whether the clinical benefits of TB preventive therapy outweigh toxicity risks for HIV infected drinkers in resource-limited settings.

Russia Cohort – Targeting HIV-Comorbidities with Pharmacotherapy to Reduce Alcohol and Tobacco Use in HIV-infected Russians U01AA020780 (JH Samet/ MS Freiberg/HA Tindle)
The **St**udying **P**artial-agonists for **E**thanol and **T**obacco **E**limination in **R**ussians with **HIV** (St PETER HIV) study, a randomized controlled trial (n=400), will compare the effects of varenicline, cytisine, and nicotine replacement therapy to reduce alcohol use and craving, smoking, and inflammation and risk for cardiovascular disease among people living with HIV.

Boston Cohort – Alcohol and HIV-associated Comorbidity and Complications: Frailty, Functional Impairment, Falls, and Fractures (The 4F Study) U01AA020784 (R Saitz)
The 4F study (n=400) will test the associations between alcohol (and illicit drugs and polypharmacy), falls, and fractures and whether frailty mediates these associations in people living with HIV infection as well as develop and pilot test the feasibility of a falls prevention intervention.

Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

URBAN ARCH Affiliated Studies Funded Since 2017

Since 2017, eleven new grants were awarded by NIH to the **U**ganda **R**ussia **B**oston **A**lcohol **N**etwork for **A**lcohol **R**esearch **C**ollaboration on **H**IV/AIDS (URBAN ARCH) Consortium that will extend the scope of our HIV/alcohol research and allow for new work examining comorbidities that are common among people living with HIV. These studies will advance URBAN ARCH's mission to conduct interdisciplinary research aimed at understanding how alcohol use impacts people living with HIV and to develop interventions to reduce alcohol use as well as alcohol and HIV-related consequences in this population.

Mobile Technology to Extend Clinic-Based Counseling For HIV+s in Uganda
R01AA024990 (JA Hahn) 4/1/17–3/31/21
This study is a randomized control trial (n=270) that aims to conduct formative work to adapt an existing brief alcohol intervention and develop two-way tailored mobile phone based messages as booster sessions, with the goal of reducing unhealthy drinking and increasing viral suppression in persons with HIV in Uganda.

1/2 Alcohol Associated Comorbidities and Microbiome Evaluation in HIV (ACME HIV)
U01AA026222 (MS Freiberg / SS Barve) 8/1/17–7/31/22
The goal of this study (n=200) is to determine if alcohol consumption changes the type of bacteria that are present in the gut. It will then determine if these changes in the bacteria of the gut are associated with changes in gut leakiness, levels of inflammation in the blood, and changes in the structure and function of the heart. This study will enroll a subset of St PETER HIV trial participants.

St PETER HIV-Alcohol, Protein Biomarkers and Cardiovascular Disease Risk Alcohol and Tobacco Use in HIV-infected Russians
R01AA025859 (MS Freiberg / JH Samet) 9/15/17–8/31/20
This study (n=360) will assess whether heavier alcohol use is associated with increased trimethylamine N-oxide (TMAO), and subsequently whether increased TMAO levels are associated with subclinical measures and biomarkers of heart failure. A subset of St PETER HIV trial participants will be asked to participate.

Internet-Based Video Conferencing to Address Alcohol Use and Pain Among Heavy Drinkers in HIV-Care
UH2AA026192 (T Palfai) 9/15/17–8/31/19
The goal of this study (n=12 in the UH2 phase) was to develop a novel, integrated behavioral approach to reduce heavy drinking and chronic pain among patients in HIV-care, delivered via internet-based videoconferencing. A subset of Boston ARCH participants were asked to participate.

Interventions to Reduce Alcohol Use and Increase Adherence to TB Preventive Therapy Among HIV/TB Co-infected Drinkers (DIPT 1/2)
U01AA026223 (JA Hahn) 9/15/17–8/31/22
The goal of this study (n=800) is to test an intervention in the Uganda ARCH cohort in which participants will receive a reward for reduced alcohol intake and for adherence to INH treatment, in order to see whether this will reduce alcohol use and increase adherence to TB preventative therapy.

Pilot Study of Opioid-receptor Antagonists to Reduce Pain and Inflammation Among HIV-Infected Persons with Alcohol Problems
UH2AA026193 (J Tsui / JH Samet) 9/20/17–8/31/19
This study (n=16 in the UH2 phase) pilot tested novel pharmacotherapies (opioid receptor antagonists) to improve chronic pain among HIV-positive heavy drinkers, and explored the hypothesis that the mechanism of action for improving pain is through decreased inflammation. A subset of Russia ARCH participants were asked to participate.

Internet-Based Video Conferencing to Address Alcohol Use and Pain Among Heavy Drinkers in HIV-Care
UH3AA026192 (T Palfai) 9/20/19–8/30/22
The goal of this (study n=48 in the UH3 phase) is to compare the Motivation and Cognitive-Behavioral Management of Alcohol and Pain intervention to treatment as usual in order to obtain effect size estimates of intervention efficacy, with the potential of implementing this intervention as part of a larger clinical trial. A subset of Boston ARCH participants will be asked to participate.

Pilot Study of Opioid-receptor Antagonists to Reduce Pain and Inflammation Among HIV-Infected Persons with Alcohol Problems
UH3AA026193 (J Tsui / JH Samet) 9/20/19–8/31/22
This study (n=45 in the UH3 phase) will compare the effects of low-dose naltrexone or gabapentin to placebo on improving pain, inflammation, and measures of HIV control among HIV-positive heavy drinkers. A subset of Russia ARCH participants will be asked to participate.

URBAN ARCH (4/5) Russia Cohort – Targeting HIV-comorbidities with Pharmacotherapy to Reduce Alcohol and Tobacco Use in HIV-infected Russians
U01AA020780-10S1 (JH Samet / MS Freiberg / HA Tindle) 9/1/20—8/31/22
This competitive revision will examine whether COVID19 co-infection among PLWH who drink and smoke increases inflammation (e.g., IL-6), alters the gut microbiome by reducing beneficial butyrate-producing bacteria which protect the gut from microbial translocation, and, by extension, alters the plasma metabolome as reflected in lower plasma butyrate levels.

COVID-19 Pandemic-Related Changes in Alcohol Use among Persons with HIV
U01AA02784-10S1 (JA Hahn) 9/1/20—8/31/22
This supplement will quantify COVID-19 pandemic-related changes in alcohol use among persons with HIV with heavy alcohol use in various settings. This research will determine the impact of changes in alcohol use during and after the pandemic on antiretroviral (ART) adherence and viral suppression in PLWH with alcohol use disorder.

URBAN ARCH (5/5) Boston Cohort – Alcohol and HIV-Associated Comorbidity and Complications: Frailty, Functional Impairment, Falls, and Fractures (The 4F Study)
U01AA020784-10S1 (R Saitz) 9/1/20—8/31/22
People living with HIV infection (PLWH) are at an increased risk for COVID-19, substance use, comorbidities, homelessness, frailty, and other symptoms that may be exacerbated by exposure to the pandemic. The goal of this study is to assess the impact of COVID-19 pandemic exposure and secondary stressors on alcohol and other drug use and HIV antiretroviral medication nonadherence among PLWH.

URBAN ARCH (2016-2021) Data Collected in All Cohort Baseline Questionnaires

Measure/Variable
Demographics
Gender
Date of birth or Age
Education
Marital status
Partner HIV status*
Housing
Incarceration
Employment
HIV & HCV
HIV diagnosis date†
HCV testing and treatment†
Opportunistic infection history† ‡
HIV transmission risk categorization‡
HIV symptom index
ART use†
Alcohol Use
Recent alcohol use/TLFB
Recent alcohol use/AUDIT-C*
Alcohol use disorder
Alcohol consequences‡
Other Substance Use
Drug use history
Tobacco use
Other tobacco/nicotine
Physical Health
VR-12 health survey
Healthcare utilization
TB testing and treatment
Falls
Mental Health
Depressive Symptoms (CES-D) (past week)
Social Support Scale

***Boston ARCH/4F does not collect.**
†Boston ARCH/4F collects from medical record.
‡Uganda ARCH/ADEPTT does not collect.

URBAN ARCH (2016-2021) Clinical Values and Samples Collected at Baseline or Screening

Tests Conducted	ADEPTT (Uganda)	St PETER (Russia)	4F Study (Boston)
HIV & Hepatitis			
CD4	x	x	x
Hep B	x		x
HCV Ab		x	x
HIV Antibody or Rapid HIV Test	x	x	x
HIV Viral Load	x	x	x
Heart, Kidney, Liver, & Lung Function			
AST/ALT	x	x	x
Blood Pressure	x	x	
Cholesterol		x	
CO		x	
Confirmatory TB (sputum)	x		
eGFR (creatinine)	x	x	x
HS CRP		x	
Substance Use			
BAC		x	x
Nicotine Metabolites (urine)		x	
PEth	x	x	
Other Clinical Values			
CBC	x		x
Height	x	x	x
Hemoglobin		x	x
Platelets		x	x

Pregnancy (urine)	x	x	
Weight	x	x	x
Samples for Storage			
Hair	x		
Heparin Plasma and PBMCs		x	
Plasma	x	x	
Saliva			x
Serum		x	
Fecal		x	
Nasal Secretions		x	
Whole Blood	Dried Blood Spots	Dried Blood Spots 5ml Tube	

Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

URBAN ARCH Baseline Descriptive Data

ADEPTT – Uganda ARCH (n=301/300)	
DEMOGRAPHICS	**N (%)**
Age, mean (SD)	40.7 (9.6)
Male	147 (48.8)
Married	202 (67.1)
Basic education or higher*	81 (26.9)
Unemployed	12 (4.0)
HEALTH INDICATORS	
Depressive symptoms†	74 (24.6)
Antiretroviral medication, current	301 (100.0)
CD4 count, mean (SD)	706 (287)
HIV viral load suppressed, n=264	269 (91.8)
Hepatitis C infection (self-report)	N/A
Moderate/extreme pain interference, past 30 days	9 (3.0)
Experienced a fall, past 3 months	4 (1.3)
Broken bone from fall, past 3 months	1 (0.3)
TB, ever told by healthcare provider‡	1 (0.3)
Yes - Active	0 (0.0)
Yes - Latent	1 (0.3)
SUBSTANCE USE	
Alcohol use disorder, past year§	96 (32.0)
Hazardous alcohol use, past 3 months‖	116 (38.7)
IDU as HIV transmission route	0 (0.0)
Any illicit opioid use, lifetime	0 (0.0)
Any illicit opioid use, past 3 months	0 (0.0)
Marijuana use, past 3 months	2 (0.7)
Cocaine use, past 3 months	0 (0.0)
Current smoker	35 (11.6)

*** ≥ 9 grades**
† Based on CESD ≥ 16
‡ Via self-report. Latent TB is an eligibility criterion, so participants are confirmed positive with a TB skin test prior to enrolling
§ Based on DSM 5 criteria
‖ Based on AUDIT-C

St. PETER – Russia ARCH (n= 400/400)	
DEMOGRAPHICS	**N (%)**
Age, mean (SD)	38.6 (6.3)
Male	263 (65.8)
Married or living with a partner	197 (49.3)
Basic education or higher*	390 (97.5)
Unemployed	140 (35.0)
HEALTH INDICATORS	
Depressive symptoms†	156 (39.1)
Antiretroviral medication, current	290 (72.5)
CD4 count, mean (SD)	392 (257)
HIV viral load suppressed (<300)	227 (57.0)
Hepatitis C infection (self-report)	315 (78.8)
Moderate/extreme pain interference, past 30 days	31 (7.8)
Experienced a fall, past 6 months	46 (11.5)
Broken bone from fall, past 6 months	2 (0.5)
TB, ever told by healthcare provider‡	52 (13.0)
Yes - Active	25 (6.3)
Yes - Latent	20 (5.0)
SUBSTANCE USE	
Alcohol use disorder, past year§	366 (91.5)
Heavy alcohol use, past 30 days ‖ ¥	398 (99.5)
IDU as HIV transmission route	303 (75.8)
Any illicit opioid use, lifetime	306 (76.5)
Any illicit opioid use, past 30 days	97 (24.3)
Marijuana use, past 30 days	46 (11.5)
Cocaine use, past 30 days	3 (0.8)
Current smoker¥	400 (100.0)

*** ≥ 9 grades**
† Based on CESD > 16
‡ Via self-report. Study testing was not done.
§ Based on DSM 5 criteria
‖ Based on TLFB, NIAAA consumption criteria
¥ Eligibility criteria at screening

4F – Boston ARCH (n=251/400)	
DEMOGRAPHICS	**N (%)**
Age, mean (SD)	52.1 (10.5)
Male	169 (67.3)
Married or partnered	129 (51.6)
Basic education or higher*	190 (75.7)
Unemployed	189 (75.3)
HEALTH INDICATORS	
Depressive symptoms†	136 (54.2)
Antiretroviral medication, current	237 (94.8)
CD4 count, mean (SD)	664 (375.1)
HIV viral load suppressed (<200)	208 (86.7)
Hepatitis C infection (ever diagnosed)	128 (51.4)
Moderate/extreme pain interference, past 4 weeks	100 (39.8)
Experienced a fall, past 6 months	87 (34.7)
Broken bone from fall, past 6 months	6 (2.4)
TB, ever told by healthcare provider‡	32 (12.7)
Yes - Active	9 (3.6)
Yes - Latent	23 (9.2)
SUBSTANCE USE	
Alcohol use disorder, past year§	106 (42.4)
Heavy alcohol use, past 14 days‖	88 (35.1)
IDU as HIV transmission route	94 (37.8)
Any illicit opioid use, lifetime€	121 (68.8)
Any illicit opioid use, past 30 days	40 (15.9)
Marijuana use, past 30 days	125 (49.8)
Cocaine use, past 30 days	61 (24.3)
Current smoker	157 (62.8)

*** ≥ High school or GED**
† Based on CESD ≥ 10
‡ Via self-report. Study testing was not done.
§ Based on DSM 5 criteria
‖ Based on TLFB, NIAAA consumption criteria
€ ARCH Bone data

Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

Uganda **R**ussia **B**oston **A**lcohol **N**etwork for **A**lcohol **R**esearch **C**ollaboration on **H**IV/AIDS (**URBAN ARCH**) Consortium Data and Sample Repository

The URBAN ARCH Repository was established in 2011 and contains data and samples from 22 studies: 17 international studies (Uganda, Russia, India) and 5 US-based studies; and approximately 65,000 samples (Dried Blood Spots [DBS], plasma, serum, PBMCs, fecal) from the URBAN ARCH Consortium cohorts (and predecessor studies).

More information about the repository is available here. Please contact Natalia Gnatienko (Natalia.gnatienko@bmc.org) for additional information.

Repository Overview and Additional Information		
Study (PI)	**Description**	**Sample Size**
Russia – HIV Latent Reservoirs (Cheng, Henderson) (2018-2021) **R61DA047032**	A study to address how opioid use alters the immune response in HIV patients and to develop a method to assess HIV latency among people who use opioids	88*
Russia – LINC-II (Samet) (2017-2022) **R01DA045547**	A two-armed randomized controlled trial among 225 HIV-positive PWID to implement and evaluate a multi-faceted intervention combining pharmacological therapy (i.e., rapid access to ART and receipt of naltrexone for opioid use disorder) and 12 months of strengths-based case management.	225
Russia – ACME (Barve, Freiberg) (2017-2022) **U01AA026222**	A study nested within the St PETER HIV trial to determine if changes in the gut microbiome are associated with heavy alcohol use; to determine the effect of dysbiosis on intestinal permeability, microbial translocation, inflammation, and trimethylamine N-oxide (TMAO) levels; and if changes in the bacteria of the gut are associated with changes in cardiac structure and function.	200*
Russia – St PETER HIV (Samet) (2017-2020) **U01AA020780**	A 4-arm placebo-controlled randomized controlled trial (RCT) among 400 HIV+ heavy drinking smokers to compare the effects of varenicline, cytisine, and nicotine replacement therapy (NRT) to reduce: 1) alcohol use and craving, 2) smoking; and 3) inflammation and risk for CHD and mortality.	400*
Russia – TMAO (Samet, Freiberg) (2017-2020) **R01AA025859**	A study nested within the St PETER HIV trial to assess whether heavier alcohol use is associated with increased trimethylamine N-oxide (TMAO), and subsequently whether increased TMAO levels are associated with subclinical measures and biomarkers of heart failure.	360*
Boston – Internet-based Video-Conferencing (Palfai) (2017-2019) **UH2AA026192**	The goal of this study (n=12 in the UH2 phase) was to develop a novel, integrated behavioral approach to reduce heavy drinking and chronic pain among patients in HIV care, delivered via internet-based videoconferencing. A subset of Boston ARCH participants were asked to participate.	12
Russia – PETER Pain (Samet, Tsui) (2017-2019) **UH2AA026193**	A pilot study to assess the feasibility, tolerability, and safety of using low-dose naltrexone and standard dose nalmefene to treat pain among people living with HIV with alcohol use and chronic pain.	14
Boston – 4F (Saitz) (2016-2021) **U01AA020784**	A prospective cohort study of HIV-positive patients with a high prevalence of exposure to alcohol, illicit drugs, and polypharmacy to 1) test the associations between alcohol (and illicit drugs and	251*

	polypharmacy) and falls (fractures secondarily), and 2) test the associations between alcohol use (and illicit drugs and polypharmacy) and acute healthcare utilization.	
Russia – SCRIPT (Lunze) (2016-2018) **R00DA041245**	A randomized, 2-arm pilot study, to support HIV-positive people who inject drugs coping with dual internalized stigma related to HIV and substance use, to compare Acceptance and Commitment Therapy (ACT) with standard of care.	111
Russia – ZINC (Samet, Freiberg) (2012-2017) **U01AA021989**	A double-blinded randomized controlled trial to assess the efficacy of zinc supplementation vs. placebo among 254 HIV+ Russians from the Russia ARCH Cohort, who were ART-naive at enrollment and had a recent history of heavy drinking.	254*
Uganda – ADEPTT (Hahn) (2011-2021) **U01AA020776**	A single-arm trial of TB preventive therapy to assess its toxicity, measure adherence, and determine whether its benefits outweigh its risks when given to TB/HIV-positive drinkers (n=300).	302*
Boston ARCH Cohort (Saitz) (2011-2016) **U01AA020784**	A prospective cohort study of 250 HIV-positive persons affected by multiple substances, a spectrum of alcohol use, and all with substance dependence or injection drug use.	250*
Uganda ARCH Cohort (Hahn) (2011-2016) **U01AA020776**	A prospective cohort study of HIV-positive persons not on ART to examine the effect of heavy alcohol consumption on HIV disease progression prior to ART initiation.	484*
Russia ARCH Cohort (Samet) (2011-2016) **U01AA020780**	A prospective cohort study of 351 HIV-positive and ART naïve individuals to assess the relationship between alcohol consumption and biomarker (sCD14 and D-dimer) concentrations.	351*
Russia – LINC (Samet) (2011-2016) **R01D032082**	A randomized control trial of 349 Russian HIV-positive people who inject drugs to improve upon the treat and retain dimensions of the "seek, test, treat, and retain" paradigm in Russia.	349
Uganda – BREATH (Hahn) (2010-2014) **R21AA015897**	A prospective cohort study of 212 HIV-positive people who drink alcohol to quantify changes in alcohol consumption during the first year of HIV care.	381*
Russia – IMPACT (Samet) (2008-2011) **R21DA025435**	A cross-sectional study of HIV-positive Russian adults from the HERMITAGE study to investigate the relationship between substance use and HIV disease progression.	167*
Boston – FASTPATH (Walley) (2007-2012) **H79TI018710**	A SAMHSA-funded clinical program of 450 patients, with alcohol or drug dependence who are at high-risk for transmitting or contracting HIV through risky drug or sexual behaviors, to provide substance use treatment in conjunction with medical care and HIV prevention and risk reduction counseling in primary care settings.	265
India – TAJ (Samet) (2007-2008) **R01AA016059**	A cross-sectional study of 500 HIV-positive men, who purchase sex, and among HIV-positive women, who sell sex, recruited from Mumbai and Guntur to enable the development of intervention research to address alcohol-related risky sex and, ultimately, reduce the transmission of HIV in India.	426
Russia – HERMITAGE (Samet) (2006-2013) **R01AA016059**	A randomized controlled trial of 700 HIV-positive patients with risky alcohol consumption to test the effectiveness of a US HIV secondary prevention program, Healthy Relationships Intervention.	700
Russia – PREVENT (Samet) (2003-2007) **R21AA014821**	A randomized controlled trial of 180 patients in treatment for a substance use disorder to develop and test the feasibility of adapting and implementing an efficacious US HIV prevention intervention in a Russian substance use disorder treatment center.	181
Boston- HIV-LIVE (Samet) (2000-2006) **R01AA13216**	A prospective cohort study of 400 HIV-positive patients with a history of alcohol use to investigate the relationship between alcohol and HIV progression and related factors in the context of the additional exposure of HCV infection.	597*
* Samples included in the Repository		

Uganda Russia Boston Alcohol Network for
Alcohol Research Collaboration on HIV/AIDS

PUBLISHING STEPS FOR MANUSCRIPTS USING URBAN ARCH DATASETS

Pre-writing phase

1. Identify topic/research question, discuss with research team/mentors to develop objectives, hypotheses and key variables (e.g. outcomes and main independent variable).
2. Begin filling in the analytic plan with this preliminary information (available at www.urbanarch.org).
3. Present analytic plan at URBAN ARCH Steering Committee meeting to consult with Admin Core and BDM Core.
4. At the meeting, discuss potential coauthors and authorship order. Authors should include the BDM analyst, the statistician, and co-investigators, as applicable. Establishing authorship upfront helps research team members understand expectations for contributing. For cross-cohort papers, the Admin Core will facilitate authorship decisions.
5. Provide the title and finalized authorship information to Natalia by email, for inclusion on the URBAN ARCH Abstract/Manuscript list.
6. Work with the analyst and statistician to complete the analytic plan. In most cases an analytic plan will need to be completed with input from a statistician and coauthors before analysis takes place. The statistician and PI/mentor should sign off on the final version of the analytic plan prior to performing analysis and should be involved with revisions. Typically there are multiple stages in the analyses, each requiring a separate or revised analytic plan (provide copies to project manager).
7. When results are received, work with coauthors and data analysts on interpreting results. This can be done by email, small group meeting, at regular research team meetings, or at the steering committee meeting.

Writing phase

8. Write the 1st draft of the paper with all sections (e.g., background, methods, results, discussion) and email it out for input from coauthors – providing a reasonable deadline. The draft should include a cover sheet with title, authors, and affiliations (consistent format).
9. Ask coauthors for potential journals in which to submit your manuscript. Seeing a 1st draft helps coauthors recommend appropriate journals. Once a journal has been decided on, properly format the paper (including references) and check submission requirements particular for that journal.
10. Incorporate feedback from coauthors and re-circulate. Several drafts will likely need to be circulated during the course of the writing process. Again, providing reasonable deadlines is helpful.
11. Acknowledge relevant funding sources and individuals in the manuscript text – ask the PI or project manager for correct grant numbers and a disclosure statement. The U01s that the data come from and the U24s should be listed. Natalia can provide details for the U24s.
12. Allow coauthors to review and approve the final manuscript (ask them to confirm their affiliation and name spelling) before it is submitted.
13. Work with the study's project manager on submission. The Admin Core can provide assistance, as needed.
14. If revisions are requested from the Editor ("a revise and resubmit"), it is the responsibility of the first and senior authors to address all comments. Input from other co-authors should be requested, as needed. Create a letter that details all comments and responses and make changes in the manuscript text. Give coauthors the opportunity to review and approve the final revision (letter and manuscript) before it is resubmitted. Journals normally give a deadline (2-3 months) to address comments, so begin work as soon as possible. Examples of revision letters and responses can be obtained from the Admin Core.
15. If an article is rejected from a journal, share news and reviewer comments (if provided) with coauthors and get input on next journal to submit to. In most cases the content of the paper won't change. Check new journal's guidelines and reformat as necessary. Submit with project manager's help.
16. If you have not heard from a journal within 3 months after submission, check on the status.

Publication phase

17. Once a paper is accepted, notify the coauthors and project manager. Also let your institution's communication department know if they prepare press releases for publications.
18. When proofs/galleys are received, share with senior author and other coauthors as applicable so that the proofs can be carefully reviewed. Check for errors, and keep other edits to a minimum. You are usually given 24-48 hours to review and reply.
19. Once a paper is accepted ("in-press"), check the publisher's guidelines on submitting the accepted manuscript to NIH pubmed central so that a PMCID number is assigned. Project manager can help.
20. Once a paper has been published, share the full citation and/or PDF with coauthors. Also let Natalia know so that she can share the news on www.urbanarch.org and update our abstract/manuscript list.
21. Ensure that the paper has been deposited into NIHMS, so that it can be linked to the appropriate grants and can receive a PMCID number. Guidelines for this process are available at http://publicaccess.nih.gov/.

Assistance:

- Check with the study's PI or project manager to see if administrative help is available (e.g., formatting references, online submission, communicating with coauthors and data managers). They can also provide examples of published manuscripts from the dataset you are using. If assistance is not available from the study, get in touch with the Admin Core.
- Guidance on publishing addiction research from the International Society of Addiction Journal Editors can be found at www.parint.org/tutorial.cfm and www.parint.org/isajewebsite/isajebook2.htm. The CARE Unit has a hard copy of this book for review.

Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

URBAN ARCH Publications (2012-2022)

2022

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URBAN ARCH International
Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS

The **International** **U**ganda **R**ussia **B**oston **A**lcohol **N**etwork for **A**lcohol **R**esearch **C**ollaboration on **H**IV/AIDS (**URBAN ARCH**) **Center** (P01AA029541; Jeffrey H. Samet, PI; 2021–2026) aims to to examine the role of alcohol use on new TB acquisition, occurrence of active TB disease after TB preventive therapy (TPT), and post-TB lung disease among people with HIV (PWH).

TRAC Project
TB Risk by Alcohol Consumption
Project Lead: Judith Hahn (UCSF)

The TRAC project aims to assess alcohol use, confounders, and mediators, through self-report and biomarkers, among people with new TB infection in Uganda. The TRAC study aims to estimate the risk ratio for high-risk alcohol use versus lower-risk or no alcohol use on acquiring new TB infection among PWH with prior negative TST results, examine potential mediators of the relationship between level of alcohol use and acquiring new TB infection, and determine the incidence of TB disease among PWH with prior latent TB infection, who received TPT, by level of alcohol use.

Site PI: Winnie Muyindike (MUST)

Administrative Coordinating (Admin) Core
Core Director: Jeffrey Samet (BMC)
The Admin Core ensures that the scientific and programmatic goals of the Center are achieved with high quality and timeliness. The Admin Core oversees the data and sample repository, coordinates the training & mentoring program, and encourages collaboration with investigators within and outside the Center.

Biostatistics and Data Management (BDM) Core
Core Director: Debbie Cheng (BUSPH)
The BDM Core provides statistical collaboration in the design and analysis of each project and develops and maintains an integrated, centralized data management system used by both projects within the Center.

SPIRIT Project
St Peter HIV Infection Respiratory Impairment & Tuberculosis
Project Lead: Kaku So-Armah (BUSM)

The SPIRIT prospective, observational, longitudinal study aims to 1) determine the relationship between hazardous alcohol use and post-TB lung disease in PWH in St. Petersburg, Russia; 2) assess whether heavy drinking is associated with post-TB lung disease progression over time; and 3) explore whether smoking modifies the association of heavy drinking and post-TB lung disease. The study will also qualitatively examine barriers to, facilitators of, and readiness to engage in alcohol and smoking interventions in this population.

Site PI: Evgeny Krupitsky (PSMU)

Please visit www.urbanarch.org to learn more.

The **Boston ARCH Comorbidity Center** was funded by the NIAAA to extend the decade of work of the URBAN ARCH Boston Cohort. The overall aims of the Center, called **ARCHER**, which stands for **A**ddressing **R**elated **C**omorbidities for **H**IV by **E**mploying **R**emote technologies, are twofold:

1. To conduct e-health clinical trials research on scalable approaches to address the HIV-associated conditions chronic pain and physical inactivity in people living with HIV with unhealthy alcohol use.
2. To support secondary analyses of the existing URBAN ARCH Boston Cohort and provide support and mentoring to trainees and investigators accessing these cohort data.

ARCHER
Addressing Related Comorbidities for HIV by Employing Remote technologies


Administrative Core (AC)
Lead: Michael Stein (BU SPH)
Administrative Director: Kara Magane (BU SPH)

The AC will coordinate both ARCHER clinical trials, and lead cross-component efforts, assuring quality and efficiency. The AC is currently working closely with the investigators leading the other components to develop strategies and approaches for overcoming unique challenges associated with implementing e-health clinical trials entirely remotely in this hard-to-reach population of people living with HIV and unhealthy alcohol use.

Biostatistics and Data Management Core (BDM)
Lead: Tim Heeren (BU SPH)

The BDM core will provide comprehensive data management and statistical support for the two ARCHER clinical trials focusing on alcohol use, pain, and physical activity in persons living with HIV. The BDM core will also provide support for secondary analyses of the existing URBAN ARCH Boston Cohort and provide support and mentoring to trainees and investigators accessing the cohort.

Integrated telehealth intervention to reduce chronic pain and unhealthy drinking among people living with HIV
Project Lead: Tibor Palfai (BU)

The chronic pain trial component of ARCHER aims to manage pain and reduce unhealthy drinking among people living with HIV using an integrated telehealth intervention based on cognitive-behavioral and motivational approaches to pain management and alcohol use. The main objective of the RCT is to test the efficacy of this intervention in a national sample of people living with HIV and unhealthy alcohol use. Ecological Momentary Assessment will provide insight into potential mediators of the intervention as well as a more precise understanding of how alcohol and pain influence one another and physical function.


Increasing physical activity among persons living with HIV engaged in unhealthy drinking
Project Leads: Ana M. Abrantes (Butler Hospital) and Lisa Quintiliani (BU SPH)

The physical activity trial component of ARCHER aims to test the efficacy of a 12-week lifestyle physical activity+Fitbit intervention among low-active people living with HIV engaged in unhealthy drinking. The trial will study changes in drinking, physical activity, physical functioning, and mental health outcomes. The primary aims are to decrease unhealthy drinking and increase physical activity. Secondary and tertiary aims include decreased negative affect and sedentary behavior, as well as increases in physical/mental functioning and adaptive coping and examining the mechanisms affecting those relationships using Ecological Momentary Assessment.

BOSTON UNIVERSITY · BOSTON MEDICAL CENTER · BROWN · BUTLER HOSPITAL · NIH National Institute on Alcohol Abuse and Alcoholism

META HIV CVD

Program Project Grant

The Microbiome, Metabolites, and Alcohol in HIV to Reduce CVD (META HIV CVD) program project grant investigates alcohol-associated gut dysbiosis and gut dysbiotic metabolites as cardiovascular disease risk factors among people living with HIV infection (PLWH) who are heavy drinkers. The goals of this research are (1) to determine if a tailored probiotic can mitigate alcohol-associated gut dysbiosis and lower levels of microbial translocation, inflammation, and improve harmful dysbiotic metabolite profiles and (2) to determine if these metabolites are associated with incident CVD and death among PLWH.

1

Project 1

Among people living with HIV, heavy drinking increases the risk of heart disease and death. Studies suggest that alcohol changes the number and kind of bacteria in your gut and these changes increase the risk of heart disease and death. This randomized controlled trial will determine whether a pill containing healthy gut bacteria can increase the number of good bacteria in the gut, lower levels of inflammation, and lower the risk of heart disease and death.

2

Project 2

The overarching theme for this project is that alcohol alters the bacteria in the gut and metabolites that the gut bacteria make among people who are infected with HIV infection and are heavy drinkers. We will examine whether this change in the bacteria and the metabolites can be reduced by taking a probiotic supplement and whether metabolites are associated with future cardiovascular disease events (e.g., a heart attack) or death.

3

Admin Core

The Admin Core provides administrative oversight of the program, including assembling a steering committee, program advisory committee, and data safety monitoring board. The core develops the policies and procedures necessary to successfully meet training initiatives, as well as services to program investigators and trainees. This is done by providing resources (e.g., data and specimens), biostatistical support, and mentorship to new investigators and promote synergy within and across other funded project program grants and assist investigators with challenges (e.g., recruitment).

4

Lab Core

The Integrated Metagenomics and Metabolomics Core (IMMC, or the lab core) provides a platform that interconnects and supports the analytical needs of Projects 1 and 2. Specifically, IMMC contributes high-quality data on gut bacteria and their metabolites and supports the assessment of the efficacy of the probiotics supplementation in improving clinical outcomes in PLWH with heavy alcohol drinking.

META HIV CVD
Microbiome, Metabolites, and Alcohol in HIV to reduce CVD
Program Project Grant

ALCOHOL, GUT-DYSBIOSIS, INFLAMMATION, AND NON-AIDS DISEASES AMONG PEOPLE WITH HIV

9:00 AM - 3:00 PM, Saturday, June 25, Orlando, Florida, USA

Organizers:
Matthew Freiberg M.Sc., M.D.
matthew.s.freiberg@vumc.org
Shirish Barve Ph.D.
shirish.barve@louisville.edu
Kaku So-Armah, Ph.D.
kaku@bu.edu

This satellite will address the following: The role of the gut microbiome among people with HIV who consume alcohol.

Participants will learn about the relationship between alcohol intake and gut dysbiosis among people with HIV. We will examine how alcohol impacts the gut microbiome and how gut dysbiosis in this population is associated with biomarkers of inflammation and gut derived metabolite profiles including trimethylamine N oxide (TMAO) from the peripheral circulation. Additional studies will examine gut dysbiosis as it relates to the alcohol associated syndemic (i.e., heavy drinking, smoking, and depression), neurocognitive changes, and liver disease among people living with HIV.

Participation in this symposium is free of charge but will be limited to the first 50 registrants. The detailed program schedule is provided below. If you would like additional information or have questions regarding the symposium, please contact **Emily Smith** at: emily.k.smith@vumc.org.

Please register to attend by May 1, 2022: https://redcap.link/METAHIVCVDRSA

9:00 – NIAAA Welcome
Kendall Bryant, PhD
Director, Alcohol and AIDS Research, National Institute on Alcohol Abuse and Alcoholism

9:15 – Alcohol and the Gut Microbiome in People with HIV: An Overview
Matthew Freiberg, MD MSc
Professor of Medicine, Dorothy and Laurence Grossman Chair in Cardiology, Division of Cardiovascular Medicine, Vanderbilt University Medical Center

9:30 – Salient Pathogenic Features of Gut Microbial Dysbiosis in People Living with HIV (PLWH) with Hazardous Drinking
Shirish Barve, PhD
Professor of Medicine, Distinguished Scholar, Division of Gastroenterology, Hepatology, and Nutrition, University of Louisville

10:00 – Gut-Dysbiosis and Gut-Derived Metabolites in People Living with HIV (PLWH) with Hazardous Drinking
Smita Ghare, PhD
Assistant Professor of Medicine, Division of Gastroenterology, Hepatology, and Nutrition, University of Louisville

10:30 - Coffee break

10:45 - The association between heavy alcohol consumption and trimethylamine-n-oxide in people living with HIV in St Petersburg Russia
Kaku So-Armah, PhD
Research Assistant Professor, Clinical Addiction Research and Education (CARE) Unit, Boston University School of Medicine

11:15 - Does Trimethylamine-n-oxide contribute to echocardiographic features of alcohol-related heart failure in people with HIV?
Samuel Mensah, MD
Research Coordinator, Clinical Addiction Research and Education (CARE) Unit, Boston University School of Medicine

11:45 – Behavioral Health Syndemics and the Gut Microbiome Among People Living with HIV
Natalie Chichetto, PhD, MSW
Assistant Professor, Department of Epidemiology, University of Florida

12:00 – Lunch Break

12:45 – HIV and Alcohol Associated Reductions in Butyrate are Associated With Reduced Neural Metabolites and Poorer Cognition
Vaughn Bryant, PhD, ScM
Department of Pharmacology C-236, University of Colorado Health Sciences Center, Denver, CO, USA

1:15 – Defining the Pathogenesis of HIV-Associated NAFLD
Curtis Gabriel, MD PhD
Instructor, Division of Gastroenterology, Hepatology, and Nutrition, Vanderbilt University Medical Center

1:45 – Panel Discussion
Moderated by Shirish Barve

2:45 – Closing

INTER-CFAR SUBSTANCE USE RESEARCH COMMUNITY(I-SURC)

INTERESTED IN HIV AND SUBSTANCE USE RESEARCH?

The I-SURC provides the platform for substance use researchers within CFARs nationwide to foster the exchange of ideas and develop collaborations, share information and training, as well as disseminate plans and progress at the intersection of HIV and substance use research.

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cfar.med.brown.edu/community/i-surc

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