

ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use





New HIV Prevention Products Are Needed

HIV/AIDS and Women



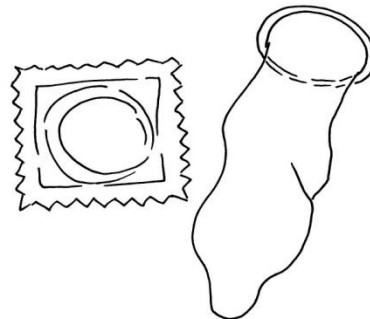
Women's Vulnerability

- Women are more vulnerable to HIV infection than men, due to biological, economic, and cultural factors.



Source = GCM presentation module, "AIDS Has a Woman's Face"

Current HIV Prevention Methods



Something New is Needed

- Researchers are trying to find new products that will work to prevent getting HIV infection.



Finding New Products That Work



ASPIRE

**A Study to Prevent Infection
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Study Products

- Dapivirine Vaginal Ring
- Placebo Vaginal Ring





Main Study Questions

- Is dapivirine vaginal ring **safe for women to use?**
- Is dapivirine vaginal ring **effective for preventing HIV?**

Other Study Questions

- What do women **think and feel about using the vaginal ring?**
- Do women **insert a new vaginal ring and leave it in the vagina for 4 week cycles?**
- How often does **HIV drug resistance** occur?
- How much **dapivirine is in the blood and vaginal fluid of the women who become infected with HIV?**



Women Who Can Join

- Able and willing to provide informed consent
- Able and willing to be contacted by the study staff
- Sexually active



Women Who Can Join

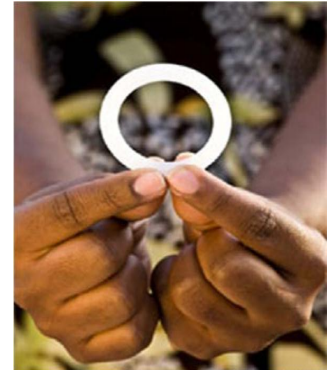
- ❑ Not pregnant and willing to use family planning
- ❑ Do not have HIV
- ❑ In general good health

Study Groups

Two Study Groups



Dapivirine
Vaginal Ring



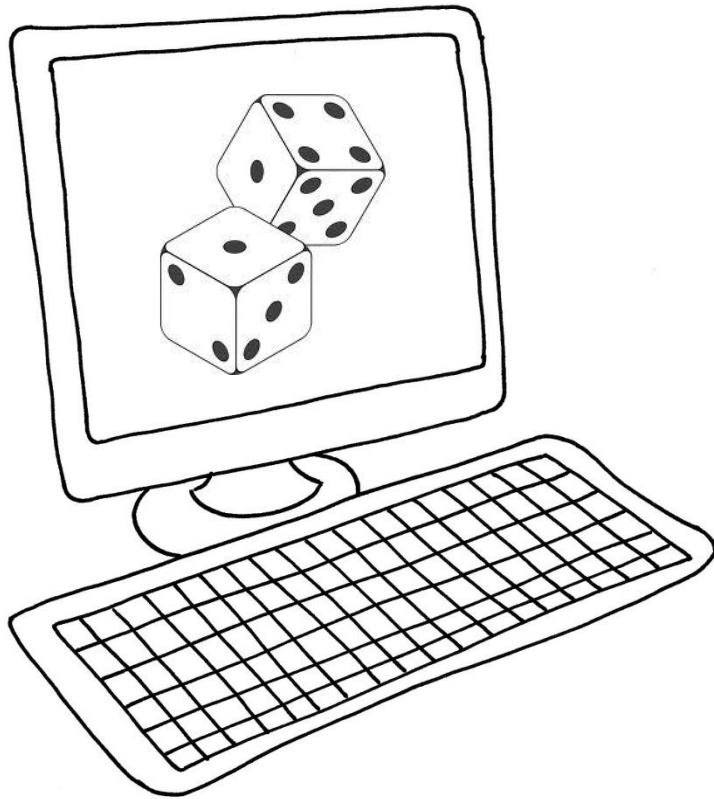
Placebo
Vaginal Ring



Study Groups

Who is receiving...	Will Participants Know?	Will Study Staff Know?
Active or Placebo Vaginal Ring	No	No

Study Group Assignments



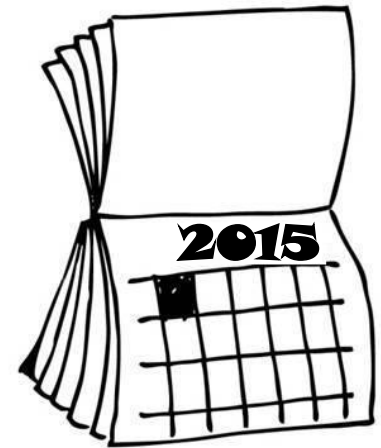
All women have an equal chance of being placed into 1 of the 2 groups.

What Happens in the Study

Length of Study

- The study will take about 3 years, from the time the first woman joins to the time the researchers have the study results.

BEGIN



END

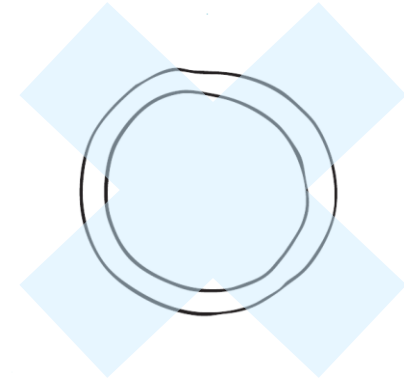
Women in the Study

- Women will place a ring in their vagina and not remove it for a month.
- After one month, the ring will be removed and replaced with a new ring.



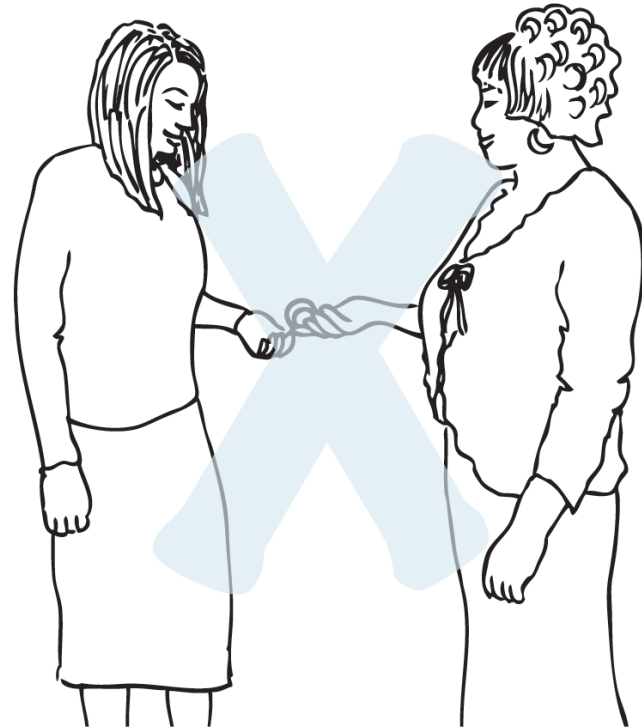
Women in the Study

- Women should not get pregnant while in this study.



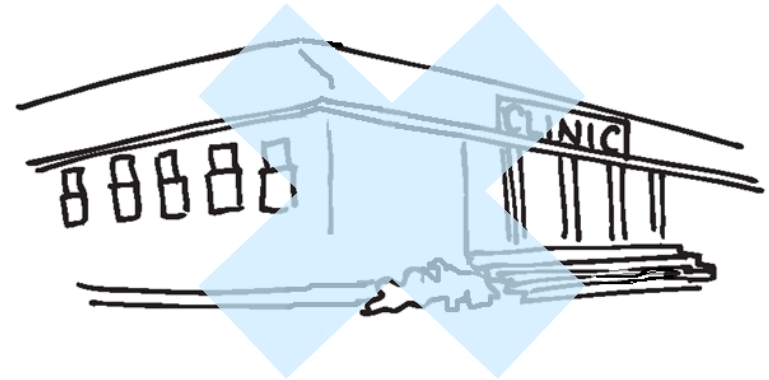
Women in the Study

- Women must never share or sell their vaginal rings.



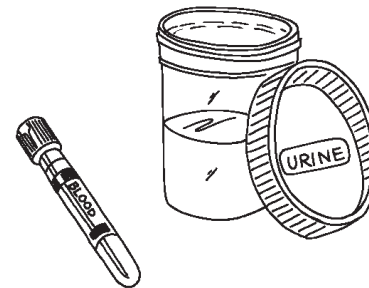
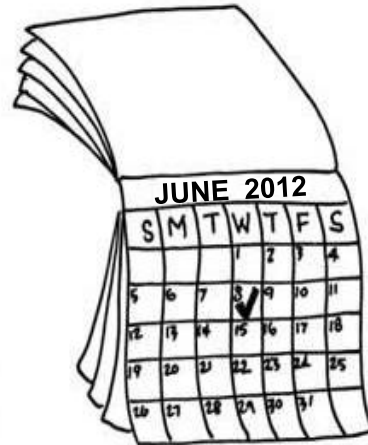
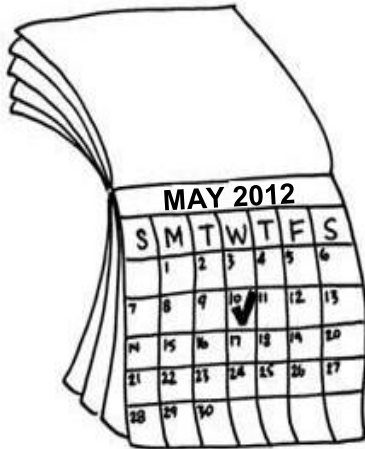
Women in the Study

- Women cannot take part in other research studies.



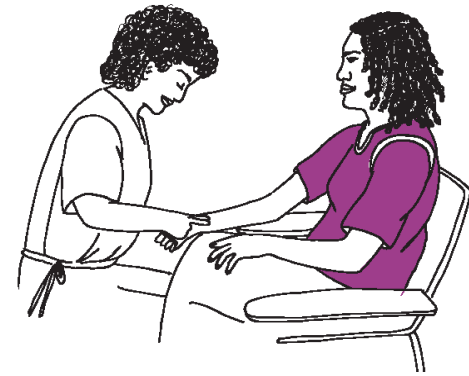
Study Visits

- Women in the study will visit the study clinic every month.



Study Visits

- Women will have examinations of their body and counseling and treatment for STIs if needed.
- Partners can come to the clinic for STI testing and treatment.



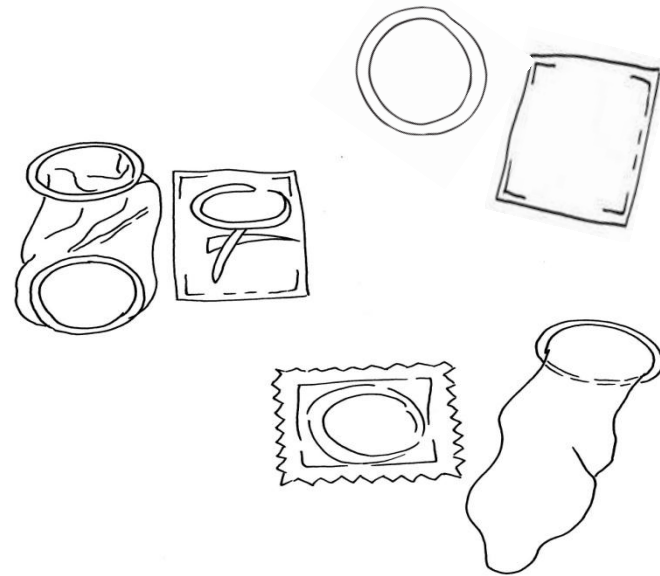


Study Results

- Is dapivirine vaginal ring safe?
- Is dapivirine vaginal ring effective for preventing HIV?

The ASPIRE Study

- There are things we do not know about the vaginal rings.



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- Women who join this study are volunteers in the fight against HIV/AIDS.





Let's Discuss Your Questions



The ASPIRE Study

- The United States National Institutes of Health is paying for this research study.



Information About HIV Drug Resistance



What is Resistance?

- To understand HIV drug resistance, we first need to understand some things about the virus itself.



Why is HIV Drug Resistance a Problem?

- When resistance happens, an ARV medicine is no longer able to stop HIV from making copies of itself.

Why is HIV Resistance a Concern in The ASPIRE Study?

- If a woman becomes infected with HIV while in the study and keeps using the dapivirine vaginal ring, the virus in her body could become resistant to the dapivirine medicine and similar ARV medicines used for treating HIV.

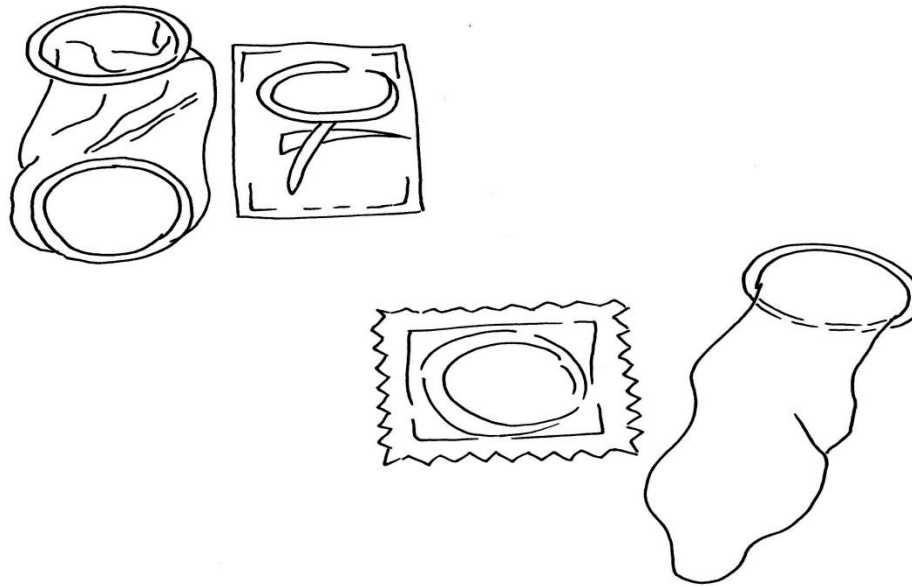


Preventing HIV Resistance

- There are 3 ways to avoid resistance in the ASPIRE study...

Avoid Getting HIV

- Use a condom correctly with every partner, every time you have sex.



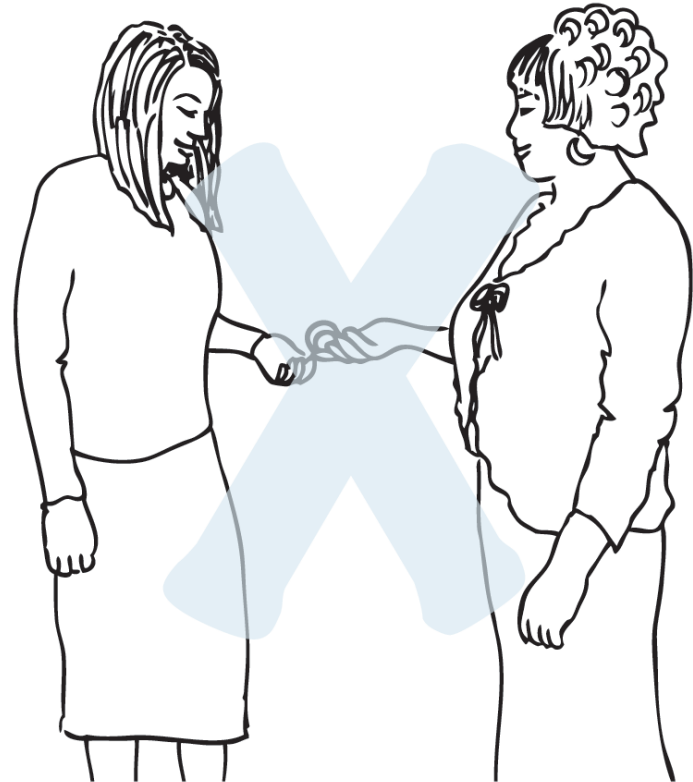
Attend Study Visits Every Month

- HIV testing will be done monthly for women in the study.



Do Not Share Vaginal Rings

- Sharing vaginal rings with other women could be harmful.





Family Planning Methods

The content of this portion of the presentation was adapted from
“Family Planning: A Global Handbook for Providers” developed by
USAID, Johns Hopkins Bloomberg School of Public Health and WHO

Male Condom

What is it?

- A male condom is a thin rubber sock that is placed over the erect penis before sexual intercourse begins.



Male Condom

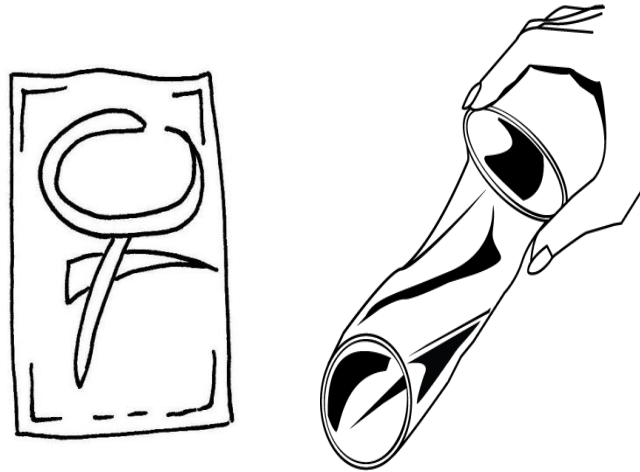
How is it used?

- A couple must use a new condom every time they have sexual intercourse. Before any genital contact, the man unrolls the condom all the way to the base of his erect penis.
- To be effective, a condom must be used correctly every time.

Female Condom

What is it?

- A female condom is a thin plastic pouch that fits loosely inside a woman's vagina.



Female Condom

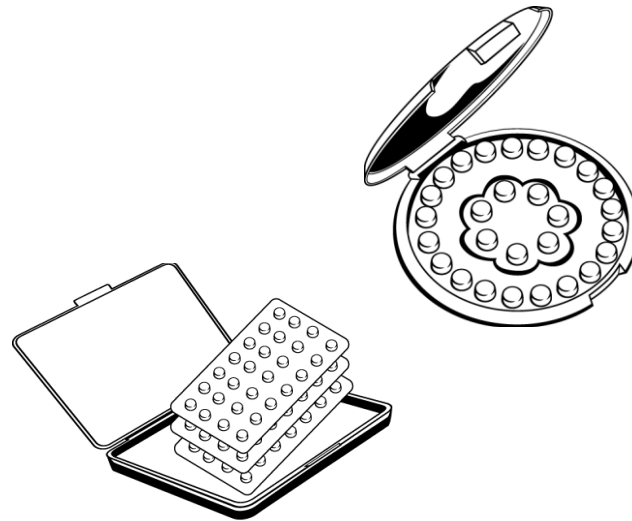
How is it used?

- A couple must use a new female condom every time they have sexual intercourse. Before any genital contact, the female condom is inserted into the vagina.
- To be effective, a female condom must be used correctly every time.

Oral Contraceptives

What is it?

- An oral contraceptive is a pill that contains hormones (estrogen and progestin) that stop the ovaries from releasing eggs.



Oral Contraceptives

How is it used?

- A woman must take one pill every day, even on days when she does not have sexual intercourse.



Injectable Contraceptives

What is it?

- Injectable contraceptives are hormone injections that stop the ovaries from releasing eggs.



Injectable Contraceptives

How is it used?

- A woman receives one injection every 2-3 months from a clinician.



Implants

What is it?

- Implants are small flexible rods or capsules that contain the hormone progestin.



Implants

How is it used?

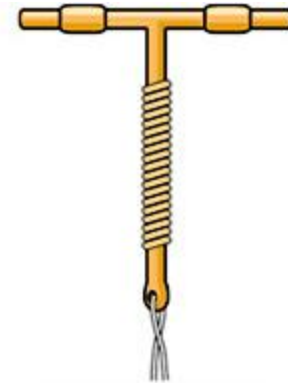
- Implants are placed just under the skin of the upper arm by a clinician.
- They provide long-term pregnancy prevention for 3 to 7 years.



Intrauterine Contraceptive Device

What is it?

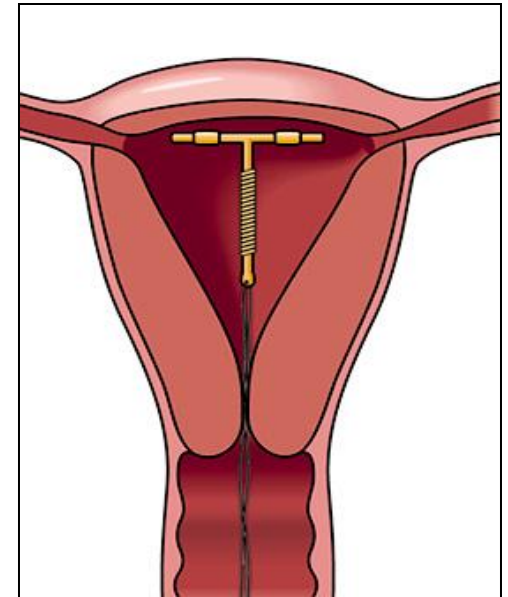
- Also known as an IUCD.
- T-shaped device that is placed in the uterus (womb).



Intrauterine Contraceptive Device

How is it used?

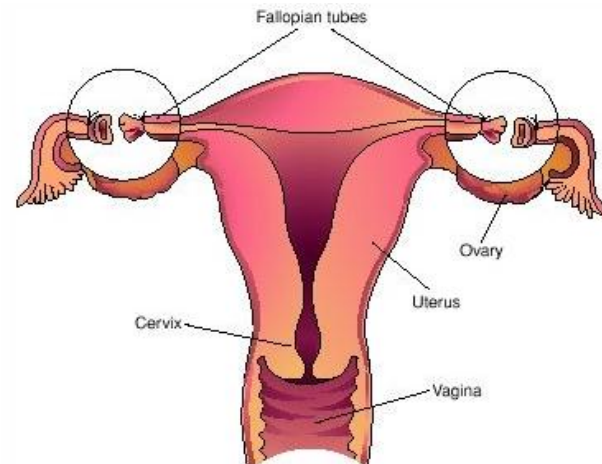
- An IUCD is placed in the uterus by a specially trained clinician.
- It can stay in place and provide pregnancy prevention for 5 to 10 years, depending on the type.



Female Sterilization

What is it?

- ❑ Female sterilization is a surgery that permanently prevents pregnancy.
- ❑ In most cases, the tubes that carry eggs from the ovaries to the uterus are cut and/or closed.





Female Sterilization

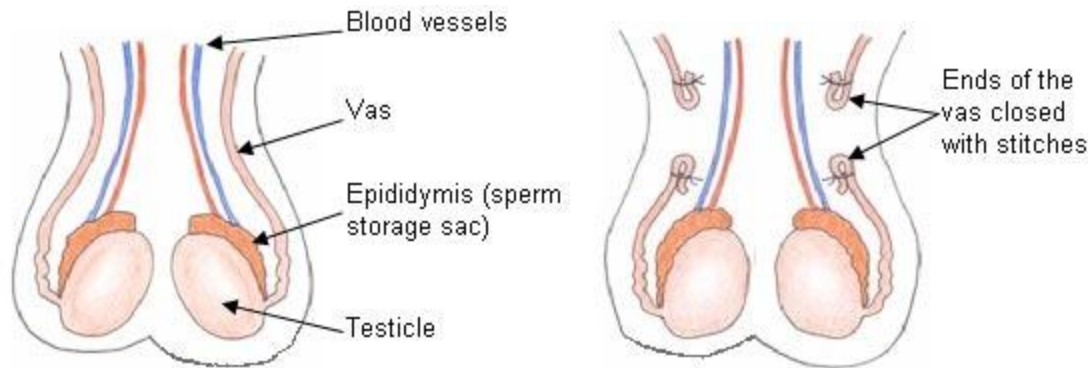
How is it used?

- Female sterilization is a surgery that a woman has only once.
- It is done by a specially trained clinician and it is permanent.

Vasectomy

What is it?

- Vasectomy is a simple and safe surgery where the tubes that carry a man's sperm are cut and closed.





Vasectomy

How is it used?

- A vasectomy is a surgery that a man has only once.
- It is done by a specially trained clinician and it is permanent.