

Addressing Alcohol/HIV Consequences in Substance Dependence - Boston ARCH Cohort
Funded by the National Institute on Alcohol Abuse and Alcoholism (grant no. U01AA020784)

This project is a component of the Uganda Russia Boston Alcohol Network for Alcohol Research Collaboration on HIV/AIDS (URBAN ARCH) Consortium, a member of the National Institute on Alcohol Abuse and Alcoholism's Consortiums for HIV/AIDS and Alcohol Research Translation (CHAART) Initiative, that requests establishment of a research framework of cohort studies that build on pre-existing cohorts, accurately characterize alcohol use and consequences in HIV-infected adults *and* test alcohol interventions. The central goal of the URBAN ARCH Consortium is to examine the consequences of alcohol on HIV disease and to mitigate its harmful effects. More information on the URBAN ARCH Consortium can be accessed here: <http://www.urbanarch.org/>.

The Boston ARCH Cohort is one of three cohorts that comprise the URBAN ARCH Consortium (that also has Administrative, and Biostatistics and Data Management cores). The specific aims of the Boston ARCH Cohort study are to:

- 1) Expand and continue a cohort of 250 HIV-infected adults affected by multiple substances. They will have a spectrum of alcohol use, and all have substance dependence or injection drug use.
- 2) Determine the effect of alcohol consumption on changes in bone health prospectively in the Cohort.

Study Design

- The first Boston ARCH Cohort study is observational and seeks to determine the effect of alcohol consumption on changes in bone health, over time, in 250 HIV-infected adults with a spectrum of alcohol use. The Boston ARCH Cohort will include approximately: 100 abstinent or not "heavy" drinkers and 150 "heavy" drinkers. "Heavy use" is >14 (>7 for women) standard drinks (12g) per week on average or any heavy use days (>4 in a day for men, >3 for women), in the past 30 days.
- Study participants are followed for a minimum of 1 and a maximum of 3.5 years.
- Data are obtained through Research Assistant-administered questionnaires, collection of urine and blood specimens, bone density and bone microarchitecture scans, medical record reviews, and alcohol breath testing. Comprehensive in-person assessments inclusive of laboratory tests are performed at baseline and every 12 months. Between the baseline and annual (12-month) study visits, briefer in-person assessments are conducted every 6 months to confirm contact information and assess recent substance use and other health questions.
- *Primary outcome*: annual mean percent change in hip (femoral neck) bone mineral density (g/cm²) between study entry and final visit
- *Main independent variable*: alcohol consumption (grams/day, continuous, per unit time)

Eligibility for Boston ARCH Cohort

Inclusion Criteria:

- Confirmation of documentation of HIV infection in any medical record, determined by: HIV antibody by ELISA, confirmed by Western Blot; or HIV viral load > 10,000; or HIV antibody by 4th generation ELISA confirmed by a "Multi-Spot" rapid test and, if necessary, nucleic acid testing (NAT) for HIV-1
- Current drug or alcohol dependence (past 12-months) or history of injection drug use
- Ability to speak English (fluency)
- Age 18 or older
- Willing to provide contact information for at least one person who is likely to know whereabouts (to assist with follow-up)

Exclusion Criteria:

- Pregnant (confirmed by urine test)
- Plans to leave Boston area in next year
- Cognitive impairment resulting in inability to provide informed consent and understand interview (determined by trained research assistant)

Primary Recruitment Site: Boston ARCH Cohort participants are recruited from clinical sites of HIV care, primarily from the Center for Infectious Diseases at Boston Medical Center. Operating since 1988, BMC's Center for Infectious Diseases serves 1,500 patients, nearly 30% of the people living with HIV in Boston. In June 2014, the Boston ARCH Cohort an additional recruitment site and began recruiting HIV patients from Boston Healthcare for the Homeless Program, a homeless primary care clinic. Recruitment for the Boston ARCH Cohort began in September 2012 and based on current recruitment rates/trajectory, all 250 participants will have completed baseline visits by December 2014.

Assessment Summary- Boston ARCH Cohort

Information Collected	Study Time Point							
	Baseline visit/ study entry	6 mo. f/u visit	12 mo. f/u visit	18 mo. f/u visit	24 mo. f/u visit	30 mo. f/u visit	36 mo. f/u visit	42 mo. f/u visit
Assessed by RA-administered questionnaire								
Demographics	X	X	X	X	X	X	X	X
Veterans Rand 12-Item Health Survey (VR-12) plus 4 cognitive questions from the Medical Outcomes Study HIV Health Survey (MOS-HIV)	X		X		X		X	
Veterans Rand 12-Item Health Survey Question 1 (VR-1)		X		X		X		X
The Montreal Cognitive Assessment (MOCA) – selected questions	X		X		X		X	
HIV Symptom Index	X		X		X		X	
Treatment, healthcare utilization and trauma	X	X	X	X	X	X	X	X
NIH Short Calcium Questionnaire (SCQ2002)	X		X		X		X	
Household Food Insecurity Access Scale (HFIAS) ^a		X	X	X	X	X	X	X
Alcohol Use Disorders Identification Test (AUDIT-C)	X		X		X	X		X
Mini International Neuropsychiatric Interview (MINI) Alcohol	X		X		X		X	
Mini International Neuropsychiatric Interview (MINI) Drug	X		X		X		X	
30-day Timeline Follow Back (TLFB) Alcohol	X	X	X	X	X	X	X	X
Addiction Severity Index (ASI) questions to assess 30-day Drug + 5 questions on current prescription medications and medicinal marijuana	X	X	X	X	X	X	X	X
Lifetime Drinking History (LDH) and lifetime drug use (supplement) ^b		X						
Date of HIV diagnosis ^b		X						
Prescribed opioids and craving (visual analogue scale)	X		X		X		X	
Obsessive Compulsive Drinking Scale (OCDS)- Obsessive Subscale		X		X		X		X
Short Inventory of Problems- Alcohol (SIP)	X	X	X	X	X	X	X	X
Short Inventory of Problems- Drugs (SIP-D)	X	X	X	X	X	X	X	X
Select HIV medication history	X	X	X	X	X	X	X	X
HIV medication adherence (visual analogue scale)	X	X	X	X	X	X	X	X
HIV risk factor categorization	X		X		X		X	
HIV risk behaviors	X		X		X		X	
Depression- Patient Health Questionnaire (PHQ-2)	X		X		X		X	
Overdose History (12 months)	X		X		X		X	
Smoking Questions	X		X		X		X	
Physical Activity	X		X		X		X	
Pain – Brief Pain Inventory (BPI) - selected questions	X		X		X		X	
Overall Anxiety Severity and Impairment Scale (OASIS)	X		X		X		X	
Bone health- includes selected questions from the National Health and Nutrition Examination Survey (NHANES)	X		X		X		X	
Biological tests and specimens								

Information Collected	Study Time Point							
	Baseline visit/ study entry	6 mo. f/u visit	12 mo. f/u visit	18 mo. f/u visit	24 mo. f/u visit	30 mo. f/u visit	36 mo. f/u visit	42 mo. f/u visit
Urine pregnancy test ^c	X		X		X		X	
Alcohol breath testing	X	X	X	X	X	X	X	X
Bone mineral density (DEXA)	X		X		X		X	
Bone microarchitecture (HR-pQCT)	X		X		X		X	
Height	X							
Weight	X	X	X	X	X	X	X	X
PEth ^d	X		X		X		X	
~5mL plasma for storage in URBAN ARCH Repository	X		X		X		X	
~5mL serum for storage in URBAN ARCH Repository	X		X		X		X	
Dried blood spot for storage in URBAN ARCH Repository	X		X		X		X	
25-hydroxy-Vitamin D (from stored serum)	X		X		X		X	
Recent test values in medical record are recorded for study purposes. If recent test results are unavailable, specimen is collected at study visit and tested for following:								
Liver Enzymes (ALT/AST)	X		X		X		X	
CD4 cell count	X		X		X		X	
HIV viral load	X		X		X		X	
Hemoglobin	X		X		X		X	
Creatinine	X		X		X		X	
Platelet count	X		X		X		X	
HBV surface antibody	X							
HBV core antibody	X							
HBV surface antibody	X							
HCV antibody ^e	X		X		X		X	
Information to be abstracted from the medical record								
History of antiretroviral medications (any med prescribed up through date of last study visit)	X		X		X		X	X
Current HIV medication regimen	X		X		X		X	X
History of treatment for Hepatitis C infection (ever up through date of last study visit)	X		X		X		X	X
Hepatitis C viral load (more recent value prior to date of baseline visit through last study visit)	X		X		X		X	X
History of CDC list of AIDS-defining conditions (ever up through date of last study visit)	X		X		X		X	X
Prior hospitalizations (number in year prior to baseline visit up through last study visit)	X		X		X		X	X
Comorbidities assessed using the Charlson Comorbidity Index and VACS Cohort Questionnaire (ever up through date of last study visit)	X		X		X		X	X
Use of medications known to impact bone health (ever up through date of last study visit)	X		X		X		X	X
Use of medications commonly used to treat addiction (ever up through date of last study visit)	X		X		X		X	X
Serum testosterone (most recent value prior to baseline through date of last study visit)	X		X		X		X	X
Use of hormonal contraception	X		X		X		X	X

^a HFIAS added after ~190 subjects were already recruited; most subjects will only complete at one or two study visits

^b Supplement will be offered at first follow up visit but can be completed at any study visit thereafter if needed.

^c Pregnancy testing will occur prior to baseline procedures as confirmation of eligible criteria and prior to any female subject receiving CT or DEXA scan at subsequent visits.

^d PEth tested from dried blood spots which are created at baseline and all annual visits and stored in URBAN ARCH Repository freezer.

^e At all time points, subjects will only be tested for HCV antibody if there is no record of a prior positive HCV antibody test or a Hep C Viral Load value ≥ 1 in the medical record.

Boston ARCH Study Team - Contact Information

Investigators

Richard Saitz, MD, MPH

Principal Investigator, Boston ARCH

rsaitz@bu.edu

Phone: 617.414.7744

Michael Holick, PhD, MD

Co-Investigator, Boston ARCH

mfolick@bu.edu

Phone: 617.638.4546

Jeffrey Samet, MD, MPH, MA

Co-Investigator, Boston ARCH

Principal Investigator, URBAN ARCH

Administrative Core

jsamet@bu.edu

Phone: 617.414.7288

Meg Sullivan, MD

Co-Investigator, Boston ARCH

meg.sullivan@bmc.org

Phone: 617.414.3574

Alex Walley, MD, MSc

Co-Investigator, Boston ARCH

alexander.walley@bmc.org

Phone: 617.414.6975

Project Management

Alicia Ventura, MPH

Project Manager, Boston ARCH

alicia.ventura@bmc.org

Phone: 617.414.6914

Seville Meli, MPH

Director of Research Operations

seville@bu.edu

Phone: 617.414.6917

Carly Bridden, MA, MPH

Administrative Director, URBAN ARCH

Administrative Core

carly.bridden@bmc.org

Phone: 617.414.5768

Biostatistics and Data Management

Timothy Heeren, PhD

Biostatistician, Boston ARCH

tch@bu.edu

Phone: 617.638.5172

Michael Winter, MPH

Senior Statistical Analyst, Boston ARCH

mwinter@bu.edu

Phone: 617.638.5015

Greg Patts, MPH

Statistical Analyst, Boston ARCH

gpatts@bu.edu

Phone: 617.638.5029

Research Assistants

Margo Godersky

Research Assistant, Boston ARCH

margo.godersky@bmc.org

Phone: 617.414.6958

Kate Haworth

Research Assistant, Boston ARCH

kate.haworth@bmc.org

Phone: 617.414.6904

Laura Vercammen, MPH

Research Assistant, Boston ARCH

laura.vercammen@bmc.org

Phone: 617.414.6920

Lucero Leon-Chi

Research Assistant, Boston ARCH and URBAN

ARCH Administrative Core

lucero.leon-chi@bmc.org

Phone: 617.414.1352