



Community Issues And Needs Associated With Microbicides Clinical Trials

Presenter:

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What is community participation?

- **Participation includes individual's active involvement in decision-making processes, in implementing programmes that improve their health, their sharing in the benefits of research and their involvement in efforts to evaluate such research.**
- **It is a process/continuum – moving from tokenism --- consultation --- real partnership and collaboration.**
- **Participation means, in its broadest sense, to sensitize people so as to increase their receptivity and ability to respond to health problems that affect them, as well as to encourage local initiatives.**



Why Community Participation In MICROBICIDES Clinical Trials?

- **Community participation in clinical trials serves ethical, practical and strategic ends.**
- **It increases transparency and builds trust among researchers and the communities.**
- **It can provide a way for researchers to hear and address community needs and concerns.**



Continuation...

- **It will also help explain the research to the large community and dispel any misperceptions. This can lead to the acceptability of the clinical trials and sustainability of the research efforts.**
- **By bringing together the knowledge and experience of communities and researchers, excellence in science is enhanced.**

Community Participation Continued...



- **Advisor/Consultant:** give their opinions and observations, make recommendations; have no accountability or input into what actions are taken next.
- **Partner/Collaborator:** provide their insight and are a part of the problem-solving and decision-making, as well as being a part of what action is taken.



COMMUNITY ADVISORY BOARDS (CABs)

- Participation through CABs helps individuals and their communities understand the research that is being done.



What Is A Cab?

- **A CAB is composed of individuals from communities where research is taking place. CABs are composed of lay people who are willing to learn about and understand often complex research protocols.**
- **The goal of a CAB is to bring researchers into close contact with the concerns and issues of their trial participants, both as individuals and communities.**



How CABs Are Formed: A Case Study of CABs in Epworth and Harare, Zimbabwe

- Potential CAB members were identified by:
 - Health department employees
 - Local boards (governmental authorities)
 - Community-based AIDS service organisations (ASOs)
 - Community leaders
- Initial meetings with potential CAB members were arranged to discuss the concept of the CAB and plan for its formation.



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- In Epworth, 16 individuals agreed to serve on the CAB and in Harare 14 agreed.



The two CABs finally included:

- **Local health workers**
- **Local political leaders**
- **Representatives from NGOs**
- **Religious leaders**
- **Directors of advocacy and service organisations working on women's health and HIV/AIDS**
- **People living with HIV/AIDS**
- **Youth leaders**
- **School teachers**
- **Village community workers**
- **Traditional midwives**
- **Members of the uniformed forces**



How did we prepare CAB members for active participation?

Time and resources were and still continue to be invested in training CAB members in:

- **Introductory courses on HIV prevention**
- **Clinical trials**
- **Ethics**
- **Participatory management**



Current Microbicides Awareness Activities At the Harare Site

- The study team is working closely with CABs preparing for the clinical trials.
- Two training workshops have taken place to discuss and educate CAB members and community leaders about microbicides.
- Those trained are now creating awareness about microbicides in their own communities.
- Three CAB members have been identified to represent their communities on the Microbicides (035) protocol team and two are participating on conference calls.



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- **We are planning training workshops to educate NGOs, CBOs, private and public institutions operating in the research communities about the microbicide research.**
- **We are developing a video and some educational materials that are culturally and linguistically appropriate.**



Suggestions from CAB members on improving community education:

- **Drama**
- **Community meetings with different groups**
- **Workshops**
- **Distribution of materials on microbicides**
- **Clinic-based education sessions**
- **Microbicides awareness days in the research communities**
- **Targeting people at large community events**
- **Active involvement of men in microbicides awareness campaigns**



Challenges in explaining clinical trials to the community:

- **Language poses a barrier to effective communication. For example, concepts like randomization, placebo, microbicides, and protocol are difficult to translate into local languages.**
- **Community educators must work closely with CAB members to find creative ways of explaining technical terms.**



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- **Some community members ask very challenging questions about microbicides, so community educators must be prepared for these questions.**

Examples of these questions are:

- **What is a clinical trial?**
- **What protections are there for people who participate in clinical trials?**
- **Who sponsors clinical trials?**
- **What is a placebo?**
- **What are the benefits and risks associated with clinical trials?**
- **What should I know before I join clinical trials?**
- **Would men benefit from a microbicide as well?**



Roles of a CAB Member

- **Evaluate the impact of the research studies on local communities.**
- **Provide a voice for the community and study participants.**
- **Bring community expertise to the research process.**
- **Inform the site team of local issues and concerns that may affect the research.**



Responsibilities of a CAB Member:

- **Attend CAB meetings and provide feedback on issues presented.**
- **Voice concerns from the community and study participants.**
- **Take the initiative to understand research and community issues.**
- **Assist site staff in developing and implementing community education activities.**
- **Identify members to participate in protocol teams.**



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- **Advise the site staff on the development and implementation of recruitment and retention strategies and review the final plans.**
- **Review and advise protocol team, site staff and CAB on the development of the informed consent process and other processes that directly affect participants.**
- **Serve as a source of information about HIV prevention to their communities.**
- **Help recruit and orient new cab members.**



Getting the Most Out of Your CABs:

- **For the CABs to function effectively they must continue to receive administrative support, which includes:**
 - **transportation, telephone usage, translation of education materials or other research related materials, interpretation during meetings, funds for meetings.**
- **In a true partnership, the Principal Investigators should be involved by attending community meetings and gatherings of CAB members and research staff.**
- **They should also provide funds to send CAB members to regional and international conferences/meetings**



Indicators of Community Participation in Research at UZ-UCSF:

- **CAB members participate in decision-making at community meetings and provide input on implementation of new research projects.**
- **They participate actively in protocol development and review. Sometimes they pose very intelligent questions which require us to conduct further research before providing the answer.**



Indicators Of Community Participation In The Research Process continued...

- **CAB members always request research study updates.**
- **CAB members provide suggestions for new research initiatives. For example, they have recently requested for research studies that include men.**