

Informed Consent Flipchart



Knowledge is Power... Did you know?

Across the world, young women are at high risk of getting HIV. In Africa, more than half of people living with HIV are women. In our daily lives, we can see the impact that the epidemic has had on our families, friends and communities.



Due to biological, economic, and social reasons, young women are at greater risk of contracting HIV than men. There has been a lot of effort globally to find a cure and create a vaccine to stop HIV, but these studies are still going on.

Because there is no cure, researchers want to find ways to prevent HIV, using different methods and medicines.



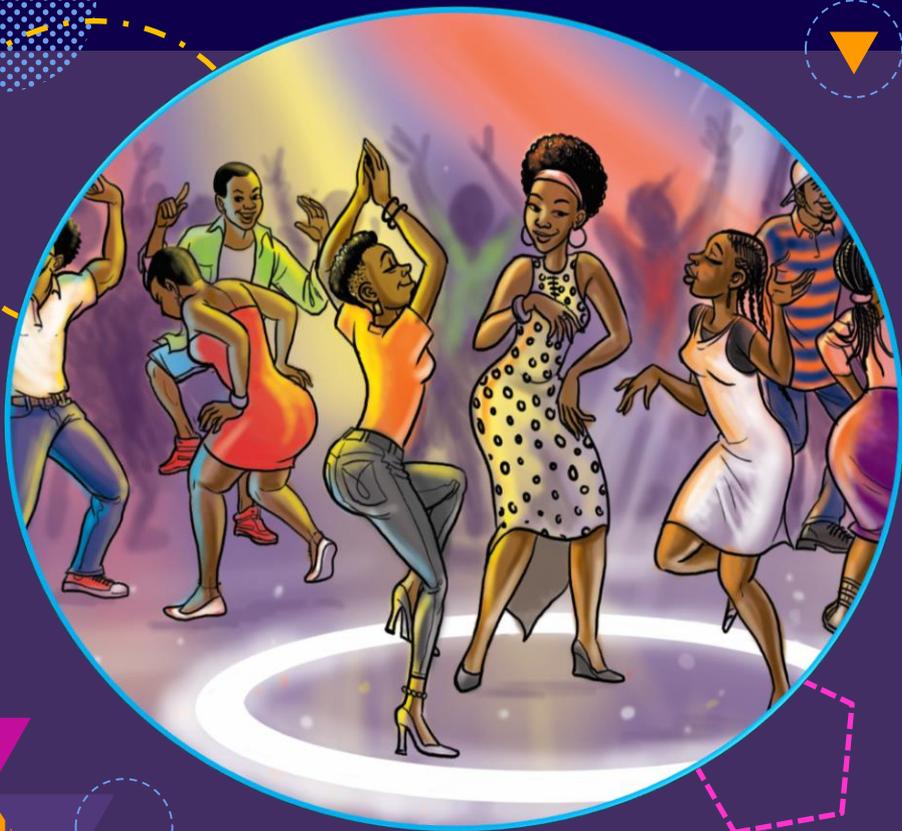
The purpose of the **REACH** study is to learn whether two HIV prevention methods, which have proven to be safe and effective in adults, are also safe for use by young women. This study will also help researchers understand which particular methods young women prefer to use.

REACH will help make these effective prevention products available to adolescent women, who need new prevention strategies.



Young women play a key role in helping to end the HIV epidemic and approaches are needed that take into account the experiences of women from different backgrounds.

Preventing HIV is possible



You may already know about some ways to prevent HIV. For example, not having sex, or using condoms every time you have sex, are effective ways to prevent HIV. Or maybe you're familiar with daily oral Truvada as PrEP (pre-exposure prophylaxis), a medicine that lowers the chances of getting infected with HIV.



But we need more ways to prevent HIV that women can control for themselves.

Through research, we find new prevention methods



Research is being done now
to find new products that
will work for young women.

Research like this starts with small groups of people to first test if the products are safe to use.

Next, larger studies are done with more people to test if the products will work and if people like to use them. For example, family planning methods such as condoms, or hormonal methods like the pill, have all gone through this process.





Do you know any family or friends that have participated in research studies before?

It is important to involve young women in these studies who may benefit from these HIV prevention methods. **REACH** is this kind of study.



Prevention methods in development

The types of products that have been developed and are now being introduced are ones that healthy women can use every day to prevent HIV in case they are exposed, like a monthly ring worn in the vagina and a daily tablet taken by mouth.



The medicines in these products stop HIV from making copies of itself if the virus gets inside the body.

Why the REACH study?

Now I would like to tell you more about the REACH study. REACH stands for **“Reversing the Epidemic in Africa with Choices in HIV Prevention.”**

In the REACH study, we are testing a ring called the dapivirine ring and a tablet called Truvada to see if they are safe and acceptable for young women who want to protect themselves from getting HIV.



More about the study products: **The Dapivirine Ring**

The ring contains an antiretroviral (ARV) drug called dapivirine. In a previous study, the ring was found to be safe and effective for older women who were asked to use it every day for a month at a time.

The ring didn't work as well in younger women, and researchers think this might be because they had trouble using the ring all of the time.



More about the study products:

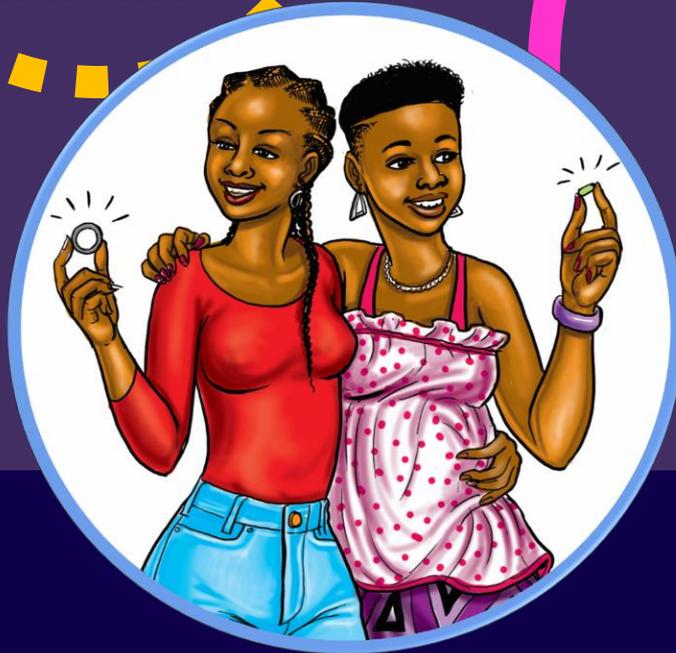
Oral PrEP – “Truvada”



The tablet called Truvada, or PrEP, contains two ARV medications, and it is approved for preventing HIV in adults.

It is also approved for treating HIV in people older than 12. Younger women also had difficulty using Truvada in some of the earlier studies.

Have you
heard of
the ring or
Truvada?



The REACH study is different from earlier studies because we now know that these products work when people use them all the time. So we now want to make sure these products are safe for younger women and find out if they are interested in using them.

Who will join the REACH study?

About 300 healthy young women will take part in the study. These young women will come from 4 different countries –

Kenya, South Africa, Uganda, and Zimbabwe.

To participate in the study, you must be 16 to 21 years old, HIV negative, and willing to use reliable contraception throughout the whole study.

If you are pregnant, planning to get pregnant within the next 2 years, or participating in a separate research study, you won't be able to join the study.



How long will you be in the study?



Time Period 1



Time Period 2



Time Period 3

If you join REACH, you will be in the study for about 18 months, or 1.5 years.

The study is split into 3 time periods of 6 months each. Young women in the study will be assigned to one of 2 groups: one that will use the ring first and another that will take the tablet first.

How long will you be in the study?

If assigned first to the **tablet**:

you will take it daily for the first six months.

Then you will switch to wearing the ring all the time, replacing the ring each month for the next six months.



How long will you be in the study?

If assigned first to
The ring:

you will wear it all the time,
replacing the ring each
month for the first six
months of the study.

Then you will switch to
taking the tablet daily for
another six months.



How long will you be in the study?

For the last six months of the study, you will be able to choose the ring, the tablet, or you may decide not to use these products anymore.

It is up to you!



What other HIV prevention methods could you use?

How are study groups assigned?



If you join the study, you will have an equal chance of being assigned to either group, just like flipping a coin.



You will not be able to choose which group you start in, and neither can the study staff - it is assigned by a computer.

Why are participants asked to use each product at different times in this study and why do they get to choose whichever they want in the last part of the study?



This will help the researchers compare how well the different products work and understand what young women prefer and why. We need to learn from you!

How you use the study products:

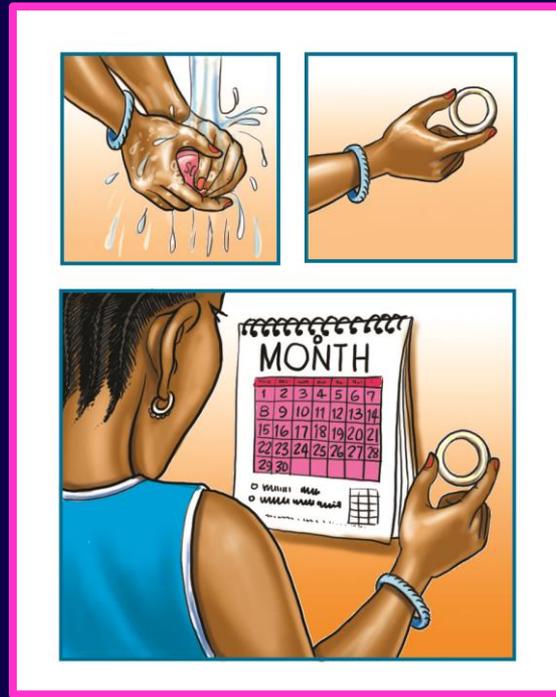
The Ring

Your life will be just like it usually is.

You don't have to remove the ring for the entire month – it will stay safely in place and you may not even feel it!

You don't need to take it out during your period or menstrual cycle or during sex.

You don't have to take the ring out to clean it, or to bathe, or when using the bathroom.



During the period when you are using the ring, you will be asked to insert it into your vagina and not remove it for one entire month.

We will help you learn how to insert it and remove it – it's easy!

How you use the study products: **The Tablet**



If you can, it is best to take the tablet at the same time each day. Study staff can help you to set up a reminder if you want!

When you are assigned to use the tablets, you should take one tablet every day, even if you are not having sex.

The most important thing to remember about these products is that the tablet and the ring offer the most protection from HIV if you use them all the time.



Do you have any questions about how women are assigned to study products and how they will be asked to use them?

What will you do in the study?



If you join this study, it is important that you follow all the instructions that the study staff gives you. This is for your safety and so that the researchers can better understand how safe these products are and if they are right for you.

Study staff will ask you to attend study visits once a month for about 1.5 years and a few additional check-ins either at the clinic or by phone. You will have about 24 total visits.

They will ask you not to have sex or insert anything into your vagina (except for the vaginal ring, if assigned, or tampons during your period) 3 days before you come to the clinic.



Being in the study will not cost you anything. The study staff will reimburse you for your time, the effort you put into coming to the clinic and the cost of your trips to and from the clinic.

What happens at study visits?



What you do at visits will depend on what type of visit it is. Most of your clinic visits will last about 3-4 hours, but some may be shorter. Here are some things to expect at each visit:

The study staff will ask you about where you live and how to contact you, your relationships, and your sex life, if you are having sex.

They will also ask you about how you are using the study products and how you feel about them. You don't have to answer any of these questions if you don't want to - it won't impact your participation in the study.

More about the study visits...

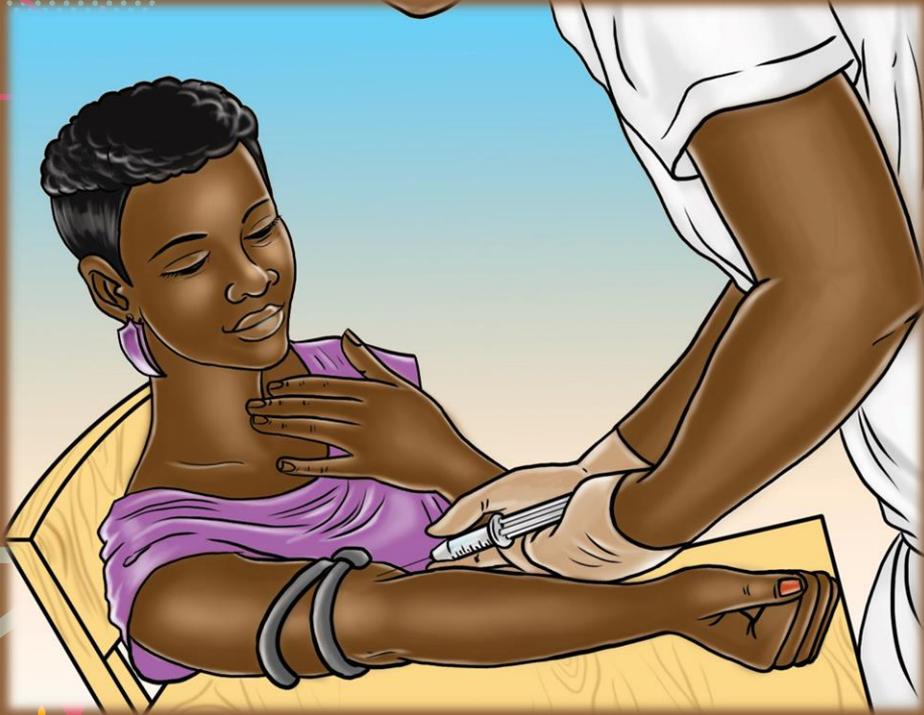
Study staff will talk to you about ways to prevent getting pregnant and how to protect yourself from getting HIV and other sexually transmitted infections. Study staff will offer you condoms, if you want them.



You may be asked to take part in an interview with site staff or in a group with other study participants to discuss what you think about the study, the tablet and the ring.

You will get a new ring or bottle of tablets if you are using one of these study products at the time and you will receive counseling about how to use them.

Even more about the study visits...



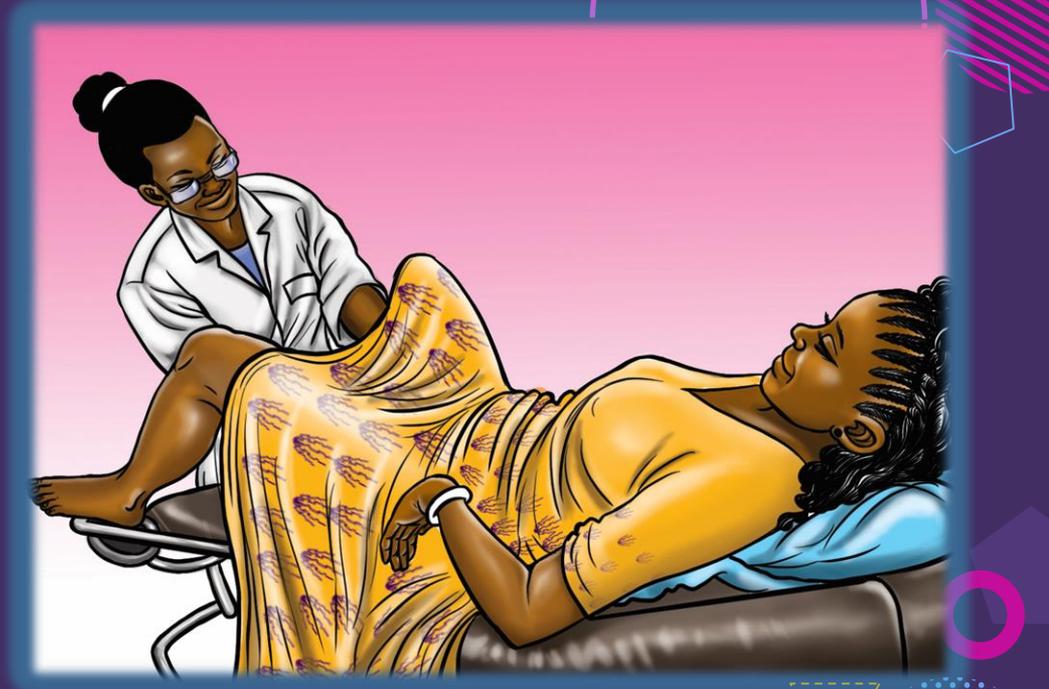
Study staff will also take samples from you so that they can do some tests. They will test your urine for pregnancy, and test your blood for HIV and to make sure you are healthy.

They will also take some samples from inside your vagina to see how well the study products are working in your body.

You will be offered the Hepatitis B and the HPV vaccines if you have not already had them.

Even more about the study visits...

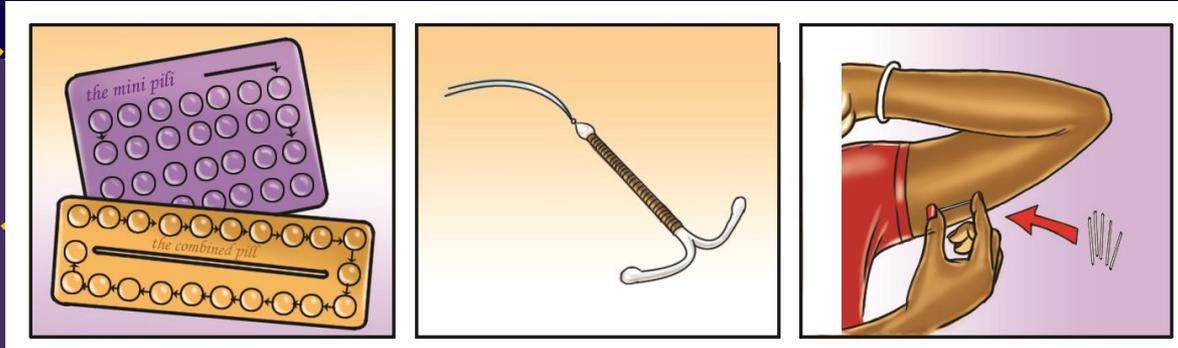
Finally, the study staff will examine your body including your pelvic area to make sure you are healthy and don't have any infections. If you have an illness, they will provide you with medicine or refer you to a place that can help you. You might stop using the study products until you are better, if that is what is best for your health.





Do you have any other questions about the study visits?

What if you become pregnant during the study?



The ring and tablet do not prevent pregnancy.

It is not known what effects the ring and tablet have on women who become pregnant while taking them, so it is important that you do not become pregnant during the study.

For this reason, study staff will help you choose a family planning/birth control method that works best for you. You will need to start using a family planning method such as depo, an IUD, an implant, or the pill, at least 2 months before you start the study, and keep using one of these methods the whole time you are in the study.

Starting the contraceptive early will allow you to get used to the method you have chosen before you start using the study products. Study doctors and nurses will be available to help you with any worries you may have while using the method.





If you get pregnant during the study:

The study staff will refer you to a place where you can get the medical care you need. You will stop using the study products, but the team will still ask you to come for study visits.

We will change the study visit procedures to protect your health while you are pregnant, and the study staff might contact you later to find out more about your health and the health of the baby.

What if you get HIV during the study?

It is possible for anyone to get HIV or another sexually transmitted infection from sex or other risky activities, so that is why it is important to always use a condom.

If you test positive for HIV during the study, the study staff will help you get treatment and other services for HIV. You will stop using the study products, but you can still come for your study visits. The study staff will do more blood tests on you to find out which medicines are best for treating your HIV.



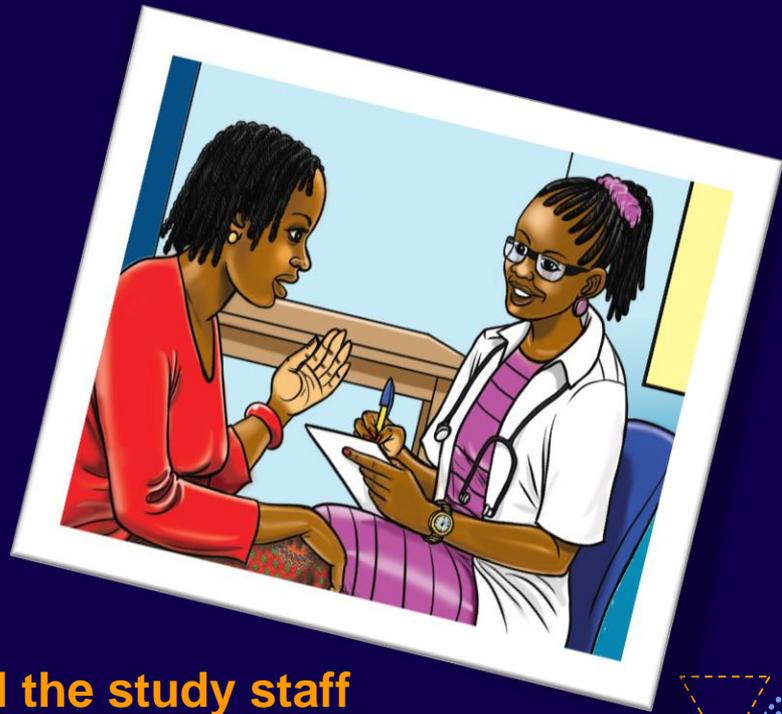
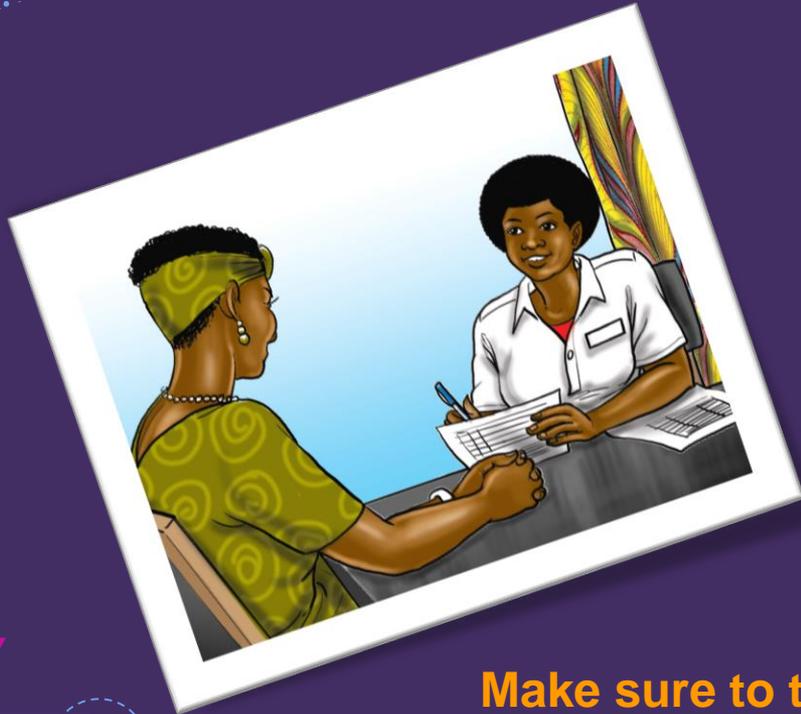
Some possible downsides to being in the study

You might not like answering questions about your personal life, or having blood tests or physical exams done.

You might feel like other people are spreading rumors about you or treating you unfairly. The study staff will do their best to stop this from happening and keep all information about you private.

You might feel worried about getting your test results, but study counselors will be available to talk to you about how you are feeling.

You might experience side effects from the study products, but the study staff will help with any health problems or side effects that happen during the study.



**Make sure to tell the study staff
about any problems you are having!**



Possible side effects of the ring include pain, itching or discomfort in the vaginal area, or bleeding between menstrual period.

Possible side effects of the tablets include headaches, body pain or weakness, nausea, diarrhea, fever or dizziness. These side effects usually go away within a few weeks without having to stop PrEP. The tablets might also cause problems with your kidneys, liver and bones. These side effects usually go away after stopping PrEP.

Do you have any questions or concerns about the possible study risks?

“



The good things about joining the study



While you are in the study, study staff will keep you updated with new information they learn about the study products, such as if the products are found to work in young women.

You will also get access to contraceptive methods that work, regular physical exams to make sure you are healthy, and treatment or referrals if any health needs arise.

The good things about joining the study



You might feel fulfilment that you are helping to find new ways of preventing HIV that work for young women!

Protecting your choices and privacy

If you decide to join the study all your personal information will be kept private. Only approved study staff will have access to your private information.



You are the only person who will receive information from your study visits, like your test results. It is up to you if you want to share any of this information with anyone else, including your parents or partner.



After the study, some of the blood, urine, and other samples that you have given may be left over. We would like to do further testing with them in the future to help us understand how the study products work to prevent HIV.

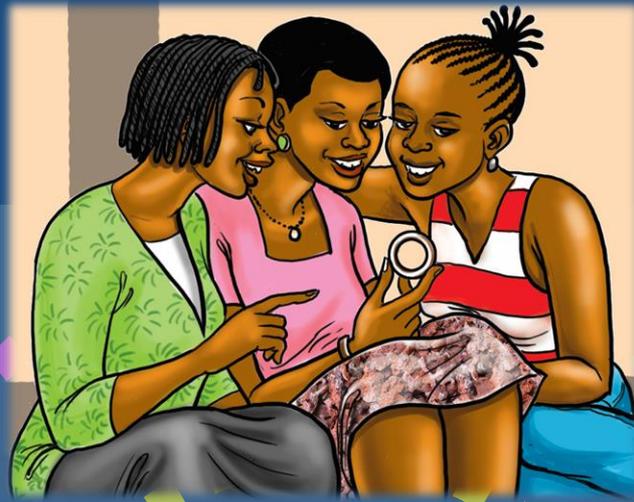
You can choose if your health information can be used in the future or if you want to have it destroyed after the study. And you can change your mind about this at any time!

It is your choice to join the study!

Think about all the information you've heard here today! It is your decision if you want to join this study or not. You can ask as many questions as you want to help you make up your mind.



Discuss it! We also encourage you to discuss your decision with your parents or other trusted people who are important to you. If you are younger than 18, your parent(s) will also need to agree for you to join the study.



Share information!
You can share what
you learned today
with others. You can
invite your partner or
your friends to the
clinic so that they can
learn about the
REACH study too!

You do not have to
join the study. If
you decide not to, it
will not affect your
health care. You can
still join other
studies in the
future if you want.

If you decide to join
the study, you can
change your mind
later. We do hope that
you will try to stay in
the study until it is
finished, so that we
can learn more about
preventing HIV in
young women!

Some key things to remember

Everyone who participates in the study will use the ring and the tablet, but at different times.



PrEP and the ring work well in older women when used regularly. We need more information about young women's experiences and preferences for PrEP and the ring.



Condoms are the surest way to protect yourself from getting HIV during sex. To keep yourself safe, use a condom every time that you have sex.



If you think of any questions later that were not answered today, you can still ask them by contacting us at any time.

We want to answer all your questions and help you feel comfortable before you decide!