Rakai Health Sciences Program
Improved Health Through Research

RAKAI HEALTH SCIENCES **PROGRAM**

ANNUAL REPORT 2021

PEPFAR

CDC Centers for Disease Control and Prevention

NIH National Institutes of Health

Johns Hopkins Bloomberg School of Public Health

The Republic of Uganda Ministry of Health

Rakai Health Sciences Program
Improved Health Through Research

THE RAKAI HEALTH SCIENCES PROGRAM

The Rakai Health Sciences Program (RHSP) is a collaborative not-for-profit health research and service organization with a focus on community-based research, treatment and prevention of HIV and other communicable diseases in 12districts (the Masaka region) of south central Uganda including Kalangala district (84 Islands).

The Rakai Health Sciences Program was established as the Rakai Project in 1987 to investigate the epidemiology of HIV/AIDSffirst identified in East Africa by Drs. David Serwadda, Nelson Sewankambo and Maria Wawer. It was expanded in 1994 as the Rakai Community Cohort Study to conduct a community randomized trial of STD Control for HIV Prevention, subsequent trials of male circumcision for HIV prevention and research on the impact of prevention on HIV incidence. The Rakai Community Cohort has provided the population base for numerous nested studies of prevention interventions, services, clinical and social behavioral studies, basic science including phylogenetics, immunology, the genital microbiome and the HIV resevoir.

Rakai Health Sciences Program Status Report 2021

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OUR VISION, MISSION & VALUES

VISION STATEMENT

To excel in **HEALTH RESEARCH, DISEASE PREVENTION** and **CARE.**

MISSION STATEMENT

To conduct innovative health research on infectious diseases, non-communicable diseases and reproductive health, and to provide health services to improve public health and inform policy.

OBJECTIVES AND STRATEGIC DIRECTIONS

- To conduct research relevant to Uganda and internationally, on HIV, other infectious diseases, reproductive health, and non-communicable diseases
- To integrate research in epidemiology, demography, clinical, laboratory and social sciences
- To improve and develop infrastructure in support of research and service delivery in the Masaka region of Uganda.
- To build human capacity via training and provision of a career structure for Ugandan investigators and senior staff
- To create and build the program as a long-term, sustainable Ugandan national resource

CORE VALUES

Creativity, Respect, Excellence, Accountability, Integrity, Team Work, Efficiency are the fundamental principles of RHSP which denote its organizational culture and create a unique environment for health research and services.

CONTENTS

ACRONYMS

ART	Antiretroviral Treatment
COVID-19	Coronavirus Disease 2019
SARS COV 2	Severe Acute Respiratory Syndrome Coronavirus 2
RCCS	Rakai Community Cohort Study
AGYW	Adolescents Girls and Young Women
HIV	Human Immunodeficiency Virus
TB	Tuberculosis
FSW	Female Sex Workers
MSM	Men Who Have Sex With Men
PWIDs	People Who Inject Drugs
VMMC	Voluntary Medical Male Circumcision
LGBT	Lesbian, Gay, Bisexual, and Transgender
AYAs	Adolescents and Young Adults
PY	Person Years
VL	Viral Load
UTT	Universal Test and Treat
PrEP	Pre-Exposure Prophylaxis
CP-NCD	Cardiopulmonary Non-communicable Diseases
CHP	Combination HIV Prevention
MOH	Ministry of Health
PCR	Polymerase Chain Reaction
CHWs	Community Health Workers
POC	Point of Care
CBO	Community Based Organisations
CSO	Civil Society Organization
OVC	Orphans and Vulnerable Children
M&E	Monitoring and Evaluation
KP	Key Population
SOP	Standard Operating Procedure

MESSAGE FROM THE BOARD CHAIR

The past 2 years have been extremely challenging with the outbreak of COVID-19 which claimed many lives and has had impact not only on individual and community health but has severely affected income and livelihoods. At RHSP we have gone to great length in ensuring the safety of our staff and those we work with closely in different communities. In a special way I would like to thank the management and staff of RHSP for their perseverance and persistence to keep working through these challenging times. The resourcefulness of our fellow scientists and funders in curbing the impact of COVID-19 has been a great support, and a tribute to their commitment to serve the people of Uganda.

" THE GREAT WORK AND SUPPORT FROM FUNDERS AND PARTNERS HAS ENABLED US ACCOMPLISH ALOT."

Further, the COVID lockdown came at a time when heavy rains across the country made majority of our region of operation inaccessible and hard to reach due to flooded roads and broken bridges. Our frontline staff had to use boats to reach some communities that were cut off by floods, while others had to commune in neighborhoods that were converted as community distribution points to avail health delivery services for those in areas unreachable by vehicles. Rakai Community Cohort Study - RCCS, our biggest cohort had to operate from premises of closed schools to ensure continuity of collection of data on different research studies. We adopted a highly virtual approach to supervising and networking field work engagements. We worked with 12 District Taskforces across Masaka region to combat the epidemic and it was an amazing opportunity working with World Health Organisation - WHO and other partners. The tenacity of the teams never wavered, and I am glad to say we came out strong.

This year our current PEPFAR/CDC grant comes to an end but we look forward to continuing our symbiotic collaboration with CDC to enable us in delivering HIV health services in Masaka region especially to communities and individuals impacted by HIV. Cognizant of the evolving expectations of our stakeholders, our commitment to provision of quality services is continuously hinged on opening up more networks that provide new strategies and technologies on service delivery.

My great gratitude to our staff, the communities we have worked in over the years, the local government and community based organizations, international service partners and research collaborators across the globe for their continued commitment to supporting us deliver on our purpose and strategy every day. Through our synergy I am confident we shall achieve more in future as we continue to make a difference in the lives of people.

D. Serwadda

Professor David Serwadda

"THESE ACHIEVEMENTS WOULD NOT HAVE BEEN POSSIBLE WITHOUT THE SUPPORT AND COMMITMENTS OF VARIOUS STAKEHOLDERS"

ACKNOWLEDGEMENTS FROM THE EXECUTIVE DIRECTOR

Despite the COVID-19 constraints over the last two years, RHSP resiliently and innovatively continued to support HIV Services and research activities in strict observance of COVID-19 SOPs. In the PEPFAR supported Masaka region, we identified over 11,000 new HIV-positive persons (274% of the target), linked 96% of them to HIV care and cumulatively supported over 130,000 patients in HIV care with minimal (~2%) loss out of care. As a result of our rapid scale-up of ART services in the Masaka region, ~ 79 percent of all HIV-positives were virally suppressed by 2020 (UPHIA 2020)—surpassing the UNAIDS 2020 95-95-95 target. Over 130,000 Adolescent girls and young women (AGYWs) graduated out of DREAMS programs, and we cumulatively circumcised over 333,000 males and provided services to over 42,000 individuals from key population groups (FSW, TGW, PWIDs, and MSM).

Mother to Child Transmission (MTCT) has declined from 4.5% (2017), 2.5% (2018) to 1.4% in 2021. As the population living with HIV ages, we look forward to integrating non-communicable diseases management (hypertension, diabetes mellitus and mental health services) into the HIV chronic care management platform.

On the research front, our community cohort surveillance has registered an important historical landmark—the 20th round of survey (~27 years of surveillance). This provides a great opportunity to study long-term trends of HIV outcomes and evaluation of the ever-improving package of combination HIV service programs. In this report we are excited to highlight some of our new findings including continued drastic declines in HIV incidence; the role of the latent HIV reservoir in HIV cure research; the influence of social structural determinants and transitions on HIV outcomes among adolescents; predictors of persistent population HIV viremia; effect of hard-to-reach populations on HIV estimates, and implications on HIV elimination; among others. We also look forward to results from ongoing studies including the WIN study: examining the effect on HIV incidence and services coverage, of a program using community scouts to identify new migrants and link them to HIV services; and the VICINITY study: effect of rural to urban migration on non-communicable disease outcomes and how this effect is modified by HIV status. I invite you to review this report and hope you find it informative.

J. Kagaayi

Dr Joseph Kagaayi

RESEARCH

1 STUDIES OF HSV-2 ACTIVATION, LATENT RESERVOIR AND VIRAL LOAD MONITORING.

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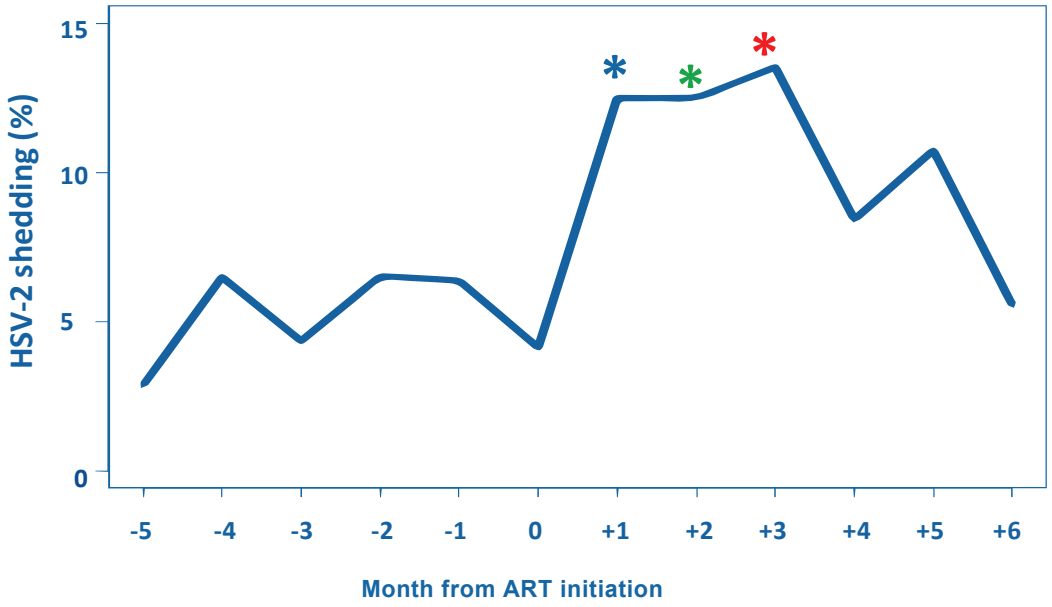
HERA - HERPES VIRUSES REACTIVATION IN HIV INFECTED WOMEN INITIATING ART.

Initiation of antiretroviral therapy (ART) can lead to a short-term increase of herpes virus-related illnesses including genital herpes flares, higher likelihood of varicella zoster virus (VZV), cytomegalovirus (CMV) uveitis or other end-organ disease, and herpes simplex virus (HSV)-associated encephalitis. Herpesvirus reactivation upon ART initiation may be related to immune restoration disease of immune reconstitution inflammatory syndrome (IRIS), but the etiology is unclear. We hypothesize that ART initiation can induce herpesvirus reactivation causing increased cellular, systemic, and localized immune activation and that alterations of interferon (IFN) pathways during initial HIV viral suppression are involved in this reactivation.

To investigate these mechanisms, we propose to document the incidence of clinical herpetic disease and viral shedding in vaginal and oral secretions from HIV-positive women initiating ART and to assess the associations between viral shedding or clinical disease and cellular, mucosal, and systemic immune activation. We will determine the role of IFN pathway in herpesvirus reactivation following initiation of ART. We will also evaluate the potential impact of herpesvirus reactivation on HIV cellular reservoirs by comparing residual HIV plasma viral replication and cell-associated virus prior to and 52 weeks after ART initiation. All follow-up visits for this study were completed in October 2020 and laboratory investigations are ongoing. The figure shows HSV-2 shedding following ART initiation and the table shows the reduction of shedding with Acyclovir use.



	-5	-4	-3	-2	-1	0	+1	+2	+3	+4	+5	+6
Total (HSV-2 shedding/visits)	2/70	5/77	4/92	6/92	6/94	4/95	12/95	12/95	13/95	7/94	9/92	5/89
(Percentage)	2.9%	6.5%	4.4%	6.5%	6.4%	4.2%	12.6%	12.6%	13.7%	7.4%	9.8%	5.6%
Acyclovir (HSV-2 shedding/visits)	0/29	0/30	0/38	0/36	0/27	0/23	0/22	1/22	2/21	0/18	1/13	0/9
(Percentage)	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	4.5%	9.5%	0.0%	7.7%	0.0%
Placebo (HSV-2 shedding/visits)	2/41	5/47	4/54	6/56	6/67	4/72	12/73	11/73	11/74	7/76	8/79	5/80
(Percentage)	4.9%	10.6%	7.4%	10.7%	9.0%	5.6%	16.4%	15.1%	14.9%	9.2%	10.1%	6.3%

A team of RHSP and MOH health worker during a home visit delivering ART treatment refills in Matete, Sembabule district.

LATENT RESERVOIR STUDY

The major barrier to curing HIV infection is the persistence of HIV in latently infected resting memory CD4+ T cells. Previous work from the RHSP/ICER Uganda teams found that the latent viral reservoir (LVR) in the Ugandan population is over 3-fold smaller than that of a previously reported American population. However, the Ugandan samples were largely from females whereas the US samples were from males, and the reservoir in men is usually greater than in women.

We found that Ugandan women have a significantly smaller replication competent LVR compare to Ugandan men. In addition, we identified unique immunological and clinical characteristics between the two sexes of treated Ugandans. In particular, we found that LVR size of men, but not women, was correlated with PD-1 expression. This work highlighted the need for expanded studies of women in HIV Cure research. This work is continuing with a detailed longitudinal analysis of changes in the reservoir and clonality in these individuals.

Researchers at RHSP, in collaboration with the IHSS/ICER Uganda, were included as a study-site and co-investigator for the Research Enterprise to Advance a Cure for HIV (REACH) Delaney HIV Cure consortium. As part of REACH, RHSP will continue to examine the latent reservoir cohort using novel reservoir monitoring technology developed through the consortium. In particular, REACH is designing an updated HIV subtype universal IPDA - Intact Proviral DNA Assay and plans to test this assay in Uganda.

REACH

For the Cure

Research **E**nterprise to **A**dvance a **C**ure for **HIV**

Blood being drawn from a client during a field visit in Rakai district

CLINICAL RESEARCH FOCUSING ON HIV CARE

Viral load (VL) monitoring is recommended for all HIV clients on ART, but identification of clients likely to experience early virologic failure (VF) could inform differentiated long-term monitoring strategies. We evaluated the predictive value of VL testing at 6 and 12 months after initiation of first-line ART to estimate the future risk of VF. The 12 months VL measurement was found to be highly predictive of long-term VF outcomes.

Compared to clients with VL<400 copies/ml at 12 months after ART initiation, the adjusted hazard ratios of VF were 6.46 (95% CI=2.7-15.7) in clients with VLs of 400-1000 copies/ml, 7.71 (95% CI=2.7-22.1) in clients with VLs of 1001-2000 copies/ml and 25.81 (95% CI=14.8-44.9) in clients with VLs greater than 2000 copies/ml. VL monitoring could facilitate differentiated care strategies currently promoted by WHO and PEPFAR by identifying individuals who could benefit from intensive monitoring to circumvent adherence challenges.

Routine viral load testing being done on a baby at the RHSP ART clinic.

2

SSTAR - STRUCTURAL AND SOCIAL TRANSITIONS AMONG ADOLESCENTS IN RAKAI

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Tusabe Robert a YAPS with guidance from Nantongo Annet, an enrolled nurse from Bigasa HCIII delivering ART medication during a home visit in Mukoza village, Bukomansimbi district.

THE MAJOR GOAL OF THIS SSTAR IS TO INVESTIGATE THE INFLUENCE OF SOCIAL STRUCTURAL DETERMINANTS AND TRANSITIONS FROM ADOLESCENCE TO ADULTHOOD ON HIV ACQUISITION.

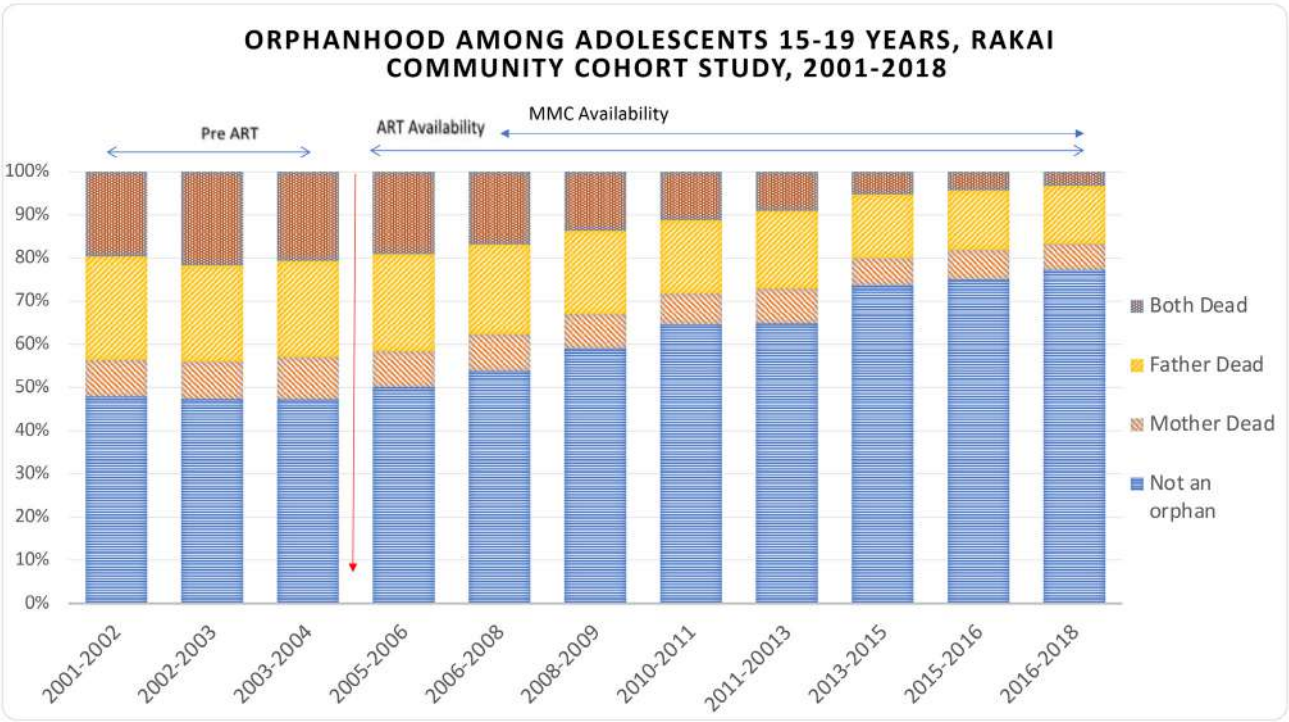
PUBLISHED QUANTITATIVE STUDIES USING RCCS DATA

The Impact of HIV Combination Prevention on Declining Orphanhood Among Adolescents, Rakai, Uganda, 2001-2018 (Preprint - Updated 16 April 2021) (SSRN Scholarly Paper ID 3835741). The Lancet HIV. https://doi.org/10.2139/ssrn.3835741

Orphanhood increased dramatically in the 1980s and 1990s in sub-Saharan Africa (SSA) due to HIV mortality among parents. Little is known about the contribution of HIV interventions such as antiretroviral therapy (ART) and male medical circumcision (MMC) to more recent trends in orphanhood. We examined the prevalence of orphanhood among adolescents 15-19 years, before and after roll out of ART beginning in mid 2004 and MMC in 2007, using data from 28 continuously followed communities within the Rakai Community Cohort Study (RCCS). We used multinomial logistic regression (MLR) with clustered standard errors to estimate adjusted relative risk ratios (adj.RRR) for maternal-only, paternal-only, and double orphanhood compared to non-orphanhood over 11 survey rounds between 2001 and 2018. Controlling for community HIV prevalence, household socioeconomic status (SES), and adolescent age, we examined the association between community prevalence of ART use among people living with HIV (PLWHIV) and prevalence of male circumcision (MC) including traditional circumcision.

As shown in figure Orphanhood declined from 52% in 2001-2002 to 23% by 2016-2018 ($p<0.001$), while double orphanhood declined from 20% to 3% ($p<0.001$) over the same time period. Community prevalence of ART use rose from 11% in 2005-2006 to 78% in 2016-2018 and MMC rose from 19% to 65%. In the MLR model, a 10% increase in community prevalence of ART use was associated with a decrease in maternal orphanhood (adj.RRR=0.90, 95% CI=0.85-0.95) and double orphanhood (adj.RRR=0.80, 95% CI=0.75-0.85). Likewise, a 10% increase in the community prevalence of MMC was associated with a decrease in paternal orphanhood in 2005-2018 (adj.RRR=0.92, 95% CI=0.86-0.97), and double orphanhood (adj.RRR=0.91, 95% CI=0.85-0.98). Widespread availability and uptake of HIV combination prevention was associated with dramatic reductions in orphanhood among adolescents. Reductions in orphanhood promise improved health and social outcomes for young people.

Figure 2. Adolescent orphanhood before and after ART and MMC availability



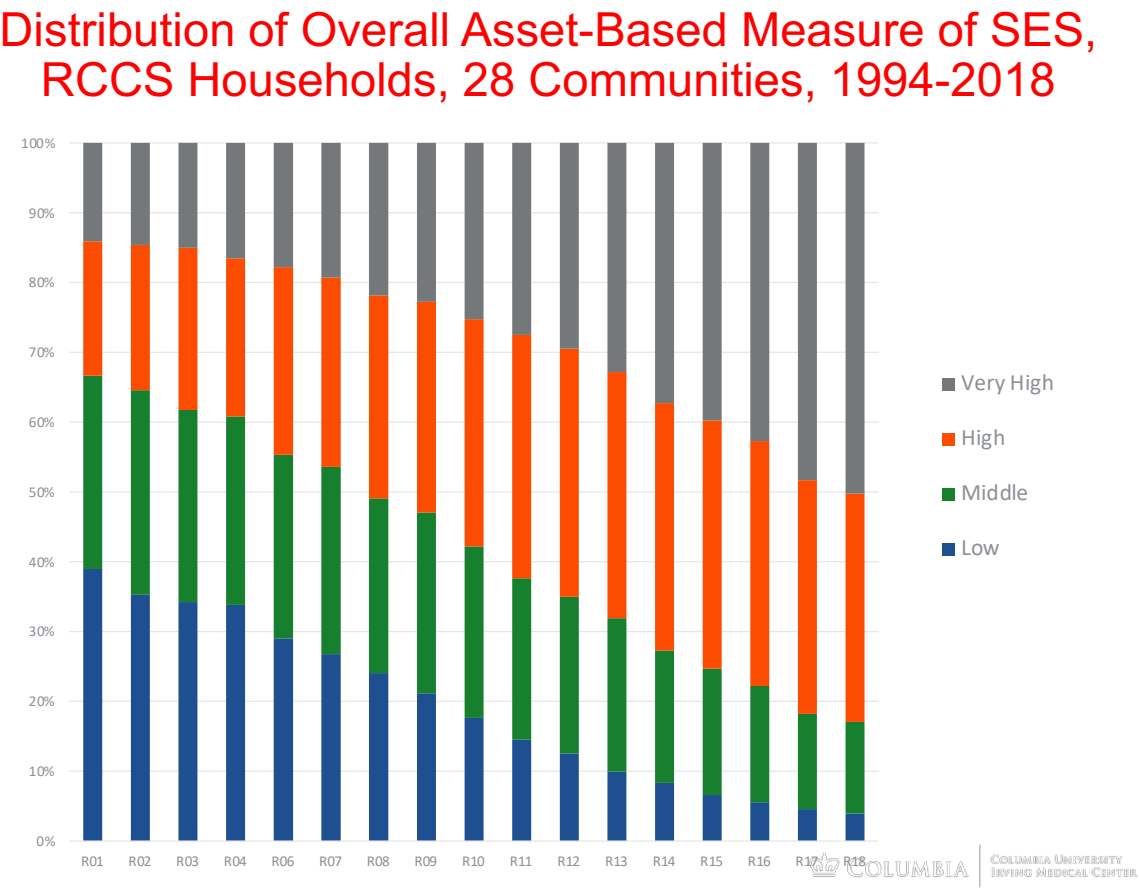
Household wealth and HIV incidence over time, rural Uganda, 1994–2018. AIDS (London, England), 35(11), 1835–1843. https://doi.org/10.1097/QAD.0000000000002989

We examined the relationship between household wealth and HIV incidence in rural Uganda from 1994 to 2018. In research conducted early in the epidemic, greater wealth (i.e. higher socioeconomic status, SES) was associated with higher HIV prevalence in sub-Saharan Africa (SSA); this relationship reversed in some settings in later years. Analysis of associations over time in a population-based open cohort of persons 15–49 years from 17 survey-rounds in 28 continuously followed communities of the Rakai Community Cohort Study (RCCS).

The RCCS sample averaged 8622 individuals and 5387 households per survey. Principal components analysis was used to create a nine-item asset-based measure of household wealth. Poisson regression with generalized estimating equation(GEE) and exchangeable correlation structure was used to estimate HIV incidence rate ratios (IRRs) by SES quartile, survey-round, sex, and age group. From 1994 to 2018, SES rose considerably (Fig 3), and HIV incidence declined from1.45 to 0.40 per 100 person-years (IRR 0.39, 95% CI 0.32–0.47, P<0.001).

HIV incidence was similar by SES quartile in 1994–1997; however, higher SES groups showed greater declines in HIV incidence over time. Multivariable analyses showed significant associations between HIV incidence and SES (aIRR 0.55 for highest compared with lowest quartile, 95% CI 0.45–0.66, P<0.001) controlling for time, sex, and age group. The association between higher SES with lower HIV incidence widened over time. The poor, like other key populations, should be targeted for HIV prevention, and treatment.

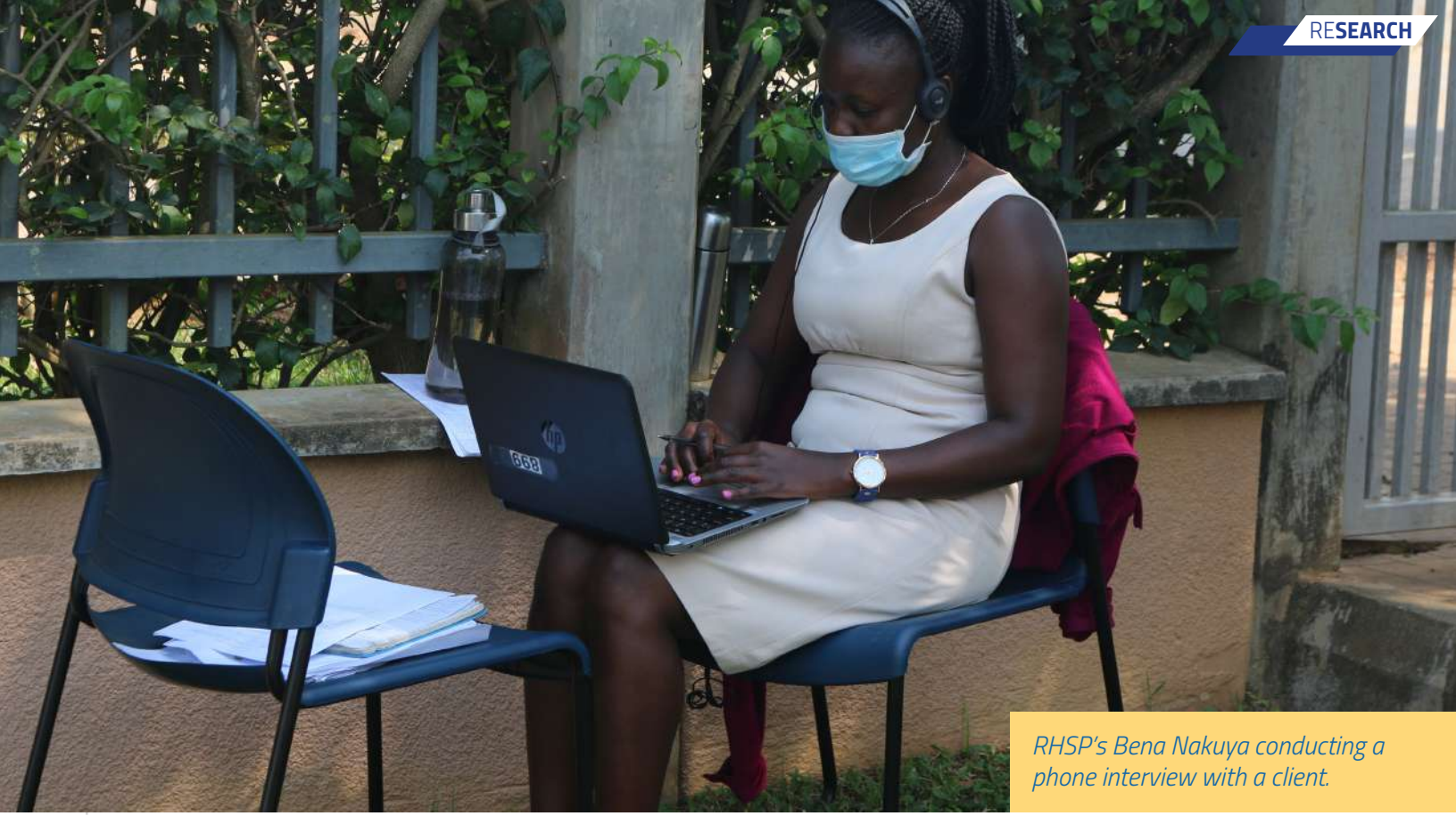
Figure 3.



Cell phones, sexual behaviors and HIV prevalence in Rakai, Uganda. (2020). AIDS & Behavior. 24(5):1574-1584. PMC7241097 https://doi-org.ezproxy.cul.columbia.edu/10.1007/s10461-019-02665-8

Cell phones have increased communication and connection across the globe, particularly in sub-Saharan Africa—with potential consequences for the HIV epidemic. We examined the association between ownership of cell phones, sexual behaviors (number of sexual partners, alcohol use before sex, inconsistent condom use, and HIV prevalence. Data were from four surveys (2010–2016) of the Rakai Community Cohort Study (N = 58,275). Sexual behaviors and HIV prevalence were compared between people who owned a cell phone to people who did not own a cell phone. We stratified analysis by younger (15–24 years) and older (25+ years) age groups and by gender.

Using logistic regression and after adjusting for sociodemographic characteristics, we found cell phone ownership was independently associated with increased odds of having two or more sexual partners in the past 12 months across age and gender groups (young men AOR 1.67, 95% CI 1.47–1.90; young women AOR 1.28 95% CI 1.08–1.53; older men AOR 1.54 95% CI 1.41–1.69; older women AOR 1.44 95% CI 1.26–1.65).Young men who owned cell phones had decreased odds of using condoms inconsistently (AOR 0.66, 95% CI 0.57–0.75). For young women, cell phone ownership was associated with increased odds of using alcohol before sex (AOR 1.38 95% CI 1.17–1.63) and increased odds of inconsistent condom use (AOR 1.40, 95% 1.17–1.67). After adjusting for sociodemographic characteristics, only young women who owned cell phones had increased odds of being HIV positive (AOR 1.27 95% CI 1.07–1.50). This association was not mediated by sexual behaviors. While cell phone ownership appears to be associated with increased HIV risk for young women, we also see a potential opportunity for future cell phone-based health interventions.



RHSP's Bena Nakuya conducting a phone interview with a client.

Mobile phones, sexual behaviors and HIV incidence in Rakai, Uganda from 2010-2018. (Accepted in JAIDS, but not yet published).

In the past decade mobile phone ownership in sub-Saharan Africa has doubled – impacting social and sexual practices. Using longitudinal data, this study examined if mobile phone ownership was associated with sexual behaviors and HIV incidence for youth and adults. The Rakai Community Cohort Study gathers demographic and sexual health information and conducts HIV testing among an open cohort in southcentral Uganda every 12-18 months. Of the 10,618 participants, 58% owned a mobile phone, 69% lived in rural locations and 77% were sexually active. Analyses were adjusted for time, location, religion and socioeconomic status.

Phone ownership was associated with increased odds of ever having had sex for 15-19-year-olds (men AOR 2.12, 95% CI 1.78-2.52 and women AOR 3.20, 95% CI 2.45-4.17). Among sexually active participants, owning a phone was associated with increased odds of having 2 or more concurrent sex partners (15-24-year-old men AOR 1.76, 95% CI 1.34-2.32; 25-49-year-old men AOR 1.81, 95% CI 1.54–2.13; 25-49-year-old women AOR 1.81, 95% CI 1.32-2.49). For men, phone ownership was associated with increased odds of circumcision (15-24-year-old men AOR 1.24, 95% CI 1.08-1.41; 25-49-year-old men AOR 1.12, 95% CI 1.01-1.24). Phone ownership was not associated with HIV incidence. Although mobile phone ownership was associated with sexual risk behaviors, it was not associated with increased risk of HIV acquisition.

PUBLISHED QUALITATIVE STUDIES USING SOCIAL BEHAVIOR SCIENCES (SBS) DATA

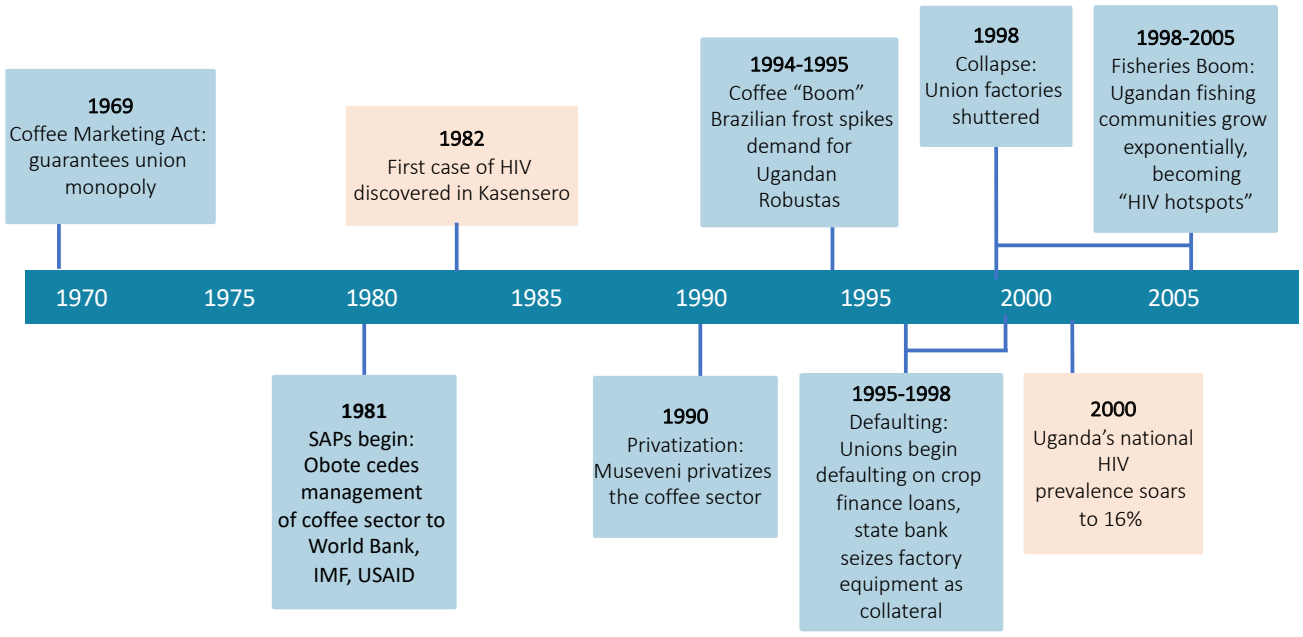
Debating Sex and Sovereignty: Uganda's New National Sexuality Education Policy. Sexuality Research and Social Policy. Moore, E. V., Hirsch, J. S., Spindler, E., Nalugoda, F., & Santelli, J. S. (2021) https://doi.org/10.1007/s13178-021-00584-9

Public outcry over comprehensive sexuality education erupted in 2016 over claims that children were being taught "homosexuality" by international NGOs. Subsequent debates over sex education revolved around defending what public figures claimed were national, religious, and cultural values from foreign infiltration. Methods This paper is grounded in a survey of Uganda's two English language national newspapers (2016–2018), archival research of newspapers held at Uganda's Vision Group media company (1985–2005), analyses of public rhetoric as reported in internationally

and nationally circulating media, textual analysis of Uganda's National Sexuality Education Framework (2018), formal interviews with Ugandan NGO officers (3), and semi-structured interviews with Ugandan educators (3). Results Uganda's current panic over sex education reignited longstanding anxieties over foreign interventions into the sexual health and rights of Ugandans. We argue that in the wake of a 35-year battle with HIV/AIDS and more recent controversies over LGBT rights, both of which brought international donor resources and governance, the issue of where and how to teach young people about sex became a new battleground over the state's authority to govern the health and behaviors and economic prosperity of its citizens. Conclusions Ethno- and religio-nationalist rhetoric used to oppose the state's new sexuality education policy was used to justify sex education as a tool for economic development. Policy Implications Analyzing rhetoric mobilized by both supporters and detractors of sex education reveals the contested political terrain policy advocates must navigate in Uganda.

When Coffee Collapsed: An Economic History of HIV in Uganda, Medical Anthropology, Moore, E.V., Nambi, R., Isabirye, D., Nakyanjo, N., Nalugoda, F., Santelli, J.S. & Hirsch, J. S. (2021) DOI:10.1080/01459740.2021.1961249

In some Ugandan fishing communities, almost half the population lives with HIV. Researchers designate these communities "HIV hotspots" and attribute disproportionate disease burdens to "sex-for-fish" relationships endemic to the lakeshores. In this article, we trace the emergence of Uganda's HIV hotspots to structural adjustment. We show how global economic policies negotiated in the 1990s precipitated the collapse of Uganda's coffee sector, causing mass economic dislocation among women workers, who migrated to the lakeside fishing communities where they entered overt forms of sex work or marriages they might otherwise avoided, arrangements that promoted the spread of HIV.



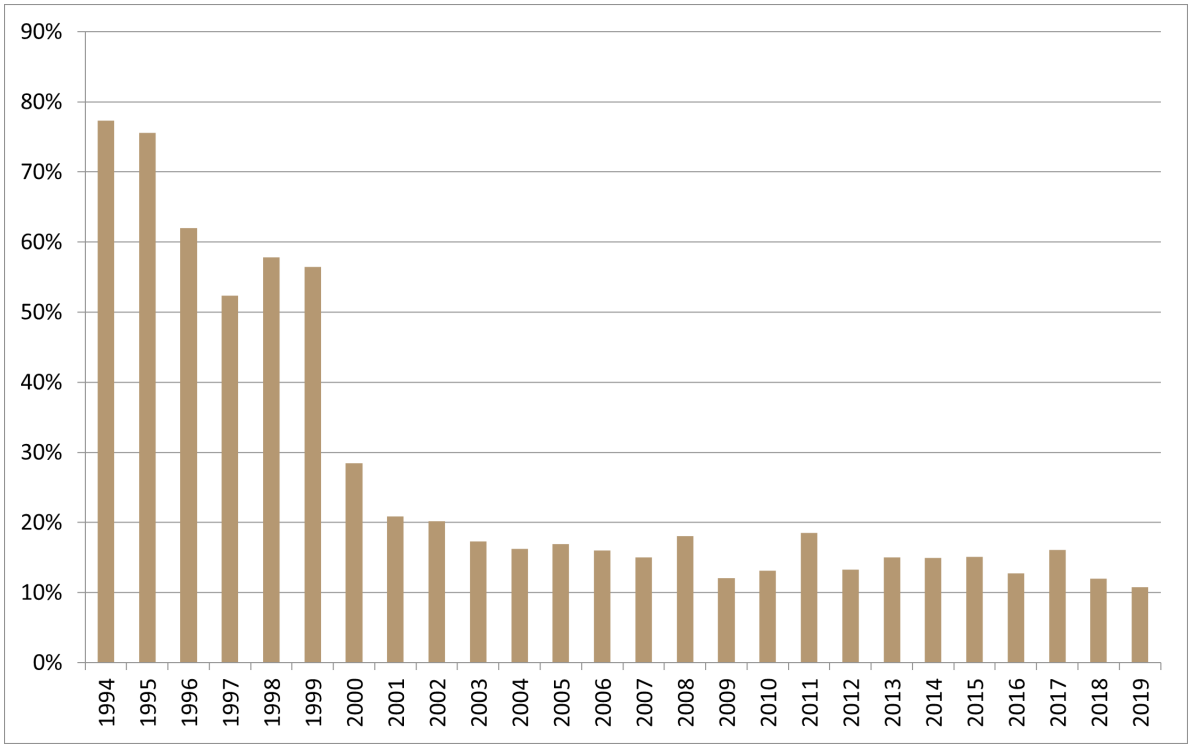


Figure 4. Coffee has long been Uganda's most exported commodity. This chart shows its percentage of Uganda's Total Export Revenue for as long as the Bank of Uganda has collected data. The coffee sector boomed from 1994–1995; southcentral Uganda's union factories were shuttered by 1998 (Bank of Uganda 2019).

The promise and peril of mobile phones for youth in rural Uganda: A multi-method study of implications for health and HIV. Kreniske, P., Basmajian, A.*, Nakayanjo, N., Dadaaki, W., Isabirye, D., Ssekyewa, C., Nakubulwa, R., Hirsch,J., Nalugoda, F. Chang, L. W., & Santelli, J. S. 23(2). Journal of Medical Internet Research (JMIR) (2021). https://www.jmir.org/2021/2/e17837/ PMID33528375

In East Africa, owning a cell phone is rapidly becoming essential for acquiring information and resources. Our analysis illuminates the perils and potential promise of mobile phones with implications for future interventions to promote the health of adolescents and young adults (AYAs) and to prevent HIV infection. The aim of this study is to describe the current state of AYAs' phone use the implications for mobile health interventions.

We identified 2 trading centers representative of southern Uganda. We stratified the sample of potential informants by age (15-19 years and 20-24 years), gender, and phone ownership and randomly sampled 31 key informant interview participants within these categories. In addition, we conducted 24 ethnographic participant observations among AYAs. AYA frequently reported barriers to using their phones, such as difficulty accessing electricity. Nearly all AYAs used mobile phones to participate in the local economy and communicate with sexual partners.

Phone use was frequently a point of contention between sexual partners, with many AYAs reporting that their sexual partners associated phone use with infidelity. Few AYAs reported using their phones for health-related purposes, with most getting health information in person from health workers. However, most AYAs reported an instance when they used their phone in an emergency, with childbirth-related emergencies being the most common. Finally, most AYAs reported that they would like to use their phones for health purposes and specifically stated that they would like to use their mobile phones to access HIV prevention information. This study demonstrates how mobile phones are related to income-generating practices in the region and communication with sexual partners but not access to health and HIV information.. Mobile phones have untapped potential to serve as tools for health promotion and HIV prevention.

3 EFFECTIVENESS OF VOLUNTARY MEDICAL MALE CIRCUMCISION

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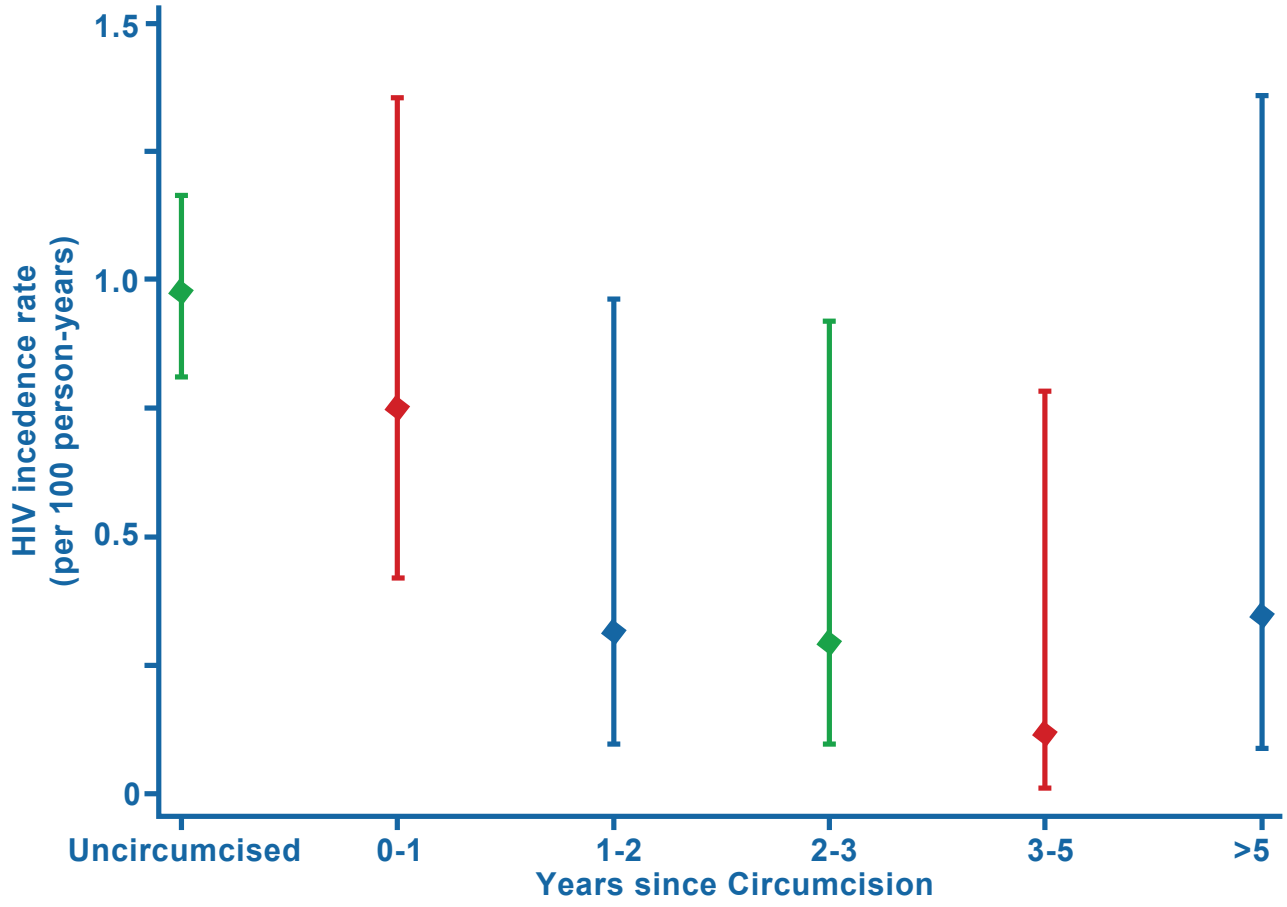
RHSP's Daniel Kayiwa supervising trainees during a circumcision procedure at Nakivale Camp Health Centre in Isingiro district.

EFFECTIVENESS OF VOLUNTARY MEDICAL MALE CIRCUMCISION FOR HUMAN IMMUNODEFICIENCY VIRUS PREVENTION IN RAKAI, UGANDA.

The efficacy of voluntary male medical circumcision (VMMC) for human immunodeficiency virus (HIV) prevention in men was demonstrated in 3 randomized trials. This led to the adoption of VMMC as an integral component of the United States President's Emergency Plan for AIDS Relief (PEPFAR) combination HIV prevention program in sub-Saharan Africa. However, evidence on the individual-level effectiveness of VMMC programs in real-world, programmatic settings is limited.

We followed a cohort of initially uncircumcised, non-Muslim, HIV-uninfected men in the Rakai Community Cohort Study in Uganda between 2009 and 2016 during VMMC scale-up. Self-reported VMMC status was collected and HIV tests performed every 18 months. We followed a total of 3916 non-Muslim men for 17 088 person-years (PY). There were 1338 newly reported VMMCs (9.8/100 PY). Over the study period, the median age of men adopting VMMC declined from 28 years to 22 years. HIV incidence was 0.40/100 PY (20/4992.8 PY) among newly circumcised men compared to 0.98/100 PY (118/12 095.1 PY) among uncircumcised men with an adjusted Incidence Rate Ratio (IRR) of 0.47 (95% CI .28-.78). The effectiveness of VMMC was sustained with increasing time from surgery and was similar across age groups and calendar time. The observed effectiveness is consistent with the efficacy in clinical trials and supports current recommendations that VMMC is a key component of programs to reduce HIV incidence.

Figure 5, HIV incidence over time following VMMC Longitudinal effectiveness of voluntary male medical circumcision for HIV prevention. HIV incidence per 100 person-years by time sinceVMMC in years.



4 PREVALENCE AND PREDICTORS OF PERSISTENT HUMAN IMMUNODEFICIENCY VIRUS VIREMIA AND VIRAL REBOUND AFTER UNIVERSAL TEST AND TREAT: A POPULATION BASED STUDY

Rakai Health Sciences Program
Improved Health Through Research

PREVALENCE AND PREDICTORS OF PERSISTENT HUMAN IMMUNODEFICIENCY VIRUS VIREMIA AND VIRAL REBOUND AFTER UNIVERSAL TEST AND TREAT: A POPULATION-BASED STUDYPERFORMANCE AND OUTLOOK

There are limited data on HIV viral load (VL) trajectories at the population-level after the introduction of universal test and treat (UTT) in sub-Saharan Africa. We assessed VLs among HIV-positive participants through 3 RCCS rounds in 4 Ugandan fishing communities surveyed between November 2011 and August 2017.

The unit of analysis was a visit-pair (2 consecutive person-visits), which were categorized as durable VL suppression, new/renewed VL suppression, viral rebound, or persistent viremia. We followed 1346 HIV+ participants (n = 1883 visit-pairs). The population-level prevalence of durable VL suppression increased from 29.7% to 67.9% during UTT rollout, viral rebound declined from 4.4% to 2.7%, and persistent viremia declined from 20.8% to 13.3%. Younger age (15–29 vs 40–49 years), male sex, never being married (vs currently married), and recent migration to the community (vs long-term resident) were associated with persistent viremia. Despite increases in durable VL suppression during roll out of UTT in hyperendemic communities, a substantial fraction of the population, whose risk profile tended to be younger, male, and mobile, remained persistently viremic.

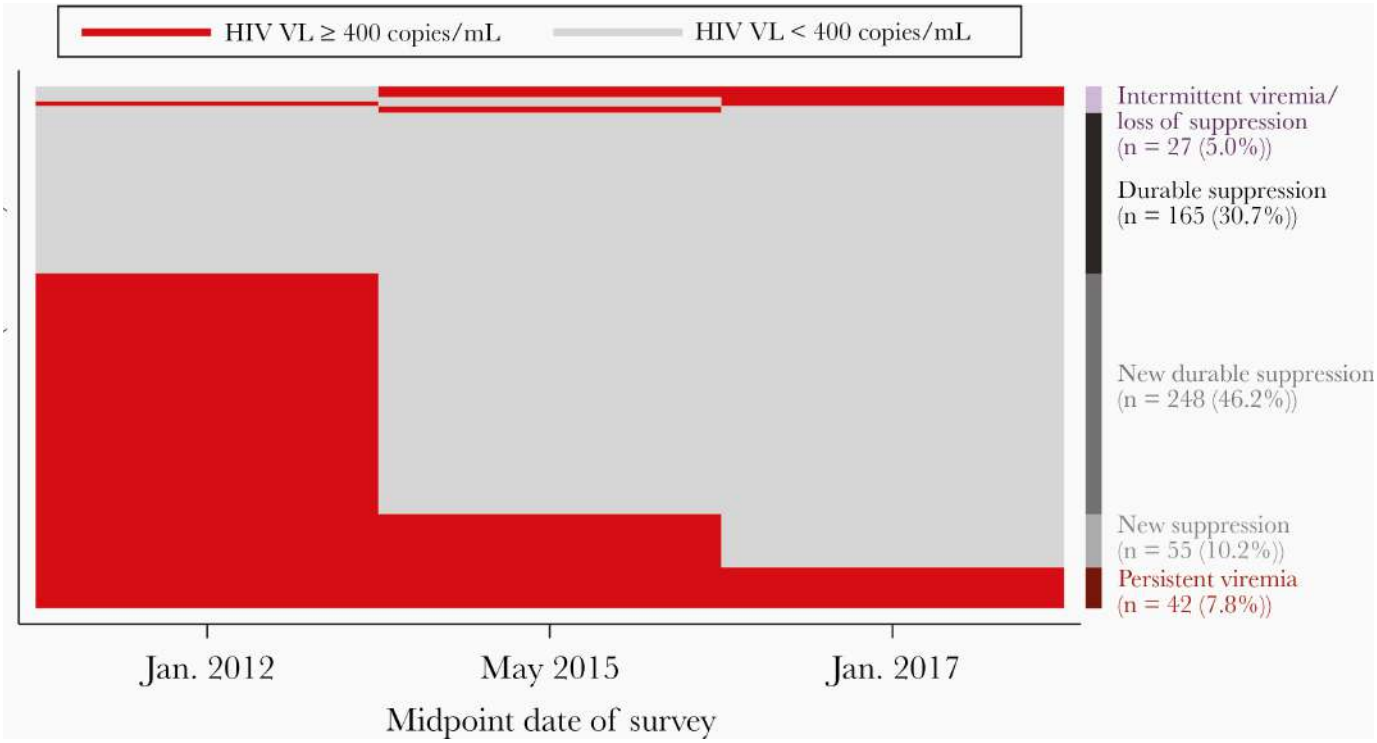


Figure 6. Longitudinal patterns in human immunodeficiency virus (HIV) viral load (VL) suppression among a closed population of HIV-positive participants observed at all 3 surveys. Note: Each row (ie, line) represents the viral load trajectory of a single study participant. The x-axis is not drawn to scale.

5 QUALITATIVE ASSESSMENT OF BARRIERS AND FACILITATORS OF PreP

Rakai Health Sciences Program
Improved Health Through Research

QUALITATIVE ASSESSMENT OF BARRIERS AND FACILITATORS OF PREP USE BEFORE AND AFTER ROLLOUT OF A PREP PROGRAM FOR PRIORITY POPULATIONS IN SOUTH-CENTRAL UGANDA

Uganda piloted HIV pre-exposure prophylaxis (PrEP) for priority populations (sex workers, fishermen, truck drivers, HIV discordant couples) in 2017. To assess facilitators and barriers to PrEP uptake and adherence, we explored perceptions of PrEP before and experiences after rollout among community members and providers in south-central Uganda. We conducted 75 in-depth interviews and 12 focus group discussions.

We analyzed transcripts using a team-based thematic framework approach. Partners, family, peers, and experienced PrEP users provided adherence support. Occupational factors hindered adherence for sex workers and fishermen, particularly related to mobility. Pre-rollout concerns about unskilled/untrained volunteers distributing PrEP and price-gouging were mitigated. After rollout, awareness of high community HIV risk and trust in PrEP effectiveness facilitated uptake. PrEP stigma and unexpected migration persisted as barriers. Community-initiated, tailored communication with successful PrEP users may optimize future engagement by addressing fears and rumors, while flexible delivery and refill models may facilitate PrEP continuation and adherence.

6 PREVALENCE OF UNTREATED HIV AND ASSOCIATED RISK BEHAVIORS

Rakai Health Sciences Program
Improved Health Through Research

A WIN (Welcome Incoming Neighbor) scout interacting with a new migrant in Kyotera district.

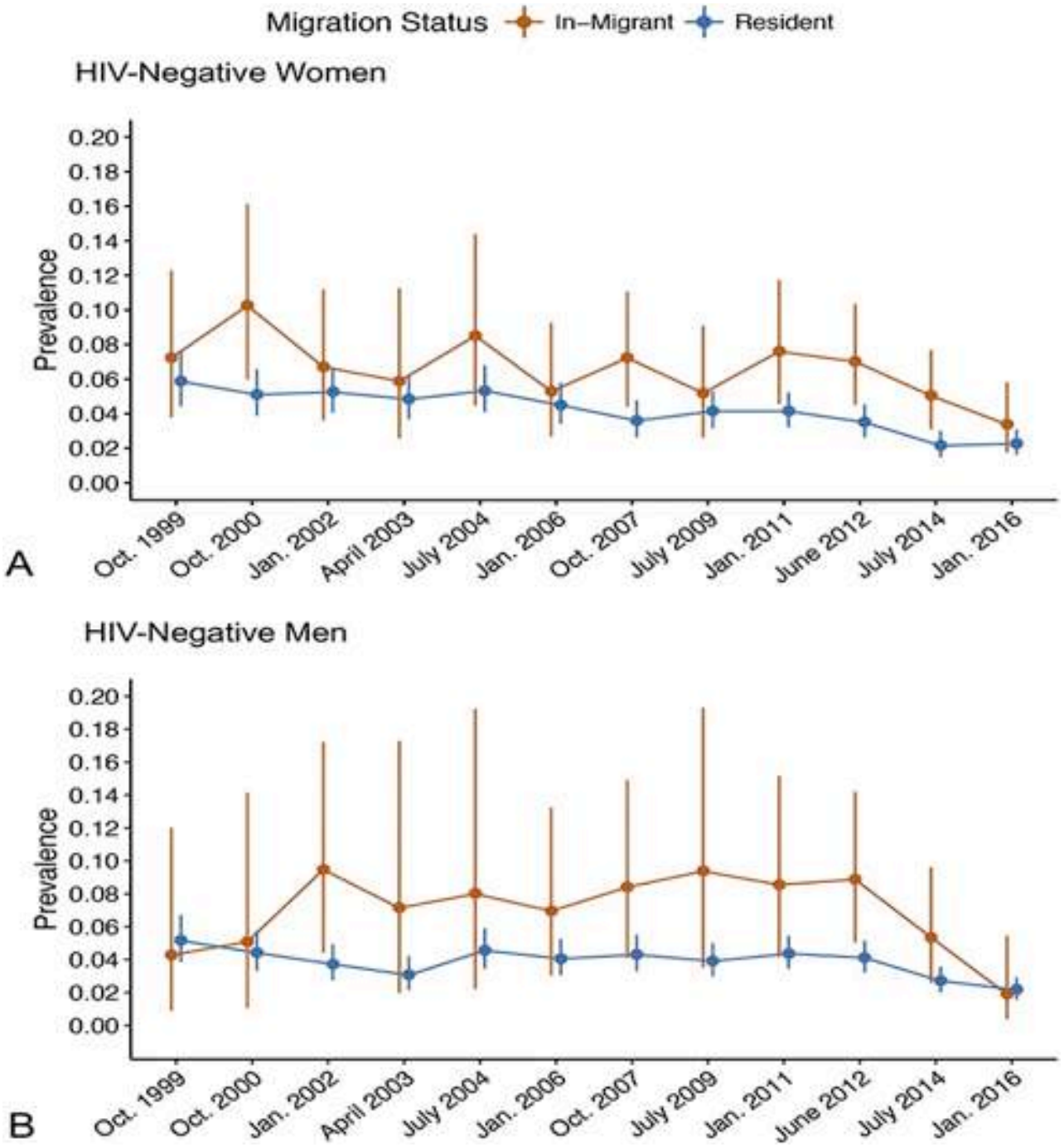
PREVALENCE OF UNTREATED HIV AND ASSOCIATED RISK BEHAVIORS AMONG THE SEXUAL PARTNERS OF RECENT MIGRANTS AND LONG-TERM RESIDENTS IN RAKAI, UGANDA

Migrants in sub-Saharan Africa are at increased risk of HIV acquisition after migration, but little is known about their sexual partners at place of destination. From 1999 to 2016, we surveyed persons aged 15–49 years in the RCCS and reported on their 4 most recent sexual partners in the last year. We compared the characteristics of sexual partners reported by migrants moving into RCCS communities in the last 2 years (i.e., in-migrants) with those of long-term residents with no recent migration history. Among a subset of participants in cohabitating epidemiologically linked couples of known HIV serostatus, we also assessed prevalence of having ≥1 untreated HIV-positive partner among in-migrants and long-term residents. One hundred sixteen thousand seven hundred forty-four sexual partners were reported by 29,423 participants.

The sexual partnerships of in-migrants were significantly less likely to be marital, more likely to span community boundaries, and shorter in duration than those of long-term residents. In-migrants also reported more sexual partners and were less likely to know their partner's HIV status or to have told their partner their HIV status. Among 7558 epidemiologically linked couples, HIV-negative in-migrants were more likely to partner with untreated HIV-positive persons compared with HIV-negative long-term residents (women: 6.3% vs. 4.1%; men: 6.9% vs. 3.9%). Overall, we find that there is a higher frequency of risky sexual behaviors among the partnerships of in-migrants compared with those of long-term residents. Also among cohabitating couples, in-migrants are more likely to partner with untreated HIV-positive individuals.

Figure 7, Prevalence of sexual partnership with an untreated HIV-positive partner among HIV-negative women (A) and HIV-negative men (B) in the Rakai Community Cohort Study (RCCS), 1999–2016. Prevalence is defined as the proportion of total couple-visits contributed by HIV-negative participants with an untreated HIV-positive partner. Data are stratified by migration status of the index HIV-negative RCCS participant.

Figure 7.


Migration Status
In−Migrant
Resident
HIV-Negative Women
Prevalence
0.20
0.18
0.16
0.14
0.12
0.10
0.08
0.06
0.04
0.02
0.00
Oct. 1999
Oct. 2000
Jan. 2002
April 2003
July 2004
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July 2009
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A
HIV-Negative Men
Prevalence
0.20
0.18
0.16
0.14
0.12
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Oct. 1999
Oct. 2000
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June 2012
July 2014
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B

7 THE VICINITY STUDY

Rakai Health Sciences Program
Improved Health Through Research

A client undergoing an ECO test at a mobile outreach camp in Rakai district.

THE VICINITY STUDY: EPIDEMIOLOGY AND IMPACT OF THE HIV, NCD, AND URBANIZATION SYNDEMIC IN AFRICA.

Rakai Health Sciences Program
VICINITY

There is a paucity of data on the impact of urbanization on cardiopulmonary non-communicable diseases (CP-NCDs) among people with HIV (PWH) in Africa. In addition, little is known about HIV and CP-NCDs health service utilization patterns as people migrate to urban settings and how HIV and CP-NCDs care might be better integrated. Longitudinal, population-level studies are needed to better guide future research, programs, and policies.

The Rakai Community Cohort Study (RCCS) is an open, population-based cohort in south-central Uganda. RCCS communities are non-urban and experience substantial out-migration of participants to two urban centers (Kampala and Masaka) and to nearby rural communities. With this unique infrastructure, RCCS offers a novel opportunity to conduct the VICINITY Study, a longitudinal, population-based research study on the HIV, CP-NCDs, and urbanization syndemic within a comprehensive health determinants framework.

The VICINITY study proposes to

- Characterize HIV-related and -unrelated risk factors for CP-NCDs in a novel Rural-to-Urban (R2U) African cohort;
- Characterize the impact of air pollution and moderating effects of HIV on cardiopulmonary outcomes among R2U migrants; and,
- Assess HIV and CP-NCDs health services utilization patterns among R2U migrants.
- CP-NCDs and risk factors will be assessed by anthropometry, blood pressure, spirometry, EKG and echocardiogram. Air pollution will be assessed by environmental monitoring.
- To our knowledge, this would be the first population-based, longitudinal cohort study of the HIV, CP-NCDs, and urbanization syndemic in Africa. Our unique ability to leverage a rural-to-urban cohort, the excellent research infrastructure, and novel will generate vital data needed for designing new research, interventions, and policies to combat the evolving HIV and CP-NCDs epidemic.

8 HARD-TO-REACH POPULATIONS

Rakai Health Sciences Program
Improved Health Through Research

RHSP staff delivering ART medication in Bunjako, mpigi district. The rains and floods had made the roads impassable and so canoes were resorted to so as to reach some communities with clients.

HARD-TO-REACH POPULATIONS: IMPLICATIONS FOR ENDING THE AIDS EPIDEMIC.

The Rakai region was the initial epicenter of the HIV epidemic in East Africa and continues to be a high burden area with an HIV prevalence of ~13%. Through the Rakai Community Cohort Study (RCCS), we reported that combination HIV prevention (CHP) decreased population-level HIV incidence in Rakai by 42% from 1.17/100 person-years (pys) prior to CHP scale-up to 0.66/100 pys by 2016 (Grabowski et al. NEJM 2017).

This study raises two issues of global importance. First, mobile persons, typically away for work or school, and, rarely, refusers are "hard-to-reach" populations which are difficult to survey, reducing RCCS participation rates to ~62%. These populations may also be hard-to-reach for engagement in HIV services. Ongoing cluster-randomized HIV prevention trials and population-based HIV impact assessments have similar challenges of potential bias due to missing these hard-to-reach populations. Second, despite reaching 59% male circumcision coverage and UNAIDS 90-90-90 goals with 75% viral suppression of all HIV-positive participants in RCCS, HIV incidence reductions were moderate and remained well above the estimated rate needed for HIV elimination (~0.1/100py). To address ongoing HIV transmission in the Rakai region, the PEPFAR program in which RCCS is nested recently began implementing additional CHP interventions:

(i) Pre-Exposure Prophylaxis (PrEP);
(ii) Assisted Partner Notification; and
(iii) Same-day antiretroviral therapy (ART) initiation with Universal Test and Treat (UTT).

This provides a unique opportunity to address the following important questions:

1. To what extent do hard-to-reach populations bias HIV coverage and incidence estimates?
2. Why do some individuals continue to acquire HIV and from whom?
3. Given hard-to-reach populations, can state-of-the-art CHP reduce HIV incidence to the levels needed for HIV elimination?

Our setting and research infrastructure strongly position us to answer these highly significant questions and inform current and future HIV prevention trials, evaluations, and programs. We thus propose a novel study with the following aims.

Aim 1 - We will first determine CHP coverage and HIV incidence among hard-to-reach persons using enhanced surveillance techniques.

Aim 2 - We will then characterize ongoing sources of incident HIV infection through partner tracing, viral phylogenetics, and sexual network analyses.

Aim 3 - Finally, we will determine if CHP services can engage hard-to-reach populations and reduce population-level HIV incidence to a level sufficient for HIV elimination by 2030.
To our knowledge, no prior HIV population-based studies have empirically determined the potential effects of participation bias on HIV epidemiology and incidence due to non-inclusion of hard-to-reach populations. This study will uniquely address questions on hard-to-reach populations which are critical to understanding the true state of the epidemic, interpreting HIV prevention trials and cross-sectional studies, and informing prospects and pathways to ending the African HIV epidemic.

Roads in Rakai district easily get washed away during rainy seasons making it difficult to deliver health services.

9 VALIDATION OF THE ASANTE HIV-1 RAPID RECENCY ASSAY

Rakai Health Sciences Program
Improved Health Through Research

VALIDATION OF THE ASANTE HIV-1 RAPID RECENCY ASSAY FOR DETECTION OF RECENT HIV-1 INFECTIONS IN UGANDA

Identifying newly HIV infected persons may enhance prevention efforts and help achieve epidemic control through intensified contact tracing. Point of care rapid recency tests for HIV-1 may be a cost-effective option. One such test is the Asante™ HIV-1 rapid recency® assay and we sought to validate its performance for use in Uganda using stored specimens (serum/plasma), collected from longitudinally observed HIV-1 recently and long-term infected participants.

Antiretroviral therapy (ART)-naive samples with known HIV seroconversions that occurred within 6 months of follow-up were tested in two independent laboratories: the Rakai Health Sciences Program (RHSP) and the Uganda Virus Research Institute HIV Reference Laboratory (UVRI-HRL). Also, samples from participants who HIV seroconverted within 6-18 months and samples from individuals with chronic HIV-1 infection of at least 18 months duration were grouped into three categories: ART naive, ART exposed with suppressed viral loads, and ART exposed with detectable viremia.
Out of 85 samples seroconverting within 6 months, 27 and 42 samples were accurately scored as "recent" by the Asante HIV-1 rapid recency test at the RHSP laboratory and UVRI-HRL, respectively.

This corresponded to sensitivities of 32% and 49%, respectively. There was 72% agreement between the laboratories (Cohen's kappa = 0.481, 95% CI = 0.317-0.646, p < .0001). Specificity was 100% (200/200) among chronically infected ART-naive samples.
Based on these results, we concluded that the Asante™ HIV-1 rapid recency® assay demonstrated low sensitivity for accurate detection of recent HIV-1 infections in Uganda and had substantial interlaboratory variability due to differential interpretation of the test strip bands. Further assessment of assay performance in other settings will help guide decisions on test utility.

10 SARS-COV-2 TESTING AT THE RAKAI HEALTH SCIENCES PROGRAM LABORATORY

Rakai Health Sciences Program
Improved Health Through Research

The Abbot Machine processing COVID-19 samples in the RHSP LAB.

SARS-COV-2 TESTING AT THE RAKAI HEALTH SCIENCES PROGRAM LABORATORY (RHSPL)

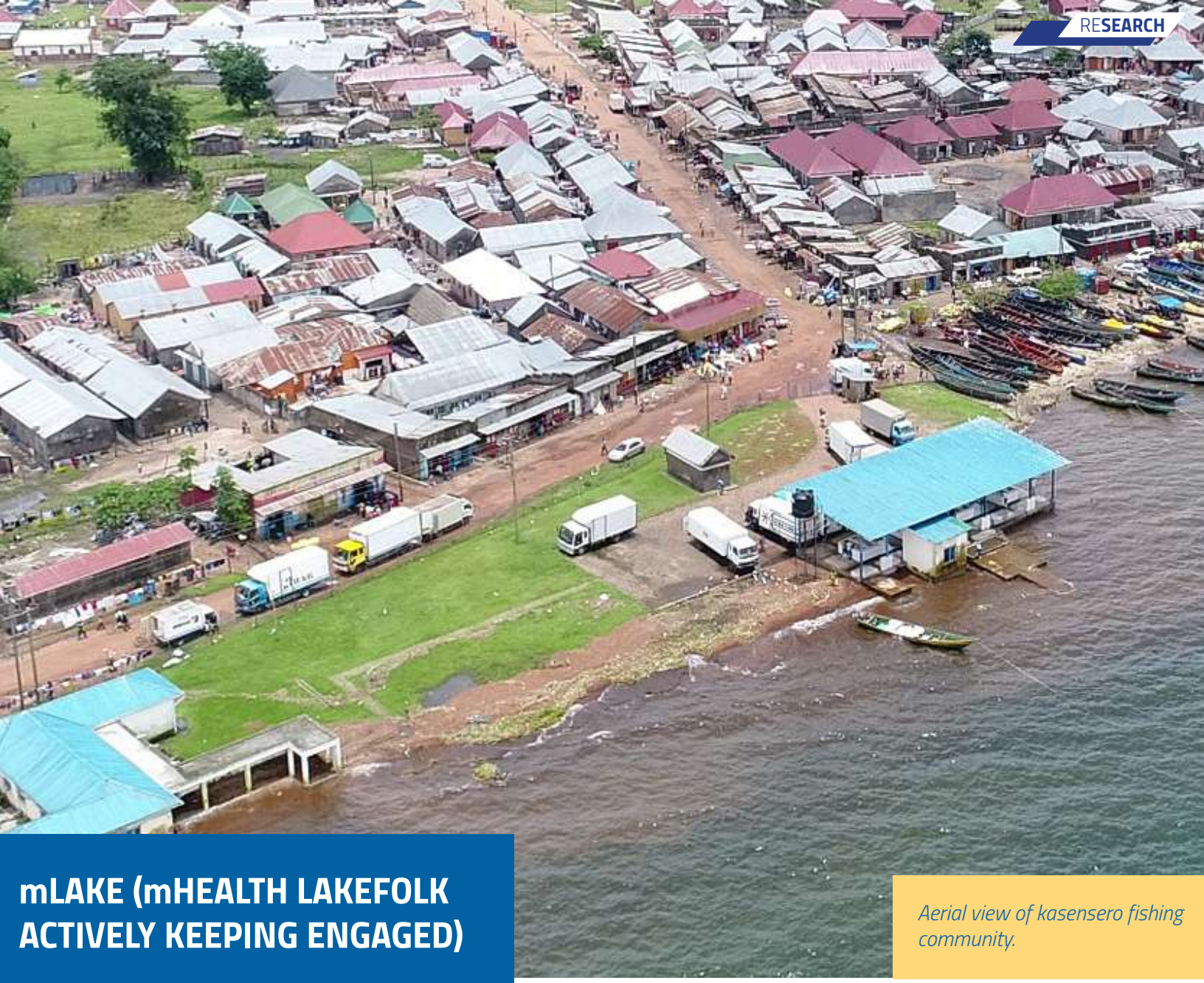
Amidst the growing need for SARS-CoV-2 testing nationwide, the biosafety, staffing and competence, equipment availability within the RHSPL were evaluated and the lab validated by the WHO and MoH for PCR testing of suspected Covid-19 samples.

The RHSPL SARS-CoV-2 testing used an in-vitro diagnostic molecular test on the m2000 Real-Time Abbott PCR system with reagents supplied by the MoH. Test results were uploaded onto a national testing server for quick access country wide. The majority of samples were from district surveillance and Mutukula a Uganda/Tanzania border entry point. By the end of 2021, over 4300 tests had been done with a positivity rate of 20%. RHSPL also offers rapid diagnostics for SARS-CoV-2 which have mainly been used to screen staff presenting with Covid-19 like symptoms.

11

mLAKE (mHEALTH LAKEFOLK ACTIVELY KEEPING ENGAGED)

Rakai Health Sciences Program
Improved Health Through Research



mLAKE (mHEALTH LAKEFOLK ACTIVELY KEEPING ENGAGED)

Aerial view of kasensero fishing community.

Community health workers (CHWs), using motivational interviewing counseling techniques, and mobile health tools to identify and address barriers, may represent a strategy to promote HIV services engagement and retention. We conducted a pragmatic, cluster-randomized trial called mLAKE (mHealth Lakefolk Actively Keeping Engaged) in an HIV hyperendemic fishing community (baseline HIV prevalence ~38%, baseline ART coverage ~67% and HIV viral suppression ~66% among HIV-positive residents) in Rakai, Uganda to assess the impact on HIV service coverage and virologic suppression of a novel motivational-interviewing-informed, theory-based, and mobile health-supported community health workers called "Health Scouts".

These community health workers were deployed in this community for about 3 years. We compared outcomes in clusters randomized to community health workers compared to clusters randomized to not having community health workers. Residents in clusters with community health workers were more likely to be in HIV care and to be on antiretroviral therapy. We found no significant changes in HIV viral suppression or male circumcision coverage. Clients reported that Health Scouts provided information about HIV prevention and treatment behaviors and helped them manage personal and social motivations to carry out health-promoting behavior. These findings suggest that community health workers may help people living with HIV engage in care and get effective treatment. This type of intervention may contribute to controlling HIV in settings with high HIV burden.

12 WIN WELCOME INCOMING NEIGHBOUR

Rakai Health Sciences Program
Improved Health Through Research

WIN team out in the field.

WIN – WELCOME INCOMING NEIGHBOUR

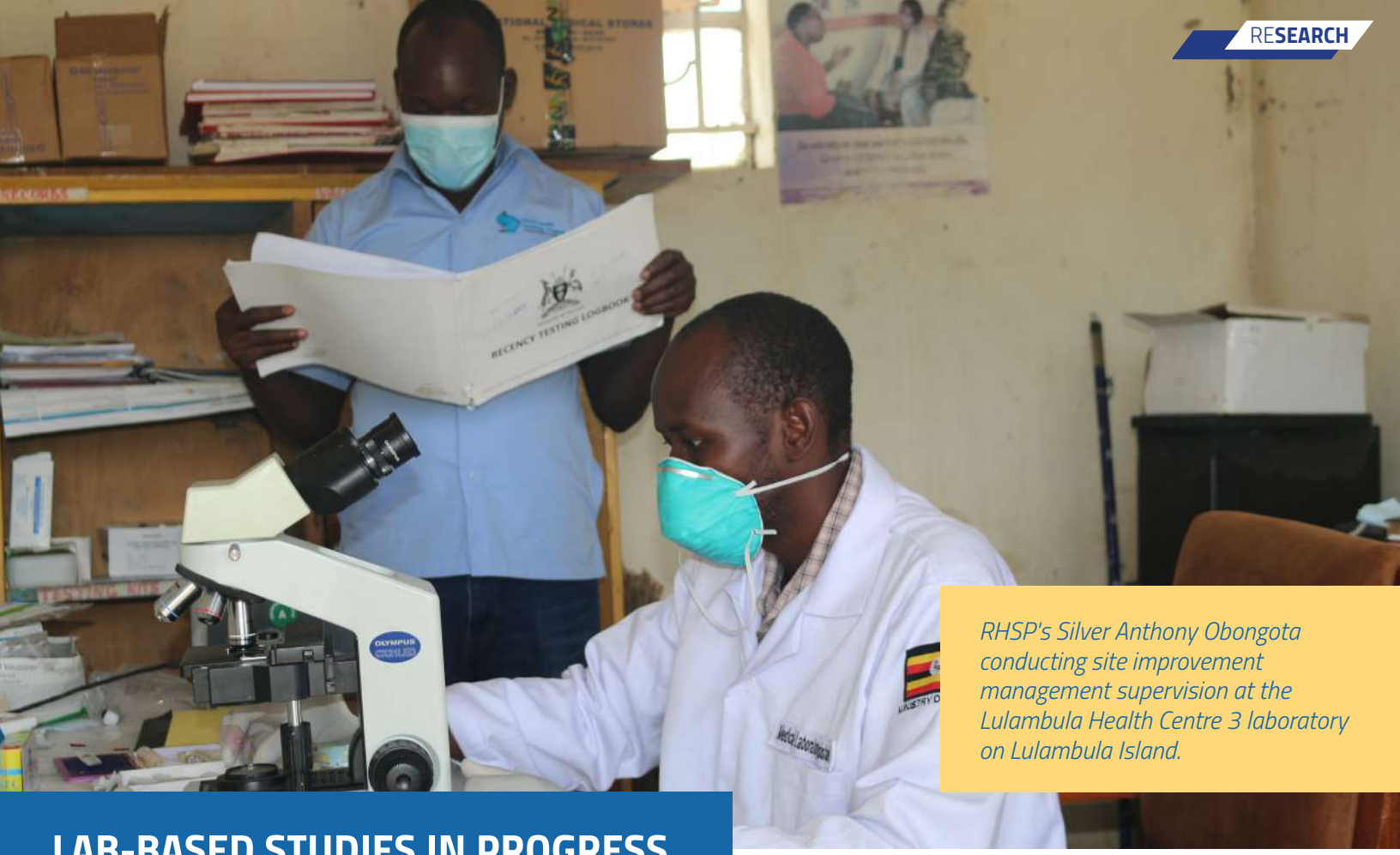
Welcome Incoming Neighbor study (WIN) is designed to test the efficacy of rapid linkage of in-migrants into the community to HIV prevention, care and treatment services and its contribution to HIV epidemic control. Specifically, the study aims to determine HIV incidence among HIV-negative in-migrants, viral suppression among HIV-positive in-migrants, and Combined HIV Prevention Services (CHPS) coverage rates in each arm.

Forty communities in Rakai Community Cohort Study were matched and randomized to control and intervention arms. In-migrants in both arms receive standard of care services from the Ministry of Health clinics. Participants in the intervention communities receive counseling by Community Health Workers (CHWs) using motivational interview techniques. During the counseling visits, CHWs agree with the in-migrant on a CHPS initiation action plan. Each in-migrant is followed up a month after the initial visit to assess linkage to CHPS . An additional follow-up is conducted for in-migrants not linked to CHPS .

Since its initiation, 9,743 new in migrants have been identified and counseled by CHWs. Of the enrolled migrants 8,460 (86.8%) completed second visit and the 4788 (49.2%) were referred to seek CHPS. Of the 4788 referred migrants 1694 (35.4%) reported to have received a CHP service during the second visit. According to the preliminary findings from the qualitative evaluation of WIN. They identified an increased awareness of risk among the study population, improved knowledge of local services in the community and increased incentive to adhere to ART. In migrants feel empowered , not judged , welcomed in the community, and live healthier lives.

13 LAB-BASED STUDIES IN PROGRESS

Rakai Health Sciences Program
Improved Health Through Research



RHSP's Silver Anthony Obongota conducting site improvement management supervision at the Lulambula Health Centre 3 laboratory on Lulambula Island.

LAB-BASED STUDIES IN PROGRESS

SARS-COV-2 INFECTION AND VARIANTS SURVEILLANCE IN SOUTH-CENTRAL UGANDA (SARS-COV-2 SURVEILLANCE STUDY).

This study carried out in southcentral Uganda will sccertain the burden and transmission patterns of SARS-CoV-2 infection using rapid antigen tests, infection and variants in high-risk communities through sequencing and RT-PCR assays. Household/community transmission will be assessed, and the burden of prior SARS-CoV-2 infection assessed by validated IgM/IgG antibody test.

SARS-COV-2 SEROPREVALENCE IN SOUTHCENTRAL UGANDA DURING 2019 – 2021

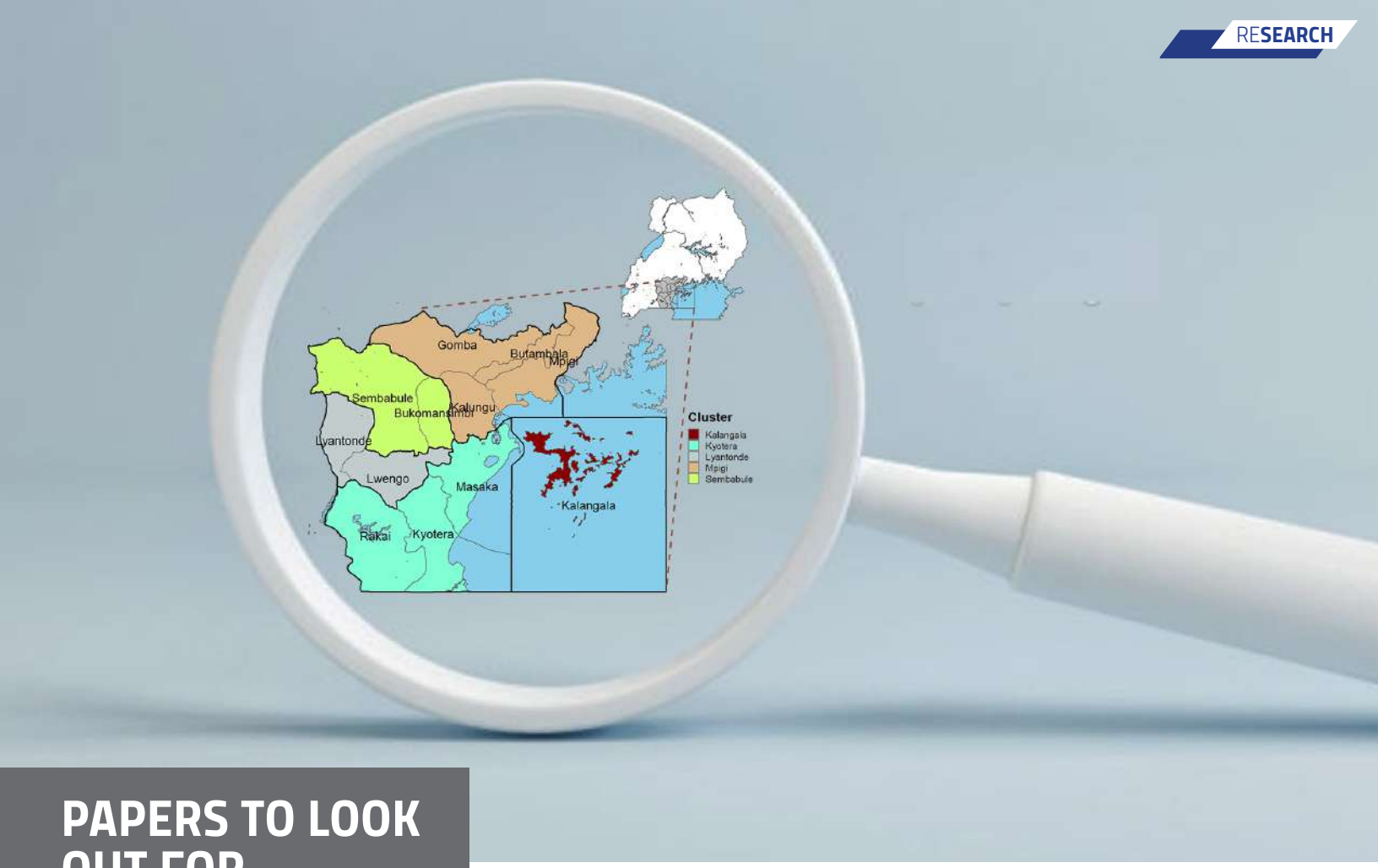
Key subpopulations e.g., healthcare workers (HCW) may be at greater risk of contracting SARS-CoV-2 due to limited access to personal protective equipment despite prolonged lockdowns and other infection prevention/control measures, resource limitations and fatigue. This study assessed SARS-CoV-2 seroprevalence in selected populations . We found a high seroprevalence of antibodies to SARS-CoV-2 among HCWs and substantial exposure among persons with COVID-19 like symptoms in the general population. However, limitations in serological test confirmation may limit interpretation of results prior to confirmation of the first COVID-19 cases.

DIAGNOSTIC PERFORMANCE, ANALYTICAL AND OPERATIONAL SUITABILITY FOR POINT-OF CARE DEVICES FOR HEMOGLOBIN ESTIMATION DEVICES (HB METER).

The objective was assess Point of Care (POC) Hb (hemoglobin) devices in routine HIV and maternity care. It evaluates accuracy and precision/reproducibility, sensitivity and specificity of POC Hb devices. using a standardized scorecard, operational cost and cost per anemia case diagnosed.

14 PAPERS TO LOOK OUT FOR

Rakai Health Sciences Program
Improved Health Through Research



PAPERS TO LOOK OUT FOR

CELL PHONE SURVEY IN RAKAI, UGANDA

Understanding access to information on COVID19, was urgently required in the early days of the epidemic. Mobile phone contacts from the Rakai Community Cohort Study (RCCS) databases sampled participants who provided a cell phone contact. HIV+ individuals were matched one-to-one with an HIV negative control by age and community type. A 30-minute phone interview was administered captured on computers to an encrypted database.

It was concluded that the use of mobile phones for rapid assessment during epidemics is feasible in rural Uganda. Access to information on COVID19 was high and access to HIV care services by cell phone was feasible.

HIGH RATE OF PRE-EXPOSURE PROPHYLAXIS (PREP) ELIGIBILITY AND ASSOCIATED HIV INCIDENCE IN A POPULATION WITH A GENERALIZED HIV EPIDEMIC IN RAKAI, UGANDA

This study estimated the prevalence of PrEP eligibility and associated HIV risk in the general population of the Rakai Community Cohort Study (RCCS), using a cross-sectional study between 2016–2018. We also estimated HIV incidence associated with PrEP eligibility using a retrospective population-based longitudinal study among RCCS participants between 2011 – 2018. The study population included HIV negative participants aged 15-49 years and PrEP eligibility was defined by the Uganda assessment tool for establishing PrEP eligibility status.

Overall, 29% met at least one of the eligibility criteria. HIV incidence was significantly higher in PrEP-eligible versus non-PrEP-eligible participants and independently higher in PrEP-eligible versus non-PrEP-eligible females. Among uncircumcised males, HIV incidence was significantly higher in the PrEP-eligible versus non-PrEP-eligible, but there was no significant difference among circumcised males.

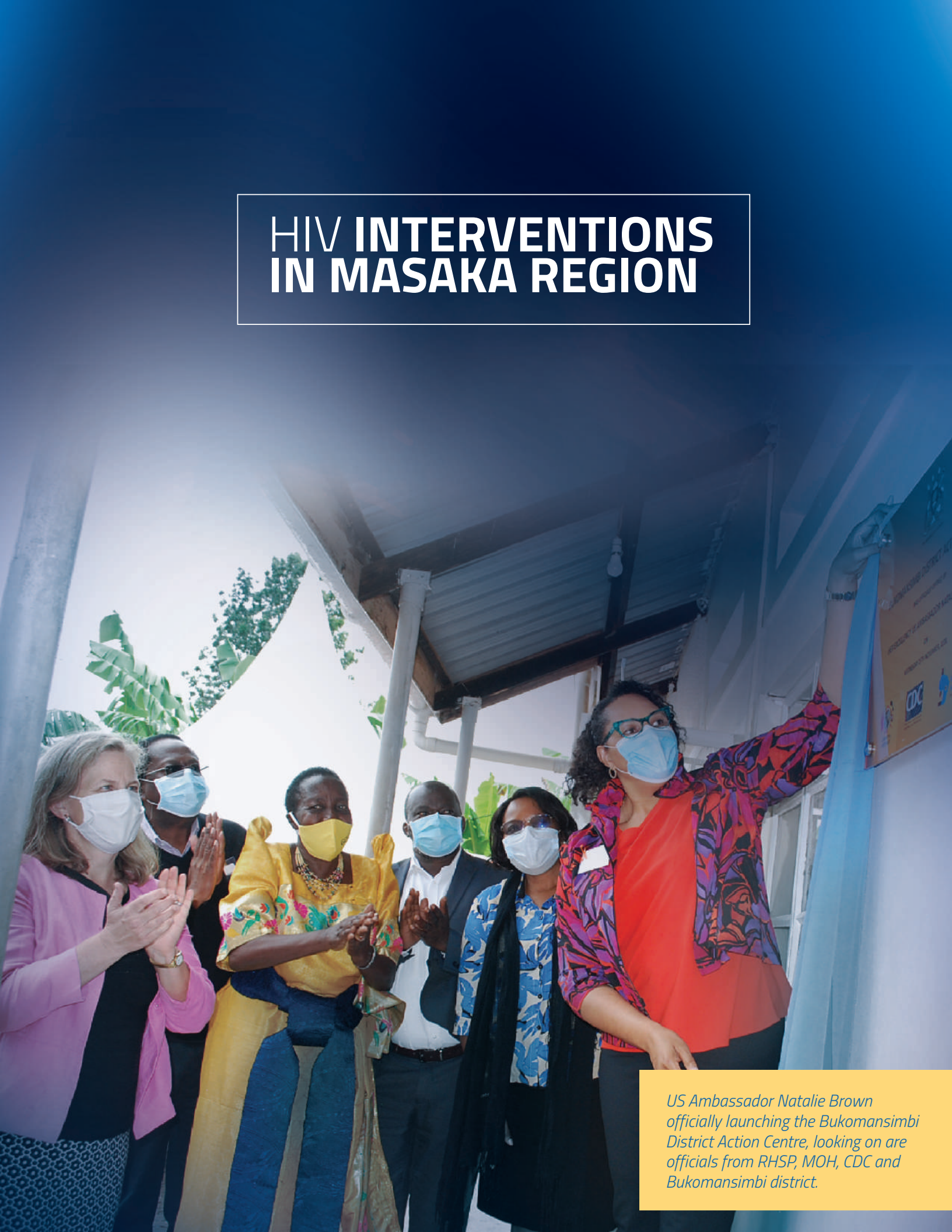
DYNAMICS OF PRE-EXPOSURE (PReP) ELIGIBILITY DUE TO WAXING AND WANING OF HIV RISK IN RAKAI, UGANDA

The primary objective was to study the waxing and waning of PrEP eligibility in the general population of the Rakai Community Cohort Study (RCCS). A population-based longitudinal study described the incidence, discontinuation, resumption, and durability of substantial HIV risk behaviors (SHR) for PrEP eligibility in HIV negative participants aged 15-49 years over four survey rounds of RCCS between 2011 – 2018.

Substantial HIV risk was adopted from the Uganda National PrEP Eligibility Assessment tool. Incidence of PrEP eligibility increased from 11.4/100 py in the 1st inter-survey period to 13.4/100 py (adjIRR=1.20; 95%CI=1.10-1.30) in the 2nd inter-survey period, and 12.6/100 py (adjIRR=1.06; 95%CI=0.98-1.15) in the 3rd inter-survey period. Discontinuation rates of PrEP eligibility were initially stable but substantial HIV risk behaviors declined over 20 months.

William Ddaaki - Social Behaviour Sciences Supervisor - conducting a focus group discussion with research participants.

HIV **INTERVENTIONS IN MASAKA REGION**



US Ambassador Natalie Brown officially launching the Bukomansimbi District Action Centre, looking on are officials from RHSP, MOH, CDC and Bukomansimbi district.

15 RETENTION IN ART CARE

Rakai Health Sciences Program
Improved Health Through Research

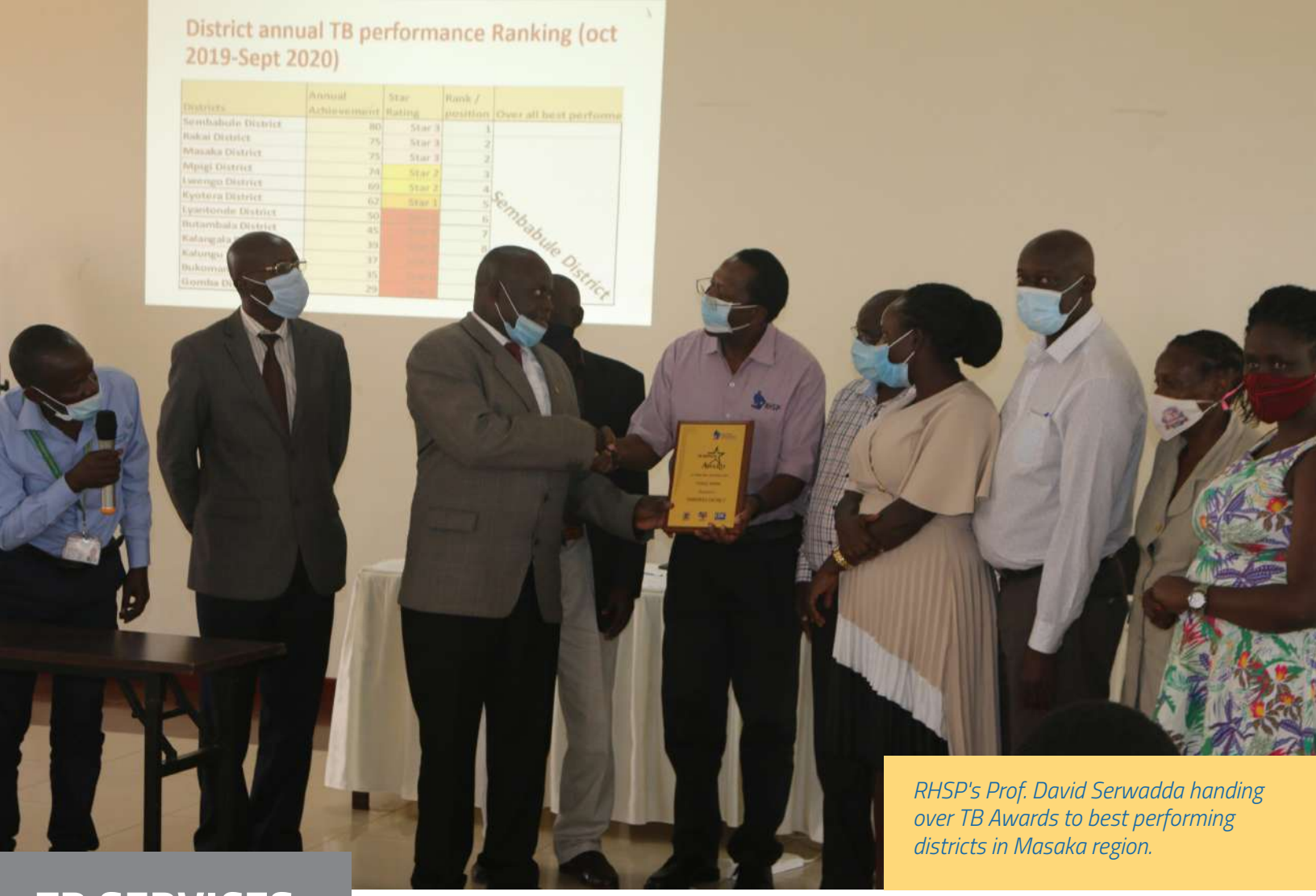
Jacent Nansamba a counsellor from Villa Maria Hospital counting pills during a home visit in Ndeeba Kibisi village in Kalungu District

RETENTION IN ANTERETROVIRAL TREATMENT CARE

Overall, ART retention increased through quarters: Q1 (94%), Q2 (95%), Q3 (97%) and Q4 (97%) due to the structured peer strategy , appointment tracking and record retrieval before the refill day, triage, updated appointment, and missed appointment registers, phone calls to clients who miss appointments, and home visits to clients not reachable by phone. There are a total of 245 facility peers and 423 community peers who received a 3-day training in psychosocial support, client follow up, and updating registers. Additionally, each district is attached to one Community Base Organization (CBO) responsible for 1-2 facilities.

Other strategies include peer to peer counselling, linkage, adherence to care and viral load suppression among adolescents; Community Drug Distribution Points and Community Pharmacy Retail Drug Distribution to reduce clinic burden.

16 TB SERVICES



RHSP's Prof. David Serwadda handing over TB Awards to best performing districts in Masaka region.

TB SERVICES

Cumulatively, 6137 new and relapsed TB cases were notified in 2020 which was 98% of the annual target, despite Covid-19 restrictions. There was progressive improvements from Q1 (19%), Q2 (24%), Q3 (25%) and Q4 (29%). . This performance is attributed to training all health workers, use of a use of a community TB tool kit (sputum container, zip lock bag, surgical mask, gloves, and sanitizer) to facilitate both TB and COVID-19 infection control.

Contact tracing of index cases and targeted TB screening in household/communities of identified TB cases, engagement of community extension workers to identify and refer presumptive TB cases, and robust sample transportation to GeneXpert sites. Weekly Tracking the TB cascade performance, introduction of a new X-ray voucher system to make clinical TB diagnoses, and awards to the best performing districts. Facility mentorships improved knowledge gaps, documentation and reporting.

17

OVC (ORPHANS AND VULNERABLE CHILDREN)

Rakai Health Sciences Program
Improved Health Through Research

RHSP's Alex Ddaama conducting an interview with an OVC beneficiary during a home visit to Nkose Island.

OVC (ORPHANS AND VULNERABLE)

RHSP supported the Orphans and Vulnerable Children (OVC) programme for April 2017 to Sept 2021. During this period, a total of 19,855 Orphans and Vulnerable Children and their care givers were supported with layered services that included psychosocial support, education subsidies, social protection services, social economic strengthening services like IGAs (Income Generating Activities), and training and support aimed at improving their ability to cope with and overcome their vulnerability all geared towards achieving HIV Epidemic Control..

The program adopted a household support model with a focus on HIV+ children, HIV Exposed Infants, Children in abusive environment, Children of sex workers AND Children with life threatening conditions. To embed the program in the community, RHSP provided technical assistance and funding to 19 Community Based organizations (CBOs) to support comprehensive OVC services accross 8 districts of the Masaka Region.

All the 15,158 children on OVC program were supported to know their status. Of the 15,158 , 3508 were HIV+ and on ART and 2912 (86%) were virally suppressed. RHSP working with the health facilities, social Workers and Para Social Workers supported these children and their caregivers with nutrition education, adherence support messages , prevention with positives messages and Viral Load monitoring. The HIV negatives continued to receive HIV prevention messages. In response to the COVID-19 pandemic, RHSP worked with the CSOs to support317 households with food assistance.
For those in school, retention was maintained through an education subsidy package that included scholastic materials and schools fees. In the last year of the program, , RHSP supported 1,112 OVCs with scholastics materials including sanitary pads for adolescent girls and 3,385 with school fees support .. In the field of household economic Strengthening, 4302 OVC caregivers were supported to join Village Savings and Loan Associations, 3826 caregivers were trained in business skills and financial literacy to enable them to manage their IGAs (Income Generating Activities) well, 562 caregivers were linked to government wealth creation programs where of Operation Wealth Creation and the Youth Livelihood Grants and 445 OVC graduated in their various vocational trades and received startup toolkits. In addition, 601 householoholds received farming inputs and 957 careivers were supported to start IGAs (Income Generating Activities) of their choice.

In order to improve on child protection environment in the families, children benefited from caring families parenting sessions and the districts local governments supported to respond to Gender and Sexual Based Violence cases.

18 HIGHLIGHTS ON EFFECTS OF RISING LAKE WATER ON HIV

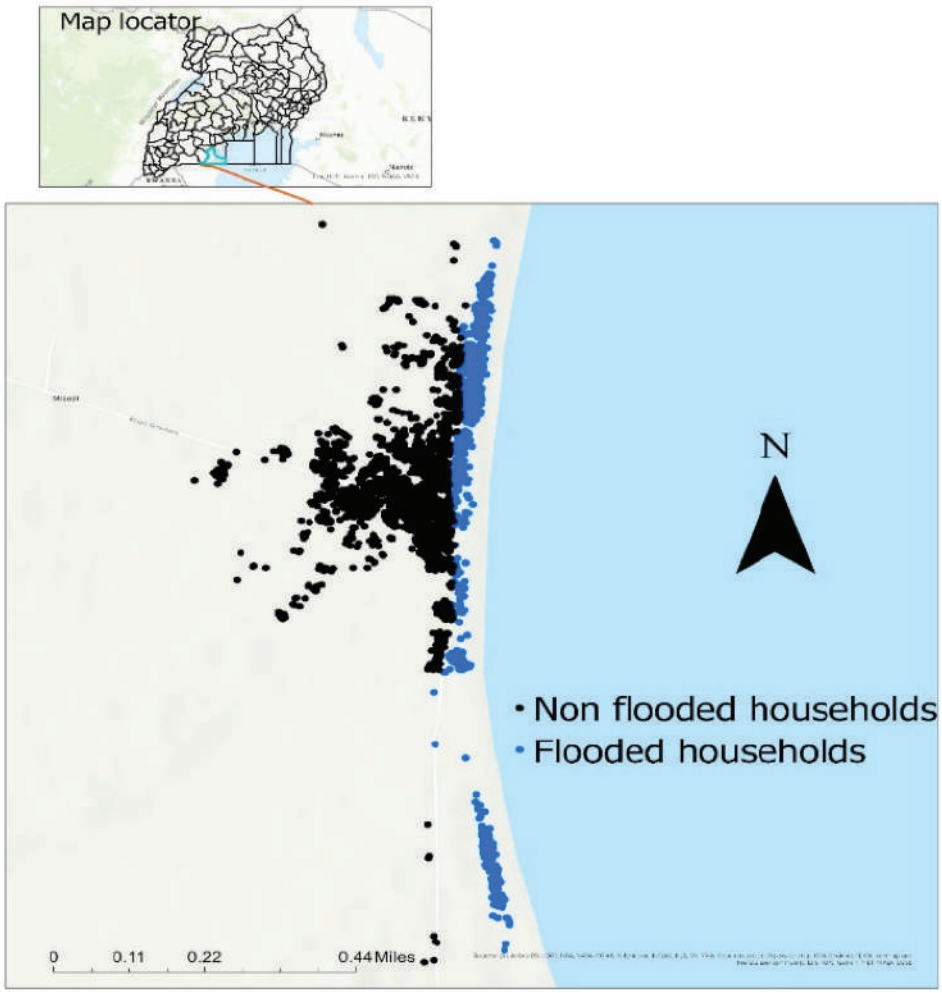
Rakai Health Sciences Program
Improved Health Through Research

People wading through dirty flooded roads in Namirembe fishing community.

THE EFFECTS OF FLOODING ON HIV EPIDEMIOLOGIC SURVEILLANCE IN FISHING VILLAGES.

The water level of Lake Victoria rose 13.2 meters in 2020 flooding communities reducing livelihood and displacing households. A total of 517 households were displaced, affecting 1425 individuals of whom 172 were HIV-positive.

MAP SHOWING FLOODED HOUSEHOLDS IN KASENSERO FISHING COMMUNITY



19 UPTAKE AND RETENTION ON HIV

Rakai Health Sciences Program
Improved Health Through Research

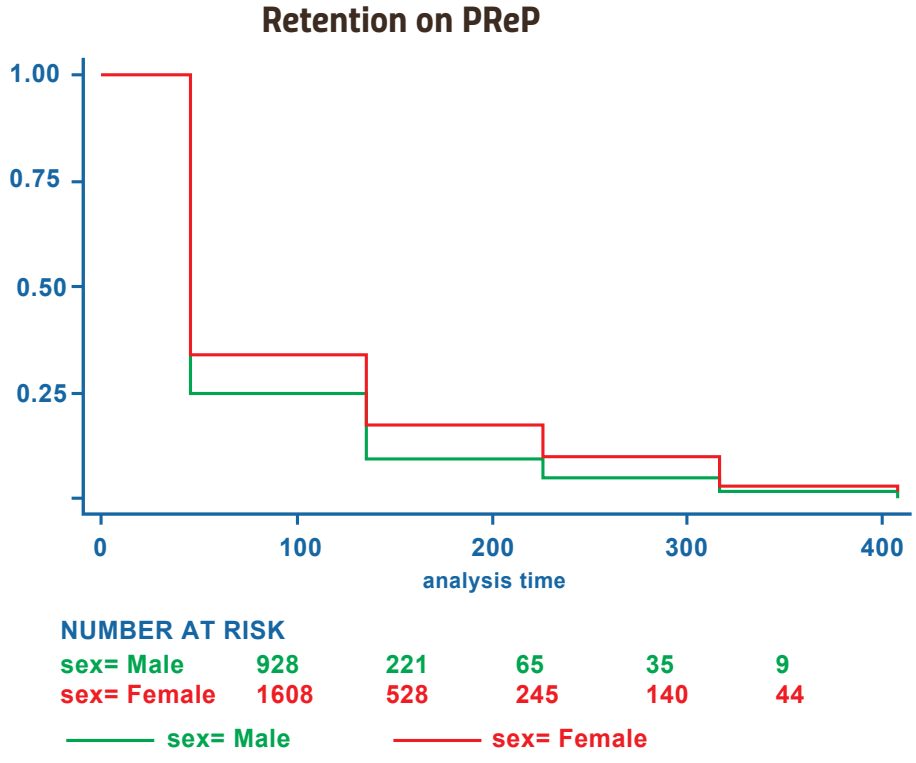
A team of RHSP and MOH health workers conducting a community outreach for ART medication refills on Kachanga island.

UPTAKE AND RETENTION ON HIV PRE-EXPOSURE PROPHYLAXIS AMONG KEY AND PRIORITY POPULATIONS IN SOUTH-CENTRAL UGANDA

In 2017, PrEP was initiated in HIV hyperendemic fishing communities on Lake Victoria and trading centers. We evaluated PrEP uptake and retention among individuals with high risk of HIV per the Ugandan National HIV-risk categorization.

2,985 individuals screened for PrEP, 169 (5.6%) were HIV positive. Of the 2816 HIV negative individuals, 2,767 (98.3 %) were at substantial HIV risk and 2,750 (99.4%) were offered PrEP. Eligible males were mainly fisher folk (48.3%) and truck drivers (36.4%) And most eligible women were sex workers (82.8%). Acceptance did not differ significantly by age or marital status. Median retention was 45.4 days , but overall retention was higher among women than men. Discontinuation decreased with age for both men and women (p for trend = 0.001).

Uptake of PrEP was high in this population but retention rates were low, especially among highly mobile among younger clients. Interventions. Tracking mechanisms are needed to optimize PrEP retention.



20 FOGARTY SUPPORTED TRAINING AND RESEARCH DEVELOPMENT

Rakai Health Sciences Program
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Since 2011 there has been a collaboration where students from Johns Hopkins University and Makerere University engage in an exchange home-visit program. For the past 9 years an average of 15 students each year have had an opportunity to stay in communities in Masaka region. During their stay in the communities they engage in a couple of community projects like; construction of pit latrines, and renovating of schools as a token of appreciation for hosting them.

FOGARTY SUPPORTED TRAINING AND RESEARCH DEVELOPMENT

Master's degree, Johns Hopkins University

1. Joseph Ssuuna (Masters of Public Healthat the Johns Hopkins Bloomberg School of Public Health) concentrating in epidemiology and biostatistics. He is completing his practicum on qualitative interview field guides to understand the lived experiences of HIV treatment interruptions, return to care, and unsuppressed viral loads during COVID-19 and HIV recency testing.

2. Hadijja Nansereko (Master of Science in Spatial Analysis for Public Health, Johns Hopkins University) is pursuing a part-time online graduate program focusing on geospatial analysis while continuing to work at the Rakai Health Sciences Program as a Data Management Officer. This will prepare her to use geographic information on the impact of migration on HIV service delivery and clinical outcomes, including the impact of COVID.

Master's degree, Makerere University

James Batte (Master's in Public Health, Makerere University) is in the third year of his Master's in Epidemiology and Biostatistics to develop programs to prevent and treat HIV.

Pauline Nalule (Master's in Public Health, Makerere University) is currently the RHSP DREAMS District Coordinator. She is finishing her second year of the distance MPH program.

Augustine Opolot (Master's in Public Health, Makerere University) is currently the RHSP Regional HIV Testing Services Coordinator. He is in the 2nd year of the distance MPH program.

Brendah Nansereko (Masters in Biostatistics, Makerere University) is a Data Management Officer with RHSP undertaking specialized graduate-level training in biostatistics at Makerere.

HIV Cure training

Dr. Ronald Galiwango, a former Fogarty completed his PhD in immunology at the University of Toronto. Fogarty provided support and mentorship to completes his dissertation papers and research on Covid-19 and HV cure research. He recently submitted a to PLoS One on Coronavirus-2 **seropositivity in South-Central Uganda, 2019 – 2021".**

Scientific conference support

Fogarty has supported many prior Fogarty degree trainees who continued their HIV research careers and submitted abstract to scientific conferences.

Dr. Joseph Kagaayi - RHSP Executive Director and former Fogarty PhD trainee gave a plenary talk at CROI (Conference on Retroviruses and Opportunistic Infections) 2020 on "What Makes Epidemics Recede?"

William Ddaaki – Supervisor Social and Behavioral Sciences, presented a poster at AIDS 2020 titled "Qualitative assessment of barriers and facilitators of PrEP use before and after implementation of a PrEP program for key populations in **Rakai, Uganda".**

Table 8. Conference presentations by RHSP/Fogarty trainees during TY4.

CROI 2021 (6-10 March 2021, Virtual)		
Poster	Darix Kigozi	Distance to HIV treatment center and association with ART use among men in Uganda
Poster	Ronald Galiwango	Comparison of Asante and Swift HIV rapid recency of infection assays
Poster	Dorean Nabukalu	Prevalence and determinants of early sex resumption postcircumcision (Rakai, Uganda)
Poster	Brendah Nansereko	Differences in sexual behaviors before and after universal test and treat in Uganda
AIDS 2021 (18-21 July 2021, Virtual)		
Oral abstract	Fred Nalugoda	The impact of the COVID-19 pandemic on provision of HIV care: perspectives of HIV-dedicated healthcare workers in East Africa
Oral abstract	J Kasule	Subtype D HIV-1 reservoir levels and viral sequent profiles in Rakai, Uganda
Oral abstract	Fred Makumbi	HIV incidence in postpartum period: findings from Uganda's national PMTCT Impact Evaluation (PMTCT-IE) 2017-2019
Oral abstract	Tom Lutalo	The importance of surveys to complement program data in informing modeled Mother to Child HIV transmission estimates and identifying and addressing hidden program gaps: a case study of Uganda
E-poster	Joseph Ssekasanvu	Transactional sex and HIV viremia among men in rural Uganda: a population-based survey
E-poster	William Ddaaki	Barriers and facilitators of risk disclosure among women at high risk of HIV acquisition and onward transmission in Uganda
E-poster	Robert Ssekubugu	HIV and COVID-19 during a national lockdown: results of a phone-based survey of participants in the Rakai Community Cohort Study - Uganda

21 GRANTS

Rakai Health Sciences Program
Improved Health Through Research

US Ambassador Deborah Malac launched the MV RHSP which was supported by CDC-PEPFAR funding.

GRANTS

GRANTS	GRANTS PERIOD	PRIME FUNDER	U$ AWARD AMOUNT	PROJECT DIRECTORS
SSTAR - Structural and social Transitions Among Adolescents in Rakai	AUGUST 2017-JULY 2022	NIH	753,656	John Santelli Fred Nalugoda
IeDEA Data Sharing: East Africa international Epidemiologic databases to evaluate AIDS	AUGUST 2016-MAY 2022	NIH	270,811	Kara Wools Kaloustin Fred Nalugoda
Mortality Measurement: Improving the measurement of adolescent and adult mortality in low income countries	SEPTEMBER 2017-JULY 2022	NIH	223,650	Stephen Hellinger Tom Lutalo
Migration: RCT to reduce HIV acquisition and viral load among migrants, Rakai Uganda	AUGUST 2018-MAY 2023	NIH	1,418,408	Maria Wawer Godfrey Kigozi
ADOLESCENT GWU STUDY Penile Microbiome, Inflamation and HIV susceptibility during sexual debut and maturation among male adolescents	MAY 2016-APRIL 2023	NIH	465,845	Lance.B. Prince Godfrey Kigozi
Hard to Reach Populations: Hard-to-Reach Populations for Ending the AIDS Epidemic	SEPTEMBER 2019-AUGUST 2023	NIH	1,051,164	Larry Chang Joseph Kagaayi
Mental Health and cognition: Mental Health and cognition inHIV Infection in Uganda	AUGUST 2019-JUNE 2024	NIH	1,176,819	Maria Wawer Gertrude Nakigozi
SAS COV-2 IDI SARS COV-2 PREV-u-CHAT, thru IDI	OCTOBER 2020-SEPTEMBER 2022	CDC	320,000	IDI (CDC) Galiwango Ronald Moses
SUUBI4HER : A Combination Intervention Addressing HIV Risk Behaviors Among Older Adolescent Girls Transitioning into Adulthood in Uganda.	AUGUST 2018-MAY 2022	NIH	324,372	Fred Ssewamala Gertrude Nakigozi

FORGARTY D43: Multidisciplinary Research Training to Understand and Reduce HIV	APRIL 2018-JANUARY 2023	NIH	418,768	Larry Chang Godfrey Kigozi
KYATEREKERA: A combination intervention addressing sexual risk taking behaviors among vulnerable populations	JUNE 2018-MAY 2022	NIH	255,063	Fred Ssewamala Joseph Kagaayi
ART DIVERSION: ART diversion in Rakai, Uganda	SEPTEMBER 2020-AUGUST 2022	NIH	100,000	Caitlin Kennedy Fred Nalugoda
NHLBI: The impact of Epidemiology and Impact of HIV,NCD, and Urbanisation Syndemic in Africa	FEBRUARY 2021-JANUARY 2026	NIH	2,660,802	Larry Chang Joseph Kagaayi
LONGVIEW: Long-term impact of universal treatment and dolutegravir on population HIV virogic incidence outcomes in Africa	APRIL 2021-MARCH 2025	NIH	1,006,160	Mary Kathryn Grabowski Joseph Kagaayi
Mental Health Measures: Phase II and Transactional Sex and HIV among Men in Rakai, Uganda	AUGUST 2021-AUGUST 2022	NIH	22,726	Caitlin Kennedy
REACH: Research Enterprise to Advance a cure of HIV	AUGUST 2021-APRIL 2025	NIH	553,201	Brad Jones Galiwango Ronald Moses
D43 COVID Supplement: Multidisciplinary Research Training to Understand and Reduce HIV Incidence in Uganda	AUGUST 2021-JULY 2022	NIH	74,219	Larry Chang Godfrey Kigozi
How sex, host microenvironment, and immune responses shape acquisition of genital bacteria that increase HIV risk	DECEMBER 2021-NOVEMBER 2026	NIH	165,540	Cindy Galiwango Ronald Moses
Mogen clamp Vs Shangring: Evaluation of Shangring Vs Mogen clamp for early infant	NOVEMBER 2016-MARCH 2022	NIH	249,715	Richard Lee Godfrey Kigozi
Penile Microbiome: Penile Microbiome, Inflamation and HIV susceptibility during sexual debut and maturation among male adolescents	FEBRUARY 2017-JANUARY 2022	NIH	531,681	Aaron Tobian Godfrey Kigozi
Mlake: CHWs, mHealth, and combination HIV prevention in a Hotspot: A randomzed Trial	MAY 2015-APRIL 2021	NIH	1,009,494	Larry Chang Gertrude Nakigozi
Alcohol in Women: Alcohol Epideniology and pilot intervention to reduce alcohol, IPV, and HIV in women in Uganda	AUGUST 2015-JULY 2021	NIH	49,822	Jennifer Ann Wagman Godfrey Kigozi
PANGEA : Fishing and inland communi ties-Caitlin`	ANUARY 2021-JUNE 2022	Bill & Melinda Gates	29,000	Neema Nakyanjo
Sexual health instrument testing	JANUARY 2021-DECEMBER 2021	NIH	20,000	Caitlin Kennedy
ALPHA GATES: Analysis of directly observed HIV incidence in the ALPHA network population-based surveillance studies.	OCTOBER 2018-SEPTEMBER 2020	Bill & Melinda Gates	130,637	Emma Slaymaker Tom Lutalo
AMFAR	OCTOBER 2018-MAY 2020	Foundation for AIDS Research, NY	50,000	Edward Nelson Kankaka
LATENT: HIV Quantitave measurement and correlates of the latent HIV reservior in virally suppressed Ugandans.	AUGUST 2019-SEPTEMBER 2020	NIH	92,856	Steve Reynolds
Mental Health Measures - Caitlin	DECEMBER 2019-NOVEMBER 2020	NIH	7,500	Caitlin Kennedy

STI Self collection of samples	DECEMBER 2019-NOVEMBER 2020	NIH	12,500	Caitlin Kennedy
KAROLINSKA INSTITUTE PREP	AUGUST 2019-JULY 2020	Swedish Medical Research Council	10,000	Godfrey Kigozi
KAROLINSKA INSTITUTE-NCDs New Health Challenges	AUGUST 2019-JULY 2020	SMRC	144,397	Godfrey Kigozi
REACH: Research Enterprise to Advance a Cure for HIV	AUGUST 2021 - April 2026	NIH	554,260	R.Brad Jones Ronald Galiwango
Verbal Autopsy: Reimagining data and automated cause assignment using APLHA network data	JULY 2021 - JUNE 2022	NIH	40,000	Tom Lutalo
HERA: Compare prevalence of herpetic disease, demostrated by viral shedding of HSV-1&2 in the verginal secretions of HIV positive women	AUGUST 2018 -SEPTEMBER 2020	NIH	71,430	Steve Reynolds
Characterizing community exposure to SARS-CoV-2 in Uganda, and assessing biological determinants of virus spread'	JUNE2020-DECEMBER 2020	MOH	21,167	Joseph Kagaayi
Public Private Mix for Tuberculosis case findings in Kyotera District:A Quasi-Experimental Study	AUGUST 2021- JUNE 2022	MOH	42,763	Joseph Kagaayi Fred Makumbi
TOTAL RESEARCH GRANTS			**14,328,429**	
PROGRAMS				
Accelerating Epidemic Control in Masaka Region	April 2017 - September 2022	CDC-PEPFAR	98,534,624	David Serwadda
CDC IDI Vaccination Project	SEPTEMBER 2021-FEBRUARY 2022	CDC	150,000	IDI Galiwango Ronald Moses
CRS to support Pediatric QI	OCTOBER 2020-SEPTEMBER 2021	CDC	306,000	Jessica Naginda
TOTAL PROGRAMS GRANTS			**98,990,624**	
TOTAL GRANTS			**113,319,053**	

22 GALLERY

Rakai Health Sciences Program
Improved Health Through Research

DREAMS Success Stories Documentary

https://www.youtube.com/watch?v=erDxWNqh2v8

Amb Natalie Brown, CDC Dr LIsa Nelson, MOH officials, RHSP senior leadership with Masaka and Kalangala district leadership at the launch of DREAMS program in masaka and kalangala districts.

CDC's Dr Emilio Dirlikov, Dr Joseph Kasumba and Sophie Nantume inspecting a DREAMS safespace in Masaka district.

Kalungu District RDC Caleb Tukaikiriza and DHO Dr Daniel Ssentamu receiving a PPE consignment from RHSP Manager PR Mckina Jackie. During the lock-down, RHSP supported all districts in masaka region with personal protection equipment which was distributed to different health facilities within the districts.

US Amb Deborah Malac, Dr Lisa Nelson, officials from CDC, RHSP, Kalangala district and MOH during a test ride of the MV RHSP on lake victoria in Kalangala district. The 400 horsepower boat transports health workers across the 52 islands easing delivery of different health services.

PWIDs (People Who Inject Drugs) interacting with CDC team during at site improvement management visit at Uganda Harm Reduction offices in Masaka town..

Group photo after US Amb. Natalie Brown officially opened the Bukomansimbi District Action Centre.

CDC and RHSP teams at Uganda Cares, in Lukaaya, interacting with sex workers who were reported to face challenges remaining on their ART medication during the COVID-19 lockdown.

US Amb Natalie Brown inspecting a DREAMS stall with different crafts made by AGYWs (Adolescent Girls and Young Women).

Masaka Deputy RDC - Daniel Kabunga Sentamu dancing with a graduand. Looking on were the Masaka RDC and DHO Dr Faith Nakiyimba.

RHSP's Abdul Lutaaya conducting a hands-on Electronic Medical Records system training of health workers at Lulamba HCII on Kachanga Island.

RHSP's Prof David Serwadda and Dr Joseph Kagaayi during a kits handover at the Masaka DREAMS graduation ceremony.

23 PUBLICATIONS

Rakai Health Sciences Program
Improved Health Through Research

PUBLICATIONS

2019 PAPERS

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