HOPE: Adherence and Accountability

Kalendri Naidoo
On behalf of the eThekwini CRS
MTN Regional Meeting 2015
Background

- Adherence to Pre-exposure Prophylaxis: Current, emerging and anticipated bases of evidence, K Rivet Amico and Michael J Stirratt, Clinical Infectious Diseases, July 2014

- Limited data on patterns of adherence in OLE studies

- Current evidence cannot yet predict uptake, adherence, or persistence with open-label effective PrEP.

- Emerging evidence suggests that some cohorts could execute better adherence in OLE studies vs RCT’s.

- Focus on personalized prevention plans and overall health and well being in OLE studies
"My diabetic research shows that test subjects are 98% more likely to take their diabetic pills if the pills are covered in chocolate."
Key Messaging for HOPE

- Product sharing
  - Product sharing will be discouraged and some key messages listed below.
  - The ring is not licensed as a preventative method against HIV
  - Reminders of the eligibility criteria for HOPE.
  - If product is shared with non-study participants, they will not have the benefit of the safety screening and monitoring participants have access too.
  - Non-study participants will not be accessing regular HIV testing and the ring may not be safe in people that are not having regular HIV testing whilst using the product.
Key Messaging for HOPE

- Changing of the ring on a monthly basis
  - The importance of using reminders to change the ring on a monthly basis will be emphasised.
  - Contact study staff if they experience any challenges
  - Encourage reporting of plans to be away from the study site which may interfere with clinic visits
Key Messaging for HOPE

- Product accountability

  - Encourage returning the used rings at clinic visits
  
  - Reporting if product was expelled and lost to study staff
  
  - Create a sense of responsibility by advising participants that the responsibility will lie with them to return the used ring/rings at their next clinic visit.
Key Messaging for HOPE

- Product adherence
  - Levels of the drug in the blood and used rings will be monitored.
  - Real time PK feedback could have a positive or negative outcome.
  - Encourage consistent ring use.
  - Contact study staff if they experience any challenges
  - Have discussions with participants when the ring looks unused, is she experiencing any challenges?
**Key Messaging for HOPE**

- Product adherence
  - Limited counselling and support as these are women that are familiar with the product but a focused, structured counselling should be done which may be geared towards incorporating the use of the product into the participants daily life.
  
  - Adherence support groups / social clubs / big sister models?
  
  - Participants that seroconvert may influence other participants negatively ie product does not work, or stop using the product as it causes HIV. To avoid these issues, more attention and support must be provided to seroconverters during implementation.
Key Messaging for HOPE

- Product adherence
  - Pharmacy staff to provide a quick counselling session when dispensing study product (depending on visit flows and site capacities) in keeping with the more “real world” approach.
  - The counselling by pharmacy staff should be complemented with counselling by clinic staff.
  - The Use of Mobile technology and Social Media as a tool for enhancing adherence
Key Messaging for HOPE

- Condom use
  - Dual method of protection will still be emphasised.
  - The need for prevention against STI’s, pregnancy as well as HIV infection.
  - Invite male partners to the clinic if the participant is agreeable to discuss the partial effectiveness of the ring and the need for condom use. ? Continue with male involvement workshops
Acknowledgements

- CAPRISA Ethekwini Staff and Participants

- CAPRISA was established as part of the Comprehensive International Program of Research on AIDS (CIPRA) of the National Institutes of Health (NIH) (grant # AI51794)

- MTN is funded by: NIAID (3UM1AI068633), NICHD and NIMH, all of the U.S. National Institutes of Health
Thank you!

CAPRISA Ethekwini - Team Building