The VOICE Study
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
The VOICE Study
Gel and Tablets

- **Vaginal Gel**
  - Tenofovir 1% gel
  - Placebo gel

- **Oral Tablets**
  - Tenofovir tablet
  - Tenofovir placebo tablet
  - Truvada tablet
  - Truvada placebo tablet
Main Study Questions

- Are Tenofovir tablets, Truvada tablets, and Tenofovir gel effective for preventing HIV?
- Are Tenofovir tablets, Truvada tablets, and Tenofovir gel safe for women to use?
Other Study Questions

- Do women take their tablets or use their gel every day?
- Do women’s behaviors change while using study products?
- How often does HIV drug resistance occur?
Study Clinics
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
Five Study Groups

- Women in the study will use either gel or tablets.
Two Gel Groups

Tenofovir gel

Placebo gel
Three Tablet Groups

- Tenofovir tablet + Truvada placebo
- Truvada tablet + Tenofovir placebo
- Tenofovir placebo + Truvada placebo
## Study Groups

<table>
<thead>
<tr>
<th>Who is receiving…</th>
<th>Will Participants Know?</th>
<th>Will Study Staff Know?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gel or Tablets</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Active or Placebo Gel</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Active or Placebo Tablets</td>
<td>NO</td>
<td>NO</td>
</tr>
</tbody>
</table>
Study Group Assignments

All women have an equal chance of being placed into 1 of the 5 groups.
What Happens in the Study
Length of Study

- The study will take about 4 years, from the time the first woman joins to the time the researchers have the study results.
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.
Women in the Study

- Women should not get pregnant while in this study.
Women in the Study

- Women must never share or sell their gel or tablets.
Women in the Study

- Women cannot take part in other research studies.
Study Results

- Is Tenofovir gel safe? Is it effective for preventing HIV?
- Is Tenofovir tablet safe? Is it effective for preventing HIV?
- Is Truvada tablet safe? Is it effective for preventing HIV?
The VOICE Study

- There are things we do not know about the gel and tablets.
The VOICE Study

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

- If a woman becomes infected with HIV while in the study and keeps using Tenofovir or Truvada, the virus in her body could become resistant to these ARV medicines.
Preventing HIV Resistance

- There are 3 ways to avoid resistance in the VOICE 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 Gel or Tablets

- Sharing gel or tablets with other people, even with a partner, 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.
Let’s Discuss
Your Questions
The VOICE Study

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