NRHS | Nyanza Reproductive Health Society

NRHS ANNUAL REPORT- 2019

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ABBREVIATIONS

1. AE – Adverse Event
2. AJAJ- Afya Jozi, Afya Jamii
3. AM- Anza Mapema
4. AMkAJ- Anza Mapema kwa Afya Jozi (AMkAJ)
5. BV- Bacterial Vaginosis
6. *CACHE*- Cups for Community Health
7. CDC – Centers for Disease Control and Prevention
8. EHPSA- *Evidence for HIV Prevention in Southern Africa*
9. EIMC- Early Infant Medical Circumcision
10. FACES – Family AIDS Care and Education Services
11. FP- Family Planning
12. GBMSM- gay, bisexual and other men who have sex with men
13. GUD- Genital Ulcer Disease
14. HIV- Human Immunodeficiency Virus
15. HTS- HIV Testing Services
16. KDHS- Kenya Demographic Health Survey
17. LGBQ - Lesbian, Gay, Bisexual and Queer persons
18. M&E - Monitoring and Evaluation
19. MoH- Ministry of Health
20. MHRC – MSM Health Research Consortium
21. MM1- Mtoto Msafi Kwanza
22. MM2- Mtoto Msafi Mbili
23. MSM- Men who have sex with men
24. NASCOP- National AIDS and STI Control Program
25. NIAID- National Institute of Allergy and Infectious Diseases
26. NIH- National Institutes of Health
27. NRHS- Nyanza Reproductive Health Society
28. PIHR – Partners in Reproductive Health
29. PITC- Provider Initiated Testing and Counseling
30. PrEP- Pre-exposure prophylactics
31. STIs- Sexually Transmitted Infections
32. QA - Quality Assurance
33. QI – Quality Improvement
34. TWG- Technical Working Group
35. UIC- University of Illinois at Chicago
36. URTC- UNIM Research and Training Centre (NRHS)
37. VMMC- Voluntary Male Medical Circumcision
38. WHO- World Health Organization

1. FROM THE DESK OF THE INTERIM DIRECTOR

The year 2019 was a good year for NRHS as it continued to pursue its mission of improving the health and quality of life of individuals and communities in Kenya and beyond. It did this through its contributions to programs designed to prevent diseases, reduce morbidity and address the reproductive health needs of Kenyan men and women, while it also conceived, initiated and executed innovative research projects to inform and drive evidence-based programs in the future. This annual report reviews these diverse programs and research projects, as well as some of the activities that NRHS leadership and staff engaged in during 2019. However, it can only scratch the surface of all that NRHS does and the many ways in which it contributes to health-related policy and practice within and outside of Kenya.

NRHS is only as effective as the people who make up the organization. We are very fortunate to have highly skilled and dedicated staff who are truly passionate about improving the lives of others and about making NRHS as good as it can be. Even with the multiple challenges of maintaining households, raising families and advancing the lives of their loved ones, our staff continue to strive to be the best in their profession and to make significant contributions to the organization and to Kenya. We are grateful for their dedication.

NRHS is blessed to have a Board of Directors, under the leadership of Prof. Walter Jaoko, whose experience and commitment have resulted in marked improvements in the structure and management of the organization in myriad ways. We are grateful to the Board for the time and thought that they contribute to NRHS. They all are very busy people with their own careers and projects to pursue, yet they take their time from those commitments to contribute their experience and wisdom to making NRHS a better organization.

NRHS divides its activities by those that are primarily programmatic (Programs) and those that are primarily research (Research). However, NRHS is committed to contributing to improving the health and quality of life of Kenyans through focusing on a continuum that begins with identifying significant problems and designing sound research to generate evidence that forms the basis for policy and advocacy that is translated to effective action in the form of programs. In this sense, it is not our intention to compartmentalize NRHS activities, but rather to emphasize their integration and synthetic nature. Nevertheless, in this report we present our activities and accomplishments achieved during the calendar year 2019 under the rubrics of Programs and Training, Research and Other.

To our members of the Board, our staff, our donors and especially to our clients and the communities we serve, I take this opportunity to wish you all a safe, prosperous and healthy 2020.

Robert C. Bailey, PhD, MPH
Interim Director NRHS
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NRHS's VISION, MISSION, CORE VALUES

Vision

NRHS envisions a world where individuals and communities are healthy and have the highest possible quality of life

Mission

NRHS promotes health and quality of life of individuals and communities in Kenya through research, evidence-based programming, advocacy and capacity building.

Core Values

1. Community participation

- NRHS builds trust and ownership by communities on its research and programs.
- NRHS involves communities to identify and prioritize their needs, and to design, implement, evaluate and improve research and programs.

2. Professionalism

- NRHS is committed to undertaking its operations in an ethical and professional manner.
- NRHS is committed to professional development through mentorship, training and continuous learning and improvement.

3. Commitment to Evidence

- NRHS conducts innovative and cutting edge research that addresses the needs of communities.
- NRHS translates research findings to inform policy development and implementation of innovative programs.

4. Integrity

- NRHS is committed to ethical principles, transparency and accountability in all its operations.

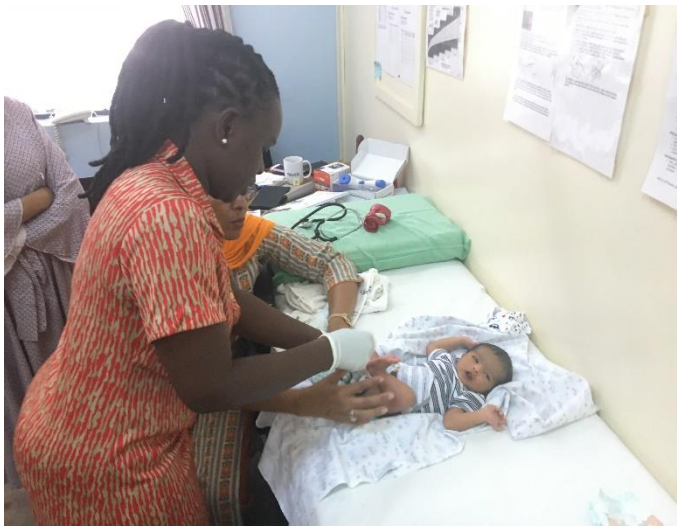
5. Non-discrimination

- NRHS is an equal opportunity employer committed to providing and maintaining a respectful work environment free of discrimination.
- NRHS values diversity, promotes respect for all and operates without any form of discrimination.

2. PROGRAMS and TRAINING

2.1 Voluntary Male Medical Circumcision (VMMC) Program

NRHS has been one of the foremost providers of comprehensive VMMC services since the onset of the national scale-up of VMMC that started in 2008. Provision of the VMMC services by NRHS continued through the year of 2019, primarily at the UNIM Research and Training Center (URTC) in Kisumu. In the face of cuts to collaborating partners, NRHS was not funded to perform VMMCs in the year 2019. However, because of its reputation in the community as the premier VMMC provider, many men came as “walk-ins” for VMMC services, and many parents brought their young adolescent sons for the services, especially around the time of school holidays. While NRHS had no funding to support these services, it continued to offer these services to walk in clients and did not turn any clients away. The costs for these procedures were absorbed by the NRHS general funds.



A total of 614 males ages 10-49 years were circumcised during the calendar year. All were circumcised using the surgical method. In addition to these adult and adolescent circumcisions, we performed 192 early infant male circumcisions (EIMC). Parents continue to seek EIMC at URTC because of its reputation as an EIMC center of excellence and so we provide the service free of charge without compensation from any donor. Remarkably, many of the parents who bring their babies to NRHS for EIMC are those who had a previous son circumcised there, or the father of the baby was circumcised by NRHS.

VMMC services were offered as a minimum package as per the national VMMC guidelines. HIV Testing Services (HTS) were offered as an integral component of services offered under the VMMC minimum package. Clients seeking VMMC services were also screened for Sexually Transmitted Infections (STIs) and syndromic treatment administered as per the Kenyan guidelines for STI treatment, in addition to condom provision as part of the minimum package of VMMC services.

2.2 PITC and STI Diagnosis and Treatment

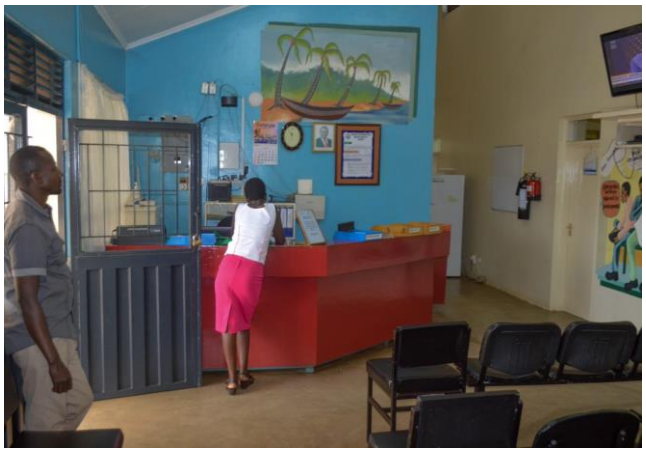
NRHS offers HIV testing and counselling and syndromic management of STIs free of charge on a walk-in basis to any client seeking services as part of its Partners in Reproductive Health (PIRH) program. During 2019, NRHS HIV tested and screened for STIs 523 walk-in clients. 288 of 340 men who were treated had a specified STD syndromic diagnosis (urethritis, GUD herpetic, GUD non herpetic, balanoposthitis). There were 183 female PIRH clients in 2019 and approximately 50% of these were diagnosed or treated for an STI. Those who tested HIV positive were actively referred to FACES, actually physically walking with the client next door to FACES for an introduction to ensure that they are linked to care and treatment services. NRHS had previously taken the opportunity to study antibiotic drug resistance in patients with urethral discharge (Mehta SD, Maclean I, Ndinya-Achola JO,

Moses S, Martin I, Ronald A, Agunda L, Murugu R, Bailey RC, Melendez J, Zenilman JM. Emergence of Quinolone-Resistance and Cephalosporin MIC Creep in Neisseria gonorrhoeae in a Cohort of Young Men in Kisumu, Kenya: 2002 – 2009. *Antimicrobial Agents Chemotherapy*, 2011 May 13), and these studies resumed in late 2019 under funding from the U.S. Department of Defense (see below).

2.3 Support of the National and Inter-county VMMC Task Force

NRHS continued to support the National, county and inter county VMMC Technical Working Groups (TWGs) through its contribution to formulation of National VMMC policies, development and revision of M&E tools and service delivery tools, offering technical assistance in quality assessment (QA) and quality improvement (QI) for VMMC service provision. In 2019, NRHS continued to contribute to the development of the EIMC training guidelines and the guidelines for mitigation of tetanus risk within the VMMC service provision. NRHS was a focal learning site, at its URTC, for EIMC by visiting local, regional, and international delegations. Delegations from the University of Manitoba and the U.S. Centers for Disease Control and Prevention (CDC) visited to learn about our operations and best practices.

2.4 Anza Mapema Programme



Since 2006, NRHS has been supporting members of the LGBTQ community, first at our support center called Kisumu Institute for Positive Empowerment (KIPE) and in recent years at our center, called Anza Mapema (AM). In 2015-2016 we recruited 711 gay, bisexual and other men who have sex with men (GBMSM) into a cohort and we provided test and treat services as well as HIV prevention services to them for over one year. The results of those studies have been published. In order to be able to continue providing much needed services to the cohort and other GBMSM in the community, we contracted with LVCT under their STEPS Project, “Increasing Access to and Availability of Sustainable, High Quality, Comprehensive Health in the Republic of Kenya”. We provide comprehensive HIV prevention services to approximately 600 GBMSM and provide treatment and care to about 60 PLHV. Anza Mapema (AM) entails extensive outreach to the GBMSM community, counselling and support for AM members, HIV testing every three months, syndromic management of STIs, provision of condoms and lubricants, and clinical services when needed. We also offer post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) along with PrEP adherence counselling.

In addition to the above “typical” mandated services NRHS offers numerous support activities for the men in the program with the aim of ensuring a safe space that is not just gay friendly, but gay affirming. These include Movie Mondays, support counseling for all men on Tuesdays, Coffee Wednesdays, Thursday Post-test Support Groups, and St. Sebastian’s, a spiritual gathering available on Sundays. Additionally, there are dance, poetry, open mics, theater and cultural shows once per quarter. NRHS also participates in International

Homophobia and Transphobia Day (IDAHOT) activities and other HIV related health days, participates in the regional and national key populations Technical Working Group TWG), collaborates with other LGBTQ organizations in Kenya, principally the MSM Health Research Consortium and the LGBTQ networks like MAAYGO and NYARWEK. The AM study has the largest cohort of GBMSMs in any individual study or program in Sub-Saharan Africa.

2.4 Training and Capacity Building

NRHS continued to be a leader in training and capacity building not only within Kenya but also internationally. In recent years, NRHS staff have provided training in the Congo, in Zambia, in India, and in South Africa and we continue to train providers in Kenya at the URTC, especially in EIMC.

In addition to these trainings, NRHS hosted quite a number of interns from colleges and universities throughout Kenya. These included two interns in our laboratory, two interns in our Human Resources Department, three interns in our Finance Department, two in our Procurement and Stores Departments, two in Data Management, one at our reception, several in our community engagement departments and several counselors who were placed under the supervision of our staff counselors at URTC and at our *Anza Mapema* site. Most of these interns have gone on to obtain positions in other organizations after successful completion of training with NRHS and some have been retained as full time employees of NRHS.

3. RESEARCH PROJECTS

3.1 Tatu Pamoja

Demonstration study to assess HIV-1 incidence and retention among HIV-negative men who have sex with men and transgender women in Kisumu, Nairobi, and Kilifi

This is a collaborative project under the MSM Health Research Consortium (MHRC) funded by the International AIDS Vaccine Initiative (IAVI) with supplementary funding from the Sub Saharan African Network for TB/HIV Research Excellence (SANTHE). In the past three years, the 'MSM health research consortium (MHRC)' has made some efforts towards harmonizing data collection at three Kenya MHRC sites in Kisumu, Nairobi, and Kilifi in preparation for a multicentre study. In the proposed demonstration study, we aim 1) to conduct a prospective study to estimate HIV-1 acquisition and retention in HIV-negative GBMSM and transgender women (TGW) enrolled in programmes or ongoing studies in Kisumu, Nairobi, and Kilifi.

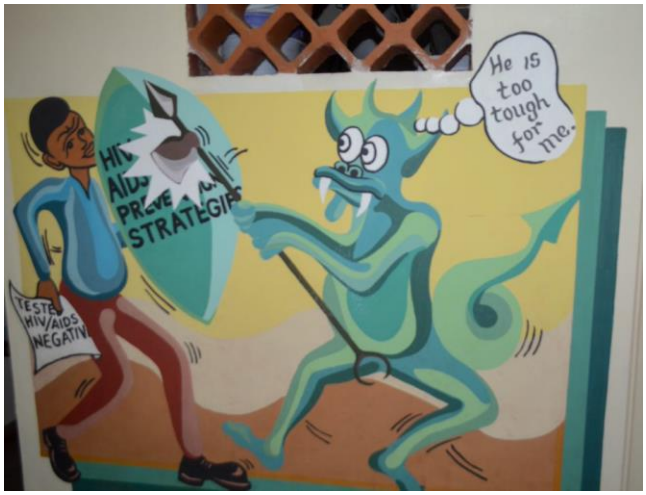
We are collecting biometric data across the 3 sites using iris scanning, enrolling and having in follow-up 900 participants at risk for HIV acquisition (300 in Kisumu, 300 in Nairobi, and 300 in Kilifi), and engaging LGBTQ community stakeholders at each site as appropriate. This study involves an enrolment visit and quarterly visits by initially HIV-negative GBMSM or TGW. HIV testing and counselling and clinical care including the offer of pre-exposure prophylaxis (PrEP) for HIV-negative men and antiretroviral therapy (ART) for men who seroconvert follow National AIDS & STI Control Programme (NASCOP) guidelines.

As of January, 2020, in Kisumu we have enrolled 240 men in the study and expect to complete enrolment by end of February. In addition to the services offered as a participant in the study, men are also offered all the services afforded to members in the Anza Mapema Program.

3.2 Pre-Exposure Prophylaxis Study

Retention and Adherence to PrEP among Gay or Bisexual Men who have sex with men (GBMSM) in the Anza Mapema Study

This study was an extension of the Anza Mapema Test and Treat cohort study. This study was funded through a grant from Evidence for HIV Prevention in Southern Africa (EHPSA) to Fredrick Otieno. Studies conducted throughout sub-Saharan Africa demonstrate that GBMSM are burdened by HIV prevalence two to four times higher than the general male population. PrEP is a biomedical HIV prevention modality that entails the daily use of the single-tablet antiretroviral medication emtricitabine (3TC) and tenofovir disoproxil fumarate (TDF) by uninfected individuals at risk for HIV infection. PrEP's efficacy in preventing HIV acquisition has been demonstrated in randomized controlled trials and open-label studies. These studies also demonstrated that better adherence dramatically enhances PrEP's efficacy.



This study had four aims: 1) To find and test 700 MSM for HIV; 2) To link and retain HIV-positive MSM in HIV care; 3) To link and retain HIV-negative MSM in a non-ART care and risk reduction program including retesting every 3 months post-enrollment; and 4) To assess uptake and adherence to PrEP. AIM 4 was added upn approval of this protocol. Recruitment of study participants occurred between October 2017 and January 2018 from HIV negative Anza Mapema participants. Each participant was follow-up at week 2, Months 1, 2 and 3, then quarterly for one year.

157 men were enrolled in the study and retention was very high at 95% of men attending all visits. The men reported a mean percentage of 92% of pills as taken in the course of the study, with full adherence by pill count at the 12th month. When we asked participants if they had missed any pills at any time point, 31% responded in the affirmative with the highest being at month 6 of 50% reporting missing <u>any</u> pills within the period preceding that visit. When we asked them how many pills they had missed, the mean was just 6 pills. When participants were asked to rate how well they were taking their medication, 90% reported to be taking their medication on a scale of Good to Excellent. In brief, by pill count and by self-report, adherence to the drug regimen appeared to be very high and at levels that would surely be protective against HIV acquisition.

However, we also collected dried blood spots (DBS) and analysed the drug actually in the participants' plasma. These samples were taken at 3 months and 9 months. Overall, only 34% of men were found to have <u>any</u> drug in their plasma, and just 10% had drug at the level

that would be protective (taken 4 days or more in the last week). These results were discouraging, but extremely informative, and we are currently initiating a follow-up study (see Shauriana below) with community members to see how we can increase adherence, while we are also working with a major drug company to assess preferences for alternative methods of HIV prevention (e.g., longer acting oral or injectable PrEP).

3.3 SHAURIANA PROJECT

A community driven intervention to address low levels of PrEP adherence among gay, bisexual and other men who have sex with me in Kisumu.

This project is funded by NIH through a grant to Dr. Susan Graham, University of Washington, with a sub-contract to NRHS. In Kisumu, testing of dried blood spot collected from GBMSM participating in our PrEP demonstration project showed no detectable TFV-DP at 178 visits (64.7%), and protective TFV-DP levels at only 28 visits (10.2%) PrEP support interventions that engage the GBMSM community and are led by community members are urgently needed to ensure that GBMSM can benefit from PrEP.

The *Shauriana Project* aims to adapt and enhance a theory-based and culturally relevant sexual health intervention to support PrEP uptake and adherence by Kenyan GBMSM and to evaluate the acceptability, feasibility, and safety of the intervention in a pilot randomized controlled trial. We established a close collaboration between PrEP and sexual health researchers and NYARWEK, a GBMSM-led community-based organization based in Kisumu. In-depth interviews were conducted by trained GBMSM community members with 20 peer educators and 40 community members with and without PrEP experience, to identify multi-level barriers and facilitators that influence GBMSM's ability to engage in the PrEP continuum of care, examining socioecological factors that impact Kenyan GBMSM's lives, including sexual and PrEP-related stigma, sexual health promotion, and resilience. In addition, we held a community meeting with 51 representatives from GBMSM and sexual minority-led organizations, to identify the barriers and facilities they have noticed in their work on HIV testing and counselling or PrEP programming in the Kisumu area.

Feedback from the interviews and community meeting identified a number of barriers and facilitators influencing GBMSM's PrEP engagement. Barriers to PrEP awareness included stigma and discrimination, mistrust and myths, lack of tailored information, and low risk perception. Barriers to uptake included fear of side effects, fear of disclosure, the perception that PrEP was only for sex workers and/or promiscuous individuals, poor ownership, and a feeling of "coercion" by programs perceived as only interested in numbers. Barriers to adherence included forgetting, side effects, pill burden, problems obtaining refills, and negative interactions with providers or peers about PrEP. Facilitators to engagement across the continuum included tailored information, theatre and drama with testimonials, community ownership and advocacy, rapport with GBMSM-friendly providers and services, and feeling safer due to PrEP.

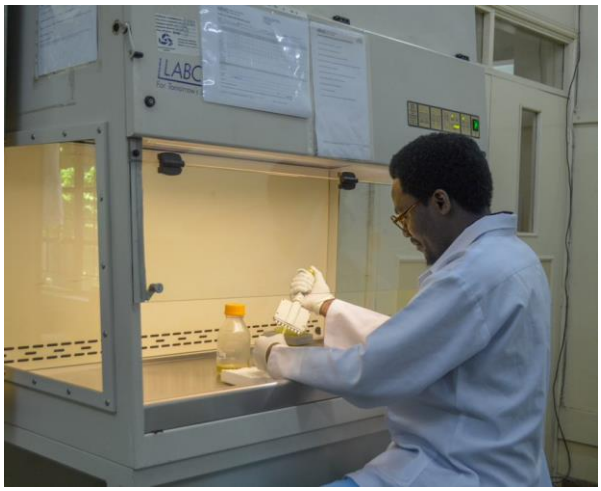
Community-led efforts are key to improving PrEP engagement by GBMSM. These results are being used by the team to adapt and enhance a theory-based and culturally relevant PrEP support intervention that includes holistic sexual health promotion strategies, including but not limited to PrEP uptake and adherence, among GBMSM in Kisumu.

3.4 DANCE GSK & ViiV Healthcare through PPDi

An open-label, single arm study to evaluate the week 48 efficacy and safety of a two-drug regimen of dolutegravir/lamivudine (DTG/3TC) as a fixed dose combination (FDC), in antiretroviral therapy (ART)-naive HIV-1-infected adolescents, ≥12 to <18 years of age who weigh at least 40 kg.

This trial is being funded by GSK and ViiV Healthcare through Pharmaceutical Product Development International Limited (PPDI). This is a Phase IIIb, single-arm, open-label, multi-center assessment of DTG/3TC in approximately 30 HIV-1 infected, treatment-naive adolescents with plasma HIV-1 RNA between 1,000 and ≤500,000 c/mL. All enrolled participants will receive an open-label, two-drug regimen of DTG/3TC for 48 weeks. Follow ups occur every 4 weeks and participants who successfully complete 48 weeks of treatment may enter the study Extension Phase for an additional 96 weeks. At the end of the study, participants who continue to receive benefit from DTG/3TC and for whom these medications are not locally accessible will have access to medication until it is available locally.

NRHS is expected to recruit and follow three patients per year with the option of adding additional participants. We have so far screened 9 adolescents and enrolled 2 with another scheduled for enrolment in the next two weeks. All the other sites have stopped enrolling and NRHS is the only site enrolling with the current cumulative deficit of 18 that we have been told to enrol if we can.



3.5 QTIR – Quality Through Inclusion

Evaluating community-led healthcare training and advocacy in Kenya: The Quality through Inclusion Study.

COC Netherlands funded NRHS to evaluate the impact of the work of COC partner organisations in sensitizing health professionals to increase their understanding about the needs of the LGBTQ and their ability to provide services to these sexual groups. Additionally, NRHS was tasked to provide evidence on how community participation and advocacy efforts affect participation in and access to healthcare. To achieve this, NRHS working closely with MAAYGO, a LGBTQ community support organization, trained LGBTQ interviewers who interviewed 200 GBMSM. Additionally, 20 health service providers and policy makers underwent in-depth interviews to get their views on program improvement. Data collection is complete and a report is under review.

3.6 *AFYA JOZI, AFYA JAMII* (AJAJ) STUDY

The effect of the penile microbiome on women's risk of BV, GUD, and genital epithelial trauma

This study, which began in May, 2014, evaluated under what conditions the penile micro biome led to: (1) Bacterial Vaginosis (BV) in female sex partners, and (2) genital ulcer

disease (GUD) and genital epithelial disruption in men and in their female sex partners. It was funded by an NIH grant to the University of Illinois at Chicago (UIC), Dr Supriya Mehta with NRHS as a sub-contractor. The study population was heterosexual, sexually active couples, with men aged between 18-35 years and women aged at least 16 years, and both had to be residents of Kisumu. Recruitment and follow-ups were completed in August 2017. Analyses are in progress.

Briefly, preliminary analyses have indicated that the penile microbiome has moderate predictive capacity for incident BV in the female partner. The predictive capacity did not differ by anatomic site of sampling. The precision of estimates was greater for microbiome derived from sampling the meatus as compared to microbiome derived from sampling the glans-coronal sulcus-distal shaft, indicating better reliability of sampling the meatus and also reflecting the recovery of BV-associated bacteria in both locations.

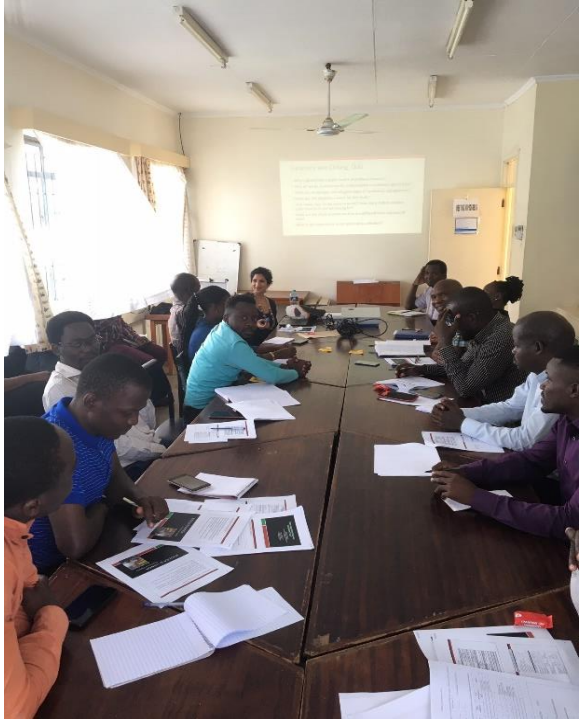
Additional preliminary analyses have been completed for: (1) changes in the penile microbiome over time, and association with behavioral and other factors, including characteristics of the female partner's vaginal microbiome; and (2) sexual quality of life among heterosexual couples and association with HIV and STIs. Laboratory studies are underway for measuring the longitudinal correlation of male and female partners' genital mucosal immunology, and how this varies in relation to the penile/vaginal microbiome, male circumcision status, BV, and other covariates of interest.

3.7 *ANZA MAPEMA KWA AFYA JOZI* (AMkAJ)

Characteristics of the penile and rectal microbiomes and mucosal immunology among MSM

This project is funded by NIH through a grant to Dr. Supriya Mehta (PI) at University of Illinois at Chicago with a sub-grant to NRHS. While our understanding of the genital microbiome and its role in health resilience and susceptibility is rapidly expanding, there is a dearth of even basic understanding of the penile and rectal microbiome in men who have sex with men (MSM) and how this relates to the disproportionate burden of STIs/HIV. In a sub-study of 50 GBMSM, mirroring specific aims of the Afya Jozi, Afya Jamii study (see above), the goal is to measure penile and rectal microbiota, and penile and rectal cytokines to better understand the microbiome and potentially-associated disease pathways and risk factors of HIV and other STI among GBMSM. Primary analyses will: (1) Determine the correlation of penile and rectal microbiome among GBMSM, and how this is influenced by sexual behavior; and (2) Compare the penile microbiome of GBMSM and men who have sex with women.

From July 4 to September 17, we enrolled 43 men aged 18-35 years old in this study. As per enrolment criteria, men were all HIV negative. Over half (56%) were currently employed, median reported income was 10,000-25,000 KSH, 72% reported drinking alcohol in the past 4 weeks, over 40% used drugs. The median number of lifetime sex partners was 10, and 3 in the past 6 months. 60% of men reported having sex with a female partner. 11% of men reported washing inside their rectum. Cytokine results indicate there is high correlation of inflammatory markers among rectal samples (0.5-0.7), but urinary cytokines have low (<0.1) to moderate (0.2) correlation with each other. Elevated (upper 25th percentile) rectal



cytokines have moderate correlation with elevated urinary cytokines (0.20 - 0.30). Microbiome analyses are pending, and will be correlated with mucosal immunology markers.

3.8 EVALUATING THE CAPACITY OF PENILE AND RECTAL MICROBIOMES TO PREDICT SEXUAL PARTNERSHIPS AMONG MSM (AMKAJ 2)

This project is funded by the Duchossois Family Foundation with Dr. Supriya Mehta as the P.I. and NRHS a sub-contractor from UIC. In a sample of 40 HIV-negative GBMSM (20 pairs of men in a sexual relationship) in Kisumu, we will measure the penile and rectal microbiomes and identify highly correlated taxa, concordance of overall microbiome structure, association with sexual practices, and association with mucosal inflammation as an indicator of disease susceptibility. Characterizing how GBMSM or other at risk individuals are connected to one another through sexual ties is of critical importance for HIV prevention interventions to be effective. Currently, objective characterization of these sexual ties is mostly performed by phylogenetic analysis; whereby, HIV viral evolution links similar HIV strains in HIV infected men to create clusters of infections. While this is increasingly utilized in public health department for prevention intervention deployment, HIV phylogenetic approaches are significantly limited. The major limitation is that identified clusters are only evident among HIV infected men; those HIV negative men who are sexually tied to these men, and most critical to interrupting onwards HIV transmission, are not included in the clusters. In addition, phylogenetic analyses using HIV virus requires a blood sample and identification of HIV status which can be highly stigmatizing in contexts where HIV and its related sexual behaviors are either criminalized or where GBMSM are already a hidden population such as in Western Kenya. This study is due to begin in early 2020. We have completed study protocol, consents, and survey instruments and IRB approval has been obtained for University of Chicago and University of Illinois at Chicago and is pending at Maseno University Ethics Review Committee (MUERC).

3.9 CUPS AND COMMUNITY HEALTH (CaCHe)

Menstrual cups, maturation of the adolescent vaginal microbiome, and STI/HIV risk

This project is funded by NIH to Dr. Surpiya Mehta (PI) at University of Illinois at Chicago with a sub-contract to NRHS. We are evaluating how menstrual cup use leads to reduced BV and STIs, and the effect of menstrual cup use on evolution of the adolescent vaginal microbiome (VMB). The specific aims are: **Aim 1:** Determine the influence of menstrual cup use on the VMB and how this is related to risk of BV and STIs; **Aim 2:** Identify the change in VMB as girls initiate sexual activity, and whether this is modified by menstrual cup use, and **Aim 3:** Augment trial pharmacovigilance through detection of *E. coli* on cups and correlation with VMB. The study is a longitudinal sub-study of 440 girls aged 14-16 years nested within a recently funded cluster randomized controlled trial to examine menstrual cup use versus cash transfer or control condition among 3,864 secondary school girls in Siaya County,

Kenya (DfID/MRC/Wellcome Trust; PI: Phillips-Howard). To achieve our aims, we characterize the VMB using high throughput amplicon sequencing of portions of the bacterial 16S rRNA gene. Participants (220 cup users, 220 controls) will be asked to provide a self-collected vaginal swab at baseline prior to allocation and at each semi-annual visit, for a maximum of 6 samples per subject (BL, 6-, 12-, 18-, 24-, 30-months). BV will be assessed at baseline at each semi-annual visit, and STIs (*C. trachomatis*, *T. vaginalis, N. gonorrhoeae*) at baseline and annually. HIV and HSV-2 are assessed at baseline and annually by the larger trial. Results from this study will provide understanding of whether microbiome modulating interventions being tested for adult women are applicable for adolescent girls. Menstrual cups could be a low-cost, multipurpose intervention to add to the prevention toolkit not just for girls, but for sex workers and women at high risk for HIV and STIs.

As of January 2020, we have completed baseline, 6-, 12-, and 18- month study visits. The 24-month study visit is planned for April/May 2020. Amplicon sequencing is complete for BL and 6 month and analysis for baseline paper is near complete. DNA extraction for 12 month is taking place, to be sequenced in April. Preliminary findings have been presented at the NIH HIV Microbiome Workshop (October 2019, Rockville, MD) and at the University of Nairobi/NASCOP Annual Meetings (2019 and 2020).

3.10 ProMIS. INTEGRATING MOLECULAR AND MICROBIOLOGIC SURVEILLANCE FOR ANTIMICROBIAL RESISTANT N. GONNORRHEA FOR MORE EFFECTIVE CONTAINMENT.

This project is funded by the U.S. Department of Defense, Global Emerging Infections Surveillance under a contract to Supriya Mehta at UIC and a sub-contract to NRHS. The project begins January 1, 2020. Its goal is to conduct systematic surveillance of *N. gonorrhoeae* and antimicrobial resistance using traditional microbiologic and molecular approaches in accordance with international recommendations for quality-assured AMR surveillance. Additionally, it will characterize core genome phylogeny, multilocus sequence typing, *N. gonorrhoeae* multi-antigen sequence typing (NG-MAST), and *N. gonorrhoeae* sequence typing for antimicrobial resistance (NG-STAR). Results of this surveillance will guide recommendations for therapy with greater curative efficacy through broader understanding of NG AMR patterns. Understanding the underlying causes of urethral discharge through etiologic testing has direct implications for syndromic management. This will inform improved specificity and stewardship in use of antimicrobials. Molecular characterization will inform relatedness of resistance strains. Identifying clusters and transmission chains will help discriminate between endemic and imported resistance, and support targeted intervention and evaluation.

3.11 PROVIDER EXPERIENCES AND OPINIONS ON COUNSELING ADOLESCENTS UNDERGOING VOLUNTARY MEDICAL MALE CIRCUMCISION IN WESTERN KENYA

This study was funded by an extension of the NIH implementation science grant to UIC with Prof. Robert Bailey as the P.I. with a sub-contract to NRHS. The results have been published in the East African Medical Journal, with George Okoth as first author (see references). Voluntary medical male circumcision (VMMC) remains an important component of comprehensive HIV prevention package. Kenya and other key countries are focusing increased attention on achieving large proportions of adolescent circumcisions. Because

little is known about the impact of adolescent VMMC counseling, we sought to capture the experiences and opinions of VMMC providers regarding effective adolescent VMMC counseling.

We purposively selected six VMMC sites: three each in Siaya and Kisumu Counties. From each site, we administered key informant interviews to two VMMC providers at a place of their choice for privacy and confidentiality. Outcomes of the study were participant responses to questions regarding their adolescent counseling practices, prior training, and opinions for improvement of counseling practices.

Three providers (25%) reported having been trained on adolescent-specific VMMC counseling. Compared to adults, adolescents receive less information during VMMC counseling. There was lack of consistency in counseling procedures, with counselors making subjective judgments as to what content to include, depending on their perception of the sexual experience of the client. Providers recommended greater engagement of parents in the VMMC process, limiting numbers of clients per day to ensure quality of counseling, and allocation of space to facilitate confidentiality.

All providers counseling adolescent VMMC clients should receive adolescent-specific counseling training, and adhere to national VMMC guidelines. Measures to assure confidentiality should be taken, and numbers of clients per day limited to ensure quality of counseling services.

4. Conferences, Workshops and Technical Meetings Attended

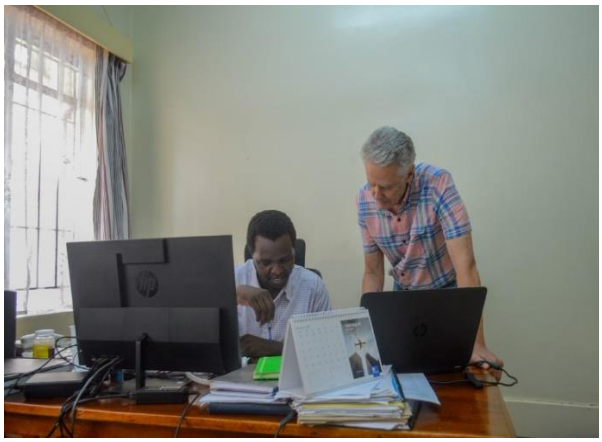
As in the past, NRHS participated in several scientific meetings and conferences, as well as technical working group meetings to review various program implementation aspects and contribute its expertise to the development of policy and program guidelines.
NRHS through its various staff and jointly with collaborating scientists from various institutions, participated in the following scientific conferences:

At the University of Nairobi Annual Scientific Collaborative Meeting the following abstracts were presented:

- Incidence and predictors of urethral and rectal Chlamydia and Gonorrhoea among MSM taking PrEP in Kenya. Presented by Frederick Otieno.
- Schistosomiasis is associated with rectal mucosal inflammation among Kenyan MSM. Presented by Supriya Mehta.
- Baseline characterization of the vaginal microbiome among secondary schoolgirls enrolled in the Cups and Community Health (CaCHe) Vaginal Microbiome Study. Presented by Supriya Mehta.
- Session on Populations: MSM, Transgender persons and PWID. Chaired by Robert Bailey

In addition to the scientific conferences NRHS was represented in various international and regional Technical Working Groups. These included NASCOP led VMMC and Key Populations TWGs where NRHS through its various representations participated in the

launch of the Framework for roll-out of PrEP in Kenya, the Kenyan EIMC Training Manual and the VMMC Tetanus risk mitigation guidelines for Kenya, as well as review of VMMC M&E tools. NRHS has also been co-opted into the National Social Science Forum spearheaded by NACC. Additionally, NRHS contributed to the County VMMC and KP TWGs, as well as the County VMMC TWG.



NRHS is a member of and was represented by Drs. Fredrick Otieno and Robert Bailey in the Men's Health Research Consortium (MHRC), a consortium of several research organizations in Nairobi and on the Coast as well as NASCOP, IAVI and LGBTQ community organizations that support and conduct research with GBMSM and TGW in Kenya. In conjunction with the MHRC, NRHS participated in the following meetings and activities:

- The annual MHRC meeting in conjunction with the University of Nairobi Collaborative meeting in January, 2019.
- The first MSM and TG Annual Scientific Conference in Kilifi
- Mtazamo Mpya Study: training for MSM and TG members in protocol development and data collection
- MHRC Meeting on use of bNAbs in HIV prevention
- MHRC meeting on use of iris scan for biometric identification
- Supervision of Mtazamo Mpya data collection in Lodwar and Kisumu

5. ADMINISTRATIVE ACTIVITIES

The number of full time salaried staff working under NRHS fluctuated during the year between 32 and 44. In addition, locums and other temporary employees worked on various projects for varying periods of time from one day up to 3 months. These totalled as many as 12 at any one time. Fluctuations in staff are a product of projects ending and others beginning. NRHS does everything it can to maintain staff continuity and to optimize their welfare. All salaried staff receive 10% pension and are covered by health insurance for themselves and up to three dependents.

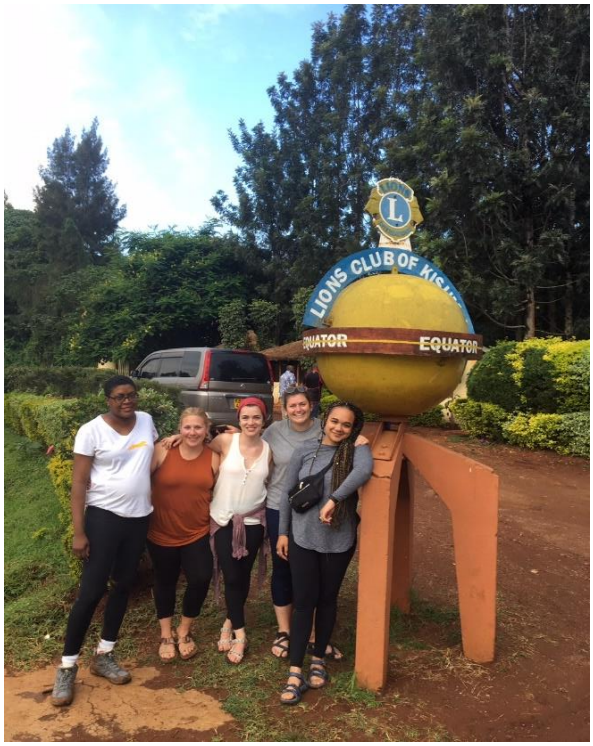
NRHS undergoes an institutional audit every year. The audit for 2018 occurred in early 2019. The audit for 2019 is underway. The organization's auditor for 2018 was Shadrack & Co. In addition, each individual project funded undergoes a separate annual audit as required by the donor.

NRHS benefitted from a financial volunteer from Accounting for International Development (AfID), which is based in the UK. Ms. Freya Riddel came and worked with our accounting department for two weeks. Some of our procedures for procurement, stores, human resources were revised based on her recommendations. She recommended development of

an overall institutional budget, which is currently lacking in lieu of individual project budgets. This is under development.

6. OTHER ACTIVITIES

NRHS hosted six Masters in Public Health (MPH) students from the University of Illinois at Chicago (UIC). Each was housed with a Kenyan family and placed in different projects to fulfilled their field practicum for their degree. Two were placed with Safe Water and AIDS Project (SWAP), one with FIDA Kenya, one with Anza Mapema, and two with Maseno University School of Public Health. They used their experiences and the data that they collected as the basis for their MPH capstone before graduating from UIC.



NRHS continued its membership with HENNET, the National Health Organizations Network, stimulating linkages between the Ministry of Health, Private Sector and Health organizations. As indicated above, it also continued its active participation in the MSM Health Research Consortium, as well as all its involvements with NASCOP, the MOH and County and regional entities.

6. Papers published or submitted in 2019[1]

Graff N, Kimani M, Otieno FO, Bailey RC, Kimani J, Sanders E, Graham S. Factors associated with incident HIV infection among gay, bisexual, and other men who have sex with men in the pre-PrEP era: A systematic review." Submitted.

Mehta S, Zhao D. Green SJ, Agingu W, Otieno F, Bhaumik R, Bhaumik D, Bailey RC. The microbiome composition of a man's penis predicts incident Bacterial vaginosis in his female sex partner with high accuracy. Submitted.

Mehta S, Okal D, Otieno F, Green SJ, Nordgren RK, Huibner S, Bailey RC, Bhaumik DK, Landay AJ, Kaul R. Schistosomiasis is associated with rectal mucosal inflammation among Kenyan men who have sex with men. Submitted.

Mehta S, Agingu W, Nordgren R, Green S, Bhaumik D, Bailey RC, Otieno F. Characteristics of women and their male sex partners predict clinical pathologic state among a prospective cohort of Kenyan women with non-optimal vaginal microbiota. BJOG: An International Journal of Obstetrics & Gynaecology. Submitted.

Fleming PJ, Doshi M, Harper G, Otieno F, Bailey RC. The integration of voluntary medical male circumcision for HIV prevention into norms of masculinity: findings from Kisumu, Kenya. Submitted.

Smith JS, Backes DM, Chakraborty H, Hudgens MG, Rohner E, Moses S, Agot K, Snijders PJF, Meijer CJLM, Bailey RC. Male circumcision reduces penile HPV incidence and persistence: a randomized controlled trial in Kenya. Submitted.

Mehta SD, Nordgren RK, Okal D, Green SJ, Otieno F, Bhaumik D, Bailey RC, Landay A. Rectal and urethral inflammation are linked to sexual practices, microbiome composition, and concordance of bacteria across mucosal sites. Submitted.

Kizub D, Quilter L, Quilter L, Atieno L, Okall DO, Otieno FO, Bailey RC, Graham SM. Challenges faced by peer outreach workers in an HIV prevention and care program for gay, bisexual, and other men who have sex with men: *The Anza Mapema Study*. Submitted

Otieno FO, Ng'ety G, Okal D, Oketch C, Obondi E, Graham S, Nyunya BO, Djomand G, Bailey RC, Mehta SD. Incident gonorrhea and chlamydia amongst a prospective cohort of men who have sex with men in Kisumu, Kenya. *Sexually Transmitted Infections* http://sti.bmj.com/cgi/content/full/sextrans-2019-054166

Korhonen C, Kimani M, Wahome E, Otieno F, Okall D, Bailey RC, Harper GW, Lorway RR, Doshi M, Mathenge J, Kimani J, Sanders E, Graham SM. Depressive symptoms and problematic alcohol and other substance use in 1,476 gay, bisexual, and other men who have sex with men at three research sites in Kenya. AIDS. 2018 Jul 17;32(11):1507-1515. doi: 10.1097/QAD.0000000000001847.

Okoth G, Bailey RC, Otieno FO. Provider experiences and opinions on counseling adolescents undergoing voluntary medical male circumcision in western Kenya. *E African Medical Journal*, Vol. 95 No. 8 August 2018.

[1] While some of the publications have a 2018 publication date, they did not appear until 2019.

Kunzweiler CP, **Bailey RC**, Mehta SD, Okall DO, Obondi E, Djomand G, Nyunya BO, Otieno FO, Graham SM. Factors associated with viral suppression among HIV-positive Kenyan gay and bisexual men who have sex with men. *AIDS Care* 2018, Vol. 30, No. S5, S76–S88. https://doi.org/10.1080/09540121.2018.1510109.

Davis S, Pals S, Yang C, Odoyo-June E, Chang J, Walters M, Jaoko W, Bock N, Westerman L, Toledo C, Bailey RC. Circumcision status at HIV infection is not associated with plasma viral load in men: analysis of specimens from a randomized controlled trial. *BMC Infect Dis. 2018 Jul 28;18(1):350. doi: 10.1186/s12879-018-3257-8*