Article Two

Early program results of long-acting Cabotegravir Pre-exposure prophylaxis in Livingstone District, Zambia: uptake, safety, and sexually transmitted infection screening findings from routine records

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Abstract

Background: HIV remains a global public health concern, particularly in sub-Saharan Africa, where the rate of HIV acquisition is unacceptably high, despite advances in treatment and prevention strategies. Long-acting injectable Cabotegravir (CAB-LA) is a notable development in pre-exposure prophylaxis (PrEP). This study aimed to assess early CAB-LA PrEP uptake, safety, and STI screening results from routine records in Livingstone District, Zambia.

Methods: A retrospective cohort study was conducted using secondary data from the medical records of recipients of care aged 16-69 who received at least two CAB-LA injections at Livingstone University Teaching Hospital, Maramba, and Mahatma Gandhi Urban Clinics between July 2024 and January 2025. Data was collected from medical records on demographic characteristics, HIV seroconversion rates, newly detected syphilis cases, side effects, and adverse reactions. Descriptive statistics were employed to analyse the data.

Results: A total of 224 recipients of care were enrolled in this study, 53.6% were female, with a median age of 32 years (IQR 26-41). Most had secondary education (73.2%), belonged to the general population (79.0%), and were single (50.0%); 45.5% were unemployed. No HIV seroconversions were observed during the follow-up period. Syphilis positivity was low at baseline (1.1%), which increased to 11.2 % at visit 2, with the highest rates among Adolescent Girls and Young Women (AGYW) (18.2%), followed by the general population (11.2%) and Female Sex Workers (FSW) (10.5%), before declining to below 10% at later visits. Mild side effects occurred in 4.9% of participants, mainly injection-site reactions, with no adverse drug reactions or discontinuations.

Conclusion: CAB-LA PrEP shows promising HIV prevention outcomes and a favourable safety profile over six months. The transient rise in syphilis highlights the need to strengthen integrated STIs prevention and pharmacovigilance alongside CAB-LA scale-up.

Introduction

The human immunodeficiency virus (HIV) epidemic continues to be one of the world's most urgent public health concerns, especially in sub-Saharan Africa (1). Approximately 40.8 million individuals worldwide were living with HIV, and about 1.3 million new cases were reported as of 2024 (2,3). HIV prevalence is still high, particularly in Eastern and Southern Africa, despite tremendous advancements in expanding access to

antiretroviral medication (ART) and prevention measures (4). Persistent infection rates underscore the need for innovative, user-friendly HIV prevention strategies to improve health outcomes (1).

Pre-exposure prophylaxis (PrEP) involves the use of antiretroviral drugs by HIV-uninfected individuals to lower HIV acquisition risk (5). The World Health Organization (WHO) recommended oral PrEP with tenofovir disoproxil fumarate (TDF) in 2015 for those at substantial risk of HIV (6). Despite its high effectiveness, uptake is hindered by challenges such as daily pill burden, stigma, privacy issues, and inconsistent access to healthcare (7,8).

Long-acting Cabotegravir (CAB-LA) is a long-acting injectable used as a PrEP method. It addresses limitations in HIV prevention by requiring administration only every eight weeks (9). This integrase strand transfer inhibitor has shown superior efficacy in reducing HIV infections in HPTN 083 and HPTN 084 studies, with reductions of 69% and 90%, respectively, among cisgender men, transgender women, and cisgender women in sub-Saharan Africa (10). CAB-LA received FDA approval in 2021 and WHO endorsement in 2022 (1).

In early 2023, following global endorsements, Zambia was among the five countries to receive a donation of CAB-LA from the US Government through the President's Emergency Plan for AIDS Relief (PEPFAR) (11). This initiative positioned Zambia as the second country globally to provide injectable PrEP. The initial implementation commenced in a phased approach, starting with six sites across five districts: Lusaka, Kitwe, Chibombo, Nakonde and Mazabuka (11). Furthermore, informed by the initial findings, additional sites were targeted to accommodate an increased number of individuals for CAB-LA uptake and to expand the inclusion of other populations, of which Livingstone was among the included districts (11). In this expanded implementation phase, Livingstone District selected three health facilities, which included Livingstone University Teaching Hospital (LUTH), Maramba, and Mahatma Gandhi urban clinics as the first sites to implement the early CAB-LA program. This intervention is in line with Zambia's National HIV Strategic Framework, aiming to enhance access to biomedical HIV prevention tools for populations at the highest risk.

CAB-LA is an effective and safe HIV prevention option, with mainly injection-site reactions, offering advantages over oral PrEP through infrequent dosing, greater privacy, and better acceptability among key populations such as adolescent girls and young women (12–14). However, its successful implementation relies heavily on maintaining user retention and administering timely injections. Missed doses can compromise drug levels, diminish protection, and heighten the risk of resistance to integrase inhibitors if HIV infection occurs during the tail phase after discontinuation (14).

Offering additional PrEP choices can enhance uptake and efficiency in HIV prevention by promoting individual preferences as well as choice. The WHO endorses HIV rapid diagnostic tests (RDTs) for those starting or continuing long-acting injectable PrEP (15). Additionally, it recommends frequent screening for sexually transmitted infections (STIs) among PrEP users, although optimal frequency lacks evidence (16). A meta-analysis of 38 studies revealed pooled positivity rates of 20% for chlamydia, 17% for gonorrhea, and 7% for syphilis (16). Increased STI screening frequency as a measure to prevent new infections may help improve the quality of life and reduce morbidity in recipients of care.

Moreover, the implementation of CAB-LA in diverse subpopulations has not been extensively evaluated, posing challenges particularly in low- and middle-income countries like Zambia. Thus, this study evaluated the early program findings of the long-acting CAB-LA injections in Livingstone, Zambia, focusing on critical factors such as uptake, short-term safety, and STIs screening. The findings of this study contributed to evidence-based decision-making regarding the potential inclusion of Cabotegravir injections in national HIV prevention initiatives.

Methodology

Study Design

This study employed a retrospective cohort study to assess the early program findings of the Cabotegravir injection PrEP method for HIV prevention in Livingstone district of Zambia. The cohort comprised of recipients of care who were initiated on CAB-LA injections PrEP between July 2024 and January 2025. This period corresponded to approximately six months following the introduction of CAB-LA PrEP in Livingstone District, reflecting early programmatic implementation. The retrospective cohort approach allowed for real-world program performance of CAB-LA uptake using clinical records from program sites.

Study Setting

The study was conducted in Livingstone District, Southern Province, Zambia, specifically in the urban area of Livingstone City. Data was collected at the district's main hospital and clinics selected to offer CAB-LA PrEP in the expansion implementation phase in the district. The primary sites were two urban health centers; Maramba Clinic and Mahatma Gandhi Clinic. The LUTH, a tertiary referral center was also included. These facilities serve as access points the local population.

Follow-up visits reflected the routine CAB-LA PrEP delivery schedule used in Zambia. Visit 1 represented the baseline initiation visit, during which eligible recipients of care received the first CAB-LA injection following HIV testing and clinical assessment. Visit 2 occurred approximately one month (30 days) later and constituted the second initiation (reinjection) visit, confirming continuation on CAB-LA. Visits 3 and 4 represented subsequent maintenance visits scheduled at approximately two-month (60 days) intervals.

Eligibility Criteria

Before the administration of CAB-LA, providers assess a recipient of care's eligibility by screening for contraindications, specifically through an HIV eligibility screening algorithm that included ruling out HIV infection using two parallel HIV rapid diagnostic and nucleic acid (NAT) tests.

Inclusion Criteria

Eligible recipients of care were identified through a review of CAB-LA initiation registers and individual medical and follow-up records. Participants were enrolled consecutively to minimize selection bias.

The study included recipients of care aged 16 years and above who received at least two CAB-LA injections between July 2024 and January 2025 at LUTH, Maramba Clinic, or Mahatma Gandhi Urban Clinic.

Only recipients of care with complete and up-to-date Visit 1 (baseline) and follow-up records were included. These records had to document required clinical and laboratory assessments, including HIV testing, syphilis testing, blood pressure, height, weight, and body mass index. Records also had to include documented laboratory results and confirmation of CAB-LA administration at the time of data collection. In addition, an up-to-date active pharmacovigilance form was required for inclusion.

Exclusion criteria

Recipients of care who received only one CAB-LA injection between July 2024 and January 2025 were excluded. Records lacking sufficient baseline or follow-up information were also excluded. This included missing clinical or laboratory assessments such as HIV testing, syphilis testing, blood pressure, height, weight, or body mass index. Files without documented laboratory results or confirmation of CAB-LA administration at the time of data collection were not included. In addition, records with incomplete or missing active pharmacovigilance forms were excluded from the study.

Study Variables

Table 1: Study Variables and Operational Definitions

Variable	Operational definition
HIV infection	New HIV* seroconversion detected during follow-up among participants who were HIV-negative at baseline (visit 1).
Syphilis infection	New positive treponemal rapid diagnostic test/ Rapid Plasma Reagent (RPR) test during follow-up. CAB-LA† is not protective against syphilis.
ADRs	Any untoward medical occurrence temporally associated with CAB-LA administration.
Side effects	Any non-serious, self-limiting symptom reported after CAB-LA administration. Such as injection-site pain, swelling, and headache.
Population category	1. AGYW (Adolescent Girls and Young Women): Female recipients of care classified by the screening tool as adolescent girls or young women. 2. ABYM (Adolescent Boys and Young Men): Male recipients of care classified by the screening tool as adolescent boys or young men. 3. FSW (Female Sex Workers): Recipients of care who self-identified or were recorded in program notes as female sex workers at enrolment. 4. GP (General Population**):** Recipients of care not classified into a key population group noted above, it included adults of both genders who access routine services and do not meet the program definition for AGYW, ABYM or FSW.

*HIV-Human Immunodeficiency Virus; †CAB-LA - Long-acting Cabotegravir

Data Sources

Secondary data were extracted from recipients of care routine medical and follow-up file and monitoring tools used by the PrEP program. Data fields included demographics, visit dates, HIV and syphilis test results, CAB-LA injection dates, side effects, and recorded adverse drug reactions. A standardized data collection tool was used to ensure accuracy and completeness.
Due to the staggered initiation of CAB-LA, only recipients of care who had been initiated on CAB-LA PrEP earlier had reached the later follow-up visits (visit 3 & 4) by the time of data collection.

Measurements

HIV status was assessed at baseline and during follow-up visits using the national testing algorithm, which includes two parallel HIV rapid diagnostic tests and nucleic acid testing while on PrEP. This approach supported early detection of any seroconversion. Syphilis screening was conducted at baseline and follow-up visits using either a rapid treponemal test or the Rapid Plasma Reagent (RPR) test, in line with Zambia's PrEP guidelines. All tests were performed by trained laboratory technicians, and results were documented in the recipients of care's medical records.

Safety monitoring was conducted through the national pharmacovigilance system. Recipients of care were actively monitored at baseline and follow-up visits, in accordance with Zambia's HIV treatment guidelines, which emphasize the detection, assessment, and prevention of adverse drug effects.

Age was recorded in years as a continuous variable and also categorized into age groups such as 16–24 and 25–34 years to allow assessment of age-specific effects. Education level, gender, population category, and marital status were recorded as categorical variables.
HIV seroconversion and syphilis status were treated as binary outcomes and coded as positive or negative.

Study sample size

This study employed a census design of the program cohort. All recipients of care that met the inclusion criteria were included. No formal sample size calculation was performed; the final sample size (n=224) was determined by the actual number of initiators during the study period.

Data Analysis

Descriptive statistics were used to summarise recipients of care characteristics. Continuous variables such as age were analysed using medians and interquartile ranges. Categorical variables, including gender, education level, population, and marital status, were reported in frequencies and percentages. Analysis was conducted using SPSS version 28.

Ethical Considerations

Privacy and confidentiality were observed, as only de-identified data was collected and encrypted with a password to avoid third-party unauthorized access. Approval from the Mulungushi University School of Medicine and Health Sciences research ethics committee (SMHS-MU1-2025-01) and the National Health Research Authority (NHRA-1848/09/01/2025) was obtained. Permission from Livingstone University Teaching Hospital and Livingstone District Health Office was sought before commencing data collection.
Results

Socio-Demographics Characteristics

A total of 224 recipients of care who met the inclusion criteria were recruited for the study. The socio-demographic dynamics of the recipients indicated that 104/224 (46.43%) were men and 120/224 (53.57%) were women. The median age of our recipients of care was 32 years (IQR 26-41); while 164/224 (73.21%) had a secondary school education level. The highest number of recipients of care were from the general population (GP) group, 178/224 (79.45%). Half, 112/224 (50.00%) of the recipients of care were single, 102/224 (45.54%) were married, and 10/224 (4.46%) were divorced. The majority of recipients of care were unemployed, 102/224 (45.54%). See Table 2.

Table 2: Socio-demographics characteristics for CAB-LA recipients in Liv District, July 2024 - January 2025 (N=224)

Variables		*N*	*%*
Age Distribution	16-26	60	26.79%
	27-37	97	43.30%
	38-48	46	20.54%
	49-59	17	7.59%
	60-70	4	1.79%
Gender Distribution	Female	120	53.57%
	Male	104	46.43%
Marital Status	Single	112	50.00%
	Married	102	45.54%
	Divorce	10	4.46%
Highest Education level	Primary	15	6.70%
	Secondary	164	73.21%
	Tertiary	38	16.96%
	No formal education	7	3.13%
Recipients of care Occupation	Government-employed	20	8.93%
	Self-employed	80	35.71%
	Unemployed	102	45.54%
	Retired	0	0.00%
	Private employment	22	9.82%
Population Category	AGYW*	22	9.82%
	FSW †	19	8.48%
	ABYM§	5	2.23%
	General population	178	79.5%
CAB-LA¶ Site	LUTH**	33	14.73%
	Maramba	121	54.02%
	Mahatma Gandhi	70	31.25%

*AGYW- Adolescent Girls and Young Women; †FSW-Female Sex Worker; §ABYM- Adolescent Boys and Young Men; ¶CAB-LA - Long-acting Cabotegravir; **LUTH – Livingstone University Teaching Hospital

HIV and Syphilis Positivity by Follow-up Visit

Table 3 shows syphilis and HIV test results among 224 recipients of care on CAB-LA PrEP across four follow-up visits, disaggregated by population category. At baseline (Visit 1), syphilis was detected in 2 of 224 recipients (0.9%), both from the general population (2/178; 1.1%), while all recipients remained HIV-negative (224/224; 100%).

At Visit 2, syphilis positivity increased to 25 of 224 recipients (11.2%). The highest burden was among the general population (19/178; 10.7%), followed by AGYW (4/22; 18.2%) and FSW (2/19; 10.5%). No cases were recorded among ABYM (0/5; 0%). At Visit 3, syphilis was detected in 11 of 149 recipients (7.4%), mainly among the general population (9/124; 7.3%), with single cases among AGYW (1/10; 10.0%) and FSW (1/13; 7.7%). At Visit 4, syphilis was detected in 4 of 56 recipients (7.1%), including 3 from the general population (3/52; 5.8%) and 1 FSW (1/1; 100%).

Across all visits, no HIV seroconversions were observed, with all recipients testing HIV-negative throughout follow-up

Table 3: Syphilis and HIV test results for CAB-LA recipients in Livingstone District, July 2024 - January 2025

Variables			STIs (Syphilis)					HIV		
		Total	*Negative*		*Positive*		*Negative*		*Positive*	
Visits	***Population category***	*n*	*N*	*%*	*n*	*%*	*n*	*%*	*n*	*%*
Visit 1	AGYW*	22	22	100.0%	0	0.0%	22	100.0%	0	0.0%
	FSW †	19	19	100.0%	0	0.0%	19	100.0%	0	0.0%
	ABYM§	5	5	100.0%	0	0.0%	5	100.0%	0	0.0%
	GP¶	178	176	98.9%	2	1.1%	178	100.0%	0	0.0%
Total (Visit 1)		**224**	**222**	**99.1%**	**2**	**0.9%**	**224**	**100.0%**	**0**	**0.0%**
Visit 2	AGYW*	22	18	81.8%	4	18.2%	22	100.0%	0	0.0%
	FSW†	19	17	89.5%	2	10.5%	19	100.0%	0	0.0%
	ABYM§	5	5	100.0%	0	0.0%	5	100.0%	0	0.0%
	GP¶	178	159	89.3%	19	10.7%	178	100.0%	0	0.0%
Total (Visit 2)		**224**	**199**	**88.8%**	**25**	**11.2%**	**224**	**100.0%**	**0**	**0.0%**
Visit 3	AGYW*	10	9	90.0%	1	10.0%	10	100.0%	0	0.0%
	FSW†	13	12	92.3%	1	7.7%	13	100.0%	0	0.0%
	ABYM§	2	2	100.0%	0	0.0%	2	100.0%	0	0.0%
	GP¶	124	115	92.7%	9	7.3%	124	100.0%	0	0.0%
Total (Visit 3)		**149**	**138**	**92.6%**	**11**	**7.4%**	**149**	**100.0%**	**0**	**0.0%**
Visit 4	AGYW*	3	3	100.0%	0	0.0%	3	100.0%	0	0.0%
	FSW†	1	0	0.0%	1	100.0%	1	100.0%	0	0.0%
	GP¶	52	49	94.2%	3	5.8%	52	100.0%	0	0.0%
Total (Visit 4)		**56**	**52**	**92.9%**	**4**	**7.1%**	**56**	**100.0%**	**0**	**0.0%**

*AGYW- Adolescent Girls and Young Women; †FSW-Female Sex Worker; §ABYM- Adolescent Boys and Young Men; ¶GP – General Population

Safety Outcomes by Follow-up Visit

Table 4 shows that side effects were seen in 11/224 (4.91%) recipients of care, with the site of injection being noted as the most common complaint. There were no adverse drug reactions recorded during the follow-up period. From the 11 recorded side effects, 8 were recorded in Visit 2 and 3 at Visit 3, and no side effects were recorded by Visit 4. Regarding the population category of our recipients of care, all 11 side effects were observed in the general population. Headache was one of the side effects reported and recorded from 2/11 (18.2%) recipients of care with complaints of side effects. All side effects were mainly mild and did not necessitate discontinuation.

Table 4: Safety outcomes for CAB-LA recipients in Livingstone District, July 2024 - January 2025 (n=224)

		Reported Side Effects (n=224)	%	Reported ADRs*	%
Overall Safety Outcome		11	4.9	0	0.0
Follow-up Visit (V)					
	Visit 1 (Baseline)	0	0.0%	0	0.0%
	Visit 2	8	3.6%	0	0.0%
	Visit 3	3	1.3%	0	0.0%
	Visit 4	0	0.0%	0	0.0%
Population Group					
	GP†	11	4.9%	0	0.0%
	AGYW§	0	0.0%	0	0.0%
	FSW¶	0	0.0%	0	0.0%
	*ABYM***	0	0.0%	0	0.0%
Type of Side Effect††					
	Injection site reactions	11	4.9%	0	0.0%
	Headache	2	0.9%	0	0.0%
Severity/Outcome					
	Mild side effects	11	4.9%	0	0.0%
	Treatment discontinuation	0	0.0%	0	0.0%

*ADRs – Adverse Drug Reactions; †GP – General Population; §AGYW- Adolescent Girls and Young Women; ¶FSW-Female Sex Worker; **ABYM- Adolescent Boys and Young Men; ††Some recipients reported more than one symptom; categories are not mutually exclusive

Discussion

Socio-demographic Characteristics

The sociodemographic characteristics observed in this study align with those reported in other studies. Consistent with this study, Duy and colleagues identified a median age of 35 years among recipients of care willing to use and adhere to Cabotegravir (17). However, they did not include young adults in their samples. In contrast, this study included a small number of adolescent recipients of care, who constituted only 2.23% of the total sample. Notably, the median age of recipients of care in this study exceeds that reported in initial studies on Cabotegravir access in Zambia, where the median age was 24 years, with a predominance of female recipients of care(18). There is a need to sensitize younger recipients of care to use this method of PrEP as a way of reducing HIV transmission in the adolescent and younger populations, to curb the disease transmission in adolescents and young people(19,20).

A study conducted in Kenya focused on women who were either pregnant or lactating, with a median participant age of 25 years; most recipients of care had attained at least secondary education and were married (21). In contrast to this study, which had higher female participation, John and colleagues reported lower female involvement in the use of injectable Cabotegravir in Australia (22). The significant number of women accessing PrEP in this study may be attributed to the high literacy levels observed among our recipients of care, as literacy has been previously associated with factors that enhance PrEP access(23). Furthermore, women have been reported to prefer injectable PrEP because of its perceived ease of use and discretion (24,25). Our study findings suggest that women in the communities are likely to accept injectable methods of PrEP as they continue to be rolled out in the future.

HIV Infections and Related STIs for CAB-LA Injectable PrEP

The absence of seroconversion observed in this study aligns with previous research, indicating the drug's high efficacy in preventing HIV infection (24,25). However, initial findings from Zambia reported a 0.66% conversion rate among the first 600 recipients of care who were initiated and monitored (18). The observed increase in the number of recipients of care who acquired a sexually transmitted infection (STI) while receiving pre-exposure prophylaxis (PrEP) in this study is consistent with findings reported in other studies (26–29). It was observed that, there was higher contraction of STI (syphilis) first return visit (visit 2) in comparison to their second return visit (visit 3) among the recipients of care. The observed reduction may have been a result of the implementation of integrated and comprehensive services offered to recipients of care as they accessed PrEP services at their health facilities (30). It is key to note that adolescents had the highest percentage of positive syphilis cases in comparison to other population categories, suggesting that syphilis remains a public health concern in this population category (31,32). Our findings correspond with studies indicating high STI prevalence in PrEP recipients of care and low condom usage among PrEP users (26,28,33). Although this study did not assess changes in sexual behaviour among recipients of care, counselling on sexual behaviour remains essential. Recipients of care should be encouraged to use barrier methods consistently. Partner notification should be strengthened. Frequent screening for sexually transmitted infections is also important. These measures should be integrated into existing adherence programmes for individuals using CAB-LA to reduce the risk of acquiring other STIs.

Side Effects to CAB-LA

In this study, 4.9% of the respondents reported experiencing side effects, which aligns with the findings of Swindells and colleagues (34). Consistent with most studies, the most prevalent side effect was pain at the injection site, accounting for 72% of reported side effects. In addition, 18% of the recipients of care reported headaches. While Swindells et al. identified headaches as a reported side effect, they also noted weight gain and gastrointestinal-related side effects in their study. Furthermore, John et al. documented serious side effects in the Australian population (22). In earlier reports concerning Zambian recipients of care, one recipient of care experienced severe pain at the injection site and a severe rash, leading to the discontinuation of treatment (18). However, in this study, the side effects did not result in treatment discontinuation, thus demonstrating that CAB-LA may be tolerable to most of the recipients of care who are using it in our setup.

Conclusion and Recommendations

No HIV infections were detected over the 6-month follow-up period among individuals who attended documented care visits. In addition, only mild side effects, which included pain at the site of injection and headache, were observed. The study further observed an increase in syphilis infections, highlighting the need to strengthen comprehensive STI packages: screening, treatment, partner notification, condoms, and risk-re-

duction counselling for individuals receiving CAB-LA injections. Furthermore, active and passive pharmacovigilance is key to scaling up CAB-LA as a new product for HIV prevention in order to document rare side effects and adverse drug reactions. Prospective longitudinal studies with longer follow-up periods are needed to understand CAB-LA implementation in low- and middle-income countries. Future research should aim to include more representative data from the adolescent age group. Further, there is a need to understand risk factors towards the acquisition of STIs among recipients of HIV long-term PrEP interventions.

Limitations

The study had some limitations, including increased selection bias, as all eligible CAB-LA initiators were enrolled in the study. However, those records with insufficient documentation were excluded. Our data collection tool lacked the assessment part for sexual risk behaviours, as the standard CAB-LA screening tool also lacked this essential aspect of PrEP uptake. A short observation time may have reduced the likelihood of observing positive HIV results.

Conflicts of Interest

The authors declare no conflicts of interest.

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Author Contributions

Authors (Jean M Mukumbuta, Japhet Mwale, Gideon Hamwaba, and Prince Sakuhuka) contributed to the conceptualization of this work and data collection. (Jean M Mukumbuta, Japhet Mwale, Gideon Hamwaba, Benson M. Hamooya, Tumelo Muyenga, Chileshe Chilangisha, Bornwell Chilale and Prince Sakuhuka) appraised the article through the various stages of development. Benson Hamooya, Jean Mukumbuta, Bornwell Chilale, and Japhet Mwale performed the data analysis. All authors reviewed successive drafts and approved the final version.

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