



ON THE MAP: ENSURING AFRICA'S PLACE IN RECTAL MICROBICIDE RESEARCH AND ADVOCACY



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ACRONYMS

AI	Anal intercourse
ARV	Anti-retroviral
<i>Project ARM</i>	Africa for Rectal Microbicides
CEDEP	Centre for the Development of People (Malawi)
EASANMIV	Eastern and Southern Africa Advocacy Network on Microbicides and HIV Vaccines
GALCK	Gay and Lesbian Coalition of Kenya
GLAM	Global Lube Access Mobilisation
ICASA	International Conference on AIDS and STIs in Africa
IRMA	International Rectal Microbicide Advocates
KAB	Knowledge, Attitudes, and Behaviours
KMRHAWG	Kenyan Microbicides, Research, Health and Advocacy Working Group
MARPs	Most At-Risk Populations
MSM	Men who have sex with men
MTN	Microbicide Trials Network
NACA	National Agency for the Control of AIDS (Nigeria)
NIH	National Institutes of Health (United States)
NHVMAS	New HIV Vaccines and Microbicides Advocacy Society (Nigeria)
PEPFAR	United States President's Emergency Plan for AIDS Relief
PrEP	Pre-exposure prophylaxis
RM	Rectal microbicide



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Dr. Gina M. Brown/US National Institutes of Health, Office of AIDS Research
Julien Burns/AVAC
Sean Casey
Cindra Feuer/AVAC
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Britt Swenson/IRMA
Dr. Berhanu Tadesse/ICASA Secretariat
US National Institutes of Health, Office of AIDS Research
Eva Westley/AIDS Foundation of Chicago

IRMA would also like to especially acknowledge the efforts of the *Project ARM* Scholarship Committee, which vetted 145 applications for 16 spots to attend the Addis Ababa meeting. The committee consisted of Darrin Adams, Kadiri Audu, Ben Brown, Brian Kanyemba, Cindra Feuer, Marco Gomes, Kent Klindera, Marc-André LeBlanc, Olumide Makanjuola, Larry Misedah, Gerard Nkundimana, Jim Pickett, Andrew Scheibe, Britt Swenson, Martha Tholanah, Gift Trapence, Eva Westley, and Morenike Ukpung.

Thanks to Marc-André LeBlanc and Jim Pickett of IRMA for *Project ARM* guidance and coordination and to Kevin Jack for copy editing this report. Many thanks also to Pascale Willi for her beautiful graphic design.

EXECUTIVE SUMMARY



Rectal microbicides should be a top priority for Africa, and we need to dedicate more time and resources to their development.

Abimbola Williams, Nigeria

Africa needs to be included in rectal microbicide (RM) research and advocacy activities—including clinical trials for safety and efficacy. Until recently, RMs have simply not been part of the HIV prevention agenda in Africa, due in part to the denial of anal sex among heterosexual men and women, pervasive homophobia that has denied the existence of gay men and other men who have sex with men (MSM), and criminalisation.

Since its founding in 2005, [International Rectal Microbicide Advocates \(IRMA\)](#) has advocated diligently to overcome these barriers and to put RMs on the African map. Those efforts are bearing fruit. Leading scientists now acknowledge the need for safe, effective, acceptable, and accessible RMs for African men, women, and transgender individuals, to complement a similar need for vaginal microbicides, oral prevention, expanded treatment, male circumcision, vaccines, and other innovative tools to combat the epidemic. In fact, the [Microbicide Trials Network \(MTN\)](#) is launching the world's first Phase II rectal microbicide trial in 2012. The trial will take place at sites in Peru, Thailand, the United States, and South Africa, making *Project ARM* all the more relevant and timely.

Project ARM is an initiative which aims to develop sustainable community capacity around RM advocacy in order to ensure broad participation in research activities and well-informed community input into an African RM agenda. The initiative is a collaboration coordinated by IRMA. First-year funding for *Project ARM* was provided by the United States [National Institutes of Health—Office of AIDS Research](#) and the [New Venture Fund](#). [AVAC](#) worked closely with IRMA on this initiative in the first year, and this partnership continues. IRMA was guided by a working group consisting of 60 advocates and community members, researchers, funders and policy-makers from a dozen African countries, as well as a few key international partners from outside Africa.

In order to develop an African RM agenda that articulates research, advocacy, and community mobilisation strategies, IRMA hosted a strategy development meeting on 2-3 December 2011 in Addis Ababa, Ethiopia. This meeting took place prior to the [16th International Conference on AIDS and STIs in Africa \(ICASA\)](#). The strategy meeting brought together African stakeholders and allies representing a wide array of perspectives, experiences, and geographies to develop action steps for RM research and advocacy, specific to the African context. The group prioritised seven key action areas.

RESEARCH

- Knowledge, Attitudes, and Behaviours (KAB) study on anal health and anal sex to generate data that can be analysed across countries and populations
- RM acceptability studies
- Mapping of sex education curricula to determine what content on anal health is included

ADVOCACY AND COMMUNITY MOBILISATION

- Advocacy for lubricant access through the “And Lube” campaign of the Global Lube Advocacy Mobilisation (GLAM)
- Documentation of best practices for integrating anal health, anal intercourse (AI), and RMs into sexual health and HIV prevention education
- Capacity-building activities for community leaders, advocates, and researchers
- Awareness-raising and education about anal health, AI, and RMs

Despite the current lack of adequate resources identified for the ongoing support of *Project ARM*, IRMA will provide guidance and coordination to the *Project ARM* working groups dedicated to moving forward the seven priority areas for action. IRMA also remains committed to raising necessary funding in support of these efforts. However, in addition to the involvement of existing and new *Project ARM* members, the active contribution of key allies will be absolutely essential to the successful implementation of these actions. It will take a village—a very big village—to follow through on these priorities. We encourage African advocates, researchers and policy-makers, as well as their allies from around the globe, to join these efforts. Please contact us at rectalmicro@gmail.com, and learn more about *Project ARM* by visiting IRMA at www.rectalmicrobicides.org.



1. BACKGROUND: PROJECT ARM—AFRICA FOR RECTAL MICROBICIDES

CONTEXT AND PURPOSE

It is critical for the entire microbicide field—community members, advocates, scientists and policy makers—to prepare now for advanced-stage (Phase IIb, Phase III) clinical effectiveness trials of rectal microbicides. The RM field has completed three Phase I safety trials and the US National Institutes of Health-funded MTN is launching the world's first Phase II RM trial in 2012. It will take place at sites in Peru, Thailand, the United States, and South Africa. While this is a momentous step, it is also important to ensure that a robust pipeline of next-generation RMs—both ARV-based as well as non-ARV compounds—are in development while clinical trials of current RM formulations are underway.

Africa needs to be included in rectal microbicide research and advocacy activities, including clinical trials for safety and efficacy. Until recently, RMs simply have not been part of the HIV prevention agenda in Africa, due in part to cultural denial of anal sex among heterosexual men and women, pervasive homophobia that has denied the existence of gay men and other MSM, and criminalisation of homosexual acts and MSM. Since its founding in 2005, [IRMA](#) has advocated diligently to neutralize these factors and to put RMs on the African map. IRMA's efforts have begun to bear fruit. Leading scientists now acknowledge the need for safe, effective, acceptable, and accessible RMs for African women, men, and transgender individuals to complement a similar need for vaginal microbicides, oral prevention, expanded treatment, male circumcision, vaccines, and other innovative tools to combat the epidemic.

The end goal—*Project ARM* activities will lead to expanded, coordinated, strategic advocacy across Africa as well as the planning and implementation of RM research on the continent (including clinical trials and acceptability studies) in an environment that is safe for participants, by building the capacity and expanding the base of RM advocates on the African continent.

PREPARATORY WORK

Project ARM is an initiative with long term goals and objectives. The project aims to develop sustainable community capacity around RM advocacy in order to ensure broad participation in research activities and well-informed community input into an African RM agenda.

This effort is a collaboration coordinated by [IRMA](#). First-year funding for *Project ARM* was provided by the US [National Institutes of Health—Office of AIDS Research](#) and the [New Venture Fund](#). [AVAC](#) worked closely with IRMA on this initiative in the first year and this partnership continues.

Project ARM evolved from discussions initiated by [IRMA](#) through its listserv and from input received from African advocates and partners at two informal meetings held in conjunction with the Microbicides 2010 (Pittsburgh) and AIDS 2010 (Vienna) conferences. A working group that formed following the Microbicides 2010 meeting has guided the process ever since. The initial working group included 60 people: advocates and community members, researchers, funders, and policy-makers from a dozen African countries, as well as a few key international partners from outside Africa.

IRMA hosted a strategy development meeting on 2-3 December 2011 in Addis Ababa, Ethiopia. This meeting took place prior to the ICASA meeting and included over 40 individuals, most of whom were provided at least partial support by IRMA to attend. The purpose of the meeting was to develop an African rectal microbicide agenda that articulates research, advocacy, and community mobilisation strategies.

IRMA awarded full scholarships to 16 individuals to attend the strategy development meeting, exceeding its original goal of awarding 12 such scholarships. The scholarship winners were selected through a competitive application process that netted 145 scholarship applications. The 16 scholarship winners were from Cameroon, Kenya, Nigeria, Rwanda, South Africa, Uganda, the United Kingdom, and Zimbabwe. Other guests and presenters invited to the meeting represented Zambia, Malawi, Ethiopia, Canada, and the United States.



Africans need rectal microbicides and they need to be part of the advocacy, research and development processes that are essential to creating products that are not only safe and effective but acceptable and accessible too. As co-principal investigator of the Microbicide Trials Network, I pledge our full support for the efforts of Project ARM.

Ian McGowan, United States



Having founded what is now IRMA Nigeria, I am really excited to see so much new energy around rectal microbicides across Africa.

Kadiri Audu, Nigeria

2. MEETING HIGHLIGHTS

The objectives of the *Project ARM* strategy development meeting were to:

SET THE STAGE AND CONTEXT

- To provide an update on RM research, the potential role that African RM research and advocacy could play as part of global efforts, and the various African contexts within which RMs could be introduced.

BUILD CAPACITY

- To enhance the capacity of African community advocates to guide RM agenda-setting, research, and mobilisation efforts.

SET THE AGENDA

- To stimulate discussion on sustainable strategies for community mobilisation and increasing African involvement in RMs; to put RMs on the research agenda in Africa; and to develop an African RM research agenda that is part of a global RM research agenda.

A series of presentations by invited speakers provided some important background information and context for the most critical part of the meeting: developing the African RM agenda.

Jim Pickett (IRMA Chair, US) led off the meeting by providing an introduction to RMs and the state of global RM advocacy. He later presented an overview of available resources from [IRMA](#) (website, blog, listserv, Facebook/Twitter, teleconferences, reports, fact sheets). [Click here for Jim's slides.](#)

Dr. Ian McGowan (IRMA Scientific Vice-Chair, Co-Principal Investigator of MTN, US) presented on the state of global RM research, including an overview of past and ongoing research, as well as plans for the future. Participants were especially excited about the planned Phase II RM clinical trial MTN 017, which will include a site in South Africa. A brief description of this trial can be found in [Section 5](#) of this document. [Click here for Ian's slides.](#)

Stefan Baral ([Johns Hopkins University](#), US), **Gift Trapence** ([Centre for the Development of People](#)—CEDEP, Malawi), and **Paul Semugoma** ([Frank and Candy](#), Uganda) addressed the opportunities and barriers related to RM advocacy and research in various African contexts. They shared information on AI and anal health among women and men, and MSM. They also discussed AI as a significant driver of HIV in Africa. And they led discussions with meeting participants on some of the structural, legal, and cultural barriers for this work (e.g. stigma, discrimination, homophobia, criminalisation of AI and MSM), as well as the challenges of community organising in this context. [Click here for Stefan's slides.](#) [Click here for Gift's and Paul's slides.](#)

Ben Brown, **Brian Kanyemba**, and **Zoe Duby** ([Desmond Tutu HIV Foundation](#), South Africa) provided an overview of the state of African research on topics related to RMs. This included a discussion of what is completed, ongoing, and planned (e.g. behavioural research on AI among men and women, and among MSM), and lessons learned from related areas of research. [Click here for their slides.](#)

Morenike Ukpong ([New HIV Vaccines and Microbicides Advocacy Society—NHVMAS](#), Nigeria) and **Brian Kanyemba** ([Desmond Tutu HIV Foundation](#), South Africa) led a discussion on the state of African advocacy and community mobilisation related to RMs. This included an overview of current advocacy and community mobilisation strategies in Africa, and lessons learned from related areas of work. [Click here for their slides.](#)

Most of the working meeting was spent in small group and plenary discussions, where participants developed lists of key activities to be conducted in connection with RM research, advocacy, and community mobilisation. (For the full lists, see [Appendix C](#) and [Appendix D](#).) Participants prioritised these lists and then generated specific next steps for the top priorities. These priority activities form the core of the African strategic agenda on RMs and are discussed in greater detail in [Section Three](#).



Even as we are enthusiastic about moving forward with activities to ensure Africa is on the rectal microbicide map, we can't forget about the issue of human rights and criminalisation. If a gay man is not safe to be himself in Malawi, or any other African country, he won't be able to gain access to rectal microbicides once they are available. A safe and effective rectal microbicide will get dusty on the shelf if people are afraid for their lives.

Gift Trapence, Malawi



Anal sex is part of the normal sexual repertoire for many men, women, and transgendered individuals in Africa, regardless of sexual orientation or sexual identity.

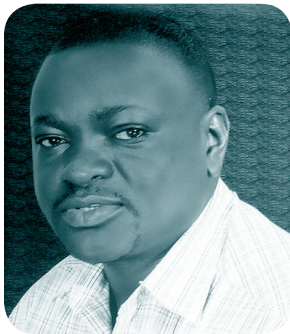
Zoe Duby, South Africa

3. PUTTING AFRICA ON THE MAP: PRIORITY ACTIONS FOR RECTAL MICROBICIDE RESEARCH, ADVOCACY, AND COMMUNITY MOBILISATION

In order to develop an African RM strategy that articulates research, advocacy, and community mobilisation strategies, IRMA hosted a working meeting on 2-3 December 2011 in Addis Ababa, prior to ICASA. Over 40 African advocates, researchers and key allies participated in the meeting, representing 10 African countries as well as Canada, the UK, and the US. After a few presentations to set the context, most of the working meeting was spent in small group and plenary discussions, where participants identified seven priority areas of action related to rectal microbicide research, advocacy, and community mobilisation.

MOVING FORWARD ON PRIORITY AREAS OF ACTION

Despite the current lack of adequate resources for the ongoing support of *Project ARM*, IRMA will provide guidance and coordination to the *Project ARM* working groups dedicated to moving forward the seven priority areas for action. However, in addition to the involvement of existing and new *Project ARM* members, the successful implementation of these actions will require the active contribution of key allies as well. It will take a village—a very big village—to follow through on these priorities. We encourage African advocates, researchers and policy-makers, as well as their allies from around the globe, to join these efforts. Please contact us at rectalmicro@gmail.com, and learn more about *Project ARM* by visiting IRMA.



Soon after the Addis meeting in December 2011, I realized how easy it would be to tap into existing networks, so we got busy! I was so inspired I couldn't wait for this report to come out to start organising and improving rectal microbicide advocacy in my region.

Thomas Muyunga, Uganda

RESEARCH

RESEARCH ACTIVITY #1:

KNOWLEDGE, ATTITUDES, AND BEHAVIOURS STUDY RELATED TO ANAL HEALTH/ANAL SEX

WHY: Little research has been conducted in African contexts related to anal health and anal sex. Generating baseline data on knowledge, attitudes, and behaviours related to anal health and anal sex—among heterosexual African men and women, among African gay men and other MSM, and among health care providers—would be tremendously useful for informing RM advocacy, HIV prevention efforts overall, as well as for gaining a better understanding of the context within which RMs might be introduced.

WHAT: *Project ARM* calls on African research partners to conduct a KAB study that would capture information on: **1)** sexual and anal hygiene practices (who, what, where, when, why Africans have anal sex; condoms and lube use; douches and enemas), **2)** health-seeking behaviours (where people get information and services), and **3)** health worker beliefs and the training they receive on these topics. A sub-study among young gay men and other MSM should be included. The study should be country-specific to account for differing practices, laws, and contexts. However, in order to compare across different regions and populations, the study should be somewhat standardised. In other words, the study should have common elements cross-regionally, but also allow for country-specific differences and adaptations.

RESEARCH ACTIVITY #2: ACCEPTABILITY STUDY

WHY: While a number of vaginal microbicide acceptability studies have been conducted in Africa and some acceptability studies of RMs have been conducted in North America and Latin America (mostly among gay men and other MSM) there is a lack of data on acceptability of RMs in African contexts.

WHAT: *Project ARM* calls on African research partners to generate a better understanding of African-specific acceptability of RMs across various populations and countries. This information can be gathered through a series of acceptability studies examining formulation (gel/lube, enema, film), packaging, cost, messaging, and social marketing. These studies should be conducted among heterosexual African men and women, and among African gay men and other MSM from various African countries.

RESEARCH ACTIVITY #3: MAPPING SEX EDUCATION

WHY: Addressing anal health, anal sex, and RMs should be done by integrating these topics into broader discussions of sexual health and HIV prevention. Examining the current content of sex education curricula in Africa will provide a picture of the extent to which anal health and anal sex are included or not.

WHAT: *Project ARM* calls on its members, with help from interested allies, to conduct an environmental scan of sex education curricula in their respective countries. This review should examine national curricula (public/private schools) and informal education (traditional and religious), to explore what is covered and not covered, what similarities/differences exist across the continent, who is providing sex education, what is taught to different age groups and at different stages of life, and what is included in health care worker training and education (e.g. anal sexually transmitted infections).



**Our diverse sexualities in Africa
shouldn't be defined only by the
prevention tools we have available.
HIV prevention tools must be adapted
to our sexualities.**

Alliance Nikuze, Rwanda

ADVOCACY AND COMMUNITY MOBILISATION

ADVOCACY ACTIVITY #4:

ADVOCATING FOR CONDOM AND LUBE ACCESS

WHY: Overcoming barriers to lubricant and condom access will prepare the ground for optimal access and use of RMs in the future and have an important impact on HIV prevention now. Starting advocacy around lube access now not only serves as a prelude to RMs, but addresses the current severe shortage of condom-compatible lubricants across Africa.

WHAT: The Global Lube Access Mobilisation (GLAM) and its tagline “And Lube” were created at the Addis Ababa meeting to address this issue. *Project ARM* calls for greater access to sexual lubricants, along with male and female condoms. The GLAM campaign will urge ministries of health and other public health entities and programs to make condom-compatible lubes a priority by positioning lubes as an absolute necessity, along with male and female condoms. Lubes should be included in national strategic plans and be a line item in HIV prevention budgets. Existing lube access programmes in Africa will be documented, as will their successes and challenges, in an effort to provide models for programme implementation.

ADVOCACY ACTIVITY #5:

DOCUMENTING BEST PRACTICES IN ANAL HEALTH AND RECTAL MICROBICIDE ADVOCACY

WHY: Implementing *Project ARM*'s strategies means relying on the active involvement of advocates, researchers, and allies. Many *Project ARM* members have been doing remarkable jobs as RM advocates, often in difficult contexts. Learning from their experiences will help new advocates and researchers to expand *Project ARM*'s reach.

WHAT: *Project ARM* will share best practices by encouraging its members to provide resources (websites, guidelines, training materials, reports) that show how they already have integrated anal health, AI, and RMs into their sexual health and HIV prevention advocacy and messaging.

ADVOCACY ACTIVITY #6:

CAPACITY-BUILDING

WHY: Implementing *Project ARM*'s strategies requires the active involvement of advocates, researchers, and allies. Building their capacity will help new and existing advocates and researchers to expand *Project ARM*'s reach.

WHAT: In addition to active recruitment to build the *Project ARM* membership, *Project ARM* will seek opportunities for its members to share its workshop and training curricula, to provide cross-training, and to encourage its members to train partners and allies within their own communities.

ADVOCACY ACTIVITY #7: AWARENESS-RAISING AND EDUCATION

WHY: There has been very little discussion about anal health and AI in Africa. In fact, awareness of the risks associated with unprotected AI is often quite low. Improving education about anal health, AI, and RMs will contribute positively to current HIV prevention efforts, and to the eventual successful introduction of RMs in Africa. Awareness education efforts should target key stakeholders, including community members, policy-makers, and healthcare providers.

WHAT: *Project ARM* calls on its members and partners to mainstream anal health and AI content into sexual health and HIV prevention work in Africa. These efforts should include raising awareness and education about risk reduction related to AI, including eventual RMs.

Beginning with the discussions at AIDS 2010 that solidified the formation of *Project ARM*, the need for communication/educational tools to discuss anal health, AI, and RMs in the African context was identified. There was great interest in developing a video that would educate African advocates, community members, and policy makers about these topics. In January of 2011—well in advance of the Addis Ababa meeting—IRMA, in partnership with Population Council, responded to this interest and established a video advisory committee with 23 members including advocates in Botswana, Nigeria, Kenya, Rwanda and South Africa. Population Council provided the seed funding to develop a concept and a script, and efforts are currently underway to raise the necessary resources to fully produce this African-focused video.



The tag line for the Global Lube Advocacy Mobilisation sums it up. Whenever someone says “condoms,” we say “And Lube.” You cannot say one without the other. Too often that is exactly what happens. Access to condom-compatible lubricant is deplorable all across Africa—it’s unacceptable, and we are working to change that.

Tian Johnson, South Africa



In Africa, female sex workers are often offered more money to have anal sex without a condom. This happens with male sex workers too. We need to ensure sex workers have access to all prevention options, including male and female condoms, lubes, and eventually rectal microbicides as well as vaginal microbicides.

Grace Kamau, Kenya

4. PRIORITY ACTIONS: PROGRESS REPORT AS OF APRIL 2012

During the December meeting in Addis Ababa, participants formed small working groups and identified leaders to move forward on a number of the priority areas of action. By April 2012, progress had already been made in key areas.

For example, the Capacity-Building working group had already delivered training to African advocates at the [Microbicides 2012](#) conference's Advocates Corner, and planned a similar training for [AIDS 2012](#)'s Global Village.

In addition, *Project ARM* and its lube access work gained attention at the [PEPFAR](#) "Prevention, Care and Treatment for MSM in Africa" regional meeting, held in February 2012 in Johannesburg, South Africa. At the meeting, Jim Pickett presented on *Project ARM* activities, as well as RM research and advocacy. Tian Johnson spoke about female condoms and the fledgling GLAM "And Lube" campaign to increase lube availability in Africa. [Click here for Jim's slides](#), and [click here for Tian's slides](#).

A number of *Project ARM* meeting participants, inspired by the urgency of the priorities and by each other, quickly sprang to action in their respective countries. These are a few examples.

KENYA

- Returning from the meeting, Kenyan advocates **George Victor Owino** and **Evans Opany** formed the Kenyan Microbicides, Research, Health and Advocacy Working Group (KMRHAWG). Their goal is to engage and sensitise MSM and male and female sex workers about microbicide, vaccine, and other HIV prevention research in Kenya.
- KMRHAWG members will disseminate information and advocate for RMs and other HIV prevention options. A one-day meeting to plan activities will be held in 2012.
- The Gay and Lesbian Coalition of Kenya (GALCK) will coordinate this new working group, and will reach out to NGOs and others working with most at-risk populations.

NIGERIA

- **Morenike Ukpog** from the [New HIV Vaccines and Microbicides Advocacy Society](#) (NHVMAS) in Nigeria sent a message to NHVMAS members and partners about the importance of recognising that AI happens, and the need for expanded prevention options such as RMs. Several dozen NHVMAS members and partners responded, creating an online dialogue on these issues. Some of the issues Morenike raised were turned into an article published in the [Nigerian Tribune](#).
- NHVMAS wrote a formal request to the Federal Ministry of Health to capture data on anal sex in their National Adolescent Reproductive Health Survey.

- NHVMAS approached the National Agency for the Control of AIDS (NACA) about the need for further analysis of rates of AI and implications for HIV prevention and public health. NACA agreed and as a result, NHVMAS has submitted a proposal for a study on prevalence and patterns of anal sex in the general population in Nigeria.

UGANDA

- **Thomas Muyunga** from [MARPs in Uganda](#) has spoken at several key events and conferences in Uganda about the importance of condoms, lubes and (vaginal and rectal) microbicides, and the need to recognise the existence of AI.
- [MARPs in Uganda](#) has created opportunities for trainings and information-sharing about HIV prevention options, including the need for condoms, lube and eventually RMs.

EASTERN AND SOUTHERN AFRICA

- Under Thomas Muyunga's leadership, fifteen eastern and southern African countries have joined the Eastern and Southern Africa Advocacy Network on Microbicides and HIV Vaccines (EASANMIV).

MANY OF THE FOLLOWING ACTIONS ARE ONES THAT YOU CAN UNDERTAKE:

- **Start a discussion with your colleagues about integrating anal health, AI, and RMs into your HIV prevention work. IRMA has the tools to help you!**
- **Urge your national AIDS councils to include condom-compatible lubricants in their procurement plans.**
- **Use existing materials from the [IRMA website](#) to host a workshop on HIV prevention options, including the development of new tools such as RMs.**
- **Talk to research partners in your country about conducting a RM acceptability study.**
- **Share your experiences, challenges and successes with other IRMA members by posting a message at rectalmicro@lists.critpath.org—the group's highly active, moderated listserv.**
- **Stay informed about the progress of the [MTN-017 rectal microbicide trial](#), which includes a site in South Africa.**

THE AFRICAN AGENDA ALREADY IN ACTION

NIGERIA:

NHVMAS wrote a formal request to the Federal Ministry of Health to capture data on anal sex in their National Adolescent Reproductive Health Survey.

NIGERIA: After the *National Agency for the Control of AIDS* (NACA) agreed about the need for further data, NHVMAS submitted a proposal for a study on prevalence and patterns of anal sex in the general population in Nigeria.

SOUTH AFRICA: The world's first Phase II RM trial will be launched in late 2012, with sites in Peru, Thailand, the United States, and Cape Town, South Africa.

SOUTH AFRICA: *Project ARM* and its lube access work gained attention at the PEPFAR meeting on MSM in Africa, held in February 2012 in Johannesburg, South Africa.

ETHIOPIA: Participants from across the continent identified seven priority action steps for RM research and advocacy, at the *Project ARM* strategy development meeting in December 2011, in Addis Ababa.

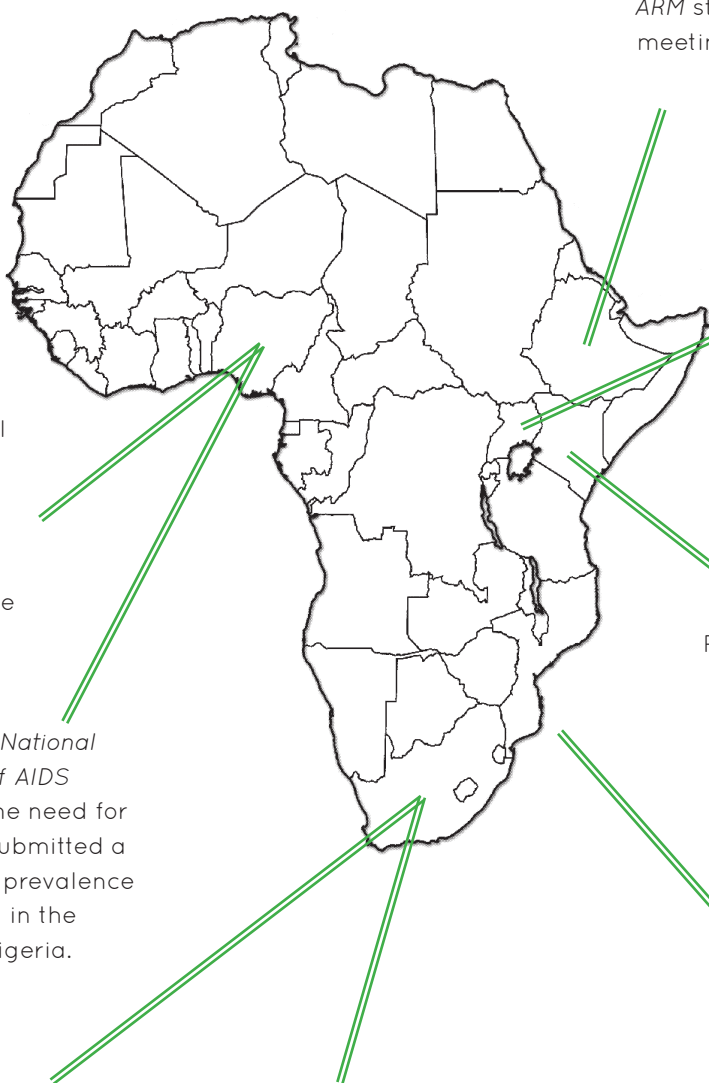
UGANDA: *MARPs* in Uganda has spoken about condoms, lubes and microbicides, and the need to recognise the existence of anal intercourse, at several key events and conferences.

KENYA:

The Kenyan Microbicides, Research, Health and Advocacy Working Group (KMRHAWG) was formed to engage and sensitise MSM and male and female sex workers about microbicide, vaccine and other HIV prevention research.

EASTERN AND SOUTHERN AFRICA:

Fifteen eastern and southern African countries have joined the Eastern and Southern Africa Advocacy Network on Microbicides and HIV Vaccines (EASANMIV).



5. RECTAL MICROBICIDE RESEARCH: A BRIEF UPDATE ON MTN 007 AND MTN 017

MTN 007: SAFE AND WILLING TO USE IT!

Rectal microbicide research is advancing rapidly. Promising results from the first clinical study of a reformulated version of tenofovir gel for use in the rectum were released early this year. The gel proved to be safe and acceptable to the 65 HIV-negative men and women enrolled in the Phase I trial, known as [MTN 007](#).

The MTN 007 study showed no significant differences in side effects among participants who were randomly assigned to use a reduced-glycerin formulation of tenofovir gel compared to those who used a placebo gel containing no active ingredient or a gel containing the spermicide nonoxynol-9 (N-9). All participants were directed to rectally apply the gel daily for a week, and to abstain from sex. The majority reported only minor side effects, and 87 percent of the participants who used the reduced-glycerin formulation of tenofovir gel indicated they would likely use the gel again.

The high acceptability results contrast with a previous study, called [RMP-02/MTN-006](#), which assessed the rectal use of the vaginal tenofovir gel. That study found the vaginal gel produced a strong antiviral effect when used in the rectum, but gastrointestinal (diarrheal) side effects were problematic. Due to these results, researchers recommended modifications to the gel. The new formulation, made with less glycerin, (a common additive found in many gel-like products) was tested in people for the first time in MTN-007.

The active ingredient in both the rectal and vaginal gels is tenofovir, a drug that belongs to a class of anti-retrovirals called nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs). These NRTIs act against HIV by targeting a key enzyme the virus needs to copy its genetic material—an essential step for the virus to multiply and infect other cells. In its tablet form, tenofovir, known by the brand name Viread®, is approved for treating HIV when used in combination with other drugs, and is widely prescribed and well-tolerated by most people.

Researchers included N-9 in the MTN-007 study to construct a detailed profile of its effects on rectal tissue and to compare it to tenofovir gel. The N-9 contraceptive spermicide found in some products sold over the counter is not recommended for HIV prevention or as a lubricant for receptive AI. In MTN-007, exposure to the product was minimal and participants were closely observed and strongly urged to remain sexually abstinent throughout the study period. No serious side effects from N-9 were seen in participants enrolled in the trial.

PAVING THE WAY FOR MTN 017

As a follow-up study to MTN-007, researchers are about to launch the world's first Phase II rectal microbicide trial. Known as MTN-017, the trial will involve gay men, other MSM, and transgender women at clinical sites in Peru, Thailand, the United States, and notably, South Africa. Participants will participate in three study regimens: reformulated (reduced-glycerin) tenofovir gel used daily, reformulated tenofovir gel used before and after anal sex, and daily oral use of the ARV tablet Truvada® as PrEP. All participants will be randomised into a specific order to complete all three regimens. MTN-017 will allow researchers to collect additional information about the safety and acceptability of the reformulated gel, and compare it to the use of daily oral Truvada as PrEP. The trial will start late 2012 to early 2013.



I work at the Desmond Tutu HIV Foundation's Men's Division at the University of Cape Town, and am incredibly proud to say we will be the very first African trial site for a rectal microbicide study—MTN 017. I hope the field will conduct rectal microbicide research in other African countries as well as South Africa!

Brian Kanyemba, South Africa

6. CONCLUSION

Project ARM's December 2011 strategy meeting engaged and mobilised African stakeholders and allies representing a wide array of perspectives, experiences, and geographies in the development of action steps for rectal microbicide research and advocacy specific to the African context. The group prioritised seven key action areas related to rectal microbicide research, advocacy, and community mobilisation. This African-led agenda has already been adopted by advocates and researchers across the continent, greatly increasing the chances that RMs will be integrated into existing efforts to increase HIV prevention options for African gay men, MSM, transgendered individuals, and heterosexual men and women engaging in AI, despite considerable cultural and legal challenges.

IRMA is committed to providing continued guidance and coordination and to raising the necessary funds for *Project ARM* efforts.

However, this work cannot happen without the continued support of community advocates, researchers, policy-makers and funders. African partners and global allies must prioritise these activities and incorporate them into their ongoing HIV/AIDS advocacy and programming. The time to act is NOW if we are to make safe, effective, acceptable and accessible RMs a reality for all Africans who need them.

And Lube!



In Zimbabwe and across Africa, we are struggling to get people living with HIV into care and treatment. We have to do much better, and we have to do much better on the prevention side. I see a rectal microbicide as an important prevention strategy for Africa to embrace.

Martha Tholanah, Zimbabwe

APPENDICES

APPENDIX A. MEETING AGENDA

2-3 DECEMBER 2011—ADDIS ABABA, ETHIOPIA

OBJECTIVES

SETTING THE STAGE AND CONTEXT

- To promote a common understanding of how rectal microbicide (RM) research is proceeding, the potential role that African RM research and advocacy could play, and the various African contexts within which RMs would be introduced.

CAPACITY-BUILDING

- To enhance the capacity of African community advocates to participate in RM agenda-setting, research and mobilisation efforts.

SETTING THE AGENDA

- To stimulate strategies for community mobilization and more African involvement in RMs; to put RMs on the research agenda in Africa; and, to develop an African RM research agenda that is part of a global RM research agenda.

2 DECEMBER 2011

TIME	AGENDA ITEM
7:00	BREAKFAST
7:30	REGISTRATION
8:00	Welcome & introductions; Review of agenda; Logistics
8:30	Introduction to rectal microbicides and the state of the global rectal microbicide advocacy Presenters: Kadiri Audu, Jim Pickett
9:30	BREAK
10:00	Rectal microbicides in various African contexts: Opportunities and barriers Presenters: Paul Semugoma, Gift Trapence, Stefan Baral
11:15	Rectal microbicides in various African contexts: Opportunities and barriers Small group discussions
12:00	LUNCH
13:00	State of global rectal microbicide research Presenter: Ian McGowan
14:00	State of African research on topics related to rectal microbicides Presenters: Ben Brown, Brian Kanyemba, Zoe Duby

14:45	Research needs and opportunities: Potential areas of rectal microbicide-related research in Africa Small group discussions
15:30	BREAK
15:45	State of African advocacy and community mobilisation related to rectal microbicides Presenters: Kadiri Audu, Morenike Upkong, Brian Kanyemba
16:45	Needs and opportunities: Potential areas of rectal microbicides-related advocacy and community mobilisation in Africa Small group discussions
17:30	Wrap-up, planning for tomorrow, review of the agenda
17:45	End of the day

3 DECEMBER 2011

TIME	AGENDA ITEM
7:00	BREAKFAST
8:00	Thoughts from the previous day Review of the agenda
8:30	Overview of available resources from IRMA Presenter: Jim Pickett
9:00	Communications
9:30	Report-back from yesterday's small groups
10:00	Priority-setting, Part 1 Voting on research questions
10:15	BREAK
10:30	Action plan, Part 1 Small group discussion on research questions
11:30	Priority-setting, Part 2 Voting on advocacy and community mobilisation strategies
11:45	LUNCH
12:45	Action plan, Part 2 Small group discussion on advocacy and community mobilisation strategies
13:45	Review of Action Plans
14:15	Taking action: What can I do? What do I need?
14:30	Next Steps and evaluation
15:00	End of the meeting

APPENDIX B. MEETING PARTICIPANTS

PROJECT ARM SCHOLARSHIP RECIPIENTS

APPLICANT NAME	AFFILIATIONS	COUNTRY
Abimbola Onigbanjo Williams	Cooper & Williams Consulting	Nigeria
Adebisi A Alimi	EATG, I-base and African, IRMA, ARM and UK African Microbicides WG	UK
Alex Medson Mello Semba	2012 AVAC HIV Prevention Research Advocacy Fellowship Applicant	South Africa
Alliance Nikuze	Member of Health Development Initiative, Rwanda/ Student at Karolinska Institute	Rwanda
Caroline Atieno Odada	Women Fighting AIDS in Kenya, Hope Alive for Children and Youth Organization, AVAC	Kenya
Evans Odhiambo Opany	Kenya AIDS Vaccine initiation, Liverpool vct care and treatment, Kenya Youth Education and Development Association	Kenya
Florita Durueke	NHVMAS	Nigeria
George Victor Owino	Ishtar MSM and GALCK (Gay and Lesbian Coalition of Kenya)	Kenya
Grace Mukuhi Kamau	Bar Hostess Empowerment and Support Programme (BHESP), AVAC 2011 Advocacy Fellow	Kenya
Harry Clayton Tembo	AIDS Clinical Trials Group	Zambia
Munyaradzi Andeck Chimwara	UZ-UCSF/MMCI	Zimbabwe
Oliver Adolphus Anene	Initiative for Improved Male Health (IMH-Initiative)	Nigeria
Peter Mwangi Michira	University of Washington Discordant Couples Study, THIKA KENYA	Kenya
Thomas Muyunga	CEO, MARPS IN UGANDA	Uganda
Tian Johnson	African Alliance for HIV Prevention and IRMA	South Africa
Tiedjou Joseph Achille	ADEFHO (Association for the Defense of Homosexuals)	Cameroon

OTHER MEETING PARTICIPANTS AND PRESENTERS

APPLICANT NAME	AFFILIATIONS	COUNTRY
Andy Lambert	Consultant	South Africa
Ben Brown	Desmond Tutu HIV Foundation	South Africa
Brian Kanyemba	Desmond Tutu HIV Foundation	South Africa
Cindra Feuer	IRMA Steering Committee, AVAC	US
Connie Osbourne	University of Zambia	Zambia
Dereje Teferi	Rainbow Ethiopia	Ethiopia
Eva Westley	AIDS Foundation of Chicago (AFC)	US
Gerard Nkundimana	University of Rwanda, GCM/IRMA/MEDSAR	Rwanda
Gift Trapence	CEDEP	Malawi
Ian McGowan	IRMA SC, University of Pittsburgh, MTN	US
Jim Pickett	IRMA SC, AFC	US
Kadiri Audu	IRMA SC, IRMA-Nigeria, National Youth Network on HIV/AIDS	Nigeria
Kent Klindera	amfAR	US
Larry Misedah	IRMA SC	Kenya/US
Kay Marshall	AVAC	US
Marc-André LeBlanc	IRMA SC	Canada
Martha Tholanah	Advocate	Zimbabwe
Morenike Ukpong	NHVMAS	Nigeria
Olumide Makanjuola	The Initiative for Equal Rights	Nigeria
Steave Nemande	MSMGF	Cameroon
Paul Semugoma	Frank and Candy	Uganda
Stefan Baral	Johns Hopkins	US
Zoe Duby	Desmond Tutu HIV Foundation	South Africa
Representative	Rainbow Ethiopia	Ethiopia

APPENDIX C. NOTES ON RESEARCH PRIORITIES

RESEARCH ACTIVITY #1

KNOWLEDGE, ATTITUDES AND BEHAVIOURS STUDY RELATED TO ANAL HEALTH/ANAL SEX

RESEARCH ACTIVITY #2

MAPPING SEX EDUCATION

RESEARCH ACTIVITY #3

ACCEPTABILITY STUDY

RESEARCH ACTIVITY #4

DOCUMENTING WORK ALREADY DONE BY *PROJECT ARM* MEMBERS

OTHER POTENTIAL RESEARCH ACTIVITIES OF INTEREST

1. **Research to maximise trial potential.** Need data/answers on why other microbicides trials were futile. Adherence—evaluating best ways/best strategies/in RCTs. Assess best way to get trial buy-in from participants to promote adherence. Communication strategies for trial communities beyond trial participants. Community takes place in adherence “counseling”/help. Integrate trial into local development project to help w/ adherence, recruitment, retention
2. **Research on intersection between MSM and heterosexual AI**—are the HIV epidemics linked?
3. **Community needs assessment for prevention tools**
4. **Documenting traditional/tribal pre-colonial identities, behaviours, AI practices, sexual diversity**
5. **Research into lubricants (efficacy/preference, safety, availability, access).**
Perceptions and current use of lube—are women using lube for AI?
6. **Commodity supply.** Document lessons learned from the female condom.
Access, supply, procurement issues—how are they being dealt with for other new HIV prevention technologies?
7. **Identify countries that have done MSM research** (which is quite a few) to approach for further studies—Kenya? Malawi?

8. **Qualitative study on criminalisation/stigmatisation of anal sex**, of LGBTI practices, of MSM—related to the spread of HIV
 - To have proof of how/whether criminalisation and stigma affect HIV
 - Should be country specific (because laws are different)
 - Include policy analysis
9. **How do people understand risk**—decision-making around sex (linked to how people interpret messaging around safe sex, condoms)

APPENDIX D. NOTES ON ADVOCACY AND COMMUNITY MOBILISATION PRIORITIES

ADVOCACY ACTIVITY #1

AWARENESS-RAISING AND EDUCATION

ADVOCACY ACTIVITY #2

ADVOCATING FOR CONDOM AND LUBE ACCESS

ADVOCACY ACTIVITY #3

DOCUMENTING BEST PRACTICES

ADVOCACY ACTIVITY #4

CAPACITY-BUILDING

OTHER POTENTIAL ADVOCACY AND COMMUNITY MOBILISATION ACTIVITIES OF INTEREST

1. **Ethics committees**—educating IRBs (both government and academic), sensitising to avoid out-of-hand rejection of anal intercourse and rectal microbicide-related research
2. **Develop materials.** Translate science into accessible language for NGOs. Continuous updates on anal sex, rectal microbicides
3. **Media campaign:** accessible language and culturally sensitive. Foster champions, celebrities, local heroes. Engage the media in the whole process so they are a partner. TV/radio soaps—“Generations”—target programs that have gay/HIV+ storylines to add rectal microbicides message (EDUTAINMENT)
4. **Advocate to decriminalise anal sex,** HIV transmission, identity, society
5. **Advocate to go to meetings and challenge discussions around rectal microbicides issues.** Lobby w/ government (i.e. ministries of health) to build support for rectal microbicides. Maybe start with civil society organisations and have them drive the process with government relations. Also focus on key policymakers and other strategic ministries/ government bodies
6. **Non-traditional advocacy strategies.** All should be contextualised to the particular community mix w/ traditional strategies. Baby showers? Kitchen parties? Initiation ceremonies (target the leaders of these activities). Community advocates (secondary education). One-on-one advocacy—peer education for example

7. **Integrate research on microbicides** in national strategic plans including vaccines/PrEP/rectal microbicides
8. **Adopt a holistic approach.** Community outreach: engage youth/MSM through sports? Music festivals/symposiums? Engage the community so projects are community driven—not coming from outsiders (this has to go both ways)
9. **Need to expand product pipeline.** Find what other products might be possible for use in rectal microbicides—anything other than ARVs? Other than tenofovir?
10. **Research literacy:** HIV prevention research, role of ethics boards, understanding trial results, etc
11. **Use social media and new technologies** (Facebook, Twitter, Blogging)
12. **Mapping guide:** who is doing rectal microbicides-related work? Possible funders?
13. **Reach out to Elders and faith communities.** The Elders—influential Africa wide, so not country specific
14. **Remove notion of anal intercourse as a western influence.** Include mention of anal sex being part of African practice/culture historically
15. **Mentoring/exchange program among advocates/NGOs** doing work around rectal microbicides
16. **Technical assistance for resource mobilisation**