QUESTIONS & ANSWERS:
The MIRA Diaphragm Trial Results

Q: What is the MIRA trial?

The MIRA trial, which stands for "Methods for Improving Reproductive Health in Africa," studied if latex diaphragms used with Replens® lubricant reduce women's chance of contracting HIV and sexually transmitted infections from men during sexual intercourse.

Q: Who conducted the trial?

The study was conducted by the Women's Global Health Imperative at the University of California, San Francisco in partnership with the Medical Research Council of South Africa, the Perinatal HIV Research Unit of the University of the Witwatersrand, the University of Zimbabwe, and Ibis Reproductive Health. MIRA was funded by the Bill & Melinda Gates Foundation.

Q: What did the MIRA study show?

The trial found that in the context of a comprehensive HIV prevention package, including condom provision, there was no added protective benefit from the diaphragm and lubricant. The HIV infection rates observed in the trial were the same in both the control arm (where women received condoms only) and the intervention arm (condom plus diaphragm plus lubricant). All women received safe sex counseling, and treatment of curable sexually transmitted diseases. Over the course of the study (2003 – 2006), 151 out of 2476 women (annual incidence: 3.9%) became HIV infected in the group that received condoms only, and 158 out of 2472 women (annual incidence: 4.1%) became HIV infected in the group that received the diaphragm, lubricant and condoms.

The study could not evaluate whether using the diaphragm was better than using nothing, because it was not designed to answer this question. Furthermore, most women in both arms of the trial reported male condom use.

Q: How many women became HIV-infected at each site?

Over the course of the study (2003 – 2006) at the Durban site, 76 out of 742 women became HIV infected in the group that received condoms only, and 72 out of 743 women became HIV infected in the group that received the diaphragm, lubricant and condoms. At the Soweto site 23 out of 505 women became HIV infected in the condom only group, and 24 out of 503 women became HIV infected in the diaphragm, lubricant and condom group. At the Harare site 52 out of 1229 women became HIV infected in the condom only group, and 62 out of 1226 became HIV infected in the diaphragm, lubricant and condom group. There was no statistically significant difference in the number of HIV infections between the two arms.

Q: Should diaphragms be used for HIV prevention?

Because the trial found that the diaphragm and lubricant did not provide extra protection compared to condoms and treatment of STIs, the researchers cannot recommend that diaphragm be used for HIV prevention. Using condoms remains the best method to prevent HIV.

Q: Why did the trial study diaphragms as a potential HIV prevention tool?

Evidence has indicated that the cervix is particularly vulnerable to HIV infection. This is because the cervix has a large amount of receptor cells that are susceptible to HIV. The MIRA study sought to examine whether covering the cervix with a diaphragm during sexual intercourse would protect women from HIV infection.

Q: Who participated in this trial?

MIRA enrolled 5,045 women at three clinical trial sites in Soweto and Durban, South Africa, and Harare, Zimbabwe. All volunteers were HIV uninfected and sexually active; pregnant women were not enrolled in the trial. Women were recruited to participate in the trial from local primary health, family planning and well-baby clinics, and from surrounding communities in Soweto, Durban, and Harare.

Q: How was the trial conducted?

All participants received thorough information about what the trial was studying and what was required to participate. Each participant gave her informed consent and received extensive HIV and safer sex counseling before entering the trial. Once enrolled, volunteers were placed randomly into one of two groups to receive either male condoms and counseling (control group), or a diaphragm with Replens® lubricant along with male condoms and counseling. The study followed these women for 12-24 months.

Q: What is Replens® and why was it being used in this trial?

Replens® is a commonly available, non-prescription vaginal lubricant. When used with diaphragms, Replens® can facilitate insertion of the diaphragm, provides a protective coating for the vagina and can help decrease friction during sexual intercourse.

Q: How many women became infected with HIV during the study?

The MIRA study showed no statistically significant difference in the number of new HIV infections among participants who received the diaphragm (intervention group) and participants who did not (control group). Over the course of the study (2003 – 2006) at the Durban site, 76 out of 742 women (annual incidence: 7.0%) became HIV infected in the group that received condoms only, and 72 out of 743 women (annual incidence: 6.7%) became HIV infected in the intervention group. At the Soweto site 23 out of 505 women (annual incidence: 3.3%) became HIV infected in the condom only group, and 24 out of 503 women (annual incidence: 3.5%) became HIV infected in the intervention group. At the Harare site, 52 out of 1229 women (annual incidence: 2.5%) became HIV infected in the condom only group, and 62 out of 1226 (annual incidence: 3.0%) became HIV infected in the intervention group.

The study was conducted in communities where HIV rates are very high, and new prevention tools are urgently needed. Of the women who were screened for eligibility for trial participation, 39 percent of women in Durban, 20 percent of women in Soweto, and 31 percent of women in Harare were HIV positive.

Q: If condoms are effective in preventing HIV, why test diaphragms?

Condoms are a proven method for HIV prevention. However, the world has learned that condoms and abstinence are not enough to stem the spread of HIV. Women are often unable to choose abstinence or to insist on condom use with their husbands or partners. New female-initiated and controlled prevention tools are still needed to help women protect themselves from HIV infection.

Q: Did MIRA participants receive any benefits?

All women in the trial received HIV counseling and testing, safer-sex and family planning counseling, free male condoms, and hormonal contraception, as well as diagnosis and treatment of curable sexually transmitted infections. Participants were also given regular Pap smears and follow-up care. Support groups and referral systems were also put in place to meet the women's diverse needs.

Q: Were women in this trial put at risk of HIV infection?

No. Women in our study received VCT and intensive education and risk reduction counseling well beyond what they could have accessed in their local communities. Women who participated in the trial were not at any additional risk for HIV infection. The diaphragm and lubricant used in the trial are both safe and have been commercially available for a long time. In addition, all trial participants were provided with counseling and free condoms in order to lower their overall risk of HIV infection. This trial was conducted according to the highest ethical standards and was regularly reviewed by a number of local, national, and international review boards.

Q: What happened to women who became infected with HIV during the study?

Although participating in the trial could not cause HIV, trial participants who became infected with HIV during the trial were offered care and referral to long-term services. MIRA provided participants who tested HIV positive with post-test counseling, support groups, and ongoing monitoring, including screening for opportunistic infections and regular CD4 counts to track disease progression. MIRA worked closely with local partners to set up referral systems and ensure that trial participants who became infected with HIV have access to long-term care and treatment services, including access to anti-retroviral treatment if necessary.

Q. Why was this trial conducted in African countries rather than in countries such as the United States?

When research trials move to the stage necessary to demonstrate whether a new product is effective at preventing HIV transmission, thousands of participants are necessary, and thus trials must take place in populations with a high enough rate of new HIV infections. Additionally, these trials are conducted where there is the most need for effective interventions.