Experiences in the implementation of IMPAACT studies

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Presentation Outline

- Network Overview
- Study Overview (HPTN 057)
- Roles and Responsibilities of the Clinical Research Site (CRS) in the study implementation
Network overview

- The International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) was organized for the purpose of evaluating potential therapies for HIV infection and its sequelae in the infant, pediatric, adolescent, and pregnant women populations.
Network overview

- IMPAACT was formed through a merger of investigators from the Pediatric AIDS Clinical Trials Group (PACTG) and the Perinatal Scientific Working Group of the HIV Prevention Trials Network (HPTN/HIVNET).
IMPAACT Mission Statement

- To decrease significantly the mortality and morbidity associated with HIV disease in children, adolescents and pregnant women.
HPTN 057 study

- A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate (TDF) in HIV-1 Infected Pregnant Women and their Infants

- Purpose
  - To evaluate the safety and pharmacokinetics of (TDF) administered to HIV infected pregnant women during labor and to their infants during the first week of life

- Design
  - Phase I, open label, non-controlled trial
  - 10 mother infant pairs were enrolled and followed up for 12 months post delivery
  - Study site: 1 site in Malawi, 4 sites in Brazil
Clinical Research site was responsible for:

- enrolling the right participants into the study,
- retaining them,
- obtaining excellent quality data and
- maintaining the community support
Study implementation

• These were partly achieved by:
  • Information dissemination
  • Education
  • Advocacy
Information dissemination

- Community sensitization sessions were held throughout the study targeting public places e.g. market places, churches, clinics...

- Men were specifically targeted (whistle stops)

- Holding sensitization meetings with stakeholders including health workers
Advocacy

- Study staff were continuously reminded of the informed Consent process in weekly protocol meetings

- Participants were encouraged to talk to CAB members with any issue that they may have and may not be comfortable to share with site staff

- Bi-monthly meetings with CAB were held to share site experiences with CAB and stakeholders and buy their ideas

- Identification of barriers to accrual and retention, and share information with protocol teams, site, CAB and stakeholders
Education

- Reminding CAB members on PMTCT, research processes, and their roles and responsibilities during trial implementation phase

- Continuous dialogue with CABs and stakeholders on study progress, other studies at the site and other relevant studies

- Continuous consultation with CABs, stakeholders and community at large on concerns raised by participants and any resulting changes in study procedures
Results

- Approached: 9307
- Screened: 239
- Enrolled: 72 Pairs (17 for Brazil)
- Retained: 72 pairs
Lessons Learnt

- Continuous Community Involvement during study implementation is as important

- Research literate community is vital to study success

- Well informed participants are easily retained

- Consultation is a magic bullet (participants, Staff, IRBs, Stakeholders)
Acknowledgements

- Study Participants
- Blantyre CAB
- IMPAACT
- Blantyre site staff
- HPTN
Thank you!