Clinician Breakout

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Clinician breakout sessions

• Clinician’s role in recruitment, retention & product adherence
• Role of PSRT in safety monitoring
• Adverse events Reporting session
• Session on preparation for MTN 015
Clinician’s role in recruitment, retention & product adherence

Objective

• To enhance the role of clinicians in study recruitment, retention & product adherence

Recruitment

• Incorporation of the male involvement agenda right in protocol budget development processes, at community entry for new protocols & thru trial implementation
  o Identification of key stakeholders for stimulating dialogue on microbicide research
  o Developing site specific strategies for engaging & motivating men coming to study clinic visits (Male peer group concept)
  o Male involvement is key for microbicide success
Recruitment

• Monitoring recruitment efforts for high risk women very critical
  
o Sites resolved to adopt the GPS system (Durban) or some less sophisticated community mapping techniques
  
o Pay particular attention to HIV incidence as a way of monitoring appropriateness of recruitment efforts (avoid getting lost in the bigger picture)
Retention

• Participant retention meetings (Harare)
  o Involving participants in finding solutions to major retention challenges

• Partners’ meetings.

• Ongoing community sensitization meetings.
Product adherence

• Little things make a big difference for both retention & adherence

• Always keep your eyes open & ears to the ground (participant meetings enhance process)

• Use small surveys (e.g. FGD’s) to more understanding of reasons behind poor product adherence (tote bag example in Lilongwe only came to site’s attention thru such surveys)

• Returning used applicators (for future trials) enhances reporting/accountability & may enhance adherence (Blantyre site using approach)
Adverse Events Reporting session

• Standardization of approach to reporting lab AE’s which turn out to be lab errors
  o Resolve AE versus deleting it
  o Repeating the labs as soon as possible was preferred

• Reporting abnormal labs closely related to defined clinical condition as separate AE’s will continue to dependent on clinicians judgment of extent of association
  o Malaria & low Hemoglobin

• Need to align reporting requirements with clinical judgment
  o Abnormal PAP smears followed with histological confirmation
PSRT session

• Sites generally happy with response process & timeliness

• Need to create/enhance use of FAQ for common PSRT queries (reduces frequency of engaging PSRT)

• Sites noted that there might be need to share safety information for studies of same product (not just DSMB findings as is case with MDP 301 & #035)
  o Feasibility of using DAIDS toxicity tables for studies of same product
  o Having similar safety review process studies of same product
MTN 015 session

Key challenges

• some ethical boards may require pregnant sero-converters to have more than local standard of care for PMTCT (combination therapy preferred to mono-therapy)

• Infants of sero-converters who test HIV positive
  o suggestion to explore options for inclusion of sero-converters into other ongoing protocols at sites CHAVI, ACTG etc)