

ANNUAL REPORT 2024



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TABLE OF CONTENTS

Abbreviations.....	2
NRHS Family.....	3
Who We Are	3
Our Vision.....	5
Our Mission	5
Our Core Values	5
From the NRHS Board	7
From the NRHS Director.....	9
Acknowledgements.....	10
Year in Numbers	11
HIV Prevention.....	12
Voluntary Male Medical Circumcision (VMMC) Programme	12
HIV Testing Services (HTS).....	13
Sexually Transmitted Infections (STI) Diagnosis and Treatment	14
Social Activities.....	14
ARV-related HIV Prevention	16
Peer Education and Commodities	17
HIV Care and Treatment	18
Research Projects	19
Oral HPV Study	19
RelCoVax Study	19
Cups and Community Health (CaChe).....	20
POWWeR.....	20
Mbili Pamoja	21
Mambo Matatu	22
Contract Laboratory Services	23
Policy and Advocacy	24
Administrative Activities.....	26
Other Activities	26
Publications	26

ABBREVIATIONS

1. AMCE: Anza Mapema Centre of Excellence
2. CDC: U.S. Centres for Diseases Control and Prevention
3. CIHEB: Centre for International Health, Education and Biosecurity
4. CT: *Chlamydia Trachomatis*
5. EIMC: Early Infant Male Circumcision
6. GBMSM: Gay and Bisexual Men who have Sex with Men
7. GBV: Gender Based Violence
8. GCP: Good Clinical Practice
9. GP: General Population
10. HIV: Human Immunodeficiency Virus
11. HSP: Protection of Human Subjects Research
12. HTS: HIV Testing Services
13. IAVI: International AIDS Vaccines Initiative
14. IDAHOBIT: International Day Against Homophobia, Biphobia, Intersexism and Transphobia
15. KWTRP: KEMRI Wellcome Trust Research Programme
16. LGBTIQ: Lesbians, Gay, Bisexual, Transgender, Intersex, and Queer
17. MSD: Merck Sharpe and Dohme
18. NASCOP: National AIDS and STI Control Program
19. NG: *Neisseria Gonorrhoeae*
20. NIH: U.S. National Institutes of Health
21. NRHS: Nyanza Reproductive Health Society
22. PEP: HIV Post Exposure Prophylaxis
23. PEPFAR: President's Emergency Program for AIDS Relief
24. PHDP: Positive Health, Dignity, and Prevention
25. PIRH: Partners in Reproductive Health
26. PNS: Partner Notification Services
27. PrEP: HIV Pre Exposure Prophylaxis
28. SNS: Social Network Strategy
29. SOP: Standard Operating Procedures
30. SSP: Study Specific Procedures
31. TG: Transgender
32. UIC: University of Illinois at Chicago
33. UNIM: universities of Nairobi, Illinois, and Manitoba
34. URTC: UNIM Research and Training Centre
35. USAID: U.S. Agency for International Development
36. UW: University of Washington
37. VMMC: Voluntary Medical Male Circumcision
38. WHO: World Health Organization

NRHS FAMILY**WHO WE ARE**

The Nyanza Reproductive Health Society (NRHS) is a Kenyan non-profit organization established in 2002 and is registered as a Society under the Societies Act, Laws of Kenya. NRHS was initiated when the universities of Nairobi, Illinois, and Manitoba (UNIM) began the randomized controlled trial to ascertain if male circumcision reduces the incidence of HIV acquisition in heterosexual men. NRHS has a strong track record and experience in research and in translating research findings into policies and programs. NRHS has been a leading institution in conducting research on sexual and reproductive health and HIV prevention. It has been a leader in the implementation of Voluntary Medical Male Circumcision (VMMC) in Kenya, providing technical assistance to the Ministries of Health and the National AIDS and STI Control Program (NASCOP) and other Kenyan governmental agencies, as well as the World Health Organization (WHO) and other international agencies.

Over the past 20 years, NRHS has mainly implemented its programs and research in Kisumu, Homa Bay, Siaya, Kisii, Busia, and Kakamega with additional outreach in areas such as Nairobi, Kilifi, and Turkana counties. NRHS's main office is in Kisumu City. The organization is governed by a Board of 6 high-profile individuals with diversified skills. Currently, it has about 50 members of staff who operate primarily from its head office in Kisumu City. The organization receives funding from a variety of sources, including the U.S. National Institutes of Health, the U.S. Centers for Disease Control (CDC), the Bill and Melinda Gates Foundation, U.S. Agency for International Development (USAID), FHI 360, the Population Council, the UHAI Foundation, and John Snow International. NRHS is headed by a Director, Dr. Fredrick Otieno, who oversees the

3 main sections namely; Programmes, Research, and Administration. NRHS implements PEPFAR programmes mainly in HIV prevention, care, and treatment under the programmes arm and carries out various research projects mainly in reproductive health, sexually transmitted infections, men's health, adolescent health and HIV prevention, care and treatment. The Administration section provides support to the programmes and research arms through finance, procurement, HR, Stores, Transport and IT.

NRHS runs the UNIM Research and Training Centre (URTC), a 782 square metre state of the art facility which was the site of the VMMC randomised controlled trial in Kisumu and is the site for many of its studies. URTC is located within the Lumumba Sub-County Hospital in Kisumu and has:



- 42m² fully equipped laboratory with safety hood, centrifuges, incubators, nitrogen tanks, Gene X-Pert, Elisa processor, freezers and all the necessary facilities to process and store specimen for its current studies
- 4 Clinical and 3 counselling rooms each together with a clinical trial pharmacy with temperature monitoring as well as stock control
- 2 VMMC operation theatres as well as a post-operative recovery room
- Records, Data and IT management rooms as well as a conference hall
- Administrative offices for the director, accounting, stores, HR and procurement
- Other support services including a central sterile supplies department, laundry, coordination and community
- A centralised sterile supplies department estimated at 8.75 square metres with the capacity to clean and sterilise surgical and medical instruments
- A Laundry 5 square metres for laundering medical linen and garments
- A community engagement office 14 square metres
- 2 coordination offices each measuring 15.75 square metres
- A reception area measuring 49.5 square metres with a wide airy open design allowing for ease of interaction as well as infotainment.

In addition, there are basic amenities including 3 toilets and 1 kitchen, and a standby auto generator power back up



NRHS also operates the Anza Mapema Centre of Excellence (AMCE) that sits on a beautiful half acre compound within Tom Mboya estate offering safety and tranquillity of residential house as well as a state of art facility for research and programming into Lesbians, Gay, Bisexual, Transgender, Intersex and Queer (LGBTIQ) issues. The facility includes:

- 3 Clinical and 2 counselling rooms each together with a clinical trial pharmacy with temperature monitoring as well as stock control
- Records and Data management rooms
- Administrative offices for coordination and community engagement
- Outdoor space for community activities
- Community shamba (farm) for support groups income generating activities

All research staff are trained in Good Clinical Practice (GCP) and Protection of Human Subjects Research (HSP) at minimum. Relevant staff undergo annual Standard Operating Procedures (SOP) training as well as Study Specific Procedures (SSP) training before the beginning of any research studies and as frequently as is required thereafter.

OUR VISION

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

OUR MISSION

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

OUR 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 ethically and professionally.
 - 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.

FROM THE NRHS BOARD

On behalf of the Board of Directors of the NRHS, I am pleased to present the 2024 Annual Report, which captures a year of resilience, innovation, and measurable impact in advancing reproductive health and HIV prevention in Kenya. The year 2024 marked NRHS's 22nd year of service, and we are proud of the organization's continued leadership in evidence-based programming, high-quality research, and policy advocacy. Our work remains anchored in our mission to promote health and quality of life through research, programming, advocacy, and capacity building—guided by our values of community participation, professionalism, evidence, integrity, and non-discrimination.



Despite a dynamic operating environment, NRHS delivered an impressive portfolio of programmes and studies. We reached over 22,700 individuals with various health services, conducted more than 1,100 circumcisions—including specialized Early Infant Male Circumcision—provided 3,020 STI screenings, and performed 2,453 HIV tests. The organization's peer education and commodity distribution efforts remained strong, with over 104,000 condoms and 8,200 water-based lubricants disseminated, alongside comprehensive GBV screenings and timely referrals.

Our research agenda continued to expand, with eight active studies in 2024, spanning HPV, STI prevention strategies, menstrual health, and microbiome research. These projects, many conducted in collaboration with leading international institutions, are generating evidence that informs both national and global health strategies. NRHS's growing capacity in contract laboratory services further demonstrates our ability to diversify and sustain our technical expertise.

Importantly, our policy and advocacy engagements ensured that the voices of key and vulnerable populations remain represented in technical working groups and health policy dialogues. Notably, NRHS assumed the chairmanship of the MSM Health Research Consortium, strengthening our leadership role in advancing inclusive, rights-based health interventions.

These achievements would not have been possible without the dedication and professionalism of our staff, the trust of our communities, and the support of our partners. The Board commends the Director, Dr. Fredrick Otieno, and the entire NRHS team for their unwavering commitment, often going beyond their mandate to meet the needs of our beneficiaries. We also recognize the vital role played by our donors, including PEPFAR/CDC, NIH, USAID, Grand Challenges Canada, and others, whose partnership sustains our work.

As we look ahead, the Board remains committed to strengthening NRHS's sustainability, expanding our research and service delivery capacity, and deepening our community engagement. We will continue to advocate for integrated, evidence-based approaches that address the evolving health needs of our populations, including the intersection of HIV, sexual and reproductive health, and emerging public health challenges.

In closing, I extend my heartfelt gratitude to every individual and institution that has contributed to our mission in 2024. Together, we have demonstrated that collaborative, community-driven health interventions can transform lives. With the same spirit of innovation and service, we look forward to building on this year's progress to ensure that all individuals and communities we serve enjoy the highest possible quality of life.

Prof. Collins Ouma, PhD, FKNAS, FAAS

Chair, Board of Directors

Nyanza Reproductive Health Society

FROM THE NRHS DIRECTOR



As NRHS marks 22 years of cutting-edge reproductive health programmatic and research activities, we have grown steadily and continues to provide the required services to our beneficiaries. In this year we continued on our mission of promoting health and quality of life of individuals and communities in Kenya through research, evidence-based programming, advocacy and capacity building as we implemented our core values in order to achieve our vision.

This year saw us continue with a variety of research activities in addition to our traditional key population and VMMC programming. Our research portfolio

varied from COVID vaccine, HPV, as well as STI studies. We had 6 research studies, which we successfully executed. We also started providing contract laboratory services, providing third party testing services, mainly for HSV-2, HPV and CT/NG. We expect to expand over time to include other panels. Overall, we were able to offer services to almost 23,000 individuals in different segments ranging from circumcisions, HIV testing services, STI management, peer education, PrEP and PEP, condom and lubricants distribution, GBV service, and HIV care and treatment. We also continued with our policy and advocacy activities as well as our administrative support activities.

Dr Fredrick O. Otieno

Director

NRHS Kenya

ACKNOWLEDGEMENTS

The NRHS family takes this opportunity to recognize the Board of Directors, Management, staff, volunteers, and students for their zealous commitment and dedication to ensure that they not only delivered on our expectations but on several occasions, went over and beyond their mandate to deliver on their tasks.

We also recognize our beneficiaries, participants in our studies, our community advisory boards, stakeholder groups, peer educators, service providers, and community service organisations that we have worked with this year to deliver on our mandate. Finally, without our donors and development partners below, we would have not realised our achievements this year and thus we say a big thank you to the listed below:

1. Centre for International Health Education and Biosecurity Kenya
2. County Government of Kisumu
3. Grand Challenges Canada
4. International AIDS Vaccines Initiative
5. Kevin Kaine
6. Laboratoire Innotech International
7. Lumumba Sub County Hospital
8. Merck, Sharpe and Dohme
9. PRISM the Gift Fund
10. University of Illinois at Chicago
11. University of Washington
12. US Centers for Disease Control and Prevention
13. US Department of Defense
14. US National Institutes of Health
15. ViiV Healthcare

YEAR IN NUMBERS

22,726	Individuals reached with different services
1,106	Circumcisions done
3,020	STI screenings and management done
2,453	HIV Tests done
8,704	Peer education contacts made
86	Persons put on PrEP and PEP
104,155	Condoms distributed
8,205	Water-based lubricants distributed
3,020	Individuals reached with GBV services
63	Patients on HIV treatment
84%	Viral load suppression
6	Research studies

NRHS divides its activities into 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 by focusing on a continuum that begins with 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 the intention of NRHS to compartmentalize its activities, but rather to emphasize the integration and synthetic nature of its activities. Nevertheless, below we present our activities and accomplishments achieved during the calendar year 2024.

HIV PREVENTION


In the year, we continued to offer HIV prevention services to both the general population as well as key populations through our minimum package of services, which include regular HIV testing, VMMC, health education, provision of condoms, PEP, PrEP, screening & treatment of Sexually Transmitted Infections (STI) and cervical cancer. HIV prevention was offered at URTC for the general population as well as AMCE and outreaches for Key populations. In the duration, we provided prevention services to reached out to 267 general population as well as 740 Gay and Bisexual Men who have Sex with Men (GBMSM) and 3 Transsgender (TG) persons.

VOLUNTARY MALE MEDICAL CIRCUMCISION (VMMC) PROGRAMME

Continuing in its footsteps as 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 2024. In 2022 October, NRHS received a PEPFAR/CDC sub-grant through the Centre for International Health, Education and Biosecurity (CIHEB) to offer comprehensive VMMC services within the catchment of Lumumba Sub-County Hospital. Our numbers in 2024 continued to increase. The sub-grant did not, however, come with funding for Early Infant Male Circumcision (EIMC) but we continued offering the service as we are the only service provider in the region offering this as a free service.

A total of 1,140 males were circumcised during the calendar year. Of these, 750 were aged 15-49 years, 65 toddlers of whom 11 had various medical conditions including phimosis and paraphimosis. Infants below 60 days were 325 (Figure 1). All the surgeries were successfully done with 4 Cases of mild infection post-surgery that were managed with resultant good

healing. Many of the parents who continued to bring their babies to NRHS for EIMC were those who had a previous son circumcised in the facility or their friend's sons, or the father of the baby had been circumcised by NRHS. There was also a lot of referrals from most of the health facilities around for those with medical indications for circumcision, cementing our place as a centre for excellence in VMMC in the country. Comprehensive VMMC services were offered per the national VMMC guidelines.

HIV Testing Services (HTS) were offered to clients as one element of the packages of VMMC. We had 113 men who were eligible for HTS, were offered the service and accepted testing, with 3 of them testing HIV positive. All 3 were linked to care. Clients seeking VMMC services were screened for STIs and syndromic treatment administered as per the Kenyan guidelines for STI treatment, in addition to condom provision as part of the package of VMMC services.

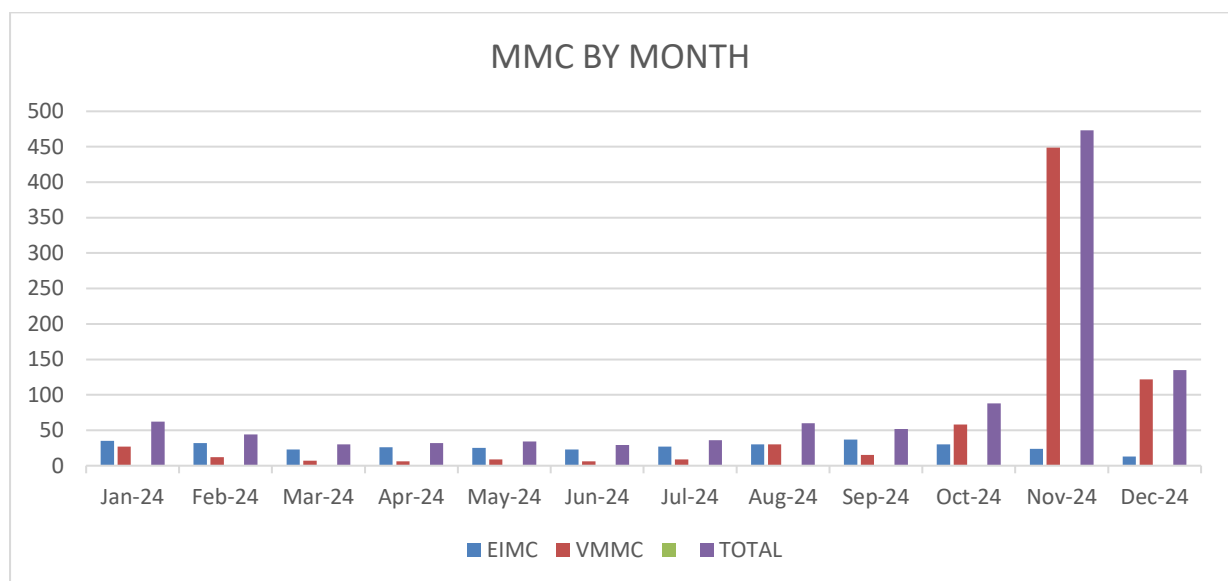


Figure 1: Medical Male Circumcision by Month 2024

HIV TESTING SERVICES (HTS)

Riding on the *Anza Mapema* programme for Key Population as well as the VMMC and the Partners in Reproductive Health (PIRH) programme for the general population, we used a mix of different modalities to offer HTS. These modalities included fixed site testing both at AMCE and URTC as well as outreaches which included targeted, Social Network Strategy (SNS) and Partner Notification Services (PNS). Using all these strategies, we were able to provide 2,453 tests excluding HIV self-test kits, as these were out of stock in the better part of the reporting period. Of the persons tested, 290 were first-time testers while 2,163 were repeat testers (Figure 2). We offered PNS to 10 indexes of whom all accepted the services. Out of these, 16 sexual contacts were contacted and all were tested. For SNS, we had 68 indexes, of these we offered 161 coupons with a total of 161 persons being tested. Our HIV positivity was 0.33% with a total of 8 positives, 3 newly tested, 2 from retesting, 2 from PNS, and 1 from SNS. All those testing HIV positive were linked to HIV care treatment programmes.

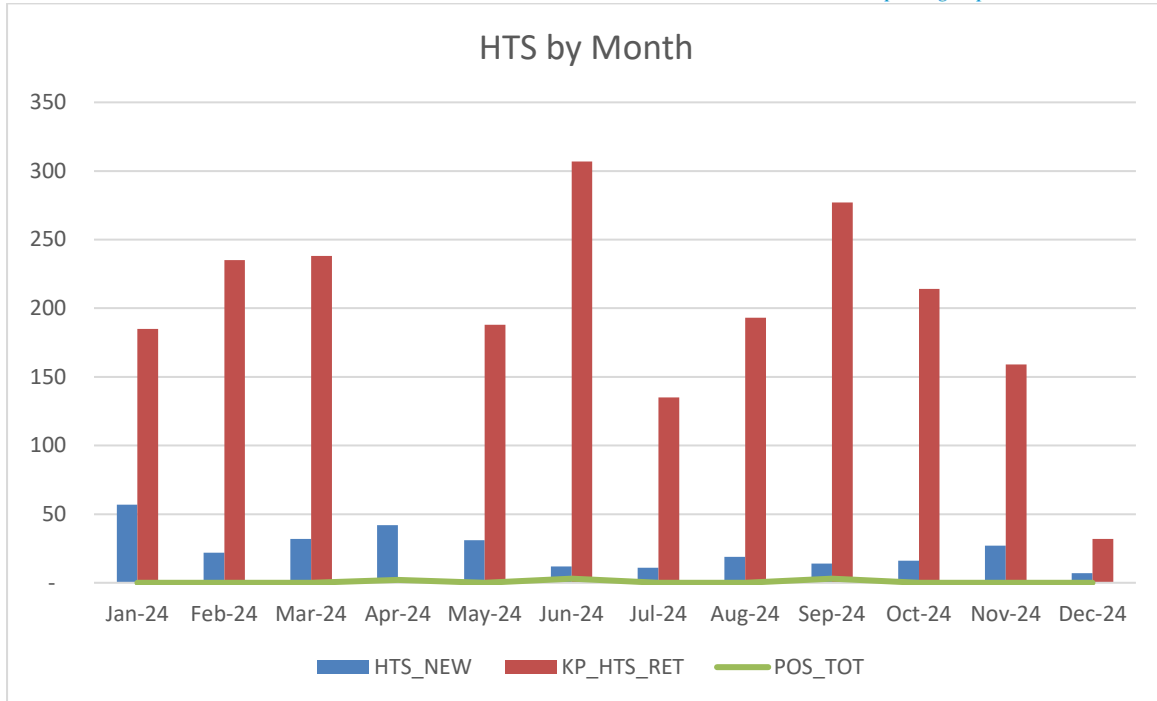


Figure 2: HIV Testing Services by Month 2024

SEXUALLY TRANSMITTED INFECTIONS (STI) DIAGNOSIS AND TREATMENT

As part of its Partners in Reproductive Health (PIRH) programme, NRHS continues offering screening, diagnosis, and treatment of STIs both as a syndromic approach and as an aetiological approach. These are offered on a walk-in basis to any client who cares to seek these services. These clients included general population clients seen at URTC and key population clients seen at AMCE. In 2024, NRHS screened 3,202 patients for STIs. Of these, 309 (9.7%) were provided with treatment following a positive diagnosis.

SOCIAL ACTIVITIES

As part of the *Anza Mapema* programme, we continued offering the time-tested social activities that were studied and validated in the *Anza Mapema* study. These included social events such as Movie Mondays, Therapy Tuesdays, Coffee Wednesdays, Therapy Thursdays, Cultural Fridays, and St. Sebastian Sundays. These social activities promoted topical discussions on issues affecting LGBTIQ communities (Movie Mondays), provided group therapy for those who have been tested for HIV (Therapy Tuesdays), promoted reduction in alcohol and substance use (Coffee Wednesdays), support groups for those testing HIV positive (Therapy Thursdays) provided an avenue for LGBTIQ to express their artistic sides (Cultural Fridays) and spiritual nourishment (St. Sebastian Sundays). Additionally, we had one International Day Against Homophobia, Biphobia, Intersexism, and Transphobia (IDAHOBIT) which is an annual tradition and has initiatives organized throughout the world to draw attention to the rights and well-being of gay, lesbian, bisexual, transgender, non-binary, queer and intersex people. In the current reporting period, we had a total of 46 movie Monday activities with a total of 3,154 persons attending. The movies screened ranged from drug and substance abuse, lived realities

of LGBT persons, feminism, patriarchy, and equality amongst other themes. Our exit interviews for these activities emphasize the importance participants accord to the social activities with a significant number of participants reporting that Movie Monday sessions create opportunities for bonding, networking, learning, and wellness.



Therapy Session

We had a total of 49 Therapy Tuesday activities with a total of 3,258 persons attending. The activities were peer-led and attendants had the opportunity to explore their challenges, opportunities, and achievements in their quest to stay negative.

Some sessions also had topical experts coming in to give information and lived experiences on being LGBT, medical conditions, income generating activities, career growth as well as self-reliance amongst others. In this period, we only had one existing client seroconverting after getting lost for a while from the programme. There was one Coffee Wednesday each week with a total of 50 Coffee Wednesday sessions. For the Alcoholic Anonymous (AA) components, we had 3,425 persons attending and 478 were in the individualised therapy sessions with 9 being referred for drug and substance abuse treatment. In the AA sessions we had peers leading the sessions while in the individualised therapy sessions we had professional providers attending to the clients. Overall, we had 134 clients graduate from individual therapy sessions to the AA sessions.

For the year in review, we had a total of 48 Therapy Thursdays targeting HIV-positive post-test club members. In these sessions, together with their 'Washikaji' (treatment buddies), they concentrated mostly on ensuring all had undetected viral loads. And we were able to achieve this for 84% of our HIV-positive clients. This spiritual nourishing activity has been going strong with 1,781 persons attending 48 fellowships within the year. We had a myriad of pastoring from Anglican, Catholic, Adventist, Protestant, Muslim, and even amongst the peers themselves. The activity has grown to include music within the services and host and wine within some services. The sermons have varied throughout the year with messages ranging from love, brotherhood, compassion, no judgment, and acceptability amongst other affirming messaging. The sessions have led to the development of a strong fellowship of LGBT persons of faith. The inclusive and affirming space has enabled the peers to be more grounded in their faith and spirituality.

We had a total of 4 cultural Friday sessions with a total of 879 attending. There had been a significant amount of growth in terms of content and ownership of the activity by the participants which has encouraged the development of queer curated content because of the wonderful platform offered by this activity. This is very vital in nurturing and utilizing the talents and skills of the LGBT community. There has also been improvement in terms of levels of bonding and

unity among the peers as a result of the activity. In the same period, we had one IDAHOBIT in which we had 214 of our participants attending. This activity created a safe space for LGBT persons where they could openly express and comfortably identify in their orientation and gender identities. This event also built on the personal integration and bodily autonomy of LGBT persons.



Additionally, we supported several advocacy and connection meetings, led by our peer educators, with different stakeholders including the community advisory board, local politicians, police, judicial officers, religious leaders, and other stakeholders. These fora allowed us to create an opportunity for the stakeholders in the general population to understand and interact with the

living and health situations of the LGBTIQ community and, thereby, advance understanding of LGBTIQ challenges and reduce homophobia in the general Kisumu population. Regular Outreaches were also undertaken at mapped hotspots that are hubs for male sex workers and LGBTIQ. During outreaches, we set up mobile HTS tents as well as other preventive and curative service provisions. Our peer educators mobilized their peers for service access with linkage to AMCE and URTC as needed to support client needs. We also continued maintaining our vegetable garden within AMCE where our clients continued vegetable farming.

ARV-RELATED HIV PREVENTION

Within the *Anza Mapema* programme, we are continuing to offer HIV Pre-Exposure Prophylaxis (PrEP) with 2,342 persons screened for PrEP eligibility. Of these, 4% (86) were eligible to start PrEP, and all consented and started PrEP. At month 3 post starting, only 84% (73) of those who started were still retained on PrEP. Generally, PrEP has continued to be seasonal with many clients getting on and off PrEP as per their need. Additionally, we offered HIV Post-Exposure Prophylaxis (PEP) for our clients including those referred as a result of sexual violence. We issued a total of 6 PEP doses in the year.

PEER EDUCATION AND COMMODITIES



Anza Mapema programme is supported by a dedicated team of 15 peer educators, 5 washikaji (treatment buddies), and 2 outreach workers who play a key role in delivering community HIV prevention activities. Over the year, we successfully made 8,704 peer education contacts

with our participants. providing essential peer education and distribution of commodities. A total of 104,155 condoms were distributed to 718 individuals over the year. While there was a high demand for water-based lubricants, we unfortunately experienced a long-standing stock-out, which prevented us from fulfilling this need with only 8,205 lubes being distributed in the last quarter of the year. In addition to condom distribution, our peer educators provided on-going risk-based peer counselling with appropriate referrals based on individual needs. They also provided comprehensive Gender-Based Violence (GBV) screenings for all our participants, focussing on sexual, physical, and emotional violence. A total of 3020 individuals were screened for GBV, with 246 (8%) testing positive. Of the positive, 26% (64) needed clinical support with a similar proportion needing legal support and the balance 48% (118) needing social support. Those who screened positive were immediately connected to necessary health services, violence prevention interventions, psychosocial support, and medico-legal services to ensure their well being and safety.



HIV CARE AND TREATMENT

NRHS continued offering HIV care and treatment services at AMCE with a client base of 63 GBMSM and TG as well as 3 GP females accessing services. In the year, there were 7 new patients enrolled and 4 exiting the programme either by transfer outs (1), deaths (1), and loss to follow-up (2). During the period, we were able to achieve an average viral suppression of 84% with the highest viral suppression seen amongst the general population at 96%. We provided management of opportunistic infections among HIV-positive clients as well as Positive Health, Dignity, and Prevention (PHDP) interventions to all our HIV-positive clients.



RESEARCH PROJECTS

In this year, NRHS was able to implement a total of 8 research studies with 5 observational and 3 clinical trials. Of these research studies, 4 were new studies while 4 were continuing projects. A further 2 studies ended in this year.

ORAL HPV STUDY

Prospective, longitudinal cohort study to evaluate the prevalence, incidence, persistence and risk-factors of Oral human papillomavirus in 199 HIV-positive and 199 at risk HIV- negative men in southwestern Kenya. The study is being conducted in Anza Mapema amongst MSM with enrolments and month 6 follow ups being completed with month 12 follow ups having started.

RELCOVAX STUDY

This is a prospective, multi-center, randomized, open label, active controlled, seamless phase 2/phase3 clinical study to evaluate immunogenicity, safety and tolerability of RelCoVax® (Protein Subunit Vaccine of Reliance Life Sciences Pvt Ltd. against SARS-CoV-2 Virus) and Comirnaty® (Bivalent mRNA Vaccine of Pfizer/BioNTech) administered as primary vaccination. Sponsored by Reliance Life Sciences Pvt. Ltd, India. Though the study was fully approved, it did not start due to futility of enrolling unvaccinated persons.

CUPS AND COMMUNITY HEALTH (CACHE)

This is a cluster randomised controlled trial of Menstrual cups and cash transfer to reduce sexual and reproductive harm and school dropout in adolescent schoolgirls in western Kenya. This project is funded by NIH through the University of Illinois at Chicago. Among 440 schoolgirls aged 14-25 years, we will study the effects of menstrual cup use on the vaginal microbiome (VMB) and whether this leads to reduced BV and STIs, and how menstrual cup use effects the adolescent VMB over time. This study is nested within a cluster randomized controlled trial involving over 4,000 schoolgirls in Siaya County, Kenya, to evaluate menstrual cup impact on school dropout, HIV, and HSV-2. The project began in December, 2017 and is still ongoing and we completed month 72 visits in December with the girls being followed in Rarieda and other places they migrated to. The study will be proceeding form month 78 in 2025.

POWVER



Periods: Optimizing Working Women's Reproductive Health (POWVER-Health) is an NIH funded Single arm trial of menstrual cups among economically vulnerable women to reduce Bacterial vaginosis and STIs through reduced harmful sexual and menstrual practices. The study recruited and enrolled 402 participants from 7th February to 25th September 2023. Participants had 5 study visits as at Dec 2024: at baseline, month 6, month 12, intervention and month 18. At the 4th visit, participants were trained on the use of menstrual cups and given menstrual cups

to use, followed by monthly telephone calls to support them on their use. Study procedures included eligibility screening and consenting, a socio-behavioural survey, medical history and physical examination including a gynaecological examination, gonorrhoea, chlamydia, trichomonas and Bacterial Vaginosis testing and treatment, HIV testing with linkage to care, vaginal microbiome and HSV-2 testing at baseline and M12. At M6 and M18, only Bacterial Vaginosis and vaginal microbiome testing were done, with a cup microbiome done at 18th month visit. The study also has a safety, pharmacovigilance and WASH component with safety assessments happening at all intervention visits, WASH assessments were done in 47 hotspots in phase one, and in 49 hotspots in phase 2. During the 5th visit, swabbing of menstrual cups was done. Additionally, the study had focus group discussions with sex workers which were done in phase 1 (6 FGDs), discussions with their clients Phase 1 (5 FGDs), and discussions with workplace establishment owners (4 FGDs). Participants were followed up at M6 (FU 80.4%), M12 (FU 80.9%) and M18 (FU 80.0%). Intervention was offered to 306 (88.4%). At enrolment, 8 participants were withdrawn, 11 at baseline, 6 at 6M, 1 at 12 M, 5 at intervention and 11 at M18 FU visit. Those who were withdrawn from intervention by investigators were 22. 6 participants had late intervention and were reported to IRB. 13 were had wrong appointment dates and all the deviations logs were filled and reported to IRB. HIV KP at Baseline were 100. So far, the study reported 3 AEs, 2 were deaths and 1 GBV case.

Characterizing the penile and rectal microbiomes, bacterial community function, and host immune response to sexually transmitted infections (STIs) among men who have sex with men (MSM) has a foundational impact on biomedical therapeutic and vaccine development. Over a one-year period, in a prospective cohort study of 500 MSM in Kisumu (n=250) and Nairobi (n=250), we measure the penile and rectal microbiomes, mucosal immune profiles, socio-behavioural and structural factors, and the incidence of urethral and anorectal STIs (CT, NG). In Aim 1, we describe the clinical history of STIs from (1) time of detection, to (2) time of treatment, to (3) post-treatment. At baseline (prevalent infection) and one year (incident infection), we characterize the clinical history of CT and NG infection in terms of bacterial community composition and function, and host immunology from time of detection, to time of treatment, to 4 weeks post-treatment. In Aim 2, we identify microbiome community composition and specific taxa associated with STI incidence and symptomatic infection. We also examine the host immune profile as an intermediate outcome, characterizing the associations between microbiome composition and inflammatory profile over time. Lastly, in Aim 3, we identify adaptive immune mechanisms that link the microbiome, STI infection, and host immunity. We also examine the frequency, phenotype, and clonality of antigen-specific T cell subsets that may mediate vaccine efficacy, and how these are impacted by baseline gut microbiota and inflammation. At the end of this study, we will generate data that addresses gaps in understanding how the microbiome-mucosal immunology changes after STI treatment, its relation to symptoms, and its association with STI incidence. Our findings on how rectal CT and/or NG infections can impair antigen-specific immunity may inform estimations and mitigation strategies for vaccine efficacy.

Enrolment procedures at each stage.

Baseline	6 Months	12 Months
<ul style="list-style-type: none"> 1 Surveys (three) 2 Medical history & exam 3 Local labs <p>Urine - Schistosomiasis (Kisumu) Urethral and rectal CT/NG Urethral and rectal HPV HIV testing</p> <ul style="list-style-type: none"> 4 Specimen collection for <p>Penile and rectal microbiome Rectal mucosal markers Systemic immune markers</p> <p>For those who test positive for CT/NG, 4 weeks after treatment</p> <ul style="list-style-type: none"> 1 Medical history & exam 2 Specimens for microbiome and immunology <p>To understand the impact of antibiotic treatment on microbiomes and immunology</p>	<ul style="list-style-type: none"> 1 Surveys (three) 2 Medical history & exam 3 Local labs <p>Urine - Schistosomiasis (Kisumu) Urethral and rectal CT/NG Urethral and rectal HPV HIV testing</p> <ul style="list-style-type: none"> 4 Specimen collection for <p>Penile and rectal microbiome Rectal mucosal markers Systemic immune markers</p> <p>For those who test positive for CT/NG, 4 weeks after treatment</p> <ul style="list-style-type: none"> 1 Medical history & exam 2 Specimens for microbiome and immunology 	<ul style="list-style-type: none"> 1 Surveys (three) 2 Medical history & exam 3 Local labs <p>Urethral and rectal CT/NG Urethral and rectal HPV HIV testing</p> <ul style="list-style-type: none"> 4 Specimen collection for <p>Penile and rectal microbiome Rectal mucosal markers Systemic immune markers</p> <p>For those who test positive for CT/NG, 4 weeks after treatment</p> <ul style="list-style-type: none"> 1 Medical history & exam 2 Specimens for microbiome and immunology

As of December 2024, we completed enrolments since its initiation on June 7, 2024. The participants ranged in age from 18 to 39 years. Among them, 36 individuals (14.4%) tested

positive for Schistosomiasis, 26 (10.4%) for Chlamydia trachomatis (CT), and 10 (4.0%) for Neisseria gonorrhoeae (NG). Treatment was administered to all 36 individuals diagnosed with Schistosomiasis (100%), while 24 out of 26 participants with CT (92.3%) received treatment with all the 10 individuals diagnosed with NG (100%) were treated. Month 1 follow ups are also ongoing for those with diagnosed STI positivity which month 6 follow ups had also commenced and the study is ongoing.

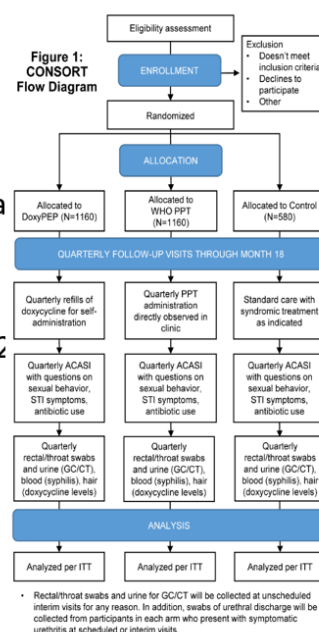
MAMBO MATATU

The proposed study is an open-label randomized controlled trial with a hybrid type 1 implementation-effectiveness component comparing WHO-recommended Periodic Presumptive Treatment (WHO PPT) versus Doxycycline Post-Exposure Prophylaxis (DoxyPEP) for STI Control to a common control among Cisgender Men Who Have Sex with Men in Kenya in a 2:2:1 ratio. Participants will undergo 18 months of follow-up at three MSM-friendly research clinics in Kisumu (Anza Mapema), Nairobi (PHDA Transform) and Coast (Hapa Kenya) in Kenya. This study will open recruitment in January 2025 and has the following aims.

- Aim 1: Evaluate effectiveness and impact on AMR in NG of two interventions: WHO-recommended PPT given every 3 months and doxy-PEP taken 24-72 hours after condomless sex, compared to standard syndromic treatment
- Aim 2: Assess acceptability, feasibility, and safety of implementing WHO-recommended PPT and doxy-PEP compared to standard care among providers and patients
- Aim 3: Model health and economic impact of scaling up WHO-recommended STI PPT and doxyPEP compared to standard of care on STI control among MSM and their partners

Arms – 2:2:1 (2,900 participants)

- STI PPT intervention: Evaluated at baseline and quarterly thereafter for STI PPT eligibility based on having had condomless anal sex and either multiple sex partners or a sex partner with an STI in the past 6 months
- DoxyPEP intervention: Provided with a 90-day supply of doxycycline quarterly and given 1:1 counselling on the self-administration of 200 mg po doxycycline within 24-72 hours after condomless anal or vaginal sex as frequently as daily if indicated but not more than once daily
- Standard care: Receive screening for STI symptoms at every scheduled visit and syndromic treatment provided, in accordance with current Kenyan guidelines



CONTRACT LABORATORY SERVICES

In the year 2024, NRHS was subcontracted by two different research organisations to conduct HSV-2 testing for their studies with an anticipated throughput of 4,500 specimen tested at different time points. Additionally, NRHS has the platform necessary to expand this to include testing for other STIs including CT/NG – Cepheid GeneXpert PCR Test as well as Atila CT/NG testing as well as HPV – Atila Ampfire PCR Test



NRHS, as has been the trend in the past, participated in several scientific meetings and conferences, as well as technical working group meetings to review various program implementation aspects and participate in the development of policy and program guidelines. NRHS participated in the following National and Kisumu County Ministry of Health Technical Working Groups:

1. NASCOP Technical Working Group for Key and Vulnerable Populations
2. NASCOP Technical Working Group on Viral Hepatitis and Sexually Transmitted Infections
3. NASCOP Technical Working Group on Harm Reductions
4. NASCOP Key Population Size Estimates
5. NASCOP VMMC Centre of Excellence Working Group

Additionally, NRHS assumed the Chairmanship of the MSM Health Research Consortium which encompasses groups doing MSM research within Kenya (<http://mhrcons.org/about-us/>). The MHRC designs and implements studies that identify and address HIV, health and other challenges faced by GBMSM in East Africa

The specific objectives of the consortium are:

- To strive to standardise data collection tools to enable the collection of data that is comparable across study sites

- To share and pool data following mutually agreed-upon protocols for analysing, writing and publishing results
- To develop new, innovative biomedical and behavioural research together, or in collaboration with agreed upon partners, with main goal of informing and assisting Kenya Ministry of Health to improve HIV prevention, care and treatment of MSM

ADMINISTRATIVE ACTIVITIES

The number of full-time salaried staff working under NRHS fluctuated during the year between 45 and 52 of whom about 60% are females. 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% employer paid pension and are covered by health insurance for themselves and up to three dependents. We held a three-day retreat for staff from 18th to 20th December 2024 in Kakamega County during which the staff were able to bond together, share their aspiration of the subsequent year and reminisce on the year 2024 achievements. We maintained unqualified audit reports for the 2023 institutional audit conducted in the financial year. In the financial year ended 31st December 2024, NRHS total expenditure was KES 80,148,509 which was financed by income of KES 84,233,558.

OTHER ACTIVITIES

NRHS continued its membership with HENNET, the National Health Organizations Network, stimulating linkages between the Ministry of Health, Private Sector and Health organizations. NRHS is also a member of the Federation of Kenya Employers. 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.

PUBLICATIONS

1. Edyth Osire, Sophie Young, Enid Awiti, Cynthia Akinyi, Fredrick Otieno, Penelope A Phillips-Howard, Supriya D Mehta and Linda Mason (2024) once they see blood then the mood for sex is spoiled' A qualitative exploration of female sex worker's male client views of menstruation, sex during menses and the menstrual disc. *PLoS One* 2024 Dec 26;19(12):e0315383. <https://doi:10.1371/journal.pone.0315383>. eCollection 2024.
2. Enid Awiti, Sophie Young, Garazi Zulaika, Fredrick Odhiambo Otieno, Elizabeth Nyothach, Penelope A Phillips-Howard, Supriya D Mehta and Linda Mason. "Whenever I help her, I am also expecting her vagina in return": a qualitative analysis to explore men's and adolescent girls' perceptions of the impact of the COVID-19 pandemic on the sexual behaviour and health of adolescent girls in rural western Kenya. *BMJ Public Health* 2024;2:e001214. <https://doi:10.1136/bmjph-2024-001214>
3. Supriya D. Mehta, Debarghya Nandi, Fredrick Otieno, Garazi Zulaika, Elizabeth Nyothach, Walter Atingu, Runa Bhaumik, Linda Mason, Anna Maria van Eijk and Penelope A. Phillips-Howard (2024). Increased reproductive tract infections among secondary school girls during the COVID-19 pandemic: associations with pandemic-related stress, mental health, and domestic safety. *Sexual Medicine*, 2024, 12, qfae045 <https://doi.org/10.1093/sexmed/qfae045>
4. Phillips-Howard PA, Osire E, Akinyi C, Zulaika G, Otieno FO and Mehta SD (2024) Water, sanitation and hygiene at sex work venues to support menstrual needs. *Front. Public Health* 12:1305601. <https://doi.org/10.3389/fpubh.2024.1305601>
5. Wahome E, Otieno FO, Kimani J, Boyd A, Okall D, Nzioka J, Gichuru E, van der Elst E, Mehta SD, Bailey RC, Graham SM, Sanders EJ; for the Tatu Pamoja (three-site) study group (2024). Impact of coronavirus disease 2019-related clinic closures on HIV incidence in young adult

MSM and transgender women in Kenya. AIDS. 2024 Mar 1;38(3):407-413.
<https://doi.org/10.1097/QAD.0000000000003782>. PMID: 37939103