Community Session Report Back

MTN Regional Meeting

Cape Town, South Africa

May 23 -24, 2007

I don't want to die before I turn 25.
I refuse to sit down and watch my generation fall to pieces.
I am going to make a difference…Will you?
Rumbidzai Grace Mushangi, age 15, Zimbabwe

Community Team

CAB members

Francis Mbawa	Malawi
Betty Tumushabe	Uganda
Rosemary Chitagu	Zimbabwe
Christine Ndapisha	Kampala
Tabisa Gqwangu	South Africa
Talent Hlongwa	South Africa

Community Team

Community Educators/Staff members

Mise Ngcozela	South Africa
Modesta Z Chileshe	Zambia
Jacenta K Shilimi	Zambia
Liness Mwafulirwa	Malawi
Daniel Gondwe	Malawi
Teopista Nakyanzi	Uganda

Community Team

Community Educators/Staff members

Emilder Tazvivinga	Zimbabwe
Engeline Murindamombe	Zimbabwe
Sibusio Nhleko	Hlabisa, SA
Neetha S Morar	Durban, SA
Yvonne Makala	Malawi
Phaleda Kumwenda	Malawi

Community Team

Facilitators

Rhonda White and Morenike Ukpong

MTN Core

Sharon Hillier, Byrna Harwood, Nancy Connolly, Lisa Noguchi, Ian McGrowan

Site PIs

David Coetzee, Mike Chirenje, Alana de Kock

SCHARP

Karen Patterson & Ben Maise

Community Team

- Roberta Black   NIAID
- Jeanna Piper   NIAID
- Andrew Forsyth   NIMH
- Nancy Padian   UCSF
- Pamina Gorbach   UCLA
- Sheila Clapp   FHI
- Manju Chatani   AMAG

Community team

- Luci
- Jonathan Baun
- Lisa Rossi
- Brad Tytel
- Victor

Outline

- Aim of session

- Content areas and outcomes:
  - Overview of MTN & Community Program
  - Safety of trial participants in MTN
  - Community Participation in Concept and Protocol Development
  - Community view on MTN 003
  - Communication and media training

- Way Forward

Overall Aim of Session

To build MTN Community Working Group's (CWG) capacity to provide support for the MTN science and research processes

Outcomes

- Active community partnership and involvement in MTN was highlighted
- Role of community in reporting safety of trial participants was outlined
- Understanding protocols and concepts and development process at MTN
- Implementing MTN 003 in Africa : challenges and opportunities
- Communication, media and messaging training for community staff

Overview of MTN & Community Program

Objective

To describe the MTN, its Community Program and its goals

Overview of MTN & Community Program

MTN CWG

- EC Community Liaison
- FHI Core Community Program staff
- 1 community educator and 1 community CAB representative from all CTU - MTN trial sites
- EWG representative
- GCM (US) and AMAG (non US) representatives

Overview of MTN & Community Program

New MTN CWG – Outcomes

CWG will ensure there is community-researcher partnership models that facilitates community preparedness and engagement activities by:

- Cross-networking and partnership: DAIDS and other funded networks.

- Engagement of relevant stakeholders on the CWG

- Monitor, assess & document community research output at trial sites

Overview of MTN & Community Program Key Discussion

- MTN structure - to ensure active and accountable community involvement and participation at site/CORE level

- Voluntarism of community representative required to implement systems in place

- Resources - site budgets, Network training and support

- Timing and efficiency of community input – meet timelines

- Challenge - efficiency vs. inclusiveness

What Does Safety Mean in the MTN?

Objective

To explain the processes the MTN has developed to monitor participant safety throughout the research agenda

What Does Safety Mean in the MTN? Key Discussion

- DAIDS process of adverse event reporting, monitoring and follow up was described
- Role of the community teams in assisting with safety of participants and reporting social harm and events reported by male partners was highlighted
- Community teams must report field events to site PIs/IoRs
- Action
  - DAIDS safety reporting SOP must be integrated with site reporting SOP
  - Site PI/IoR to train community staff on their role in adverse event reporting and documentation process

Community Participation in Concept and Protocol Development

Objective

To outline the MTN's protocol development and approval process and discuss plans for ensuring community participation in the process by identifying potential barriers and proposing possible solutions

Community Participation in Concept and Protocol Development
Key Discussion

- Process - community input at site level on MTN 003 at concept phase

- Challenges - access to funding to contact community members, PI availability, resources to explain design concepts

- Action
  - Sites to send resources needs to CWG and site PIs
  - Skills building programme on protocol review planned by CWG for Thursday – pilot session
  - Site training needs to be submitted to CWG and PIs as these occur

MTN-003…
What is it? What are our questions/concerns/suggestions for improvement? How will our communities react to the study?

Objective

To explain the proposed design of MTN-003, why this could be a pivotal study in the microbicide research agenda and to engage in discussion regarding concerns, suggestions for improvement and anticipated community reactions

MTN-003…
Key Discussion

- Concept to be presented to NIH & other partners on 27th June 2007

- Community preparedness will start in 2007

- Community input in the protocol process will begin at version 0.1

MTN-003…
Key Discussion

4 questions

- Do we need to study both products or test one product

- Is it acceptable to do monthly HIV testing?

- How extensive will drug sharing and drug selling?

- How would participants respond if they are randomised to gel vs. tablet

MTN-003…
Key Discussion

- Sharing of drugs - gel vs. tablets
  - Some populations – habitual to share chronic medication thus may occur in the MTN 003
  - STI treatment shared in the community
  - Patients share ARTs
  - Drug sharing - common in many populations
- Strategies
  - Engage the community and explain study objectives
  - Develop/adapt counselling guides on drug sharing for participants
  - Explore preference of drugs in terms of community needs
  - Community may be engaged regarding not sharing drugs

Media Training for Community Staff and Representatives

Objective

To practice basic communications and messaging techniques for interacting with the media

Media Training for Community Staff and Representatives

- Partnership

- Experiences

- Challenges

- Key Messages

Skills Building Session: How to Review a Protocol and Provide Feedback

Objective

- To examine CAB responsibilities

- To review and explain information located in each section of a protocol

- To identify sections of the protocol where community input should focus and identify sections where community input might not be provided

Skills Building Session: How to Review a Protocol and Provide Feedback, continued

Objectives

- To brainstorm and develop questions to assist in reviewing a protocol

- To practice providing constructive feedback

- To evaluate responsibilities of members of the protocol development team for ensuring community involvement in protocol development and determine operational feasibility at the site-community level

THANK YOU