



**Rakai Health
Sciences Program**
Improved Health Through Research



STATUS REPORT 2018



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. With PEPFAR support, it is also an implementing partner for HIV prevention and treatment services in 12 districts (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/AIDS first identified in East Africa by Drs. David Serwadda, Nelson Sewankambo and Maria Wawer. It was expanded in 1994 and renamed the Rakai Health Science Program (RHSP) 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 RHSP's Rakai Community Cohort Study (RCCS) 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 reservoir.

Rakai Health Sciences Program Status Report 2018

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Vision Statement

To excel in Health Research, Disease Prevention and Care

Mission Statement

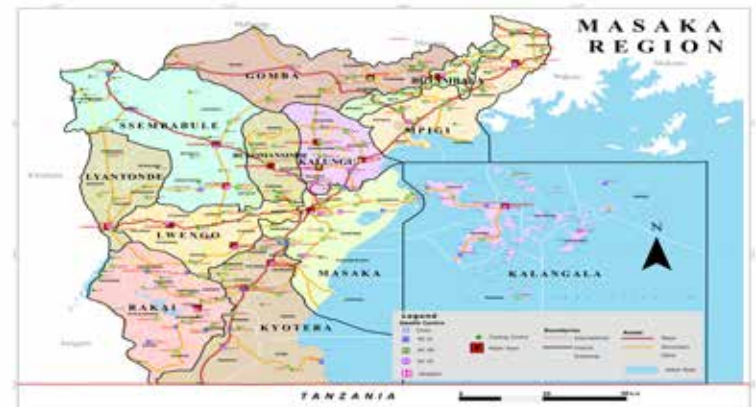
To conduct innovative health research on infectious diseases, non-communicable diseases and reproductive health, and to provide health services to improve public health and inform policy.

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 define its organizational culture and create a unique environment for health research and services.



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Acronyms

ART	Antiretroviral therapy	COP	Cooperative Agreement
CDC	Centre for Disease Control	HMIS	Health Management Information System
CME	Continuing Medical Education	EMR	Electronic Medical Record
DHO	District Health Officer	DHIS	District Health Information System
DLP	District Led Programming	METSP	Monitoring & Evaluation Technical Support Program
GoU	Government of Uganda	M&E	Monitoring & Evaluation
HPV	Human Papilloma Virus	DTLS	District Tuberculosis and Leprosy Suspension
HIV	Human Immune Virus	NTLP	National Tuberculosis and Leprosy Program
HSV2	Herpes Simplex Virus Type 2	ICER	International Center for Excellence in Research
HUE	HIV-Uninfected Exposed	NIAID	National Institute of Allergy and Infectious Diseases
HUU	HIV-Uninfected Unexposed	GBV	Gender Based Violence
IP	Implementing Partner	KP/PP	Key Populations/Priority Populations
MoH	Ministry of Health	DLFP	District Laboratory Focal Person
NIH	National Institutes of Health	OCICB	Office of Cyber Infrastructure and Computational Biology
PEPFAR	President's Emergency Plan for AIDS Relief		
RHSP	Rakai Health Sciences Program		
VMMC	Voluntary Medical Male Circumcision		
SMX	Sulphamethoxazole		
TMP	Trimethoprim		



From Chair Board of Directors

Professor David Serwadda

Welcome to the 2018 edition of the Rakai Health Sciences Program (RHSP) status report. This year marks 30 years since Rakai Health Science Program, initially called Rakai Project, was established. The Program is recognized locally and internationally as a health research, training and service provision organization. We are pleased to share with you the academic, administrative, structural and scientific accomplishments over a three-year period to 2018. In the pages to follow we describe our continued commitment to collaborate with international and government agencies and scientists to promote health research and services. Our work is primarily community-based, engaging the communities and their leaders through meetings, educational drama shows, videos, radio and other communication methods to provide information on research and health services. Our shared responsibility with the district leadership to providing appropriate health service continues to grow stronger over the years.

In the last three years there are several major accomplishment and changes I would like to highlight. In order to cater for

growth and effectiveness expanding research and service portfolio, Rakai Health Science Program restructured in 2015 into three directorates namely research, Program and administration. Secondly, in 2016 RHSP was awarded a PEPFAR CDC grants to implement comprehensive HIV prevention, care and treatment services in the Masaka region. Masaka region consists of 12 districts (including Sese Islands) in South western Uganda. This has significantly expanded the geographical area of operation for RHSP and significantly increasing the number of RHSP staff to the current level of 725. Thirdly, in December 2017 RHSP published a landmark paper in the New England Journal of Medicine, which was the first in Uganda to demonstrate the impact of scaling up Circumcision and HIV treatment at a population level on HIV incidence. A 42% percent decrease was observed after about 10 years of scaling up. This paper illustrated the benefit of our continuous population based HIV surveillance for over 12 years in order to evaluate HIV intervention of public health importance.

Our open population-based prospective cohort, the Rakai Community Cohort Study (RCCS), has continued to enrol consenting residents aged 15-49 in approximately 40 communities distributed throughout Rakai and neighbouring districts. In this reporting period, we have been able to complete three census and survey rounds

and now have embarked on the 18th round of surveys. Regarding our Masaka Region HIV care program, since April 2017, we have been able to undertake over 491,229 HIV tests, 96,540 have been maintained on ART treatment and 92,414 circumcisions have been undertaken. Challenges remain high on list is engagement of more men in HIV prevention and treatment program

Our Safe Male Circumcision (SMC) program continues to offer services and training throughout Uganda and provided relevant research findings. We have continued to train local and international scholars, provided refresher courses for health care workers, provided SMC skills training with follow up mentorship, and hosted local and international interns. RHSP's staff have also pursued studies at Bachelors, Masters and PhD levels.

As we look forward to our 30th celebration, we wish to thank all the community members for participating in the research and service activities. You have made us who we are! The program also extends heartfelt gratitude to the administrative and political leadership in the districts and to our scientific, administrative and support staff for tireless efforts throughout the years. We appreciate this dedication and devotion to RHSP. We also thank our past and present funders, who make this partnership and collaboration possible.

From the Executive Director

Dr Joseph Kagaayi

It is my pleasure to present the 2018 Rakai Health Sciences Program (RHSP) report at a time when we are marking 30 years of existence. This report comes at a time when RHSP's profile in Research and service programs has greatly expanded. Over the last three years our population-based approach to research through the Rakai community cohort study, has provided cutting edge scientific evidence for the impact of Combination HIV prevention (CHP) on the HIV epidemic; both in the general population and among fisher folk, who make up the greatest majority of the HIV priority population in Rakai and neighboring districts. The cohort has also highlighted the important contribution of migration to the HIV epidemic and informed generation of hypotheses to mitigate the effects of migration on the epidemic; some of which will soon be tested through studies nested within the cohort. Through our cohort we showed the importance of phylogenetic

analysis in understanding complex HIV transmission networks; knowledge that has the potential to improve targeting of populations and locations at the greatest risk of HIV with HIV preventive interventions.

With funding from PEPFAR through CDC-Uganda, we have expanded HIV service provision from Rakai and Kyotera districts to ten other districts including Kalangala district, which is composed of 84 hard-to-reach Islands. A district-led approach to service provision is used in these districts with RHSP offering technical, logistical and financial support through partnership with local government administration and district health teams. This partnership is already helping to ramp up service provision to communities.

Rakai Health Sciences Program owes its success to the great partnerships built over time



including community, district, national and international partnerships. In this regard, we would like to express our sincere gratitude to our collaborators at Makerere University, Ugandan Ministry of Health, Uganda virus research Institute, Johns Hopkins Bloomberg School of Public Health, NIAID division of intramural research, CDC-Uganda, Columbia University, Karolinska Institutet, the district local governments and to all residents in the communities we support.

It is my sincere hope that you will find it rewarding to review a detailed account of our achievements in research and service provision in the chapters which follow.

From ICER Scientific Director

Dr. Steve J. Reynolds

The National Institute of Allergy and Infectious Diseases through the ICER program continues to appreciate the valuable collaboration with the team at Rakai Health Sciences Program. Together we have built state of the art laboratory, data, and information management systems, which contribute to the programs ability to produce groundbreaking research and high quality service delivery. Our combined goal is to achieve HIV epidemic control and provide evidence based strategies for effective HIV prevention and quality HIV care in addition to tackling other Infectious Disease challenges in the region. Together we are achieving that goal and at the same time building the next generation of research staff poised to respond to the many health challenges facing Uganda.

Our current scientific focus spans from bench to bedside. At the bench we are in the fourth year of studying the Latent HIV reservoir in HIV infected Ugandans receiving ART. Data from this study will be crucial in guiding HIV Cure strategies in Uganda and beyond. Through an NIH bench to bedside award we are also conducting a study to understand Herpes virus reactivation and its impact on immune activation among women starting ART. We also continue



to study the best ways to monitor individuals receiving ART including optimal timing of viral load monitoring with the ultimate goal of improving population level viral suppression in Rakai.

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Al Sumait Award



RHSP was one of three joint recipients of the 2018 Al Sumait Award in Health, administered by the Kuwait Foundation for the Advancement of Sciences (KFAS). RHSP was recognized for its 30 years of effort in HIV prevention and services, and its high impact research in Uganda. His Highness Sheikh Sabah Al-Ahmad Al-Jabar Al-Sabah presented the Al Sumait medal and shield to Dr. David Serwadda and Dr. Maria Wawer, who received it on behalf of the RSHP at a special ceremony in Kuwait.



RHSP Senior Management Team in receipt of the Al Sumait Award in Kampala.



Research

01

Rakai Community Cohort Study - RCCS

The Rakai Health Sciences Program (RHSP) has conducted the Rakai Community Cohort Study (RCCS) since 1994. The RCCS is an open population-based prospective cohort which enrolls all consenting residents aged 15-49 in ~40 communities distributed throughout Rakai and neighbouring districts. Prior to each survey, the communities are engaged in a series of health sensitization and mobilization activities during which information is communicated on research results about health and relevant behavioural trends and information pertaining to the next survey visit is provided. A household census is

performed prior to the survey, to enumerate all residents with no age limits, within RCCS communities, collecting and collect data on demographic characteristics, deaths, births, marriages, migration, household socioeconomic status and GPS coordinates. At the surveys consenting participants complete a detailed sociodemographic, behavioural, sexual network, mobility, health and health service utilization interview, and provide a blood sample for HIV testing. Survey information is recorded on mini laptops. Current surveys take place at a central place in the community ('hub site') over 5-8 days. The 'hub'



also provides HIV counselling and testing and referral for care. Approximately 18-20,000 individuals participate in the RCCS; the response rate among age eligible persons present at time of survey is over 90%, and annual follow up is approximately 75%, with losses due primarily to absence for work or education, out-migration and aging beyond age 49. Through RCCS we are able to document;

- Trends in HIV prevalence, incidence, risk behaviours and demographic trends in Rakai
- Evaluate the impact of health programs on HIV incidence
- Efficiently conduct a wide range of relevant nested research studies including randomized clinical trials.



Data entry clerks capturing client data at a remote Hub.



HIV Prevalence in RCCS Communities

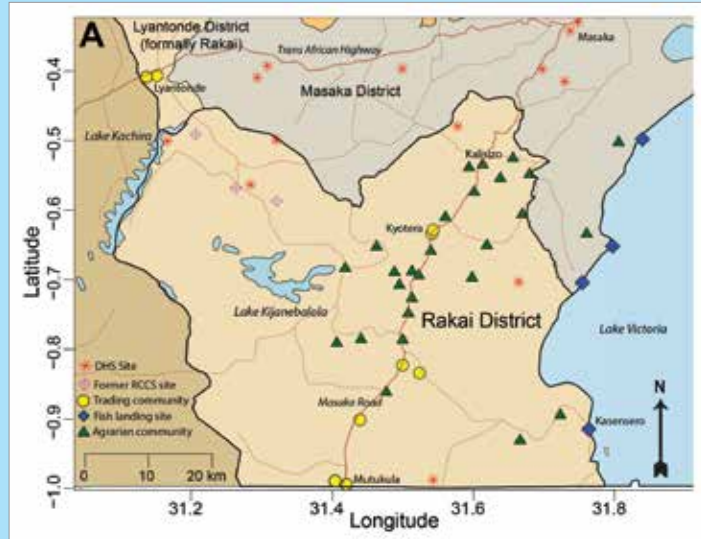
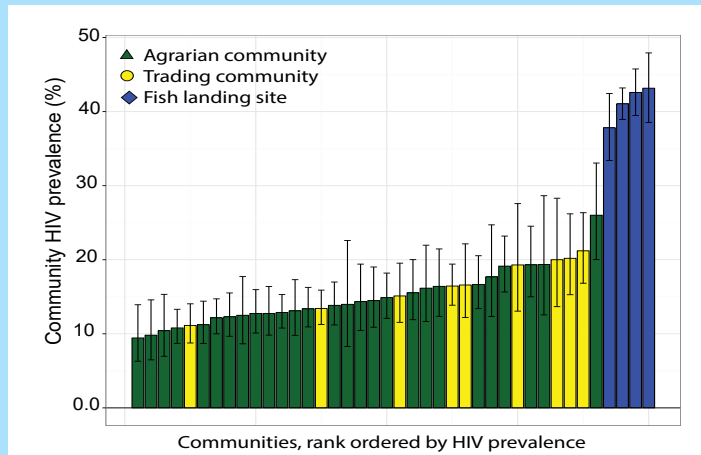


Figure 1: HIV Prevalence by Community in RCCS



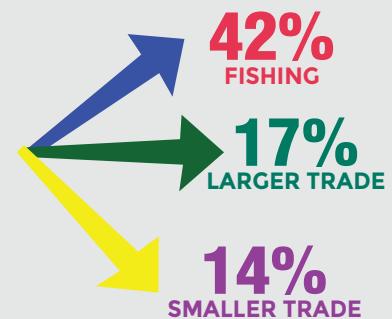
Key RCCS Statistics:

- As shown in Figure 1, HIV prevalence is ~14% in trading villages on secondary roads, ~17% in larger trading centers on main roads which serve as transport hubs, and is highest in fishing communities along Lake Victoria’s shores (~42%.)
- HIV incidence ranges from ~0.9/100 person years in the more rural communities to ~3.54/100 PY in the fishing villages
- The HIV epidemic in Rakai is composed of subtypes A,D and recombinants
 - Among adults, almost all transmission occurs through heterosexual intercourse.
- RCCS findings on trends in the rate of new HIV infections (incidence) are reported in the next section (Section 2).

HETEROGENEITY
HIV PREVALENCE



Prevalence



02

RCCS research documents reductions in new HIV infections across fishing, trading and rural communities following the roll out of combined HIV prevention and treatment interventions

a) Trends in HIV Incidence and Coverage of ART and VMMC

An analysis of HIV incidence in trading and agrarian communities between 1999 and 2016 showed a 42% reduction in HIV incidence from 1.17 per 100 person years (py) to 0.66/100 py. This reduction was associated with substantial increases in ART coverage (to 69%) among all HIV+ persons and VMMC coverage (59%). The reduction in HIV incidence was more marked among men (59%) than women (32%) because men were protected both by their VMMC status and by ART use by their female sexual partners.

There was also an increase in the proportion of adolescents who had not initiated sex from 30% to 59%. (Grabowski et al NEJM, 2017).



HIV incidence from
1999



to 2016

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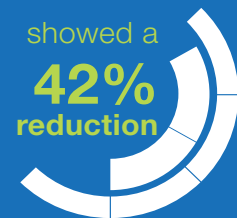
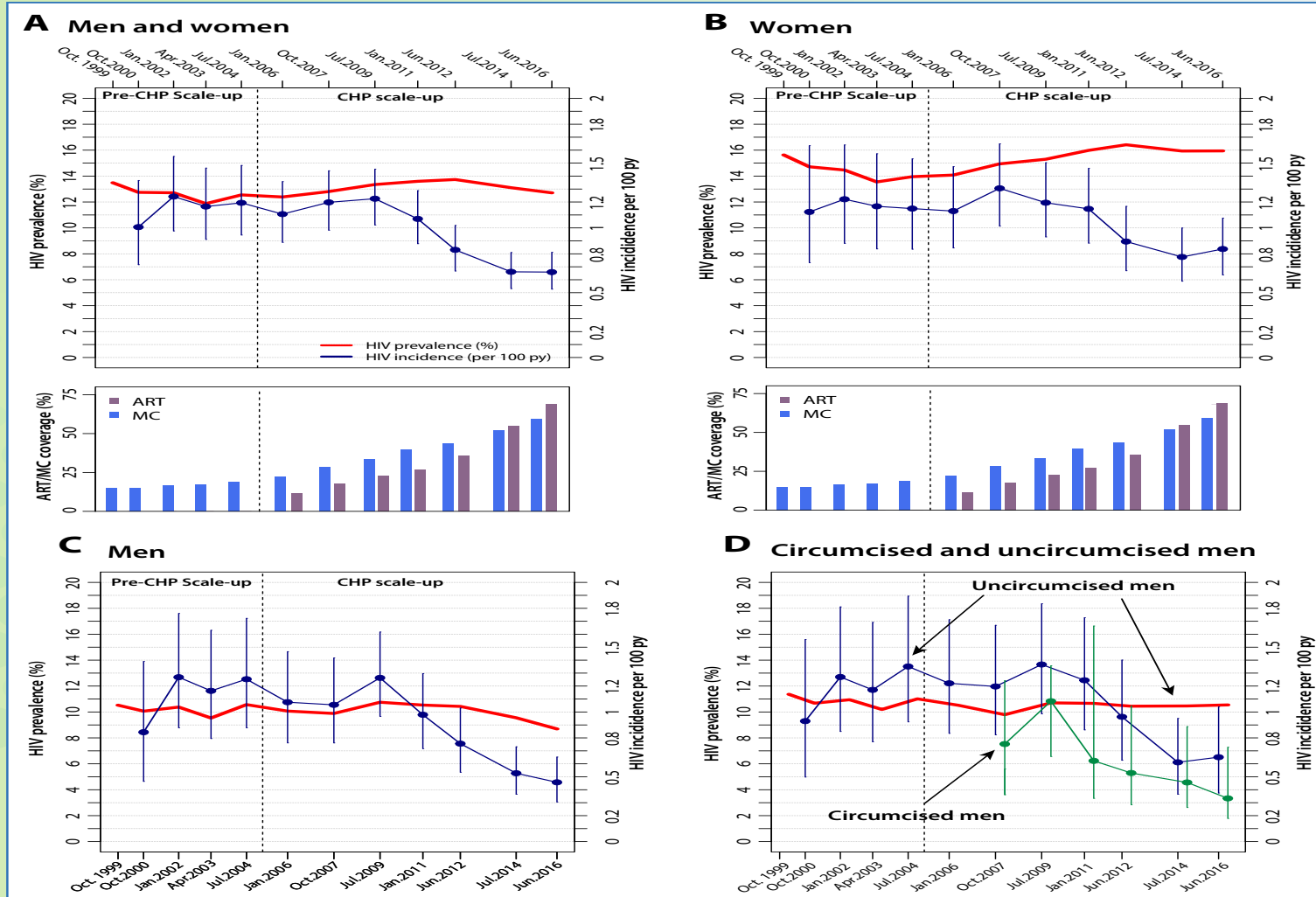


Figure 2: HIV incidence and prevalence by ART and VMMC coverage 1999-2016



KEY	— HIV prevalence	— HIV incidence Time of ART and voluntary medical male circumcision (VMMC) rollout
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Fishermen along the Kasensero fish landing site.

b) Declines in HIV incidence have occurred in fishing communities from 3.5/100py in 2011 to 1.5/100py in 2016 due to increased coverage of ART and VMMC.

Prior analysis of RCCS up to 2013 showed that a high proportion of HIV infections in a community were from sexual partners who lived outside of the community (Grabowski et al PLOS Med 2014). This led to studies of migration and mobility in Rakai using geocoded places of origin and

destination for migrants.

Recent migrants had an increased risk of incident HIV (1.9/100 py) during the first 2 years among those migrating to the community compared to 0.92/100 py among long term residents. HIV incidence among migrants declined with longer duration of stay >2 years in a community. HIV incidence among residents declined over time with scale up of ART and SMC, but remained elevated among migrants who had lower rates of CHP use.

(Olawore et al. Lancet HIV 2018.)

There is a need to expeditiously identify migrants and link them to HIV care and prevention services.

Importantly, hot-spot fishing communities on Lake Victoria were a major destination for in-migrants who had high rates of HIV infection, but out migration from hot-spots was relatively low and diffuse.

Thus, hot-spots appear to serve as “sinks” for HIV rather than as a source of transmission to the general population.

c) Mortality after the introduction of Antiretroviral Therapy in the Rakai Community Cohort Study

- The reductions in mortality were accompanied by increases in life-years lived in adulthood.
- The increases in the population-wide number of years lived in adulthood started before the rollout of ART at local health facilities.
- Among PLHIV, the years lived in adulthood increased by more than 10 years following the introduction of ART (Figure 1a).
- The burden of HIV mortality at the population level was initially higher among women than among men: 8.1(95% CI: 6.5, 9.5) compared with 4.3 years (95% CI: 2.9, 5.7) in 2000, respectively (Figure 1b).
- By 2014 the adult life-year deficits were much smaller, and similar in magnitude between sexes: 1.3 years (95% CI: 0.3, 2.5) for women and 0.4 years (95% CI: -0.4, 1.3) for men (Figure 1b).

Fig 1a. Life years lived by HIV negatives and the population as a whole

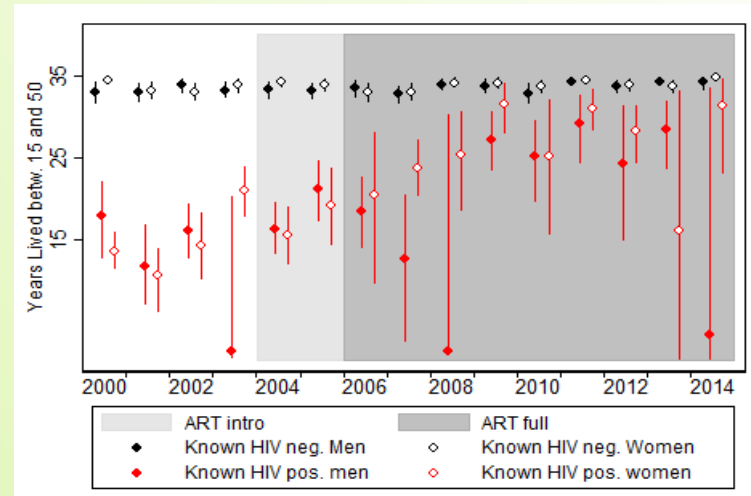
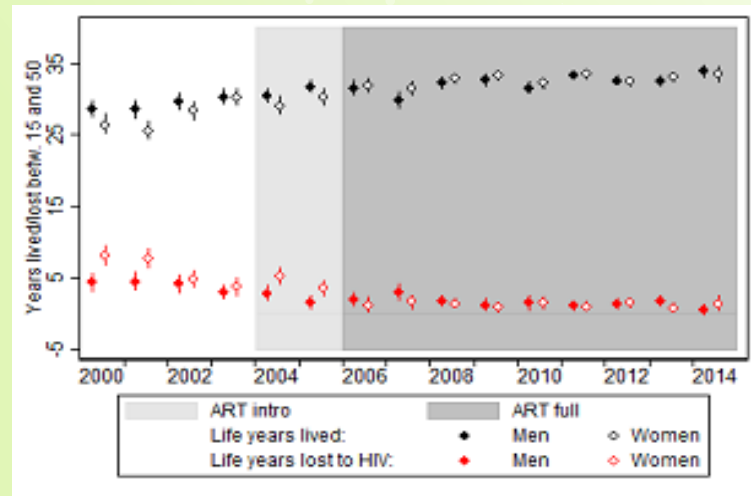


Fig 1b. The population wide life years lost to HIV and life years lived by the population as a whole.



03

Qualitative Research

The Qualitative Research Section provides insights into the perspectives of study populations and health services recipients. This guides project formulation and design, project monitoring and understanding/interpretation of quantitative findings. Methods include focus group discussions (FDGs), in-depth interviews with key informants (IDIs), participant observation (PO). Face-to-face IDI interviews explore a research topic by eliciting individual perspectives independent of community norms and group dynamic.

Informed consent for study participation and permission to audio-tape interviews and discussions are sought and

in rare occasions where a participant is uncomfortable with recording, we rely on field notes. All data collected is transcribed verbatim in Luganda by the primary data collector and translated into English. Data cleaning and entry are completed expeditiously. Transcripts are reviewed for main themes which are imported into QSR NVivo Version 9 for coding and identification of “nodes” for construction of matrices of interconnections for cross-informant-group analyses of themes by demographic and behavioural and geographic/societal strata. Selected qualitative studies are summarized in the studies section of this report.



Focus group discussions and in-depth interviews with key informants.



04

Implementation Science Studies

A randomized trial of self-selected “treatment buddies” to support patients in pre-ART care showed improvement in the activities of daily living but had no effect on adherence to monitoring visits or eligibility for ART (Nakigozi *et al.* JAIDS 2015). Another trial of pre-ART patients assessed the use of peer support versus standard of care among initially care naïve individuals, and showed improved rates of cotrimoxazole use (78% vs 58%, $p=0.04$) and use of safe water vessels (20% vs 4%, $p=0.02$). (Chang *et al.* AIDS Behav 2015.) A current trial is assessing the impact of community health workers on HIV treatment and prevention in a hot spot fishing community (Chang *et al.* Trial 2017). In a study of 1,841 patients on ART, 8% had unsuppressed viral loads, but after additional adherence support, 60% of this group had

suppressed viremia at 48 weeks (Billieux *et al.* PLOS One 2015). Treatment failure on first line ART was low at 4.2% between 2004- 2011 and 66% of those failing switched to second-line ART (Ssempijja *et al.*, 2017). There are very low rates of transmitted drug resistance in Rakai (Reynolds *et al.* AIDS Res Hum Retroviruses, 2017.) A risk index was developed to identify persons most at risk of acquiring HIV and was shown to successfully identify the upper quartile of individuals at highest risk (Kagaayi *et al.* PLOS One 2014).

We also assessed self-selection of men who accepted or declined VMMC and showed that acceptors were younger (26.1 vs 28.5 years), more likely to reside in urban areas (21.1% vs 12.4%), more likely to be never married (63.5% vs 54.2%)

and to report multiple sex partners (48.3% vs 41.6%). Thus the VMMC program was attracting sexually active men at higher risk of HIV (Kagaayi *et al.* AIDS 2016). The marginal costs of SMC via mobile camps (\$23) was substantially lower than services via fixed facilities (\$35) and mobile camps served a larger number of SMC clients (Alfonso *et al.* JAIDS 2016). To determine progress to the UNAIDS 90-90-90 goal we assessed the treatment cascade in Rakai. From 2013-15, 98% of the RCCS population had received HCT, 74% of HIV+ persons were enrolled in care, 63% initiated ART of whom 92% were virally suppressed after 12 months of ART (Billieux *et al.* J Int AIDS Soc 2017). The 63% initiating ART largely reflects the WHO eligibility criteria at that time, but the introduction of test and start is likely

05

Social and Behavioral Science studies

Numerous qualitative studies are conducted to support field research. In-depth interviews in a high prevalence fish landing site assessed drivers of HIV transmission and identified the importance of commercial sex, risk denial by fishermen, alcohol and drug abuse, peer pressure and poverty as key factors (Lubega et al. PLoS ONE, 2015). Other studies assessed the role of women to motivate men to accept VMMC. All female participants preferred circumcised men because of perceived reductions of HIV and STI risk, improved penile hygiene and increased sexual pleasure. There were concerns about abstinence and loss of income during wound healing and potential male sexual disinhibition and infidelity. Participants supported the role of women in SMC

acceptance. Studies of HIV-infected couples showed 75% disclosure of results after the availability of ART compared to 58% before ART was available ($p < 0.001$). In the post-ART period, disclosure was 39% among persons not in care compared with 85% among persons on ART (Haberlen et al. JAIDS, 2015.) A study of the effects of family structure on risk behaviors in adolescent girls showed that the presence of a biological father in the household was associated with reduced risk of multiple sexual partners among out-of-school girls (Pilgrim et al. Int Adolesc Med Health, 2014.) The prevalence of sexual activity among adolescents declined after 2002 as school enrolment increased over time (Santelli et al. J Adoles Health, 2015.)



In depth interviews and focus group discussions being carried out at kasensero fish landing site.

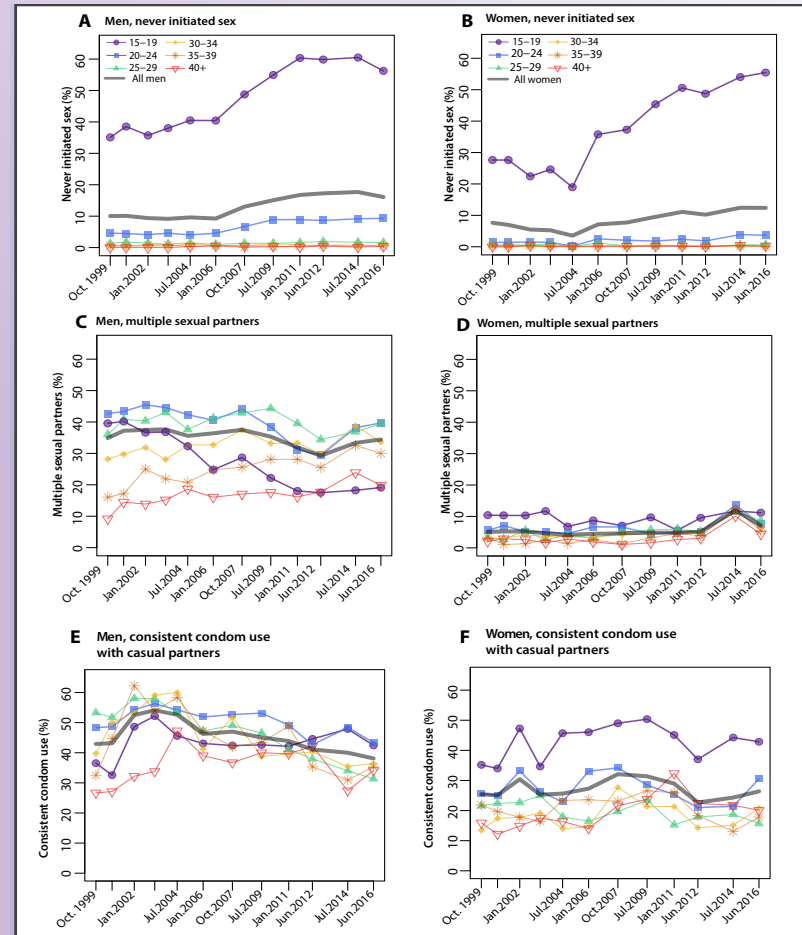


06

Studies of adolescents and youth

In collaboration with Columbia University, we found that sexual debut and sexual concurrency (multiple overlapping partners) decreased among adolescent girls (15-19), but not among young women (20-24). The decline in sexual experience was primarily attributed to increasing school enrollment (Santelli et al. AIDS, 2015). Another study showed HIV incidence was higher in adolescent girls than boys (1.4 vs 0.8 per 100 py), and the risk of new infection was associated with social transitions such as leaving school, marriage and divorce (Santelli et al JAIDS 2013).

Sexual debut and concurrency decreased among adolescent **girls (15-19)**, but not among young **women (20-24)**





a) Delayed Sexual Debut Among Adolescent Boys and Girls in RCCS

Focus group discussions and in-

depth interviews with sexually active girls aged 15 to 17 documented coerced intercourse, unwanted sexual touching, verbal harassment, and transactional sex. Sexual

coercion was perceived to be common in intimate relationships reflecting a woman's lack of decision-making authority or choices in sexual encounters.

07

HIV and Liver Disease

RHSP previously found that the prevalence of significant liver fibrosis was higher among HIV- infected individuals (17%) than uninfected persons (11%).

The HIV-accelerated liver disease study assessed the etiology of liver disease and HIV associated liver fibrosis using liver biopsy. The study enrolled participants with liver stiffness measurements >9.3 kPa based on transient elastography scores or elevated liver function tests consistent with liver disease.

One hundred and forty three (143) HIV- positive and 45 HIV-negative participants were enrolled of whom 113 HIV-positive and 31 HIV-negative had liver biopsy. Biopsies were histologically staged and graded but

there was no correlation between elevated liver stiffness and biopsy proven liver pathology. No active Hepatitis C virus (HCV) was detected in Rakai (Mullis et al. CID, 2013) and HBV was 5% in HIV+ persons (Redd et al AIDS Res and Hum Retrovir, 2013).

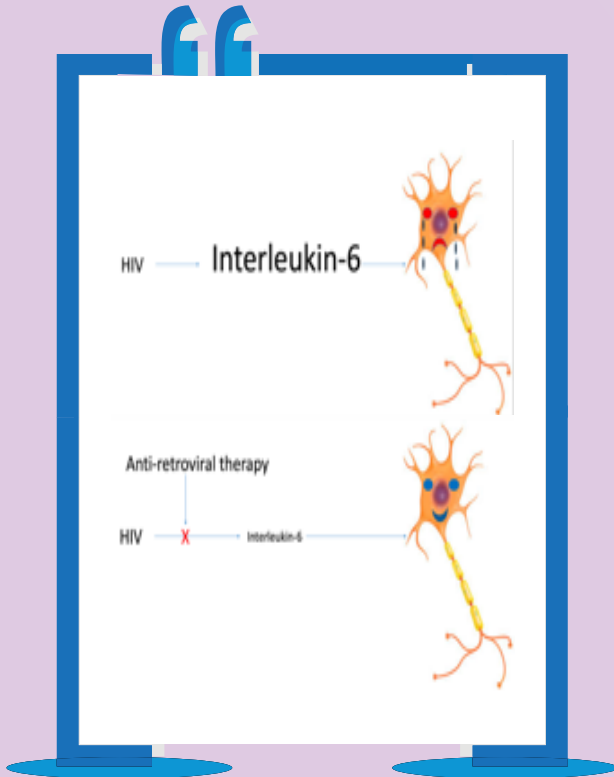
In a retrospective cohort analysis, we investigated the incidence and risk factors associated with HBV among HIV-infected adults and found HBV incidence was significantly lower with ART use (0.49/100 py) compared with (2.3/100 p-y) without ART [aHR=0.25 (95% CI, 0.1-0.5) $p<0.001$]. HBV incidence also decreased with HIV RNA suppression: (0.6/100 p-y) with ≤ 400 copies/mL and (4.0/100 py) with >400 copies/mL [aHR= 6.4(2.2-

19.0), $p<0.001$] and with age: 15-29 years vs 40-50 years [aHR=3.2 (1.2-9.0)]; 30-39 years vs 40-50 years [aHR=2.1(0.9-5.3)] (Seremba et al, AIDS 2017)



08

Neurologic Studies



Under a NIH grant we have established the Rakai Neurology Cohort Study (RNCS), which enrolled 400 HIV+ ART naïve individuals and 400 HIV-negative controls to evaluate neurocognitive comorbidity associated with HIV infection and to determine whether it varies by HIV subtype. At baseline, the prevalence of HIV Associated Neurocognitive Disorder (HAND) was 59% in the HIV+ individuals. HIV Associated Dementia (HAD) was 15% in HIV+ and 4% in the HIV- participants. Peripheral neuropathy was 19% in the HIV+ and 7% in the HIV- individuals (Saylor et al. in press). The HIV infected participants were initiated on ART and followed up over 2 years. HAND stage improved for 32% of persons on ART and dementia declined to 5%, comparable to the

prevalence in uninfected individuals. However, 17% of HIV+ persons on ART had a deterioration in their HAND stage (Sacktor et al. CROI Seattle, 2017). Immunologic studies of cerebrospinal fluid (CSF) in ART naïve HIV+ persons showed an increase in inflammatory cytokines and neurodegenerative markers in patients with lower CD4 counts and dementia. IL-6 was identified as the main driver of CNS inflammation (Abassi et al. J Neurovirol, 2016). Phylogenetic analyses suggest a higher prevalence of HAND with subtype D (60%) than subtype A (43%). Preliminary data suggest that 50% of HIV+ ART naïve patients have CSF compartmentalization consistent with virologic replications in the CNS.

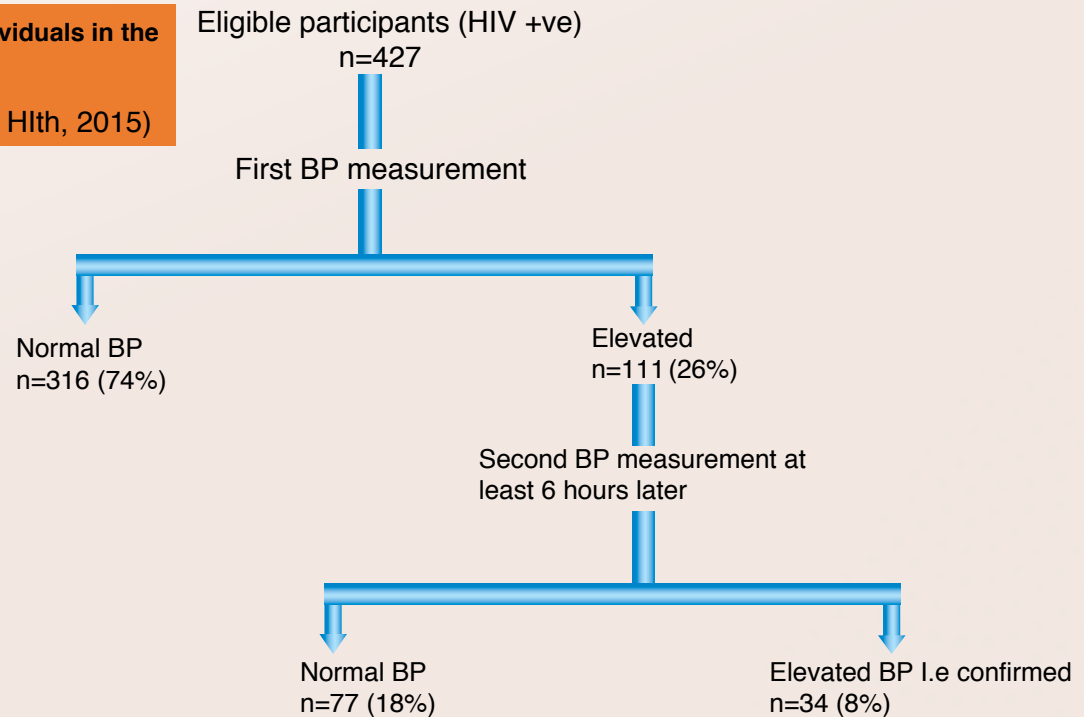
09

Studies of Cardiovascular Disease

427 HIV+ individuals were assessed for hypertension. The prevalence of hypertension (two elevated blood pressures at different times) was 8% and the prevalence of elevated blood pressure (elevated at only one time) was 26%. No patient had diabetes (Sander *et al* Trop Med Int Hlth, 2015).

Hypertension in HIV +ve individuals in the RCCS cohort

(Sander *et al* Trop Med Int Hlth, 2015)



10

Results of Early Virologic Monitoring May Facilitate Differentiated Care Monitoring Strategies for Clients on ART, Rakai, Uganda

Background

Viral load (VL) monitoring is standard of care in HIV-infected persons on ART. We evaluated the predictive value of VL measurements at 6 and 12 months after initiation of firstline ART to estimate the future risk of virologic failure (VF).

Methods

HIV-infected persons with VL measurements at 6 and 12 months post-ART initiation and at least 2 additional VL measurements thereafter were assessed for risk of future VF, defined per World Health Organization guidelines. VL at 6 or 12 months post-ART was categorized into <400, 400–1000, 1001–2000, and >2000 copies/mL. Cox proportional hazard models were used to compare VF incidence associated with 6-month, 12-month, and a composite of 6- and 12-month VL (Figure 1)

Results

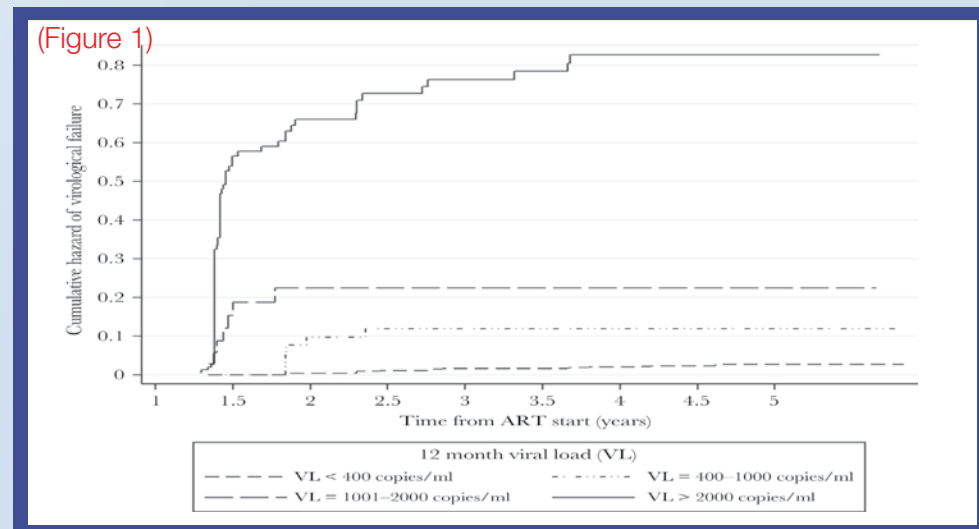
Overall, 1863 HIV-infected adults had a 6- and 12-month VL measurement, and 1588 had at least 2 additional VLs thereafter. At 12 months post-ART, 90% had VL <400 copies/mL, 3% had 400–1000 copies/mL, 2% had 1001–2000 copies/mL, and 5% had >2000 copies/mL.

The predictive value of the 12-month VL measurement was comparable to the composite of both the 6- and 12-month

VL measurements and better than the 6- month VL measurement.

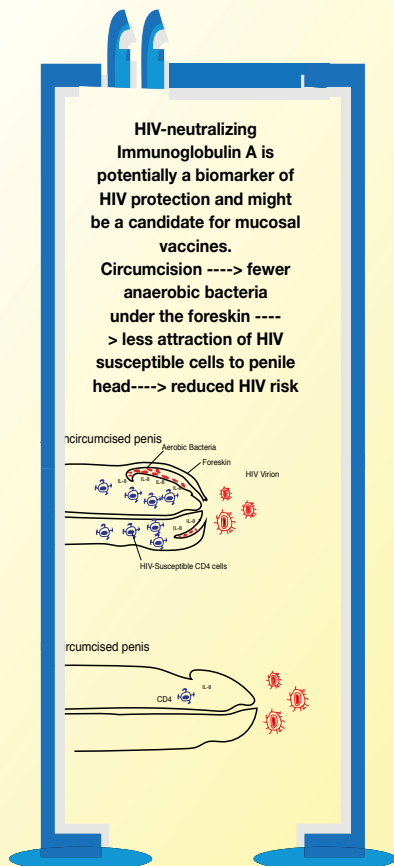
Conclusions

At 12 months after ART initiation, 90% of patients were virally suppressed with a low likelihood of future VF. VL measurement at 12 months post- ART initiation predicts risk of VF and could inform differentiated virologic monitoring strategies.



11

Penile immunology studies



Voluntary Medical Male Circumcision (VMMC) reduces the risk of HIV acquisition by ~ 60% but the exact mechanisms of this protection are not known. Understanding the biological basis of this protection may guide design of new prevention tools. In collaboration with immunologists at Karolinska Institutet, Stockholm and University of Toronto, Canada, RHSP has assessed the role of penile cellular and humoral immunology in male HIV acquisition risk. In a case control study, levels of HIV-neutralizing IgA from penile swabs were compared between 99 HIV seroconverters versus 109 uninfected controls. Seroconverters had lower levels of HIV-neutralizing IgA compared to the controls (OR=0.21, 95%CI 0.11- 0.39), (Hibrod et al. PLOS Pathogens 2014.) Another study explored correlates of protection against HIV in HIV-exposed but seronegative (HESN) men with HIV infected female partners and found that HESN men had elevated HIV neutralizing IgA (50% versus 13.5%) compared to non-exposed men (Prodger et

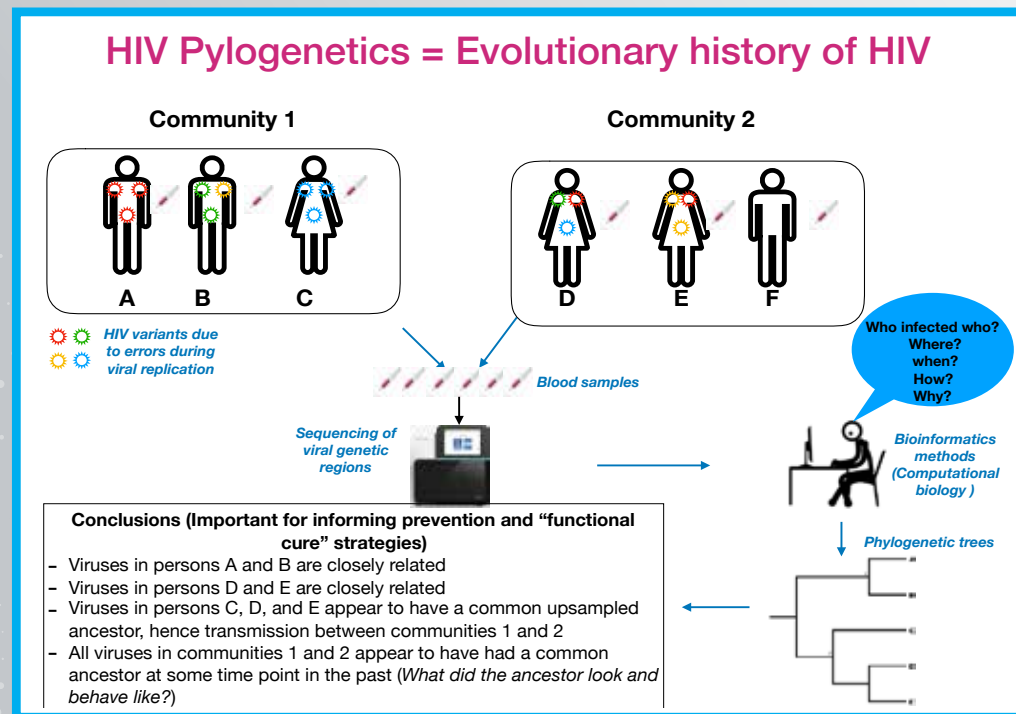
al. Mucosal Immunology, 2013). This suggests that HIV-neutralizing IgA is potentially a biomarker of HIV protection and might be a candidate for mucosal vaccines. Further studies show that male circumcision significantly reduces the penile anaerobe burden, HIV acquisition was associated with the presence of pre-circumcision specific anaerobic bacteria and elevated pro-inflammatory chemokines especially IL-8 (IL-8, OR=2.26, 95%CI 1.04-6.40) in coronal sulcus swabs (Liu et al MBio 2013, Prodger et al PLOS Pathogens 2016; Liu et al MBio 2017). The levels of IL8 correlated with both the density of anaerobic bacteria on the penis and with increased HIV target cell density in foreskin tissues. Taken together, these findings suggest that the presence of specific anaerobes on the uncircumcised penis are key drivers of sub-clinical inflammation, which mediates increased immune cell trafficking; including highly susceptible CD4+ T cells, to the foreskin and this in turn increases male HIV susceptibility. It is notable that post-coital washing does not reduce HIV acquisition in uncircumcised men (Makumbi et al. AIDS 2016).

12

Phylogenetics

Rakai Health Sciences Program (RHSP) is a member of the Phylogenetics And Networks for Generalized HIV Epidemics in Africa (PANGEA) consortium, whose aim is to use HIV phylogenetics (study of evolutionary history using HIV genetic information) to study HIV transmission and refine preventive interventions for epidemic control. PANGEA includes several collaborators in sub-Saharan Africa. We have members on the executive and steering committees of the PANGEA network.

We also use phylogenetics methods to study the latent viral reservoir (hiding HIV) to inform strategies for an HIV functional cure. We do this work with key collaborators at the Johns Hopkins University and the NIH; and Oxford



University. Key findings thus far are that viral sequencing can determine the source of transmission and

show that high prevalence fishing communities are not a major source of infection in the general population.

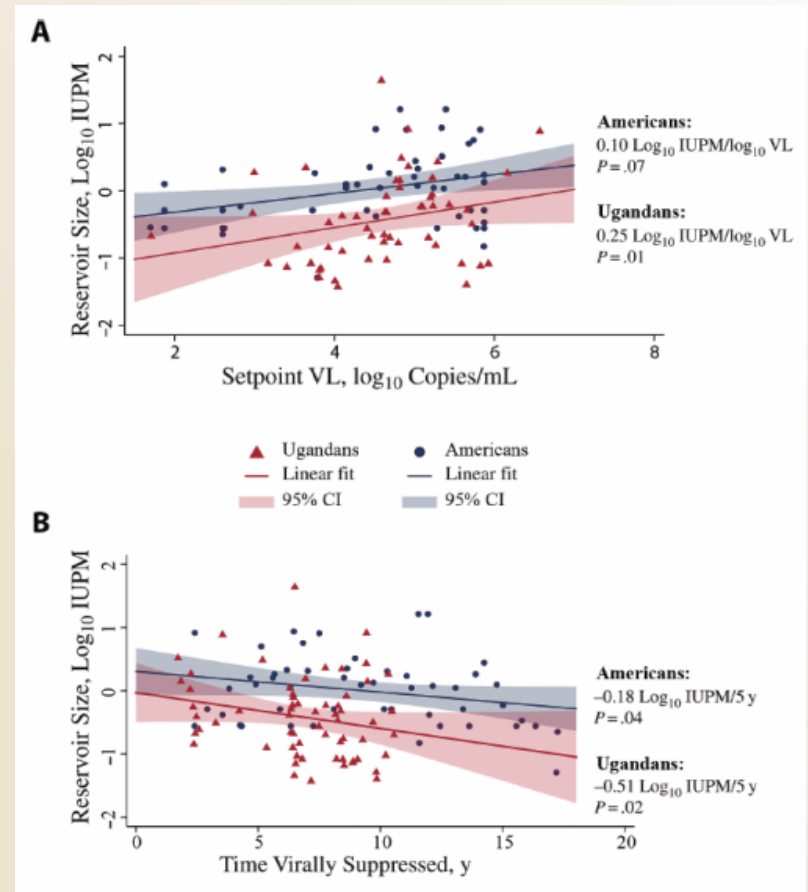
13

Quantitative Measurement and Correlates of the Latent HIV Reservoir in Virally Suppressed Ugandans

The study was the first to describe the latent HIV reservoir in a sub-Saharan African population. 90 HIV-infected participants on ART with suppressed viral loads (<400 copies per ml for a minimum of 10 months) were enrolled and followed with annual blood draws for latent HIV quantification.

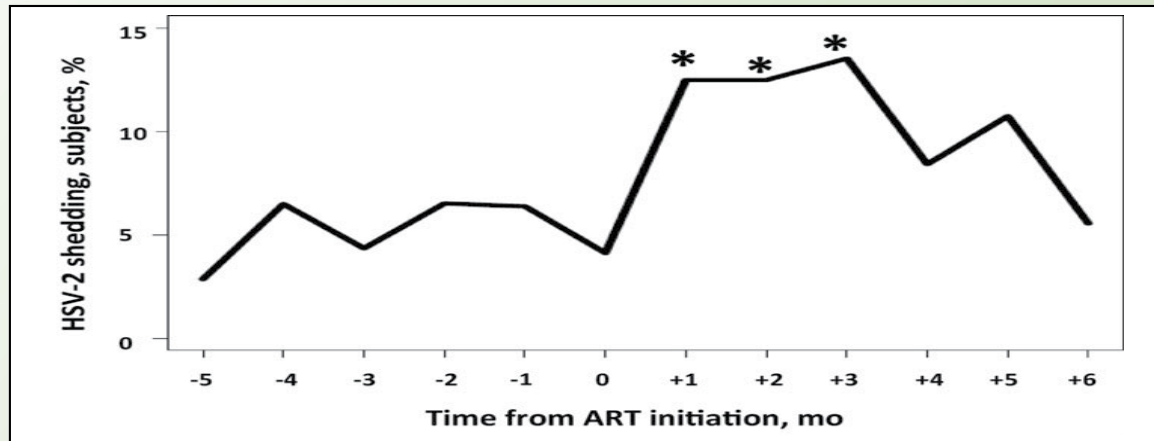
A quantitative viral outgrowth assay was used to determine the frequency of rCD4 cells containing replication-competent virus in enrollment samples. Initial findings (Prodger et al CID 2017) are that the viral reservoir size in Ugandans is 61% lower than comparable African American populations (0.36 vs. 1.08 infectious units per million cells (IUPM)). Reservoir size was positively correlated with set point viral load and negatively correlated with the duration of viral suppression (Figure 4).

The biological mechanism driving the observed smaller reservoir in Ugandans is of interest and may be of significance to HIV cure efforts. We are currently investigating relevant virologic and immunologic characteristics and quantifying latently infected cells in annual follow-up samples, us to determine if latently infected cells are being eliminated more quickly in Ugandans compared to Americans.



14

Herpes Virus Reactivation after Starting ART



The figure shows the increase in HSV-2 shedding following ART initiation.

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) lesions, cytomegalovirus (CMV) uveitis or other endorgan disease, and herpes simplex virus (HSV)-associated encephalitis. (Tobian et al, JID 2013, Gianella et al JID 2015)

Herpes reactivation upon ART

initiation may be related to immune reconstitution inflammatory syndrome (IRIS) but the etiology is unclear

Herpesvirus reactivation upon ART initiation may be related to immune restoration disease of immune reconstitution inflammatory syndrome (IRIS), but the etiology is unclear. To investigate these mechanisms we have begun a new study (Herpes Virus Reactivation

among HIV-infected women initiating ART) 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 also evaluate the potential impact of herpesvirus reactivation on HIV cellular reservoirs.

15

Stylish Man – Stylish Living Campaign

The “Stylish Man – Stylish Living” campaign is a novel community mobilization and multimedia demand generation campaign designed to improve the health and wellbeing of men, women and their families, through a combination of community mobilization, “edutainment” and mass media. The campaign seeks to “de-medicalize” health communication by promoting modern “stylish” values. The Stylish Man – Stylish Living campaign is being evaluated in a community randomized trial whereby 10 intervention communities receive a “Stylish Event” plus mass media, and 10 control communities receive mass media messages alone.

The campaign promotes the utilization of health services by depicting these services as trendy and desirable for modern stylish living. Key campaign Health Services include: Voluntary Medical Male Circumcision (VMMC), HIV Counselling and Testing (HCT), Family Planning (FP), Prevention of Mother to Child Transmission (PMTCT), HIV care and treatment and condom promotion. For VMMC, the Target Audiences are uncircumcised men aged 18+ years since these men have the highest rates of HIV incidence. Utilizing a combination of mass media and interpersonal communication, the campaign positions HIV prevention, care and treatment and FP as attributes of modern stylish living and desirable for every man and woman in Rakai. The campaign makes learning fun and stylish through a combination of entertaining approaches such as the “The Stylish Van,” community games and contests, and interactive



Community mobilized for sensitization about Mwami Mulembe campaign.



Community champions of the Mwami Mulembe campaign.



radio programs. The “Stylish Van” is equipped with a stage and multi-media communication system providing intervention communities with motivation, health education, and HIV and FP mobile services. The control arm received radio messages and VMMC services by a mobile clinic as well as HIV care via static clinics.

The hypothesis is that de-medicalisation of health services portrayed as fashionable embodiments of modern stylish living will increase adoption of these services.

The campaign is evaluated at three levels:

- a) Uptake of health services by priority target groups in intervention and control communities.
- b) Via the RCCS we assess the population level coverage of VMMC, HCT, ART and FP as well as knowledge and attitudes in intervention compared to the control communities.
- c) In the intervention communities we assess knowledge and exposure to the campaign.

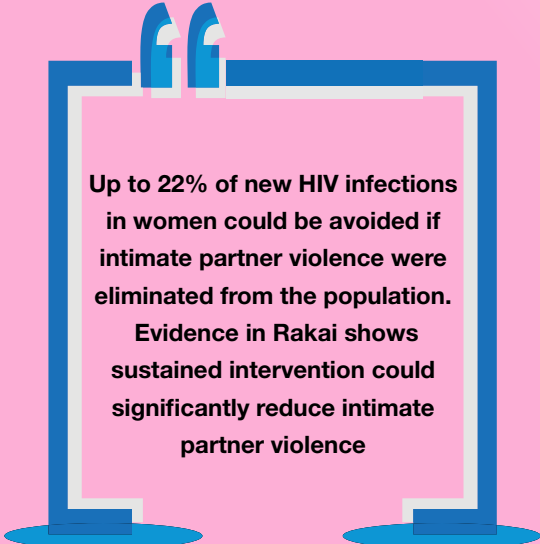
Preliminary findings

The objective was to increase uptake of VMMC among men older than 18. At baseline 30% of non-Muslim men in each arm were circumcised.

Preliminary results show that clinic attendance for VMMC services is substantially higher in the intervention arm and importantly, 44.22% of intervention arm VMMC recipients are aged 18+ years, compared to 24.2% of in the control arm ($p < 0.001$). 90.8% of men in intervention arm knew about the campaign, compared with 24.2% in the control arm.

16

Intimate Partner Violence (IPV) associated with incident HIV infection



Up to 22% of new HIV infections in women could be avoided if intimate partner violence were eliminated from the population.

Evidence in Rakai shows sustained intervention could significantly reduce intimate partner violence

Using RCCS data for a longitudinal analysis we found the incidence rate ratio (IRR) of HIV acquisition was increased in women reporting IPV (IRR=1.55, 95%CI 1.25-1.94). The risk of HIV was increased with longer duration of IPV and more severe forms of IPV. The population attributable fraction of IPV on incident HIV infections in women was estimated to be 22.2%. (Kououmdjian et al AIDS 2013).

In a community randomized trial of IPV and HIV prevention, nested in RCCS, we showed a reduction in

prevalence of IPV (12% intervention vs 16% in control arm), and sexual IPV (10%vs 13%). The intervention was associated with a reduction of HIV incidence (IRR=0.67, 95%CI 0.46-0.97), but this differential was not sustained after cessation of the intervention (Wagman et al. Lancet Glob Hlth 2015.)

17

mLAKE (mHealth Lakefolk Actively Keeping Engaged) Cluster-Randomized Controlled Trial

Effective yet practical strategies are needed to increase engagement in HIV treatment and prevention services, particularly in high HIV prevalence hotspots. We designed a community-based intervention called “Health Scouts” to promote uptake and adherence to HIV services in a highly HIV prevalent fishing community in Rakai, Uganda. Using a situated Information, Motivation, and Behavioral skills theory framework, the intervention consists of community health workers, called Health Scouts, who use motivational interviewing strategies and mobile health tools to promote engagement in HIV treatment and prevention services.

The Health Scout intervention is being evaluated through a pragmatic, parallel, cluster randomized, controlled trial with an allocation ratio of 1:1. The study setting is a single high HIV prevalence fishing community in Rakai, Uganda divided into 40 contiguous

neighborhood clusters each containing about 65 households. 20 clusters received the Health Scout Intervention; 20 clusters received standard of care. The Health Scout intervention is delivered within the community at the household-level, targeting all residents 15 years of age. The primary programmatic outcomes are self-reported HIV care, antiretroviral therapy, and male circumcision coverage; the primary biologic outcome is population-level HIV viremia prevalence;. Follow-up is planned for about 3 years. HIV treatment and prevention service engagement remains suboptimal in HIV hotspots. New, community-based implementation approaches are needed. If found to be effective in this trial, the Health Scout intervention may be an important component of a comprehensive HIV response.



18

Studies of Voluntary Medical Male Circumcision - VMMC

a) Studies of voluntary circumcision in HIV+ men

HIV-infected men cannot be denied VMMC because it would be stigmatizing and VMMC has benefits for HIV+ men such as reduced genital ulceration and reduced HPV infections. RHSP studies showed that VMMC safety was comparable in HIV+ and HIV-negative men, although healing was delayed in the HIV-infected (Kigozi et al PLoS Med 2014). Subsequent studies showed that SMC did not increase plasma viral load in HIV-infected men irrespective of CD4 count (Kigozi et al. PLOS One, 2014). Penile shedding of HIV is increased for three weeks after surgery (Tobian et al PLOS Med, 2015), which could place uninfected female partners at risk of HIV



Voluntary Male Circumcision surgery in progress at a circumcision camp.

acquisition if intercourse is resumed before wound healing. However, after healing of the circumcision wound penile HIV shedding was

significantly reduced compared to the uncircumcised state, and this could provide long-term protection for female partners.

b) Studies of Circumcision devices

RHSP assessed the acceptability safety of the Shang Ring and PREPEX circumcision devices compared to the surgical dorsal slit procedure. Among 620 men who accepted VMMC 82% chose the Shang Ring in preference to the dorsal slit. Moderate and severe adverse events were 1% with the Shang Ring and 0.8% with dorsal slit. However, healing was delayed with the Shang Ring. (Kigozi et al JAIDS 2013). In a comparable study the PREPEX was compared to the dorsal slit among 429 men. 82% men preferred the PREPEX when offered a free choice of procedure. In 5.7% of men the PREPEX was contraindicated due to a tight foreskin or phimosis. The PREPEX was associated with 1.4% severe adverse events due to premature self-removal of the device leading to edema and urinary obstruction requiring emergency surgery. Healing was also slower with PREPEX and 71.8% complained of an unpleasant odor. The conclusion was that the PREPEX device presents potential risks of complications (Kigozi et al, JAIDS 2013). We also assessed the penile microbiome following circumcision and found a significant decrease in anaerobic bacteria following conventional surgical procedures (Liu et al MBio 2013), however with the PREPEX device the necrotic foreskin was associated with an increase in anaerobes (Liu et al MBio, 2015). This potentially increased the risk of tetanus following PREPEX circumcision and WHO now recommends two tetanus toxoid immunizations, 28 days apart, prior to PREPEX circumcision.



Demo of shang ring circumcision device



Demo of the Mogen Clamp circumcision device

c) Evaluation of the Shang Ring vs. Mogen Clamp for Early Infant Male Circumcision in sub-Saharan Africa.

Voluntary Medical Male Circumcision (VMMC) has been shown to reduce HIV acquisition in males by 50-60% in three Randomized clinical trials. Observational studies of men circumcised in infancy or childhood have shown long term protection from HIV Acquisition in adulthood (Bailey RC et al.,2007).

Though HIV prevention may be achieved through continued scale-up of VMMC in adolescents and adults, long-term sustainability will likely be better achieved through early infant male circumcision (EIMC). EIMC is technically simpler, safer, and less expensive compared to VMMC performed in older children or adults. Part of the barrier to wider use of EIMC stems from the scarcity of trained providers and resources in sub-Saharan Africa. Device-assisted VMMC has therefore been proposed to simplify the procedure, enable safe task-shifting, and reduce the burden on healthcare providers, thus increasing the availability of EIMC services. While several devices are currently in use for patients of various ages, the use of a single device requiring only topical anesthesia across all age ranges would dramatically simplify supply chain logistics, streamline personnel training, and most importantly enhance patient/parent acceptability and demand uptake.

This randomized controlled study, which started participant enrollment in August 2018, examines the safety and acceptability of the Shang Ring compared to the Mogen clamp device. Participants are followed up weekly up to day 42 or until complete wound healing. To date 44 babies, 21 in the Shang ring and 23 in the Mogen clamp arm have been enrolled surgeries.



RHSP staff giving pre operative health education to mothers before they commit their babies to the Shangring - Mogen Clamp study

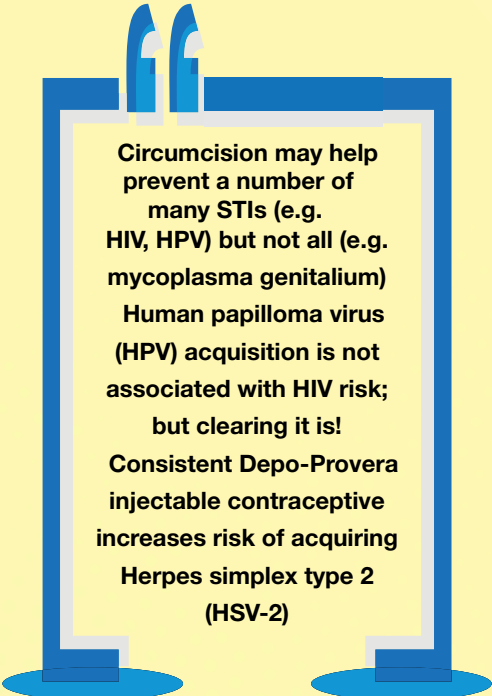


Principal Investigators of the Shangring Vs Mogen Clamp study

d) Sexually Transmitted Infections

The Rakai Health Science Program has conducted numerous studies of STIs. In a case-control study, we assessed HPV acquisition and clearance and the association with HIV acquisition in 44 male seroconverters and 787 controls. HPV acquisition was not associated with HIV seroconversion, but HPV clearance was significantly associated with HIV acquisition (OR=3.25, 95%CI 1.11- 9.55). The risk increased with the number of HPV genotypes cleared. Dendritic cells in the foreskin epidermis were also higher among men who cleared an HPV genotype (72 cells/mm²) compared to persistently HPV negative men (32 cells/ mm²). (Tobian *et al* JID 2013). A study of HPV genital viral load showed that viral shedding correlated with Linear Array Signal Intensity which provides a surrogate measure for HPV viral load and that circumcision reduced HPV shedding (Wilson *et al* STIs 2012). In a longitudinal study assessing HPV load and transmission among heterosexual couples, higher HPV shedding was associated with a linear increase in

risk of partner HPV acquisition. Male circumcision was also associated with reduced HPV detection in both men (RR=0.53, 95%CI 0.30-0.95) and their female partners (RR=0.42, 95%CI 0.23-0.76). (Grabowski *et al*. JID 2016). In a case control study of 682 women using DMPA hormonal contraception, we found that consistent DMPA use increases the risk of acquiring herpes simplex virus type two (Grabowski *et al*, Lancet Global Health 2015). A study of Mycoplasma genitalium showed no effects of male circumcision on M genitalium infection in either men or women. (Tobian *et al* STI, 2013).



Circumcision may help prevent a number of many STIs (e.g. HIV, HPV) but not all (e.g. mycoplasma genitalium)

Human papilloma virus (HPV) acquisition is not associated with HIV risk; but clearing it is!

Consistent Depo-Provera injectable contraceptive increases risk of acquiring Herpes simplex type 2 (HSV-2)

19

Family Planning

The use of modern contraception among women who wished to limit further childbearing increased from 38% to 50.3%, and among these women 63.1% said they would accept voluntary sterilization if it were made available (Lutalo *et al.* Contraception, 2015). A study among HIV-discordant couples did not show an association between use of hormonal contraception and HIV transmission or acquisition (Lutalo *et al.* AIDS, 2013). A randomized trial of depot medroxy progesterone acetate (DMPA) intramuscular injections and intradermal DMPA in a Uniject system (Sayana Press [SP]) showed more skin irritation with SP but fewer side effects than DMPA (30% vs 40.4%). 64% of women and 73% of providers preferred SP to DMPA (Polis *et al.* Contraception, 2014).



17

PMTCT National Impact Evaluation

The Rakai Health Sciences Program (RHSP) is supporting the Ministry of Health (MoH) Uganda to carry out an evaluation of the Impact of the National Program for Prevention of Mother-to-Child Transmission of HIV (PMTCT) in the country. Because the MoH has for more than a decade now been implementing the PMTCT program and successfully scaling it up for more than a decade to include almost all eligible health facilities, there was need to assess the milestones reached.

Rakai Health Sciences Program (RHSP) was selected to support the MoH as the implementing partner with funding from among others PEPFAR (through Centre for Disease Control (CDC Uganda) and USAID), UN agencies (UNICEF, WHO,

UNAIDS) and Uganda AIDS Commission.

The goal of the study is to assess the impact of the national PMTCT program on HIV-free survival in children aged 18 months in Uganda. The study set out to screen 35,000 infants with their caregivers/mothers to be able to enrol close to 1,536 exposed infants. For each exposed infant enrolled, 5 non-exposed infants would be enrolled for follow up.

Recruitment and follow-up of study participants is being conducted at 206 randomly selected health facilities offering immunization services across 89 districts in the country. The infants and their mothers are followed up at 6, 9, 12, 15 and 18 months postpartum. From this study, the Ministry of

Health and country in general will be able to:-

1. Identify PMTCT missed opportunities along the cascade
2. Measure uptake of referral services from prevention (PMTCT) to care and treatment.
3. Strengthen the National Early Infant Diagnosis (EID) program.
4. Provide critical information on maternal morbidity and mortality outcomes, viral load suppression, and unmet need for family planning among postpartum women

All the above will help better target future program interventions. The evaluation is running from September 2017 to December 2019.

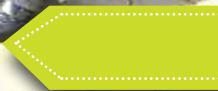
Protocol Title	Short Name and funding
Rakai Community Cohort Study	RCCS
Men's Health and Alcohol Epidemiology and Pilot Intervention, Rakai, Uganda	Alcohol Study
Stylish Man/Woman Program for Demand Generation for Combined HIV Prevention Services, Rakai Uganda	Evaluation of the Stylish Man Campaign (NIH)
Bottlenecks study: A qualitative investigation of the barriers and enablers to successfully investigating the HIV care system in south-western Uganda, in the era of widespread ART availability	Bottlenecks study
Mobile Behavioral Ecological Momentary Assessment and Intervention in Rakai, Uganda: A Pilot Study	EMAI Study
Characterizing immune correlates of HIV susceptibility and protection in the male genital tract among Ugandan men	MTGI Study (NIH)
East Africa international Epidemiologic databases to evaluate AIDS (leDEA Data Sharing)	leDEA Data Sharing (NIH)
CHWs, mHealth, and combination HIV prevention in a Hotspot: A randomized Trial	mLAKE (NIH)
Quantitate measurement and correlates of the latent HIV reservoir in virally suppressed Ugandans.	Latent HIV (NIH)
Impact Evaluation of Combination HIV Prevention to reduce population level HIV Incidence	CHPIE

Protocol Title	Short Name and funding
Revealing women's hidden role as critical components of HIV transmission networks in Rakai	Women's hidden role (NIH)
Penile Microbiome, Inflammation and HIV susceptibility during sexual debut and maturation among male adolescents	Penile Microbiome - GWU
Penile Microbiome, Inflammation and HIV susceptibility during sexual debut and maturation among male adolescents	Penile Microbiome - JHU
Compare prevalence of herpetic disease, demonstrated by viral shedding of HSV-1&2 in the vaginal secretions of HIV positive women	HERA
Social Structural Transitions of Adolescents in Rakai	SSTAR (NIH)
Evaluation of Shangring Vs Mogen clamp for early infant male circumcision in sub Saharan Africa	Mogen clamp Vs Shangring (NIH)
Mortality Measurement	NIH
Suubi For Her	SUUBI4HER (NIH)
Male Circumcision and use of foreskin tissues for HIV prevention in Uganda	Fogarty Training (NIH)
Addressing New Health Challenges, the Non-communicable diseases	NCDs (Karolinska Institutent)
Fogarty International Center (FIC) to support Long-term, Degree Training and Sandwich PhDs to create local research capacity to better understand and reduce HIV incidence in Uganda and beyond	Fogarty D43 (NIH)
Welcome-incoming Neighbor	WIN (NIH)

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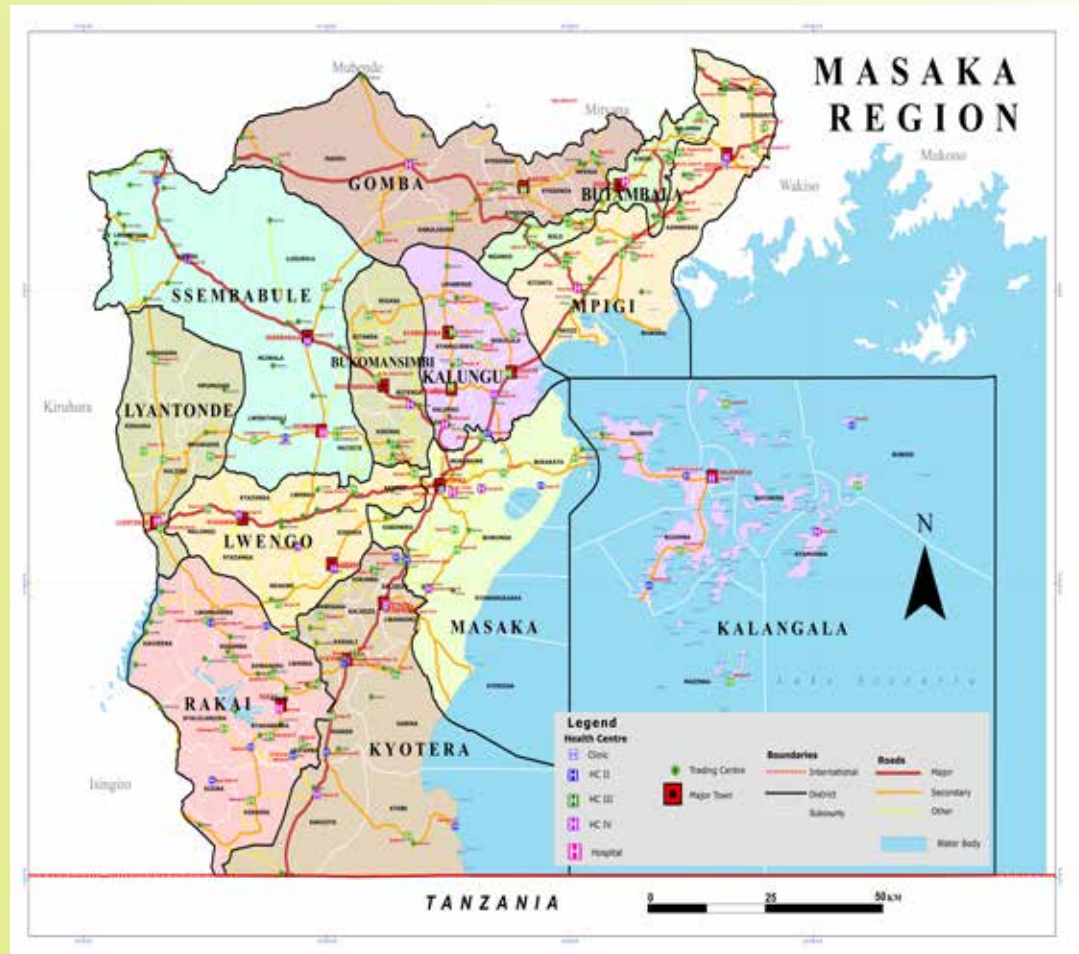


Programs



In April 2017, RHSP was awarded, a cooperative agreement aimed at accelerating HIV epidemic control in the Masaka region of Uganda; which has the highest overall prevalence of HIV in Uganda (8%). This region has an estimated population of 2,373,700 people distributed across 12 districts namely; Bukomansimbi, Butambala, Gomba, Kalangala, Kalungu, Lwengo, Lyantonde, Masaka, Mpigi, Rakai, Kyotera and Sembabule. The scope of work in the 12 districts includes: provision of targeted HIV testing plus key population services; HIV basic care plus antiretroviral therapy to adults and children; prevention of mother-to-child transmission of HIV (PMTCT); early infant diagnosis services (EID), Early Infant diagnosis services, support for TB/HIV services; laboratory systems strengthening, Strengthening of Supply chain systems;

Map of the Masaka Region



Voluntary Medical male circumcision services ; Safe male circumcision (SMC) skills training; implementation of programs for orphans and vulnerable

children and DREAMS programming. All these are supported in the context of district led programming.



RHSP senior staff with Masaka district leadership after a courtesy call.



Dr Gertrude Nakigozi - RHSP Programs Director with Kalangala district leadership after a stakeholder engagement.

District-Led Programming in Rakai

Rakai district has one of the highest HIV burden in Uganda in part due to fishing communities on Lake Victoria and trading centers on the Uganda-Tanzania highway. Over 35,000 HIV positive patients have been enrolled into care since 2004. RHSP works closely with the District Health Team to enhance governance, build capacity, generating and implementing evidence-based strategies and work plans, monitoring and evaluation to inform continuous quality improvement and harmonized reporting.

Under the District-Led Programming (DLP), RHSP provides technical, logistical and financial support, capacity building through training, continuing medical education, mentorship, support supervision, monitoring and evaluation (M&E) and quality improvement. RHSP also supports the district supply chain and reporting, the scale up of electronic data entry using the Open MRS system, training of record officers, provision of computers and solar power installations at health facilities. Health facilities include district

hospitals, health centers IV and IIIs, and a few high volume health center IIs, as well as private and private-not-for profit facilities. RHSP directly supports the district health office to implement core activities such as provider and stakeholder review meetings and district leadership support supervision. With funding from PEPFAR, we have supported infrastructure improvement at health facilities to increase space for HIV care at HIV clinics, maternities and laboratories.

HIV Prevention, Care and Treatment



RHSP runs a clinic in Kalisizo providing comprehensive HIV services to over 2300 HIV+ patients. The clinic serves as a referral center for the district, providing specialized laboratory services, consultation, Ultrasound and X-ray. RHSP provides free treatment for STIs at the Kalisizo clinic, for an average over 300 patients per month. All STI patients are offered free HTC, and HIV positive patients are linked to care at a clinic of their choice. HIV negative persons receive prevention education and condoms and are screened for Pre-Exposure Prophylaxis (PreP.) The clinic also provides community access to free

medical consultation and outpatient services for RHSP staff and their children under 5, who are enrolled in UAP insurance services. In 2016, a total of 7200 clients were seen at this clinic.

The pharmacy section has two mini stores which are well-stocked with essential medicines for common illnesses, STIs, opportunistic infections and ART. All drugs are prescribed free of charge. The pharmacy team works closely with district health facilities providing mentorship and support supervision to ensure effective supply chain management.



Indicator	Annual Target COP 17 (FY 2018)	COP17 Cumulative FY 2018
# Counseled Tested & Received Results	365,760	593,107
# tested Positive	26,575	23,803
# started on Treatment	25,087	16,156
# currently on treatment	136,308	98,457
# males circumcised	30,031	29,895

The above summarizes the cumulative performance of the Masaka Regional Mechanism

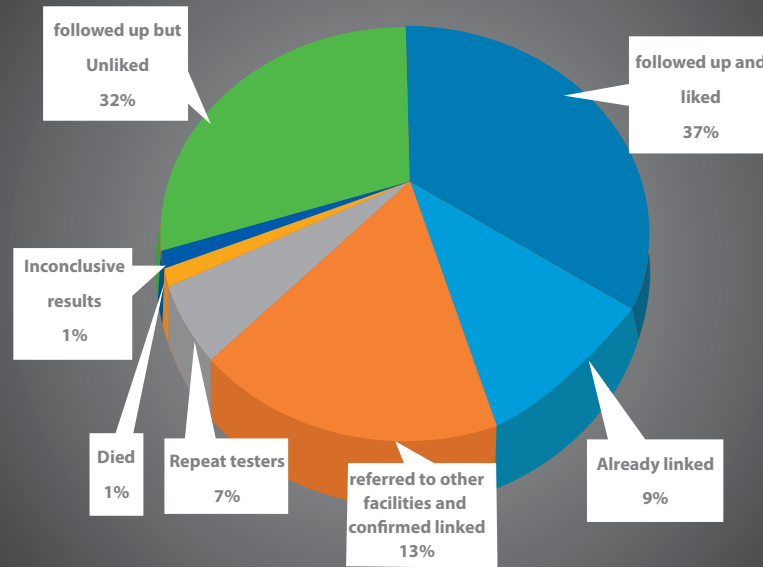
The number of males circumcised (29,895) in 2018 represented 99% percent of the annual target of 30,031.

Cumulative, a total of 593,107 individuals were counselled, tested & received results which represented a 162% achievement against the annual target of 365,760 set by PEPFAR. Of these, 23,803 individuals were found HIV positive; representing a 90% achievement ainst the annual targe t of 26,575 and In total, 68% of these newly identified HIV positives were successfully linked to start ART as part

of TEST & TREAT; which represented a 64% achievement against the annual target of 25,087. Major reasons given by HIV-positive persons for delaying ART initiation included needing to first inform their partners and requiring time to accept their newly discovered HIV status.

To improve rapid adoption of ART, RHSP is working with the DLP in implementing intensified mentorship and training for facility health workers, support for peer counselors, and client follow up.

Graph showing follow up outcomes for those previously unlinked



During the year we also implemented the "surge strategy" which was aimed at increasing the number of newly identified HIV positives and initiating them on treatment. This was achieved through

activities such as increased targeted testing, linkage facilitators who actively follow up identified positives to ensure complete linkage, and use of starter packs (i.e. initial ART supplies) during

targeted outreaches.

Below is a pie chart summarizing reasons for not initiating ART on the same day diagnosis of HIV is made.



CQI Officer taking the staff through the TB indicators during a data use meeting at Bulu HC III in Butambala district.

CQI methodology is used to support continuous quality improvement across all HIV programs. Using tools like cause-effect analysis, Fish borne diagram, brainstorming, the gaps that are affecting performance are identified. Using a prioritisation matrix, the gaps are ranked according to feasibility, available resources, impact on indicator output, likely hood to succeed, timeliness etc., and a Quality improvement project is initiated to test the agreed upon changes to address the gaps. The model used is a Plan, Do, Study, Act (PDSA) cycle;

This model involves;

- (i) setting aims (goals that are time specific, measurable & specifies the population that will be affected,
- (ii) Establishes measures using QI tools like Fish borne diagram, flow charts, pare to charts, brainstorming etc.,
- (iii) Selects changes that are most likely to result in improvement,
- (iv) Testing changes (planning it, Trying it, observing the results and acting on what is learned. Data management tool shall include the check sheets, Histograms, run charts, benchmarking etc.

Some of the activities include, the weekly surge meetings where performance is monitored on a weekly basis, and what is not working is identified in real-time, to enable the teams to re-strategize.

Data use meetings at health facilities:

During the learning visit, teams that are having similar problems or challenges are grouped together, share experiences with those that have tested changes to address similar challenges and a change package addressing gaps or challenges for different indicators is drawn and shared.

Voluntary Medical Male Circumcision - VMMC



Men at a health centre receiving pre-counseling before they undergo safe male circumcision.

Circumcision Section comprises of two areas; Circumcision Research/ Studies and Circumcision Services. Our circumcision service adheres to the Ministry of Health policies and comprises of; surgical camps, satellite/ static clinics, male circumcision skills training and TOT for MC skills trainers, support supervision/mentorship and Continuous Quality Improvement.

Circumcision has been demonstrated

to reduce HIV infection among men and is recommended for HIV prevention in countries like Uganda with high HIV but low circumcision prevalence.

The priority in Masaka Region remains targeting HIV- negative males aged between 15-29 years since they are at increased risk. HIV incidence in men is highest in the age group 25-34. Several strategies have

therefore been implemented with the aim of increasing voluntary male medical circumcision (VMMC) status coverage to 80% in the Masaka region.

RHSP has worked with District Health Offices to establish 11 circumcision satellite clinics at government health units in the nine districts. Circumcision is done using either surgical method or surgical devices

like; Prepex, Shang Ring, and Mogan Clamp. Men seeking VMMC services are provided with HTS and the HIV positive males linked to HIV care. We provide intensive health education to VMMC seekers, addressing key HIV prevention issues including promotion of delayed sexual debut, abstinence, sexual partner reduction, and being faithful to one partner; providing and promoting correct and consistent use of male condoms.

Also provide services for the treatment of sexually transmitted infections to

males with any STIs and clients with penile abnormalities or any other condition that would need further management are referred to the RHSP urologists. We provide tetanus toxoid (TT) / tetanus, and diphtheria (TD) vaccination before circumcision and provide 48 hours, 7 days and 14 days follow up visits to track any adverse events and manage them appropriately.

Facility (static) and circumcision mobile camps/outreaches service

delivery VMMC is offered at the health facility and clients are encouraged to come at the health facility for circumcision. Due to long distances travelled by the males seeking circumcision, mobile camps have been conducted to take circumcision services nearer to the communities.

Circumcision camps/outreaches are conducted by the MOH staff and supervised by RHSP staff.

Circumcision camps tend to yield high numbers in a limited period.



Mobile Surgical Camps/ Outreaches are held in collaboration with the DHOs and RHSP centre in Kalisizo. After the camps, the teams allocate a staff who remains behind to attend to Adverse events and conduct follow up to clients circumcised. Clients are given a cell phone number that they call in case of any problem after the camp and advise given. The government

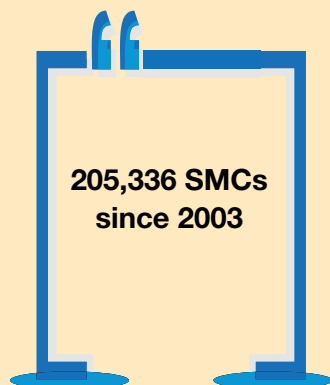
facilities are empowered to run the satellite clinics.

Mobilizations strategies include use of mobilization meetings in villages and schools, static

(community radios) and mobile megaphones mounted on vehicles or motorcycles, door to door sensitizations conducted through the VHT system, use of satisfied clients in addition

to the use of influential people and religious leaders. Engage local political, religious & community leaders, use of Drama shows, Film shows, MC promotion songs, and Radio talk shows to capture a wide range of coverage.

RHSP VMMC contribution since 2003 to national target



Circumcisions per FY





DREAMS



Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women - DREAMS

DREAMS is an acronym for Determined, Resilient, Empowered, Aids-free, Mentored, and Safe Women. It is a program embedded within the USG's Global Health Initiative Strategy, which aims at preventing more than 12 million new HIV infections. Evidence indicates that in the long term, improving the health of women enhances their productivity and improves the livelihoods of their families. Based on a review of the prevalence and burden of HIV, 7 districts from greater Masaka region were selected for DREAMS implementation. These are Rakai, Kyotera, Lwengo, Lyantonde, Bukomansimbi, Sembabule and Gomba districts. The target groups are adolescent girls (AG) aged 15-19 who are in school, married or pregnant, adolescent girls and young women (AGYW) aged 15-24,

who have given birth by age 15, and AGYW (15-24) engaged in transactional sex.

It is also important to reduce HIV incidence in men so as to reduce transmission to their female partners. Therefore, DREAMS promotes male circumcision and engagement of HIV-positive men who are not enrolled in care. RHSP works with 7 Community Based Organizations and the Districts' Health, Probation and Education teams. In addition, we work with community leaders (religious, political, and cultural), police, Community Development Officers, leaders of key populations such as boda-boda cyclists, fisher folk, commercial sex workers, village health teams, para-social workers, and expert clients.



A mother dances for her disabled daughter who had graduated at Bukomansimbi DREAMS graduation ceremony.



DREAMS drama team in Bukomansimbi reciting a poem at the graduation ceremony.



Graduands at Gomba DREAMS graduation giving testimonies on the impact of the project on their lives.



Girls graduating from DREAMS program celebrate with dance during a graduation ceremony.



Representatives from partner organisations in masaka region who jointly implement DREAMS program with RHSP.

The goal of DREAMS is to reduce the HIV incidence among AGYW by 40% within 2 years. In order to achieve this, RHSP has enrolled the AGYW and created an open cohort which will be followed up for the duration of the project. RHSP provides the AGYW with as many layers of services within the DREAMS core package by segment. The figure below reflects the layering within the DREAMS project in Rakai.



DREAMS girls in safe spaces learning skills in tailoring and bead making.



CDC Director Lisa Nelson and RHSP Regional Manager Ismail Mbabali at a stall of items made by DREAMS girls.

Enrolment of AGYW is through the community and health facilities. The AGYW are screened for eligibility for the services in the DREAMS package which include HIV testing and counselling, condom promotion and provision, expanded and improved contraceptive mix, STI screening, post-violence care, parenting and caregiver programs using the SINOVUYO approach, which combines socioeconomic approaches, educational subsidies, cash transfers, SMMC for partners and linkage to care for HIV positive partners. DREAMS activities are centered around community mobilization approaches; Stepping Stones and SASA! Stepping Stones is an evidence based, age-appropriate, and culturally sensitive approach aimed at changing norms and behaviors for HIV prevention, and strengthening relationship skills. SASA! is a community sensitization approach that seeks to change community attitudes, norms and behaviors associated with gender inequality, violence and increased HIV vulnerability for women.

Enrolled girls are linked to economic strengthening interventions.

The team also implements parenting and caregiver programs using the SINOVUYO approach, which utilizes 14 sessions attended by both girls and their parents/ caregivers.



CDC's Michelle Adler and Rose Apondi having a moment with RHSP ED Dr Joseph Kagaayi and Dr Kintu Denis during a recent visit to Kasensero.



CDC Michelle Adler checking out items crafted by DREAMS girls.



DREAMS Girls in Sembabule district perfecting their skills in hairdressing.

The Orphans and other Vulnerable Children (OVC) programme supports critically vulnerable OVC and their households infected and affected by HIV by providing social support services that contribute to achievement of the 90, 90, 90 targets. In these households the focus is on the following categories of OVC: HIV Infected Children, Children of HIV Positive Caregivers, Sexually abused Children, Pregnant Adolescents girls (15 – 17yrs), Children of Commercial Sex Workers and HIV Exposed Infant. To draw the OVC service delivery closer to target beneficiaries, RHSP provide sub grant to 24 Community Based organizations (CBOs) to provide a comprehensive OVC services in their respective sub counties. The target OVC/Households receive layered services of psychosocial support, education subsidies, protection services, good parenting education for caring families, economic support services to the households and age appropriate OVCs, among others. The value this support in responding

to the HIV/AIDS epidemic and preparing OVCs for later life cannot be underestimated. The social support services provide children with opportunities for emotional support, interaction with other children, and the development of social economic capital for their households. Social support services also reduce vulnerability to infections of HIV and its effects through increasing knowledge, awareness, skills and opportunities for life.

Below are some of Highlights of the year:

Healthy: All OVC on program were linked to HTS services and supported to know their status and supported to complete the HIV cascade and 287 OVC caregivers living with HIV positive received nutrition education services

Education: a total of 2969 OVC received scholastic material and school fees (2741) support and all OVC on education support were visited at school to monitor

progression, retention and offer school based psychosocial support

Economic Strengthening: 3307 OVC caregivers were supported to join Village Savings and Loan Associations, 172 caregivers were trained in business skill to enable them to manage their IGAs well, 562 caregivers were linked to government wealth creation programs where of Operation Wealth Creation and the Youth Livelihood Grants and 437 OVC graduated in their various vocational trades and received startup toolkits

Child Protection: 689 children from families which were register to receive birth certificates, 829 OVC caregivers and children benefited from SINUVYO caring families parenting sessions and the districts were Local Governments were supported to respond to Gender and Sexual Based Violence cases.



Other prevention department, headed by a Regional Manager and supported by 2 Prevention Officers per district, is one of the departments in the programs directorate charged with the primary duty of seeking the remaining undiagnosed individuals living with HIV and provide them with HIV Testing Services (HTS). By doing so, the department fulfills its mandate for the first pillar on the 95-95-95 treatment targets. The targets for the first 95 are met through the following program areas: general HTS interventions, APN interventions, Key populations and

Priority population programs, Male specific interventions, HIV self-testing services to mention but a few.

Key and Priority Populations

In this program area, we support health facilities to conduct key and priority population targeted community outreaches focusing mainly female sex workers (FSW), Men who have sex with men (MSM) and prisoners. At minimum, the following service package is provided to key populations: HTS, condoms and lubricants, contraceptives, STI



screening and treatment, ART initiation for individuals testing positive and referral to the nearby facilities. About prisoners, every month in all the peripheral prisons in the region, we have a designated day to prison outreaches. We have continuously engaged district prisons commanders and officers in command of the peripheral prisons in meetings to discuss prison HIV services.

Male specific HTS interventions

The department started providing community outreach HIV testing services to different male segments within WHO's essential 5Cs: consent, confidentiality, counselling, correct test results and connection to care with an objective of increasing both HTS coverage and yield among men. The program targets men in bars and lodges, welders & mechanics,

saloon operators, brick makers and road constructors. In reaching out to the different male segments, we identify the leaders/owners of the sites and talk to them individually about providing HTS to men they lead/congregate in their premises rather than inviting them to the facilities.

HIV self-testing

HIV self-testing is one of the innovative HTS approaches to access several undiagnosed under-served populations like key and priority populations, partners of pregnant and lactating mothers, young people 18-24years. We have scaled up HIV self-testing in 8 districts with HIV self-testing targets. The districts with targets are: Kyotera, Rakai, Masaka, Kalungu, Bukomansimbi, Mpigi and Lyantonde.



‘A holistic approach to care of HIV exposed infants and keeping their mothers alive in the masaka region’

Timely identification of HIV positive mothers and initiating them on ART is only the first step in elimination of MTCT. Mothers and their exposed infants need to be followed-up and retained in care for at least 18 months after delivery for good health outcomes. Appointments for the mother-baby pair need to be synchronized. Whenever they come, an integrated service package needs to be provided to minimize the number of visits the Mother-baby pair have to make to the health facility. RHSP has partnered with the districts to redesign the MBCP model by integrating Family Support Groups (FSGs) in the MBCP clinic days at the 194 supported health facilities. Mothers are provided ART refills, VL testing, nutrition counselling, family planning services, STI

screening and treatment and risk reduction counselling for mothers and their partners. HIV Exposed Infants (HEIs), are provided with early infant diagnosis (EID) services at 6 weeks, 9 months, 6 weeks after cessation of breastfeeding and a final rapid test at 18 months. All bleeding is done by the MCH testers that RHSP has put at high volume sites. Infants receive routine services such as immunization, growth monitoring and deworming. Mothers and their infants receive psychosocial peer support services that are important for retention. The model is more sustainable and ensures that maternal and infant benefits are maximized per visit, by providing a comprehensive package to the pair.

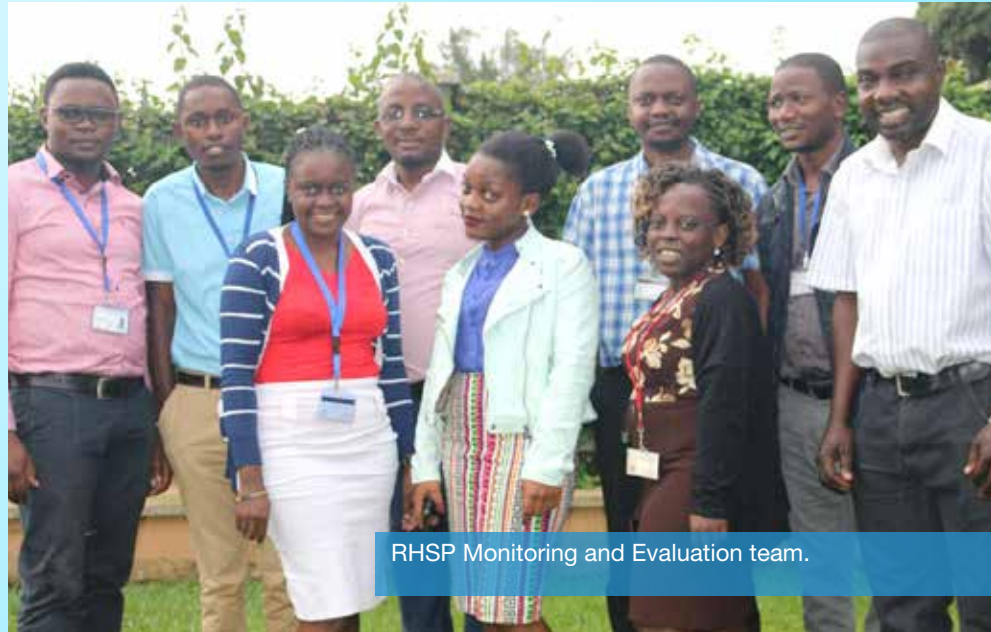


Monitoring & Evaluation

Since 2013, facilities in Central Uganda have received support towards improving patient level data and reporting through health information system. This includes provision of standard HMIS tools for reporting through DHIS2, trainings and regular mentorships, installation of EMR in 78 sites and DQAs conducted to ensure quality information is provided for decision making. As a result, averagely reporting rates for HIMS 105, 106a and 108 have improved from 87 to 98% between Jan 2018 and July 2018). Despite this, data inconsistencies between reported data and facility remain in selected sites most notable in Bukomansimbi and Kalangala districts. RHSP has strengthened the National HMIS system through the following activities.

Quantification and distribution of HMIS tools

The Rakai Health Science Program (RHSP), working the biostatisticians and MESTs, RHSP uses facility performance data to quantify tools needed and submitted for printing. Once delivered, the tools are then be delivered to the facilities in the district during the routine M&E activities.



RHSP Monitoring and Evaluation team.

Monthly onsite HMIS reporting support and PEPFAR data collection

The Biostatistician and DTLS offer onsite mentorship on HMIS changes based on the revised HIV guidelines. In addition, RHSP conducts monthly and quarterly onsite validation of HMIS reports before submission to the districts for entry in DHIS2.

PEPFAR data collection; RHSP works with HMIS Focal persons to collect

PEPFAR data on a monthly and a quarterly basis which is followed by data entry into HIBRID.

Performance review meetings

RHSP conducts quarterly performance review meetings focusing on HIV, Prevention and PMTCT to share district performance on implementation progress, identify best practices that can be adopted by poorly performing facilities and document lessons learnt.



Participants during a recent METS training in masaka.

Implementing quality improvement approaches to improve data quality

Districts are supported to conduct quarterly data quality audits and enforce the use of data collection guidelines. In addition, regional data cleaning exercise are conducted with support from MOH and METs on a quarterly basis to reduce on the errors in reporting and data discrepancies.

Capacity building for quality data management

To improve on the quality of TB data focusing on recording and reporting, RHSP in collaboration with the National TB & Leprosy Program conducted district based and regional based training on recording and reporting for TB services through DHIS2. This included the integration of TB

reporting into DHIS2 to ensure that the facility reports submitted to MOH through DHIS2 concurs with the DTLS reports submitted to NTLP. Training strengthens health worker capacity to understand, collect, analyze and interpret data. Additionally, the role of the DTLS, DLFP and Biostats to mentor and support facilities, validate compiled data and convene district level exchange meetings is enhanced.

RHSP conducts a M&E mentorship to follow up on recording and reporting as per the new HIV care guidelines, KP/PP, GBV services, non-suppressed registers and Viral load addendum reports and as well on the documentation of the services provided to clients in differentiated care.

Strengthen data management for HIV services

RHSP provides supported facilities with primary data capture tools and supported HMIS monthly reporting, data validation and quarterly Data Quality Assurance. The RHSP further supports districts to conduct monthly data review meetings to identify and correct data quality bottlenecks, improve on correct use of primary data tools and data quality such as during onsite mentorship and coaching. We supported scale up of the electronic medical records for HIV services. To strengthen data management for differentiated care, facilities were supported with patient suspension files and filing racks to ease categorization and clinical management of stable and unstable patients.



Data Management

Staffing

The team is comprised of a head of department, deputy head, 5 data management officers and 10 data entry clerks. Background training in statistics is required for data management, and secretarial for clerks.

Data Management And Programming

Offline data collection using laptops has been supported by programmed client server systems written in VBA with a SQL server back-end. The Graphical user interfaces are embedded with validation code to ensure quality data is captured. DATAFAX systems are used for paper-based source documents. Double data entry is used for any manual entries. Data is consolidated in a data mart for central data processing and analysis.

Statistics

Section is comprised of 1 full time statistician, 1 part time statistician and 2 senior statisticians who sit at the Makerere School of Public

health and UVRI main campus, Entebbe respectively. Background training in statistics is required plus a masters in a related field. The section collaborates with a number of networks including leDEA, INDEPTH network and ALPHA network. Main software package for analysis is STATA. The section supports all directories of the RHSP and work ranges from proposal development, data collection, data management, report generation to scientific reporting (among others). The section is also responsible for compiling and updating the demographic profile of the population in the communities of operation.

Department Output

A data sharing policy is in place to allow researchers access to secondary data for analysis. Data analysis findings are submitted for academic work and publication.

REDCap server

The Office of Cyber Infrastructure and Computational Biology (OCICB) National Institute of Allergy and Infectious Diseases (NIAID), NIH,

has installed a redcap server in the Kalisizo data center to support mobile data capture model for the RHSP International Center for Excellence in Research (ICER). The server is currently used for hosting a SURGE database used to remotely enter CDC weekly progress reports for monitoring service uptake towards prevention of HIV.

Data Mart

With support from the OCICB, NIH all RCCS data (census, interview, lab results) have been migrated to a Data Mart longitudinal SQL Server format using the upsizing wizard. The cleaned files have been frozen. This facilitates analyses either by time period or longitudinally by participant in a readily accessible form. Clinic data for HIV patients has also been incorporated to support centralized monitoring of enrolment, follow-up and treatment outcomes for the multiple facilities. This data is manually picked as SQL dump files from the facilities and extracted on a central SQL server at the RHSP main office.

Dashboard

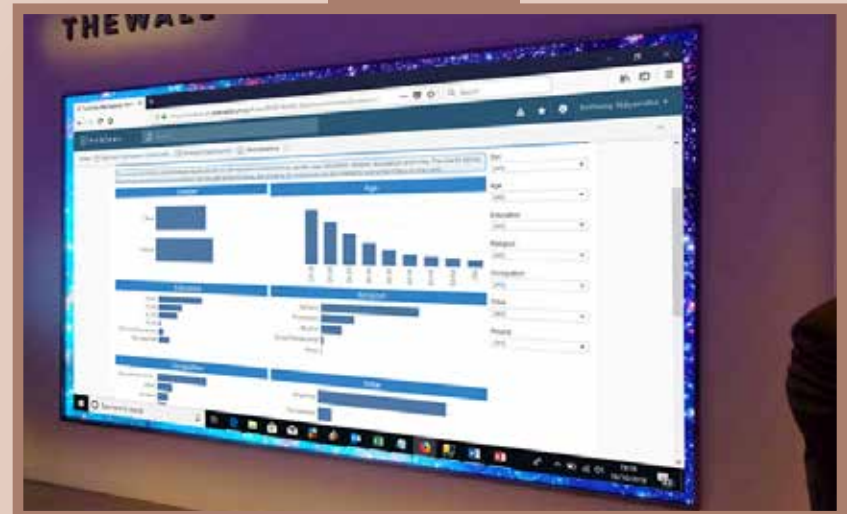
The Office of Cyber Infrastructure and Computational Biology (OCICB) has set up a dashboard using Tableau Server Version: 10.3.2 to visualize the RCCS data by both cross-sectional and longitudinal aggregated summaries for trends. The dashboard allows you to analyze results across demographic characteristics: gender, age, education, religion, occupation and tribe. The charts can be used as benchmarks. Benchmarks for subgroups can be created by using the filters on any variable of interest.

Comparisons of responses between any two questions can be done for cross-tabulation kind of analysis. Correlation and co-occurrence across responses can be done to every pair of questions in a matrix form.

Foxpro to MsAccess

Migration

The RCCS field data collection system has been migrated from FoxPro to MSAccess 2016 in compliance with the Microsoft recommendation to drop FoxPro.

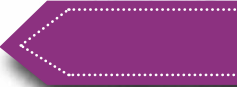




NIH leadership team during a recent visit to RHSP premises in kalisizo, kyotera.



Information Technology



Staffing

The IT team is comprised of both local and international teams. The local team includes 6 staff with extensive experience in Network and Server infrastructure, clinical data management, enterprise backup and disaster recovery solutions, VoIP collaboration solutions among others. The International team from NIH/NIAID/OCICB compliments the local team with expert skills to offer high level IT Services to the Program.

Data Center Infrastructure

Our datacenter is equipped with modern robust and efficient server, storage and network systems from some of the world's leading computing systems manufacturers like HP, NetApp, Cisco systems, Meraki, Security Hawk, Vaisala View link among others all configured to meet high performance computing needs for the Program and its partners.

IT Services

- **Internet** – The 3 programs stations located at Kalisizo, Entebbe and Kampala are interconnected using the RENU “ Research and Education Network Uganda” high speed fiber backbone and internet capacity of 40Mbps through RENU-- →Ubuntunet-- →Geant.
- **Storage.** High performance storage systems from NetApp are being used to store all the Program data with aggregated capacity exceeding 28TB all on RAID double-parity.
- **Office 365.** In 2018, we migrated our messaging infrastructure from exchange 2007 to Microsoft Office 365 and we are able to use;
- **Office 365 applications** – Outlook, Word, excel, power point, Onenote, Publisher and Access.
- **Office 365 services** – Exchange, OneDrive, Sharepoint, Skype for Business, Teams, Sway, forms, Stream, flow, PowerApps, School Data Sync and bookings
- **Unified communications.** The network has intercom of over 100 Cisco IP Phones allowing scientists and administrators to collaborate across all the 3 research stations and back to to the US using a SIP trunk.
- **Clinical Data Management and Bio-thermics.** A temperature monitoring system was installed to monitor the temperature of the laboratory specimens stored in the freezer house.
- **Electronic Data Capture** from the field. REDCap web system is in place allowing online clinical research records collection.
- **Power and Cooling Systems.** Two 10KVA UPS systems are powering the datacenter, and 3 Air Conditioners are running making the datacenter cool for equipment safety.
- **Eduroam.** This allows scientists and administrators from other research and university institutions to securely connect to our WIFI for internet from RHSP campuses using their home institutional login credentials.
- **Monitoring.** Real time alerting systems for SMS and email have been installed in the datacenter and Freezer Repository to notify the concerned personnel in case of an incident.
- **Federated and Access Management** – Here users are authenticated locally and authorized globally to access various systems.
- **Patch Management.** Computers on the network are installed with Bitdefender Enterprise security antivirus and Panorama9 for updates and monitored from a single web portal.



Central Public Health Laboratories top management headed by Dr. Susan Ndidde Nabadda visited RHSP on 15th May 2018 to review progress of laboratory services and challenges faced.



Laboratory staff working under a safety hood



The Director of the intramural program at NIAID, Steve Holland touring the lab on 27th August 2018.

Laboratory Department



RHSP staff working in the laboratory.



Freezer room which is an archive store for samples for long term durations.

Responsibility

The primary responsibility of our laboratory is to ensure that samples collected for both research and service programs are of good quality and that results generated are accurate and are availed in a timely manner. To maintain quality, we conduct training, re-training and support supervision for our field and laboratory staff on a regular as well as on as needed basis. The laboratory is staffed with 15 qualified, well trained, well mentored and very competent staff.

Lab capacity

The lab is equipped with well-maintained equipment with capacity to handle different sample types (blood, urine, swabs, stool, CSF, sputum, foreskins, etc.) and to do tests including hematology, clinical chemistry,



serology, flowcytometry, molecular biology and microbiology. We also acquired a Genexpert machine which has improved our ability to diagnose M. Tuberculosis and resistance to rifampicin. Since its installation in 2014, 325 smear negative samples have tested positive on the Genexpert. We are grateful to the ICER and the CDC funded PEPFAR Programs which provide some of the support for laboratory equipment, maintenance and supplies.

Sample repository

Our lab has a sample repository with capacity to house 40 (forty) -80°C freezers (85 X 30ft) and a cold room. The repository is powered by the main grid which is backed up by two standby generators.

Lab proficiency

The lab participates in proficiency testing programs including the College of American Pathologists (CAP) and UKNEQAS as an external quality assurance measure. Internal quality control (IQC) systems are also in place to ensure quality test results. Our laboratory

is compliant to ISO: 15189:2012 and is working towards accreditation.

Mobile Laboratory

We have established capacity to provide mobile (outreach) laboratory support to both research and service programs when needed. Processing of RCCS samples is now done in the field to improve on sample integrity. Our lab provides technical support to lab hubs that support government and private health facilities in 12 districts in Masaka region through mentorship, support supervision and supply chain management.



Finance & Administration

Financial Management

RHSP has an efficient financial management and systems team. The Accounts and Finance section is staffed by certified accountants and supported by an automated financial management system to report on financial management of over 13 research and training grants and contracts worth over USD \$5,000,000 annually from multiple funders. RHSP segregates project funds but maintains flexibility in reporting across time periods and dimensions as required by users and funders. RHSP conforms to International Financial Reporting Standards (IFRS) and is subject to rigorous audits by international audit firms. Its current auditors are Diamond Consulting Group (internal audit) and Ernst & Young (external audit). In addition, the RHSP Executive management has a standing audit committee to oversee finances.



Estates and Transport

RHSP functions in a number of locations within Rakai District and elsewhere. We have a fleet of over 30 vehicles and 20 motorcycles. A team of 4 in-house mechanics and 26 drivers.

Human Resources

The Human Resource section is staffed with qualified practitioners who are registered members of the Human Resource Managers' Association of Uganda. This team is backed by an HR Management system where all staff profiles and documentation are maintained for auditing on a quarterly basis to ensure compliance with required standards.

Security

RHSP has a large campus and provides security for the staff, clients and visitors and assets of the organization.

Procurement and Stores

The Procurement and Stores section is staffed with qualified personnel using an automated financial management system for all procurement and stock management.





REBECCA KAKEMBO
Head Grants

GRANTS ANNUAL REPORT- PERIOD COVERED OCTOBER 2017 TO SEPTEMBER 2018

The Grants department falls under the Directorate of Finance and Administration.

The major role of the Grants department is to support the research, and program activities achieve their goals in a timely manner as far as grants financing and reporting is concerned, adhering to the donor compliance world.

The department handles both pre and post award activities.

Some of the key post award activities include:

- Submission of various donor progress reports and invoices.
- Managing burn rate and informing management of the need to modify budgets by redirection, reallocations and carryover requests, no-cost extensions etc
- Ensuring RHSP has an updated registration status in SAMs, grants,

gov and other grants management systems,

- Ensuring the PIs and Key personnel have updated information in the grants management systems.
- Ensuring the organisation has enough funds to run activities at all times, supporting the going concern.
- Ensuring the sub grantees have enough funds to run the activities and submit timely accountabilities.

Under pre-award the department supports the award process by budgeting for the activities, address pre-award questions, upload the application packet and manage the granting process.

The current portfolio stands at a project amount of \$67,452,003 out of which \$8,353,992 are Research funds and the former Program funds. Attached is the detailed current grants portfolio.

A group of approximately 20 people, including men and women of various ethnicities, are seated at long wooden tables in a classroom or training room. They are looking towards the front of the room, suggesting they are attending a presentation or lecture. Several laptops are open on the tables, and some individuals are taking notes. The room has large windows with blue vertical blinds, a door on the left, and decorative wall panels. The overall atmosphere is professional and focused.

Training & Capacity Development



Interns during a presentation of their reports.



Some of the Ugandan interns from various universities.

Internships

Students apply through the HR office and a list is forwarded to the Training Committee to determine the number and placement of interns. Internships are offered throughout the year, however the largest number of students come from June to August.



David Kalinoski, 27

His hometown is Harrisburg, Pennsylvania. Doing dual Masters programs; in Public Health majoring in Population & Family Health; and Masters in social Work from Columbia University. He majored in Communications during his Undergraduate degree from Temple University. He loves the music and dance in Uganda so far.



Veronica Nakalyango,

At 21 years, Veronica is a 3rd year student in Makerere University pursuing a Degree in Business Administration. Her first encounter with accounting systems like Navision for data entry, requisitions and payments was at RHSP during her internship. Her passion for accounting has helped her plan her life career as an auditor. For a young lady who hails from Masaka, she is proud to have gained this experience so close to home.



Kaiyue Wu, 22

Originally from Beijing , China, she has fallen in love with Ugandan food and animals especially the black pigs. She did her undergrad from Peking university found in her hometown where she studied biology and economics. She is currently pursuing a Master in Public Health majoring in Health Policy & Management – infectious Diseases from Columbia University.



Stanley Mpiima

When Stanley couldn't make it for secondary level education, that did not deter him from pursuing his dream to become a mechanical engineer. Through government sponsorship he was enrolled at the Uganda Military Engineering College in Lugazi where he studied a Diploma in Mechanical Engineering. During his internship at RHSP, the 28 year old was intrigued about the new technology and equipment being used in the workshop. He worked with a technical team that had a lot to teach him in a short time. He hopes to pass on the knowledge he amassed to his home people of Kabwoko, in Rakai district.



Interns from Columbia University undergoing orientation at Kalisizo Head Office.



Some of the Ugandan interns who have done their internship at RHSP.

UGANDAN INTERNS JUNE 2018-DATE 2018

NO.	NAME	COURSE	INSTITUTION	SECTION/ DEPT
1	Mpiima Stanley	Dip. Mechanical Engineering	Uganda Military Engineering College	TRANSPORT
2	Kwagala Irene	BA. Public Admin.	Muteesa 1 Royal University	DREAMS
3	Kayizzi Augustine	BA. Social Sciences	Kyambogo University	DREAMS
4	Mbabazi Maria Ann	BA. Science in Business Statistics	Makerere University	DATA
5	Manyangati Sam	BA. Business Admin	Cavendish University	PROCUREMENT
6	Nakalyango Veronica	BA. Business Admin	Makerere University	ACCOUNTS
7	Lubega Naswifu	BA. Economics & Statistics	Kyambogo University	DATA
8	Kateregga Augustine	BA. Commerce	Makerere University	ACCOUNTS
9	Muyunga Edwin	BA. Statistics	Makerere University	DATA
10	Musaazi Ronald	BA. Business Management/Accounting	Muteesa 1 Royal University	ACCOUNTS
11	Nakalanzi Patience Cathy	BA. SWASA	Makerere University	DREAMS
12	Musaasizi Moses	BA. SWASA	Makerere University	DREAMS
13	Muhaise Cleophas	BA. Office & Informantion Mgt	Makerere University	FRONT DESK
14	Muwazi Dennis	BA. SWASA	Makerere University	DREAMS
15	Nagawa Jovita	Bs. Biomediacal Lab Tech	Makerere University	LAB
16	Namuyamba Olive Imelda	Bs. Biology Chemistry	Makerere University	LAB
17	Nakyajja Josephine	BA. Business Admin	Makerere University	ACCOUNTS
18	Namaalwa Rose	BA. Social Sciences	Makerere University	DREAMS
19	Samiri Jamiru	Bs. Medical Laboratory Science	Makerere University	LAB
20	Mukwaya Joshua	Dip. Journalism	Buganda Royal Institute	DREAMS
21	Kaweesi Ibrahim	BA. Business Computing	Ndejje University	IT
22	Politique Jonevah	BA. SWASA	Makerere University	DREAMS
23	Faridah Kasumba	BA. Guidance And Couselling	St. Lawrence University	COUNSELLING
24	Nabaweesi Haawa	Dip. Informantion Technology	Muteesa 1 Royal Univ. Masaka	IT
25	Nalugo Rosemary	Certificate In Medical Lab	St. Joseph Hospital Kitovu	LAB
26	Kiberu Aloysious	BSC. ECON& STATISTICS	Uganda Christian University	M&E
27	Ngobi Faith Tabusa	Dip. Informantion Technology	Datamine Technical Busn School	IT

Staff Training

CME training is conducted monthly at the Kalisizo ART clinic to update staff about advances in HIV care and treatment. Two health workers from each health facility in Rakai are included. Clinical cases are presented and discussed and

internship placements organized.

Training for Bachelors, Masters and PhD degrees either “in-country” or “out-of-the- country.” For in country training, there is a committee that selects candidates. Most trainees are supported by Fogarty International Center grants.

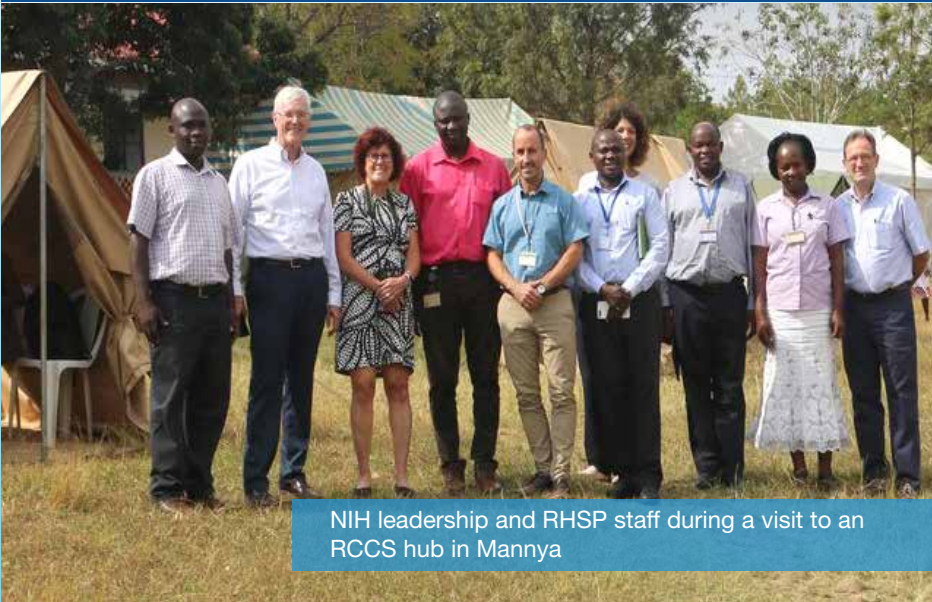
STAFF SCHOLARSHIPS

TRAINEE	Start Date	DEGREE	INSTITUTION	ADMINISTRATION	STATUS
Fred Nalugoda	October 2008	PhD - Sandwich	Makerere Univ.	UVRI	Completed - 2014
Godfrey Kigozi	May 2010	PhD - Sandwich	Makerere Univ.	UVRI	Completed - 2015
Gertrude Nakigozi	May 2010	PhD - Sandwich	Makerere Univ.	UVRI	Completed - 2015
Tom Lutalo	November 2012	PhD - Sandwich	Makerere Univ.	UVRI	Completed - 2017
Barbra Nanteza	December 2015	PhD - Sandwich	Makerere Univ.	UVRI	in training
Roland Galiwango	January 2014	PhD	Univ. of Toronto	Toronto	in training
Ismail Mbabali	July 2014	MPH	JHSPH	JHSPH	Completed - 2015
Apollo Kivumbi	July 2015	MPH	JHSPH	JHSPH	Completed - 2016
Edward Kankaka	July 2016	MPH	JHSPH	JHSPH	Completed - 2017
Alice Kisakye	July 2016	MPH	JHSPH	JHSPH	Completed - 2017
Stephen Sebagala Kutta	August 2014	MPH	Makerere Univ.	UVRI	Completed - 2013
George William Ddaaki	August 2014	MS	UCL	UVRI	Completed - 2015
Jesca Basiima	August 2014	MPH	Nkozi University	UVRI	Completed - 2015
Emanuel Kato	August 2014	MPH	Nkozi University	UVRI	Completed - 2016
Daniel Nkakalukanyi	August 2014	MMED - Surgery	Makerere Univ.	UVRI	Completed - 2017
Anna Lawino	August 2014	MPH	Makerere Univ.	UVRI	Completed - 2018
Richard Muwanika	August 2014	MS	Makerere Univ.	UVRI	Completed - 2016
Lucy Amaniyo	August 2015	MPH	Makerere Univ.	UVRI	Completed - 2017
Stephen Kigongo	August 2015	MPH	Makerere Univ.	UVRI	in training
James Ssenfuka	August 2016	MPH	Makerere Univ.	UVRI	in training
Aggrey Byaruhanga	August 2016	MPH	Makerere Univ.	UVRI	in training
James Nnamutete	August 2013	BS	Mbarara U.S.T.	UVRI	Completed - 2016
Joshua Mwinike	August 2014	BPH	Mountain of the Moon	UVRI	Completed - 2017
Fred Wandera	August 2014	BPH	Mountain of the Moon	UVRI	Completed - 2017
Ronald Mutebi	August 2016	MPH	Makerere Univ.	RHSP	in training
Asaani Kasango	August 2016	MPH	Makerere Univ.	RHSP	in training
Alex Daama	August 2018	MPH	Makerere Univ.	RHSP	in training
Ivan Ssebugenyi	August 2017	Lab	Makerere Univ.	RHSP	in training
Darix Kigozi	July 2016	Certificate - GIS	JHSPH	JHSPH	Completed - 2016
Anthony Ndyanabo	July 2016	Certificate - GIS	JHSPH	JHSPH	Completed - 2016
James Batte	July 2017	Certificate in Epi and Biostat	JHSPH	JHSPH	Completed - 2017
Moses Sakor	July 2017	Certificate in Epi and Biostat	JHSPH	JHSPH	Completed - 2017



Partnerships and Collaborations

Partnerships and Collaborations



NIH leadership and RHSP staff during a visit to an RCCS hub in Manya



Uganda CDC team and RHSP staff during a field visit in Kasensero health centre



Uganda CDC team, RHSP staff and Kalangala district leadership team during a recent visit to Kalangala district.



RHSP Uganda team with key partners and collaborators.



Uganda's Vice President Edward Sekandi at an RHSP stall during the Presidential Fast Track Initiative celebrations in Kalungu district.



RHSP DREAMS Regional Manager explaining to VP about the DREAMS project.



RHSP partner implementers from Ministry of Health.



Uganda CDC Team during a field visit to Mpigi health centres.



A team of RHSP Health Scouts in Kasensero.



RHSP district coordinators with DREAMS partner implementers from Kitovu Mobile and RAIN during a graduation ceremony in Kyotera. RHSP



A team of trainees from Kenya and Tanzania together with trainers of the Shangring and Mogen Clamp study during a resident training in Kalisizo.



Publications

- Abassi M**, Morawski BM, Nakigozi G, et al. Cerebrospinal fluid biomarkers and HIV-associated neurocognitive disorders in HIV-infected individuals in Rakai, Uganda. *Journal of neurovirology*. 2017;23(3):369-375.
- Alfonso YN**, Bishai D, Nantongo A, et al. Trends in the Marginal Cost of Male Circumcision in Rural Rakai Uganda. *Journal of acquired immune deficiency syndromes (1999)*. 2016;73(5):564-571.
- Atuyambe LM**, Baingana RK, Kibira SPS, et al. Undergraduate students' contributions to health service delivery through community-based education: A qualitative study by the MESAU Consortium in Uganda. *BMC medical education*. 2016;16:123-016-0626-0620.
- Billieux VG**, Chang LW, Reynolds SJ, et al. Human immunodeficiency virus care cascade among sub-populations in Rakai, Uganda: an observational study. *J Int AIDS Soc*. 2017;20(1):21590.
- Blanquart F**, Grabowski MK, Herbeck J, et al. A transmission-virulence evolutionary trade-off explains attenuation of HIV-1 in Uganda. *eLife*. 2016;5:10.7554/eLife.20492.
- Borquez A**, Cori A, Pufall EL, et al. The Incidence Patterns Model to Estimate the Distribution of New HIV Infections in Sub-Saharan Africa: Development and Validation of a Mathematical Model. *PLoS medicine*. 2016;13(9):e1002121.
- Brahmbhatt H**, Boivin M, Ssempijja V, et al. Impact of HIV and Atiretroviral Therapy on Neurocognitive Outcomes Among School-Aged Children. *J Acquir Immune Defic Syndr*. 2017;75(1):1-8.
- Chang LW**, Grabowski MK, Ssekubugu R, et al. Heterogeneity of the HIV epidemic in agrarian, trading, and fishing communities in Rakai, Uganda: an observational epidemiological study. *The lancetHIV*. 2016;3(8):e388-e396.
- Chang LW**, Mbabali I, Kong X, et al. Impact of a community health worker HIV treatment and prevention intervention in an HIV hotspot fishing community in Rakai, Uganda (mLAKE): study protocol for a randomized controlled trial. *Trials*. 2017;18(1):494.

- Grabowski MK**, Kong X, Gray RH, et al. Partner Human Papillomavirus Viral Load and Incident Human Papillomavirus Detection in Heterosexual Couples. *The Journal of infectious diseases*. 2016;213(6):948-956.
- Grabowski MK**, Serwadda DM, Gray RH, et al. HIV Prevention Efforts and Incidence of HIV in Uganda. *The New England journal of medicine*. 2017;377(22):2154-2166.
- Kagaayi J, Kong X**, Kigozi G, et al. Self-selection of male circumcision clients and behaviors following circumcision in a service program in Uganda. *AIDS (London, England)*. 2016;30(13):2125-2129.
- Kagaayi J, Serwadda D**. The History of the HIV/AIDS Epidemic in Africa. *Current HIV/AIDS reports*. 2016;13(4):187-193.
- Kankaka EN**, Kigozi G, Kayiwa D, et al. Efficacy of knowledge and competence-based training of non-physicians in the provision of early infant male circumcision using the Mogen clamp in Rakai, Uganda. *BJU international*. 2017;119(4):631-637.
- Kankaka EN**, Murungi T, Kigozi G, et al. Randomised trial of early infant circumcision performed by clinical officers and registered nurse midwives using the Mogen clamp in Rakai, Uganda. *BJU international*. 2017;119(1):164-170.
- Kankaka EN**, Murungi T, Kigozi G, et al. Randomised trial of early infant circumcision performed by clinical officers and registered nurse midwives using the Mogen clamp in Rakai, Uganda. *BJU Int*. 2017;119(1):164-170.
- Kibira SP**, Sandoy IF, Daniel M, Atuyambe LM, Makumbi FE. A comparison of sexual risk behaviours and HIV seroprevalence among circumcised and uncircumcised men before and after implementation of the safe male circumcision programme in Uganda. *BMC public health*. 2016;16:7-015-2668-2663.
- King EJ**, Maman S, Namatovu F, et al. Addressing Intimate Partner Violence Among Female Clients Accessing HIV Testing and Counseling Services: Pilot Testing Tools in Rakai, Uganda. *Violence Against Women*. 2016.
- Kong X**, Kigozi G, Ssekasanvu J, et al. Medical male circumcision coverage in Rakai, Uganda. *Aids*. 2017;31(5):735-737.
- Liu CM**, Hungate BA, Tobian AA, et al. Penile Microbiota and Female Partner Bacterial Vaginosis in Rakai, Uganda. *mBio*. 2015;6(3):e00589-00515.
- Liu CM**, Prodger JL, Tobian AA, et al. Genital Anaerobic Bacterial Overgrowth and the PrePex Male Circumcision Device, Rakai,

- Uganda. *The Journal of infectious diseases*. 2016;214(4):595-598.
- Liu CM**, Tobian AA, Gray RH. Ockham's Razor and the PrePex Male Circumcision Device. *The Journal of infectious diseases*. 2016;214(7):1126.
- Long A**, Mbabali I, Hutton HE, et al. Design and Implementation of a Community Health Worker HIV Treatment and Prevention Intervention in an HIV Hot Spot Fishing Community in Rakai, Uganda. *Journal of the International Association of Providers of AIDS Care*. 2017;16(5):499-505.
- Makumbi FE**, Ssempijja V, Sekasanvu J, et al. Postcoital penile washing and the risk of HIV acquisition in uncircumcised men. *AIDS (London, England)*. 2016;30(10):1669-1673.
- Marston M**, Nakiyingi-Miiró J, Hosegood V, et al. Measuring the Impact of Antiretroviral Therapy Roll-Out on Population Level Fertility in Three African Countries. *PloS one*. 2016;11(3):e0151877.
- Mathur S**, Higgins JA, Thummalachetty N, et al. Fatherhood, marriage and HIV risk among young men in rural Uganda. *Culture, health & sexuality*. 2016;18(5):538-552.
- Mathur S**, Romo D, Rasmussen M, Nakyanjo N, Nalugoda F, Santelli JS. Re-focusing HIV prevention messages: a qualitative study in rural Uganda. *AIDS research and therapy*. 2016;13:37.
- Matovu JK**, Todd J, Wanyenze RK, Kairania R, Serwadda D, Wabwire-Mangen F. Evaluation of a demand-creation intervention for couples' HIV testing services among married or cohabiting individuals in Rakai, Uganda: a cluster randomized intervention trial. *BMC infectious diseases*. 2016;16:379-016-1720-y.
- Nachega JB**, Adetokunboh O, Uthman OA, et al. Community-Based Interventions to Improve and Sustain Antiretroviral Therapy Adherence, Retention in HIV Care and Clinical Outcomes in Low- and Middle-Income Countries for Achieving the UNAIDS 90-90-90 Targets. *Current HIV/AIDS reports*. 2016;13(5):241-255.
- Nason MC**, Patel EU, Kirkpatrick AR, et al. Immunological Signaling During Herpes Simplex Virus-2 and Cytomegalovirus Vaginal Shedding After Initiation of Antiretroviral Treatment. *Open forum infectious diseases*. 2016;3(2):ofw073.
- Newell K**, Kiggundu V, Ouma J, et al. Longitudinal household surveillance for malaria in Rakai, Uganda. *Malaria journal*. 2016;15:77-

016-1128-1126.

Nsubuga H, Sekandi JN, Sempeera H, Makumbi FE. Contraceptive use, knowledge, attitude, perceptions and sexual behavior among female University students in Uganda: a cross-sectional survey. *BMC women's health*. 2016;16:6-016-0286-0286.

Olwenyi OA, Naluyima P, Cham F, et al. Brief Report: Differential Associations of Interleukin 6 and Intestinal Fatty Acid-Binding Protein With Progressive Untreated HIV-1 Infection in Rakai, Uganda. *Journal of acquired immune deficiency syndromes (1999)*. 2016;72(1):15-20.

Osingada CP, Okuga M, Nabirye RC, Sewankambo NK, Nakanjako D. Prevalence, barriers and factors associated with parental disclosure of their HIV positive status to children: a cross-sectional study in an urban clinic in Kampala, Uganda. *BMC public health*. 2016;16:547-016-3235-3232.

Patel EU, Gianella S, Newell K, et al. Elevated cytomegalovirus IgG antibody levels are associated with HIV-1 disease progression and immune activation. *Aids*. 2017;31(6):807-813.

Ratmann O, Wymant C, Colijn C, et al. HIV-1 full-genome phylogenetics of generalized epidemics in sub-Saharan Africa: impact of missing nucleotide characters in next-generation sequences. *AIDS Res Hum Retroviruses*. 2017.

Reniers G, Wamukoya M, Urassa M, et al. Data Resource Profile: Network for Analysing Longitudinal Population-based HIV/AIDS data on Africa (ALPHA Network). *International journal of epidemiology*. 2016;45(1):83-93.

Reynolds SJ, Ssempijja V, Galiwango R, et al. Low Rates of Transmitted Drug Resistance Among Newly Identified HIV-1 Seroconverters in Rural Rakai, Uganda. *AIDS Res Hum Retroviruses*. 2017;33(5):448-451.

Saylor D, Nakigozi G, Nakasujja N, et al. Peripheral neuropathy in HIV-infected and uninfected patients in Rakai, Uganda. *Neurology*. 2017;89(5):485-491.

Schuyler AC, Edelstein ZR, Mathur S, et al. Mobility among youth in Rakai, Uganda: Trends, characteristics, and associations with behavioural risk factors for HIV. *Global public health*. 2017;12(8):1033-1050.

Schuyler AC, Edelstein ZR, Mathur S, et al. Mobility among youth in Rakai, Uganda: Trends, characteristics, and associations with behavioural risk factors for HIV. *Glob Public Health*. 2017;12(8):1033-1050.

- Seremba E**, Ssempijja V, Kalibbala S, et al. Hepatitis B incidence and prevention with antiretroviral therapy among HIV positive individuals in Uganda. *Aids*. 2017;31(6):781-786.
- Ssempijja V**, Nakigozi G, Chang L, Gray R, Wawer M, Ndyababo A, Kasule J, Serwadda D, Castelnuovo B, Hoog AV, Reynolds SJ. Rates of switching to second-line antiretroviral therapy and impact of delayed switching on immunologic, virologic, and mortality outcomes among HIV-infected adults with virologic failure in Rakai, Uganda. *BMC Infect Dis*. Aug 22 2017;17(1):582. doi: 10.1186/s12879-017-2680-6. PubMed PMID: 28830382; PubMed Central MCID:PMC5568262.
- Wagman JA**, Charvat B, Thoma ME, et al. Intimate partner violence as a predictor of marital disruption in rural Rakai, Uganda: a longitudinal study. *International journal of public health*. 2016;61(8):961-970.
- Wagman JA**, Gray RH, Nakyanjo N, et al. Process evaluation of the SHARE intervention for preventing intimate partner violence and HIV infection in Rakai, Uganda. *Evaluation and Program Planning*. 2018;67:129-137.
- Wagman JA**, King EJ, Namatovu F, et al. Combined Intimate Partner Violence and HIV/AIDS Prevention in Rural Uganda: Design of the SHARE Intervention Strategy. *Health care for women international*. 2016;37(3):362-385.
- Wagman JA**, Paul A, Namatovu F, Ssekubugu R, Nalugoda F. Ethical Challenges of Randomized Violence Intervention Trials: Examining the SHARE intervention in Rakai, Uganda. *Psychology of violence*. 2016;6(3):442-451.
- Blanquart F**, Grabowski MK, Herbeck J, Nalugoda F, Serwadda D, Eller MA, Robb ML, Gray R, Kigozi G, Laeyendecker O, Lythgoe KA, Nakigozi G, Quinn TC, Reynolds SJ, Wawer MJ, Fraser C. A transmission-virulence evolutionary trade-off explains attenuation of HIV-1 in Uganda. *eLife*. 2016;5.
- Chang LW**, Grabowski MK, Ssekubugu R, Nalugoda F, Kigozi G, Nantume B, Lessler J, Moore SM, Quinn TC, Reynolds SJ, Gray RH, Serwadda D, Wawer MJ. Heterogeneity of the HIV epidemic in agrarian, trading, and fishing communities in Rakai, Uganda: an observational epidemiological study. *The lancet HIV*. 2016;3(8):e388-e96.
- Grabowski MK**, Kong X, Gray RH, Serwadda D, Kigozi G, Gravitt PE, Nalugoda F, Reynolds SJ, Wawer MJ, Redd AD, Watya S, Quinn TC, Tobian AA. Partner Human Papillomavirus Viral Load and Incident Human Papillomavirus Detection in Heterosexual Couples. *The Journal of infectious diseases*. 2016;213(6):948-56.
- Kong X**, Kigozi G, Ssekasanvu J, Nalugoda F, Nakigozi G, Ndyababo A, Lutalo T, Reynolds SJ, Ssekubugu R, Kagaayi J, Bugos

E, Chang LW, Nanlesta P, Mary G, Berman A, Quinn TC, Serwadda D, Wawer MJ, Gray RH. Association of Medical Male Circumcision and Antiretroviral Therapy Scale-up With Community HIV Incidence in Rakai, Uganda. *Jama*. 2016;316(2):182-90.

Nason MC, Patel EU, Kirkpatrick AR, Prodger JL, Shahabi K, Tobian AA, Gianella S, Kalibbala S, Ssebbowa P, Kaul R, Gray RH, Quinn TC, Serwadda D, Reynolds SJ, Redd AD. Immunological Signaling During Herpes Simplex Virus-2 and Cytomegalovirus Vaginal Shedding After Initiation of Antiretroviral Treatment. *Open forum infectious diseases*. 2016;3(2):ofw073.

Newell K, Kiggundu V, Ouma J, Baghendage E, Kiwanuka N, Gray R, Serwadda D, Hobbs CV, Healy SA, Quinn TC, Reynolds SJ. Longitudinal household surveillance for malaria in Rakai, Uganda. *Malaria journal*. 2016;15:77.

Prodger JL, Gray RH, Shannon B, Shahabi K, Kong X, Grabowski K, Kigozi G, Nalugoda F, Serwadda D, Wawer MJ, Reynolds SJ, Liu CM, Tobian AA, Kaul R. Chemokine Levels in the Penile Coronal Sulcus Correlate with HIV-1 Acquisition and Are Reduced by Male Circumcision in Rakai, Uganda. *PLoS pathogens*. 2016;12(11):e1006025.

Billieux VG, Chang LW, Reynolds SJ, Nakigozi G, Ssekasanvu J, Grabowski MK, Ssekubugu R, Nalugoda F, Kigozi G, Kagaayi J, Serwadda D, Gray RH, Wawer MJ. Human immunodeficiency virus care cascade among sub-populations in Rakai, Uganda: an observational study. *Journal of the International AIDS Society*. 2017;20(1):21590.

Chang LW, Mbabali I, Kong X, Hutton H, Amico KR, Kennedy CE, Nalugoda F, Serwadda D, Bollinger RC, Quinn TC, Reynolds SJ, Gray R, Wawer M, Nakigozi G. Impact of a community health worker HIV treatment and prevention intervention in an HIV hotspot fishing community in Rakai, Uganda (mLAKE): study protocol for a randomized controlled trial. *Trials*. 2017;18(1):494.

Grabowski MK, Serwadda DM, Gray RH, Nakigozi G, Kigozi G, Kagaayi J, Ssekubugu R, Nalugoda F, Lessler J, Lutalo T, Galiwango RM, Makumbi F, Kong X, Kabatesi D, Alamo ST, Wiersma S, Sewankambo NK, Tobian AAR, Laeyendecker O, Quinn TC, Reynolds SJ, Wawer MJ, Chang LW, Rakai Health Sciences P. HIV Prevention Efforts and Incidence of HIV in Uganda. *The New England journal of medicine*. 2017;377(22):2154-66.

Mangal TD, Progression UWGoC, Mortality Amongst HIVSitCCiE. Joint estimation of CD4+ cell progression and survival in untreated individuals with HIV-1 infection. *Aids*. 2017;31(8):1073-82.

Monroe A, Nakigozi G, Ddaaki W, Bazaale JM, Gray RH, Wawer MJ, Reynolds SJ, Kennedy CE, Chang LW. Qualitative insights into implementation, processes, and outcomes of a randomized trial on peer support and HIV care engagement in Rakai, Uganda.

BMC infectious diseases. 2017;17(1):54.

Patel EU, Gianella S, Newell K, Tobian AA, Kirkpatrick AR, Nalugoda F, Grabowski MK, Gray RH, Serwadda D, Quinn TC, Redd AD, Reynolds SJ. Elevated cytomegalovirus IgG antibody levels are associated with HIV-1 disease progression and immune activation. *Aids*. 2017;31(6):807-13.

Prodger JL, Lai J, Reynolds SJ, Keruly JC, Moore RD, Kasule J, Kityamuweesi T, Buule P, Serwadda D, Nason M, Capoferri AA, Porcella SF, Siliciano RF, Redd AD, Siliciano JD, Quinn TC. Reduced Frequency of Cells Latently Infected With Replication-Competent Human Immunodeficiency Virus-1 in Virally Suppressed Individuals Living in Rakai, Uganda. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. 2017;65(8):1308-15.

Reynolds SJ, Ssempijja V, Galiwango R, Ndyababo A, Nakigozi G, Lyagoba F, Nazziwa J, Redd A, Lamers SL, Gray R, Wawer M, Serwadda D, Quinn TC. Low Rates of Transmitted Drug Resistance Among Newly Identified HIV-1 Seroconverters in Rural Rakai, Uganda. *AIDS research and human retroviruses*. 2017;33(5):448-51.

Seremba E, Ssempijja V, Kalibbala S, Gray RH, Wawer MJ, Nalugoda F, Casper C, Phipps W, Ocamo P, Serwadda D, Thomas DL, Reynolds SJ. Hepatitis B incidence and prevention with antiretroviral therapy among HIV-positive individuals in Uganda. *Aids*. 2017;31(6):781-6.

Ssempijja V, Nakigozi G, Chang L, Gray R, Wawer M, Ndyababo A, Kasule J, Serwadda D, Castelnuovo B, Hoog AV, Reynolds SJ. Rates of switching to second-line antiretroviral therapy and impact of delayed switching on immunologic, virologic, and mortality outcomes among HIV-infected adults with virologic failure in Rakai, Uganda. *BMC infectious diseases*. 2017;17(1):582.

Billieux VG, Grabowski MK, Ssekasanvu J, Reynolds SJ, Berman A, Bazaale J, Patel EU, Bugos E, Ndyababo A, Kisakye A, Kagaayi J, Gray RH, Nakigozi G, Ssekubugu R, Nalugoda F, Serwadda D, Wawer MJ, Chang LW. HIV viral suppression and geospatial patterns of HIV antiretroviral therapy treatment facility use in Rakai, Uganda. *Aids*. 2018;32(6):819-24.

Boon D, Redd AD, Laeyendecker O, Engle RE, Nguyen H, Ocamo P, Boaz I, Ndyababo A, Kiggundu V, Reynolds SJ, Gray RH, Wawer MJ, Purcell RH, Kirk GD, Quinn TC, Stabinski L, Rakai Health Sciences P. Hepatitis E Virus Seroprevalence and Correlates of Anti-HEV IgG Antibodies in the Rakai District, Uganda. *The Journal of infectious diseases*. 2018;217(5):785-9.

Grabowski MK, Reynolds SJ, Kagaayi J, Gray RH, Clarke W, Chang LW, Nakigozi G, Laeyendecker O, Redd AD, Billieux V,

Ssekubugu R, Nalugoda F, Wawer MJ, Serwadda D, Quinn TC, Tobian AAR. The validity of self-reported antiretroviral use in persons living with HIV: a population-based study. *Aids*. 2018;32(3):363-9.

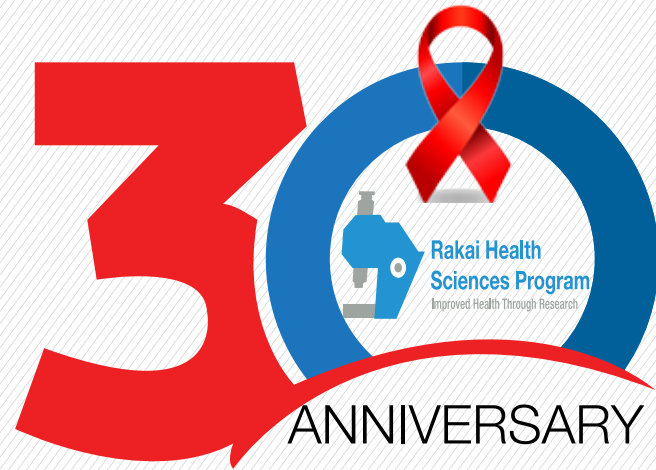
Kasule J, Gabriel EE, Anok A, Neal J, Eastman RT, Penzak S, Newell K, Serwadda D, Duffy PE, Reynolds SJ, Hobbs CV. Sulfamethoxazole Levels in HIV-Exposed Uninfected Ugandan Children. *The American journal of tropical medicine and hygiene*. 2018;98(6):1718-21.

Olawore O, Tobian AAR, Kagaayi J, Bazaale JM, Nantume B, Kigozi G, Nankinga J, Nalugoda F, Nakigozi G, Kigozi G, Gray RH, Wawer MJ, Ssekubugu R, Santelli JS, Reynolds SJ, Chang LW, Serwadda D, Grabowski MK. Migration and risk of HIV acquisition in Rakai, Uganda: a population-based cohort study. *The lancet HIV*. 2018;5(4):e181-e9.

Otiti-Sengeri J, Colebunders R, Reynolds SJ, Muwonge M, Nakigozi G, Kiggundu V, Nalugoda F, Nakanjako D. Elevated inflammatory cytokines in aqueous cytokine profile in HIV-1 infected patients with cataracts in Uganda. *BMC ophthalmology*. 2018;18(1):12.


Poon AFY, Prodger JL, Lynch BA, Lai J, Reynolds SJ, Kasule J, Capoferri AA, Lamers SL, Rodriguez CW, Bruno D, Porcella SF, Martens C, Quinn TC, Redd AD. Quantitation of the latent HIV-1 reservoir from the sequence diversity in viral outgrowth assays. *Retrovirology*. 2018;15(1):47.

Ssempijja V, Chang LW, Nakigozi G, Ndyababo A, Quinn TC, Cobelens F, Wawer M, Gray R, Serwadda D, Reynolds SJ. Results of Early Virologic Monitoring May Facilitate Differentiated Care Monitoring Strategies for Clients on ART, Rakai, Uganda. *Open forum infectious diseases*. 2018;5(10):ofy212.




In 2019, RHSP will hold a celebration for its 30th Anniversary. We hope to see you at that time.





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**Rakai Health
Sciences Program**

Improved Health Through Research