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**NO CHOICE,
NO PREVENTION**

**GET PREGNANT
GET DUMPED**



THE PROBLEM

Informed choice is easy to advocate for and hard to implement. Cost, provider time and public health priorities can all work against investment in services that offer and support choice in strategies.



THE RISK

Embracing informed choice in biomedical prevention is tricky. There isn't enough money for primary prevention basics like male and female condoms and VMMC. Advocating for more choices such as PrEP, multiple testing approaches, etc. means finding ways to do more with existing resources and also demanding additional funds.



THE PATH TO A SOLUTION

Identify, cost and adapt best practices in informed choice programming and monitoring from family planning and HIV programs as part of planning for new biomedical tools.

Choice is a dangerous word in public health these days. It's always been politically loaded, but it's been even more risky since January 23, 2017, when the Trump Administration implemented a vastly expanded version of the Global Gag Rule (GGR), a statute historically implemented by Republican US presidents restricting foreign NGO recipients of US funding from speaking about, referring women for, or advocating for expanded access to abortion. Previous versions of the GGR applied only to foreign recipients of US family-planning funds. The Trump Administration's GGR applies to foreign recipients of all global health funds. The International AIDS Conference brought documentation of its pernicious effects. It is already causing services to close, reproductive-health coalitions to falter due to confusion about allowable activities, and imperiling women's health and lives as unsafe abortions and poor outcomes from unplanned pregnancies take their toll.⁷ Curtailing choice—especially when that choice is when and how to become pregnant or to remain pregnant—is dangerous.

⁷ Bound and gagged: Exposing the impact of the expanded Mexico City policy. AIDS 2018. Available at: <http://programme.aids2018.org/Programme/Session/130>.

Informed Choice: How it adds up

Informed choice is about much more than supplies, though that is part of it. It's about a respectful, open-ended conversation between provider and client that works best when the provider is supported in her role, and the client is treated with dignity.



Procurement of a range of options



Provider training, compensation and time



Human rights-based approach: providing full information and trusting that people can make their own decisions



Informed choice

To fight back, all champions of women's health and HIV prevention need to use the word choice frequently, passionately and strive to protect the programs women and girls most need. This is true in terms of direct resistance to the misogynist, anti-science politics at play in the expanded GGR. It is also true in other contexts, including primary prevention, antiretroviral treatment and contraceptive programming. Indeed, it is no exaggeration to suggest that the future of biomedical HIV prevention depends on the field assuming a leadership role as a champion of and expert on informed choice.

As the graphic above depicts, informed choice, in the context of health care, encompasses elements

including but not limited to information, staffing, commodities, and time and space for conversation that, when assembled, allow an individual to make the health decision that is right for him or her.

The term "informed choice" is frequently used in the context of family planning programs (see p. 29) and was used with regards to HIV in the context of the WHO guidelines for infant feeding by women living with HIV. First issued in 1991 and updated many times over the years, these guidelines are among the most conflicted of HIV policy documents. They were first issued at a time when women with HIV who were not on ART had to choose between breastfeeding and formula feeding, knowing both options carried health risks for their babies.

The implementation of the WHO infant-feeding guidelines, in their various forms, has provided a wealth of information about how the concept of choice has been understood, implemented and ignored by providers, funders, governments, women and their families. As one study from

The future of biomedical HIV prevention depends on the field assuming a leadership role as a champion of and expert on informed choice.

Senegal⁸ found, when WHO began to recommend antiretroviral treatment for all pregnant women living with HIV, the related shift away from formula feeding as an option had a range of consequences. Social and organizing spaces for women living with HIV had emerged at the community centers where they were instructed to go to pick up formula. Removing infant feeding meant an end to these spaces; so the loss of choice was also a loss of community and agency. The author writes, of formula-based programming, “It introduced women caught in medically-defined relationships to a type of biosociality they could assert in associations, without necessarily becoming an ‘expert’ [...]” It wasn’t the specific option, but the framework that supported choice that mattered. Single-option approaches, while supported by science, can feel over-medicalized and undermining of clients’ agency.⁹

Still, informed choice is not simple. Many studies have documented all the ways that informed choice is challenging to implement and measure due to provider biases, varying degrees of training, limited time per client and so on.

Yet today, most biomedical prevention programs are only just beginning to grapple with the complexities. Countries and implementers consider the provision of PrEP or VMMC or condoms, but rarely all of these options together. The research arena is also siloed, with leaders often advocating for a specific approach rather than effective prevention by whatever means work best for a person at a given moment in his or her life. It can be tempting to think that the right prevention option might allow for a large-scale, single-strategy push. But history says otherwise.

Put affirmatively, there is an opportunity today to reverse a decades-long tradition of foot-dragging, penny-pinching and corner-cutting when it comes to HIV and contraceptive services, and to fully embrace a human- and choice-centered approach to delivering services.

Choice and Contraception: Rings as a real choice

In August 2018, the US Food and Drug Administration approved the first contraceptive ring that can be worn vaginally for up to a year. “Annovera”, developed by the Population Council, is a flexible silicone ring that contains synthetic hormones that prevent conception. (A similar ring, containing the ARV dapivirine, is under regulatory review with a decision pending in the coming year (see Fig 14, p. 33).) The contraceptive ring developers have lauded this approach as being the first contraceptive providing year-long protection wholly under a woman’s control—a reference to the fact that women can insert and remove the ring themselves. Vaginal rings are also in development as multi-purpose prevention technologies that contracept and reduce the risk of HIV or other STIs (see Fig 16, p. 37). Both family planning and HIV prevention programs will need to incorporate rings as a choice sooner or later. This advance is a great chance to build collaborative programming, including with civil society, which has raised concerns that messages about the new one-year ring could prompt confusion about other discrete methods that also provide long-term protection.

What does this mean, exactly? In Section One, we talked about the need to invest in demand-side thinking: ensuring that people’s mindsets, ideas, preferences and decision-making “journeys” inform the messages, products and services offered to them. At a very simple level, adding “informed choice” to this approach means that, at the end of the journey, people have more than

⁸ Alice Desclaux. *After the withdrawal of ‘informed choice’: the meanings and social effects of mothers’ choice for HIV prevention in Senegal*. 2014. *Anthropology & Medicine*, 21:2, 113-124, DOI: 10.1080/13648470.2014.927194.

⁹ Key Barriers to Women’s Access to HIV Treatment: A Global Review. AVAC, ATHENA and Salamander Trust. 2017, UN Women. <http://www.unwomen.org/en/digital-library/publications/2017/12/key-barriers-to-womens-access-to-hiv-treatment>.

one option to choose from. Is it male circumcision or PrEP? Is it daily oral PrEP during periods of migrant labor and condoms when home? Is it partner testing and counseling focused on gender-based violence? In an informed choice approach to

biomedical prevention, various options will be offered, with information about pros and cons, risks and benefits. Demand-side thinking will help counselors and peers tailor information to a given person, but she or he alone will make the choice.

Choice and HIV Testing: Can a “high-yield” focus uphold human rights?

Early in 2018, the US AIDS program, PEPFAR, declared that 30 percent of all new HIV diagnoses in its testing programs should come from index testing, an approach that relies on individuals to provide the names and contact information of sexual and needle-sharing partners and children who may have been exposed. The program then uses this information to trace and test these contacts, without revealing the source of the information.

Data from index-testing programs show high “yield”, meaning a greater proportion of newly identified positives versus other testing approaches. But advocates are concerned that yield could come at a cost of confidentiality about HIV status and/or about aspects of a person’s life such as same-sex partners or sex work. Data from couples-based index testing don’t show that the strategy increases the risk of violence, but couples programs are different from the index testing being rolled out today, which puts gay people, sex workers and other marginalized groups in a position of potentially coerced disclosure of contacts and, by extension, identity. This has raised real concern about human rights abuses that could be triggered by index testing that’s overly focused on yield, not on informed consent. Monitoring and measuring adverse outcomes of these programs is essential, as is documenting how many people opt out of index testing, since this is a proxy for people having the right to choose.

Our bodies, our choice: Women’s fight for dolutegravir

Recent developments demonstrate just how critical it is to budget for and design programs that are platforms for a range of options, not a single strategy. Consider dolutegravir (DTG), an antiretroviral that is well-tolerated, powerful and has a highly favorable resistance profile. DTG is such a good drug that many countries are planning to or have already switched to DTG as a first-line option, replacing efavirenz, which can cause tough side effects in the first weeks and months of use.

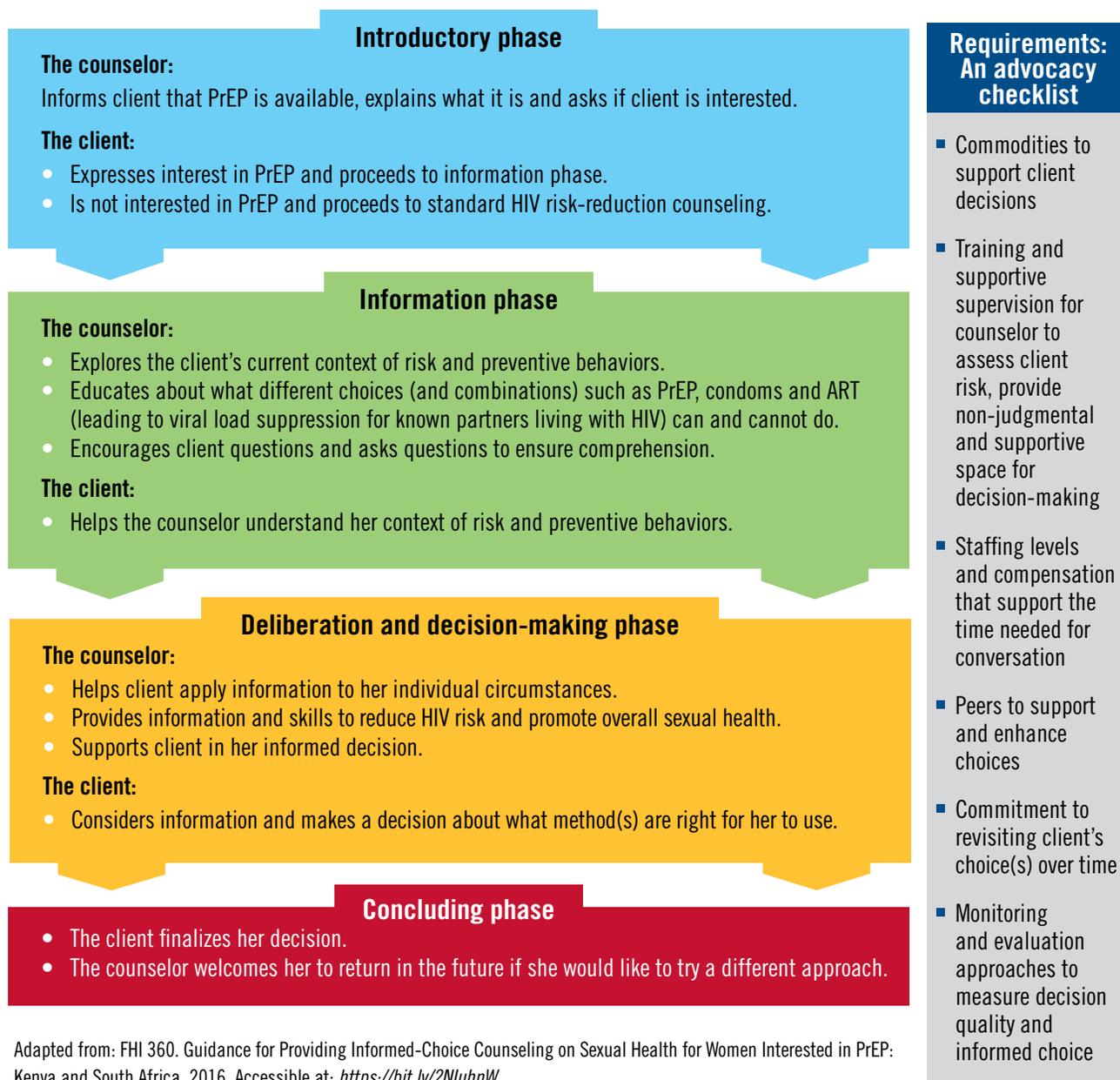
Yet the momentum behind the transition to DTG came to a whiplash-inducing pause in mid-May 2018. That’s when WHO issued a statement, based on data from a cohort of women in Botswana, indicating that DTG might increase the risk of neural tube defects (NTD) in infants born to women living with HIV who were on DTG-based regimens at the time of conception, compared to women using efavirenz. The risk of an NTD is within the very early weeks of pregnancy (through about day 28), so women on DTG who are in later stages of pregnancy, or who start DTG while pregnant, would not face that risk or need to switch.

In response, several African countries moved swiftly to adapt the WHO statement, with proposed guidance that DTG only be offered to women over the age of 49 (i.e., women who were less likely to become pregnant). This move prompted outrage from women living with HIV and their allies who demanded that they be given the choice to take DTG-based regimens—ideally with the offer of effective contraceptives—and that those women who wanted to stay on or switch to efavirenz also be allowed to do so.

FIG. 9

Phases of Informed-Choice PrEP Counseling

This flow chart emerged from socio-behavioral research, including surveys and in-depth interviews with Kenyan and South African women. The research team set out with the goal of adapting the informed-choice approach used in family planning programs for use in PrEP, a prime example of fields learning from each other. The result is very clinic-centered; AVAC has added the column at the far right to reflect additional elements. However, it is a step towards much-needed exploration of how to make informed choice a reality in HIV prevention today.



Acting on this demand means procuring both DTG and efavirenz. It means helping counselors with simple, clear decision-making tools and ensuring support for robust treatment literacy

delivered by and for people living with HIV. It is one of the ironies of the HIV epidemic that, as treatment access has expanded, resources for literacy have decreased. In short, the conditions

— RESEARCH TO INFORM CHOICE-BASED PROGRAMS: THREE GAPS —

Funders don't always prioritize investment in the types of research that enhance, focus and provide the basis for informed choice. While low-cost compared to clinical trials, the research and information-gathering that should be done to support informed choice often isn't funded. Here are three examples:

-  Pregnancy registries for women on ART aren't adequate, as the DTG developments have made clear.
-  Research into how to convey complex choices to clients and providers is underfunded and not translated from field to field. There is nothing in peer-reviewed literature about counseling women about DMPA and similar contraceptive products in the context of uncertainty about HIV risk, even though that uncertainty is more than eight years old. Contraceptive programs and infant-feeding programs for women living with HIV provide examples but are seldom cited by HIV practitioners.
-  The ECHO trial is smaller than its leaders originally proposed, simply because of funding. One of the proposed arms that got dropped was the injectable NET-EN, which contains a different synthetic progestin from DMPA. NET-EN is a potential alternative to DMPA-IM, but its absence from ECHO means that there will be unanswered questions about how different it is from DMPA, if at all.

to support informed choice existed when there was little choice in treatment; today, when such choice is possible, these resources are much diminished.

The DTG developments—still evolving as this report went to press—also highlight the ways in which the HIV field has missed opportunities to invest in the studies and data collection needed to inform choice in the first place. As Polly Clayden, veteran HIV activist and expert on women, HIV and pregnancy, wrote in a July 2018 review, “Despite massive global investment, aggressive transition plans—as well as calls for years for more systematic recording of outcomes when women receive ART in pregnancy—few prospective birth registries have been established in other settings that can refute or confirm this finding.”¹⁰

This type of inaction can make a fallacy of informed choice. If better data are not collected, then the choice will not be any more informed in a year—or ten—than it is today.

Inaction on informed choice: The case of Depo-Provera and similar products

In 2019, the ECHO trial that is asking whether DMPA-IM (depot medroxyprogesterone acetate or Depo-Provera, delivered via intramuscular injection), the copper IUD (intrauterine device) or the Jadelle implant impact women's risk of HIV, is expected to release results. These data could shape policy and programs, and yet by that time it will have been two years since WHO reclassified DMPA and other progestin-only contraceptives as having a theoretical or possible risk related to women's HIV acquisition. And it will have been seven years since an earlier classification stipulated that women at high risk of HIV should be informed about the uncertainty related to DMPA and similar products. As African women and their allies have said repeatedly, these classifications should have triggered a substantial investment in programs that provided women with comprehensive information on the

¹⁰ Clayden, Polly. *Dolutegravir preconception signal: time is up for shoddy surveillance*. HIV i-base, July 11, 2018. Accessible at: <http://i-base.info/htb/34459>.

risks and benefits of different methods, along with choices between methods. They didn't. Most governments did nothing. Many stakeholders chose to emphasize the WHO statement that all women could continue to use the methods, rather than the statement that use should be based on informed choice. Convenience supersedes choice too often in public health. WHO itself recognized this in its 2017 reclassification of DMPA, which notes that women's right to informed choice hadn't been served by the previous guidance.¹¹

During the same interval, subcutaneous DMPA (or DMPA-SC) has been rolled out—under the brand-name, Sayana Press—with many positive reviews from providers and women. It can be administered by a lay person (and even self-administered), is easy to store and has great potential.

There is no conclusive evidence that DMPA-SC is any different from DMPA-IM. The Reproductive Health

Supplies Coalition “advocacy pack” for DMPA-SC talks about the uncertainty related to HIV risk and urges advocates to call for more choices and better integration of HIV and family planning.¹² But DMPA-SC is not being systematically rolled out with choices for women who might want a comparably long-acting option or better HIV prevention to offset the uncertainty. By the same token, if ECHO shows that DMPA-IM does exacerbate women's HIV risk, it is still a totally reasonable and rational choice for some programs to choose DMPA-IM or DMPA-SC as an option, and for some women to choose either as their option.

Will the champions of choice please step up?

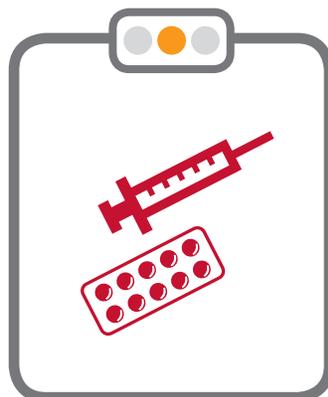
As Figure 11 (p. 28) shows, ongoing discussions regarding DTG and hormonal contraception are converging on common areas: the degree to

FIG. 10

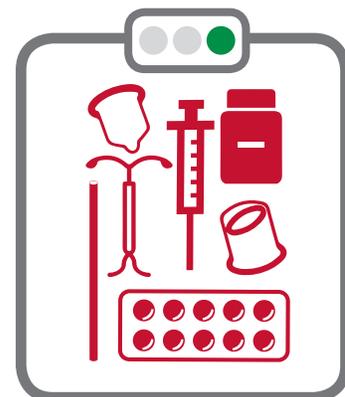
Contraception and HIV Prevention: A clear picture of women's needs



A range of scientific models predict that a world without DMPA is bad for women. It's a discrete, long-acting method that many women want and prefer. But this isn't a scenario that's likely to occur unless there's profound negligence and poor communication.



In many parts of Eastern and Southern Africa—the parts of the world where DMPA use and HIV prevalence are high—the shot is the only long-acting option on the shelf in programs that provide little or nothing in the way of comprehensive HIV prevention. Women need contraception, so this is better than nothing—but not good enough by a long shot.



One woman faces many choices about HIV prevention and contraception. Funders and governments need to move to integrate programs that provide all these services in one place.

¹¹ World Health Organization. Hormonal Contraceptive Eligibility for Women at High Risk of HIV. 2017. Accessible at: www.who.int/reproductivehealth/publications/family_planning/HC-and-HIV-2017/en/.

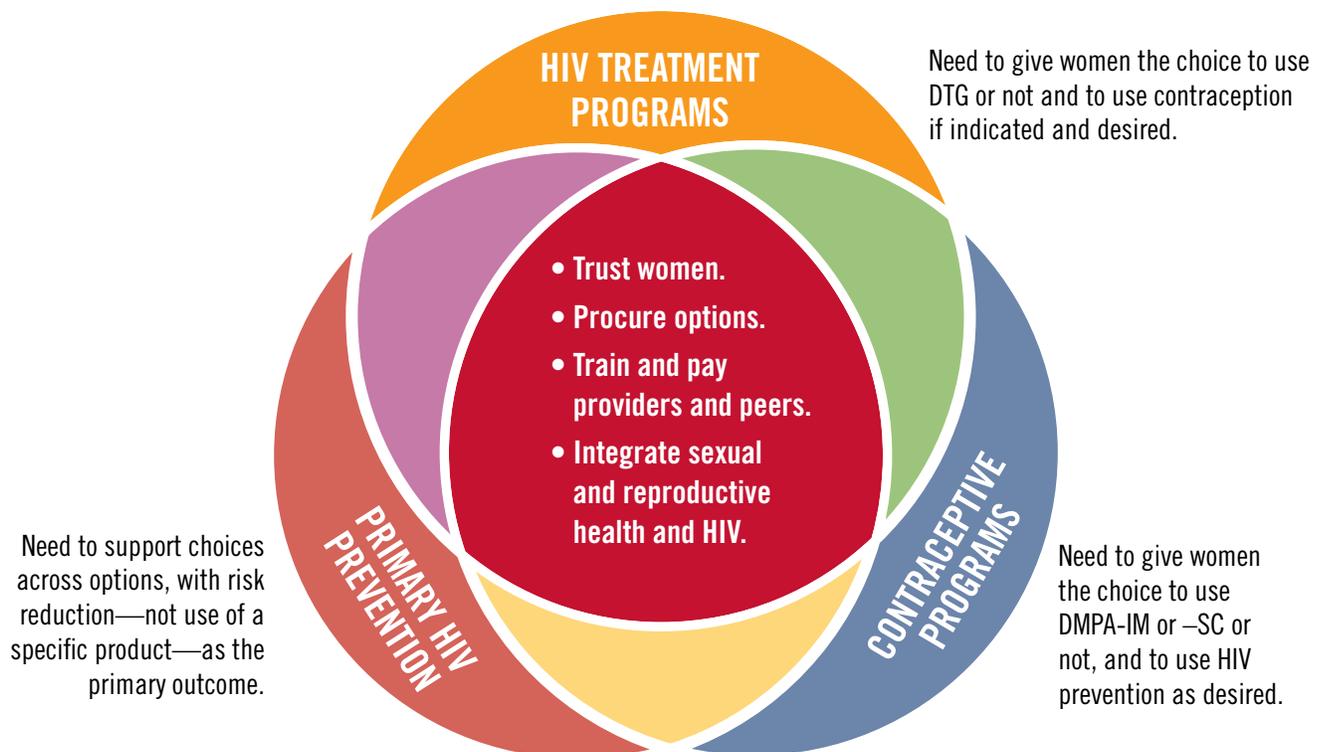
¹² Reproductive Health Supplies Coalition. Advocacy Pack for DMPA. 2017. Accessible at: www.rhsupplies.org/activities-resources/tools/advocacy-pack-for-subcutaneous-dmpa/.

which public health systems and funders trust women to make their own choices, the degree to which those rare systems that do trust women are resourced to procure the products and train the providers in ways that support choice, and the ways in which choice is understood to be about overall health rather than a specific option.

This is the best if not the only context for delivering new biomedical prevention strategies. Many scientists and advocates in the field recognize this and pursue it in their work every day. This is why the biomedical prevention field has the potential to become a leader in informed choice. Done right, this leadership from the biomedical field will build trust among potential users, by demonstrating the clear understanding that the world is organized around

people, not products. There are not women who just need HIV prevention or women who just need contraception, nor are there people who only need information on dolutegravir and others who need clarity on DMPA. Products aren't perfect. The programs that deliver them need to provide full information about risks and benefits in language that's clear and in the context of choice between options and the integration of services—contraception, HIV prevention, sexual and reproductive health and rights. A good information sheet on dolutegravir or DMPA won't do the trick because it isn't an issue-by-issue problem. The need for proactive investment in simple, robust strategies for communicating about and providing choices is essential in all fields.

FIG. 11 Putting Women* at the Center: Informed choice in 2018 and beyond



* This graphic uses issues of primary relevance to cisgendered women and does not reflect diversity within those communities. The principles at the center could be adapted to apply to every category of person affected by HIV, including but not limited to transgender women, gay men and other men who have sex with men, heterosexual men and migrants. We also stand firm in the belief that the needs and issues of cisgendered women must be continually and specifically foregrounded as central to any epidemic response.

INTEGRATION WITH FAMILY PLANNING: THE TIME IS NOW

“It’s time for an integration index,” said South African researcher and women’s health advocate Helen Rees at AIDS 2018.¹³ She made the remark at a panel that was a first for the international AIDS Conference: a joint session including FP2020, HIV prevention researchers and civil society activists. FP2020 is a global partnership dedicated to expanding women and girls’ right to decide whether, when and how many children to have. The index Rees proposed would measure the integration of family planning and HIV services in clinics, programs and policies, and could be a meaningful way of tracking a merger that’s essential to ending HIV. In many countries, including South Africa, the young women most at risk of HIV are far more concerned about pregnancy. Services have to be co-located, non-judgemental and centered on choice.

Beth Schlachter, the Executive Director of FP2020, shared some of the ways that FP2020 is working to expand women and girls’ right to control their bodies. Some of FP2020’s indicators could be adapted for HIV prevention and used as the cornerstone of the integration index. Watch for advocacy on this in 2019!

As part of its annual evaluation of progress, FP2020 has developed a trio of indicators to measure rights-based family planning, which it defines as programs that aim to fulfill the rights of all individuals to: choose whether, when, and how many children to have; act on those choices through high-quality sexual and reproductive health services, information, and education; and access those services free from discrimination, coercion and violence.

Core Indicator 14, the Method Information Index (MII), serves as a proxy for quality of counseling and reflects the extent to which women are informed about side effects and alternate methods. The MII is a summary measure constructed from three questions asked of current contraceptive users about the occasion when they obtained their current method:

- Were you informed about other methods?
- Were you informed about side effects?
- Were you told what to do if you experienced side effects?

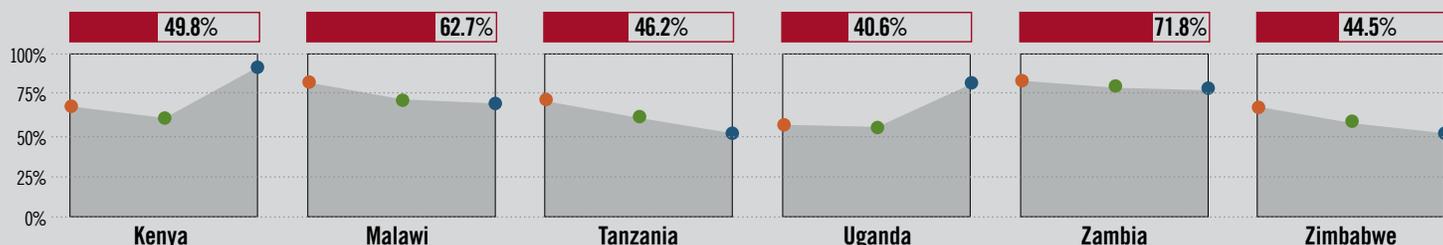
In 2019, the ECHO trial will release data on whether DMPA or two other contraceptive methods affect women’s HIV risk. These data are most relevant to countries where HIV prevalence and DMPA use are both high. The MII values for some of these countries are shown below.

Core Indicator 15 measures the proportion of women who have received any kind of family planning information in the last 12 months, either from a health worker in a facility or in the field (among both those using and not using contraception).

Core Indicator 16 measures the percentage of women using family planning who made family planning decisions either by themselves or jointly with their husbands or partners. This indicator shows a high level of women’s participation in contraceptive decision-making, yet it is also important to note that in 15 of 35 countries with data, at least 1 in 10 female users reported that they were not involved in such important choices as whether and when to use contraceptives and what method to use.

Method information index in countries most impacted by uncertainty about DMPA and HIV

The x-axis measures the percent of women who answered “yes” to each individual question; the bar at the top of the graphic shows the percentage of women who answered “yes” to all three questions.



Adapted from: FP2020. *Core Indicators 14-16: Measuring Rights: Counseling, Informed Choice and Decision Making*. Accessible at: <https://bit.ly/20k0dMA>.

¹³ Hormonal contraception and HIV risk at the crossroads: What do the latest research, advocacy and program developments mean for women, providers and programs? Proceedings of the AIDS 2018 Conference, 2018 July 23; Amsterdam, Netherlands.

FIG. 12 Peers are Primary: Towards a systematic approach to lay cadres

Across treatment and prevention programs, peer navigators, mentor mothers and lay counselors are recognized as essential to good services. Yet many countries don't have clear schemas for quantifying the number of individuals needed, budgeting for their remuneration and defining the roles and responsibilities that lead to impact. Activists are working to ensure clarity by demanding that governments, funders and implementers take steps to:

- Quantify the need and coverage gap for lay workers supporting HIV and other health services;
- Recognize lay cadres in government human-resources-for-health plans;
- Monitor performance in sites and programs with different types of lay workers;
- Provide updates on investments in human resources for health by cadre as part of all PEPFAR Country Operational Plans, AIDS reviews and other annual surveys.

Defining the peer or lay person's roles and responsibilities is essential. The graphic below is one example of what a specific job description could look like.

