

# Managing Communication Challenges: The MMCI

Microbicides Trial Network

Lori Heise, Director  
Global Campaign for Microbicides



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# 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



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# 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



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# 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



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# "We will not let Cambodians be used as guinea pigs..."

Cambodian prime minister



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## Violent protest over drug trials

Antonette Miday and Susan Mwangi

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

The demonstrators, the Asian Pacific Network of Sex workers and Act Up-Paris claim that the company is using people from the developing countries as guinea pigs in trials of its HIV drug Viread (tenofovir disoproxil fumarate).

verse transcriptase, an enzyme involved in the replication of HIV. The drug should only be used in combination with other antiretroviral agents in the treatment of HIV infection.

Trials to evaluate the drug are underway in Cameroon, Ghana, Nigeria and Cambodia. Participants in the study comprise uninfected women who have high-risk occupational sex and a past history of sexually transmitted infections.

"The trials are unethical," said Liz Cameroon, a protestor



Viread is Gil medication. tablet taken drug works



# Cameroon falls next



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LA NOUVELLE EXPRESSION SPECIAL TENOFOVIR

## TOUT SUR LES PROSTITUÉES COBAYES DE DOUALA

JEAN MARI TALOM

### “Le Tenofovir soulève beaucoup de problèmes”

Les projets de recherche pour le traitement ou dans la prévention du VIH/Sida se multiplient et ne ressemblent pas. L'un de ces projets concerne l'antirétroviral dénommé Tenofovir, et destiné exclusivement aux prostituées est ouvert chez nous depuis près de deux années. La Nouvelle Expression a rencontré le président du Réseau sur l'Éthique, le Droit et le Sida (Reds) qui commente ce projet d'un autre genre.

**LA PRISE EN CHARGE DEVAIT ÊTRE MAXIMISÉE**

“Il faudrait d'abord souligner en quoi consiste l'essai Tenofovir. C'est un antirétroviral qui a été utilisé jusqu'ici dans le traitement des malades du sida. C'est une molécule bien connue qui a fait l'objet de pas mal de publications. Que ce soit lors de la dernière conférence de l'Asa, ou celle tenue aux Usa. Ce que vise à montrer cet essai, c'est l'aspect préventif du Tenofovir. Parce que jusqu'ici il a été utilisé pour le traitement. Maintenant, il est question de voir si administré tous les jours, le médicament peut empêcher de contracter le virus. Cet essai a cours dans quatre pays, dont le Cameroun, le Cambodge, le Kenya, et au Nigeria. Dans ces pays les groupes ciblés sont les prostituées. 400 ont été enrôlées dans notre pays. C'est certes un projet novateur, qui va ouvrir la porte à d'autres études de même nature. Nous ne sommes pas outillés sur le plan scientifique pour discuter des éléments de ces tra-

pour toutes difficultés liées à leur santé. Mais si ces problèmes sont requièrent Ce qui nous inquiète encore ici, c'est que jusqu'à la date à laquelle nous avons ren- protéger, elles pourront éduquer les personnes de leur milieu. D'autre part, le sur une longue durée, il laisserait des séquelles sur la masse osseuse. Nous

ABOU

DOCTEUR, SI APRÈS M'AVOIR “TCHOUKÉ” TON TENOFOVIR LÀ J'ATTRAPE LE SIDA?

TU TE PRENDS EN CHARGE

TU VENDS QUAND MÊME LE “PISTACHE”!

...our hope that the study will con...

# 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



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# Lessons from N-9

- Initial framing of the findings is critical
- Avoid press conferences
- Communicate findings to trusted knowledge leaders

"If you are not a scientist, you are wasting your time. If you are not a scientist, you are risking your life"

Spokesperson at N-9 press conference at the Durban AIDS conference



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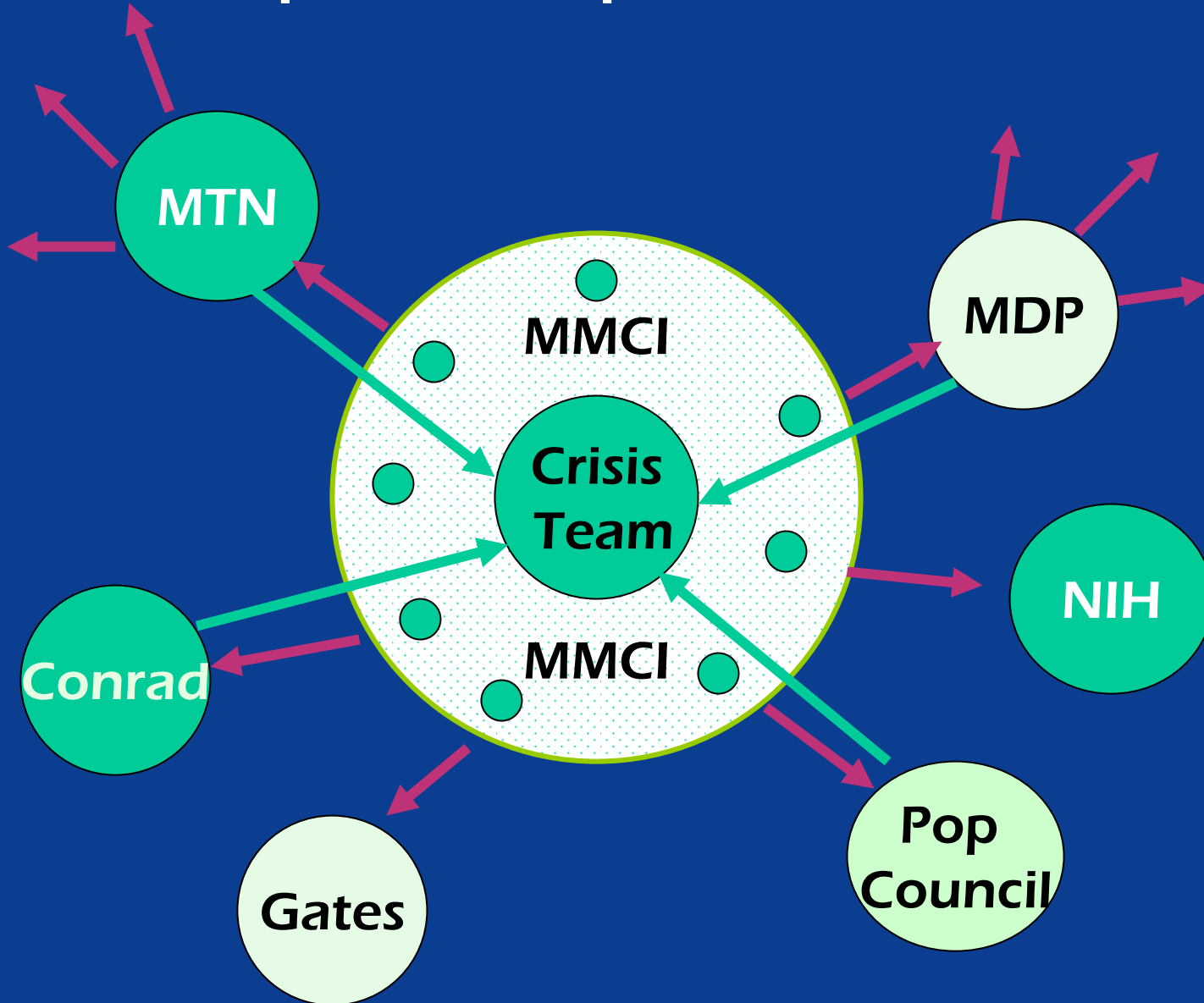
# Being proactive

- 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



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# Rapid Response Plan



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# 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)



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# 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



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# 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



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# News cycle

**fhi** Family Health International

## PRESS RELEASE

**For Immediate Release**  
January 31, 2007

**Contact:** Beth Robinson  
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### Phase III Trial of Cellulose Sulfate Microbicide for HIV Prevention Closed

**Research Triangle Park, NC** – Family Health International (FHI) announced today that it has halted a Phase III clinical trial of cellulose sulfate – a potential microbicide being tested for HIV prevention in women – in Nigeria. Simultaneously, CONRAD, a health research organization based in Arlington, Virginia, has announced that it has halted its Phase III clinical trial of cellulose sulfate at sites in Benin, Uganda, and India.



**C|O|N|R|A|D**

**For Immediate Release**  
January 31, 2007

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Cell: +1-703-772-6427  
annettelarkin@rationalpr.com

### 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 III clinical trial of cellulose sulfate – a topical microbicide gel being tested for HIV prevention in women – because preliminary results indicated that cellulose sulfate could lead to an increased risk of HIV infection in women who use the compound. The trial was being conducted in South Africa, Benin, Uganda, and India.

Simultaneously, Family Health International (FHI) has halted a second Phase III cellulose sulfate trial in Nigeria. Although the FHI trial did not detect an increased HIV risk given the preliminary results in the CONRAD trial, the decision was made as a precautionary measure, as four microbicides currently in effectiveness trials for prevention of HIV and other sexually transmitted infections.

At this point, it is not clear why use of cellulose sulfate was associated with an increased risk of HIV infection in the CONRAD trial. The Independent Data Monitoring Committee (IDMC), an independent advisory group of experts overseeing the trial, will conduct a detailed review of the data to better understand the findings, and help determine any implications for other microbicide studies.

Dr. Lut Van Damme, principal investigator of the CONRAD trial, stated: "It was our hope that this product would have helped women in protecting themselves from HIV. While the findings are unexpected and disappointing, we will learn scientifically important information from this trial that will inform future research."

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Relevant Links

- [East Africa](#)
- [Uganda HIV-Aids and STDs](#)

Arts by [Goonnongole](#)

[New HIV treatment](#)  
A new herbal extract increases CD4 and lowers virus courts  
[NatureProducts.Net](#)

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Remarkable tea has been almost 80% effective against AIDS and HIV.  
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Last Updated: Thursday, 1 February 2007, 13:59 GMT

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## 'Anti-Aids gel' trial is stopped

**Clinical trials of a new drug designed to help prevent women contracting the Aids virus have been stopped.**

The World Health Organization said the drug, which uses a microbicidal gel, did not help the women and made them more vulnerable.

African women are often unable to make men use condoms

The tests were carried out on more than 1,300 women in South Africa, Benin, Uganda and India.

The WHO and the United Nations Aids agency said it was not clear why the product did not work.

A similar test in Nigeria has also been halted but trials of three other microbicides are still continuing.

The cellulose sulphate gel, based on cotton and made by Canadian company Polydex Pharmaceuticals, was supposed to release an active ingredient designed to kill HIV during sexual intercourse.

**“The closure of these trials is a stark reminder that drug development in general is a difficult and unpredictable process.”**  
IPM's Zeda Rosenberg  
[Are trials worth the risk?](#)

"This is a disappointing and unexpected setback in the search for a safe and effective microbicide that can be used by women to protect themselves against HIV infection," said WHO and UNAids in a joint statement.

Around 30 women had contracted HIV since the trial started in 2005, the AFP news agency quotes study co-ordinator Tim Farley as saying.

## Uganda: HIV Microbicide Trials Halted

**New Vision (Kampala)**  
**February 1, 2007**  
Posted to the web February 2, 2007

**John Odyek And Agencies**  
**Kampala**

TRIALS of a new product designed to help women protect themselves against HIV virus were halted on wednesday after women using it became infected at a higher rate than women not using it, researchers said.

Toronto, Canada-based Polydex Pharmaceuticals said the gel, known as a microbicide, apparently made women more vulnerable to the virus, not less vulnerable, as intended.

Uganda is one of the countries where the gel was being tested.

**THE New Vision**  
KAMPALA'S LEADING WEBSITE

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# 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



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# Negative media erupts in South Africa



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# 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



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# 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



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# 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



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# 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*



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# 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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# Special thanks to:

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- Gita Ramjee, MRC
- Members of the MMCI
- IPM and the Alliance for Microbicide Development



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# Global Campaign FOR Microbicides

*Working to accelerate access to new HIV prevention options*



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**Sign the petition**

to expand research  
into microbicides



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



**Click on your region to learn more about microbicide advocacy in your community.**

## 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 FHI's Phase III 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 (AMAG).



## STUDENT ADVOCACY

Get involved with Students for Microbicides (S4M)!

**Timeline**

Check out our  
new website  
at:

[www.global-campaign.org](http://www.global-campaign.org)