“HOPE: CONSIDERATIONS FOR COMMUNITY ENGAGEMENT IN OPEN LABEL EXTENSIONS”
MU-JHU Kampala Site-ASPIRE Meeting
MTN Regional Meeting
Cape Town
05/October/2015
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
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

A Study to Prevent Infection with a Ring for Extended Use
Panel discussion
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
Training on family planning methods in the community
Demonstrating Female Condom in the community
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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