Managing Communication Challenges: The MMCI

Microbicides Trial Network

Lori Heise, Director
Global Campaign for Microbicides
MMCI

• Created to respond to special communication challenges posed by large-scale trials

• Includes communications officers of all sponsoring groups, key advocacy networks, and allied scientists
  – Seeking more site representation

• “Community of practice” and platform for capacity building for entire field
MMCI roles

• Creation of common resources
  – Responding to misperceptions about trials

• Crisis planning and response

• Capacity building at site level
  – Media training, communications plans

• Tracking media and correcting misinformation
Why now?

• Community or media controversy can derail a trial as easily as any scientific setback

• Transnational research is under increasing ethical scrutiny

• Once lost, public and community trust is difficult to regain

• As a field we are only as strong as our weakest link
“We will not let Cambodians be used as guinea pigs…”

Cambodian prime minister

Violent protest over drug trials

Carrying placards and chanting anti-exploitation songs, protestors held the first violent protest at the conference yesterday, knocking down the stand of Gilead pharmaceuticals which they claimed has been conducting unethical trials in some developing countries.

The demonstration, the Asia Pacific Network of Sex workers and ActUp India claims that the company is using people from the developing countries as guinea pigs in trials of its HIV drug Truvada (tenofovir disoproxil fumarate). Truvada is Gilead’s oral medication, a pill taken daily for drug workers.

The drug is being developed to delay the onset of AIDS, but some say it has side effects which could be disabilities.

“Tenofovir is powerful enough to be a potential ingredient for death,” said a protestor.

The company claims that Truvada is the most effective treatment available for HIV.

The protestors are calling for an end to unethical drug testing and for better compensation for the people involved in the trials.
Cameroon falls next
Lessons learned: Oral Tenofovir trials

- It is no longer possible to “fly under the radar screen”
- Failure to respond breeds distrust – “what are they trying to hide?”
- Proactive communication and transparency are essential
- The absence of facts and information will be filled by rumor
Lessons from N-9

- Initial framing of the findings is critical
- Avoid press conferences; reach out first to trusted known reporters

“If you use nonoxynol-9, at best you are wasting your money, at worst you are risking your life”

- UNAIDS spokesperson at N-9 press conference at the Durban AIDS conference

“Spermicide Suspected of Spreading AIDS”
Being proactive

• Anticipate information needs
  – Communication plans
  – Q & As; backgrounders

• Plan for “adverse political events” as you would for “adverse clinical events”

• Media training for key site personnel
MMCI in action:
Premature closure of CS trials

- IDMC met on Friday Jan 26 -- 35 seroconversions -- trend toward harm
- Alerted sites to stop enrolling; rechecked gel lots and codes; contacted FHI DMC
- Decision made to halt trial January 29
- CONRAD notifies PIs, local IRBs, ministry officials, regulatory authorities, key stakeholders, and MMCI crisis coordinator (Lori Heise)
MMCI holds first of many emergency calls

- Security and Exchange Commission (SEC) rules apply because Polydex is publicly traded company
- Negotiated with NASDAQ for 24-hour delay in issuing press release
- NASDAQ monitored trading activity
- MMCI members discuss and agree upon top-line messages
Who will be affected by the news?

• Women in CS studies
• Staff working on CS studies in field sites
• Host country governments, NACs, IRBs
• Participants in other microbicide trials
• Other research teams: HPTN 035, MDP
• Health advocates: NHVMAG, etc.
• Donors and bilaterals: NIH, WHO, and UNAIDS
News cycle

24 hours

For Immediate Release
January 31, 2007

Phase III Trials of Cellulose Sulfate Microbicide for HIV Prevention Closed

Arlington, VA — CONRAD, a reproductive health research organization, announced today that it has halted a Phase II clinical trial of a contraceptive microbicide that is being developed for HIV prevention. The trial was halted due to an increased risk of a severe side effect associated with the microbicide.

Commentary

The suspension of this trial is a significant setback for the development of a safe and effective microbicide. Microbicides have the potential to provide an additional layer of protection against HIV, which is critical given the current lack of a vaccine or cure. This decision highlights the need for continued research and development in this area.

Uganda: HIV Microbicide Trials Halted

New Vision (Kampala)
February 1, 2007

TNAULS of a new product designed to help prevent women from getting HIV has been halted. The product, known as the gel, was found to be ineffective in preventing HIV transmission.

Commentary

The suspension of these trials is a disappointment for the global HIV prevention community. It is a reminder that the development of new prevention strategies is not without challenges and setbacks. However, it also highlights the importance of continued investment in research and development to find effective and safe microbicides.
Media coverage:
US & Europe

• Fair, balanced coverage
• Strongly embraced top tier messages
• Reporters largely up to speed
• Appreciated swift, straightforward approach
• Story over in top tier press within the week
Negative media erupts in South Africa
Advocates’ response

- GCM/AMAG communicate with their steering committees and issue joint statement the same day as CONRAD
- Conference call held 2 days later for 45 advocates in 17 countries
- Q&A based on questions submitted by email
- Outreach to partner groups and development of possible advocacy responses
- Letter of support to site staff
What worked

- 24-hour delay in distributing release
- Communications/crisis training for PIs
- Transparency and telling the truth
- NOT having a press conference call in U.S.
- Reporter relationships
- Collaboration within MMCI
Fallout at other sites

- Created site and network-specific Q&As for use with trial communities
- How is my gel different?
- Confusion in the press about products
- Need for community meetings
- Importance of including participant confidentiality clause in the CAB terms of reference
Crisis as a learning opportunity

- Clear benefits to coordination & collaboration
- Desperately need more communications support at trial sites
- Advocates want ongoing participation in trials, not just role in damage control
- Donors need to support communications and participation of civil society as part of the research
Next steps

• Recruiting Coordinator to be located in South Africa

• Scenario planning for release of MIRA trial results and Carraguard

• Development of communications tool kit with real life examples
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- Mitzy Gafos, MDP
- Gita Ramjee, MRC
- Members of the MMCI
- IPM and the Alliance for Microbicide Development
Global Campaign for Microbicides

Check out our new website at:
www.global-campaign.org

The Global Campaign for Microbicides is a broad-based, international coalition of organisations working to accelerate access to new HIV prevention options.

What are Microbicides?
Microbicides are topical products that can reduce the risk of HIV and other sexually transmitted diseases when inserted prior to sex.

Download Materials
Presentations, briefing papers, fact sheets, and more.

LEGISLATIVE ADVOCACY
The Microbicide Development Act (MDA) was introduced in the U.S. House and Senate on March 8th, International Women’s Day

CELLULOSE SULFATE
This year both Conrad and Phl’s Phase II trials of the candidate microbicide Cellulose Sulfate were discontinued. Learn more.

MALE CIRCUMCISION
Read about male circumcision and HIV prevention.

AFRICAN ADVOCACY
Learn more about the African Microbicides Advocacy Group (AMAS).

STUDENT ADVOCACY
Get involved with Students for Microbicides (S4M)