



“HOPE: CONSIDERATIONS FOR COMMUNITY ENGAGEMENT IN OPEN LABEL EXTENSIONS”

MU-JHU Kampala Site-ASPIRE Meeting

MTN Regional Meeting

Cape Town

05/October/2015

ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use



INTRODUCTION



- Communities play an important role in research trials from protocol input, community preparedness, implementation and results dissemination
- Involving communities through community engagement activities is crucial for successful study execution

COMMUNITY MESSAGING ABOUT OLE TRIALS IN GENERAL



- Definition of OLE
- Why OLE trials?
- Design of OLE trials
- Feasibility of OLE
- Who is eligible?
- Examples of OLE trials done
- Community role in OLE trials

HOPE AND DAPIVIRINE RING

- Community Messaging includes;
 - ✓ Recap of ASPIRE study
 - ✓ HOPE study-continued safety and adherence objectives
 - ✓ More data on resistance-Are there concerns
 - ✓ Who is eligible to enroll
 - ✓ Reason for monthly & quarterly schedule-mimicking “real world scenario”
 - ✓ Possible drug licensure



ACTIVITIES DONE SO FAR



- Held staff meeting (28 May 2015) to plan ahead after ASPIRE close out
 - ✓ Trained on HOPE study
 - ✓ Brainstormed on how to retain ASPIRE participants, how to hold the family planning workshops, community education and sensitization on FP & research in general
 - ✓ Debate - “*Does PrEP work, are we ready*”
 - ✓ Sustaining staff cohesiveness as we wait for ASPIRE results and possibility HOPE

Staff engagement workshop



STUDY CLOSE-OUT PARTICIPANT MEETINGS



- Held 4 meetings
 - ✓ Recap of ASPIRE & achievements
 - ✓ Educated participants about HOPE and what OLE means
 - ✓ Informed participants on continued provision of family planning and support
 - ✓ Discussed post ASPIRE participant retention strategies
 - ✓ Discussed willingness to participate in community activities
 - ✓ Appreciated their participation in ASPIRE, dance, cake cutting and appreciation



Appreciating our participants



Cake cutting



STUDY CLOSEOUT MALE INVOLVEMENT MEETING



- Held on 17 Jul 15
- ✓ MUJHU Activities
- ✓ ASPIRE milestones
- ✓ Planned HOPE study and male partner support & their roles in studies



STAKEHOLDERS ENGAGEMENT- BREAKFAST MEETING



- Held on 21 Aug 2015. (IRBs, CAB, Media, IPM representatives)
 - ✓ Overview of MUJHU Activities
 - ✓ Presentations on PROMISE&IMPAACT studies
 - ✓ ASPIRE -where we are
 - ✓ HOPE study presentations and future timeline (especially on approvals)
 - ✓ Brainstormed on possible challenges that may arise with the HOPE study

Stakeholders' Meeting



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The task at hand



The task at hand...

- ❑ In just a few months we will know whether or not the ring is effective SO we need to plan for possible success **NOW**
- ❑ If the ring is effective, our goal will be to provide former participants access to the ring as soon as possible
- ❑ We want to hear your views about the proposed open-label trials
 - These will follow **ASPIRE** if the ring is found to be effective
 - ⇒ This planned study is **MTN-025('HOPE')** for **ASPIRE** participants and will be presented by Dr Brenda Gati

ASPIRE

08/21/2015

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microbicide trials network

Panel discussion



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MEDIA ENGAGEMENT



- Dr Clemensia Attended media organized workshop on 21 Aug 15
- Messaging to media
 - Importance of research
 - Importance of media in research
 - How to communicate research findings
 - Who to contact incase of a question

Health Journalists Network in Uganda (HEJNU) workshop



COMMUNITY OUTREACHES



- We have held 4 so far. Done from where we recruited our *ASPIRE* participants. (*ASPIRE* participants as entry points)
 - ✓ MUJHU research Activities
 - ✓ Family planning education and referrals (CAT as facilitators)
 - ✓ Linked communities to local health centre FP providers
 - ✓ Sensitization on importance of research



Community outreach-landing site



08/24/2015

Training on family planning methods in the community



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Demonstrating Female Condom in the community



FAMILY PLANNING GROUP DISCUSSIONS



- ❑ Invited former ASPIRE participants
- ❑ Have held 4 discussions at the site (CAT as facilitators)
- ❑ Followed with provision of family planning services & referrals if need be
- ❑ Any new locator updates obtained

CAB MEETINGS



- Held 3 meetings
 - ✓ ASPIRE milestones & close out
 - ✓ HOPE study-OLE
 - ✓ Dissemination strategies for ASPIRE results
 - ✓ Challenges for HOPE accrual

Planned activities for HOPE



- Following results dissemination, we plan to also contact the following stakeholders like;
- IRBs----for HOPE Approval
 - M.O.H—Policy implication of results
 - U.A.C—Advocacy
 - NDA---Importation & LICENSURE of the ring
 - UNAIDS&WHO—Policy and Advocacy
 - MEDIA---Advocacy
 - CAB---How to engage the community for HOPE

OLE CHALLENGES & SOLUTIONS



- Messaging about partial efficacy
 - *Work with community partners, activists, CAB in collaboration with Lisa Rossi on communication materials.*

- Temptation to share active product
 - *Counseling and community sensitization during HOPE trial*

CHALLENGES CONT'D



- Community demand for the ring before licensure & non ASPIRE participants wanting to join HOPE
- *Involve the stakeholders ,media ,community activists, to sensitize the public*
- Resistance concerns especially with regulatory bodies
- *Make use of previous OLE study experiences such as Partners PrEP*

CHALLENGES CONT'D



- RING study(IPM) continuity compromised
- *Educate the communities & close contact with RING study team for discussions*
- Behavioral disinhibition
- *Ongoing community education & counseling*
- Domestic violence due to non disclosure as a result of participants having more rings at home
- *Encouraging disclosure during counseling*

CONCLUSION



- The site has engaged in a number of activities in preparations for ASPIRE results dissemination and OLE(HOPE) trial.
- More activities & considerations are underway as we receive updates and guidance from Protocol teams(ASPIRE,HOPE,RING study)

Thank You



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