

IT TAKES A VILLAGE: COMMUNITY AND STAKEHOLDER PERSPECTIVES ON DELIVER

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042 Protocol Co-Chairs

MTN Regional Meeting

Cape Town, 2019



Village and Community

- A small community or group of houses in a rural area, and usually smaller than a town



- The inhabitants of such a community collectively



What do I see?

- Authority
- Power structures
- Diversity
- Individuals
- Belonging
- Identity
- Common purpose
- Conflicts
- Challenges
- Autonomy
- Resilience

A COMMUNITY

Stakeholder engagement/participation

- Advocated by researchers, communities, regulatory agencies, and funders with the aim of building meaningful relationships that can help shape the research process.
- Strong argument to involve communities affected by the disease under investigation, especially in biomedical research in public health areas
- Fosters conduct of *relevant research* and *vigilance* for the safety of participating subjects
- Potential to improve dissemination, uptake, and implementation of research findings
- Good Participatory Practice (GPP) is becoming a familiar concept

Stakeholder engagement/participation

- Relationships between communities and research is on ongoing process and can take different forms:
 - community consultation in specific stages of the research
 - community representation during the whole research process
 - a long-term and more complex partnership
- Different types of stakeholder involvement could be appropriate in different situations:
 - informal consultations may be more useful in some studies
 - more formal consultations or partnership may be advised, especially if research involves vulnerable populations



MTN-042: DELIVER



- A study to evaluate the safety of PrEP and the dapivirine vaginal ring in pregnant women
- Participants randomized 2:1 (ring to PrEP)
- Primary endpoints:
 - Safety: Serious adverse events, Grade 3 and higher adverse events for mothers and infants
 - Pregnancy outcomes: full term delivery, preterm delivery, pregnancy loss
- Stepwise enrollment in 4 cohorts from later gestational age to earlier gestational age



Clear need for Stakeholder input

- Traditionally “vulnerable” population
- Cultural practices surrounding pregnancy
- Use of an investigational product (dapivirine ring)
- Complicated study design
- Need to bridge maternal health and HIV prevention spheres

Two phases: Before and after the protocol was finalized

- Hosted by AVAC, MTN and local sponsor
 - Discussed both MTN-042 and MTN-043
- Regional Stakeholders meeting held FIRST
 - Johannesburg, April 2018
 - Representatives from each country (S Africa, Uganda, Malawi, Zimbabwe)
 - Held **before** the protocol was finalized
 - Important input into study design and implementation
- Country specific Stakeholders meetings held **after** Version 1.0 of the protocol
 - Blantyre, March 2019
 - Johannesburg, March 2019
 - Kampala, June 2019
 - Harare, January 2020

Objectives of the in-country stakeholder meetings

- To present the rationales and designs of DELIVER and B-PROTECTED to a broader audience
- To seek input about the studies
- To assess how Stakeholders view MTN-042 and MTN-042 within the context of the current HIV prevention landscape, especially with regard to PrEP
- To solicit views about how best to overcome the ethical, sociocultural and structural challenges inherent in the studies
- To establish new ties and strengthen existing relationships between researchers and key in-country stakeholders
- To create a framework for continued engagement on issues of relevance in each country

Participants

- Health care providers
 - HIV and maternal health
- Public health officials
- IRB/ethicists
- Community activists
 - HIV and maternal health
- Religious and community leaders
- Former ring participants
- PrEP users
- PMTCT recipients



Agenda at each in-country meeting

- General background to get everyone on the same page
 - HIV risks associated with pregnancy and breastfeeding
 - Pregnancy complications
 - How drug safety is assessed in pregnancy
 - What is known and not known about the two prevention products' safety in pregnancy and breastfeeding
- Deliver/ B-Protected study specifics
 - Review of study design
 - MTN-041 lessons learnt
 - Safety measures in MTN-042
 - Messaging and communication
- Presentations, ARS and small group
- Emphasis on discussion



Lots of discussion!

- All meetings ended with consensus that pregnant and breastfeeding women deserved to be included in an HIV prevention trial given their heightened risk
- Agreement that the study design maximized participant safety
- Midwives need to be included at all stages of implementation
- Recruitment will be challenging, especially for the first and last cohorts
- Partner, family and community support will be key



Important themes

- Given that PrEP is not readily accessible despite its proven benefit, how will MTN042 ensure that the study is not science for science sake, but will actually lead to an *accessible* product, if proven safe?
- Poor pregnancy outcomes are a reality. How will the study team ensure that the first bad pregnancy outcome doesn't create mistrust in the community and derail the study?



After the meeting, solicited written feedback
from key participants....



Participant feedback



I found the meeting very helpful; in the first place, the novelty of the subject under discussion was an eye opener about other HIV and AIDS prevention strategies which I did not know about. I also was in a position to relate other existing strategies, their deficiencies and how this strategy can further mitigate the spreading of HIV and AIDS. I was exposed to other players in the fight against HIV and AIDS and was able to add to my contacts for further networking.



Lindirabe Gareta-Mazinyane

Director, Blantyre Synod Health and Development Commission Blantyre

Participant feedback



Very helpful meeting. At the beginning of the meeting I noticed most people felt that involving pregnant women in HIV prevention trials was not right, but by the end of the meeting stakeholders were convinced that blocking pregnant women from participating in these trials was inappropriate.

Tiwonge Mtande

Study Coordinator, University of North Carolina Project
Kamuzu Central Hospital - Lilongwe

Participant feedback

A multisectoral approach that was utilized in HIV Prevention needs to be adopted even more extensively if that woman deep-seated in a remote village or township has to benefit from this phenomenal invention. The killer assumption is that the ring shall be affordable. Leaders at all levels need to be brought on board slowly but surely. Cultural and social disapproval should be expected from negative-thinking people plus some politicians who always think that everything must pass through them!!!



Johnson Acon

Chairman, Institutional Review Board/Ethics Committee,
Joint Clinical Research Centre - Kampala

Participant feedback



What I took away from the meeting was that researchers are trying so hard to find possible prevention ways that are different, to make sure that we women have choices, a variety of prevention tools to choose from. And also that they want all women not to be left behind or feel excluded.

Gcobisa Madlolo

Former EMPOWER Study Participant; Wits RHI -Joburg

Participant feedback

Stakeholder engagement is critical because it provides an opportunity to assess beneficiary needs as justification for implementation. In addition; stakeholder meetings also help promote/market an initiative or service. Again; stakeholder meetings allow for structured input and feedback into the initiative/product processing before final implementation. Furthermore; stakeholder meetings enhance broader and inclusive participation on the initiative/service/product important for ownership and sustainability.

David Black Kamkwamba

Executive Director, Network of Journalists Living with HIV; Chairperson :
CSO Advocacy Forum on HIV and Related Conditions - Lilongwe

Edward Moses – Maikhandanda Trust



Way to go. This should be done for all research projects

Edward Moses

Director of Programs, MaiKhanda Trust - Lilongwe

My Perspectives

- Despite doing research since 2006, I have never had the opportunity previously to hear the input of community stakeholders in Africa
- I learned the stakeholders were really interested and engaged and wanted to contribute to our work
- The stakeholders were incredibly motivated to support the study- they wanted partnership.
- The “context” in each country was really different with some countries eager for the research, and others advocating for access as well



“The Terminator” from Malawi

Conclusion

- There was broad support for Deliver and B-Protected
- Well-designed stakeholder meetings foster understanding between community and researchers
- Stakeholders can positively influence important aspects of a study design. Stakeholder engagement makes the research better.
- Stakeholders want to be involved well before implementation
- Community leaders can influence community members participation
- Important to adapt the agenda to suite needs and context- local speakers, local issues, local partners

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International Community
of Women Living with HIV
Eastern Africa



THE WHITE
RIBBON
ALLIANCE
HEALTHY MOTHERS
HEALTHY WORLD

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