

UNEXPECTED COMPLEXITY OF TRACING PARTICIPANTS FOR AN OPEN LABEL EXTENSION (OLE) Trial

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Presentation Outline

- Introduction
- Tracing process – MU-JHU experience
- Results
- Challenges
- Conclusion
- Acknowledgement



Introduction

- OLE trials are conducted to;
 - Provide access to efficacious products
 - Understand better the factors of adherence, acceptability, safety etc. in context of known efficacy
- MTN025/HOPE, IPM032/DREAM are examples of such trials
- Time between end of efficacy trial and start of OLE may have impact on accrual



MU-JHU Tracing Experience for HOPE

- Mar 2016 – realization that HOPE will take place
- Jun 2016 – Durban meeting
- Jul through Aug – 5 participant engagement workshops
 - Inform them about HOPE
 - Difference between HOPE and ASPIRE
 - Introduce concepts of **CHOICE, ADHERENCE and OPEN REPORTING**
 - Obtain current contact information
- Jul thru Aug – 10 community engagement workshops
 - Disseminate ASPIRE results
 - Inform them about HOPE study

Accrual/Tracing process (1)

- Recruitment Tools
 - Contact Log
 - Recruitment Log
 - Pre-screening Checklist
 - ASPIRE Locators
 - Attendance lists with participants contacts form Pre-HOPE Engagement workshops
- Site Activation occurred 05 Nov 16(16months)



Accrual/Tracing process(2)

- 242 potentially eligible former ASPIRE participants assigned to our site
- Community educators randomly distributed ASPIRE PTID lists amongst themselves (4)
- Each was tasked to contact at least 4 participants on weekly basis--accrual targets
 - Weekend calls
- Screening visits scheduled based on clinic workload



Accrual/Tracing process (3)

- Several tracing approaches used;
 - Phone calls
 - Home visiting using ASPIRE locator maps if phone contacts unsuccessful
 - Use of former ASPIRE participants
 - Use of HOPE study staff
 - Community contact persons

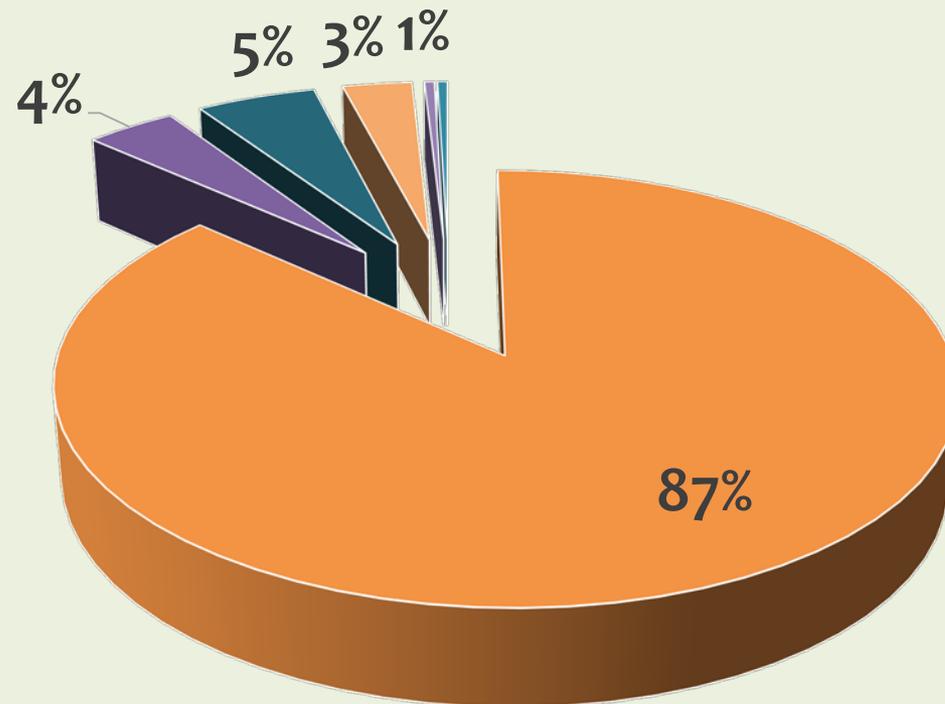


Results(1)

- Successfully contacted 227 of 242 (94%)
 - Successful phone contacts – 197
 - Home visits – 9
 - Through fellow participants –12
 - Through HOPE staff – 7
 - Opportunistic accrual – 1 (had come for FP)
 - Community Contact person – 1
- Totally failed to contact – 14
- Did not give PTC – 1
- All successful contacts had prescreening checklist administered

Results (2)

- Successfully contacted 227 of 242 (94%)



Home contacts
HOPE staff

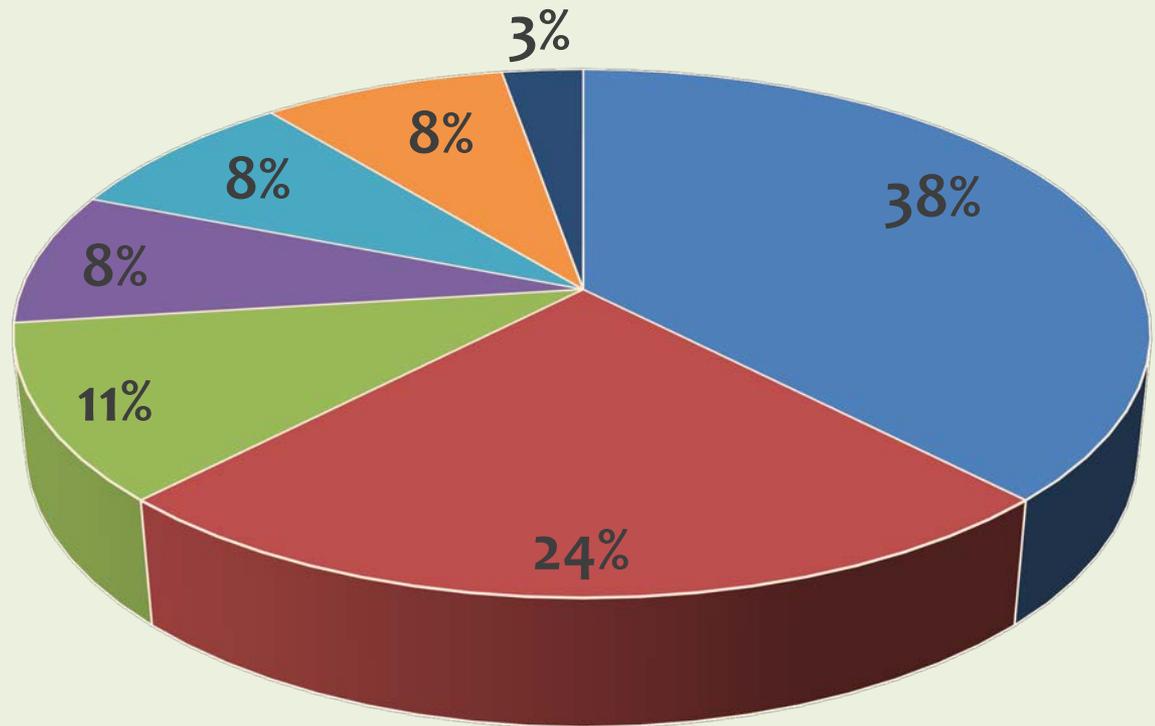
Home visits
Opportunistic

Participants
Community

Pre screening failure reasons

- Total – 38 (never came for screening)

- B/Feeding
- Not Interested
- Pregnant
- Intends to Conceive
- Not Willing to use FP
- Relocated
- HIV Infected



Screening Enrol Status(15 Sep 17)

- Total screened--189
- Enrolled (72%)
 - Main study –171
 - Decliner – 4
- Screen out reasons
 - Out of window (7)
 - HIV infected (2)
 - Refused by mother (1)
 - IoR discretion (1)



Challenges

- Relocations (Oman, Dubai)
- Many pregnant, breastfeeding..
- Change in phone contact, locator information
- Network/connectivity issues
- Convincing women to wait for their turn
- Participants not keeping appointments
- May 2017 saga—all unregistered phones to be switched off....



In conclusion

- Accrual for OLE requires multifaceted approach given that people are not static
- Starting early to sensitize potential participants for possible OLE is crucial
- Good coordination, TEAM work are paramount
- Never give up – go extra mile!



Opportunistic engagement



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