Chapter 4
Advocating for Rectal Microbicides and Safe Lubricants

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> I would love a microbicide gel. But right now, even cheap water-based lubes are simply NOT available in many settings. So what would be the case with a specially formulated gel? Of course, something to consider is that in some of our countries, something that "promotes homosexuality" like a rectal microbicide for anal sex, God forbid, might be banned before it is even actually produced! But, the biggest advantage with a rectal microbicide is that most of us need a lubricant for anal sex. Even if we despise condoms, we just can't do without lubrication. We love the pleasure of sex, not pain. So combining a microbicide and lubrication in the same product in our pockets or bedside table is a no-brainer. We would use it. It would be fun. We would even forget that it is a medicine—it's just a lube, and lube is good with sex.
> –Dr. Paul Semugoma, HIV and LGBT activist, IRMA member, Uganda

What will it take to develop safe, effective, acceptable, accessible, and affordable rectal microbicides (RMs)? What will it take to create such products for the men, women, and transgender individuals the world over who engage in anal intercourse (AI) and need/want options beyond male and female condoms to protect themselves from HIV infection? What will it take to ensure that condom-compatible lubricants are safe and widely available? What will it take to put such products on nightstands, in pockets, backpacks, and purses; in pharmacy shelves and next to the bowls of condoms in community-based organizations (CBOs); in national strategic plans and the portfolios of prevention programmers and funders? This is an enormous question, or more accurately, an enormous series of questions. We will not attempt to answer them all here.

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Making Rectal Microbicides a Reality: Overcoming Scientific and Sociocultural Challenges

We will not tackle the science of protecting the rectum from HIV, although it is absolutely critical for us to understand. After all, unprotected AI is 10–20 times more likely to result in HIV infection compared to unprotected vaginal intercourse, mostly owing to the fragile mucosa of the rectum and the hordes of T cells waiting on the other side—"ideal" conditions for HIV infection to take hold. Inhibiting HIV in that fragile, fertile environment while also causing no harm is no small feat, and we are thankful to the scientists, particularly those connected to the Microbicide Trials Network (MTN), who have made RM research a priority. Their commitment to this field of inquiry requires an advocacy mindset and a sense of fearlessness that is not necessarily common in much more "mainstream" and "respectable" pursuits.

When microbicides were first imagined, they were "vagina-centric." While many embraced the notion of creating vaginal products women could control, the majority of the HIV/AIDS community—scientists and advocates alike—dismissed the possibility of developing RMs for use during AI as an HIV prevention method. It was not considered feasible and the pursuit was seen as hopeless, even laughable. At best, the RM field would consist of testing vaginal microbicides for rectal safety, because these products would undoubtedly end up in the rectum despite their intended destination. But rectal efficacy? No way.

Biological challenges certainly played a role in the widespread lack of enthusiasm for RM research. Additionally, the political and sociocultural context reinforced the dismissal of RMs. Pervasive homophobia across the globe has resulted in a lack of adequate attention and resources devoted to gay men and other men who have sex with men (MSM) despite the disproportionate HIV burden borne by this population. And few knew, or acknowledged, that AI is a common practice among heterosexuals, not just gay men. Thus, homophobia and evidence-free assumptions relegated the rectal portion of the microbicide field to a small, dark corner.

Despite this array of challenges, including only a small fraction of total microbicide funding specifically directed to RM research and development, the field has moved from simply being an adjunct to vaginal studies to a force in its own right. This is owing to passionate and dogged scientists and advocates, and critical support from the United States National Institutes of Health (NIH) the funder responsible for nearly the entire array of past and present RM studies.

Making Rectal Microbicides a Reality: Overcoming Challenging Contexts and Barriers to Eventual Access

Addressing political, sociocultural, human/civil rights considerations are vital to creating enabling environments. In much of the world, the act of AI is ignored, denied, stigmatized, demonized, and criminalized. According to ILGA (International

Lesbian, Gay, Bisexual, Trans, and Intersex Association), 78 countries and six entities call for the imprisonment of individuals for same-sex activities; five countries and parts of Nigeria and Somalia call for the death penalty. As of this writing, Uganda is once again taking up their infamous "kill the gays" legislation, inspired by Christian fundamentalists from the United States that would call for the death penalty for gay and lesbian Ugandans. The speaker of the Parliament is actually calling it a "Christmas gift" to Uganda. At the same time, politicians in Nigeria are also looking to enact harsher anti-gay laws. In the United States, only 21 states and the District of Columbia prohibit discrimination based on sexual orientation; one can be fired from their job simply for being gay in more than half the country. Most places in the world criminalize sex work.

If you can't be who you are wherever you are, if your very being puts you in harm's way, you won't be able to access RMs. If your sexual behaviors are ignored or shamed or grounds for criminal prosecution, it's not likely you will have a bottle of RMs next to your bed. It's not likely you will ask for them at the pharmacy, or that your local CBO will distribute them. We can have a fantastic RM product that is safe, super effective, and highly acceptable and it won't matter one bit if the people who need this intervention are unable to get their hands on it because of a hostile environment.

Poverty, food and housing insecurity, unemployment, poor healthcare access, lack of education, failed criminal justice systems, sexism, and racism are equally significant structural challenges that must be addressed in the fight against HIV. These enormous, seemingly intractable issues also will contribute to whether RMs actually make it into the hands—and bodies—of those who need them.

While we recognize the importance of addressing the challenging contexts and barriers we mention above, our remit here is less broad, less overwhelming, and more narrowly focused. What we would like to do first is share our perspectives and provide some examples of international advocacy specific to RMs. Next, we will discuss the need for substantive scientific engagement with impacted communities in the global north and south, and finally we will lay out the interconnected and vexing issues of lube safety and lube access. Pursuing these activities and issues are as essential as maintaining a robust, adequately funded scientific agenda and reducing, or eliminating, the array of structural barriers. We feel they are critical to realizing the day when safe and effective RMs are affordable and within reach of anyone, anywhere.

International Rectal Microbicide Advocates—Who We Are

We represent IRMA (International Rectal Microbicide Advocates— "the bottom line in HIV prevention"—www.rectalmicrobicides.org), a global network of advocates, scientists, health educators, policy makers, and funders housed at AIDS Foundation of Chicago (AFC) and dedicated to the research and development of RMs. Founded in 2005 by a small handful of individuals from AFC, the Canadian AIDS Society,

Community HIV/AIDS Mobilization Project, and the Global Campaign for Microbicides, the group now boasts a dynamic membership of more than 1,200 people from over 100 countries.

IRMA is the first and only network in the world to focus on RM advocacy. The story of RM advocacy is the story of IRMA. Central to its efforts, IRMA nourishes multiple platforms, including a highly active, moderated listserv, by which the stakeholders involved in RM research and advocacy and other new prevention technologies can regularly discuss and debate the issues of the day.

In addition to a host of education, awareness, and advocacy activities, with special initiatives in South America and Africa, IRMA produces a variety of printed, video, and web-based materials and reports to further understanding and discussion of RMs and AI. IRMA has brought attention to past and current scientific endeavors, noted the inadequate funding devoted to RM research, forecasted funding needs for the field up to 2020, characterized data on the frequency of AI (heterosexual and homosexual) and its underreported role in the AIDS epidemic, called for an African-specific RM research and advocacy strategy, analyzed the impact of homophobia and criminalization on the field, described global patterns of lubricant use for AI, called attention to issues of lube safety and access, and pushed for a more coordinated RM research agenda. While IRMA's focus is RM research and issues related to AI and lubricant safety and access, the group also actively supports the development and implementation of other forms of prevention, including new strategies such as PrEP (pre-exposure prophylaxis) as well as underutilized tools like female condoms.

International Rectal Microbicide Advocacy—South America

Following the Microbicides 2008 conference in Delhi, India, Peruvian investigators, advocates, and allies, led by IRMA member Jerome T. Galea, decided to form an IRMA chapter that concentrated on South and Latin America. Dubbed IRMA-ALC (América Latina y el Caribe), IRMA's Spanish-speaking sister is based at a gay men's community health center in Lima called Epicentro (founded by Galea) that provides a host of services for gay men and transgender individuals modeled on the successful Magnet health center in San Francisco, California. Galea has also researched and published on RM acceptability, lubricant use, and rectal douche behaviors among gay men and other MSM from Peru, Ecuador, and Brazil.

In collaboration with IRMA and AVAC, IRMA-ALC translates existing materials into Spanish, produces new ones, and conducts education and advocacy efforts to increase the awareness of RM research and its relevance to communities in the region. Other biomedical strategies such as PrEP and improved treatment access are included in these efforts. In fact the group is currently advocating for access to the ARV drug Truvada in Peru, which is not yet available in the country. Truvada is the drug which was tested in the iPrEx PrEP trial among gay men and transgendered women, showing high levels of efficacy when used consistently and correctly. The vast majority of iPrEx participants were from Peru, and these individuals as well as

their communities should be able to access Truvada for PrEP, as well as treatment for that matter.

IRMA-ALC also works to reduce the stigma and silence around AI. A trait that distinguishes IRMA-ALC is the fun and sense of humor with which it imbues its efforts. In 2012, the group created an animated character named Tia IRMA (Auntie IRMA) who shares her knowledge of AI, RMs, and HIV on YouTube in a sassy, colloquial, rapid-fire manner that is both hilarious and informative. She not only appears on YouTube, but exists in the physical world as well. In larger-than-life costume, Tia IRMA shows up at community events to spread awareness—and pose for photo opportunities—in person. IRMA-ALC members and allies are there with her, proudly wearing pink "Pasivista" t-shirts, a witty reference to those who take on the passive role (are penetrated) during AI.

Tia IRMA and her "Pasivistas" help to reduce the shame, stigma, and "ick factor" felt by many of us when the discussion includes anuses and rectums. Laughter breaks the tension and the silence and allows us to better understand that AI is a normal part of the human sexual repertoire.

International Rectal Microbicide Advocacy—Africa

For far too long the operating principle concerning the HIV epidemic in Africa has been that it is solely heterosexual, and that sexual transmission is entirely driven by unprotected vaginal intercourse between men and women. But an increasing body of evidence tells us quite clearly that unprotected AI is happening all across the continent—among heterosexuals as well as gay men, other MSM, and transgender individuals. Therefore, RM research and advocacy efforts must not neglect Africa. "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" states Alliance Nikuze, IRMA member from Rwanda.

In advance of the 2011 International Conference on AIDS and STIs in Africa, held in Addis Ababa, Ethiopia, IRMA convened a two-day consultation as part of its Project ARM initiative (Africa for Rectal Microbicides). Over 40 African advocates and allies met to develop strategies to ensure substantive African involvement in RM research and advocacy. The results were published in a report called "On the Map: Ensuring Africa's Place in Rectal Microbicide Research and Advocacy" released at the Microbicides 2012 conference. The report calls for a set of activities related to research and community mobilization designed to fully engage Africans, including a Knowledge, Attitudes, and Behaviors study on anal sex, advocacy for increased condom-compatible lubricant access, and communication and education activities. "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," said Dr. Ian McGowan (United States), MTN co-principal investigator and IRMA Scientific Vice Chair.

"We still face significant hurdles regarding human rights for gay men, MSM, and transgender individuals in Africa, but the collective, long-term efforts of advocates and scientists are indeed lifting the denial around anal sex in the African context," said Morenike Ukpong, New HIV Vaccines and Microbicides Advocacy Society in Nigeria, IRMA member, and one of the chief architects of the Project ARM strategy. "Great efforts have long been underway to develop safe and effective vaginal microbicides for African women. We need the same level of commitment and resources for the development of safe, effective, acceptable and accessible rectal microbicides for Africans regardless of gender identity or sexual orientation."

International Rectal Microbicide Advocacy—Material Development

As the RM field expands from small Phase I safety studies to larger Phase II safety studies, and eventually efficacy trials, appealing materials are needed to accurately explain RM clinical trial participation and engage interested community members in RM development. In December 2012, IRMA, the MTN, and the Population Council released a jointly produced video called "The Rectal Revolution is Here: An Introduction to Rectal Microbicide Clinical Trials." While explaining the basics of RM clinical research, the 13-min video is designed to facilitate clinical trial recruitment, ensure consistency and accuracy of messages, and educate clinic staff and communities on RM development. It includes information on concepts such as voluntary participation, risks and benefits, and participant protections.

The video was developed through an intensive process that involved the participation of an international video advisory committee comprising individuals from RM trial sites and other IRMA members. A "rough cut" was viewed by over 80 participants at the Microbicides 2012 conference who provided feedback, and was subsequently tested in 13 focus group discussions of gay men and transgendered women in the United States, Peru, South Africa, and Thailand. The collective feedback obtained was critical in shaping the final video, now available in English, Spanish, and Thai on YouTube.

International Rectal Microbicide Advocacy—The Bottom Line

Anal intercourse is a common human behavior practiced the world over. Gay men and others who engage in AI in Boston, Bangkok, Cape Town, and Lima—and all points in between—need RMs, but advocacy and educational efforts to engage these disparate communities need to be unique and informed by the communities themselves. They must be tailored, contextually relevant, and culturally resonant. The science of RM development should be made appealing and accessible, and accurate information on AI and anal health should underpin these efforts. Materials developed should be in multiple formats and available on multiple platforms.

Scientific Engagement with Communities

The MTN's MTN-017 trial, set to launch in 2013, represents a major milestone: it is the first-ever phase II expanded safety and acceptability study of an RM and is the first RM trial to include clinical research sites outside of the United States. The 186 gay men, other MSM, and transgender women who will be recruited into MTN-017 will more than double the total number of human beings who have participated in RM clinical trials to date. This landmark study—taking place in the United States, Puerto Rico, Peru, South Africa, and Thailand—will investigate the safety and acceptability of reduced glycerin tenofovir gel, and will directly compare acceptability and adherence to daily oral Truvada.

To prepare for the MTN-017 trial, the MTN and IRMA, in conjunction with trial sites and local HIV and LGBT organizations in each city held in-person consultations with community members to obtain feedback on the draft protocol as well as AI and RM research in general.

"The MTN strongly believes that effective communications and meaningful community engagement are essential for the successful and ethical conduct of HIV prevention trials," said Clare Collins, MTN's Associate Director of Communications and External Relations who organized and implemented the MTN's consultation efforts. "Although MTN-017 is a relatively small trial, engagement with civil society and advocates occurred during the design phase of the study and prior to study implementation to address questions and concerns about rectal microbicides and the study protocol. Given that MTN-017 is the first-ever phase II trial of a rectal microbicide and will take place in multiple countries, we believed it was especially important to conduct consultations with key stakeholders and advocates at each trial site to address cultural differences and the sites' unique and specific needs."

Collins explained that MTN was looking for insight from community members about social norms, practices, and perceptions related to AI and biomedical approaches to HIV prevention that could affect the way MTN-017 was designed and implemented. Consultations were conducted while the protocol was still in the design phase to allow changes to be made before the protocol was submitted for final approval.

"MTN-017 also represented the first time the MTN was conducting clinical research in Thailand and Peru, which made it important to introduce key community members to the network by explaining our process of conducting clinical research and giving needed background on our approach to rectal microbicides research," she explained.

In addition to seeking general comments and questions about RMs and MTN-017, some of the specific questions posed to consultation attendees included: Should MTN-017 include transgender women as well as gay men and other MSM? What are the biggest challenges to conducting MTN-017 in your community? How can these challenges be addressed? Do you foresee any concerns about confidentiality and privacy related to people enrolling and participating in MTN-017? Are there any factors you think could negatively impact adherence to the study regimens? How

can we best address these concerns? What are the biggest challenges recruiting and retaining volunteers in MTN-017?

"The feedback MTN received from the consultations directly resulted in changes to the design of the study and its eligibility requirements," said Collins. "It also gave study investigators and site staff important feedback on challenges related to conducting the study." Collins shared the specifics of what was learned from the series of consultations: (1) the initial study design was confusing and difficult to follow; (2) transgender women should be included in the study; (3) the eligibility criteria needed to be revised to exclude couples from participating in the study at the same time; (4) informed consent and study compensation needed to be carefully considered on a site-by-site basis; (5) study materials needed to be as simple as possible and appropriately translated; (6) there could be acceptability challenges to the use of the rectal microbicide applicator; (7) sites that required more invasive procedures such as sigmiodoscopy and biopsy may find it difficult to recruit; and, (8) it may be challenging to recruit young gay and other MSM in the United States since the perception for many is that HIV is seemingly irrelevant to their lives.

"The feedback MTN received from the face-to-face consultations was extremely valuable to the protocol development team. It provided community input that we may not have otherwise obtained and gave us an opportunity to learn from community members and vice versa," Collins said. "Provided funding is available to support additional consultations for rectal microbicide studies, the approach is certainly something MTN is committed to continuing into the future." Collins emphasized that "conducting face-to-face consultations before a protocol has been submitted for approval provides an opportunity for the research team to address any concerns about the study early-on in the protocol development process. It allows the team to learn more about a particular community's social norms and practices that could impact the way the study is perceived and conducted. Holding consultations at an early stage in the research process also helps to create trust and promote collaboration among community members and the research team well before the study launches, setting the stage for future engagement."

MTN's co-principal investigator Dr. Ian McGowan is considered the leading RM researcher in the world. The community consultations for MTN-017 were conducted under his guidance and direction. He and his colleagues have heard from advocates and community members alike that using an applicator to deliver an RM may be a "deal breaker." It is one thing to acquiesce to using an applicator in a trial; it is quite another to ask men and women who have AI to use an applicator in their real lives. After all, people who use lube most commonly use their fingers to apply it, utilizing the "dab will do ya method." And if more lube is needed, "another dab will do ya." In the MTN's recompete application to the NIH, McGowan reported that the network put in a placeholder for a very novel Phase I RM safety, acceptability, and pharmacokinetics (PK) study. Participants will be asked to apply product to the insertive partner's penis and the perianal area/anal canal of the receptive partner. They will then have anal sex. "We want to see if the tissue PK exposure is similar to when product is applied with an applicator. Obviously this would be a challenging study and will need significant development including discussion with advocacy/community

representatives," McGowan said. "However," he continued, "the fact that the study is in the recompetition underscores our commitment to doing this type of research and our responsiveness to community feedback on how these products might be used."

Scientific Engagement with Communities—The Bottom Line

If we are to have RM products that real people are going to use in their real lives, scientists and impacted communities must continue to engage with one another. Tapping community wisdom before, during, and after trials is not a luxury, or something nice to do—it is absolutely essential. And this sort of engagement should not be "trial-centric" but more expansive.

In an ideal world, there will be safe and effective microbicides that work against HIV as well as other sexually transmitted infections (STIs) in both the vagina and the rectum. Having products that work in both "compartments" can effectively reduce the stigma associated with something designed specifically for the rectum. It will also avoid the fumbling for various tubes and lubes by women who are engaging in AI and vaginal intercourse as well. These microbicides will be easily applied, delivered in multiple manners, and available in contraceptive and noncontraceptive versions. Additionally, non-ARV microbicides will be developed so people living with HIV are able to take advantage of this prevention strategy as well.

We recognize we are in the "car phone" phase of microbicides—vaginal and rectal. Early products will be similar to the brick-like car phones of decades ago—perhaps a bit clunky and not as effective as we would like. But it will be what we have, and we will need to make the best of it while keeping our eyes on the prize. Said prize will be products that are like the smart phones of today—efficacious, sleek, strongly desired, and accessible/affordable. Like the evolution of all technologies, this will take time. One only need recall the early years of highly active antiretroviral therapy, with the high pill burdens, complicated dosing regimens and plethora of side effects and compare that to the current array of HIV drugs which are much easier to take, and in some instances, consist of only one pill a day.

Lubricant Safety and Access

As shocking as it may seem, we do not know much about the safety of sexual lubricants and whether or not they contribute to the spread of HIV. More than 30 years into the HIV pandemic, we do not know whether sexual lubricants (lubes) increase, decrease, or have no impact on the risk of acquiring HIV and STIs. In fact, it is only quite recently that most advocates, HIV prevention workers, researchers, and policy makers have even realized that we do not know the answer to this fundamental question.

For years there was very little attention paid to lube safety. Before 2010, researchers and advocates who worked on this issue were voices in the wilderness.

Researchers in Belgium tested lubes on slugs; at the Population Council they tested lubes in mice; at the University of Texas Medical Branch they tested lubes in the laboratory; and, at Johns Hopkins they conducted what still remains the only study testing lubes in humans. Meanwhile, IRMA began advocating for more research on lube safety.

Now a few more studies have been conducted or are underway. Researchers at the Population Council and the University of Pittsburgh have tested many lubes in the laboratory; at UCLA they have explored links between lube use and rectal STIs; and, at the U.S. Centers for Disease Control (CDC) they are testing lubes in the laboratory and in monkeys.

Equally shocking is the deplorable level of access to condom-compatible lubes around the globe, particularly in low-income and middle-income countries. For people at high risk through sexual transmission, including women, men, and transgender people who engage in AI, and sex workers, the situation is even worse. This is despite the fact that we know that condom-compatible lubricants help reduce the risk of condoms breaking or slipping. And as we know, using male or female condoms is considered a very effective way to prevent acquiring both HIV and STIs during intercourse. There is one thing that is clear: we will not get an answer to the lube safety question, nor will we improve lube access without advocacy. We need advocates to urge researchers, manufacturers, funders, donors, and policy makers to make this a priority.

Many men, women, and transgender individuals use lubes during sexual intercourse, and there are hundreds of products on the global market. Sexual lubricants used for intercourse, anal or vaginal, have generally not been tested for safety in humans. Regulatory bodies such as the Food and Drug Administration (FDA) in the United States do not require safety data from testing in humans. At most, the FDA requires manufacturers to demonstrate that lubes are safe in the vaginas of rabbits or guinea pigs. Meanwhile, a number of studies have revealed that some lubricants cause cell inflammation and damage, and another study identified an association between lube use and acquisition of rectal STIs.

It is unclear what laboratory tests should be used to assess lube safety. Furthermore, even when a study shows that a lube causes damage in the laboratory, we do not know how that finding transfers to the real world. We do not know to what extent—if any—using such a lubricant might lead to a higher risk of acquiring HIV or other STIs. Based on current evidence, we do know that lubes with higher osmolarity (a measure of the concentration of soluble components—or solutes—present in a solution) are associated with higher levels of inflammation and cell damage.

IRMA has prioritized the issue of lubricant safety for several years, and we work on a number of fronts. We coordinate a global Lube Safety Working Group comprising researchers, advocates, educators, and policy makers from 12 countries—including all researchers who have worked on rectal safety of lubes, as far as we know. We conducted a global survey on rectal use of lube in 2007. The survey provided valuable information on lube use, preferences, and acceptability among nearly 9,000 men and women from over 100 countries, establishing a list of the most widely used lubes. We disseminate information on lube safety through key documents available in seven

languages and through regular global teleconferences. We gather information on how lubes are regulated in various countries. So far that includes the United States, Canada, the United Kingdom, Nigeria, South Africa, and Australia. We have reached out to a number of manufacturers to get their perspective on lube safety, and to identify ways of working together. We are developing a research agenda to articulate key research objectives that could ultimately help us answer the question of lube safety.

We need to determine whether lubes increase, decrease, or have no impact on the risk of acquiring HIV and/or STIs. Even when microbicides that have been shown to be safe and effective and are widely available, potentially in the next decade, they will still be competing with hundreds of other lubricants that will remain on the market. We need a lube safety research agenda that provides a roadmap toward answering the question of lube safety. This requires more studies and more research funding. It requires the involvement of manufacturers, researchers, and funders. It requires ongoing monitoring of regulatory oversight and adjustments to regulatory requirements. All of this necessitates sustained advocacy to ensure that lube safety remains on the HIV prevention research agenda and on the radar of funders, policy makers, regulators, researchers, and manufacturers.

Another concern is lubricant availability; for many people around the world, sexual lubricants are not accessible in the first place. Although the science has not been able to tell us much about lube safety yet, we do know that condom-compatible lubes help reduce the risk of condoms breaking or slipping. Condom-compatible lubes should be part of any HIV prevention campaign or program that distributes condoms, especially to individuals who engage in AI. Sadly, on a global level, this is the exception, not the rule. This must change, and it is unlikely to do so without advocacy.

That is why IRMA, through its Project ARM initiative, recently unveiled a new campaign called GLAM—Global Lube Access Mobilization. The GLAM campaign is focused on increasing access to condom-compatible lubes. Because it was developed through Project ARM, the initial focus is on Africa where lube access is especially poor. A number of analyses in various settings indicate the use of oil-based products is the most common form of lubrication—and is known to significantly reduce condom effectiveness. Faced with the lack of condom-compatible lubricants, people often resort to such products as body lotion, soap, cooking oil, spit, precum, antibiotic creams, and even motor oil to provide lubrication during AI. This lack of appropriate lubricant products for people who practice AI is unacceptable.

IRMA collaborated with its cadre of Project ARM members as well as amfAR and AVAC to develop a "toolkit" to help improve lube access. The toolkit, launched in December 2012, contains a list of proposed action steps, African case studies, and other resources that advocates can use to ramp up their lube access advocacy efforts in African contexts. Along with a set of three microgrants, recently awarded to organizations in Liberia, Nigeria, and Zambia through a competitive process, it is hoped that advocates utilizing the toolkit are successful in getting governments, funders, and CBOs to include condom-compatible lubes in their policy and programmatic priorities and their prevention budgets.

All men, women, and transgender individuals across the globe deserve the right to have safer sex and protect themselves and their partners from HIV and other STIs. Safe, condom-compatible lubricant must be a priority, positioned as an absolute necessity, along with male and female condoms. Advocates should work together through coalitions of natural allies on this issue—HIV prevention advocates, sexual and reproductive health organizations, advocates for LGBT rights, and advocates for sex workers' rights. Policy makers, donors and funders, public health officials, Ministries of Health, UN agencies, and other development partners must be engaged as well.

Advocacy for lube safety and lube access is gaining momentum. In 2013, we are poised to realize significant progress on both lube safety and lube access.

Some of the more recent research, as well as the increased level of advocacy from IRMA in favor of both lube safety and lube access, have caught the attention of critically important players. This includes several lubricant manufacturers, regulators such as the FDA, funders such as the NIH, policy makers and donors such as the U.S. Office of the Global AIDS Coordinator (OGAC), which administers the President's Emergency Plan for AIDS Relief (PEPFAR), normative bodies and multilateral agencies such as the World Health Organization (WHO) and the United Nations Population Fund (UNFPA), and major distributors of sexual and reproductive health commodities such as Population Services International (PSI). At the time of this writing, PEPFAR has drafted its own Lube Safety Research Agenda to focus on the need for answers to the fundamental questions about lube safety and HIV risk. When finalized and released, this document is expected to provide both direction and much-needed global energy on the issue of lube safety.

Lubricant Safety and Access—The Bottom Line

IRMA believes that the advocacy momentum generated by its dual efforts on lube safety and lube access will lead to a world where men, women, and transgender people from around the globe who engage in vaginal intercourse or AI have access to safe, condom-compatible sexual lubricants. Rectal microbicides are in the future; the need for safe lube is now. It is as urgent and "of the moment" as you can get. If we cannot ensure access to safe, condom-compatible lube for people who need it today, how in the world do we think we are going to be successful in distributing RMs? Developing new pathways for lube distribution, and improving current ones, will have a direct impact on RM accessibility. It bears repeating that the best, most effective, wildly acceptable RM will be for naught if it is inaccessible.

Final Thoughts

It may be a blessing for the RM field to be behind (pun intended) the development of vaginal microbicides and PrEP. Rectal microbicide researchers have been able to

learn valuable lessons from the outcomes of vaginal microbicide and PrEP trials, such as recently reported results from the VOICE trial which revealed most trial participants were not using study products, and adjust accordingly. Advocates have learned how to better engage communities around complicated science and products that are not yet available, and perhaps not seen as a priority in comparison to voluntary counseling and testing, linkage to care, and expanded treatment.

Currently, Truvada as PrEP has been proven to work among gay men, other MSM and transgender women, and among heterosexual men and women, and among persons who inject drugs. While this is an incredible scientific achievement that could be of significant benefit to individuals of all stripes across the world, many policy makers, funders, program implementers, community stakeholders—and most importantly, people at high risk of HIV infection—are just confronting this new strategy now. Consequently, there is a fair amount of resistance, confusion, and misinformation among all these groups. A strong PrEP-specific advocacy movement has never really existed until after the iPrEx trial reported its results, and could explain some of the current challenges in implementing PrEP programs.

The RM advocacy movement, in contrast, has been in place since the early days of rectal studies. It will be up to advocates, scientists, policy makers, funders, and impacted communities to continue preparing the ground so the first day an RM is introduced on the market is not seen as a surprise or an unwelcome diversion.