

The 12th Annual National Research Ethics Conference

Community Engagement in Protocol Design, Defining Objectives, Implementation, and Study Outcomes: MTN-042 as a case study

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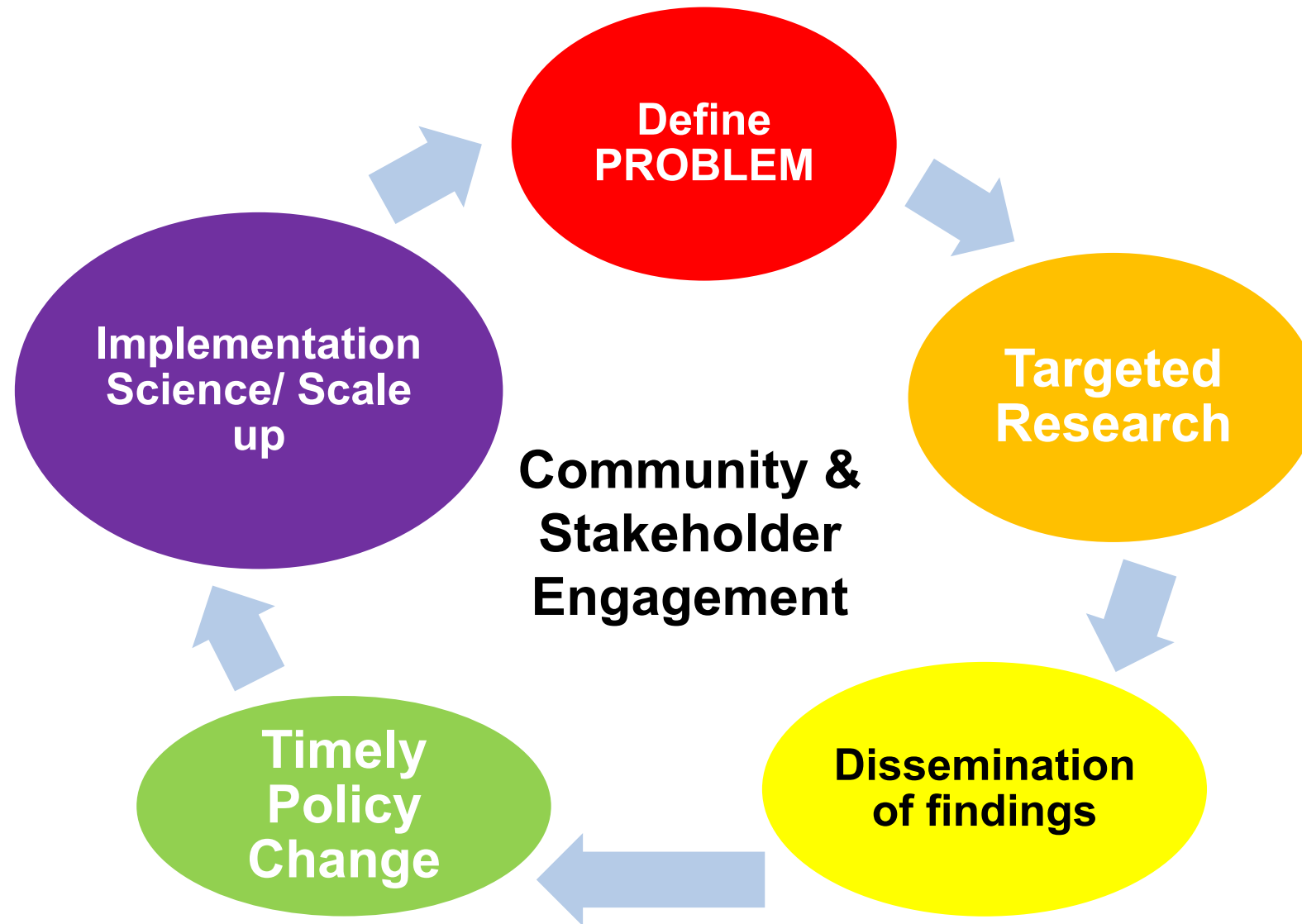
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About MTN-042/DELIVER

- Was a phase 3b, Randomized, Open Label Safety Trial of Dapivirine Vaginal Ring and Oral TRUVADA® Use in Pregnancy.
- Aimed to evaluate the safety, adherence, and acceptability profiles of two HIV prevention methods—monthly Dapivirine Vaginal Ring (DVR) and daily oral Truvada in HIV-uninfected pregnant women.
- Used a stepwise approach to dosing across three cohorts based on gestational age at enrollment: Cohort 1 (36 0/7–37 6/7 weeks), Cohort 2 (30 0/7–35 6/7 weeks), and Cohort 3 (12 0/7–29 6/7 weeks).

Generic Research Cycle



Who was the Community?

- **Community Advisory Boards (CABs)**
 - Formal groups of local stakeholders who provided input on study design, acceptability, recruitment strategies, and implementation.
- **Potential and enrolled participants' communities**
 - Women of reproductive age and their families in the catchment areas where MTN-042 was conducted
- **Local health care providers and clinic staff**
 - Mulago National Referral Hospital & Kawempe National Referral Hospital
- **Community leaders and local stakeholders**
 - District health officers, traditional and religious leaders, women's group representatives, and staff from Community Based Organizations
- **Community-based health-care providers**
 - Kampala Capital City Authority Health centres, Village Health Teams (VHTs), Traditional Birth Attendants (TBAs)

Who was the Stakeholder?

- **Policy Makers**
 - WHO, MoH, UNAIDS
- **Regulatory Authorities**
 - IRBs& NDA, *UNHRO*
- **Civil Society Organizations**
 - AVAC, White Ribbon Alliance, ICWEA, UNASO, RHU & Community Based Organizations
- **Media**
 - Reporters, Social media

Determining community needs

- Before the trial, the MTN-041 (MAMMA) study explored community attitudes toward the vaginal ring and oral PrEP in pregnancy and breastfeeding.
- The study was conducted in Malawi, South Africa, Uganda, and Zimbabwe, the same countries where MTN-042 (DELIVER) would later take place.
- Participants included:
 - Male partners
 - Mothers and mothers-in-law
 - Community leaders
 - Healthcare providers
- Findings highlighted that women were at high risk of HIV, emphasizing the need for multiple prevention options.
- Acceptance of interventions was strongly influenced by:
 - Healthcare provider support
 - Male partners and in some cases, mothers/mothers-in-law

Involving the community in the design of a trial

- In April 2018, the Microbicide Trials Network (MTN) and AVAC convened high level stakeholders from Uganda, Malawi, South Africa and Zimbabwe.
- The meeting was a two-day regional consultation in Johannesburg and it focused on the design of the MTN-042 Protocol.
- Prior to the consultation, AVAC organized a preparatory session for civil society participants.
- The consultation brought together 35 experts from all four sites in:
 - Bioethics
 - Maternal and infant medicine
 - HIV prevention clinical trial design
 - Regulatory affairs
 - Community engagement



The regional **Stakeholders Consultation on MTN-042** ensured that stakeholder feedback could shape the study's scientific framework and design.

Participants from Uganda

Charles Olaro	Ministry of Health, Director Clinical Services
Dr. Clemensia Nakabiito	MU-JHU Research Collaboration, Site Investigator of Record
Olive Sentumbwe-Mugisa	World Health Organization, Family Health and Population Advisor
Beth Mutumba	Uganda National Council for Science and Technology, Science Officer-Research Registration, Clearance and Analysis
Evelyn Nabunya	Mulago National Referral Hospital, Clinical Head Directorate of Obstetrics and Gynaecol
Doreen Birabwa-Male	Mulago National Referral Hospital, Deputy Executive Director
Donna Kusemererwa	National Drug Authority, Secretary to the Authority
Henry Mugerwa	Joint Clinical Research Centre, Head of Research and REC Representative
Lillian Mworeko	International Community of Women Living with HIV Eastern Africa (ICWEA), Executive Director

Consensus Reached

- General agreement was more data is needed to support the safety of oral PrEP!
- General agreement was that the Dapivirine ring should be studied among pregnant women!

Recommendations from the Johannesburg consultation

- Study messages to emphasize the need to offer HIV protection to women during pregnancy and ensuring that their babies are born healthy.
- Transparent and truthful communication about the risks and realities of pregnancy; that serious complications are a possibility — **study or no study**.
- Continuous Stakeholders engagement throughout the study, especially before and after interim safety reviews.

Recommendations	Yes	No
Inform Participants enrolling of study results from previous studies	√	
Follow up infants up to 1 year	√	
Collect background pregnancy outcome data from the participating hospitals – birthed MTN 042B	√	
Consider restricting enrolment to >21 years old		×
Facilitate autopsies	√	
Adopt standardized definitions for pregnancy complications	√	
Provide oral PrEP to mothers 6-week post partum		×
Include African experts in the Interim Safety Review	√	

Shaping the Implementation approach of the MTN 042 Study

MTN-042/043 Stakeholder Meeting at MU-JHU on **17th – 19th June 2019** with 64 participants

- AVAC
- Policy Makers
- Regulators Including UNHRO
- Community Advisory Board
- Community members (representatives of the broader community)
- Civil Society Organizations (CSOs)
- Community Based Organizations (CBOs)
- Former Study Participants



In-country stakeholder meeting group photo
June 2019



Sharon Hillier
Principal Investigator,
Microbicide Trials Network



Katie Bunge
Protocol Chair, DELIVER
(MTN-042)



Clemensia Nakabiito
Site Investigator of Record
MU-JHU Research
Collaboration



Phionah Kibalama Ssemambo
Study Coordinator, MTN-042 (DELIVER)



Ice Breaker Session



Margaret Happy, International
Community of Women Living with HIV



Stakeholder examines the briefs
www.mujhu.org



Olive Sentumbwe-Mugisa, WHO
Highlights- June 2019



Breakout session

Key Discussions

- **Grounding the Study in Local Context**

Sessions on HIV risk in pregnancy and breastfeeding and maternal/infant outcomes in Uganda provided scientific and contextual framing. This ensured the study design and implementation would reflect real health priorities and realities in Uganda.

- **Building Understanding of the Intervention**

Presentations on PrEP and the dapivirine ring (including what is known and unknown in pregnancy/breastfeeding) equipped stakeholders to engage meaningfully. This prepared them to raise informed concerns and recommendations about feasibility, safety monitoring, and counseling approaches



Update on PrEP in Uganda

Dr. Herbert Kadama

National PrEP Coordinator, Ministry of Health



The Research Review Process

Ms. Beth Mutumba

Clearance and Analysis Officer, Research Registration
UNCST



Complications of Pregnancy and Maternal/Infant Outcomes in Uganda

Dr. Annette Nakimuli

Head of Department, Obstetrics and Gynecology,
Mulago National Referral Hospital

- **Elevating Community Perspectives**

Voices from the MTN-041 (MAMMA study) were shared, along with interactive discussions about different views on pregnant women using PrEP and the ring. This directly shaped how researchers would approach recruitment, informed consent, and community engagement for MTN-042.



- **Clarifying Decision-Making Processes**

Session titled “Whose opinions matter? Who decides?” addressed how ethics committees, regulators, and community members influence trial approvals. This reinforced the need for transparency and inclusion in decision-making structures for MTN-042.





- **Strengthening Communications & Messaging**

Dedicated sessions on messaging around pregnancy complications encouraged participants to co-develop strategies for clear, culturally appropriate communication with trial communities. This was critical for recruitment, retention, and trust-building.



- **Practical Next Steps for Implementation**

Closing sessions asked participants to report back, share candid feedback, and outline next steps. This ensured local partners (MU-JHU and others) were not just consulted, but actively involved in shaping protocol finalisation, country-level rollouts, and ongoing community engagement.

Recommendations from the In-country consultation

- Joint review of the protocol by IRBs to avoid delay in approvals.
- Intensive sensitisation of health workers within the areas of recruitment / Provide study information sheets.
- Sensitise study participants of all possible congenital abnormalities.
- Partner Involvement – very critical in research ++++
- Disclosure – very important +++
- Consider offering the necessary medical care for the participants
- Rigorous safety monitoring

Pre-Study Implementation

- Sensitization meeting with Kawempe National Referral hospital staff & Obstetrics & Gynecology Department about MTN-042.
- Sensitization meetings with staff of KCCA health centers and surrounding catchment area facilities where women may seek care before reaching Kawempe.
- Community stakeholder meetings in communities where participants came from.

Study Rollout

Continuous broader community education by:

- **Re-engagement with the community based on the enrolling cohort at the time that helped with the actual referral of potential study participants**
 - ☐ To avoid community resistance and gather support in participant recruitment
- **Solicited community male partner involvement as suggested by the women who were being identified for study participation**
 - ☐ His baby
 - ☐ MTN-041: Male partner ranked highest influencer during pregnancy and breast feeding

Study Rollout

- Continuous sensitization of Private Community Health Workers & TBAs about the study
- Study specific education video projected in the Antenatal Clinics for information about the study

MTN-042 Study Education video



Dissemination

Study findings were shared via community forums, posters, and other accessible formats to ensure results reached participants and wider communities.



CAB and Contact Persons
Dissemination Meeting 2023

www.mujhu.org



CAB chairperson, Vincent Sserunjogi
Dissemination Meeting 2023



Bukedde Morning Show
Media Dissemination 2023



MTN-042 and MTN-043 Results Dissemination at Kawempe HRH
March 2023

Challenges & Opportunities

Challenges	Opportunities
Unrealistic expectations of immediate benefits from the community	Continuously engaging the community creates trust and transparency
Cost and limited resources	Account for community engagement activities during the budgeting process
Cultural sensitivities around pregnancy & HIV	Empowered women as advocates for HIV prevention within their communities
Regulatory delays due to novel interventions	A joint review by IRBs/ethical committees was conducted, bringing reviewers together at one table to discuss and agree on the way forward

Impact of Community Engagement on the MTN-042 Study

- High recruitment and retention rates (up to 98%) through local engagement strategies
- Strengthened ethical integrity, cultural relevance, and community ownership of research
- Community feedback shaped study design, consent processes, and messaging
- Findings informed national guidelines on HIV prevention for pregnant women

Lessons from Stakeholder Engagements

Actively involving Key stakeholders & Key influencers in research protocols enables researchers to:

- Obtain a comprehensive protocol
- Establish a strong research support system
- Smoothens the research review process
- Implementation of the protocols is well informed
- Sets ground for advocacy
- Enables the communities to own the research

When you plan a consultation meeting remember...

- Get stakeholders to the table early
- Do not confuse an update with a consultation
- Include the right people and spotlight community voices
- Put everyone in the room on equal footing
- Encourage discussion and questions with new meeting practices
- Commit to ongoing stakeholder engagement
- Action recommendations from stakeholder consultations

Acknowledgements

- Our Communities and Stakeholders
- The MU-JHU Community Team and MTN-042 Staff at MU-JHU
- ANREC Organizers
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Thank You!

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