



Dapivirine Ring Advocacy Messaging Resource Package

A TOOL FOR DEVELOPING A MESSAGING
FRAMEWORK AND IMPLEMENTATION PLAN
IN SUPPORT OF ADVOCACY ACTIVITIES FOR
THE DAPIVIRINE RING

JUNE | 2021

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About this Advocacy Messaging Resource Package

This resource package was developed to support HIV prevention and treatment, sexual and reproductive health (SRH), and youth, girl's and women's health advocates working to generate support for the introduction of the dapivirine ring, also known as the PrEP ring (the "ring"). In recognition of the important role that advocates play in ensuring that research is translated into effective policies and programs, reflected in country guidelines, and disseminated within communities — and their role as champions for expanding the range of HIV prevention tools for women — this resource is intended to support advocates in developing messages specific to the ring.

[The PROMISE and CHOICE Collaborations](#) support planning for early product introduction of the ring in sub-Saharan Africa. PROMISE and CHOICE country partners,¹ with technical support from FHI 360 and AVAC, collaborated with local advocates to organize a series of workshops in Kenya, Zambia, and Zimbabwe. The purpose of these workshops was to co-create advocacy messaging frameworks and top-line implementation plans that local advocates can use to influence key decision maker's actions to update policies, guidelines, and financial commitments to support ring integration into existing HIV prevention programs. Through a series of interactive activities, workshop participants identified specific decision makers to target, developed key messages for each decision maker, and selected implementation tools and materials to support their advocacy activities. These country-specific messaging frameworks were synthesized and are presented as examples throughout this package.

AVAC also convened a small group of experienced advocates from several countries throughout sub-Saharan Africa to review the package. These advocates provided critical feedback and inputs to ensure it is responsive to advocacy needs in the region and can be easily applied.

The [AVAC Fellows Program](#) refers to "advocacy" as a process that seeks to transform values, attitudes, policies, and/or behaviors at a community, national, or global level. Advocacy projects identify a change that is needed and lay out a set of activities that aim to affect that change.

In HIV prevention, "advocacy" refers to the use of various strategies and activities to:

- Engage, critique, and improve research and implementation processes, including calls for meaningful stakeholder engagement.
- Recommend specific actions to improve access to and rollout of new HIV prevention methods.
- Participate in setting the research and programmatic agendas at local, national, and international levels.
- Bring under-represented voices of individuals and communities most vulnerable to HIV to the forefront of HIV research, policy, and program design.
- Target guidelines and national and local policies or laws to ensure respect for people's rights and responses to their needs.
- Ensure funding for HIV research, implementation, programs, and continued advocacy.

Advocacy also refers to the work by civil society groups and concerned individuals to transform public health programs, national policies and laws, and international guidelines with the goal of increasing benefits for all people and communities in need of new and expanded choices of HIV prevention methods.

¹ LVCT Health (Kenya), Pangaea Zimbabwe AIDS Trust (PZAT) (Zimbabwe), and FHI 360 (Zambia)

What is the monthly ring?

It is a flexible ring that a woman inserts into her vagina for monthly protection against HIV. The ring is designed to provide a woman-centered, discreet, and long-acting option for HIV prevention. The ring contains the antiretroviral drug dapivirine, which is released slowly to reduce the risk of HIV infection locally in the vagina with few effects elsewhere in the body.

What do we know about the ring?

Several research studies have concluded that the ring is safe and — when used correctly and consistently — effective. Its use can reduce the risk of HIV acquisition through vaginal sex by about 50%. These studies have also found that some women prefer the ring over other HIV prevention options. Importantly, a number of studies have shown that women who have used the ring like it and that adherence (correct and consistent use) improves as they become more comfortable using it.

Information about the studies demonstrating the safety, effectiveness, and acceptability of the ring:

ASPIRE (2012–2015): [Overview](#) – [Results](#)

The Ring Study (2012–2016): [Overview](#) – [Results](#)

HOPE (2016–2018): [Overview](#) – [Results](#)

DREAM (2016–2019): [Overview](#) – [Results](#)

What is the potential public health impact of the ring?

Modeling studies show that multiple prevention options are needed to end the HIV epidemic. Therefore, products such as the ring could have a meaningful public health impact as part of a comprehensive prevention strategy. If approved and effectively rolled out, the ring would expand choice and increase the number of individuals successfully using an HIV prevention method. New, user-centered options, such as the ring, are crucial to achieving HIV epidemic control.

Why do women need additional HIV prevention options, such as the ring?

Despite progress in prevention and treatment, women remain vulnerable to HIV infection in many settings, especially in sub-Saharan Africa. Adolescent girls and young women are especially vulnerable due to biological, social, economic, and gender equity factors. No single HIV prevention method will meet the needs of all women. A range of options is needed for individuals to protect themselves and to curb the HIV epidemic. Several new pre-exposure prophylaxis (PrEP) products — including the ring and long-acting injectable — provide an opportunity to expand the range of HIV prevention options. The ring has already been approved by the World Health Organization (WHO) and can now be integrated into national HIV prevention portfolios. (You can learn more about other next-generation PrEP products [here](#).)

The ring can be used discreetly by women at times in their lives when they may be unable to negotiate condom use or to use daily oral PrEP or when they find it the most convenient option. Choice is key: women need options for HIV prevention that fit different needs and preferences. The ring fills a gap for a long-acting, reversible, and easy-to-use HIV prevention method.

BEFORE YOU BEGIN: Accurate, evidence-based information is important when you are advocating for accelerating access to new prevention tools, resource mobilization, and changes in policies and guidelines. Before beginning to develop ring advocacy messages and tools, educate yourself about the ring, including the clinical trial results. The following resources are good places to begin your orientation to the ring:

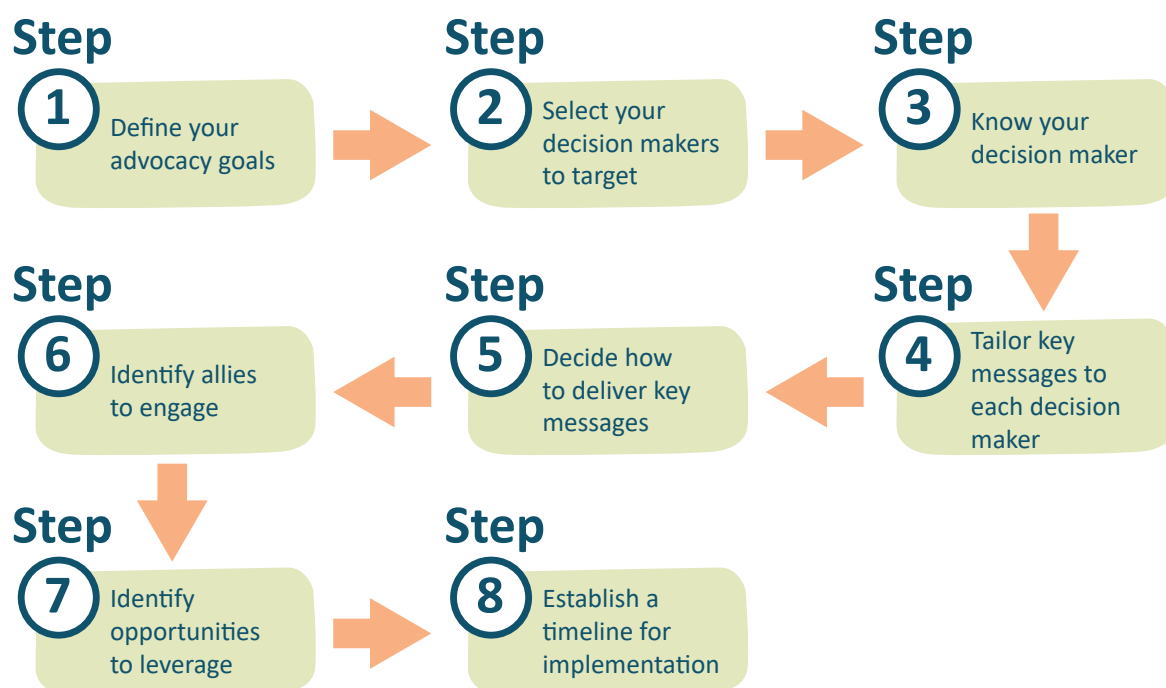
- A [background document](#) from the ring developer
- A [frequently asked questions document](#) from the ring developer
- A [video featuring personal testimonials](#) from ring users
- A [summary of key results](#) from the clinical trials
- An [animated 3-minute video](#) explaining what the ring is and how it works

Overview of the process

This package suggests an eight-step process (Figure 1) to develop a messaging framework and top-line implementation plan for your ring advocacy activities.² A messaging framework is used to organize key messages and ensure they are aligned with the needs, perceptions, and preferences of the decision makers you hope to engage. When key messages are aligned with the interests and concerns of specific decision makers, they are more likely to result in the expected change.

You will develop your messaging framework in the first five steps of the process. In steps 1 and 2, you will define the goals of your advocacy activities and select the decision makers you will target. In steps 3 to 5, you will explore what motivates each decision maker, and then use that information to develop key and supporting messages and strategies for delivering them to each decision maker. Once you have developed your messaging framework, in steps 6 to 8 you will identify the partnerships you may need to establish, inventory opportunities you can leverage to increase your impact, and establish a timeline for the implementation of your activities.

Figure 1. Messaging Framework Development Process



² Note that the 8 steps highlighted in this package include many elements needed to develop a full advocacy strategy and action plan. You can read more about developing a full strategy and action plan at [ACT 2015: Advocacy Strategy Toolkit](#) and [What makes a brilliant advocacy strategy?](#)

Step

1

Define your advocacy goals

State up to three overarching goals for all your advocacy activities. These goals can be very focused (e.g., changing a specific policy) or broad (e.g., gaining Ministry support for integrating ring introduction with other SRH services). The goals will help frame your advocacy activities and can be used later to determine how successful your efforts have been. The more specific your goals, the better able you will be to hone your messages. List your advocacy objectives in Part 1 of the messaging framework template in Annex A.

Examples of advocacy goals generated through the country workshops:

- Raise awareness among Ministry of Health leaders about the ring and its importance to achieving HIV prevention goals so they will consider championing rapid introduction.
- Influence the development or amendment of policies to support ring promotion and distribution within a comprehensive sexual and reproductive health and rights framework.
- Increase budget allocations by the government and development partners to implement ring promotion and distribution activities.
- Expand eligibility criteria by removing age and other policy restrictions to ensure more users have access to the ring.
- Ensure that community members and end-users are engaged in developing the national ring introduction plan, including demonstration studies, demand creation strategies, and training materials.

Step

2

Select your decision makers to target

Reflect on which decision makers you will need to influence to achieve your advocacy goals. Think about all the departments of the Ministry of Health (MOH) and related agencies that determine and implement new policy decisions, such as national HIV prevention departments and family planning and reproductive health departments.

Beyond government agencies, think about development partners who provide funding to support national HIV prevention priorities, as well as nongovernmental partners and other civil society organizations (for example, academia, research institutions, media outlets) that implement HIV programs. Other decision makers might include, but are not limited to, members of the relevant committees of the national regulatory body and the legislature (such as the parliamentary health committee) and community leadership structures. Community gatekeepers (such as religious leaders, community political leaders, etc.) have important roles in the community and can influence support for ring introduction and be powerful allies if you are able to make the issue important to them.

Take an inventory of all these decision makers and prioritize not only those who are most critical, but also those you have the time and resources to engage as your targets of advocacy. Note that different decision makers have varying levels of influence; the most critical person to reach may not necessarily be the most accessible. In these cases, identify the gatekeepers you do have the ability to reach and use them as a springboard to engage their superiors. Importantly, be as specific as possible about whom you consider a decision maker: the sharper your focus, the more targeted your messages will be. List the decision makers you want to target in Part 2 of the messaging framework template in Annex A.

Examples of targets of advocacy generated through the country workshops:

- Permanent Secretary, Ministry of Health
- HIV Prevention Manager, National AIDS Control Program
- HIV Focal Point at the Ministry of Women's Affairs
- Leaders/gatekeepers of international development partners (donors)
- Specific Members of Parliament
- District or County Health Management Team member(s)
- College or university leaders, including student leaders
- Leaders/gatekeepers of local and international implementing partners
- Leader/gatekeeper of sexual and reproductive health and rights (SRHR) civil society organization or coalition
- Leader/gatekeeper of religious organizations

Step

3

Know your decision maker

Collect information about each decision maker to determine their current level of knowledge about the ring and their interests or agenda. Sometimes it is helpful to think about the questions or concerns each decision maker or gatekeeper may have (or that you have heard them express) to identify their interests and agenda. Use this information to determine how the ring responds to that decision maker's interests and to consider the specific action you will ask the decision maker to take. Document your findings in Part 3 of the of the messaging framework template in Annex A.

Example of a decision maker profile generated through the country workshops:

| DECISION MAKER | ROLE |
|---|--|
| Permanent Secretary, Ministry of Health | Provide technical guidance to the Minister of Health; provide policy direction and guidance; disseminate information to other ministries; approve activities developed by MOH staff and partners |
| What is this decision maker's current level of knowledge about the ring? | |
| The Permanent Secretary knows about the ring but may not have complete information about the results of the latest research. | |
| What are the key interests or agenda of this decision maker? | |
| <ul style="list-style-type: none"> As the lead technical specialist for the health system, he wants to be viewed by the Minister as a competent leader who can be trusted to make sound, evidence-based decisions. He cares about the well-being of the population and wants to make long-term contributions to the Ministry's goal of improving health across all population groups. For family planning, he has publicly expressed the importance of expanding choice for women. | |
| How does the ring align with or respond to this decision maker's key interest or agenda? | |
| <ul style="list-style-type: none"> The evidence shows that the ring is an effective HIV prevention option. The ring is safe and has the potential to contribute to national HIV prevention efforts by providing an additional option for women who cannot or prefer not to use other options, such as oral PrEP and condoms. | |
| What specific actions do we want this decision maker to take? | |
| <ul style="list-style-type: none"> Authorize countrywide rollout of the ring. Ensure expedited rollout of the ring by supporting national regulatory approval and directing departments to update HIV prevention policies and guidelines to include the ring. | |

Step

4

Tailor key messages to each decision maker

Using the information you have gathered in Step 3, write up to three key messages about the ring that you can use to communicate to this decision maker. A key message is what you want the decision maker to remember about the ring. A strong key message will build on the interests of the decision maker. For example, if the decision maker is interested in expanding options for people at risk of HIV infection through vaginal sex, key messages would emphasize how the ring achieves that interest.

Next, for each key message, write up to three supporting messages. Supporting messages provide the facts, examples, and explanations to support your key message. Be sure you use the right language for the decision maker and focus on the facts, examples, and explanations that will resonate with them. You may want to try out your messages with partners to ensure they are clear. Input your key and supporting messages into Part 4 of the messaging framework template in Annex A.

Markers of a strong key message

- It is simple and direct.
- It is credible.
- It is linked to what the decision maker cares about.
- It is memorable.

Examples of key and supporting messages for a Permanent Secretary generated through the country workshops:

| KEY MESSAGE #1 | KEY MESSAGE #2 | KEY MESSAGE #3 |
|--|--|---|
| The ring is a safe and effective HIV prevention method. | Users want different HIV prevention options to meet their diverse needs. | Adding the ring to the existing package of HIV prevention methods will contribute to increased coverage with HIV prevention options. |
| SUPPORTING MESSAGE #1A | SUPPORTING MESSAGE #2A | SUPPORTING MESSAGE #3A |
| Studies have concluded that the ring reduces the overall risk of acquiring HIV through vaginal sex by about 50%. | Users are diverse, with different circumstances and needs that also change over the stages of their lives. | The ring fills a critical gap in HIV prevention programs for users who cannot or prefer not to use condoms or oral PrEP. |
| SUPPORTING MESSAGE #1B | SUPPORTING MESSAGE #2B | SUPPORTING MESSAGE #3B |
| Less than 5% of the users had product-related adverse reactions or side effects in the clinical trials, which were mild to moderate. | The ring is a user-centered option that allows them to take control of their own HIV prevention. | As has been shown with contraception, it is likely that when more options are available, overall use of prevention options will increase. |
| SUPPORTING MESSAGE #1C | SUPPORTING MESSAGE #2C | SUPPORTING MESSAGE #3C |
| In January 2021, WHO recommended that countries offer the ring as an additional choice for HIV prevention during vaginal sex. | Studies have shown that many users like the ring, especially since it is a long-acting method. | Giving users additional effective HIV prevention options they want to and can use will make it easier to achieve national HIV prevention goals. |

Step

5

Decide how to deliver key messages

List the channels you can use to deliver your key messages to each decision maker. Delivery channels might be in-person meetings, social media, audio-visual presentations at meetings, or newspaper editorial pages. Consider which channels the decision maker is most likely to engage with and which messages are best suited for that channel. Next, list the tools and materials you will use to support delivery of your key messages through each channel. And finally, list any messengers you might engage to help you deliver your message. These messengers should be people who are viewed as credible by the decision maker. Input your delivery channels, associated tools and materials, and messengers into Part 5 of the messaging framework template in Annex A.

Examples of delivery channels generated through the country workshops:

| DELIVERY CHANNELS/PLATFORMS | ASSOCIATED TOOLS AND MATERIALS | MESSENGERS |
|-----------------------------|--|--|
| Roundtable discussions | Talking points; testimonials from users; fact sheets | Users who have used the ring; ring researchers |
| Newspaper opinion pieces | Quotes from community members; key messages including important statistics | Respected private physicians ; well-known women's health champions (advocates or policymakers) |
| In-person meetings | Talking points; presentation slide deck; leaflets | Respected private physicians; ring researchers; ring users; allied religious leaders |
| Petition letters | Petition letter template | n/a |

Step

6

Identify allies to engage

Working in coalition is one of the most powerful advocacy tactics. Consider which allies can help you get out the message and what their motivation would be to support your campaign. Are they already engaged, or do you need to put this issue on their radar? What is the synergy between their missions and advocacy campaigns and yours? You may need to do some advocacy to bring these allies on board as partners in your campaign. Insert this information into Part 6 of the messaging framework template in Annex A.

Examples of allies generated through the country workshops:

| ALLIES: OTHER ADVOCATES AND ADVOCACY GROUPS | FOCUS OF THEIR WORK | THEIR INTERESTS |
|---|--|--|
| HIV prevention implementers | Delivering HIV prevention services and products | Achieving project results; contributing to reductions in new HIV infections |
| National women's health advocacy group | Influencing government policies that affect women | Ensuring equitable access to HIV prevention products and services for women |
| SRH advocacy organizations | Promoting the sexual and reproductive health rights of individuals | Expanding access to new products that contribute to their SRH goals |
| Youth-focused civil society groups | Improving quality of life for all young people | Ensuring young people are engaged in designing youth-focused programs |
| Leaders of religious or cultural groups | Ensuring their communities have access to essential services | Keeping their community safe and healthy; influencing new health-related initiatives |

Step

7

Inventory opportunities to leverage

Take inventory of any specific processes (e.g., budgeting periods, MOH strategic planning, specific events or meetings) that you might want to engage with during your advocacy campaign. You can use this information to coordinate the timing of your activities to feed into and influence these processes. Input this information into Part 7 of the messaging framework template in Annex A.

Examples of key processes to leverage generated through the country workshops:

| PROCESS | DATE |
|---|------------|
| World AIDS Day celebrations | 1 December |
| Annual government budgeting cycle | March–June |
| International Women’s Day celebrations | 8 March |
| Southern African Development Community Council of Ministers | March |
| PEPFAR annual Country Operating Plan development | March–May |

Step

8

Establish a timeline for implementation

Develop a general timeline for the implementation of your advocacy campaign, including designation of who will be responsible for each task. This timeline should consider the additional development and engagement work you will need to complete before launching your campaign. It should also sync with the timelines of the key processes you hope to influence, as indicated in Step 7. Add your timeline to Part 8 of the messaging framework template in Annex A.

Resource mobilization for advocacy

If you require funding to implement your ring advocacy plan, the [Compass for SBC](#) offers tools to help develop a resource mobilization plan. You can also explore the [Guidebook on Alternative Funding Models for Civil Society Organisations in Africa](#).

Example of a timeline generated through the country workshops:

| TASK | RESPONSIBLE | DEADLINE |
|---|----------------|--------------|
| Adapt sample presentation slide deck, talking points, and leaflet. | Mario | 15 July |
| Organize meeting with allies to review roles and coordinate contributions to the campaign. | Sandra | 30 August |
| Identify and engage users to provide testimonials during roundtable discussions and in-person meetings. | Sandra | 30 August |
| Schedule roundtable discussion with HIV Prevention TWG. | Mario | 30 September |
| Set in-person meeting with Permanent Secretary's office. | Mario | 30 November |
| Write editorial, circulate for review, and submit for publication. | Leonard/Sandra | 1 December |
| Set in-person meeting with PEPFAR Coordinator. | Mario | 31 December |
| Develop, circulate for review, and finalize budgeting meeting talking points and presentation slides. | Leonard | 31 January |
| Participate in MOH community engagement sessions for annual budgeting exercise. | Leonard/Sandra | 18 March |

In conclusion

Advocates have an important role to play in expanding the range of HIV prevention tools, including the ring, available to communities and users. With the messaging framework and top-line implementation plan you have developed using this resource package, you are better equipped to continue effecting change to improve the health of your communities. Your work adds to an incredible legacy of advocates who broke down policy and other barriers to improve access to HIV prevention and treatment products and services that have saved countless lives.

Please feel free to reach out with any feedback to improve this resource package or to share how you have applied it to develop and implement ring advocacy activities in your country. You can reach us at sbc@fhi360.org.

Other Advocacy Planning Tools and Resources

Below is a list of additional tools and resources you might find useful for planning, tracking, and budgeting your advocacy activities.

[UNAIDS ACT 2015: Advocacy Strategy Toolkit](#) – step-by-step modules and simple tips to develop an advocacy strategy.

[What makes a brilliant advocacy strategy?](#) – short article and video reflecting on how to maximize the impact of advocacy efforts.

[Handbook for Budget Analysis and Tracking in Advocacy Projects](#) – guidance and tools to help organizations incorporate public budget analysis and monitoring into their advocacy work.

[Guidebook on Alternative Funding Models for Civil Society Organisations in Africa](#) – guidance to help organizations understand and implement funding models to advance their goals.

Annexes

Annex A: Advocacy Messaging Framework Template

Annex B: Sample Tools and Materials

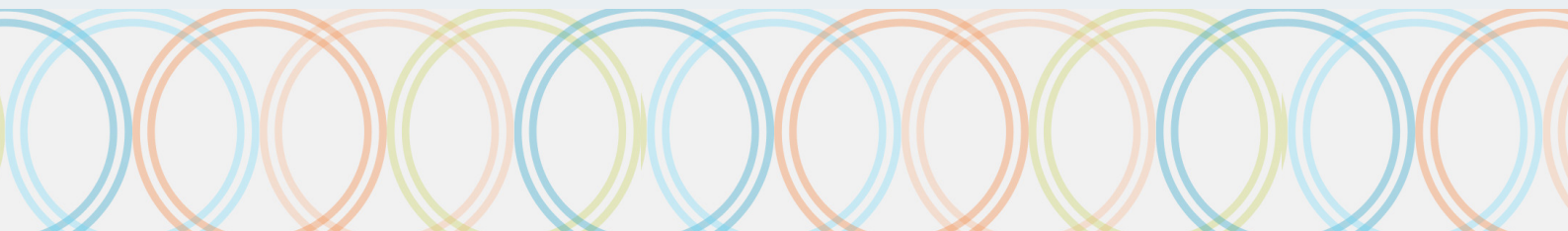
Frequently Asked Questions

HIV Prevention Ambassadors Toolkit tools

Answering Your Questions – The Ring

Tips for Using the Ring

Dapivirine Ring Slide Deck



Annex A: Advocacy Messaging Framework Template

Part 1: Advocacy goals

State up to three overarching goals for all your advocacy activities.

Goal #1: _____

Goal #2: _____

Goal #3: _____

Part 2: Decision makers to target

List those decision makers you will need to influence to achieve your goals.

Decision maker #1: _____

Decision maker #2: _____

Decision maker #3: _____

Decision maker #4: _____

Decision maker #5: _____

Important note: Although key messages may be the same for all of your decision makers, you may need to complete Steps 3–5 for each decision maker. This will help you ensure that key messages are aligned with the interests, agenda, and needs of each decision maker.

Part 3: Key information about the decision maker

Document each decision maker's current level of knowledge about the ring and their interests or agenda.

| DECISION MAKER (TITLE/PERSON TYPE) | ROLE |
|--|------|
| | |
| What is this decision maker's current level of knowledge about the ring? | |
| | |
| What is(are) the key interest(s) or agenda of this decision maker? | |
| | |
| How does the ring align with or respond to this decision maker's key interest or agenda? | |
| | |
| What specific actions do we want this decision maker to take? | |
| | |

Part 4: Key advocacy messages

Write up to three key messages you can use to communicate to each decision maker. Write up to three supporting messages for each key message.

| KEY MESSAGE #1 | KEY MESSAGE #2 | KEY MESSAGE #3 |
|------------------------|------------------------|------------------------|
| | | |
| SUPPORTING MESSAGE #1A | SUPPORTING MESSAGE #2A | SUPPORTING MESSAGE #3A |
| | | |
| SUPPORTING MESSAGE #1B | SUPPORTING MESSAGE #2B | SUPPORTING MESSAGE #3B |
| | | |
| SUPPORTING MESSAGE #1C | SUPPORTING MESSAGE #2C | SUPPORTING MESSAGE #3C |
| | | |

Part 5: Delivery channel and tools

List the channels, tools and materials, and messengers you can use to deliver your key and supporting messages to each decision maker.

| DELIVERY CHANNELS/PLATFORMS | ASSOCIATED TOOLS AND MATERIALS | MESSENGERS |
|-----------------------------|--------------------------------|------------|
| | | |
| | | |
| | | |
| | | |

Annex B: Sample Tools and Materials

Frequently Asked Questions (International Partnership for Microbicides, 2021)

This leaflet was produced by the ring developer to provide information about the ring and respond to common questions. The content of this leaflet could be adapted or used to inform the development of leaflets for decision makers.



NEW HIV PREVENTION CHOICES FOR WOMEN

Women and girls continue to bear the global burden of HIV/AIDS. And in sub-Saharan Africa:

- Nearly 60% of all new adult infections are among women
- Young women ages 15-24 are more than twice as likely to acquire as young men

What is the monthly dapivirine ring?

The dapivirine ring is a long-acting vaginal ring that a woman can use to reduce the risk of HIV transmission during vaginal sex.

The ring:

- Is woman-controlled
- Reduces but does not eliminate HIV risk
- Has no safety concerns and minimal side effects in studies to date
- Can be used discreetly
- Is easy to store – does not require refrigeration

THE RING

How the ring works

A woman would insert the flexible silicone ring herself and replace it with a new one each month.

The ring sits inside the vagina near the cervix where it slowly releases an antiretroviral drug called dapivirine at the site of potential infection.

Dapivirine works by blocking HIV's ability to make copies of itself inside healthy cells.

It is important that the ring is left in place for the full month to ensure that risk reduction is achieved.

REPLACE EVERY 28 DAYS

WOMEN URGENTLY NEED NEW OPTIONS FOR HIV PREVENTION, SO THEY CAN CHOOSE ONE THAT BEST MEETS THEIR NEEDS AND CIRCUMSTANCES.

Frequently Asked Questions (International Partnership for Microbicides, 2021) (continued)

THE DAPIVIRINE RING: A LONG-ACTING HIV PREVENTION OPTION

How safe is the ring?

No safety concerns have been seen in studies to date. Side effects such as urinary tract infection, vaginal discharge and itching were mild to moderate. However they were resolved with no interruptions in ring use.

How effective is the ring?

The ring was shown to reduce HIV risk by 35% in one large randomized clinical trial and by 27% in another. Later open label studies saw increased ring use and suggested greater risk reduction—by about half overall.

Important points about the ring

- **The ring must stay inserted to do its job.** A woman can go about her daily activities as usual. There is no need to remove the ring during menstruation, and the ring can be used with a tampon. There is also no need to remove the ring during sex, and it is rarely felt by either partner during sex.
- **The ring does not eliminate the risk of HIV infection,** and it does not prevent other STIs or unintended pregnancy, so it should be used with either a male or female condom.
- **The ring would be an additional HIV prevention choice.** As a woman-controlled and long-acting method, the monthly ring could be an important option for women who are either unable to use higher efficacy methods, such as daily oral PrEP, or who choose not to do so.
- **The ring can also be used with other forms of contraception,** but should not be used with contraceptive vaginal rings, diaphragms, menstrual cups or cervical caps.

The ring's status

The dapivirine ring received a positive scientific opinion in July 2020 from the European Medicines Agency (EMA) for use among women ages 18 and older in developing countries.

The product also received a recommendation from the World Health Organization in 2021. IPM is seeking country regulatory approvals in sub-Saharan Africa. The ring is also currently under review by the US Food and Drug Administration.

SCAN TO WATCH FREE VIDEO

WWW.IPMGLOBAL.ORG

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

Position of the female condom in relation to the vaginal ring

Position of an intrauterine contraceptive device (IUCD) relative to vaginal ring

Position of a tampon, IUCD and vaginal ring

OFFERING WOMEN NEW HIV PREVENTION CHOICES

SCAN TO WATCH FREE VIDEO


WWW.IPMGLOBAL.ORG

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES

HIV Prevention Ambassadors Toolkit tools (PROMISE/CHOICE, 2021)

Although intended for potential ring users, rather than decision makers, these tools are good source material for any nonmedical decision makers and gatekeepers because they use simple terminology to explain the ring and respond to common decision maker concerns.

Answering Your Questions – The Ring



Hi! I'm an HIV Prevention Ambassador. Do you have any questions about the ring?

What is the ring?

The ring is a flexible silicone ring that contains the ARV dapivirine and provides protection from HIV. The ring is inserted into the vagina and worn for a full month, and then replaced with a new ring. It is designed to be easily inserted and removed by the user.

How does it work?

The ring slowly releases dapivirine into the vagina over the course of the month. Dapivirine works by stopping HIV from making copies of itself in the body. Because HIV cannot replicate in the body, the virus dies.

How effective is it?

If you wear the ring continuously and replace it each month, the ring can provide 50% or more protection from HIV. It takes about 24 hours after insertion for the ring to provide maximum protection from HIV, and dapivirine quickly leaves the body after removal. Therefore, it is important to use a back-up form of HIV protection, for example a condom or abstaining from sex, for the first 24 hours, and keep the ring inserted at all times.

Is the ring right for me?

That's your decision. It's your body, so it's your choice! You might consider the ring if you are having unprotected sex and want to protect yourself from HIV. You may choose to use the ring if you cannot get or use oral PrEP. It is also a discreet option that no one has to know about! The ring only needs to be used during times in your life when you are vulnerable to HIV.

Will the ring protect me from other STIs and pregnancy?

No! The ring will not prevent other STIs or pregnancy. It's best to use condoms (with water-based lubricant, when possible) and other contraception with the ring to prevent infections and pregnancy and to increase protection from HIV. The ring can be used with almost any method of family planning except the contraceptive ring.

Are there any side effects?

The ring is just like any other medication. Some people experience side effects, like changes in vaginal wetness or odour, or itching, but these are usually mild and go away after a few days without removing the ring. If you experience vaginal changes while using the ring, it is important to visit your health care provider to make sure these are not symptoms of an STI.

Can I use the ring if I am taking other medications, or if I drink or use recreational drugs?

The ring is safe to use with alcohol and drugs. The medication in the ring when released stays local to the vaginal area; the medication does not circulate throughout the body. But make sure to keep yourself safe when drinking or using drugs. If you're having sex, make sure to use condoms (with water-based lubricant, when possible) and contraception to protect yourself from other STIs and pregnancy.

Should I take the ring out for sex, bathing or during menses (monthly menstruation/bleeding)?

The ring is designed to be kept in all the time and will only provide protection if worn consistently. The ring does not need to be taken out to be cleaned. The vagina is a self-cleaning environment. The ring will not affect frequency of menses, length or amount of bleeding. It is safe to use tampons or a menstrual cup with the ring, and the ring will not block the flow of blood. Menstrual bleeding may change the color of the ring but this is ok and will not change the ring's ability to protect from HIV. The ring does not affect a women's libido (sex drive). Most men do not feel the ring during sex. Some men and women even report that the increased vaginal wetness increases sexual pleasure!

What do I need to do if I want to use the ring?

The first step is to see a health care provider. They will help you take the next steps.

Tips for Using the Ring

1 Set a reminder to replace the ring each month.



- Reminders could be on your phone, diary, or a note in a place you look each day, like on a mirror.
- Set reminders to request more rings from your provider. You can also use your phone to keep notes about things you want to tell your health care provider.

4



Keep back-up rings.

It is always good to have a back-up supply in case the ring comes out in an unhygienic place or comes out without you noticing. Check with your health care provider to see if you can receive more than one ring at a time.

6 Get comfortable with inserting and removing the ring so that you can do it on your own.



The ring is designed to be easy to insert and remove. You can learn to feel confident in doing this yourself in case the ring falls out or has to be replaced when you are not near your health care provider. Practice on your own. It is easy! And if you have questions ask your health care provider.

2 Join or start a ring support group with friends.

You're not the only one using the ring. Connect with other girls and young women so you can support each other. Some support groups meet in person, others use social media or virtual chat groups



5

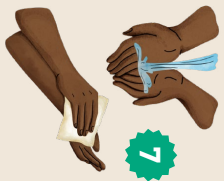


Use your fingers to adjust it

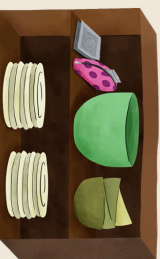
Use clean hands when inserting and removing the ring.

Always have clean hands when inserting anything in the vagina to avoid introducing harmful bacteria. If the ring falls out in a clean place such as a bed or underwear, rinse with water before reinserting. If the ring has been somewhere dirty, such as a toilet/latrine, replace it with a new ring.

7



3



Store your back-up rings in a dry, cool place away from children and animals.

Make sure you choose a safe, private spot, away from small children and animals. The location should be dry and not in direct sun. Some women like to hide or carry their rings in a small change purse or toiletry bag for more privacy. It's best to store unused rings in their original foil packaging unopened, to keep them clean.

Only remove the ring if you are replacing it.

Remember, the ring does not have to be removed for sex, bathing or menses or to clean. The ring cannot protect you if it is not in place in your vagina. If the ring is causing discomfort, use your fingers to adjust it or push it further up into the vagina. The ring is flexible enough to easily insert but firm enough to 'hug' the vagina to stay in place. If you are having discomfort while using the ring, contact your health care provider for support.

8

Never share your used or unused ring with others.


Everyone should see their health care provider to get their own rings.



No



Dapivirine Ring Slide Deck (PROMISE, 2021)

This presentation provides a brief orientation to the ring, including milestones in its approval, results from the clinical trials and open label studies, and key functional benefits. The content of this slide deck could be adapted and used during in-person engagements with decision makers.




Dapivirine Vaginal Ring (“the ring”)

An additional, user-controlled HIV* prevention option for those who cannot or choose not to use oral PrEP



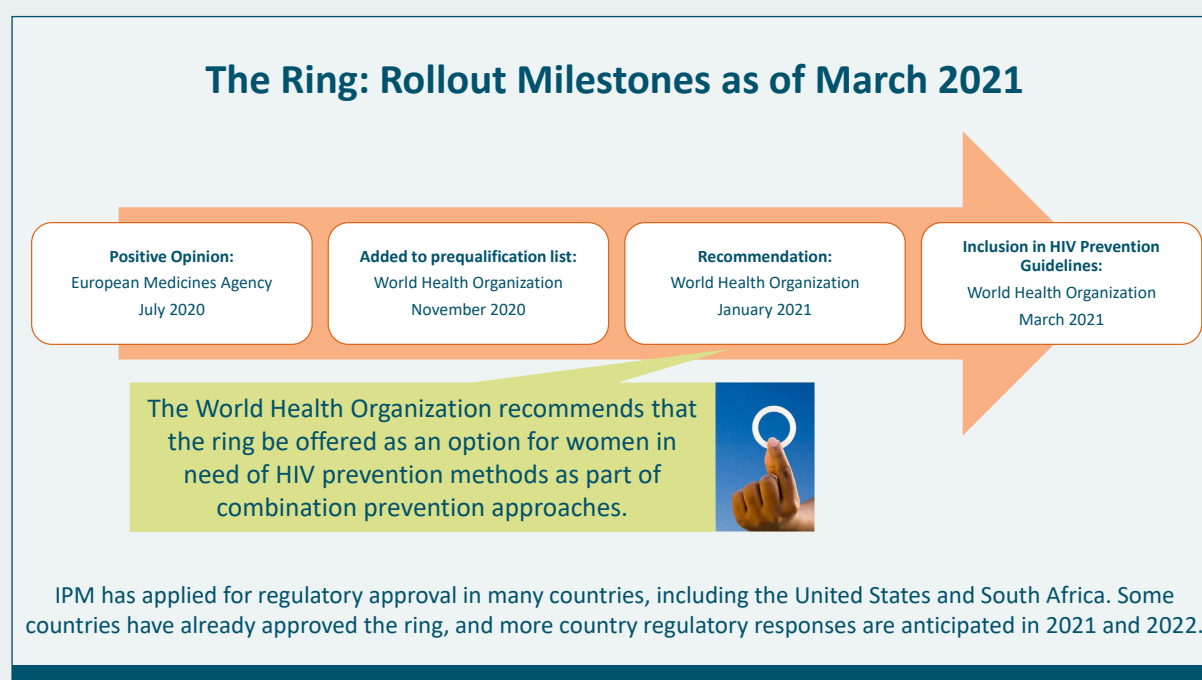
What is the Dapivirine Ring?



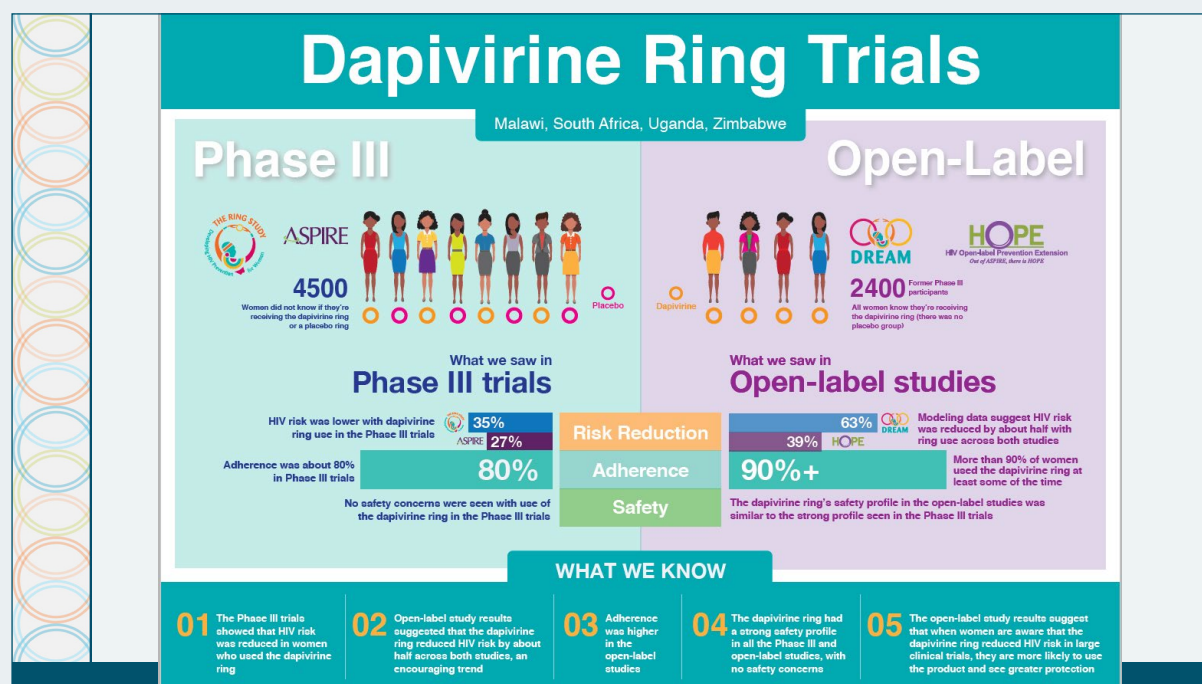
- Flexible, one-size-fits-all vaginal ring developed by the International Partnership for Microbicides (IPM)
- Slowly releases an anti-retroviral (ARV) called dapivirine into the vagina over the period of one month
- The first long-acting HIV prevention product
- User-controlled HIV prevention method

Dapivirine Ring Slide Deck (*continued*)

| The Ring Fills Gaps in the Current Portfolio | | | | |
|--|-------------------------------|---------------------------------------|----------------|-----------------|
| | Current options | | | Innovation |
| | Condoms | Treatment as Prevention | Oral PrEP | Dapivirine Ring |
| Frequency | At time of sex | Daily | Daily | Monthly |
| Site of action | Non-systemic | Systemic | Systemic | Non-systemic |
| Role of male partner in use | Male partner consent required | Controlled by partner living with HIV | User-initiated | User-initiated |



Dapivirine Ring Slide Deck (continued)




The Ring: Efficacy

- The ring is clinically shown to reduce the risk of HIV-1 acquisition by about 30%
- In addition, recent open label studies suggest that the chance of acquiring HIV is reduced by about 50% with consistent use of the ring**


Consistent Use = Increased HIV Risk Reduction!

Dapivirine Ring Slide Deck (*continued*)



The Ring: Safety

- No safety concerns related to ring use have been identified in previous and ongoing trials
- The ring delivers dapivirine in the location where exposure to HIV is likely to occur, so less of the drug is absorbed in the rest of the body
 - The Phase III clinical trials did not indicate ARV resistance associated with use of the dapivirine ring, or interference with antiretroviral therapy (ART) effectiveness in those women who became HIV-positive while participating in the trials
 - Minimal side effects – some women in clinical trials experienced mild vaginal discharge or itching, but these usually went away within a week or two

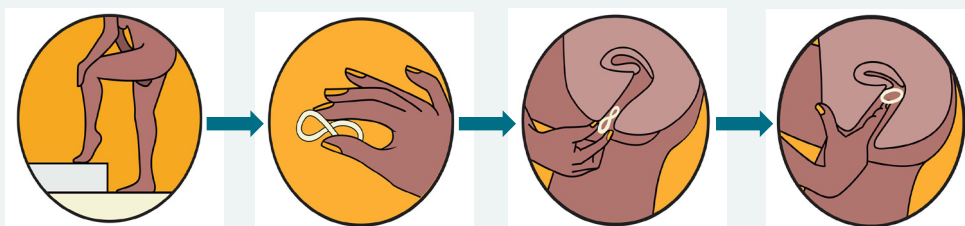


The Ring: Safety

- It can be used with most family planning methods
- Information from multiple studies has shown no safety concerns to ring users or their infants as a result of brief use of the ring in early and late pregnancy.
- A small study of breastmilk among ring users who had weaned their infants showed no safety concerns and indicated that only very small amounts of dapivirine got into breastmilk.
- Studies to confirm the safety of the ring during all stages of pregnancy and breastfeeding are ongoing.

Dapivirine Ring Slide Deck (*continued*)

The Ring Insertion and Placement




Users can insert and remove the ring **themselves** with little or no support from a health care provider.

The Ring: Ease of Use


- The ring can be inserted without help from a health care provider
 - A health care provider may insert the first ring, if wanted, to ensure that the user is familiar with how the ring should be inserted
- Studies have found that the ring has little to no impact on sexual activity – many women and their partners reported that they could not feel the ring during sex

Dapivirine Ring Slide Deck (*continued*)




The Ring: Long-Acting

The dapivirine ring provides steady release of drug over one month without the need for maintenance



Low maintenance means less burden on the user to remember doses, and may encourage more consistent use



The Ring: Privacy

- The ring can be inserted and removed in private
- During clinical trials, it was rarely felt by women or male partners
 - Most women in clinical trials reported that they could not feel the ring when it was inserted correctly
 - Many women in clinical trials reported that they and their partners could not feel the ring during sex

Dapivirine Ring Slide Deck (*continued*)

What did women have to say?

Study participants report...

I like that the ring stays inside you and nobody can see it.... you don't have to disclose ring use to others if you want. My family doesn't know that I am using the ring. ... And the partner can't feel it as well.¹

It wasn't difficult, I got enough education before using it because I was really scared when I first saw it... But during education I learned that the ring was soft, I thought the ring was hard and painful. They showed that to insert the ring you need to twist it like 8 and when I tried it, it was easy and doable."¹

I don't feel the ring when it is inside me, I only feel it during insertion. I don't feel it though when I'm seated or walking. The ring has never fallen; it's not painful... the ring is not felt when you are walking or sleeping; it doesn't even move.²

Potential Public Health Impact

Modeling data show that:

- A range of prevention options alongside scaled-up treatment is needed to achieve epidemic control
- Prevention methods with even modest efficacy would have a meaningful impact as part of a comprehensive strategy that could avert millions of HIV infections over time
- The ring would prevent acquisitions among women that would otherwise not be averted by any other method

**New, user-centered options like the ring
will be crucial to achieving epidemic control**



Dapivirine Ring Slide Deck (*continued*)

Ongoing Trials

- Further trials are underway to gather more data on the safety of ring use during adolescence, pregnancy, and breastfeeding
- Research is in progress on a 3-month Dapivirine Vaginal Ring and a Phase 1 study that includes dapivirine or HIV prevention and levonorgesrel for contraception.

