

## SUMMARY REPORT

### **Rectal Microbicides for HIV Prevention: A Transgender Update and Consultation San Francisco May 19, 2013**

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*Rectal Microbicides for HIV Prevention: A Transgender Update and Consultation* served as an opportunity for Be the Generation Bridge (BTG Bridge) and the Microbicide Trials Network (MTN) to engage civil society representatives and advocates from US and International transgender-focused health organizations in a conversation about recent advances in biomedical HIV prevention research. The meeting provided a forum to discuss issues of importance to transgender communities related to biomedical HIV prevention research and the rectal microbicides landscape, and strategies to encourage greater involvement of transgender communities in rectal microbicide research moving forward. The consultation allowed for in-depth discussions about various aspects of these efforts and the sharing of ideas for continued engagement and partnerships among transgender communities and HIV prevention researchers.

This report is structured according to the meeting's agenda (which is attached at the end of the document) and summarizes the main issues that emerged.

#### **Meeting Attendees**

Meeting attendees included some 29 representatives from a multitude of US-based organizations, as well as representatives from Peru, Thailand and South Africa.

#### **I. Welcome and Introductions** (Aamina Morrison, TIP Coordinator, GALAEI)

Aamina Morrison welcomed meeting attendees, asked what they had heard about microbicides, discussed meeting ground rules, and asked each meeting attendee to introduce themselves to the larger group.

#### **II. Introduction to BTG Bridge and MTN: Who We Are and Where We Are Going** (Cornelius Baker, Project Director and Senior Communications Advisor, HPTN/FHI 360 & Ian McGowan, Co-Principal Director, MTN)

Cornelius Baker provided the group with an overview of BTG Bridge, explaining that BTG Bridge was created by the National Institute of Allergy and Infectious Diseases (NIAID) to sustain the momentum of the former NIAID HIV Vaccine Research Education Initiative (NHVREI).

The goal of BTG Bridge is to foster relationships with highly impacted communities in order to promote dialogue, awareness and understanding of HIV prevention research, and increase support for research participation.

Ian McGowan provided an overview of MTN's structure and mission, and background on MTN's scientific portfolio, focusing on its flagship studies: MTN 003 (VOICE), MTN 020 (ASPIRE), and MTN-017. The MTN is a US National Institutes of Health-funded worldwide collaborative clinical trials network focused on preventing the sexual transmission of HIV through the development and evaluation of products used orally or applied topically in the rectum or vagina.

### **III. HIV Infection in Transgender Communities** (JoAnne Keatley, Director, Center of Excellence for Transgender Health, University of California San Francisco)

JoAnne Keatley provided the group with global HIV prevalence data focusing on transgender women and reviewed the drivers of HIV among transgender people, including stigma, discrimination and lack of access to health care. Participants' comments and concerns highlighted the barriers, challenges, gaps and needs related to transgender people and HIV prevention research. Some of the participants' comments included the following:

- Why is there still so little information regarding transgender people and HIV? This data is an alert for public health. A call to action.
- Transgender people are tired of being guinea pigs for intervention protocols. Scientists take from the participants, but these studies do nothing to change the lives of transgender people. Transgender people continue to die.
- If microbicide research is going to be done with transgender people, research design will need to include interventions that will raise consciousness and build self-esteem. Researchers need to humanize the transgender experience. Recognize what influences people to participate in research. Some transgender people participate in research just to meet their basic needs.
- We need to think about why people are joining studies and also think about all the issues that people face in their lives that will prevent them from using a daily product. When transgender people have to get up every day to prepare to present to the larger community this might be more important than taking a daily pill or gel. If they don't present correctly, they are placed at risk for social harm.
- Transgender people and community advocates need to utilize the legal system to decrease the burden of HIV in transgender populations.
- We need to make transgender people more visible in the larger community. There should be a social campaign focusing on transgender people so that they are not invisible. This can aid in reducing social stigma.
- We need to utilize gay media to give the larger community an insight into the lives that transgender people live. There is a lot that the larger community does not know about transgender people.

- Some transgender people do want to transition and assimilate. This is because they do not want to deal with the stigma any longer. This does not serve the transgender community well. Transgender people must honor and claim their history and not discard it.
- A number of transgender people engage in sex work because they are denied safety, support and employment opportunities, not because it is an occupation of choice.
- Social context must be addressed. In most of Africa, MSM are criminalized. This also includes transgender people. In South Africa, transgender people have begun working with women's organizations saying that we need not focus on how we are the same, not on how we are different.
- People should be able to identify their own experiences. Gender does not capture a person's sexual experience. There option for multiple gender selections should be provided.
- A lot of transgender people are labeled because of their sexual behavior and misperception of what that may include. This prevents transgender people from seeking care and support from others. The transgender experience is complex and should not be simplified.
- We need to make sure the language that we use is correct. Transgender-inclusion means all transgender people and not just transgender women. In research, "parts, pieces and behaviors" should be focused on, not sexual identity.

#### IV. Transgender People and Biomedical HIV Prevention (JoAnne Keatley)

JoAnne Keatley provided the group with information on the inclusion of transgender women in biomedical HIV prevention studies. Discussion was structured around the questions below. Participants' comments are reflected in the bullets.

Why do you think so few transgender people enroll as participants in biomedical HIV prevention research?

- Far too many studies couple transgender women with gay men and MSM. As a transgender woman, my life experience is different than that of a gay man. There should be studies dedicated to transgender people that do not include other groups.
- There are very few HIV biomedical research studies that include transgender people. There are transgender men who want to participate, but they are not included.
- The language used should be appropriate for the transgender community and consistent across all sites doing transgender research.
- Transgender people should be hired as clinical staff and investigators. There should be transgender people on the protocol design team and not just used to review the protocol. Research should be designed that is responsive to the needs of transgender communities.
- People should be able to identify as they want and not have to fit into a box because of what researchers assume.

- Transgender people are afraid to participate in biomedical research. What will the drugs do to them and what will the outcome be?
- Researchers need to include partners outside of community-based organizations for community engagement.
- Social marketing and outreach materials should include transgender people.

Biomedical HIV prevention typically involves transgender women because they are at high risk of HIV. What role do you think transgender men should play in biomedical HIV prevention research?

- Transgender men should play as large a role as transgender women. There are transgender men who have sex with men. Biomedical HIV prevention research doesn't target transgender men or women. Instead, transgender women are included in MSM studies.
- Everyone is at risk for HIV. We need to get rid of assumptions and determine what is high-risk. What makes transgender people at increased risk for HIV?
- Transgender men will not participate in a study that targets transgender men. These men do not want to disclose and will not participate in a transgender focused study. We need to focus on "parts, pieces and fluids." A transgender man will only be successfully recruited by another transgender man.
- You must approach transgender people not as transgender but as how they identify.
- There is an assumption that transgender people value their lives enough to protect themselves by people who have social advantages that transgender people do not have. Be aware of this assumption.
- We do not have a comprehensive view of how to reach transgender men or their culture. We need to be mindful to target HIV prevention in relevant ways.
- There must be transgender people involved all aspects of studies, as researchers, clinicians, outreach workers, social workers, etc. Participants are validated when they see people like themselves doing the research.
- In Thailand, transgender men are an invisible population. Research should be generalized when designing research for transgender men.

**V. Lunch and Video Screening of "The Rectal Revolution is Here"** (Jim Pickett, Chair, International Rectal Microbicide Advocates, IRMA, and Director, Prevention Advocacy and Gay Men's Health, AIDS Foundation of Chicago)

During lunch, Jim Pickett facilitated a screening of "[The Rectal Revolution is Here – An Introduction to Rectal Microbicide Clinical Trials](#)", a video developed by the International Rectal Microbicide Advocates (IRMA), Population Council, and the MTN, as a tool for clinical trial sites as well as HIV prevention educators and advocates to introduce rectal microbicides. He also referred to a facilitator's guide for the video, available in [English](#), [Spanish](#) and [Thai](#), that can be used as a preparation tool for people utilizing the video in community discussions, workshops, and/or recruitment sessions.



## VI. The Road to Rectal Microbicides (Ian McGowan)

Ian McGowan provided the group with background on rectal microbicide research and the MTN's scientific agenda related to rectal microbicides development and clinical evaluation. Questions and comments posed by attendees included the following:

### Questions:

- Has there been any research done on interaction of microbicides and hormones?  
We don't have answers about this yet. We need more research to look at possible interactions.
- How are microbicides actually used?  
Right now, product is dispensed with an applicator inside the vagina or rectum.
- Is there a risk for reaction to microbicide for the insertive partner?  
There has been research done with men to look at these reactions. None were significant.
- In trials you are encouraged to use gel and condoms. But if you want to see an effect how can you get this information if you are encouraging participants to use condoms?  
We do research where the annual incidence is at least 3 percent. We encourage people to use condoms, but unfortunately many people have sex without condoms.
- What is the conversation between pharmaceutical and research entities. What are the MTN and pharmaceutical companies willing to invest in transgender populations?  
All of the funding for MTN comes from the government and not from pharmaceutical companies. The NIH works to build up infrastructure in the communities where we do research.
- How long will we wait before there is research done on microbicides in the neo-vagina?  
MTN is currently re-competing for funding, but this would be an important research question to address.
- Is there a risk of resistance?  
Yes. But there are safety measures in place in MTN research to prevent this.
- How will these microbicides be available?  
They will be available with prescription as these are ARV drugs.
- If a bottom is positive can the gel prevent transmission of HIV or if both parties are positive can the gel prevent mutation?  
At the moment, we are just testing these products in negative people.

### Comments:

- Data should be captured on men who top and bottom for transgender women. There is sex that is personal choice, and there is sex that happens for money.
- Transgender people need microbicides. People who carry condoms in some places can be arrested for sex work. Women in sex work may also be discouraged from using condoms in order to make more money.

- Be mindful that you are not just talking about a body part for transgender people because we haven't been allowed to have certain body parts. We haven't been allowed to have an anus or a penis of our own.
- MTN should have images that are reflective of the transgender experience. Not all transgender people look like super models or porn stars.

**VII. Tell Us What You Think/Giving a Voice to Transgender People in Microbicide Research**  
(Aamina Morrison)

Aamina Morrison facilitated a discussion as follow-up to Ian's presentation and asked participants a series of questions, which are included below. Participants' comments are reflected in the bullets.

What questions would you have before enrolling in a rectal microbicide clinical trial? Would you be concerned about hormone use?

- This is a very important question for transgender people. We do not fully understand whether hormones have an impact of the use of ARVs. Many transgender people who are on ARVs take more hormones to overcompensate for the use of the ARVs.
- We must reassure transgender people that there will be no interaction of the microbicide with the use of hormones.
- There needs to be someone on staff who will monitor interactions of microbicide and hormone use.
- Will there be access to additional care?
- What are my chances of contracting HIV when using a microbicide?
- Will it affect HIV testing if a test is sought somewhere else?
- What does it taste like?

Moving forward, how can the rectal microbicide research agenda best address the needs of transgender women and transgender men?

- Provide services that transgender people want as part of care. Have a formal referral process to other providers.
- Recognize that transgender men have vaginal sex.
- Humanize the transgender experience. Concentrate on sexual behaviors and gender identification.
- Collect adequate information on side effects and provide that information to study participants.
- Emphasize that condoms must be utilized in conjunction with microbicides.

What could be done to increase awareness of rectal microbicide research trials?

- Educate providers and outreach workers.
- Conduct open forums and community engagement sessions.
- Utilize social networks like sex toy parties to increase community awareness of rectal microbicides. Sponsor events that are in sex positive environments.
- Work with people who have social capital in the communities you are trying to reach.
- Introduce microbicides in a larger HIV prevention conversation.
- Encourage a peer referral program – a seed program for people who refer others to be enrolled.
- Find the gate keepers and invest in the community. Also conduct focus groups.
- Social marketing that targets transgender people.
- Address the immediate (and basic) needs of transgender people.
- The rectal video was a great idea. It helps demystify what a microbicide is.
- How can the MTN function more like a community participatory based research model. The more the MTN invests in the community, the more the community will trust the MTN. What will the MTN do to make sure that the sites are culturally appropriate? Is there transgender inclusive health coverage?
- There needs to be transgender people at all levels of the network operation and study design. Manuscripts, questionnaire design, social marketing campaign development, etc.

What are the best avenues/ outlets for communicating about biomedical HIV research within transgender communities? For example, web site, surveys, blogs, news media, or social media, etc.?

- Partner with organizations outside of CBOs.
- In house/ball communities, provide information during house meetings, and fund balls and other house functions. Also offer free entry for participants who have been through a certain number of educational sessions. If you directly fund a category as a grand prize, for example, bring it with a certain biomedical message.
- Create a leadership committee in the ballroom community. Provide biomedical research information during ballroom breaks. Give away materials. Sponsor categories. Give a 5 minute speech on what biomedical research is.
- Train transgender people to do the work and provide support to those individuals doing so.
- Be thoughtful about the incentives that are provided. (For example, a laser hair removal gift card instead of a subway gift card.)
- Team up with pageant systems and challenge them to include biomedical HIV as part of their national platform.
- Transgender people feel as if they are the “hunted” as many researchers are looking to enroll them into their studies. Make sure that you care for transgender people more holistically.

- Glam card project – told personal stories about sex practices. Angels of change runway show is another potential venue to get the word out about biomedical research.
- Partner with local doctors who work with transgender populations.

What messages have you heard or seen in your community about biomedical HIV research? Where did the messages come from? What were your impressions of the messages? Which of those messages were most effective and why? Which of those messages were least effective and why?

- Most messages are not targeted to transgender populations.
- Institutions are generally resistant to hearing the needs of transgender people.
- Transgender women need to have campaigns that validate their womanhood, sisterhood and sexuality.
- In order to market, you need a visual marketing campaign. You need to work with IRBs to utilize images that they may deem are not appropriate.
- Messages are needed that make the potential participant feel respected.
- Love and sex should be separated in messages.
- Images often target people who are under 25 and transgender people over that age bracket may dismiss those messages.

#### **VIII. Closing Remarks and Next Steps (Cornelius Baker & Ian McGowan)**

Cornelius Baker and Ian McGowan thanked attendees for the frank and open discussion, and emphasized the commitment on the part of BTG Bridge and the MTN for continued engagement with representatives from transgender communities, including at conferences and meetings. They also conveyed their intention to keep the group apprised of new developments in rectal microbicides research and other HIV biomedical prevention modalities. Cornelius ended the consultation by asking each participant to share what they would take away from the meeting. Responses included the following:

- It is important to include transgender populations in the design and conduct of research focusing on transgender people.
- There is value in consultation and we need to take this information back to the people who matter most.
- This was a wonderful effort for exchange of information and we appreciate you taking the time to listen.
- Thank you for being direct about the research. It makes us feel comfortable that the research will be carried out appropriately.
- Thank you for thinking about us and working to ensure that we are adequately included in microbicide trials.
- Today I have learned a lot about transgender men and will focus on making sure transgender men are included in our conversations about research and transgender people.



- Be sure to consult with transgender people as this research process moves forward.
- Today has reminded me about what I need to be doing as it relates to HIV prevention.
- We need to continue to have these conversations on a regular basis.
- Today was very informative as it relates to research. I cannot put myself in a transgender persons shoes as I have not lived that experience.
- We need to put forth a project that will focus specifically on transgender men and women.
- This conversation has made me think about how I can take this information back to the community and how to include transgender people at all levels of the research.
- I am leaving with a renewed call to action.
- This meeting has helped think about how to inform transgender people in research.
- This meeting has helped inform me about the terrible discrimination that transgender people deal with on a daily basis.
- This meeting has made me optimistic about the direction that the MTN is taking. Any person at high risk for HIV infection should be included in research.
- I have gotten new tools and information. I also have the power of the group behind me to make sure that my voice is heard.
- I am taking away with me the plight of women in the context of HIV infection.
- Transgender people have a full range of love that needs to be appreciated and acknowledged.
- I am hopeful about the partnerships that can happen here.
- What is our responsibility as a follow up to this meeting? What are we doing next?
- I will be taking information back to my community advisory board and community at large.
- This work is more than just a check and I am thankful for being offered to have my voice heard.
- I am an ally of transgender people and I must support transgender people as they move through their life experiences.
- The meeting has brought out a passion that I once had for HIV prevention.
- This meeting has given me a snapshot of the rich diversity of the transgender community. We don't have to agree on everything to get the work done.
- The discussions on language have been very helpful. Different language can be used in different contexts.
- We need to spread the word about PEP.
- I feel confident that the work that needs to be done is being done across the globe.
- This consultation was very well planned. It has allowed many people to attend the National Transgender Health Summit who would not have been able to otherwise.
- This consultation was a reminder that there is a lot of discourse and there are many voices to be heard. We do not have all the answers yet but we must continue to inform the research organizers what our needs are. I was thrilled with the level of participation.

- Transgender people have real challenges. But this conference reinforces that I come from a beautiful brilliant people who are resilient. The fight has been worth it. We are accustomed to being gathered, but not being heard. I want to charge the MTN to be transgender-specific. There need to be funds specifically allocated for research among transgender people.
- Let's continue to heal our people. We have the cure among ourselves.

### **Web Resources**

- MTN – <http://www.mtnstopshiv.org>
- BTG Bridge – <http://betheneration.nih.gov>
- The Rectal Revolution is Here – <http://www.youtube.com/watch?v=ulqFQ87dIf0&list=PLkDJ5X2nRNSeouU1zqvwNPol4u7Mi5w4D>
- The Rectal Revolution is Here Facilitator's Guide English – [http://www.rectalmicrobicides.org/docs/RR\\_Guide\\_English\\_FINAL.pdf](http://www.rectalmicrobicides.org/docs/RR_Guide_English_FINAL.pdf)
- The Rectal Revolution is Here Facilitator's Guide Spanish – [http://rectalmicrobicides.org/docs/RR\\_Guide\\_Span\\_FINAL.pdf](http://rectalmicrobicides.org/docs/RR_Guide_Span_FINAL.pdf)
- The Rectal Revolution is Here Facilitator's Guide Thai – [http://rectalmicrobicides.org/docs/RR\\_Guide\\_Thai\\_FINAL.pdf](http://rectalmicrobicides.org/docs/RR_Guide_Thai_FINAL.pdf)

## CONSULTATION AGENDA

**Rectal Microbicides for HIV Prevention: A Transgender Update and Consultation**  
**Renaissance San Francisco Stanford Court Hotel, California Room**  
**May 19, 2013**

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|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>8-8:30 a.m.</b>     | <b>Coffee and Breakfast</b>                                                                                                                                                                                                                          |
| <b>8:30-9 a.m.</b>     | <b>Welcome and Introductions</b> – Aamina Morrison<br><i>Ice Breaker: What have you heard about microbicides?</i>                                                                                                                                    |
| <b>9-9:30 a.m.</b>     | <b>Introduction to BTG Bridge and MTN</b> – Damon Humes & Ian McGowan<br><i>Brief presentations from each organization followed by Q&amp;A</i>                                                                                                       |
| <b>9:30-10:30 a.m.</b> | <b>HIV infection in Transgender communities</b> – JoAnne Keatley<br><i>Who is at risk? What kind of data is available? Where are the gaps?</i>                                                                                                       |
| <b>10:30 a.m.-noon</b> | <b>Transgender people and biomedical HIV prevention</b><br>– Facilitated Discussion – JoAnne Keatley<br><i>Past and current involvement of transgender people in biomedical HIV prevention studies – opportunities and barriers</i>                  |
| <b>Noon-12:45 p.m.</b> | <b>Lunch</b><br>Video screening of “The Rectal Revolution is Here – An Introduction to Rectal Microbicide Clinical Trials” – Jim Pickett                                                                                                             |
| <b>12:45-1:15 p.m.</b> | <b>The road to rectal microbicides research: Current and future trials</b> – Ian McGowan – <i>Overview and update of ARV-based prevention research landscape, focusing on the development and testing of rectal microbicides followed by Q&amp;A</i> |
| <b>1:15-2:30 p.m.</b>  | <b>Tell us what you think: Discussion and questions</b> – Facilitated Discussion – Aamina Morrison<br><i>How can the rectal microbicides research agenda best address the needs of transgender people?</i>                                           |
| <b>2:30-3:30 p.m.</b>  | <b>Giving a voice to transgender people in microbicide research</b> – Facilitated Discussion – Aamina Morrison<br><i>How can we best engage transgender communities in microbicide research?</i>                                                     |
| <b>3:30-4 p.m.</b>     | <b>Closing remarks &amp; Next steps</b> – Damon Humes & Ian McGowan<br><i>Moving forward: Next steps and future community engagement with transgender communities</i>                                                                                |