Microbicide Trials Network: Communications Planning Survey

Name of Site:_____ Date:_____

I. Site Capacity and Experience

1. Within the last year, which of the following audiences have you proactively engaged? What were your primary aims for communicating with these groups?

Important Audiences Within Last Year		
Audience	**Y/N**	**Aims**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		
NGOs		
Media		
Local Government		
Regulatory Bodies		
(other)		

2. Are there particular methods of communication or engagement that you find preferable for these audiences? Methods may include telephone contact, written correspondence, face-to-face meetings, community meetings, briefings, flyers, drama, radio programming, etc.

Methods Of Communication Or Engagement		
Audience	**Y/N**	**Method**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		

NGOs		
Media		
Local Government		
Regulatory Bodies		
(other)		

3. Does anyone on your staff have communications expertise?

Yes___ No___

If yes, please describe:

4. Does your site have experience interacting with news media?

Yes___ No___

If yes, please indicate the level of experience: Extensive___ Moderate___ Minimal___

5. Does your site have procedures for dealing with media inquiries?

Yes___ No___

6. Does your site conduct its own outreach and/or training programs with local journalists, or has the site ever considered doing so?

Yes___ No____

If yes, please describe:

7. How would you rate your site's relationship with local journalists?

Excellent___ Good___ Fair____ Poor___ Nonexistent___

8. Does your site have staff who regularly communicate with advocacy groups and NGOs?

Yes___ No___

9. Does your site conduct its own outreach and/or consultations with advocacy groups and NGOs, or do you partner with these groups for any reason?

Yes___ No____

If yes, please describe:

10. How would you rate your site's relationships with the following types of groups?

Women's Health

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

Microbicide Advocacy

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

HIV/AIDS Treatment Advocacy

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

PLWHA

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

NGOs

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

Government Groups

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

Health Agencies

Excellent___ Good___ Fair_____ Poor___ Nonexistent___

11. Does your site have a designated crisis communications team?

Yes___ No___

12. Who is likely to be the primary media spokesperson or spokespersons for your trial?

Name: _____

Name: _____

13. Who is likely to have primary responsibility for organizing outreach efforts with the following?

Does he/she have previous experience interacting with these groups?

Who Will Be Talking To Whom?		
Audience	**Primary Responsibility**	**Done Previously?**
Participants		
Male Partners		
Community Groups		
Advocacy Organizations		
NGOs		
Media		
Local Government		
Regulatory Bodies		
Health Agencies		
(other)		

14. Has your site ever involved former and/or current trial participants in outreach activities?

Yes____ No____

If yes, please describe:

15. Have current and/or former trial participants ever been interviewed by the media?

Yes____ No____ Not certain____

16. If yes, was the site involved in making arrangements?

Yes____ No____

17. Does your site have a process to obtain consent for media interviews or photographs?

Yes____ No____

18. Does your site oppose the idea of current and/or former participants engaging in outreach or media activities?

Yes____ No____

If yes, why?

II. Communications Challenges and Needs

1. Locally or elsewhere in your country, are there HIV prevention trials that are ongoing, have been completed, were stopped prematurely, or are being planned that could shape perceptions of your trial?

HIV Prevention Trials Landscape				
	Microbicide	**PrEP**	**Vaccine**	**Other**
Ongoing				
Completed				
Stopped				
Planned				

2. When do you anticipate being ready to start enrolling participants in your trial?

3. Are there any significant local or national-level events that might take place between now and the time you expect to begin enrolling participants? Events may include government elections, the launch of another trial, etc.

Yes____ No____ Not Certain____

If yes, please describe:

4. Looking back, what communications issues have been the most challenging for your site? These may include rumors in the community, negative media coverage, or situations that have stoked common misperceptions about clinical research.

1.

2.

3.

5. What do you perceive will be the most difficult communications challenges for your trial?

1.

2.

3.

4.

5.

6. What aspects of your trial do you anticipate will be of greatest concern or most likely to generate misconceptions for each of these audiences?

Potential Concerns	
Audience	
Participants	
Male Partners	
Community Groups	
Microbicide Advocates	
HIV Treatment Advocates	
NGOs	
Media	
Local Government	

Regulatory Bodies	
Health Agencies	
IRBs or ECs	
(other)	

7. Which of the above audiences do you expect to be the most challenging to deal with in regard to your trial?

8. On a scale of 1 to 5, how would you rate each audience's awareness of your trial at the current time, with 5 being extremely aware and 1 signifying having no awareness?

Community Groups___ Local Government___

Microbicide Advocates___ Regulatory Bodies___

HIV Treatment Advocates___ Health agencies___

NGOs___ IRBs, ECs___

Media___ Other (Specify) ___

9. Which audiences do you consider the most critical for the success of your trial?

10. In the event of a communications crisis, are there individuals or groups within the community you think would show public support on behalf of the site?

11. Please list any key messages about your trial that you anticipate the site may wish to emphasize.

1.

2.

3

4.

12. On a scale of 1 to 3, which of these materials would you find most useful for communicating with external stakeholders, with 1 being the most useful and 3 being the least useful?

___Study Q&A

(with questions such as: What is the aim of this trial? What is a microbicide? What is PrEP? What happens if a participant acquires HIV?)

___Study backgrounder (2-3 pages)

___Site-specific study Q&A

(with questions addressing study procedures, potential community concerns, etc.)

_____Products fact sheet

_____PrEP backgrounder/fact sheet

_____Microbicide backgrounder/fact sheet

_____Role of DSMBs and interim reviews for this trial

_____PowerPoint presentations

_____Biographies of investigators

_____Other (specify):

13. Have you begun to consider or to plan specific outreach activities for your trial?

Yes___ No___

If yes, please describe:

14. In which areas or for what types of activities would your site potentially request planning assistance, direct on-the-ground support, or capacity building?

___Media training for key site staff

___Planning consultations or briefings for journalists

___Preparing materials for consultations or briefings with journalists

___Conducting consultations or briefings for journalists

___Planning consultations or briefings with advocacy organizations

___Preparing materials for consultations or briefings with advocacy organizations

___Conducting consultations or briefings with advocacy organizations

___Planning consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Providing materials for consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Conducting consultations or briefings with IRBs, ECs, regulatory groups, or health ministries

___Other (specify):

Thank You!

Source: Microbicide Trials Network. Communications Planning Survey. 2009.

Appendix 2.2

A Risk-Assessment Tool

PATH, an international nonprofit organization that studies vaccines for infectious diseases in developing countries, developed a simple risk-assessment tool to determine the expected level of communications risk for each of its vaccine trials. The tool does not evaluate the technical or scientific risk that may be involved with a trial; instead it looks at the potential for controversy, the risks to PATH's reputation, and expected communication challenges that could affect the trial. A similar approach can easily be adopted for other types of research and clinical trials.

All PATH vaccine trials are checked against the indicators below. Each indicator is given the appropriate number of "flags" (0, 1, or 2) depending on the risk. The tally of flags for that particular trial determines the trial's overall "communications risk factor" (see below), which in turn indicates the level of communications effort and financial resources required.

Determining the risk factor is an internal process at PATH—the results of the assessment are not shared with partners or other external groups. In principle, this tool should provide more consistent judgments and planning for communication related to clinical trials.

Below is the chart filled out for an imaginary Phase III trial in India evaluating the safety and efficacy of an experimental pediatric vaccine (as tested by a "challenge") against pneumonia.

"Thirty Tough Questions" for Trial Staff

This tool can teach staff members about the scientific basis of the research and help them learn how to explain the research clearly. Staff members can cut the following questions into strips so that each one appears on a separate strip. They can put the individual questions in a hat and practice answering them at staff meetings or workshops. Over time, their answers will improve, and they will have the opportunity to see how their colleagues manage challenging questions.

1. Has the product you are studying been proven to be safe?

2. What are some of the side effects?

3. Why are you doing the study in this community, not in the United States or Europe?

4. If a participant gets HIV while in the study, what treatment will she have access to and for how long?

5. How does the community benefit from the research?

6. Why is this study potentially exposing healthy women to HIV?

7. Is it the first time that this product or drug is being tested?

8. By giving women this product to use, are you discouraging them from using condoms?

9. What if women become pregnant during the study?

10. If you are encouraging people to use condoms, how are you going to find out if the product or drug is really effective?

11. Why are you focusing only on women?

12. Is the trial taking advantage of a vulnerable population that is in need of help and cannot say no?

13. What kind of participants are you looking for?

14. What is the purpose of this study?

15. How well does this product work in preventing women from becoming infected with HIV?

16. What HIV prevention methods are offered to women throughout the study?

17. What does risk-reduction counseling mean?

18. What are the benefits of participating in this study?

19. What are the risks of participating in this study?

20. Why can't everyone get the product or drug, since researchers think it might work?

21. What does randomization mean?

22. Won't participating in the trial ultimately put women at higher risk than if they had not participated?

23. If proven to work, will the product or drug be available and affordable to the people in the settings where the trials are taking place?

24. If you think the drug will be effective, is it ethical to give some women a drug with nothing in it to prevent HIV when you could be providing protection for all women in the study?

25. Why do the participants have to use a modern form of contraception?

26. Why are pregnant women excluded from the clinical trial?

27. I have heard that the doctors take a lot of blood. How much blood will they take from participants and why?

28. If the participants and researchers are blinded, how does anyone know who is getting the placebo or the treatment?

29. How will the researchers protect participants who are at risk of partner abuse for participating in this trial?

30. Will participants who seroconvert (get HIV) receive free ARVs for the rest of their lives?

Source: Family Health International, 2009.

Appendix 3.1

Sample Strategic Communications Plan

Below is a sample plan developed by Family Health International to guide trial communications in one country. It has been left partially filled out to show what a written plan contains.

Strategic Communications Plan for X Trial

Below we describe the study's major vulnerabilities (issues, groups, individuals, or community concerns that could limit the success of the study) and our plans to address these issues before they become problems (what we will do, why, with whom, and how). The key elements in the plan include:

- Environmental scans
- Partnering and networking
- Ongoing communication with stakeholders
- Engagement with activists
- Public information and research dissemination
- Selective outreach to news media
- Good internal communications
- Research dissemination

Introduction/background

[Fill in here]

Team/roles

[Fill in here]

Environmental scan and analysis of vulnerabilities

[Fill in here]

Objectives (internal/external)

[Specify objectives clearly, as shown in examples below.]

1. *Improve how scientific information is disseminated within the network.*
2. *Improve dissemination of scientific information to the community where trials are conducted.*
3. *Improve the utility, accessibility, functionality of the Web site.*
4. *Increase visibility of the network among interested stakeholders internationally and locally to facilitate community and stakeholder engagement.*

Existing relations and outreach to key research partners and stakeholders

The study team will continue making contact with researchers and community members at various levels. The two PIs are well recognized in their areas and will be quite useful in keeping contact with the network of researchers in their site. Existing communication with partners and stakeholders includes the following: [List as appropriate for your trial.]

1. *Relations with government officials and other decision makers*
2. *Relations with the local study communities*
3. *Relations with local, national, or regional advocacy groups*
4. *Donors active in supporting HIV programs: USAID, DFID, WHO, Gates Foundation, Clinton Foundation, EGPAF, UNAIDS*
5. *Health professionals*

Strategy for rapid response to controversy

As a controversy emerges, the communications team will work with appropriate individuals from the groups listed above to identify: [Write down what is relevant for your trial.]

1. *Possible steps to change the course of the issue's progression: This may include communication intended to inform, advise, demonstrate due diligence, demonstrate caring, etc.*
2. *Other communications activities will be implemented to build consensus or support among opinion leaders and key stakeholders, such as meetings, press briefings, and the placement of op-ed pieces by prominent colleagues with credibility in health and human rights.*
3. *Site-specific communications: In all network sites, we will depend very heavily on local CABs to acquire information and to respond to community concerns, rumors, and other misinformation within the sites. CAB members will be trained on the importance of their role. The PIs will be the project's spokespeople at the sites, and the network can assist them to prepare responses to issues as they emerge.*

Ongoing communications that target specific audiences

[Write down key groups you will need to inform on an ongoing basis, and how you will do that.]

1. *News media: The network can stay in touch with a small group of journalists through whom communications about the network will be made. These journalists will be identified through their previous work on covering research and HIV/AIDS and through their media affiliation.*
2. *Local community: Community education forums will be conducted by site teams.*
3. *Government or ministry officials: Quarterly briefing sessions will be organized for Ministry of Health officials to keep them up to date with the site-level activities. They will also receive regular information through the newsletter.*
4. *Public health professionals will receive updates through the newsletter.*
5. *Study staff/research teams: Staff members will be trained in the area of research literacy and will learn how to answer tough questions that may be asked by community members during community education forums.*
6. *Activists or other civil society groups.*

Materials needed to support communication and dissemination plans

We will identify the communications materials that will need to be written and distributed (including language and target audience) and determine who is responsible for each of these materials. These will include: [List materials you need to support your plan.]

1. *A statement about the network*
2. *A list describing other HIV prevention studies being conducted in each country and key events for these*
3. *Annotated lists of activists in each country*
4. *Calendar of relevant meetings and conferences, nationally and globally*
5. *Q&A*
6. *Contact list of site staff*
7. *Media guidelines governing coordination and procedures for media inquiries*
8. *Materials to include in training of study team: presentation on communications, research literacy issues (including research concepts and study procedures as well as issues pertaining to prevention trials) and how to answer difficult questions*
9. *Rapid response plan*
10. *List of key resources*
11. *Internal Web portal/Basecamp site with network materials*
    - *Protocol*
    - *Community assessments*
    - *News clips*
    - *Photographs*
    - *Backgrounders and Q&As*
    - *Contact lists*

"Getting to Know Your Stakeholders" Template

Stakeholder group	Level (who do they communicate with?)	Values/goals	Concerns
Host community members			
Trial participants			
Local leaders			
Religious leaders			
Local health care workers (including traditional healers)			
Ethics committee(s)			
Community advisory board			
National policy makers			
National/international advocates			
National policy and opinion makers			
Employees and management of host institutions			
Funders/sponsors/network			
Leadership of related trials			
Local/national media			
International media			
Wider scientific community			

Contact List Template

Surname	First name	Organization	Title	Address	Phone	E-mail	Category	Comments	Staff contact

Samples of Newsletters for Clinical Trials

FEM-PrEP

Trial Update

Pre-Exposure Prophylaxis for HIV

Putting HIV in its Place in Pretoria

FEM-PrEP scientists use an innovative strategy to recruit participants

A few years ago, the massive metropolis that includes Pretoria, South Africa, was renamed *Tshwane*—a word that means, "we are the same," according to city officials. The name change, and even the meaning of the word *Tshwane*, are controversial subjects in South Africa. What remains uncontroversial is that the HIV epidemic has not affected the two million residents of Tshwane in the same way.

For various reasons, the virus has affected some communities more than others. The FEM-PrEP researchers need to identify these communities because an HIV-prevention trial can only be effective in places where there is a high incidence of HIV. In other words, the women who volunteer for the trial must be at "higher risk" of acquiring the virus.

Finding and recruiting these women is often a significant challenge for HIV-prevention trials. However, FEM-PrEP's socio-behavioral and community (SBC) team is taking a novel approach to recruiting participants for the clinical trial. "The approach combines a method called *Priorities for Local AIDS Control Efforts* (PLACE) with computer-based mapping strategies to identify promising recruitment areas to focus recruitment efforts," says Amy Corneli, the SBC principal investigator.

The PLACE method was originally developed to improve the reach of AIDS-prevention programs. The SBC researchers are using modified PLACE questionnaires to interview members of the community, asking them about the places where people go to meet potential sex partners. The researchers visit these places—*shebeens* (informal taverns), guesthouses, and even bushes by the side of the road—where they talk to the people who go there to socialize.

Business owners are asked about the clientele and about the busiest times at the establishment. The interviewers also collect information from the patrons about their alcohol consumption, sexual practices, and risky behaviors.

Local research staff based at the Setshaba Research Centre conduct these interviews. Among them is Dimakatso Molete, who has extensive knowledge of the social networks in the area. Molete, who is known as *Aus Maki*, has conducted hundreds of interviews with establishment owners and patrons. It's a task that has its challenges.

"Establishment owners are difficult to get in touch with," says Aus Maki. "This takes much of our time as we may visit the place several times before we can find them. At first, their staff are suspicious of people they do not know," she says.

(continued on page 4)

Stella Vivienda/FHI

Interviewers, Dimakatso Molete and Ross Malamatsho, use a global positioning system device to map the coordinates of a recruitment area.

USAID
FROM THE AMERICAN PEOPLE

fhi Family Health International

Issue No. 2 July 2009

Source: Family Health International. FEM-PrEP Trial Update. 2009.

Source: Pre-Exposure Prophylaxis Initiative (i-PrEx). Global i-PrEx Update. 2009. Reprinted with permission.

NÚMERO 12 – DICIEMBRE 2009

Unidad de Educación Comunitaria e Involucramiento

En este número

Difusión del servicio de diagnóstico de VIH de Impacta a través de la guía Gay Epicentro.

Diálogo entre investigadores y comunidad respecto a los estudios

"Para el mejor papi del mundo! Te amaré por siempre, con cariño: Muñequita"… mensaje exhibido en una de las mantas de amor

1. Notas Breves

El 09 de Diciembre **participamos** en el II Encuentro de Lucha contra el VIH-SIDA organizado por el Congreso de la República y la Asociación Hogar de Vida. En dicho evento se hizo una revisión sobre los últimos hallazgos en prevención, así como se brindó un reconocimiento al doctor Alberto La Rosa Domínguez entre otros, por su dedicación y aporte al tema del VIH-SIDA. ¡Felicitaciones al Dr. La Rosa!

El 12 de Diciembre se presentó el **Plan Anual de Educación Comunitaria e Involucramiento** de la unidad de ensayos clínicos peruana para los estudios de la red de vacunas. Dicho plan ha sido elaborado por los miembros del equipo y describe las estrategias de reclutamiento y retención a ser implementadas durante el año 2010 con el objeto de alcanzar la cuota de reclutamiento programada en el tiempo establecido.

El servicio de diagnóstico de VIH que nuestra clínica Impacta ofrece, se sigue difundiendo a través de la Guía Turística Gay de Lima de Epicentro, quien quincenalmente actualiza y extiende los puntos de distribución.

El **centro de llamadas** ha atendido a través de la línea SIDA, 181 contactos telefónicos de los cuales 139 (76.8%) corresponden a participantes de TARGA principalmente.

2. Reclutamiento

El 1 de Diciembre se realizó en el Centro de Salud Cuartel General (Pentagonito) un encuentro con la finalidad de informar y sensibilizar a la población militar acerca del estudio de investigación en vacunas contra VIH e identificar potenciales voluntarios. La convocatoria estuvo a cargo del personal de salud del Pentagonito, Lic .Patricia Vilchez y Lic Paola Coahila, alcanzando la asistencia de 80 personas aproximadamente entre personal militar de tropa y administrativo.

De igual forma, el 10 de diciembre se presentaron los estudios de la red de tratamientos en reclutamiento activo a las profesionales enfermeras de la Región de Salud del Callao. 42 profesionales de los establecimientos participaron del mismo.

La red de salud revisó y aprobó la implementación del sistema de referencia Plus de los establecimientos de sus respectivas jurisdicciones los estudios presentados: a) Lima Sur: A5259, A5253 Y A5255; b) Lima Este: A5253 y c) Callao: A5259.

3. Retención

59 visitas domiciliarias han sido efectuadas, de las cuales 30 corresponde al estudio EBV, 15 corresponden a estudios de vacunas y 14 a estudios de tratamiento. Los participantes que no fueron recuperados (8) corresponden en su mayoría a participantes del HVTN 504, quienes se han mudado (6) o han viajado fuera del país (2).

Sample of Study "Backgrounder"

Family Health International

Backgrounder

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

Since 2004, Family Health International has been working in Africa to study whether a widely used HIV treatment drug, called tenofovir, can also prevent HIV in women who are at high risk of HIV infection. In particular, researchers have looked at the drug's safety and effectiveness in preventing HIV infection in these women.

This study is important because a new HIV prevention approach, such as using a drug like tenofovir to prevent infection, could be used with other prevention strategies such as condoms to substantially reduce the number of people who become infected with HIV worldwide. It could make an especially large impact in Africa, where more than 70 percent of all HIV infections occur, and would be of particular benefit to people who have difficulty negotiating condom use.

The FHI study involved heterosexual women from the African countries of Ghana, Cameroon, and Nigeria who had multiple sex partners. Because the women were at high risk of being infected with HIV, they were also the most likely to benefit from tenofovir if it can be shown to safely and effectively prevent HIV.

Tenofovir is not a new drug. It has already been tested in thousands of HIV-infected people, it is approved by regulatory agencies, and it is being used in an oral form in many countries for HIV treatment. The FHI study is among the first to begin testing the oral form for both safety and effectiveness in preventing HIV infection.

The study was designed according to the most rigorous international ethical standards. It was approved by institutional review boards at Family Health International and by regulatory authorities in the countries where the study took place.

Half of the participants received daily oral tenofovir and half received a daily placebo, which is a pill that looks and tastes like tenofovir but does not contain any drug. At monthly visits during the study, participants received HIV prevention counseling, were given condoms to use during all sexual acts, and were provided treatment for any symptomatic sexually transmitted infections, all actions which have been shown to reduce the risk of HIV infection.

Liver and kidney functioning were evaluated every three months to confirm the safety of tenofovir for HIV-uninfected individuals and to identify any possible side effects of the drug. Participants were also tested for HIV each month to determine the drug's effectiveness at preventing HIV. Those who became infected with HIV during the study were provided enhanced referral to care and support services in their communities, including

access to care that involves antiretroviral drug provision when needed. Local investigators identified facilities within each country that offer low-cost, HIV-related psychological, social, and medical services. HIV-positive participants were counseled and referred to those sites. Those who experienced medical problems that were directly related to their participation in the trial received medical services free of charge.

If this or other tenofovir studies conclusively demonstrate that tenofovir is safe and effective for preventing HIV, then Gilead Sciences, the U.S.-based manufacturer of tenofovir, has agreed to provide the drug at a no-profit cost to HIV prevention programs in resource-poor countries. Gilead has provided tenofovir free of charge for the FHI study, which is being supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation. Preliminary results will be available August 17, 2006, at the International AIDS Conference in Toronto. Final results will be submitted for publication in 2006.

For more information on Family Health International, see http://www.fhi360.org.

Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention, care, and treatment. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems. FHI has a staff of 1600 and offices in nearly 40 countries.

Sample External Questions and Answers (Q&A)

Questions and Answers

August 10, 2006

Family Health International Study of Daily Oral Tenofovir to Prevent HIV among Women at High Risk of Infection

What is tenofovir?

Tenofovir is an anti-HIV drug that works by inhibiting an important enzyme in the HIV life cycle, called nucleotide reverse transcriptase. In HIV-infected individuals, tenofovir stops HIV from invading cells that have not yet been infected with the virus. It is taken in the form of a pill, it is long lasting, it has relatively few side effects, and most strains of HIV are slow to develop resistance to it. Tenofovir is approved by regulatory agencies and already used in many countries as part of a drug combination to treat HIV. Studies in monkeys have also shown that it can prevent transmission of a virus that is similar to HIV, but it is not yet known if it can prevent HIV transmission in humans. Tenofovir is manufactured and was provided free of charge for the study by Gilead Sciences, located in Foster City, California.

What was this study testing?

This clinical trial was conducted in three African countries to study daily oral tenofovir for the prevention of HIV among heterosexual women at high risk of infection. To do so, participants were randomized to receive either tenofovir or a placebo once a day for the duration of the trial. All participants also received HIV risk-reduction counseling, condoms, and treatment for sexually transmitted infections as medically indicated during monthly clinic visits throughout the trial.

Why was this study important?

Current HIV prevention programs stress abstinence, being faithful to uninfected partners, and—if neither is possible—using condoms. Despite knowledge of these prevention strategies, an estimated 11,000 people become infected with HIV each day. Moreover, many sexually active individuals, especially women, have difficulty ensuring faithfulness or negotiating condom use in their relationships, and additional prevention strategies are needed. If effective, tenofovir could be a promising addition to condoms because it is taken orally and would provide a constant level of protection against HIV, regardless of the timing of intercourse.

Who conducted the study?

Family Health International, a non-profit research and service organization based in Research Triangle Park, North Carolina, managed the trial and was responsible for all aspects of the study. Local staff from the study sites in Africa served as the research investigators. The research was supported by a grant awarded to Family Health International in 2002 by the Bill & Melinda Gates Foundation.

Where did the study take place?

The study was conducted in the three African cities of Douala, Cameroon; Ibadan, Nigeria; and Tema, Ghana. These sites were selected because their populations have high rates of HIV infection, which is an important factor for determining the effectiveness of possible HIV prevention drugs. If tenofovir is shown to be safe and

effective, HIV prevention programs that provide tenofovir can be established at these sites, so that women at risk for HIV can be reached and can benefit from this intervention.

Who participated in the study?

Nine hundred thirty-six heterosexual, HIV-negative women were included in the study. Four hundred were from Ghana, 400 from Cameroon, and 136 from Nigeria. To be eligible, all volunteers had to be sexually active HIV-uninfected women between ages 18 and 35 years.

How were participants evaluated throughout the study?

Participants were tested for HIV at a screening visit, an enrollment visit, and once a month during follow-up. With each HIV test, pre-test and post-test HIV prevention counseling was also provided. Side effects and any reported changes in health, whether considered by the study investigators to be potentially related to the study drug or not, were evaluated, treated if necessary, and recorded each month. In addition, liver function and kidney function were evaluated every three months to identify other possible reactions to the drug.

What precautions were taken to help participants prevent HIV?

Women were counseled monthly on safer sexual practices such as reducing their number of sexual partners and using condoms during every sexual act. Male condoms were also provided to them. In past prevention trials, these services have been proven to reduce the risk of HIV among participants. For example, results of a microbicide trial conducted by Family Health International in Cameroon, which used similar HIV prevention strategies, showed a 50 percent lower incidence of HIV among trial participants than among community members tested before the trial.

How long did the study last?

Enrollment began in June 2004 and ended in March 2005. After enrollment, each woman was to be followed for up to 12 months. Follow-up data available differed by trial site. Because of early withdrawal of the study drug from Cameroon and Nigeria, women there did not complete the trial as planned.

When and why was the study drug withdrawn in Cameroon and Nigeria?

The study drug was prematurely withdrawn in Cameroon in February 2005 and in Nigeria in March 2005. In Cameroon, the study was closed after the Ministry of Public Health suspended provision of the study product to participants to allow review of study procedures in the wake of media controversy over oral tenofovir research there and elsewhere. However, follow-up of women already enrolled in the trial continued until September 2005. In Nigeria, FHI closed the study due to operational issues.

What did the safety data from the study show?

No statistical differences were found in severe liver or kidney abnormalities between women in the tenofovir group and women in the placebo group. The numbers of other side effects and health changes were also similar between the two groups. The most common reported events for both groups were malaria, vaginal yeast infections, stomach pains, and headache.

How many women became infected with HIV during the study?

Eight women on study drug or placebo became infected with HIV. Two of the infections occurred among women receiving tenofovir, and six occurred among women receiving placebo.

How do the HIV data break down by country?

Of the two women in the tenofovir group who became infected with HIV, one was from Ghana and one was from Cameroon. Of the six in the placebo group, two were from Ghana, one was from Nigeria, and three were from Cameroon.

What can we conclude from the results?

These results provide no evidence that short-term use of oral tenofovir for HIV prevention causes harm, since the women receiving tenofovir and those receiving placebo did not differ substantially in terms of liver and kidney function or other health changes. However, not enough data are available to determine whether tenofovir protects against HIV infection.

What happened to participants who became infected with HIV?

Those who became infected were referred to HIV care and support services. Local investigators identified facilities within the study countries that offered HIV-related psychological, social, and medical services, and participants who become infected were counseled and referred to those sites.

What procedures are in place to ensure that the women who became infected with HIV are receiving the services they were promised?

All of the women who became infected with HIV during the study were referred to a health counselor who referred them to local hospitals for HIV care and support services. The health counselor also offered to accompany each woman to her first visit to help her register for services. Family Health International has also been in contact with study staff, local hospitals, and local nongovernmental organizations to ensure that the women will have continuing access to such services. In Cameroon, for example, Family Health International has signed a contract with a local hospital to provide 15 years of care and treatment to the women who became infected there, and a nongovernmental organization has agreed to provide additional psychosocial support. Similar negotiations are under way in Ghana. In addition, the one woman from Nigeria who became infected was enrolled in the President's Emergency Plan for AIDS Relief program there.

What are the implications of this study?

Daily oral use of TDF in HIV-uninfected women was acceptable and was not associated with increased clinical or laboratory adverse events. Although the effectiveness data are inconclusive, the trial strongly supports the need for additional studies to test the effectiveness of oral tenofovir in preventing HIV infection in humans. Now that tenofovir has been demonstrated to be safe and acceptable for HIV-negative individuals at risk, it is crucial to determine if this approach can effectively reduce risk for HIV infection.

What similar studies of oral tenofovir are being conducted?

The Centers for Disease Control and Prevention is testing tenofovir among diverse populations in two countries: injecting drug users in Bangkok, Thailand, and men who have sex with men in Atlanta and San Francisco, USA. The Centers for Disease Control and Prevention is also studying tenofovir in combination with another drug, emtricitabine, in heterosexual men and women at high risk of HIV infection in Gaborone and Francistown, Botswana. Finally, the National Institutes of Health and The University of California at San Francisco are planning to study the same combination of drugs in men who have sex with men in Lima, Peru.

Does Family Health International have any plans to continue studying tenofovir for HIV prevention?

Family Health International is identifying and preparing potential sites for future studies of tenofovir alone or tenofovir plus emtricitabine among both men and women at high risk of HIV infection. A protocol is also being developed in conjunction with the CAPRISA Project of Mandela University in Durban, South Africa, to study whether a topical gel containing tenofovir, used as a microbicide, can also prevent HIV infection.

What is Truvada? Why study two different drugs?

Truvada is the name for the fixed-dose combination of tenofovir and emtricitabine, described above. Family Health International and others are interested in studying this drug combination because there are significant data suggesting the promise of both tenofovir and tenofovir plus emtricitabine. Because we don't yet know for certain how the animal data will correlate to human protection, we believe it is essential to move forward as quickly as possible to evaluate both of these promising interventions.

Template for a Monthly Summary Report on Communications

Nyanza Provincial Task Force on Male Circumcision (Communications Subcommittee)

Monthly summary report on communications

District (specify):	Month (specify):	
Communications activities (performed by staff that involve or target these groups)	Type of activity (summary of activity or channels used to reach the target groups, such as interpersonal meetings, sensitization forums, newsletters, presentations, media, others)	Outcome of activity (summary of the outcome of the communications activity,such as concerns, issues raised, how your team handled situation, lessons learned)
Community groups (FBOS, CBOs, youth groups, women, elders; specify other stakeholders)		
Health providers (Describe the cadre of providers, e.g., DHMTs, MDs)		
Policymakers (PHMTs, provincial administrators, etc.)		
News media (Reporters, editors; specify others)		
Others (Please let us know about any issues or themes that you think are important in the meetings or other communications activities that you have been involved in or helped organize in the last month. Describe any meetings or problems that do not fall into the categories above.)		

Communications concerns (Describe the concerns gathered during these forums, e.g., rumours, myths, misconceptions, misinformation)		
Future communications activities planned (e.g., meetings, outreach activities, personal visits, brochures, development and testing of key messages to use with specific communities/ stakeholders)		
Other progress or comments		

Prepared by: Date:

E-mail completed form to: xxxx@fhi.org, Secretary, Provincial Task Force on Male Circumcision

How Unexpected Closures Can Affect Other Trial Sites: The Cellulose Sulfate Trial Closure in South Africa

In January 2007, a study in South Africa on cellulose sulfate (CS), a potential microbicide, closed prematurely after its Independent Data Monitoring Committee identified a safety concern during a review of preliminary results and recommended that enrollment stop at trial sites. The research team at the HIV Prevention Research Unit at the South African Medical Research Council (MRC), which managed several sites around Durban, and CONRAD, the trial sponsor in the United States, worked quickly to plan how to share the news with local, national, and international stakeholders, including trial participants. In South Africa, the MRC released a press statement and contacted a well-respected South African health journalist, hoping her article on the closure would set a balanced tone for press coverage to follow.

Meanwhile in Mtubatuba, a small town in KwaZulu-Natal 200 kilometers north of Durban, a research site affiliated with the Africa Centre for Health and Population Studies was conducting a separate large-scale microbicide study testing a different product called PRO 2000 gel. On Friday of the week of the MRC's public announcement of the CS study closure, the Africa Centre contacted members of its community advisory board (CAB) in Mtubatuba to invite them to an urgent meeting. The Centre's staff planned to brief CAB members the following Monday about the sudden closure of the CS trial and reassure them that their PRO 2000 microbicide study was not affected.

That weekend, however, a journalist from Durban posing as an insurance official with the health department traveled to Mtubatuba, hunting for the inside 'scoop' on the closure. He located a CAB member for the Africa Centre's PRO 2000 trial in Mtubatuba who—convinced by this guise—took the journalist to the home of a PRO 2000 trial participant. Other participants joined and were encouraged by the undercover reporter to share their perceptions, unaware that they were being interviewed by a journalist (Gafos 2009).

The next day, the City Press, a national newspaper, ran the headline, "Women used as AIDS guinea pigs" (Hlongwa and others 2007). The article claimed that hundreds were feared to have contracted AIDS during the CS study and that women were selling their gels in the townships as AIDS cures. More articles by the same journalist followed, accusing the CS study of unethical conduct and claiming that women were instructed to have promiscuous unprotected sex and that the researchers had purposely infected participants with HIV. Not only were these assertions not true, the article was based on interviews with participants from a completely different trial than the CS trial that was prematurely halted.

While coverage of the CS trial closure remained balanced and accurate in the United States, a wave of negative press and sensational headlines followed in local press in South Africa as well as in Uganda (where another CS trial site was located). These articles painted a picture of poor, uneducated, and vulnerable women taken advantage of by researchers and duped into participating in clinical trials.

The closure of the CS study in South Africa and related concerns about safety had snowballed into a narrative of exploitation, affecting perceptions among the community and the entire microbicide field of the ethical conduct of microbicide trials. The research organizations directly involved in the South African CS study and a related CS study in Nigeria implemented intensive communications efforts to respond to the events. Other research and stakeholder groups also offered technical assistance and support behind the scenes, both locally and internationally, including the Microbicides Media and Communications Initiative, which set up teleconferences and worked on coordinating messaging.

Advocacy groups, such as the Global Campaign for Microbicides and the African Microbicide Advocacy Group, facilitated civil society calls and online discussions, while South Africa's Treatment Action Campaign and Gender AIDS Forum wrote articles and statements of support to refute the rumors and myths.

These combined efforts were successful in calming the waters and promoting more accurate news coverage. The participation of local groups introduced African voices into the media coverage. While these "damage control" efforts improved the situation, the experience highlighted for all that what happens in one trial can easily affect other trials. Investigators, research groups, and communities in this area have put these lessons learned into action. They now plan ahead to avoid controversy, develop integrated communication strategies, and work collaboratively to discuss messaging for trials and results.

Illustrative Crisis Communications Plan

In 2005, India saw one of the country's most severe outbreaks of Japanese encephalitis (JE), a mosquito-borne illness that occurs in Asia and the Western Pacific. More than 6,500 cases and close to 1,700 deaths were reported—the majority of them children. Widespread coverage of the outbreak—including photos of dying children— in local, national, and international media led to a public outcry.

The government of India rapidly launched a national JE vaccination campaign and PATH, an international health nonprofit organization, was asked to provide technical assistance. A few weeks into the campaign, news broke of severe adverse reactions and even deaths among some children receiving the vaccine. The vaccine had an excellent safety record, so most technical experts felt that the deaths did not result from the vaccine, but rather from another cause among this very vulnerable population.

Local and national media ran speculative stories questioning the vaccine's safety. The communications and management team gathered to determine the best approach to dealing with the situation. Weighing their options, they considered a formal institutional response that could have helped get accurate information out to the public and set PATH up as a reliable source for future media inquiries. But given that the investigation into the deaths had not yet concluded, PATH initially decided not to respond directly, but to help the government of India respond appropriately.

However, when a national television network decided to film a panel discussion on the issue, PATH's lead technical officer in India recommended to the U.S.-based program director that PATH should participate despite the initial strategic decision not to engage. This example highlights the importance of being flexible and the need to account for specific country considerations in developing and adapting a communications strategy.

The following year, PATH helped the government of India develop its communications strategy with an emphasis on the lessons learned from 2006. They encouraged early engagement with the media and placed a greater emphasis on the buy-in of local officials. For example, one district health minister brought his son for vaccination at a launch event, illustrating his confidence in the program.

Finally, they revised their internal Q&A, including the results of an investigation into the deaths, which found no relation between the vaccine and the deaths. If reporters brought the issue up again, spokespersons now had clear messages to use to correct the false accusations and instead communicate positive messages about the campaign.

(See below for a copy of the full crisis communications plan for the Japanese encephalitis project.)

Japanese Encephalitis (JE) Project Crisis Communications Plan

Overview

This plan describes the process by which PATH will address any inaccurate and/or potentially negative press coverage or other misperceptions associated with activities conducted under the PATH JE project. This plan is specific to activities related to the Government of India's (GOI) 2009 JE vaccination campaigns.

A communication crisis is a situation that threatens the integrity or reputation of the partners or partnership, usually brought on by adverse or negative attention from community members or the media. This includes any rumor, adverse event, legal dispute, accident, or manmade disaster attributed (rightly or wrongly) to the project or partners. It can also include situations where, in the eyes of the media or general public, the partnership did not react in an appropriate manner.

Routine activities

The communications associate for the JE project monitors daily media coverage addressing JE disease and vaccines, keeping a related log and copies of media clips. This monitoring is particularly acute and intensified following outreach to media generated by PATH or GOI regarding the 2009 Indian campaigns.

Process for preparation and response following concerning media report or crisis situation

- Upon learning of an inaccurate or concerning news media report, the communications associate forwards a copy of the article with relevant questions to the Management Team. The senior communications officer from PATH External Relations is copied on this e-mail.
- The management team responds to the communications associate with their initial read of the situation and appropriate plan of action (or inaction).
- The communications associate summarizes the team's reactions and proposed strategy and e-mails this summary, along with a link to the associated media report, to the PATH Senior Management Group and Strategic Program Leader. The involvement of the SMG is to keep leadership aware of the report, as well as the team's plan for response.
- The communications associate works with the management team to prepare a holding statement and/or internal Q&A. (Example of holding statement: "On [date], at [health center], the death of a [#] year old child who had been given JE vaccine was recorded. This incident is under investigation. Additional details will be provided as they become available.")
- The team's plan, holding statement, and Q&A documents are shared with primary partners (to be identified case-by-case), which may include Ministry of Health officials, funders, and others. These documents are shared via e-mail, but the management team may also contact partners via telephone when appropriate.
- A primary spokesperson is assigned to respond to media inquiries, and technical experts identified as potential media contacts are notified via e-mail or telephone.
- Note: A designated spokesperson should be forthright in dealing with media questions. There are, however, some questions he or she cannot answer, including those related to financial estimates of damage, insurance coverage, causal speculation, allocation of blame, or anything "off the record."
- The communications associate provides regular updates to SMG and broader PATH team.
- When the situation is resolved, all related parties are asked to debrief and document lessons learned.

Relevant team members

I. Communications team

The primary role of this team is to help assess the potential for a situation becoming a communications crisis. The team routinely monitors media coverage and provides initial notification of a potentially concerning or inaccurate report. Communications team members also assist in drafting and collecting technically accurate and up-to-date materials in response to the situation.

Senior communications associate, JE project

Senior communications officer, External Relations

Media relations officer, External Relations

II. Management team

The management team is responsible for providing initial reactions to the inaccurate or concerning news report and for developing an appropriate plan of action. (It must be noted that sometimes the appropriate plan will call for no response from PATH.) The management team is also responsible for notifying relevant partners and funders and designating appropriate spokesperson(s), either internal or external, depending

upon the particular situation.

JE project director

JE project deputy director

Senior program manager, India

Country office director, India

Country partners – to be contacted as needed by management team representative

Assistant Commissioner, Immunization

Ministry of Health & Family Welfare

III. PATH Senior Management Group and Strategic Program Director
Involvement of the PATH Senior Management Group (SMG) and the Strategic Program Director is to ensure that leaders are aware of potentially harmful reports about PATH and PATH activities. Following notification according to the process outlined above, SMG should be regularly updated on the team's plan for response. If no response is warranted, SMG should also be notified of this approach. Senior management may also provide input on decisions that could affect the overall organization.

IV. Other staff and partners to keep informed
Additional senior members of the JE project team and PATH External Relations may be notified throughout the process, as determined by the management team.

JE project vaccine development advisor	
JE project administrator	
JE project health policy and economics officer	

Notifying the project funder
The JE project director or a member of the PATH Senior Management Group (whomever is most appropriate in a given situation) will keep the responsible program officer of the project funder informed. As noted in the process above, the funder should be contacted after initial reactions and the planned response are summarized.

Key JE project partners
Representatives from partner organizations, including but not limited to national governments or Ministries of Health, may need to be notified if a situation requires specific clarification and it falls within their area of expertise or capacity to respond. Internal documents may also be shared with external partners at the discretion of the JE project director, in order to prepare for potential contact by journalists.

External statement or response
When appropriate, as determined by the JE project director, a response to or statement regarding negative press coverage may be drafted and posted to the following online forums:

Forum	URL	Instructions
ProMED	www.promedmail.org	Submit post to [e-mail here], include full name, affiliation, and country.
TechNet	www.technet21.org	
Other listservers TBD		

Source: PATH. 2010. Reprinted with permission.

Sample of a Results Dissemination Plan by a South African Site

HPTN 039 RHRU Results Dissemination Plan

By Sinead Delany-Moretlwe, Reproductive Health Research Unit (RHRU), University of the Witwatersrand, Johannesburg, South Africa

Overview

The Reproductive Health Research Unit (RHRU) HPTN site is situated inside the Esselen Street clinic, a local municipality clinic in Hillbrow, Johannesburg. RHRU does not anticipate much controversy or media coverage upon the release of the results of HPTN 039. However, if the results show harm, one can anticipate the possibility of negative media coverage, given past reporting on the cellulose sulfate clinical trial (a microbicide). More recently, an HIV vaccine trial was stopped because of futility, and in that case, the media coverage was fair and balanced.

Our results dissemination plans focus around five main efforts:

1. Early communication of results to the IRB/Ethics Committee, the Ministry of Health, and the Community Advisory Board (CAB) just before the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, USA
2. Presentation of results to participants and community members after CROI
3. Press release to present results
4. Distribution of a study summary to local colleagues and other key stakeholders with a presentation of results after CROI
5. Surveillance of local media and community attitudes after CROI to respond to any negative press, rumors, or needed clarifications

Site background

Hillbrow is an urban area in the inner city of Johannesburg characterized by high unemployment and decay. The HPTN site in Hillbrow is housed inside a local municipality clinic that provides services related to sexually transmitted infection (STI), family planning, and voluntary testing and counseling for HIV (VCT).

Approaches for results dissemination to potential results recipients

The RHRU site staff has discussed the possible entities that should be told of the results of the HPTN 039 study based on the template developed by Family Health International (see Box 6.1). A summary of the decisions is provided below:

Tier 1—early results

1. *The chairman of the IRB/Ethics Committee* will be informed of the results 24 hours before the CROI announcement. The principal investigator (PI) of RHRU site will e-mail the chairman a summary of the results, including attachments of key messages, a press release, and a frequently asked questions (FAQ) document. The PI will also follow up with a telephone call to the chairman to ensure that he has received the results. We believe that the IRB understands the requirement to keep results confidential until they are announced at CROI.

2. *The University of Witwatersrand press office and local journalists experienced in scientific reporting* who have worked closely with RHRU in the past will be alerted by the PI 24 hours before the results are announced at CROI.

3. *The National Department of Health* will also be notified through the Chief of the Division of HIV/AIDS and the Head of Epidemiology, 48 hours before CROI, and will be sent key messages, the press release, and the FAQ. The PI will follow up with a telephone call that same day to answer any questions.

Tier 2—results released during CROI or after

1. *Other local researchers, AIDS activist groups, provincial and local government representatives, and other key stakeholders:* The RHRU plans to present the results to these stakeholders about a month after CROI. The site has successfully held a similar meeting for one of the completed herpes simplex virus/HIV clinical trials in August 2007. We will use the same database and list to start inviting all interested parties as early as the second week of January 2008.

2. *Local community leaders, the trial CAB, participants, and community-based media:* The CAB members will be notified 48 hours before CROI, and they will sign a confidentiality document prior to learning the trial results. In mid-February 2008, we will hold a community appreciation event and information session at the site. This will consist of light refreshments and a PowerPoint presentation to discuss the study and its outcome. A one-page summary of the results, provided by FHI, will be distributed to all attendees. A question-and-answer session will be conducted at the end of the presentation.

   It will be important to reach as many people as possible for this event, so advertising will begin in early January. Community health workers for the trial will distribute invitations to local clinics and other previous recruitment venues for the trial (churches, community centers, local civic organizations). Community health workers for the trial will also spread the word to participants. Those participants who have phone numbers or who can be contacted through family or friends will be invited directly, and those inaccessible by telephone will be paid home visits, wherein invitations will be delivered at their last known address. The latter activity will be guided by permission the participants granted during the study. The CAB, local AIDS activists, community-based print media, and local radio station will be individually invited by the study coordinator or the Community Liaison Officer (CLO).

Potential problems and post-results activities

As noted in the summary, we do not anticipate any problems from results dissemination, unless use of the study product causes harm to participants. However, if the 039 results are mixed or complicated, we will have a more difficult time with our responses, and the news will be more politicized. If there is likely to be controversy, the site will need three to four days to prepare and communicate with key contacts (Tier one). If the results are not that newsworthy, the team estimates needing 48 hours to inform those stakeholders.

Journalists always ask, "What does this mean and why is it important?" If the news from CROI is that there is no increase in harm, the team estimates that the results will not filter back into news media in South Africa. If use of the study product causes harm, there are two concerns: HPTN 039 participants and government officials especially are likely to be concerned. We will need to have plans in place to deal with this scenario and respond to concerns.

If the treatment causes harm, we will try to allay anxiety of participants at the community appreciation event and through the press releases. We will tell participants at the event that they can come to the clinic at any time to discuss the results or their feelings further. The site will explore whether (a) representative participant(s) might be identified to speak for the participant perspective, if that becomes important. This role might also be assumed by a CAB member who can speak for the participants. We will also encourage participants to return to the clinic when unblinded treatment assignment is available (around April) so we can inform them of their group assignment. We will emphasize that those who did not seroconvert during the trial were not harmed by taking the study product and are not now at any greater risk than if they had not been in the trial.

To counter a possible community backlash against research in this scenario, we will adopt two strategies. First, the study coordinator and the CLO will return to the organizations that helped us in recruitment and answer questions, explaining that very few people who used the study product were put at greater risk of HIV acquisition; that most participants in both trial arms were probably better off from counseling, STI treatment, and free condoms than if they had not been in the study; and other messages to promote research literacy. Second, for the two months after public dissemination of trial results at CROI, the PI or someone senior within the organization will monitor the local press daily for stories about the results and respond to queries as they arise. We will also ask the CAB and community health workers to report any rumors or negative feelings they have heard within the community and among participants in other clinical trials conducted at the site, and we will respond to each situation proactively.

Staff assignments for results dissemination and response to inquiries

Because little reaction is expected in Johannesburg, South Africa, to the results of HPTN 039, the PI will be the primary spokesperson for the site when releasing or presenting results, and when inquires come in from media (if any). In the event that the PI is not available, the executive director of the RHRU or any other senior RHRU staff member within RHRU may serve as spokesperson. To prepare for general inquiries about the study or the results, the entire staff will have a meeting with the PI a few days after CROI to discuss how to talk to participants and community members about the key messages. Staff will also be trained to direct any media inquiries to the PI or other designated senior RHRU staff member. The CLO or community health workers will serve as spokespeople at the community meetings where results will be discussed. We will also work with the CAB to prepare them to answer questions in an informed way about the results.

Needed resources

- PowerPoint presentations for community and stakeholder presentations
- Press release
- FAQ document
- Study summaries
- Key messages document
- Invitations to promote community event

Sample of a Results Dissemination Plan by a Peruvian Site

HPTN 039 Results Dissemination Plan for Peru

By Pedro Goicochea, MSc, MA, Former Co-Investigator, HPTN 039, Asociación Civil Impacta Salud y Educacion, Lima, Peru

Background

The HPTN 039 study of the safety and effectiveness of acyclovir for HIV prevention was initiated in December 2003 in Peru with three sites, one in Pucallpa (Asociación Civil Cayetano Heredia), and two in Lima (Impacta in Lince and Miraflores). By late 2005 and early 2006, two new sites in Peru were incorporated to the study, one in Iquitos (Asociación Civil Selva Amazonica) and another in Lima (Impacta San Miguel). In total, 1,384 men who have sex with men (MSM) have been enrolled in the study in these sites in Peru.

Since there are several individuals involved in three different cities with different Investigators of Record for each site, we will need a plan specifically tailored for each city and will have to consult with and get input on the draft plan from the site investigator of record and community educators at each site.

Dissemination of results

This plan will include:

Tier 1 entities

We plan to work and produce a final report or "Memoria" on the HPTN 039 study in Peru to be printed and distributed to the entities below. This document will present the story of the HPTN 039 study in Peru and worldwide, including its rationale, the trial design and results, major challenges overcome, and lessons learned and outcomes.

The site team plans to have all components of the document—except the results— written and laid out before February 2008, when the results will be publicly announced at the Conference on Retroviruses and Opportunistic Infections (CROI) in Boston, USA. The dissemination of the report to these institutions can take place immediately after or 24 hours before the announcement at CROI via e-mail. We will also distribute other explanatory, background materials about the trial to these groups:

- Impacta Ethics Committee
- Peruvian National Institute of Health
- Peruvian National Strategy for Prevention and Control of Sexually Transmitted Infections and AIDS of the Ministry of Health
- Directorate of Population Health of the Ministry of Health
- Directorates of Health of Ucayali (for the Pucallpa site) and Loreto (for the Iquitos site)
- General Directorate of Epidemiology of the Ministry of Health
- Country Coordination Committee for the Global Fund to Fight AIDS, Tuberculosis and Malaria
- Congress Health Commission
- Ministry of Health Counselors Committee
- Minister and Vice Minister of Health

Tier 2 entities

- Materials about the 039 study and results will also be distributed to the following entities via the mechanisms and according to the time lines listed in Appendix I:
- Universidad Cayetano Heredia HIV/AIDS research projects
- Scientific societies (Peruvian Colleague of Physicians, Peruvian Society of Infectious and Tropical Diseases)
- Community Advisory Board
- Nongovernmental organizations working on reproductive and sexual health
- Development funding agencies (USAID, the German Cooperation Agency–GTZ, the Dutch Cooperation Agency)
- Peruvian AIDS Network (Red SIDA Perú)
- GLBT agreement forum (all the organizations that belong to the forum)
- Press releases to Web pages for gay Peruvian audiences
- Medical-oriented journal (Gestión Médica)
- Press releases to other media (radio, TV, and press), depending on the city

Dissemination strategy

Public forums. We plan to disseminate results to the community and to participants through public forums in the different cities where the trial took place. We will present the process, the challenges, the lessons learned, and the preliminary results, primarily through interactive slide presentations.

Jorge Sanchez, Abner Ortiz, and Martin Casapia, site investigators from Lima, Pucallpa, and Iquitos, will invite participants to the forums through a formal letter to all above-mentioned organizations.

We will distribute a copy of the final report and a copy of the video "Gracias Perú" to participants of the public forum.

At the public forum, participants will have the chance to ask questions, and these will be answered during the talk.

Inform a wider group of stakeholders. A second step will be the distribution of the brochure to a broader list of organizations in the different cities as noted above and detailed in Appendix I. We will also place a link on the Impacta Web page and the ACSA Web page with the final report and an e-mail link for the public to ask questions. HPTN 039 investigators and community education staff will reply to all questions. Every press release will include the Web page address and an e-mail address for further information.

Prepare participants for results. To prepare participants for the disclosure of results and possible distribution of free acyclovir post-trial, we will discuss these issues during the annual participant appreciation event, scheduled for mid-January, in each of the cities where the study took place.

Other preparatory activities. In October 2007, site staff hosted a general forum on the connections between HIV and HSV-2. The format was a slide presentation with handouts. Attendees included nongovernmental organizations (NGOs), Ministry of Health representatives, and medical colleagues. The site is planning to conduct similar events in Ucayali and Loreto, the districts in which Pucallpa and Iquitos are located.

Media efforts

The site staff will continue to monitor Peruvian news media for reports that could affect perceptions of the HPTN 039 trial. The site has experience responding quickly to stories that do not portray the study in an ac-

curate light by contacting the source of the story to present correct information and by issuing press releases. The site will continue this approach, and will work with colleagues at other sites on stories or controversy picked up in the media, so that we can collaborate in developing a unified response across all study sites.

Staff assignments for results dissemination activities

This will be described in an Excel spreadsheet showing individual responsibilities for communication tasks.

Challenges

At this point, there are a few challenges:

1. HVTN 502 Step Study: The decision to suspend vaccination of participants in the HVTN study—a separate HIV prevention trial—has spurred us to disseminate information about it to our Ethics Committee, Community Advisory Boards, participants, and the community at large in the different cities. We have planned forums to inform Ministry of Health staff and NGO representatives about the HVTN study. Following recommendations from the HVTN, we have helped distribute press releases on the vaccination study to different media. Nevertheless, news coverage of HVTN 502 may be affecting community trust in HIV prevention studies in general.
2. Herpes suppression trial in Tanzania: Results of this study that were released at the International AIDS Society conference this year have not been broadly disseminated yet in the Peruvian community but may affect perceptions of all HIV prevention research, including our trial.
3. PrEP study: The pre-exposure prophylaxis (PrEP) for HIV prevention study in Peru is evolving with no major challenges. However, this project has been so controversial in other parts of the world that we are being very cautious with the potential pitfalls that may jeopardize our study in Peru, including participant recruitment.
4. There is a possibility that neither our HPTN 039 study of acyclovir, nor the Partners in Prevention study will show efficacy. The local community may feel that regardless of their willingness to contribute enrolling in alternative HIV prevention strategies that are being studied, these alternatives do not work. The community may grow tired of volunteering as a result.

Materials/Events we foresee producing for the results dissemination phase of this study include:

- Dissemination of the CROI 2008 abstract, translated to Spanish
- Preparation of a publication as an "HPTN 039 Final Report"
- Bulk production of "Gracias Peru" in DVD format for wide distribution in public forums and to interested organizations
- Press releases
- A Web page on the HPTN 039 results
- Organization of forums in every HPTN 039 city to share results with the community at large
- Appreciation events in every city for dissemination of results to the MSM community
- Appreciation events in every city for dissemination of results to HPTN 039 participants
- Merchandizing to be distributed to HPTN 039 participants at a cost not higher than US$6 each

These are some of the ideas we intend to work on for the coming months. This proposed plan will be circulated to HPTN 039 site Principal Investigators in a first round for comments, feedback, and input from them and other HPTN 039 staff.

For further comments, please contact Pedro Goicochea by e-mail.

Case Study: Timelines and Tasks for Disseminating the Results of HPTN 035

By Lisa Rossi, Director of Communications and External Relations, Microbicide Trials Network, University of Pittsburgh, Pittsburgh, PA

HPTN 035 was a multi-center clinical trial that evaluated the safety and effectiveness of two candidate microbicides, BufferGel® and 0.5% PRO 2000, for preventing HIV infection in women. The study was conducted between February 2005 and September 2008 among 3,099 HIV-negative women at seven clinical research sites in Malawi, South Africa, Zambia, Zimbabwe, and the United States by a team of researchers associated with the Microbicide Trials Network (MTN). The MTN is an HIV/AIDS clinical trials network funded by the National Institute of Allergy and Infectious Diseases (NIAID), with co-funding by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health (NIH). Prior to 2006, the study was conducted by the NIAID-funded HIV Prevention Trials Network (HPTN), from which the study gets its name.

Preparations for and discussions about the conclusion of the study and the dissemination of its results were well under way when we formed a communications group to work on developing a formal plan in August 2008. The group comprised NIAID Division of AIDS (DAIDS) leadership, a representative from NIAID's Office of Communications and Government Relations, MTN leadership, the MTN communications director and the study's protocol chair and clinical research manager. Our work revolved around three results scenarios, and we outlined a time line with specific tasks that assumed the study results would be presented as a late-breaker abstract at the Conference on Retroviral and Opportunistic Infections (CROI) in Montreal in early February 2009.

As the sponsor of HPTN 035, NIAID/DAIDS directed overall planning and determined the parameters for stakeholder engagement, which needed to be in accord with CROI's embargo policy and U.S. Securities and Exchange Commission (SEC) regulations. CROI's embargo policy stipulated that the research being presented at the meeting would be embargoed until the date and time of the presentation unless an official CROI press conference occurred first, in which case the embargo would be lifted. A break in the embargo could jeopardize presentation of the study results at the meeting. Because Indevus, one of the study's co-sponsors, was a publicly traded company, the timing of the public release would also need to be dictated by SEC regulations. Indevus would be obligated to publicly disclose the results within 24 hours (excluding holidays and weekends) of it becoming aware of the findings. This meant we would need to calculate precisely when Indevus (and ReProtect, the other co-sponsor) would be told of the results.

At the outset, we understood our plan would require careful orchestration of activities across several different time zones; CROI and the SEC added another layer of complexity. These challenges aside, it was essential that all relevant stakeholders and interested communities—in the United States, Canada, and each trial-site country—receive accurate information in a timely fashion.

For its part, the MTN worked with the trial's staff at each of the sites, helping to guide the development of site-specific plans and providing whatever communications tools and support was needed for successful implementation of these plans. As a first step, we encouraged sites to update their "stakeholders directories" so they would have at their fingertips the names and contact information for government, regulatory, civil society, advocacy, news media, and other important stakeholders, as well as key allies who might issue statements or speak out in defense of the study if need be. The stakeholder directory also required identifying key site-level contacts, including designated spokespersons, members of the crisis communications team, IRB/EC and CAB representatives and superiors within the organization. In addition, sites were asked to update their media relations standard operating procedure (SOP) or to develop an SOP if one was not already in place. A template we provided helped sites define what procedures to follow when responding to media inquiries, including how requests involving participants would be handled.

A template was also provided to guide sites in the development of individual dissemination plans. The template consisted of 11 sections in order to capture in detail the activities, personnel to be involved in these activities, and specific time lines for engaging different groups of stakeholders. Moreover, the template asked sites to identify what steps would be taken for advance notification of certain stakeholders to let them know how and when they could expect to learn the results. Sites were also encouraged to reach out to key journalists as early as possible so they would be better prepared and informed when the time came and, hopefully, be more fair and accurate in their reporting.

To help jumpstart planning at the site level, NIAID prepared draft press releases and messages for each of the three main scenarios. In the meantime, we began drafting a number of documents about the actual results. Clear and concise materials would be required for different audiences (such as media, community, scientific community, and participants) that sites could use as is or adapt as they saw fit. As soon as allowed, we provided study staff with both NIAID's and MTN's final press releases, the final set of messages and a package of materials—some 20 documents in all. These included a "fill-in-the-blank" press release with fill-in-the-blanks for site or local information, internal and external Q&As, PowerPoint presentations, and various fact sheets.

Disseminating the results of HPTN 035 was not without challenges, some anticipated, some not. It required extensive planning and hard work. It was a collaborative effort at every level. Lessons learned will be carried forward.

The following is a time line with many of the activities involved in the planning for and dissemination of the results:

2008

Aug.-Sept.	Sites updated their stakeholder directories and media SOPs
Sept. 8	HPTN 035 team meeting–Cape Town–possible strategies and scenarios were discussed
Nov. 20	Dissemination plan templates sent to sites; sites encouraged to notify keystake holders to expect results (template letter provided)
Dec. 4-5	Data review meeting with study co-chairs, DAIDS–confidentiality agreements in place
December	Ongoing discussions with sites on dissemination planning

2009

January	Ongoing discussions with sites on dissemination planning
Jan. 2	Late-breaker abstract submitted to CROI

Jan. 14	Scenarios, messaging, draft releases sent to sites
Feb. 6	Final materials posted on password-protected portal for internal use
Feb. 5-6 (Thursday-Friday)	NIAID informed primary stakeholders
a) Feb. 5	Gel manufacturers (Indevus, ReProtect), U.S. Food and Drug Administration, Medical Research Council (MRC), South Africa
b) Feb. 6	Other stakeholders
Feb. 6 (Friday)	Sites informed their respective Ministry of Health and IRB/Ethics Committee chair
Feb. 9 (Monday a.m., local time)	Sites informed their in-country drug regulatory agencies
Feb. 9 (Monday, 8:30 a.m. EST)	CROI embargo lifted at conclusion of CROI press conference; sites could issue press releases or media advisories at this time
Feb. 9 and 10	Sites held press events
Feb. 9-onward	Sites continued implementation of their dissemination plans; participants and other stakeholders notified of results

Sample Questions to Include in an Internal Q&A for Trial Results, Based on Three Outcome Scenarios

Below are examples of questions that might be included in an internal Q&A, for each of three possible outcome scenarios. Preparing answers for these questions allows you to think through in advance how to respond to challenging questions.

Positive effect

- When did researchers first observe positive results (such as a protective effect) with use of this product, and why did they not immediately halt the study and begin making it available to all of the study participants?
- Are you now providing all study participants with the product at no cost? If not, when?
- How can you be sure that your results are accurate, especially since they contradict the results of a similar study completed earlier by another research group?
- Is this study conclusive or are more studies needed to confirm the results?
- What are you doing to help the participants who may have acquired HIV during their participation in this study?
- Now that you have positive results, what are you doing to ensure that public health authorities can quickly begin to develop policies and implement strategies that support widespread distribution and use of the product?
- Can enough of the product be manufactured fast enough to meet the demand?
- What are you doing to ensure that persons who can benefit from use of the product have easy access to it free or at low cost?

Minimal or no effect

- Why did researchers continue this study after results from a similar study showed that the use of the product did not reduce the risk of someone becoming infected with HIV?
- Given that a higher dose of the product might have reduced the risk of participants becoming infected with HIV, are you going to provide them with a free supply of the appropriate dose?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Why should donors continue to fund studies of products that do not work?
- What more must researchers do to ensure that all studies are well designed and no study becomes a missed opportunity to prevent the spread of HIV?
- What impact do you think the failure of these studies to find effectiveness will have on how public and private donors evaluate research proposals?

Negative effect

- When did researchers first observe negative results and why did they not immediately halt the study to protect study participants?
- What are you doing to get the word out about these findings and prevent harm to all persons taking this product who may be at risk of becoming infected with HIV?
- What caused the negative results?
- If you do not know definitively what caused the negative results, what are you doing to find out?
- What are you doing to help the participants who may have acquired HIV because of their participation in this study?
- Are there other studies under way of use of this product for HIV prevention that should be halted?
- Who is to blame for what happened?
- Why was this study conducted on humans in the first place? Why in developing countries?
- Why should donors continue to fund HIV prevention studies?
- How can you expect anyone to participate in HIV prevention studies if they know that such participation may harm them?
- Are these negative trial outcomes having a negative impact on recruitment for HIV prevention studies?
- Why did you do this study here and harm our people?
- Did you have any indications from other research that the product is harmful?

Sample Letter to Ethics Committee Requesting Review of Materials Needed for Dissemination

HIV Prevention Research Unit

1st and 2nd floors, Westville Village Market,
123 Jan Hofmeyr Road, Westville, 3630, Kwazulu Natal.
PO Box 70380 Overport 4076, South Africa
Tel: + 27 31 242 3600; Fax: + 27 31 242 3800

05 November 2009

Chair: Biomedical Research Ethics Committee
Westville Campus
University of KwaZulu-Natal

PROTOCOL: An international multi-centre, randomised, double-blind, placebo-controlled trial to evaluate the efficacy and safety of 0.5% and 2% PRO 2000/5 gels for the prevention of vaginally acquired HIV infection (MDP 301). G Ramjee, MRC
MRC Ref: T267/05
Africa Centre Ref: T111/05

RE: Approval of Trial Results Dissemination Presentation, Q & A Document and MDP Backgrounder

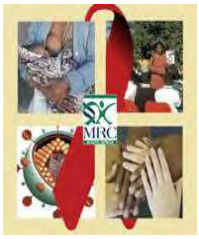
Dear _____,

The above-mentioned trial is now closed to participant follow-up and data has been locked. We are expecting the results to be released sometime in December 2009, depending on the review of the data analysis in late November 2009.

As we have done in the past, please find enclosed a Powerpoint presentation, which will be used to provide the information to communities and trial participants. We would appreciate your feedback on this. We also enclose the Q & A document and study backgrounder for your information.

As we are blinded to the data and we have no results, we have some slides which do not have final data and there are three outcome scenarios each with a possible explanation. Once the trial results are available, this data and the final outcome scenario will be added for your expedited review at a later stage.

Sample Letter Inviting Community Stakeholders to Learn Study Results



02 December 2009

To: Community Members/Stakeholders/Gatekeepers

RE: FINAL RESULTS UPDATE ON MDP 301 RESEARCH STUDY

The HIV Prevention Research Unit (HPRU) of the Medical Research Council (MRC) in Durban has been conducting the MDP 301 clinical trial at the MRC research sites based in Tongaat, Verulam and Isipingo since December 2005. To date, we have been working in partnership with community members and provided regular feedback on the research progress and held several community based trainings, outreach and education sessions.

This clinical trial has been recently completed and final results are expected to be available to the public on 14 December 2009.

As an important stakeholder, we would like to share the final results before they become available to the public. We therefore humbly request your presence at this meeting where we will provide the community with the final results of the MDP 301 Trial. The trial would not have been successfully completed without the support, assistance and collaboration of community members and all stakeholders involved. Your participation and input at this meeting will be most appreciated.

The meeting details are as follows:

DATE: **14 December 2009, Monday**

VENUE: **MRC Isipingo Site, 3-13 Police Station Road, Isipingo**

TIME: **10:30 -12:30**

Yours Sincerely

_____

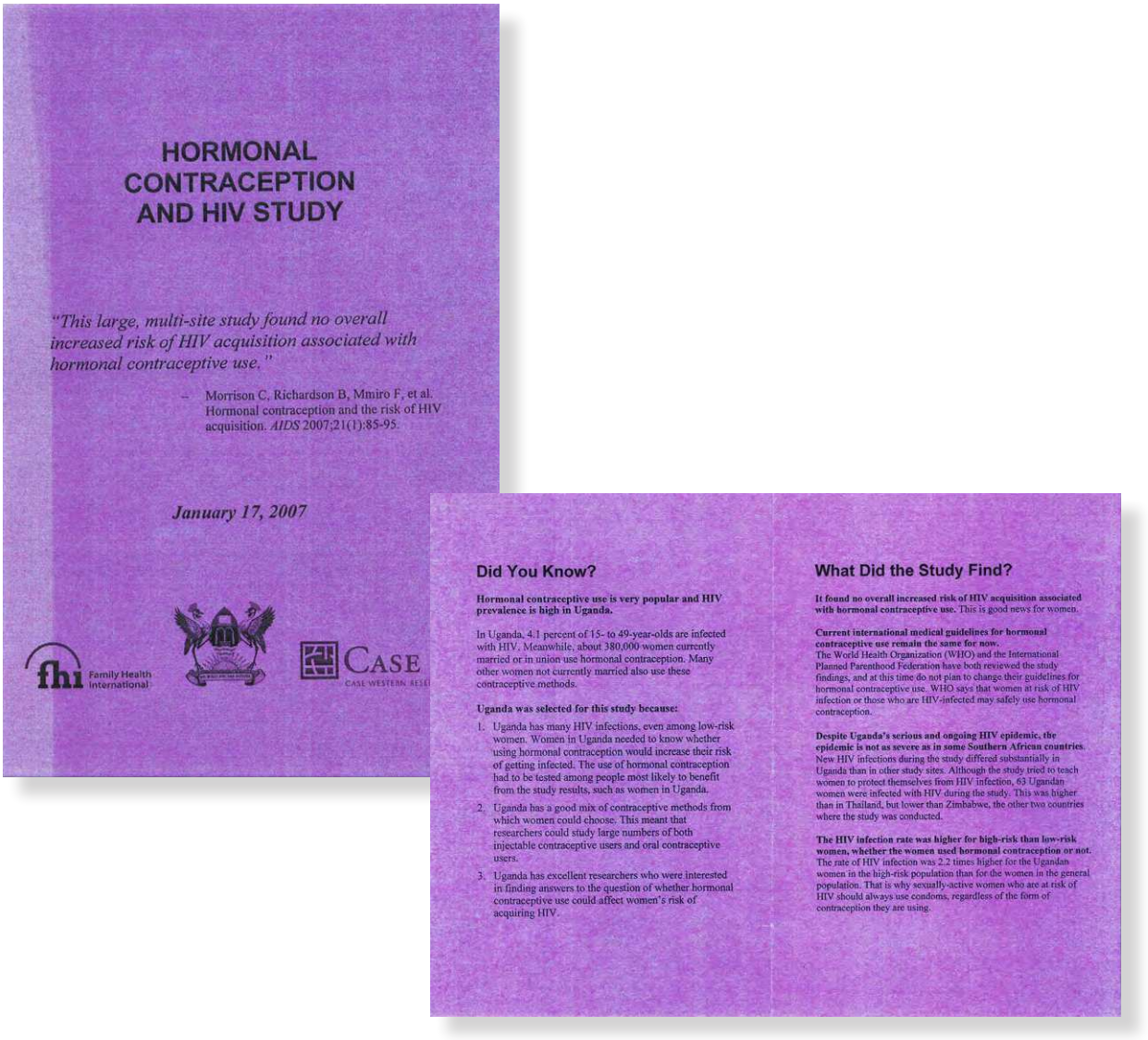
Yuki Sookrajh
MDP Manager

Cc Prof Gita Ramjee

RSVP: Mduduzi Ngubane
Tel: 031 – 9027494
Fax: 031 – 902 7938

Sample Brochure to Share Study Results with a Community

Messages in this FHI brochure were written for an audience of community members.



HORMONAL CONTRACEPTION AND HIV STUDY

"This large, multi-site study found no overall increased risk of HIV acquisition associated with hormonal contraceptive use."

– Morrison C, Richardson B, Mmiro F, et al. Hormonal contraception and the risk of HIV acquisition. *AIDS* 2007;21(1):85-95.

January 17, 2007

fhi Family Health International

CASE

CASE WESTERN RESE

Did You Know?

Hormonal contraceptive use is very popular and HIV prevalence is high in Uganda.

In Uganda, 4.1 percent of 15- to 49-year-olds are infected with HIV. Meanwhile, about 380,000 women currently married or in union use hormonal contraception. Many other women not currently married also use these contraceptive methods.

Uganda was selected for this study because:

1. Uganda has many HIV infections, even among low-risk women. Women in Uganda needed to know whether using hormonal contraception would increase their risk of getting infected. The use of hormonal contraception had to be tested among people most likely to benefit from the study results, such as women in Uganda.
2. Uganda has a good mix of contraceptive methods from which women could choose. This meant that researchers could study large numbers of both injectable contraceptive users and oral contraceptive users.
3. Uganda has excellent researchers who were interested in finding answers to the question of whether hormonal contraceptive use could affect women's risk of acquiring HIV.

What Did the Study Find?

It found no overall increased risk of HIV acquisition associated with hormonal contraceptive use. This is good news for women.

Current international medical guidelines for hormonal contraceptive use remain the same for now.
The World Health Organization (WHO) and the International Planned Parenthood Federation have both reviewed the study findings, and at this time do not plan to change their guidelines for hormonal contraceptive use. WHO says that women at risk of HIV infection or those who are HIV-infected may safely use hormonal contraception.

Despite Uganda's serious and ongoing HIV epidemic, the epidemic is not as severe as in some Southern African countries.
New HIV infections during the study differed substantially in Uganda than in other study sites. Although the study tried to teach women to protect themselves from HIV infection, 63 Ugandan women were infected with HIV during the study. This was higher than in Thailand, but lower than Zimbabwe, the other two countries where the study was conducted.

The HIV infection rate was higher for high-risk than low-risk women, whether the women used hormonal contraception or not.
The rate of HIV infection was 2.2 times higher for the Ugandan women in the high-risk population than for the women in the general population. That is why sexually-active women who are at risk of HIV should always use condoms, regardless of the form of contraception they are using.

Sample Brochure to Share Study Results with a Ministry of Health

Messages in this FHI brochure were written for an audience of health professionals and policymakers.

Study of Hormonal Contraception and the Risk of HIV Acquisition

"This large, multi-site study found no overall increased risk of HIV acquisition associated with hormonal contraceptive use."

– Morrison C, Richardson B, Mmiro F, et al. Hormonal contraception and the risk of HIV acquisition. *AIDS* 2007;21(1):85-95.

January 16, 2007

fhi Family Health International

STUDY SYNOPSIS:

A recent study funded by the U.S. National Institute of Child Health and Human Development (NICHD) has found **no statistically significant overall association between the use of either combined oral contraceptive (COC) pills or depot medroxyprogesterone acetate (DMPA) and HIV acquisition**. A total of some 6,100 HIV-negative women participated in the four-year study, which was led by Family Health International (FHI) in conjunction with seven other institutions, and conducted in Uganda, Zimbabwe, and Thailand. In this prospective, cohort study, women were equally divided among the three groups (users of COCs, users of DMPA, and women not using hormonal contraception). The primary finding of this study provides the best reassurance to date for women in need of highly effective contraception in settings of moderate to high HIV risk.

The study also explored whether sexually transmitted infections (STIs) modified the relationship between hormonal contraceptive use and HIV acquisition. Among STIs included in the analyses were vaginal infections (trichomoniasis, bacterial vaginosis, and candidiasis), cervical infections (chlamydia and gonorrhea), and infection with herpes simplex virus-2 (HSV-2). The African data found only one relationship between hormonal contraceptive use and STIs: Surprisingly, among the approximately half of African study participants testing *negative* for HSV-2 at enrollment, those who used either COCs or DMPA had a statistically significant increased rate of HIV acquisition compared to non-users. This finding was unexpected and has no clear biological mechanism. Thus, as is often the case with unexpected study findings, further research must evaluate this potential association. Of note, the study found that participants who were infected with HSV at the beginning of the study had higher rates of HIV infection than did those women who were HSV-negative at the start.

The results from the study do not indicate that any changes should be made in the provision or use of DMPA or COCs. Neither the World Health Organization nor the International Planned Parenthood Federation, which have reviewed the study results, plans at this time to change its guidelines for hormonal contraceptive use by such women.

Besides no overall increased risk of HIV acquisition associated with hormonal contraceptive use, what else did the study find?

The HIV epidemic is serious and ongoing in Uganda.
Of 3,654 women screened in Uganda, 601 (16.4 percent) were already HIV-infected. This observed HIV prevalence observed was substantially higher than the prevalence of 4.1 percent among all 15- to 49-year-olds in Uganda reported in 2005 by the United Nations. This may have been because all of the women in this study were sexually active at the time of study enrollment and because women were recruited several years before the UN data were collected.

HIV incidence (new infections during the study) differed substantially in Uganda than in other study sites.
The HIV incidence rate among all study participants in Uganda was 1.55 per 100 woman years. (A total of 63 Ugandan women were infected.) This was higher than in Thailand (0.15 per 100 woman years), but lower than Zimbabwe (4.07 per 100 woman years). Despite Uganda's serious and ongoing HIV epidemic, the epidemic is not as severe as in some Southern African countries.

Hormonal contraceptive users in Uganda, and especially DMPA users, when compared to women not using hormonal contraception had a somewhat higher risk of acquiring HIV than did such women in Zimbabwe.
Possible explanations include chance, measurement differences in potential confounders by country, or that the effect of hormonal contraception differs by HIV subtype. In Uganda, the HIV subtypes are predominantly A and D. In Zimbabwe, the predominant subtype is C.

The HIV infection rate was higher for high-risk than low-risk women in Uganda, whether the women used hormonal contraception or not.
The rate of HIV infection was 2.2 times higher for the Ugandan women in the high-risk population than for the women in the general population. That is why sexually-active women who are at risk of HIV should always use condoms, regardless of the form of contraception they are using.

HPTN 039 Acyclovir Study Results: These are important results that challenge us to explore further.

Based on previous research linking herpes as a risk factor for HIV, this study answers key questions but clearly tells us we need to know more about how these viruses interact.

Multiple studies showed a 2-3 fold increased risk of HIV acquisition among persons with HSV-2 infection:

- It is thought HSV-2 creates an easier portal of entry recruiting immune cells that are "targets" for HIV entry
- Learned that suppression of HSV-2, with a standard dose of acyclovir (400mg twice daily), did reduce genital ulcers but did not prevent HIV infection among men & women infected with HSV-2
- The study answered primary and secondary objectives
- Surprises from this study included:
  - 37% reduction in visible genital ulcers (substantially lower than in past studies in the US & Europe)
  - In 2 of the 3 regions, less reduction in amount of HSV-2 in breakthrough ulcers
- Next steps to explore from HPTN 039: 1) acyclovir absorption/ pharmacokinetics in different populations, 2) HSV-2 susceptibility to acyclovir from different populations, 3) other etiologies of genital ulcers
- The door is still open to evaluate HSV-2 interventions for HIV infectiousness and transmission

Previous research suggested that acyclovir, the successful treatment for herpes, might be a pathway to HIV prevention.

- Acyclovir has been a safe and effective treatment for HSV-2 for more than 20 years
- Researchers theorized that acyclovir's ability to suppress HSV-2 and prevent genital outbreaks could block HIV infection in people infected with herpes

This well-designed, conducted, and monitored study reinforced proven prevention strategies and provided safeguards to protect the well-being of study volunteers.

- Volunteers were provided with condoms, regular exams, episodic herpes treatment, and extensive counseling on how to reduce their risk for HIV infection throughout the study
- Largest trial of its kind:
  - 3,172 HSV-2 infected people
  - 9 sites, 5 countries
- Sites achieved high volunteer recruitment and excellent retention
- No serious adverse events related to the study drug
- Full disclosure and full consent
- Participants who became infected with HIV during the study have been referred for appropriate medical care and treatment in their community
- Grateful to volunteers

Millions with genital herpes are at risk, so studies to determine the effect of HSV-2 on HIV are essential along with other initiatives.

- 1/3 of new HIV infections in Africa are estimated to be due to HSV-2 infection
- 20% of adults in the U.S. and ~ 50% of women in Sub-Saharan Africa and men having sex with men (MSM) in Latin America have HSV-2 infection
- Although HSV-2 is common, it is often unrecognized in spite of frequent reactivations
- Partners in Prevention study is determining whether HSV-2 can reduce HIV transmission and delay the rate of progression to AIDS
- Need research on:
  - Biology of HSV: factors related to HSV-2 activation
  - Treatment of HSV: effect of higher doses of current drugs, new drugs, combination therapy on clinical and subclinical HSV
  - HSV vaccines
- Clinical trials are needed to move from epidemiologic and biologic observations in order to identify effective interventions

Adapted from: materials developed by Dr. Connie Celum, Principal Investigator, HPTN 039.

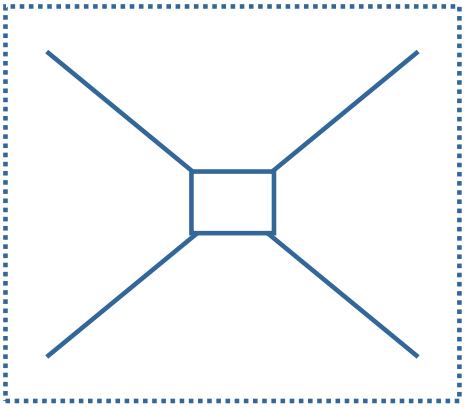
Alternative Sample Grid to Create Compelling Messages

Spitfire Strategies

Messaging Tip Sheet: Create compelling messages

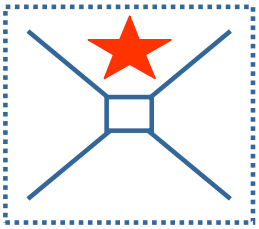
Developing Message Points
Once you know who you want to reach and have determined what they care about, you can create message points that will resonate with this audience. Good messaging has no more than four main points. These points need to be both concise and compelling. It is that easy, and that hard.

To help you think through your message points, try using a message box. The message box is in this shape for a reason. The circular nature of it reminds you that you can start at any message point and hop around to your heart's desire in a speech, during an interview, in a press release – any time you are communicating about your issue. Just stay in the message box. If the messages were presented in a linear fashion, the inclination would be to start at the top and work down. Instead, messages should remain flexible so you can deliver the ones that best fit an audience's knowledge and interest.

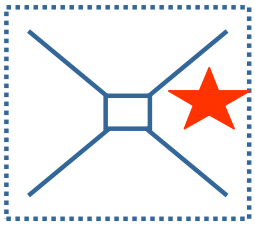


For each different target audience that you are trying to reach, you should have a different message box. This is because every audience has different values and your messages will be most effective if they are tailored to each of your target audiences. Tailoring your messages doesn't mean starting from scratch, but rather adjusting each of the points as needed for the new audience.

Once you have filled in the four core messages in your box (described below), you can develop supporting points for each message including compelling facts, stories and statistics.



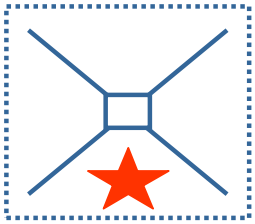
The Value Message – Top (North) Section
This is where you connect with your audience and tap into a specific value that your audience has. This message point reminds them of your common ground, or says something that will get them to agree or at least nod their heads. For newcomer audiences this is a point that you may spend a great deal of time on when making a speech or preparing materials. For the choir this is more of a touch and move on point. Remind them quickly and move to other points that are more pressing.



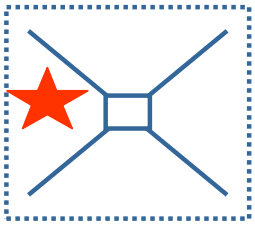
The Barrier Message – Right (East) Section
With so many different opinions out there, the chance for misconception is high. People may not realize the extent of a problem – or they may not realize they are basing all their decisions on an incorrect fact.

Think about all the seemingly credible stories you have heard that have ended up being urban legends. It took a lot of people passing around false information before the story made its way to you and countless others. It doesn't take long to take an incorrect fact and circulate it as the truth. The barrier message point addresses this challenge by countering your audience's key misconception about your issue.

The key to a successful barrier message is that you do not repeat your audience's misconception. Rather, you provide new or unexpected information to overcome this barrier to your audience buying in to your message.



The Ask – Bottom (South) Section
At least one message point should be focused on getting the target audience to do something. What's the point in getting their attention if you don't use it to reach your goals? This is where the ask comes in – the more doable it is the better. Asking someone to save the children isn't helpful – it's overwhelming. People have no idea how to do this. Increasing a school budget to allow for more qualified teachers, however, is something people can get behind.



The Vision Message – Left (West) Section
This message point echoes the value message point. It says to people: If you do what I ask you to do, then you get what you want.

Testing Your Message Box
Once you have finished your message box, pat yourself on the back. Then find a way to test your messages among some audience targets. This could be as simple as asking three or four members of your audience what they think, or it may mean fielding a national poll. Either way, try it out on someone who can evaluate the messages from a neutral standpoint – this rules out you and anyone who helped you complete your message box.

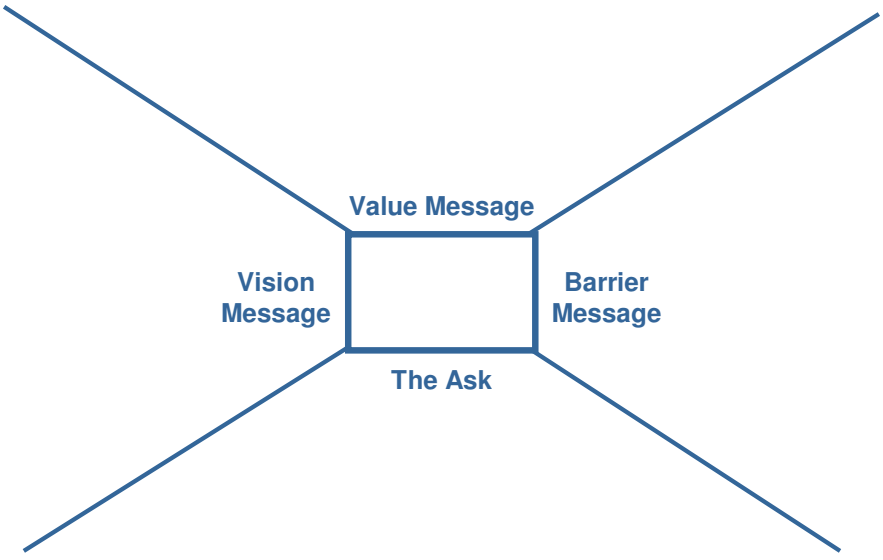
Creating Compelling Messages Worksheet

Who are you trying to reach with this message? *(Remember to keep your audience as narrow as possible. And only select one audience at a time – different audiences need different message boxes.)*

_____

Brainstorm a list of values that your audience has. Circle the one that is most important that you will tap into with your message.

Now fill in the four sections of your message box.



Managing Media Inquiries: Worksheet for Media Calls

Worksheet: When the media calls
Collect the following contact information from the journalist:
Name of journalist:
Publication:
Office number:
Mobile number:
E-mail address:
Ask the journalist the following questions:
What is the story about? What is your angle?
Who else are you interviewing?
If the interview is for radio or television, what is the format? Will it be broadcast live? Will it include call-in questions? What time is it scheduled for and for how long?
What times are good for you? Please give a few options so I can check with the spokesperson's schedule. (What is the deadline?)
Deliver information to the spokesperson:
Brief the person to be interviewed, including all the information gathered above.
Find a few articles the journalist has written on the topic and provide them to the person who will be interviewed.

Sample Standard Operating Procedures (SOPs) for Media Inquiries

SOP for Media Inquiries

1. Purpose

The purpose of this Standard Operating Procedure (SOP) is to outline the procedures that need to be followed on site and off site (within catchment areas and the community) with the media and management of any events that occur and are of concern.

2.Introduction

It is important that we have mechanisms for ensuring that there is effective communication with the media and community. Responsible persons have an obligation to ensure that the media and community receive accurate and relevant information about the study and the study procedures at all times.

3.Responsibility

Principal Investigator (PI)

Sub-investigator

Project Co-ordinators (PCs)

Community Educating Officer (CEO)

Reception staff

Any staff member who might be in contact with media

Communication with the Media:

- The primary media point person shall be the Site PI. In the absence of the Site PI, the back-up point persons shall be the study coordinators (clinical trial and socio-behavioral component).
- All study staff will refer media inquiries to the primary media point person (the Site PI) or in her absence, the back-up (study coordinators). For international media inquiries, the Site PI and study coordinator should contact XXX as well as the PI and clinical monitors.

4.Equipment And Materials

Internal documents (not to be distributed outside the study team and Community Advisory Board [CAB]):

- Internal Frequently Asked Questions (FAQs) about the study
- Tips on how to deal with the media
- Media Call Log Sheet
- Media Visit Log Sheet

External documents (documents that can be distributed to the community):

- Backgrounder on trial
- Frequently Asked Questions about clinical trials

5. Procedures

5.1. Media-Initiated Telephone Calls or Visits

5.1.1. When a caller or unexpected visitor asks to speak with someone about the trial, determine whether the person is a member of the media. Ask: "May I have your name and the name of your organization? What is the reason for your call? What is your phone number and your e-mail address?"

5.1.2. If the person is from the media, request and write down all the information you can get on the Media Call Log Sheet. Tell the caller that the site PI would be the best person for him or her to talk to. Make sure you have the reporter's phone number and inform him or her that you or the PI will call back shortly (to give the PI time to prepare). The PI should then be reached and should consider whether to accept doing an interview. (In some cases, it may be best to postpone or decline an interview. In some cases, it would be a mistake not to accept an interview. Seek advice if in doubt.)

Call the reporter back to schedule or decline the interview.

5.1.3. If the PI is unavailable, connect the reporter to the PI's designee while informing the designee that you are doing so. The PI or spokesperson should always have background information on the reporter's request and consider the advisability of discussing the trial at that time before scheduling the interview. If the reporter is unknown to the spokesperson, inquire among colleagues about the reporter's reputation for fairness, or Google the reporter's name to get a sense of his or her knowledge of research, accuracy and tone, and attitudes toward HIV prevention trials. If the reporter has a reputation for inaccuracy, it is best to conduct the interview by e-mail so that quotes cannot be distorted. The PI or spokesperson can say, "I'm busy at the moment but would be happy to answer questions if you send them to me by e-mail."

5.1.4. If all the people responsible for media communication are unavailable, please take a message on the Media Call Log Sheet. Ask "When do you need this by?"and assure the reporter that the appropriate person will call back quickly with a response to the request, one way or the other. Inform the media person when he or she should expect to hear from the PI or designee. If the media person is a visitor, schedule an appointment and say that you will call to confirm or reschedule after you have talked to the PI. Be respectful of the reporter's deadline.

5.1.5. Call the PI immediately and inform her of the media interest, the topic, and any necessary action. If the PI does not answer, leave a message and call a designee.

5.1.6 Send an e-mail copying the PI, the SBC site specialist, the clinical monitors, and the communications point person to inform them of this contact from the media.

5.1.7. If the media call or visit needs to be responded to, the PI or designee should return the call within 24 hours and in time for the reporter to meet his or her deadline, whether accepting or declining the interview.

5.1.8. Document what has been done (such as call to PI, or e-mails) and the responses received from the PI or designee on the Media Call Log Sheet.

5.2. On-Site Media Visits

5.2.1. If an unexpected visitor asks to speak with someone about the trial, follow the steps outlined in section 6.1.

5.2.2. If the person is from the media, seat him or her in the staff dining area and inform all staff in the

area that a reporter is visiting. Assign someone to ensure that that the visitor does not communicate with anybody while waiting and does not take photographs of participants without permission. Because of the need to protect the confidentiality of study participants, the reporter must not tour the center during hours of operation.

5.3. Communicating with the Media Off Site

In instances where the community outreach team or any other staff are involved in activities within the community and there are media people present, the following must be done:

5.3.1. The preferred procedure is to invite the media staff to visit the center and meet with the PI. If this is not possible, and if the person responsible has received media training, he or she can answer the reporter's questions.

5.3.2. If the person responsible is not media trained, he or she must set up an appointment for the reporter to visit the site for full information from the people trained in communicating with the media.

5.3.3. Record all necessary details about the reporter: full name, name of the organization, contact details, and the topic of interest or angle of the story.

5.3.4. Inform the PI immediately of the media interest, the topic, and any necessary action.

5.3.5. Send an e-mail copying the PI to inform him or her of this contact with the media.

5.3.6. If the media contact needs to be responded to, the PI or designee should return the call within 24 hours and in time for the reporter to meet his or her deadline.

5.3.7. If the media person is persistent about asking you for information, ensure that you give the correct information and do not answer more than what is asked. Get all contact information; ask if this is going to be published, and where and when. Write down everything you say to the reporter media for the records and inform the PI as soon as possible.

5.4. Media Training and Responsibilities

5.4.1. People responsible for the above-mentioned procedures need to be adequately trained and frequently updated in media relations and communications. The training will be prepared in advance with the trial sponsor.

5.4.2. It is the responsibility of the CEO who is conducting community education or community meetings to know who is in the audience and whether the media is represented at the community meetings or education sessions.

5.4.3. It is also the responsibility of the CEO who conducted the community meeting or education session to notify the PC or PI about any media personnel who were present, to record what was said, and to assist in follow-up, including finding out when the information will be published or broadcast and obtaining copies of published articles.

5.4.4. Before publication or broadcast, the PI or designee should contact the reporter to offer assistance and any clarification that might be necessary and to reinforce key messages. Also, the PI or spokesperson should follow up by e-mail to clarify in writing any information that the reporter appeared to have difficulty understanding, or to emphasize an important point that may have been missed. The PI or spokesperson should also offer to review a reporter's draft story for technical accuracy to ensure that factual information is disseminated.

5.4.5. It is the responsibility of the PI and PC to inform the sponsor about the above-mentioned activities.

5.4.6. It is also staff's responsibility to update the FAQs used for community education.

6. Acknowledgment Of Reading And Comprehension Of A Document

SOP Title: Media Communication For X Trial

	NAME	SIGNATURE	DATE
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

Sample Letter to the Editor in Response to a Negative News Article

News Article

MPs warn on Depo Provera family planning method

Women should be encouraged to use other methods of family planning than Depo Provera, due to its terrible side-effects, MPs have said.

Sharing their experiences, the female legislators said the method causes delay in conception and excessive bleeding during menstruation.

The women also said they had their menstrual cycle altered after using the contraceptive.

One women MP said she failed to conceive for seven years, a matter that brought conflict in her home. "After my first-born, I decided to use Depo Provera. I had planned to have the next baby after three years. But it took me seven years to conceive again. My husband was very angry and wondered whether I had only one egg," she said.

She narrated that a woman in her constituency used it and failed to conceive. "When she did after eight years, she developed pressure. Unfortunately, she died."

Excerpted from New Vision (Kampala, Uganda).

Response By Scientist

Contraception for women who want to get pregnant–later

Dear Editor,

Millions of women in countries all over the world use Depo-Provera—or DMPA—as a way to prevent pregnancy. Injectable contraceptives are one of the most popular forms of birth control, and have been available for more than 20 years. Recent news reports have put the spotlight on injectables. Women want to know is Depo-Provera safe? And if they use Depo-Provera, will they still be able to get pregnant when ready to have children?

The scientific research says yes, on both counts. Some women who have experienced problems getting pregnant after they stop getting the shots assume that their infertility was caused by DMPA. This is not the case: the scientific evidence proves that DMPA does not cause infertility. Often, problems getting pregnant are the result of infertility caused by sexually transmitted infections. Infertility is often perceived as only a woman's problem. But in about half of the cases, men are either the single cause of or contribute to the couple's infertility.

The Ministry of Health supports DMPA as a recommended form of family planning and is helping with a project to make it available to women who are interested. This is an important public health initiative, as many women in rural areas have limited access to clinical services. When used with condoms—which reduce the risk of getting a sexually transmitted infection—injectable contraceptives can help prevent infertility and improve the chances that women will become pregnant when they choose to do so.

Sincerely,

Author Data Form for Writing a Press Release

Use this form for internal purposes to assist in preparing a press release.

Name and degrees: Affiliation: Address: E-mail: Telephone: Fax:	
Name of publication:	Expected publication date:
1. What are the three most important findings of your research in relationship to their significance in the field?	
1)	
2)	
3)	
2. Explain the topic in lay-person's language. (How would you explain it to your neighbor?)	
3. Please indicate if your research affects (check all that apply):	
_____ Health care providers	_____ Changes in clinical practice
_____ Health program managers/policymakers	_____ Health policy/government
_____ Other research organizations	_____ Further research and grants
_____ Regular individuals going to their doctor	_____ Public health programs and practice
_____ Other: If other, please specify	
4. Do you have any media contacts that would be interested in your article? If so, please list them here.	
5. Should a journalist require more information from which to write an article, do you wish to be interviewed? (Y/N)	
6. If yes, how would you like to be contacted: _____ Telephone: _____ Best time: _____	
_____ E-mail: _____	
7. Does a research partner institution have a press office? (Y/N) If yes, please provide a contact:	

Adapted from Beyond Scientific Publications

Press Release Template

[insert organization's or study's logo]

For Immediate Release

Contact:

Author's Name, Title

School/Department

Address

Telephone

Fax

E-mail

One-Line Attention-Getting Title

(City, STATE) Date of Distribution–This is a sample press release. Every release should begin with a short (25 words or less), one-line paragraph that hooks the reader's interest.

The purpose of a press release is to provide newsworthy information to the media. "Newsworthy" means that the information is **(1)** timely (has some immediate impact on readers); **(2)** novel (the first, the best, etc.); **(3)** consequential (a development that will have significant impact on readers); **(4)** dramatic (reveals something quirky or colorful about the human condition or character); **(5)** prominent (relates to a public figure or organization); or **(6)** proximate (affects people living in an area). Contrary to popular belief, newspapers and television stations are not sitting around with empty space to fill, nor do they feel a moral responsibility to write about PSU.

The press release should be a concise (no more than two double-spaced pages), factual, informative, and straightforward piece of writing that describes what you want the public to know. The most important and indispensable information (who, what, when, where, etc.) is located at the beginning of the story; the most expendable information is at the end. Make every paragraph, sentence, and word count.

Text in all press releases should be typed in the font Tahoma, size 10. If you don't have Tahoma, use Palatino, Helvetica, or Times Roman.

If you are unable to fit your information in the preferred one-page format, end page one with:

(more)

Add the following heading at the top of page two:

Page 2—Key Words from Title

Otherwise, end the body of the press release with the following symbol:

###

If you are announcing an event, be sure to include accurate information about the time, date, location (including street address and room number), and cost. Proofread, proofread, and proofread. Most media require at least 2 to 3 weeks lead time to publish your event.

If you use a quote, and it is recommended that you do, give it its own paragraph so that the reporter can easily pick it out.

At the end, add "boilerplate" text about your research institution. For example: The Center for Interdisciplinary Research on AIDS (CIRA) was established in 1997 and is currently New England's only National Institute of Mental Health (NIMH)-funded AIDS research center. CIRA brings together scientists from 20 different disciplines and two institutions, including Yale University in New Haven, CT and The Institute for Community Research in Hartford, CT.

Research institution name here

Physical/mailing address here

Telephone number here

Fax number here

# #

Adapted with permission. This work was supported, in part, by Yale University's Center for Interdisciplinary Research on AIDS (CIRA), through grants from the National Institute of Mental Health to Paul Cleary, Ph.D. (No. P30 MH 62294).

Sample press release

For Immediate Release

January 25, 2005

Contact: Kim Best, Science Editor

919.544.7040

Oral Contraceptives and Weight Gain

Updated research review still finds no evidence that oral contraceptives cause weight gain

Research Triangle Park, NC—Many women stop using oral contraceptives early or never start using them because of concerns about gaining weight. But an updated review of studies examining the relationship between hormonal contraceptive use and weight change continues to find no evidence that contraceptive pills increase weight.

This review, published in the latest issue of the Cochrane Library, includes two additional studies beyond those originally reviewed by researchers at Family Health International (FHI) and published in 2003 in the Cochrane Library. In total, 44 hormonal contraceptive trials containing information about study participants' weight changes—the majority of which addressed oral contraceptive use—have now been examined.

One strength of the review, which was an exhaustive search of the scientific literature on this topic, was that it was limited to randomized controlled trials, the "gold standard" of trial designs for reducing the potential for bias.

Three of the trials compared weight changes in women taking oral contraceptives versus weight changes in women taking placebos. None of the three showed an association between oral contraceptives and weight gain. The remaining trials that considered oral contraceptive use compared weight changes between women taking different oral contraceptive regimens. While some women gained weight and some lost weight over time, overall differences between groups were minimal. The largest difference in weight change between groups was less than five pounds.

"In comparing different combination contraceptives, you would expect differences between groups if the estrogen or progestin in the pills or the type of pill was causing weight gain," says FHI researcher and review coauthor Laureen Lopez. "But we did not see any major differences between groups taking different types of pills," she says.

Combined oral contraceptives are the most common form of contraception in the United States and are used by more than 100 million women worldwide. If taken correctly and consistently, they are more than 99 percent effective at preventing pregnancy. Under typical use, they are less effective.

Studying the association between oral contraceptives and weight gain has been difficult for multiple reasons, including the facts that many different oral contraceptive regimens exist and some women gain weight over time regardless of whether they use contraception. "It is very reassuring news," says coauthor Dr. David Grimes of FHI. "A widely held myth suggests that oral contraceptives cause weight gain, but the answer as best we can tell is they do not," he says.

The Cochrane Library is an electronic database of the Cochrane Collaboration, an international organization committed to helping people make informed health care decisions by preparing, maintaining, and promoting systematic reviews of the effects of health care interventions. Family Health International contributes to the Cochrane Collaboration by producing reviews of randomized clinical trials of contraceptive methods. For more information on the Cochrane Collaboration, see http://www.cochrane.org/. To learn more about Family Health International, see http://www.fhi.org/.

Source

Gallo MF, Lopez LM, Grimes DA, Schulz KF, Helmerhorst FM. Combination contraceptives: effects on weight (Cochrane Review). In: The Cochrane Library, Issue 1. Chichester, UK: John Wiley & Sons, Ltd., 2006.

Family Health International is dedicated to improving lives, knowledge, and understanding worldwide through a highly diversified program of research, education, and services in family health and HIV/AIDS prevention and care. Since its inception in 1971, FHI has formed partnerships with national governments and local communities in countries throughout the developing world to support lasting improvements in the health of individuals and the effectiveness of entire health systems.