Incidences of Pregnancy During Concurrent Use of Hormonal Contraceptives and Antiretroviral Therapy at Nakuru County Referral and Teaching Hospital in Kenya

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ABSTRACT

With concerns on the efficacy and effectiveness of hormonal contraceptives and antiretroviral therapy in curbing incidences of unplanned pregnancies among women living with Human Immunodeficiency virus infection, a study to examine these concerns was carried out at Nakuru County Referral and Teaching Hospital (NCRTH). A cross-sectional retrospective study was carried out at the Comprehensive Care Centre (CCC) at NCRTH from March 2023 to April 2023 with a sample size of 226 participants however the estimated sample size using the Taro Yamane formula was 358. Data was collected using structured questionnaires with both open and close-ended questions and analyzed using the Statistical Package for Social Sciences (SPSS). Frequency tables, bar graphs, and percentages were used to present descriptive statistics. Chi-square was used to conduct inferential statistics, and $P<0.05$ was considered significant. The majority (86.7%) of participants were on TLD (Tenofovir, Lamivudine, Dolutegravir). Most participants (37.17%) had used ART for 6-10 years. 79.65% of participants avoided pregnancy with concurrent hormonal contraceptives and ART, while 20.35% experienced pregnancies. 15.22% of pregnant participants also used other medications, especially anti-TBs, due to drug-drug interactions. Injectables were the most common contraceptive (41.3%) used by participants who had pregnancy incidences. A significant association was noted between the incidence of unplanned pregnancy and the use of combined oral contraceptives. Incidences of unplanned pregnancies were higher among those aged 30-34 (32.61%), married (73.91%), with secondary education (43.48%), self-employed (60.87%), and Protestant (73.91%). From this study, TLD was the most commonly used antiretroviral, injectables were the most commonly used contraceptive, and the majority of the participants had used antiretrovirals for 6-10 years. Despite the concurrent use of hormonal contraceptives and antiretrovirals to avoid pregnancy incidences, 20.35% of the participants had unplanned pregnancy incidences. 15.22% of these participants who got pregnant were using other medications. Unplanned pregnancies were more common among certain demographic groups. From this study, data on pregnancy incidents during concurrent use of hormonal contraceptives and antiretroviral therapy is availed however limitations such as study design and time limit necessitate more research. To reduce the risk of unplanned pregnancies and ensure the appropriate use of hormonal contraceptives, more support and counseling programs should be established for women using antiretrovirals.

Keywords: *Hormonal contraceptives, ARVs, unplanned pregnancies*

INTRODUCTION

Unplanned pregnancy is a common problem facing both HIV-positive and HIV-negative women globally. However, women living with HIV (WLHIV) are at a higher risk of not only getting unintended pregnancy but also risk transmitting HIV to their unborn child; despite using contraception. This is because, in the presence of ART medications and HIV infection, the effectiveness of hormonal contraception is erratic. Despite HIV infection being a global health burden, nearly 60% of the global resides in Sub-Saharan Africa with almost half of this population comprising females (Worke et al., 2016). Evidently, each year, these women experience nearly 1.4 million pregnancies of which more than half are unintended (Nhoeve, 2022).

Correspondingly, such statistics raise the question of the efficacy and effectiveness of hormonal contraceptives among women living with HIV who are on antiretroviral therapy. Indeed, Robinson et al. (2012) report that there is decreased serum estrogen and progestin levels when combined oral contraceptives are co-administered with certain ARVs. Further, Krishna & Haddad (2020) suggest possible pharmacologic interactions between progestin-based contraceptive implants when co-administered with efavirenz and also when combined hormonal contraceptives are co-administered together with protease inhibitors. Such findings are even being reiterated by government organizations; for instance, the Centers for Disease Control and Prevention (CDC) notes that co-administering ritonavir-boosted protease inhibitors substantially decreases the serum levels of steroidal contraceptives (CDC, 2023). Consequently, such interactions reduce the effectiveness of such hormonal contraceptives which puts WLHIV using them at a higher risk of having unintended pregnancy. In Kenya, there is a paucity of information regarding the assessment of the effectiveness of hormonal contraceptives among WLHIV who are on ART in different geographical regions. The study objectives include the utilization of antiretroviral regimens among women living with HIV who are concurrently using hormonal contraceptives at NCRTH, the distribution of incidence of pregnancy based on socio-demographics of women living with HIV and at the same time using hormonal contraceptives at NCRTH, and to determine the antiretroviral regimen and hormonal contraceptive used concurrently at the incidence of pregnancy in women living with HIV at NCRTH. Against this backdrop, this study sought to examine Incidences of Pregnancy during Concurrent Use of Hormonal Contraceptives and Antiretroviral Therapy in Women Afflicted with Retroviral Disease (HIV) at Nakuru County Referral and Teaching Hospital in Kenya.

METHODOLOGY

Study Design and Location

This study utilized a cross-sectional retrospective research design, combining attributes from both retrospective and cross-sectional methodologies. This hybrid approach encompassed the acquisition of data about a defined population at a specific temporal point, coupled with a retrospective analysis of historical data. This study design only allowed the determination of outcomes of using hormonal contraceptives in WLHIV on antiretroviral therapy up to the time of data collection. It does not provide a means of determining the outcome of using hormonal contraceptives in this population in the future. To get future trends of the outcomes, other similar studies need to be conducted in the future and the results compared to the ones of this study. The investigation was conducted at the Comprehensive Care Centre (CCC) of Nakuru County Referral and Teaching Hospital (NCRTH), located on Nakuru-Sigor Road within Nakuru City.

Target & Study Population

The study's target population encompassed women within the reproductive age range who were receiving antiretroviral treatment at the Comprehensive Care Centre (CCC) of Nakuru County Referral and Teaching Hospital (NCRTH) and were concurrently utilizing hormonal contraceptive methods. Nakuru County Referral and Teaching Hospital operates as a pivotal primary healthcare establishment serving a populace exceeding 2.1 million individuals. The hospital manages an approximate patient cohort of 7,600 individuals engaged in antiretroviral therapy, with approximately 3,417 of these individuals being women. The documented tally of HIV-diagnosed patients in Nakuru County Referral and Teaching Hospital alone reached 58,575 as of May 2022 (Mwangi, 2022). The hospital's service purview extends beyond Nakuru County Referral and Teaching Hospital, encompassing neighboring regions including Baringo, Laikipia, Kericho, and Kiambu counties. The institution delivers a diverse range of preventive, therapeutic, and diagnostic healthcare services, and presently functions as a center for education and research for diverse healthcare professionals.

Inclusion Criteria

Those included in the study were patients who:

i.   Are women of child-bearing age.

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ii. Attend the Comprehensive Care Clinic at the NCRTH.

iii. Are adherent to Antiretroviral Therapy i.e. those who do not miss taking their antiretroviral drugs and stated they were adherent in their routine refill.

iv. Are on at least a hormonal method of contraception for pregnancy prevention.

v. voluntarily provided consent to be included in the study.

Exclusion Criteria

Those excluded from the study were:

i. Women on non-hormonal methods of contraception.

ii. Women suffering from mental illness or disorders affecting mental function as these are patients who may not be able to give voluntary and well-informed consent due to impaired judgment.

iii. Women who are HIV positive and not on ART.

iv. women who decline to provide consent to be included in the study.

v. Expectant mothers were automatically excluded from the study as they could not be on any form of hormonal contraception.

vi. Participants between the ages of 13 and 18 years who were not accompanied to the clinic by their guardians hence consent could not be obtained.

Sample Size Determination

The study cohort comprised 3,417 women undergoing antiretroviral therapy. To determine the appropriate sample size, the Taro Yamane formula (Israel, 2003) was employed, yielding a calculated sample size of 358 with a 95% confidence level. However, due to specific constraints and considerations, only 226 participants were successfully recruited within the stipulated time frame. From the obtained results, it was determined that there was a pattern that could allow predictability of the accuracy of the results as the hormonal contraceptives with high incidences of pregnancy had not much variation. One of the major constraints faced was limited time and the estimated sample size would have been achieved if there was enough time thus the study results would improve generalizability and accuracy. One contributory element was the reproductive age of the target group, resulting in the automatic exclusion of pregnant participants from the study. Additionally, engaging with individuals aged 13 to 18 posed challenges, as a signif-

icant number of them attended clinic appointments unaccompanied by guardians, thereby impeding the acquisition of informed consent. The convergence of these factors consequently led to a sample size smaller than initially estimated.

Research Instruments

The data collection process employed a meticulously designed structured questionnaire, comprising both open and close-ended inquiries categorized into discrete sections. The questionnaire underwent scrupulous examination by the research supervisor to guarantee the incorporation of solely relevant and precise information crucial to the study. In the initial segment, Section A, of the questionnaire, inquiries were centered around determining which antiretroviral therapy the participants were on and the duration over which they had been receiving this treatment. In Section B, the focus shifted to investigating the occurrences of pregnancy in the context of concurrent utilization of hormonal contraceptives and antiretroviral therapy. Additionally, this section explored the potential use of medications other than antiretrovirals at the time of experiencing pregnancy while under contraceptive usage.

Validity and Reliability of Research Instruments

A pilot study was conducted involving a cohort of 20 women diagnosed with HIV/AIDS, who were concurrently undergoing antiretroviral treatment and employing a hormonal contraceptive regimen. This preliminary investigation aimed to validate and establish the reliability of the questionnaire utilized in the primary study. The pilot study procedure was instrumental in assessing the clarity, accuracy, brevity, and conciseness of the questions within the questionnaire. Furthermore, this pilot phase contributed to determining the optimal time required for administering each questionnaire and assessing its efficacy in capturing data that aligned with the overarching study objectives. Any identified shortcomings in the questionnaire were addressed to ensure congruence with the study's objectives before commencing the primary research phase. Importantly, it should be noted that the data collected during the pilot study were not incorporated into the subsequent formal data analysis process.

Sampling Procedure

This study's methodology employed a simple random sampling technique to select participants. Unique numerical identifiers were randomly generated and allocated to eligible study participants who had provided informed consent. However, due to the daily arrival of approximately 10 eligible par-

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ticipants at the Comprehensive Care Centre (CCC), it was determined that achieving the predetermined sample size within the designated time frame would not be feasible. As a result, a final sample size of 226 participants was ultimately obtained. This approach was adopted to ensure the impartial inclusion of eligible participants in the study, thereby safeguarding against any potential bias or favoritism.

Data Collection Procedure

Data collection commenced after obtaining approvals from the Kabarak University Research and Ethics Committee (KUREC), the National Commission for Science, Technology, and Innovation (NACOSTI), and the CCC-pharmacy permission at NCRTH. The study's particulars were thoroughly communicated to eligible participants who were recruited at the CCC pharmacy at NCRTH, and explicit consent was then obtained from them. Following this, participants were furnished with self-administered questionnaires. These questionnaires adhered to standardization measures to ensure consistency in terms of format, language, and terminology, thereby presenting uniform questions to all participants. Respondents were allotted approximately 20 minutes to complete the questionnaires. In cases where participants encountered challenges due to illiteracy or difficulties in comprehending the questions, research investigators extended assistance to ensure the accuracy of the acquired information. Completed questionnaires were securely stored within a lockable file cabinet, accessible exclusively by the research investigators. Subsequently, the data extracted from the questionnaires was meticulously entered into a structured database using Microsoft Excel, facilitating efficient sorting and systematic analysis of the collected data.

Data Protection Procedure

This study involved the interaction with study participants, and the provision of study information sheets, consent forms, and questionnaires. Similar interactions also occurred during the screening phase to assess participants' eligibility. To ensure the protection of study participants, these interactions were exclusively conducted within a specifically designated private room, restricting attendance to only the study investigators and the respective participants. This precaution was implemented to uphold participant confidentiality and create an atmosphere conducive to open and confidential communication.

Data Monitoring Plan

To uphold the integrity and comprehensiveness of data during the data collection process, a meticu-lous data screening procedure was conducted. This screening involved the examination of data for any instances of missing values, outliers, and other data-related anomalies that could potentially influence the overall data integrity. Any missing data from retrospective sources was handled by imputation of means from the available data. This imputation helped in filling the values that were missing hence ensuring data robustness and reducing biases that arise due to missing data values. Following the data screening phase, a data cleaning process was executed to systematically eliminate errors and discrepancies from the dataset.

Data Analysis

Data obtained from the questionnaire was checked for any inconsistencies following which it was systematically organized and entered into the Microsoft Excel software (*v-Microsoft Excel 2019*). Subsequently, the data was subjected to analysis through Statistical Package for the Social Sciences (SPSS). Data analysis encompassed the application of descriptive statistics and inferential analysis to check for association at a 95% confidence interval. The descriptive statistics determined were the mode, mean, and mean. The inferential statistics were determined by chi-square analysis

Ethical Considerations

Before the initiation of the research, the necessary ethical clearances were procured through the Kabarak University Ethics Review Committee (KUREC), as indicated by reference number KABU01/KUREC/001/02/04/23. Authorization to conduct the study was further obtained from the National Commission for Science, Technology, and Innovation (NACOSTI), with reference number 170694. Additionally, formal permission was acquired from the CCC department of Nakuru County Referral and Teaching Hospital (NCRTH) before the commencement of data collection. To ensure participants' understanding, an exhaustive information sheet detailing all pertinent aspects of the study was provided. Any inquiries participants had were addressed during this period. To uphold participants' privacy, the questionnaires were securely stored within a lockable file cabinet. The extracted data from the questionnaires was stored on a laptop secured with password protection. The handling and accessibility of the collected data were strictly restricted to the research investigators, with no external parties granted access to the data. The accumulated data will be retained for 5 years, after which electronic records will be expunged through deletion, while the physi-

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cal questionnaires will be destroyed via shredding. In adherence to ethical standards, consent was obtained from eligible patients before their involvement in the research, ensuring that participation was entirely voluntary and free from any form of coercion. To uphold anonymity, unique codes were assigned to participants in place of their names within the questionnaires. Rigorous confidentiality measures were applied to all gathered information.

RESULTS

Utilization of Different Antiretroviral Regimens

Figure 1 below shows that 196 (86.7%) participants were on TLD (Tenofovir, Lamivudine, and Dolutegravir). Sixteen (7.07%) of the participants were on TLE (Tenofovir, Lamivudine, and Efavirenz). Seven (3.14%) were initially on TLE and then changed to TLD. Five (2.21%) participants were on AZT/3TC/ATV/r (Zidovudine, Lamivudine, and Atazanavir) while only two (0.88%) were on TDF/3TC/ATV/r (Tenofovir, Lamivudine, and Atazanavir).

Figure 1:
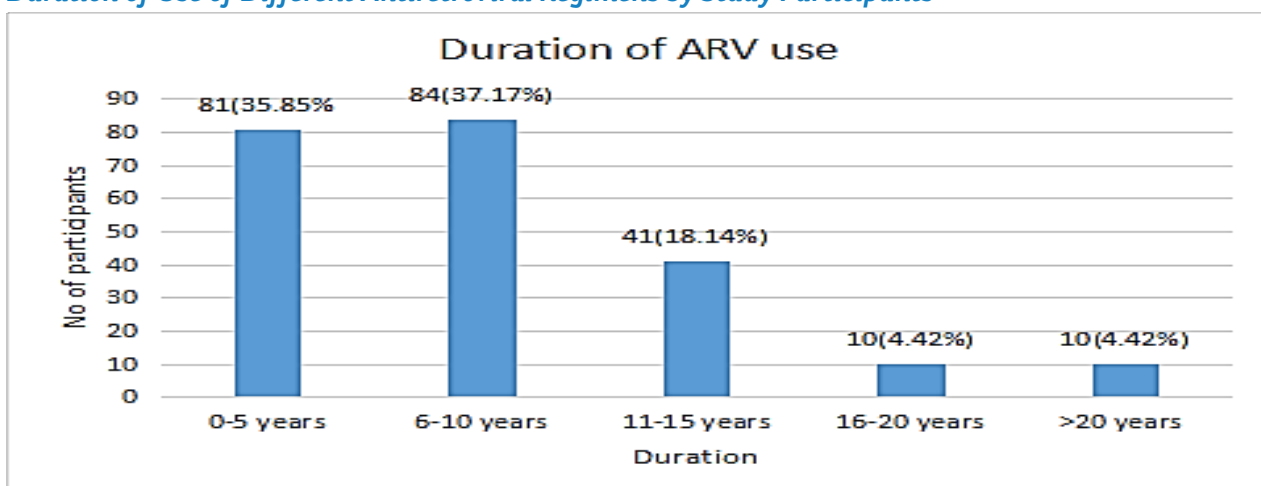### Distribution of Study Participants Based on the Antiretroviral Regimen They Are Using
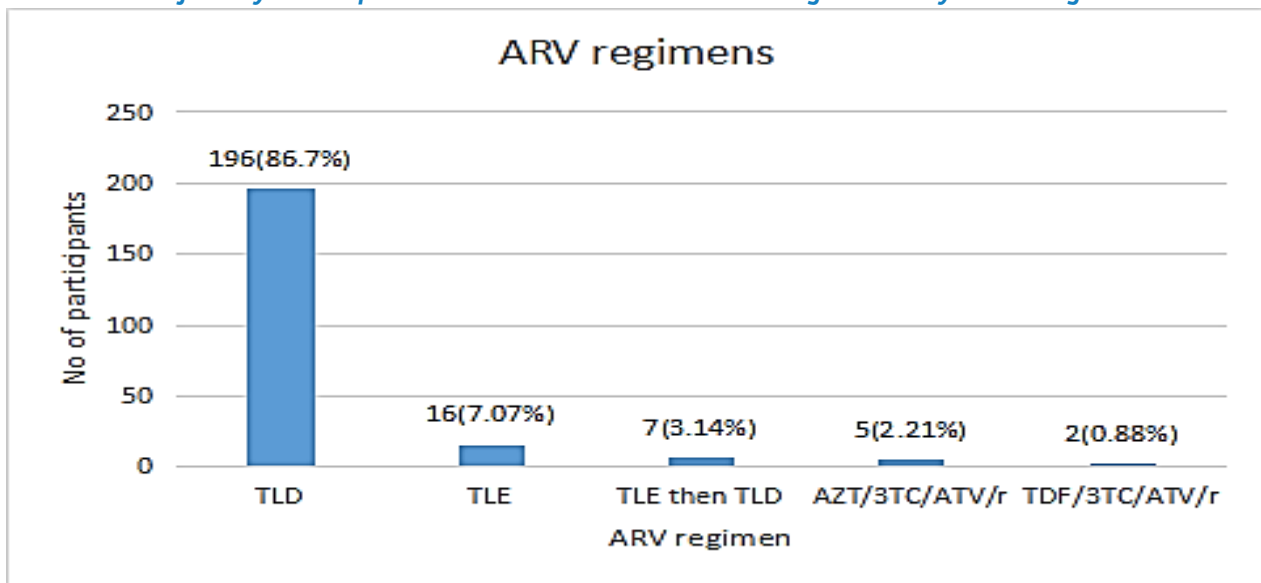
Duration of Use of Different Antiretroviral Regimens

Figure 2 below shows that 84 (37.17%) participants had used antiretrovirals for a period between 6-10 years which was the highest frequency. Eighty-one (35.85%) participants had used antiretrovirals for 0-5 years. Forty-one (18.14%) participants had used antiretrovirals for 11-15 years. Ten (4.42%) participants had used antiretrovirals for a period between 16-20 years and also ten (4.42%) participants had used antiretrovirals for more than 20 years. The duration of use of antiretroviral regimens is not specific to any regimen as the antiretroviral regimens have been changing over time.

Figure 2:
Duration of Use of Different Antiretroviral Regimens by Study Participants

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Distribution of Incidences of Unplanned Pregnancy Based on Sociodemographic Characteristics

Table 1 below shows that the highest number of participants who had an incidence of pregnancy had the following characteristics: were of the age group 30-34 years (32.61%), were married (73.91%), had three children (36.96%), were educated up to secondary education level (43.48%), were self-employed (60.87%) and they were protestants (73.91%).

Table 1:

Distribution of Incidences of Unplanned Pregnancy Based On Sociodemographic Characteristics of Study Participants

Sociodemographic characteristic	Pregnancy incidences	
	N	Percentage
Age (yrs.)		
13-19	0	0%
20-24	1	2.17%
25-29	9	19.57%
30-34	15	32.61%
35-39	10	21.73%
40-45	9	19.57%
46-49	2	4.35%
Marital Status		
Married	34	73.91%
Divorced	4	8.70%
Single	8	17.39%
Widowed	0	0%
Occupational Status		
Employed	6	13.04%
Self Employed	28	60.87%
Unemployed	12	26.09%
Level Of Education		
None	0	0
Primary	15	32.61%
Secondary	20	43.48%
College	8	17.39%
University	3	6.52%
No Of Children		
1	7	15.22%
2	13	28.26%
3	17	36.96%
4	8	17.39%
5	0	0.00%
6	0	0.00%
7	1	2.17%
Religion		
Catholic	12	26.09%
Protestant	34	73.91%

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Hormonal Contraceptives, Antiretrovirals, and Concurrent Medication Use in Pregnancy Incidents

Table 2 below shows 180 (79.65%) participants stated they did not get pregnant while on hormonal contraceptives and at the same time using antiretrovirals. Forty-six (20.35%) participants did get pregnant while on a hormonal contraceptive and at the same time they were using antiretrovirals. Seven (15.22%) participants who had gotten pregnant while on contraceptives and at the same time using antiretrovirals were also using other medications at the time of incidence of pregnancy. Four of these participants were using anti-TB medications while three of these participants could not remember the names of the other medications they were using. Thirty-nine (84.78%) participants who had gotten pregnant while on contraceptives and at the same time using antiretrovirals were not using any other medications at the time of incidence of pregnancy.

Table 2:

Frequency of Pregnancy Incidences While On ART, Hormonal Contraception and Other Medications

Variable	Yes	No
Did you get pregnant while on hormonal contraceptives and at the same time using antiretrovirals	46(20.35%)	180(79.65%)
At the time of getting pregnant, were you on hormonal contraceptives, ART and also using other medications	7(15.22%)	39(84.78%)
Other medications used apart from antiretrovirals and hormonal contraceptives at the incidence of pregnancy		
Anti-TBs	4 (57.14%)	
Other medications (Participant not able to remember)	3 (42.86%)	

Table 3 below shows that 36 (72.86%) participants who got pregnant were using TDF/3TC/DTG, five (10.87%) participants were using TDF/3TC/EFV and five (10.87%) participants were using AZT/3TC/ATV/r. Nineteen (41.3%) participants who got pregnant were using injectables. Ten (21.74%) participants who got pregnant were using implants. Nine (19.57%) participants who got pregnant were using hormonal IUDs and eight (17.39%) participants who got pregnant were using combined oral contraceptives.

Table 3:

Pregnancy Incidences Based on Type of Contraceptive Used, ART Regimen

ART Regimen	Pregnancy Incidence (n)	Percentage
TLD	36	78.26%
TLE	5	10.87%
AZT/3TC/ATV/r	5	10.87%
Contraceptive		
Injectable	19	41.30%
Implant	10	21.74%
Hormonal IUD	9	19.57%
COCs	8	17.39%

ARV Regimen and Contraceptive Used at Time of Pregnancy Incidence

Table 4 below shows that at the time of incidence of pregnancy, nineteen participants were using injectables (medroxyprogesterone); of these nineteen, eleven were using TLD, five were using AZT/3TC/ATV/r and three were using TDF/3TC/EFV as their ARV regimen. At the time of incidence of pregnancy, ten participants were using implants; of these ten, nine were using TLD and one was using TDF/3TC/EFV as their ARV regimen. At the time of incidence of pregnancy, nine participants were using hormonal intrauterine devices and at the same time using TLD as their ARV regimen. At the time of incidence of pregnancy, eight participants were using combined oral contraceptives and at the same time using TLD as their ARV regimen.

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Table 4:

Contraception Method and ART Regimen at The Time of Getting Pregnant as Indicated by Study Participants

ARV Regimen	Pregnancy Frequencies (n)			
	Injectable	Implant	Hormonal IUD	COCs
TLD	11	9	9	8
AZT/3TC/ATV/r	5	0	0	0
TLE	3	1	0	0
Totals	19	10	9	8

Association between use of contraceptives and incidence of pregnancy

Table 5 below shows the association between the use of different hormonal contraceptives with incidences of pregnancies. There was a significant association between the occurrence of unplanned pregnancies and the use of COCs only. The was no significant association between the other hormonal contraceptives and the incidence of pregnancy.

Table 5:

Association Between Occurrence of Pregnancy and Use of Different Types of Hormonal Contraception as Highlighted by Study Participants

	Pregnant	Not pregnant	P-value
Injectable	19 (16.49) [0.38]	62 (64.51) [0.10]	0.386553
Others	27 (29.51) [0.21]	118 (115.49) [0.05]	
Implant	10 (14.25) [1.27]	60 (55.75) [0.32]	0.129079
Others	36 (31.75) [0.57]	120 (124.25) [0.15]	
Hormonal IUD	9 (6.51) [0.95]	23 (25.49) [0.24]	0.23863
Others	37 (39.49) [0.16]	157 (154.51) [0.04]	
COCs	8 (4.48) [2.77]	14 (17.52) [0.71]	0.049643
Others	38 (41.52) [0.30]	166 (162.48) [0.08]	

DISCUSSION

The knowledge of the effectiveness of hormonal contraceptives among WLHIV is crucial not only to avoid unplanned pregnancies but also to minimize the risk of vertical transmission of HIV. Such effectiveness in the presence of other medications and disease conditions is erratic and there is a need for more data to distinctively determine which contraceptives have reduced efficacy when co-administered with antiretroviral medications. Additionally, there are different antiretroviral regimens used to suppress viral replication. In this study, the majority of participants, 86.7%, were found to be on the TLD regimen (Tenofovir, Lamivudine, and Dolutegravir). This regimen is the recommended first-line treatment for HIV, known for its efficacy and low risk of adverse effects (World Health Organization, 2019). A smaller proportion of participants, 7.07%, were receiving the TLE regimen (Tenofovir, Lamivudine, and Efavirenz), while 3.14% initially started on TLE and later switched to TLD. The use of TLE is relatively common and has been a standard treatment option, particularly in resource-limited settings (World Health Organization, 2014). It is interesting to note the transition from TLE to TLD in some participants, which could reflect adjustments made to optimize treatment outcomes or manage side effects as reported by Allahna et al. (2022). Furthermore, a small fraction of participants, 2.21%, were on the AZT/ATV/r regimen (Zidovudine, Lamivudine, and Atazanavir), and only 0.88% were prescribed the TDF/3TC/ATV/r regimen (Tenofovir, Lamivudine, and Atazanavir). These regimens, which include protease inhibitors like Atazanavir, are often considered for patients with specific clinical and therapeutic considerations, and they might be selected based on factors such as drug interactions, comorbidities, and previous treatment failures (Council, 2021; AIDS Education and Training Center Program, 2021).

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It's worth mentioning that the distribution of ART regimens among the study participants reflects the evolving landscape of HIV treatment guidelines and the availability of antiretroviral medications. The prevalence of the TLD regimen underscores its widespread adoption due to its favorable profile in terms of effectiveness, tolerability, and reduced potential for resistance development (Kouamou et al., 2019). The presence of participants on TLE and other regimens highlights the diversity of treatment options and the need for individualized approaches in managing HIV/AIDS. These findings emphasize the importance of considering the specific ART regimens participants are using when assessing the interactions between hormonal contraceptives and antiretroviral therapy. The variations in regimens could potentially impact drug interactions, side effect profiles, and overall health outcomes, which may in turn influence contraceptive choices and the occurrence of pregnancies among women living with HIV.

Figure 2 reveals that a substantial proportion of participants, 84 participants in total, had been on antiretroviral therapy for a duration ranging between 6 to 10 years. This timeframe emerged as the most common, representing the highest frequency of participants' ART usage. This observation highlights the sustained engagement of a significant subset of the study population with antiretroviral treatment over a relatively extended period. Interestingly, a notable proportion of participants, accounting for 4.42%, reported an even more prolonged exposure to ART, specifically between 16 to 20 years. This subgroup of participants may have been consistently adherent to ART for a substantial portion of their lives. Such long-term adherence to antiretroviral therapy is a positive indicator of treatment success and disease management, with potential implications for both clinical outcomes and the prevention of HIV transmission (Li et al., 2010). Additionally, an equal percentage of participants, also amounting to 4.42%, reported using hormonal contraceptives for a duration exceeding 20 years. This finding is intriguing, as it indicates a significant subset of participants who have been actively utilizing contraceptive methods for a prolonged period. Prolonged use of contraceptives might reflect a strong commitment to family planning and reproductive health management among these individuals. The distribution of participants across various duration intervals of ART usage underscores the dynamic nature of long-term treatment for individuals living with HIV. It showcases the success of antiretroviral therapy in enabling individuals to manage their condition effectively and maintain their health over extended periods. Furthermore,

the concurrent utilization of hormonal contraceptives for equally extensive durations underlines the importance of integrating family planning strategies into the broader context of comprehensive healthcare for women living with HIV (Cohen et al., 2017). These findings emphasize the need for healthcare providers to consider the duration of both antiretroviral therapy and contraceptive usage when offering counseling and support to women with HIV. Long-term therapy can influence health decisions, potential drug interactions, and overall well-being.

Table 1 sheds light on the demographic and sociodemographic characteristics of participants who experienced an incidence of pregnancy while using hormonal contraceptives and antiretroviral therapy. An examination of the age distribution reveals that the age group 30-34 years had the highest number of participants who experienced incidences of pregnancy, accounting for 32.61% of the cases. The results of this study are similar to the results of another study conducted by Patel et al. (2021) where the majority of the participants were aged between 28-38.5 years and the median age was 33.3 years. This finding suggests that women in this age bracket may be more susceptible to unintended pregnancies despite the use of hormonal contraceptives and antiretroviral therapy. The results of this study are similar to the results of a study conducted by Pyra et al. (2015) on the effectiveness of hormonal contraceptives among HIV infected on antiretroviral therapy as the age 30 years was the baseline age for more than 50% of the participants. The influence of factors such as fertility preferences, contraceptive adherence, and hormonal interactions could be contributing to this trend (Britton et al., 2020). Marital status emerged as another significant characteristic. Participants who were married constituted the majority of those who experienced incidences of pregnancy, accounting for 73.91% of the cases. The results of this study are similar to the results of another study on pregnancies among WLHIV using contraceptives and antiretroviral therapy in Western Kenya where the majority (49%) of the participants were married (Patel et al.,2021). This finding raises important questions about the effectiveness of contraceptive decision-making and communication within marital relationships. The role of spousal support, shared family planning decisions, and communication barriers could be influential factors in this context. Among participants who experienced an incidence of pregnancy, a noteworthy proportion had three children (36.96%). This finding could suggest that participants with this number of children might have specific fertility preferences that influence their

contraceptive choices or adherence behaviors. The findings of this study concur with the findings of a study on pregnancies among WLHIV using contraceptives and antiretroviral therapy in Western Kenya where the majority (65%) of the participants had at least one child (Patel et al.,2021).

Education level also emerged as a relevant factor. Participants with up to secondary education levels comprised 43.48% of those who experienced incidences of pregnancy. This observation highlights the potential need for targeted reproductive health education and counseling interventions, particularly for women with lower levels of formal education. The findings of this study concur with the findings of a study on pregnancies among WLHIV using contraceptives and antiretroviral therapy in Western Kenya where 38.9% of the participants had primary level education or higher (Patel et al., 2021) Occupation was another dimension explored in the study. Self-employed participants accounted for the majority of those who experienced an incidence of pregnancy (60.87%). This finding could reflect the autonomy and flexibility that self-employment might afford in terms of family planning decision-making and contraceptive use. However, these results differ from the findings of another study about high incidences of unplanned pregnancy after ART initiation where the majority (60%) of participants were employed. Religious affiliation also exhibited an interesting pattern. Among participants who experienced an incidence of pregnancy, a significant percentage identified as protestants (73.91%). This finding might suggest variations in contraceptive attitudes, beliefs, and practices across different religious groups, potentially warranting further investigation into the religious and cultural contexts shaping contraceptive behaviors.

The findings presented in Table 2 shed light on the incidence of pregnancy among participants who were concurrently using hormonal contraceptives and antiretroviral therapy. The data reveals that out of the total participants, 79.65% (n=180) reported that they did not experience pregnancy while using both hormonal contraceptives and antiretrovirals simultaneously. This significant proportion indicates the success of the dual approach in preventing unintended pregnancies, suggesting that the combination of these two interventions effectively contributed to family planning efforts among these women. This finding is consistent with the documented efficacy of using hormonal contraceptives alongside antiretroviral therapy in reducing the risk of unintended pregnancies (Nanda et al., 2017). On the other

hand, 20.35% (n=46) reported experiencing pregnancies despite using both hormonal contraceptives and antiretrovirals. This subgroup of participants highlights the challenges and limitations that can arise even when employing dual interventions. The reasons for these pregnancies could be multifaceted, including factors such as imperfect adherence to either hormonal contraceptives or antiretroviral therapy, individual variations in drug metabolism, or potential drug interactions (Nanda et al., 2017). These cases underscore the complexity of managing reproductive health in the context of HIV treatment and contraception.

Within the subset of participants who experienced pregnancies while on both interventions, 15.22% (n=7) were also using other medications at the time of the pregnancy incidence. Notably, four participants were using anti-tuberculosis medications concurrently. This observation raises potential concerns about drug interactions and underscores the importance of comprehensive medication management for individuals managing both HIV and other medical conditions. The fact that some participants could not recall the names of the other medications they were using further highlights the need for clear and consistent communication between healthcare providers and patients to ensure safe and effective treatment regimens. Conversely, 84.78% (n=39) of those who became pregnant while using both contraceptives and antiretrovirals were not using any other medications at the time of pregnancy incidence. This subgroup provides insights into the circumstances under which pregnancies occurred despite the dual intervention. It suggests that factors beyond medication interactions might have contributed to these pregnancies, such as inconsistent contraceptive use, variations in hormonal responses, or individual preferences and behaviors collectively underscoring the importance of personalized and comprehensive reproductive health care for women living with HIV. The cases of pregnancies within this group emphasize the need for ongoing counseling, monitoring, and support to ensure optimal adherence to both interventions and to address potential challenges, such as medication interactions and individual variations in response.

Table 3 provides an in-depth analysis of the contraceptive methods used by participants who experienced pregnancies while concurrently using antiretroviral therapy. The findings reveal that the majority of participants (72.86%) who experienced pregnancies while on antiretroviral therapy were using TDF/3TC/DTG (Tenofovir, Lamivudine, and Dolute-

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gravir). This antiretroviral regimen appears to be the most commonly used among the pregnant participants, possibly due to its effectiveness and popularity in this population (Pintye et al., 2017). Interestingly, 10.87% of the participants who experienced pregnancies were using TDF/3TC/EFV (Tenofovir, Lamivudine, and Efavirenz), and an equal percentage were using AZT/3TC/ATV/r (Zidovudine, Lamivudine, and Atazanavir). These proportions suggest that multiple antiretroviral combinations were associated with pregnancies, indicating that the choice of antiretroviral regimen may not be the sole factor influencing contraceptive effectiveness. According to Pyra et al. (2015), all hormonal contraceptives were reported to be less effective when used concurrently with the EFV-containing regimen and this suggests that efavirenz-ART-containing regimens should be avoided unless it is the only regimen the patient tolerates and benefits from. Other factors such as adherence to both antiretroviral therapy and contraceptive methods, hormonal interactions, and individual variations in response could also contribute to these outcomes (Nanda et al., 2017; Haddad et al., 2014).

In terms of contraceptive methods, 41.3% of participants who became pregnant were using injectables, making it the most common contraceptive choice among this subgroup. These results support the results of another study done by Pyra et al. (2015) where 40% of the participants who got pregnant were using injectables. Injectables are known for their convenience and effectiveness (Lunani et al., 2018), but the occurrence of pregnancies suggests that factors beyond the choice of contraceptive may be at play. In a study conducted by Steiner et al. (2017), the risk of pregnancy was lower in women using injectables as compared to those using combined oral contraceptives. In another study conducted by Pyra et al. (2015), the contraceptive with the highest incidences of pregnancy in HIV-infected women who were using EFV as antiretroviral therapy was combined oral contraceptives. In this study, 21.74% of participants using implants experienced pregnancies, while 19.57% using Hormonal IUDs and 17.39% using combined oral contraceptives also became pregnant. In another study conducted by Nanda et al. (2017), the participants using oral contraceptives were more compared to those using implants. This difference in results when compared to the results of this study is because the antiretroviral regimen used mostly in the study contained efavirenz (Nanda et al.,2017), and efavirenz is known to have drug-drug interactions with COCs and implant (Nanda et al.,2017). These proportions highlight the need to assess individual

preferences, adherence, and possible interactions between contraceptive methods and antiretroviral drugs when guiding women with HIV in their family planning decisions. Furthermore, the data reveals that a significant portion (57.14%) of participants who became pregnant while using contraceptives were also using anti-TB medications. This finding underscores the importance of considering potential drug interactions (Pooranagangadevi & Padmapriyadarsini, 2022) and their impact on contraceptive effectiveness. The fact that some participants could not recall the medications they were using further emphasizes the need for clear and comprehensive patient education, counseling, and monitoring to ensure optimal health outcomes and effective contraception.

Table 4 provides valuable insights into the specific antiretroviral regimens used by participants who were utilizing different contraceptive methods at the time of pregnancy incidence. Among participants who were using injectables (medroxyprogesterone) as their contraceptive method at the time of pregnancy incidence, the majority (57.89%) were also on the TLD (Tenofovir, Lamivudine, and Dolutegravir) antiretroviral regimen. This may indicate that injectables, which are a popular contraceptive choice due to their ease of use and effectiveness (Lunani et al., 2018), were commonly paired with TLD among participants who experienced pregnancies. The presence of AZT/3TC/ATV/r (Zidovudine, Lamivudine, and Atazanavir/ritonavir) and TDF/3TC/EFV (Tenofovir, Lamivudine, and Efavirenz) as antiretroviral regimens in this group suggests that multiple antiretroviral combinations were associated with pregnancies among injectable users. The results of this study support the findings of another study done about pregnancies among WLHIV using contraceptives and antiretroviral therapy in Western Kenya where the use of medroxyprogesterone with Efavirenz-containing ART regimen had higher incidences of pregnancy as compared to concurrent use of implants and Efavirenz-containing ART regimen (Patel et al.,2021). Among participants using implants at the time of pregnancy incidence, the majority (90%) were on the TLD antiretroviral regimen. Implants are known for their long-acting and reversible contraceptive nature (Matos et al., 2021), and the preference for TLD in this group may reflect a consideration of compatibility with this contraceptive choice. According to Patel et al. (2021), the participants who got pregnant while using an EFV-containing ART regimen and at the same time using implants were encouraged to switch to a dolutegravir-containing regimen as dolutegravir lacks drug-drug interactions with hormonal contra-

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ceptives. Notably, one participant (10%) was using TDF/3TC/EFV as their antiretroviral regimen. Furthermore, participants who were using intrauterine devices (Hormonal IUDs) and combined oral contraceptives at the time of pregnancy incidence were predominantly on the TLD antiretroviral regimen. These findings collectively underscore the importance of considering the compatibility and potential interactions between contraceptive methods and antiretroviral regimens when providing reproductive health care for women living with HIV. While TLD appears to be a prominent antiretroviral choice across different contraceptive methods, the presence of other antiretroviral regimens alongside specific contraceptive choices indicates the complex interplay of individual preferences, medical considerations, and potential drug interactions.

Table 5 provides insights into the association between different types of hormonal contraceptives and the occurrence of unplanned pregnancies among study participants. Upon examining the association between hormonal contraceptives and the occurrence of pregnancy, it is evident that there was no statistically significant association between injectables (P-value =0.386553), implants (P-value =0.129079), Hormonal IUDs (P-value =0.23863) and occurrence of pregnancy. Notably, with a calculated p-value of 0.049643, this analysis indicates a statistically significant association between the use of COCs and the occurrence of unplanned pregnancies. According to Schwartz et al. (2012), the incidences of unplanned pregnancy were observed in participants using injectables and COCs. The failure of the COCs was stated to be a result of poor compliance. The failure of injectables was due to drug-drug interactions with the ART regimens (nevirapine and efavirenz-containing ART regimens). These findings underscore the complex interplay of various factors influencing contraceptive efficacy and the occurrence of unintended pregnancies among women living with HIV. It is important to recognize that contraceptive choices are multifaceted and can be influenced by individual preferences, adherence to usage protocols, and potential interactions with antiretroviral therapy.

CONCLUSION

Demographic insights highlight the influence of age, marital status, education, occupation, and religious affiliation on contraceptive outcomes. The TLD regimen emerged as the most common, comprising 86.7% of participants, followed by the TLE regimen at 7.07%. Long-term engagement with antiretrovi-

ral therapy is demonstrated, revealing a sustained commitment to managing HIV and overall health. A significant proportion of participants did not experience pregnancies while using both hormonal contraceptives and antiretrovirals; however, some pregnancies occurred despite dual interventions, the complexities of contraceptive choice, and the efficacy of antiretroviral regimens. Variability in contraceptive methods, antiretroviral combinations, and their associations with pregnancies underscores the need for personalized counseling and clear communication.

STRENGTHS AND WEAKNESSES

There is limited literature available on incidences of pregnancy specifically amongst women on antiretroviral therapy while at the same time using hormonal contraceptives in Kenya, especially in Nakuru county. This study was able to provide information on the incidences of pregnancy while using hormonal contraceptives among women living with HIV on ART.

This study was a cross-sectional study that was prone to reporting bias as the participants might have given information to please the investigators. The population to be sampled was of reproductive age and as a result, expectant mothers were automatically excluded from the study as they could not be on any form of hormonal contraception. Also, there were no questions on the questionnaire to obtain information on whether the expectant mothers got pregnant while using hormonal contraceptives.

Participants between the ages of 13 and 18 were also difficult to interact with as most were not accompanied to the clinic by their guardians hence consent could not be obtained. These factors contributed to a lower sample size than previously presumed and this had an effect on the data's expected accuracy.

This study does not provide a means for predicting future trends of the incidences of pregnancy while using hormonal contraceptives among women on antiretroviral therapy. Thus there is a need for other studies to be conducted in the future to determine the outcomes retrospectively or use of prospective or case-control study designs to be employed when research on this similar topic is being done.

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RECOMMENDATIONS

Based on the study findings and discussion, we recommend:

- Healthcare providers should offer comprehensive contraceptive counseling to women living with HIV, focusing on the effectiveness of hormonal contraceptives while co-administered with antiretroviral medications. Clear communication about potential drug interactions, adherence, and individual responses is essential to optimize contraceptive choices.

- Recognize the diversity of antiretroviral regimens and their potential impacts on contraceptive effectiveness. Healthcare providers should adopt individualized approaches, taking into account the specific ART regimens participants are using, along with factors such as drug interactions, side effects, and overall health outcomes.

- For participants who experience pregnancies despite dual interventions, regular monitoring and ongoing support are crucial. Address challenges such as medication interactions, adherence, and individual variations in response to ensure optimal outcomes.

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