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Fighting for an AIDS-free generation

Women's and health care providers' knowledge and tolerances of risk for HIV treatment during pregnancy:

A qualitative study in Homa Bay County, Kenya

Study Report
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Acronyms

ART:	Antiretroviral therapy
ARV:	Antiretrovirals
DTG:	Dolutegravir
EFV:	Efavirenz
HCW:	Healthcare workers
NASCOP:	National AIDS and STIs Control Program
PMTCT:	Prevention of mother-to-child transmission
RRI:	Rapid response initiative
SD:	Standard deviation
WLHIV:	Women living with HIV
WRA:	Women of reproductive age

Introduction and background

In 2020, there were 15.4 million children born to women living with HIV (WLHIV) globally who did not acquire perinatal HIV infection, evidencing the milestones made in preventing vertical HIV transmission [1]. Treatment options for HIV can be complex and have various levels of effectiveness, differing side effects, and potential risks for fetuses when taken by pregnant women. As with all medications for use during pregnancy, individuals and society must weigh the benefits and risks of antiretroviral therapy (ART) for both mother and fetus.

Women and girls in Sub-Saharan Africa accounted for 63% of new HIV infections in 2021, with those 15 to 19 years being especially susceptible to new infections [2]. Additionally, WLHIV face the challenge of preventing vertical transmission to children during pregnancy, at delivery, and in the first two years of life via breast milk [3]. Significant gains have been achieved for ART coverage during pregnancy, with coverage doubling in 2019 compared to 2010 and a reduction of the maternal-to-child transmission rate from 27.2% in 2010 to 16.9% in 2019 in Sub-Saharan Africa [4]. These gains need to be sustained through timely ART initiation in combination with other interventions in order to reduce these rates further [5].

Advances in research continue to make more potent and tolerable medication available for HIV treatment, such as dolutegravir (DTG), which after various trials was recommended as a preferred first-line treatment based on superior virologic efficacy, better tolerance, and reduced discontinuations due to adverse events compared to other currently available regimens [6], [7], [8]. More recently, long-acting injectable cabotegravir/rilpivirine given once every two months has demonstrated long-term efficacy and durability [9]. Initial results call for further research among populations that would most benefit from cabotegravir/rilpivirine, including pregnant women [10].

Complications arising from the antiretroviral (ARV) drugs expose WLHIV to higher risks of adverse pregnancy outcomes compared to HIV-uninfected women [11]. Pregnancy outcomes may also be affected by whether one conceives while on ART or starts ART after conception [12]. Since research ethics consider pregnant women as vulnerable and protected populations, they are mostly likely to be left out of drug trials, and thus may end up lacking information regarding the benefits and risks they may get from use of new medication during pregnancy [13], [14].

Immediate among the concerns that WLHIV have is giving birth to an HIV-uninfected baby [15]. New HIV treatment guidelines provide information for counseling patients on potential risks and benefits of ARVs during pregnancy. However, these are seldom comprehensively communicated by HCWs to women. [1616]. As new evidence emerges, guidelines on use, risks, and benefits of receiving ART while pregnant need to be generated and disseminated to facilitate decision-making.

We implemented a study at the time DTG use was being optimized in Kenya to understand women and healthcare workers (HCW) knowledge and preferences regarding ART regimens and associated risks during pregnancy [1717].

Study Objectives

The study objectives were:

1. To describe the knowledge and understanding of HIV healthcare providers and national managers/policymakers with regard to:
 - a. Side effects and maternal and fetal risk factors of various HIV medications (including DTG and efavirenz [EFV]-based first-line treatment options)
 - b. The extent to which health care providers are counseling women and conveying the risks and benefits of DTG
 - c. Views on the importance of choice of women in selecting their regimen in the face of potential side effects or drug-related fetal risks
 - d. Their views on the possibility of providing consistent reliable contraception and information to women of reproductive age to enable them to make informed decisions regarding ARV choice and pregnancy
2. To describe the knowledge and views of HIV-positive women (pregnant or of reproductive age) with regard to:
 - a. HIV treatment options, side effects, and maternal and fetal risk factors
 - b. Feasibility of accessing and utilizing consistent reliable contraception and contraceptive preferences
 - c. Perceived risks and benefits of and preferences for or concerns about different ART options, especially with regards to risks and benefits during pregnancy

Methods

Study Setting

The study was conducted in Homa Bay County, the region in Kenya with the highest prevalence of HIV, with 19.6% of the population estimated to live with HIV [18]. HIV prevalence among women (22.1%) is higher than that of males (19.1%) [19]. This was a qualitative study, and data were collected between July and August 2020.

Site selection

Five sites were randomly selected from 164 sites within Homa Bay County where DTG rollout had been done. DTG in Kenya started off as a pilot in 2017 and was implemented countrywide soon after [20]. Four sites were randomized to participate at cluster level (by facility type), with one sub-county hospital, two health centers, and one dispensary selected, and the fifth site was the county referral hospital.

Study design, population, and sampling

The study used qualitative methods to describe the views and preferences of women of reproductive age living with HIV, HCW working in the HIV clinics for at least three months, and policymakers involved in policy development and/or implementation at county level within Homa Bay County. From the five selected study facilities, a convenience sample of 30 women living

with HIV (15 pregnant and 15 nonpregnant) were interviewed by consecutively enrolling them until the desired sample size was reached. In addition, 12 HCW directly involved in providing HIV care to the women (clinicians, psychosocial counselors, and nurses) were purposively selected for interviews. Six policy makers/program managers were purposively selected from representatives of local health management teams and HIV programs working in HIV service delivery in the county.

The in-depth interview guides were pilot tested before the data collection was done and the feedback discussed among the study team and incorporated before data collection was conducted.

Data collection and analysis

A team of research assistants trained in qualitative methods conducted in-depth interviews with participants who met study eligibility criteria and provided informed consent prior to any data collection. Women were interviewed at the selected study health facilities. They were recruited by HCWs at the five selected study facilities, who used recruitment scripts to inform potential participants about the study and referred those interested in getting more information to the research assistants. The in-depth interviews asked women about their medication experiences, interactions with healthcare providers, and knowledge about their HIV medication.

Program and policy makers and implementers were approached by study investigators, first to check if they were interested in being a part of the study, and then research assistants confirmed their consent to participate. They were approached based on their roles in county-level policy implementation with regard to ARV treatment and reproductive health and managing and implementing HIV programs within the county. Interviews were conducted with women in the participants' language of choice (Dholuo or English); HCWs, program managers, and policymakers were interviewed in English. Interviews with women and HCW took place in person at study facilities, while the other interviews were conducted virtually via Zoom audio calls.

Interviews were transcribed and translated from Dholuo into English where necessary. A member of the research team selected random transcripts and checked them against the audio files for quality. Transcripts were coded using NVIVO 12 software. An independent analyst was engaged for coding the transcripts. The analyst, together with a member of the research team developed the coding framework. Each independently coded two transcripts, and then combined the codes to merge the themes for congruence, and the final coding framework was used by the analyst to code the rest of the transcripts.

Results

Demographics

We interviewed 30 WLHIV of reproductive age, half of them pregnant at the time of the interview. The median age was 28 years (SD 6.2); 11 women were ≤ 25 years. Mean parity was 2.4 births (SD 1.9). Over a third (70%) knew their HIV status for < 5 years and 72% were on treatment < 5 years. Among the participants were two women who acquired HIV perinatally and one who self-reported a discordant relationship. Among the women of reproductive age, two had conceived

while not on ARVs. One pregnant participant had just started treatment at her clinic. Ten women had been diagnosed with HIV and on treatment for < 1 year (Table 1).

Table 1.

Characteristics	N=29, n(%)
Age in years	
Median age (IQR) years	28(22, 32)
Level of education	
Primary	17(58.6%)
Secondary	10(34.5%)
Tertiary	2(6.9%)
Marital status	
Single	3(10.3%)
Married	10(34.5%)
Missing	16(55.2%)
Occupation	
Unemployed	27(93.1%)
Employed	2(6.9%)
Parity	
Median parity (IQR)	2(1, 4)
Gravidity	
Median gravidity (IQR)	3(2, 5)
Duration known HIV status	
< 1 year	10(34.5%)
2-<5 years	10(34.5%)
5-<10 years	5(17.2%)
10+ years	4(13.8%)

Duration on ARV medication	
< 1 year	10(34.5%)
2-<5 years	11(37.9%)
5-<10 years	5(17.2%)
10+ years	3(10.3%)
Conceived while on ARVs	25(83.3%)

Note 1: One participant did not have demographic data collected.

HCWs had a mean age of 29 years (standard deviation [SD] 8.8), had worked in their current position for an average of 4 years (SD 9.5) and 10 out of the 12 (83%) had diploma or certificate level of education. The HCWs interviewed were clinical officers, nurses, and adherence counselors.

Conversations on ARV medication

WLHIV reported that the discussion about ARV medication started immediately once an individual tested positive for HIV and was a continuous engagement/discussion with HCWs. After testing positive, women were allowed to decide when to start medication, though most reported starting immediately. During follow up visits, the HCWs would engage with them about progress, side effects, adherence, medication changes, and challenges.

These conversations were useful in providing counseling to women and getting them to take their medication. One woman recounted how the support she received during such an engagement encouraged her to start HIV medication:

They gave me some time because I was afraid to start using the drugs... But they guided me, they counseled me till my heart opened and I started using them. (Pregnant woman)

Conversations with HCWs were described to be driven more by HCWs, and mainly focused on adherence to medication, although a few women indicated that the HCWs would ask whether they had concerns regarding their medication.

It's just teaching as usual basically telling me how I am supposed to take my medicine, take the dosage on time, being free with your partner; when going on a journey you should not put some of the tablets in a piece of paper, just carry the whole bottle. (Pregnant woman)

WLHIV generally felt adequately prepared to engage with ARV treatment, as they were given time to decide when to start treatment and received counseling before starting. HCWs considered that WLHIV made informed decisions to use ARVs because of the treatment preparation offered to the women before starting medication; the fact that the women could decide whether or not to start treatment; and because women also received communication about when changes to their medications were made. One HCW expressed that women did not have the technical expertise to

choose their ART medication, while another expressed that this was limited by guidelines, which provided guidance on the regimen to be used.

A new patient does not have the technical know-how on how to choose the medications since most of them are not well versed with the medicines, but we use the guidelines during the initiation. (HCW)

Engagement and knowledge on treatment among women living with HIV

A majority of the women knew their medication, some could mention the name, and most the color of the packaging and the pills. Four women acknowledged that they did not know their medication. Five pregnant women and a couple of women of reproductive age reported their medication had been changed. Reasons they were given for the change included loss of weight, reduced pill burden, to reduce the viral load, and that the medicine would work better than the previous regimen they were using. They indicated satisfaction with the reason given for the change.

They said it was the weight that alerted them. So I was told that the one I was using may not be suitable for me, it used to make my weight drop every now and then. So ever since I started using this one it has been like two to three months. (Pregnant woman, 30 years old)

However, several WLHIV also reported having their medication changed with no communication about why it was changed.

Medication-related concerns

Among WLHIV, the main concern expressed was their desire to have a child who was not HIV-infected. This was cemented by a recently diagnosed woman, who discussed initial thoughts of terminating the pregnancy she was carrying since she did not want to infect the unborn baby [*...she shared that at some point she thought of terminating the pregnancy; her main fear was the baby getting infected with HIV (research assistant field notes)*] HCWs reiterated the same, noting that women were afraid of passing on the infection to their unborn children:

Some women have the fear of getting pregnant while on HIV care because they feel like the ARVs may affect their children, their unborn children. (HCW)

To this end, HCWs provided information on adherence, and affirmed the possibilities of having healthy children, provided the women were adherent and on medication during pregnancy and after delivery, and gave ARV prophylaxis to their infants and followed guidance on infant feeding.

While talking to women about their interactions with HCWs, some of the women described conversations in which HCWs sought to explain reasoning behind being given medication and changing medication, while for some women, no explanations were provided. Among those who had received explanations, some were detailed, giving information on changes in the drug, the number of times the drug is taken a day, and why it was better than what they were previously taking. Other explanations were brief, such as they were receiving the medicine that was currently available.

Some of the women reported experiencing side effects, but not asking the HCWs about them. One pregnant woman pointed out that she had asked about effects of the drugs on her baby, to which she was asked to adhere and was told the drugs would not harm the baby in any way. Another pregnant woman was informed DTG is best for pregnancy because it was best for pregnant women.

What I was told about the drug because I had asked about it and the difference it could bring and they said that this one was the best for pregnant people. (Pregnant woman)

Available information for WLHIV on ARV risks and benefits

Pregnant women expressed their concerns and fears of transmitting HIV to their unborn babies. Most of the women had received information on HIV transmission risk from HCWs; one who was new to medication stated she had not, and another was uncertain as to whether the information was provided. They also discussed the information they had received on minimizing the risks of transmission. Adherence to medication, facility delivery, and exclusive breastfeeding for the first six months were among the ways of minimizing risk that they had been informed about.

The nurse told us that one can give birth to a HIV-positive child, and she was trying to encourage us that we should keep time for taking the drugs so that you should not give birth to a HIV-positive child. (Pregnant woman, 27 years)

Women of reproductive age (WRA) recalled receiving information during their pregnancies that was mainly about risks of infecting their unborn children and centered on adherence to ARVs during pregnancy and giving ARV prophylaxis to the baby after delivery. The women stated that HCWs asked them to adhere to taking their medication at a specific time, and missing medication was a threat to the baby getting infected. They were instructed to give prophylaxis to the baby before they started breastfeeding and maintain the same time for giving the medication.

I didn't have any [fear] because when I was being given medicine at the hospital the healthcare worker explained to me how I should use the medicine and assured me that if I use it as advised I will give birth to a healthy baby and all my children are healthy all five of them (WRA, 37 years)

One pregnant woman described how she had been given the infant ARV prophylaxis to carry home before delivery, as she had expressed concerns that she may not be able to make it to the facility for delivery.

Most women, both pregnant and those of reproductive age, had received information about the risk of birth defects, preterm deliveries, and stillbirth from HCWs. Among those who had received this information, previous successful delivery experiences and guidance from HCWs during pregnancy gave them confidence that these outcomes were highly unlikely to occur.

A couple of women shared information received or observed from the community regarding negative birth experiences for those who had defaulted on ARVs, thus associating the negative outcomes to non-adherence.

HCWs explained that they discuss precautions pregnant women should take to prevent infection in utero with their pregnant clients. The precautions include maintaining a suppressed status

through adherence to HIV treatment, having their viral load (VL) monitored every three months, and maintaining good nutrition. Counselling services were offered to pregnant women to encourage adherence. They were also screened for STIs like syphilis to avoid transmission to their babies. During birth, the women were encouraged to deliver their babies at the hospital.

Healthcare worker concerns about sharing information on risk

HCWs reported gaining knowledge of policies and guidelines through various avenues including physical copies shared, dissemination forums, and soft copies available online and disseminated through social media pages.

There is peer-to-peer method of getting information; we have the internet, journals, scientific writings, scientific literature that we refer to. (HCW)

HCWs discussed their interpretation of guidelines provided for dispensing ARV medication, and especially DTG. Overall, their understanding of the guidelines was that DTG was safe for pregnant and women of reproductive age according to the current guidelines at the time. However, some noted that initial communication had indicated that it was not safe.

Currently we have a NASCOP [National AIDS and STIs Control Program] circular on children and adolescents to be optimized to DTG. In my understanding adolescence starts between 10 to 24. And we are doing an RRI [rapid response initiative] currently which started in June to I think September. If it [DTG form women of reproductive age] was not recommended, why was it recommended [by NASCOP] for children and adolescents who are also between 15 to 24, who are actually in childbearing stage? So to me initially it was an issue and that issue of childbearing was there, long term family planning and birth defects, but I remember some time in 2019, the WHO said that the DTG has no issue on pregnancy. (HCW)

With regard to discussing risks from HIV medication, few HCWs stated that they covered the topic with their clients, alluding to guidelines indicating the information that needs to be provided to WLHIV is more related to benefits.

What we advise the concern we give is just the benefits of drugs, the ARVs, if the side effects which are very minimal of the drugs, if there's any concern, we do advise them to seek medical advice. Yeah if there's any side effects or even at the delivery, we encourage them to deliver at the hospital for just good monitoring if there's any problem. (HCW)

Among those who did discuss risks, one expressed that they only gave brief detail, as they had a previous experience of a woman who had been told about risks, experienced a miscarriage, and wanted to stop taking ARV medication. A HCW noted that sharing the risk information was not a problem, but how the women would receive the risk information was dependent on how the HCW relayed the information. Another one also stated that restricting information sharing was not an ethical practice.

Several HCW expressed concern that sharing risk information may result in women not adhering to medication in the event that they experienced an adverse pregnancy event. Three HCWs stated

that there were no risks to pregnancy from using ARVs. Three HCWs noted that although there was risk, this had not been observed in their setting, and thus considered ARVs relatively safe.

None [risk] that am aware of because most of the drugs that we are giving, the ARVs we only had the issue with DTG with the neural birth defect, but it was cleared so we also trust them that they said it was cleared, so we just tell the mums there are no risks that can happen to the baby. (HCW)

Discussion

We sought to understand knowledge about and preferences for HIV medication among WLHIV and HCWs and how communication about HIV medication risk to WLHIV occurs, especially around pregnancy. WLHIV are invested in their treatment and understand their medication, and there is a continuous flow of information from HCWs to women through various engagements in routine clinics and during counseling.

Both WLHIV and HCWs express the greatest concern being delivery of a HIV-free baby and avoiding transmission at delivery and in early years. This information is well-discussed by the HCWs and women, and adherence messaging comes out strongly. Access and adherence to ARV is a key component of addressing this concern [3].

Further, our results indicate that although the guidelines provide information for HCWs to pass on information to WLHIV regarding the medication they take, HCWs use different approaches and pass on messages in varied ways, with only some HCWs speaking about ARV risks with their clients. There are HCWs who expressed discomfort at discussing risk information for fear of interference with adherence to ART by the woman, whereas there are those who are confident in sharing the message and still having good ART adherence by WLHIV. The ARV guidelines provide information that HCWs can use for advice and counseling on ARV pregnancy risk alongside provision of contraception, thus allowing women to choose whether to remain on a regimen or change based on information provided [20].

From their end, women who received risk information referenced their previous experiences and assurance from HCWs, which informed their belief that any risk from taking drugs would be minimal. Having knowledge of how ART works to prevent transmission may influence and motivate women to take their medication [2121]. A study conducted on responses to counseling messages communicating the potential for enhanced risk of HIV infection for women using the contraceptive depo-provera showed that structured counseling messages integrated into routine service delivery and a high understanding of the messages by HCWs did not result in diminished use of the contraceptive [2222]. On the contrary, when messaging is not done in a comprehensive and engaging way, the recipients may misinterpret this as a way of HCWs pressuring the woman to initiate ART rather than providing needed care other than ART [25].

Overall, HCWs express they have enough time to engage WLHIV during routine visits, albeit with some challenges for high-volume clinics and when there are shortages of HCWs. Despite the challenges, HCWs can work towards effective communication which can enable trusting

relationships for the women to receive the information they need within the available contact time with HCWs [2323]. Even when information is available in guidelines and medication pamphlets, structuring the information in a way that is easier to deploy by HCWs and easy to understand by WLHIV should be developed, and messages reframed and repeated to the satisfaction of the recipient [2222].

Whereas pregnancy intention is ingrained as a part of routine service delivery, women seldom discuss their pregnancy intentions with healthcare providers, showing up when they are already pregnant. Women may fail to discuss this with their HCWs because of provider indifference, opposition, or anticipation of negative reactions [2323]. Unintended pregnancy has been associated with late initiation of antenatal care and low birth weight in some settings, which may also translate to late initiation into HIV care [27], [28]. Some HCWs then consider messaging on risk of birth defects with drugs irrelevant when the risk period for such exposure to cause a defect has passed. Integrating ARV risk messaging as part of continuous counseling, including when conducting pregnancy screenings, may support communicating the message well in advance and not only when women overtly express their pregnancy intentions [2424]. Application of pregnancy screening tools, followed up with counseling, may help patients to more clearly articulate their reproductive health intentions [26].

Whereas they could point out bits of information received from HCWs, some women responded that they had not received any information on risk, when specifically asked about it.

Limitations

Some of the women had been on ARV medication for a long time and were not pregnant at the time of data collection. Thus, their accounts may have been more generalized to their ARV experiences and not specific to the pregnancy period. Although the interview guide had questions directly addressing the pregnancy period, recall bias may have influenced these responses. We did not collect documented information from patient records on patient ARV history and current regimen.

Conclusion

For WLHIV, prevention of vertical transmission remains a major concern when pregnant. HCWs relay information regarding adherence and prevention of infection, but may not always provide information regarding the risks associated with ARV medication during pregnancy. Development of structured messages delivered as part of routine care and counseling can be considered to support risk communication.

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