## HIV–1 RNA Genital Tract Shedding after Cryotherapy for VIA–positive Cervical Lesions in Western Kenya

## 2022 Lifespan Research Day Abstract

<b>Research Cat</b>	egory: Clinical & Translational					
Primary Research Location: Academic Model Providing Access to Healthcare (AMPATH), Lifespan laboratories						
Funded By: This research was supported by the Providence/Boston Center for AIDS Research [5P30AI042853], the NIH D43 International						
Authors(s): University 2019 Summer Assistantship Award, and the Academic Model Providing Access to Healthcare (AMPATH) Partnership.						
Elkanah O Orang'o, Anne E Bocage, Me Tao Liu, PhD, Assoc Peter M Itsura, MD, Philip K Tonui, MD, I Kapten Muthoka, M Kiptoo Stephen, Ms Angela Caliendo, M Soya Sam, PhD, Th Susan Cu–Uvin, ME	MD, PhD, Professor, Moi University. Dept of Reproductive Health dical Student, Brown University. Warren Alpert Medical School iate Professor, Brown University. Dept of Biostatistics Professor, Moi University. Dept of Reproductive Health Professor, Moi University. Dept of Reproductive Health PH, Academic Model Providing Access to Healthcare (AMPATH). Program Manager c, Moi University. Dept of Reproductive Health D, PhD, Professor, Rhode Island Hospital, The Miriam Hospital, Brown University. Dept of Medicine e Miriam Hospital. Division of Infectious Diseases D, Professor, The Miriam Hospital, Brown University. Division of Infectious Diseases					
	Abstract					
Background & Aim:	This study quantified genital tract HIV–1 RNA (GT–HIV RNA) shedding among women living with HIV (WLHIV) before and after cryotherapy. We conducted a prospective, longitudinal study of 39 WLHIV on antiretroviral treatment (ART) undergoing cryotherapy for VIA–positive lesions in Kenva from 2015–2017. Eligibility for cryotherapy were lesions that					
Methods:	covered <75% of the cervix, with clear margins, no extension into the endocervix and no satellite lesions. Most recent plasma viral load (PVL) was collected from medical records. Endocervical secretions (TearFlo strips) were collected before cryotherapy and at two–weeks and eight–weeks follow–up visits. Abbott Realtime HIV–1 assay quantified GT–HIV RNA before and after cryotherapy.					
Results:	Detectable GT–HIV RNA was found in 4/39 (10.3%) participants pre–cryotherapy, 1/30 (3.3%) 2–weeks post– cryotherapy and 3/26 (11.5%) 8–weeks post–cryotherapy. Only 6/39 (15.4%) participants had detectable GT– HIV RNA at any point. 2/6 had recent high PVL (range: 49,124–150,695 copies/mL) within 3 months of the study and detectable GT–HIV RNA at follow–up visits. 4/6 had undetectable recent PVL within 3–11 months but detectable GT–HIV RNA pre–cryotherapy. The mean GT–HIV RNA among 4/39 WLHIV with shedding pre–cryotherapy was 43,109 (range: 21,812–73,625) copies/mL. Only one participant had GT–HIV RNA (73,125 copies/mL) at 2– weeks post–cryotherapy (N=30); she had no pre–cryotherapy shedding but had a PVL of 49,124 copies/mL 3 months beforehand. The mean GT–HIV RNA at 8–weeks post–cryotherapy was 44,668 (range: 21,256–64,812) copies/mL among 3/26 participants. One of the 3's PVL was 150,695 copies/mL 3 months pre–cryotherapy while 2/3 had detectable pre–cryotherapy GT–HIV RNA despite undetectable most recent PVL. However, their undetectable PVL was 8–11 months prior to cryotherapy which may not accurately reflect PVL at baseline.					
Conclusion:	Most GT-HIV RNA shedding was detected before cryotherapy, which suggests that cryotherapy was not the primary cause of GT-HIV RNA shedding. Non-adherence to ART might have played a major role. The small sample size and failure to perform paired GT-HIV RNA and PVL tests at each visit are limitations of the study.					
Clinical Implications:	Cryotherapy did not increase detectable GT–HIV RNA and thereby risk of sexual transmission of HIV. Further research on cryotherapy's effect on GT–HIV RNA shedding in ART non–adherent compared to ART–adherent WLHIV is needed.					

## Table 1. Plasma and Genital Tract HIV Viral Loads Before and After Cryotherapy of Participants with Detectable Genital Tract HIV RNA

Participant with	Most Recent PVL	GT-HIV RNA Viral Load		
detectable GT- HIV RNA		Pre-cryotherapy	2 weeks post- cryotherapy	8 weeks post- cryotherapy
#1	150,695 copies/mL (3 months pre-cryotherapy)	Undetectable	Undetectable	21,256 copies/mL
#2	49,124 copies/mL (3 months post-cryotherapy)	Undetectable	73,125 copies/mL	Undetectable
#3	Undetectable (4 months pre-cryotherapy)	38,625 copies/mL	Undetectable	Undetectable
#4	Undetectable (1 month pre-cryotherapy)	38,375 copies/mL	No sample	Undetectable
#5	Undetectable (11 months pre-cryotherapy)	73,625 copies/mL	No sample	64,812 copies/mL
#6	Undetectable (8 months pre-cryotherapy)	21,812 copies/mL	No sample	47,937 copies/mL

PVL: plasma viral load, GT-HIV VL: genital tract HIV RNA. Abbott Realtime HIV-1 assay quantified GT-HIV RNA with a detection range of 40 copies/mL to 10 million copies/mL.