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ORIGINAL PAPER

Measuring Oral Pre-exposure Prophylaxis (PrEP) Continuation Through Electronic Health Records During Program Scale-Up Among the General Population in Zambia

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Abstract

HIV pre-exposure prophylaxis (PrEP) is being scaled-up in Zambia, but PrEP continuation data are limited by paper-based registers and aggregate reports. Utilization of Zambia's electronic health record (EHR) system, SmartCare, may address this gap. We analyzed individuals aged ≥ 15 years who initiated PrEP between October 2020 and September 2021 in four provinces in Zambia in SmartCare versus aggregate reports. We measured PrEP continuation using Kaplan–Meier survival analysis and Cox proportional hazards models. SmartCare captured 29% (16,791/58,010) of new PrEP clients; 49% of clients continued at one month, and 89% discontinued PrEP by February 2022. Women were less likely than men to discontinue PrEP (adjusted hazard ratio [aHR]: 0.89, 95% CI 0.86–0.92, z = − 6.99, p < 0.001), and PrEP clients aged ≥ 50 years were less likely to discontinue PrEP compared to clients 15–19 years (aHR: 0.53, 95% CI 0.48–0.58, z = − 13.04, p < 0.001). Zambia's EHR is a valuable resource for measuring individual-level PrEP continuation over time and can be used to inform HIV prevention programs.

Keywords Oral pre-exposure prophylaxis · PrEP · HIV prevention · Africa

Introduction

Daily oral pre-exposure prophylaxis (PrEP) has been recommended by the World Health Organization since 2015 for the prevention of HIV among populations at substantial risk of HIV infection [1]. As of 2020, more than 50 countries had begun offering PrEP [2]. Tenofovir-based oral PrEP was adopted as an HIV prevention strategy in Zambia in 2016 and is available to individuals at substantial risk of HIV infection [3–5]. As Zambia continues to strive toward HIV epidemic control, PrEP has become one of the key interventions in combination HIV prevention; more than 100,000 Zambians accessed PrEP in 2020 alone [2].

Initiating individuals on PrEP is just one hurdle to effective HIV prevention through PrEP. Clients also face adherence challenges similar to people living with HIV on antiretroviral therapy (ART). Unlike traditional ART, PrEP does not need to be a lifelong therapy; it can be used during periods of high risk for HIV infection. Effective PrEP use is difficult to measure as risk fluctuates, but PrEP continuation can be a useful proxy indicator [6]. Understanding patterns

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of PrEP continuation is critical for identifying programmatic gaps in service delivery and client engagement, but data are limited. Research on PrEP continuation in Africa comes mainly from clinical trials and demonstration studies in specific sub-populations, and therefore may not represent real-world continuation during scale-up in the general population. Furthermore, programmatic PrEP data are often captured in paper-based registers, limiting the ability to assess longitudinal continuation due to the need for arduous manual data extraction. Electronic health records (EHR) may provide an opportunity to track client-level PrEP interactions over time, but their widespread application for PrEP continuation has not been reported on in sub-Saharan Africa.

During PrEP program scale-up in Zambia, emphasis was placed on initiating high risk HIV-negative clients on PrEP, and data collection and reporting tools reflected this priority. Registers were designed to accommodate individual PrEP interactions which could be easily tabulated for monthly reports. This method facilitated quick summarization of new and returning PrEP visits in a reporting period but could not inform patterns of PrEP continuation as clients were not tracked longitudinally. An alternative register was designed to track multiple visits of individual PrEP clients following the schedule outlined in the national PrEP guidelines: initiation, 1-month follow-up, 3-months follow-up, and every 3 months thereafter [5]. This register was suitable for cohort monitoring and measuring PrEP continuation; however, it created new challenges for aggregate reporting as PrEP visits could be scattered throughout the register. Furthermore, neither register could easily track clients who cycled on and off PrEP, remained on PrEP for an extended period (> 1 year), or followed a visit pattern deviating from the national guidelines. EHR may address these shortcomings by linking all PrEP interactions to a unique client identifier to enable both longitudinal tracking and data aggregation by visit type and reporting period. We sought to describe the coverage of PrEP clients in Zambia's EHR system and to measure continuation of clients captured in the EHR.

Methods

Study Design and Setting

We conducted a retrospective analysis of individuals aged ≥ 15 years who initiated PrEP between October 2020 and September 2021 in Eastern, Lusaka, Southern, and Western provinces in Zambia. Analyses were restricted to these four provinces due to programmatic differences in scale-up of PrEP and utilization of the EHR for PrEP which resulted in very low coverage (< 10%) of PrEP clients in the EHR in the remaining six provinces. Health facilities at all levels of the healthcare system in Zambia offer HIV prevention services, including daily oral PrEP, with support from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR).

Data Source

PrEP initiations were aggregated by 5-year age band and sex from paper reports at facility level and reported quarterly by PEPFAR implementing partners. Cumulative PrEP initiations between October 2020 and September 2021 were extracted using PEPFAR's Data for Accountability, Transparency, and Impact (DATIM) platform.

PrEP initiations captured in Zambia's EHR system, SmartCare, between October 2020 and September 2021 were identified; we used Palantir Foundry software to access integrated, harmonized, and de-identified individual-level data from date of PrEP initiation through February 2022. SmartCare was first introduced in 2004 for clinical management of people living with HIV [7]. As of 2021, SmartCare was in use in ~ 1500 Zambian health facilities to record client interactions either in real-time or retroactively from paper forms. In 2018, SmartCare was expanded with a PrEP module to track facility interactions of clients accessing PrEP for HIV prevention. Digitized SmartCare data from health facilities are routinely consolidated and de-duplicated at the district and provincial levels, transported to Zambia Ministry of Health headquarters in Lusaka, and stored in Zambia's National Data Warehouse.

Data Analysis

EHR coverage of PrEP clients was assessed by first comparing the number of facilities reporting PrEP initiations by province and facility type in DATIM and SmartCare between October 2020 and September 2021. Then the number of PrEP initiations captured in SmartCare compared to DATIM was measured by province, sex, and age band.

PrEP continuation analyses were completed for clients captured in SmartCare who enrolled between October 2020 and September 2021 and were followed-up through February 2022. PrEP discontinuation was defined as no PrEP interaction recorded in SmartCare > 28 days past the expected appointment date in alignment with national ART program guidelines on continuity of care and management of missed appointments [5]. If a client discontinued and restarted PrEP multiple times, time to first discontinuation was used for the survival analysis. Active time on PrEP was calculated as the cumulative time between a health facility PrEP interaction and the next scheduled appointment during which the client was assumed to possess PrEP pills and take them as prescribed.

Kaplan–Meier survival analysis was used to assess PrEP continuation over time. Clients were right censored if they

were continuously active on PrEP through February 2022 or if they had incomplete records during their follow-up period. Log-rank tests were used to assess differences in continuation by sex, province, and age group. Cox proportional hazard models were used to calculate crude and adjusted hazard ratios for associations of covariates with PrEP discontinuation. Analyses were completed using R version 4.0.4 (R Foundation for Statistical Computing) with *survival* and *survminer* packages [8, 9].

Ethical Considerations

The protocol covering this project was approved by the ERES Converge IRB in Lusaka, Zambia; it was also reviewed in accordance with CDC human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes. Consent was waived as the project utilized data collected during routine health services and the authors had no access to personally-identifiable information.

Results

Between October 2020 and September 2021, 834 health facilities reported PrEP clients through DATIM in Eastern (150), Lusaka (156), Southern (302), and Western (226) provinces. PrEP was provided at all levels of the healthcare system: 315 health posts, 357 rural health centers, 112 urban health centers, and 50 hospitals. During the same period, 375 facilities (45%) reported initiating PrEP clients through SmartCare. Facility use of SmartCare for PrEP was highest in Lusaka Province (69%) and in hospitals (84%) and lowest in Southern Province (33%) and at health posts (25%).

A total of 58,010 clients initiated PrEP between October 2020 and September 2021, and 16,791 (29%) were captured using SmartCare (Table 1). While only 43% of all PrEP initiations were men, they were over-represented in SmartCare. Lusaka Province, which contributed a third (34%) of all PrEP initiations reported in DATIM, accounted for nearly half (47%) of PrEP clients in SmartCare. More than half of the PrEP clients from both data sources were aged < 30 years, but SmartCare captured greater proportions of older PrEP clients.

The 16,791 new PrEP clients captured in SmartCare were active on PrEP for a median 51 days (interquartile range [IQR]: 38–95) between October 2020 and February 2022 (14,910 total person-years on PrEP). Most PrEP clients (89%) discontinued at least once by February 2022, but 14% restarted PrEP (1884 restarted once, 176 twice, and 11 three times). Among those who restarted, the median time from date of missed appointment to restart was 92 days (IQR: 70–135).

Table 1 Characteristics of individuals newly initiated on PrEP in Eastern, Lusaka, Southern, and Western provinces of Zambia, October 2020-September 2021

	PrEP initiations in DATIM N = 58,010		PrEP initiations in EHR N = 16,791		EHR coverage of PrEP initiations Overall = 28.9%
	n	%	n	%	%
Sex					
Male	24,778	42.7	7997	47.6	32.3
Female	33,232	57.3	8794	52.4	26.5
Province					
Eastern	5833	10.1	2014	12.0	34.5
Lusaka	19,720	34.0	7942	47.3	40.3
Southern	21,954	37.8	4441	26.4	20.2
Western	10,503	18.1	2394	14.3	22.8
Age group					
15–19	5498	9.5	1075	6.4	19.6
20–24	13,951	24.0	3710	22.1	26.6
25–29	12,451	21.4	3864	23.0	31.0
30–34	9304	16.0	2825	16.8	30.4
35–39	7089	12.2	2135	12.7	30.1
40–44	4544	7.8	1456	8.7	32.0
45–49	2620	4.5	864	5.1	33.0
50 +	2552	4.4	862	5.1	33.8

PrEP pre-exposure prophylaxis; *DATIM* Data for Accountability, Transparency, and Impact; *EHR* electronic health records

Kaplan–Meier survival curves for time to first discontinuation are shown in Fig. 1. Overall, median time to discontinuation was 30 days; 49% of new clients returned for their 1-month follow-up visit. Twenty-six percent of clients remained active on PrEP at 3-months, 12% at 6-months, 7% at 9-months, 5% at 12-months, and 3% at 15-months post-initiation. Sex, province, and age group were all significantly associated with PrEP continuation (sex: log-rank $\chi^2 = 16$, degrees of freedom [df] = 1, $p < 0.001$; province: $\chi^2 = 376$, df = 3, $p < 0.001$; age group: $\chi^2 = 391$, df = 7, $p < 0.001$). Half of the women continued PrEP at one month, and female sex was associated with a 10% lower risk of discontinuing PrEP compared to men, adjusting for age and province (Table 2). Compared to PrEP clients in Lusaka Province, those in the other three provinces had a significantly higher hazard of discontinuing PrEP. Lusaka was chosen as the referent province because it had the most PrEP initiations and the highest EHR coverage. PrEP clients aged 15–19 years were at highest risk of discontinuing PrEP and only 37% continued to their 1-month appointment. The risk of discontinuing PrEP was inversely related to age group with clients aged ≥ 50 years nearly half as likely to discontinue PrEP compared to clients aged 15–19 years.

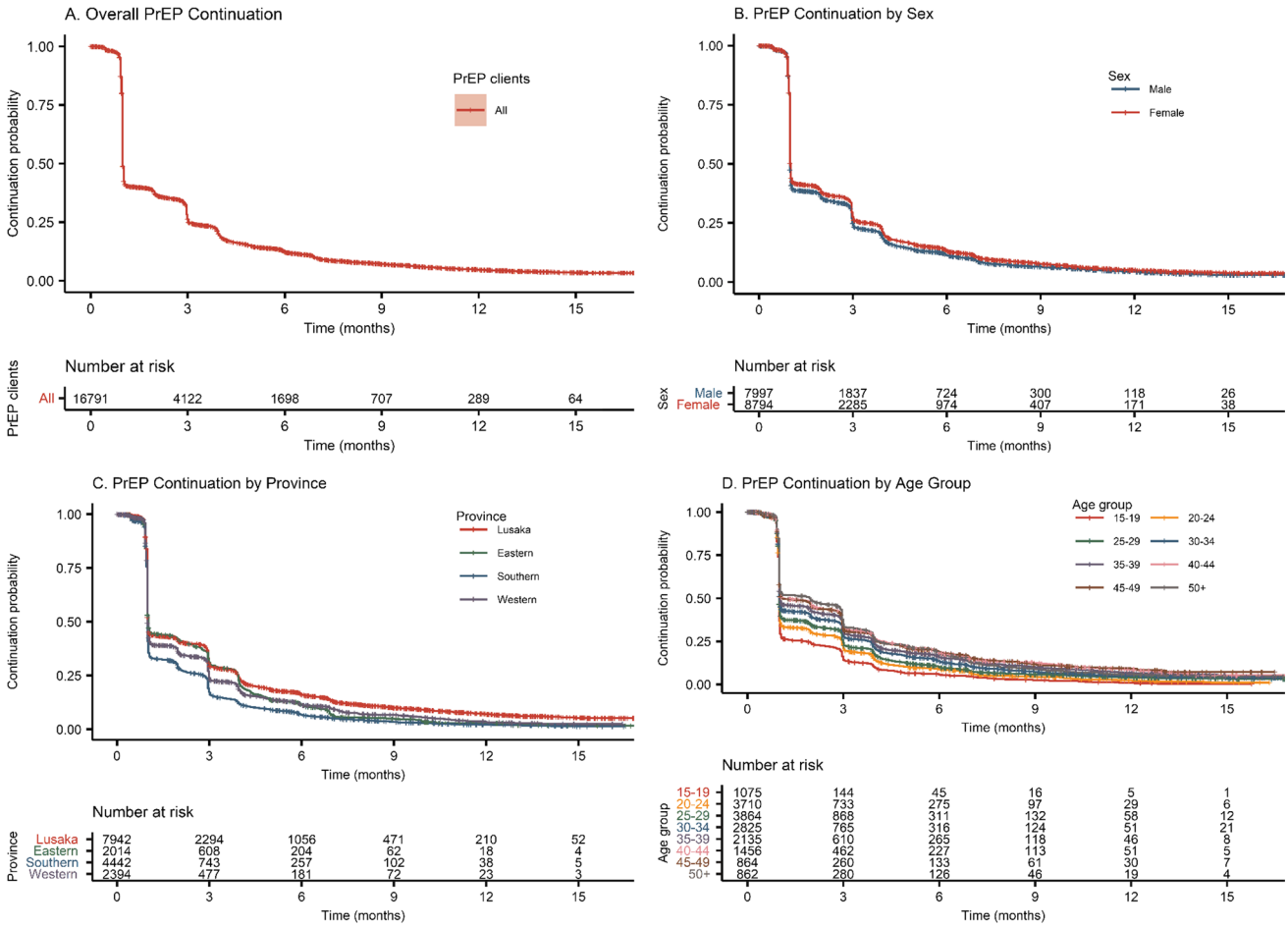

Fig. 1 Kaplan–Meier survival curves for PrEP continuation **A** overall and by **B** sex, **C** province, and **D** age group. *PrEP* pre-exposure prophylaxis

Discussion

PrEP continuation was very low in the study population; less than half of new clients continued at one month and most discontinued at least once during follow-up. Although definitions of PrEP discontinuation vary in the literature from missing an appointment by seven days to missing more than two expected quarterly visits, our general findings are consistent with reports on programmatic data from PrEP use among the general population in other parts of Africa [10, 11]. During PrEP scale-up in Kenya, only 31% of PrEP clients returned at one month, and individuals at substantial risk for HIV in Uganda continued PrEP for a median 45 days [10, 12]. Despite high discontinuation among PrEP clients in SmartCare, many clients restarted PrEP after a period away, similar to a PrEP trial among serodiscordant couples in Kenya in which 12% of those who discontinued PrEP restarted with a median 90 days between date of discontinuation and restart [13]. Early discontinuation and time spent off PrEP do not necessarily reflect poor use; such periods may indicate that clients choose to take PrEP during perceived periods of high HIV risk or transition to other HIV prevention methods. A qualitative study of clients who discontinued PrEP in Eswatini found that the most clients discontinued PrEP because of a reduction in HIV risk and that most would take PrEP again if needed [14].

We observed differences in PrEP continuation by age, sex, and province. Other studies found similar associations with females and older age groups more likely to continue PrEP [11, 12, 15]. Differences by province may indicate variations in counseling strategies and service delivery during program implementation. While our study does not capture reasons for discontinuing PrEP, many qualitative studies have explored this issue. Common barriers to PrEP continuation include side effects, pill burden, partner disapproval, and social stigma [14, 16–19]. Distance from a PrEP-dispensing health facility may also impede continuation; a study in rural Uganda found that PrEP clients who traveled ≥ 2 km to receive PrEP had 70% lower odds of returning [20]. Adherence clubs, peer mentors, and SMS

Table 2 PrEP continuation at 1-month follow-up and hazard ratios of PrEP discontinuation among new PrEP clients in Eastern, Lusaka, Southern, and Western provinces, Zambia

	1-month PrEP continuation[a]	Crude PrEP discontinuation hazard ratios				Adjusted PrEP discontinuation hazard ratios[b]			
	%	cHR	95% CI	z	p	aHR	95% CI	z	p
Sex									
Male	47.4	Ref.				Ref.			
Female	50.1	0.93	[0.90, 0.96]	−4.19	< 0.001	0.89	[0.86, 0.92]	−6.99	< 0.001
Province									
Eastern	53.1	1.14	[1.09, 1.20]	5.11	< 0.001	1.16	[1.10, 1.22]	5.69	< 0.001
Lusaka	52.1	Ref.				Ref.			
Southern	41.0	1.45	[1.39, 1.51]	18.85	< 0.001	1.50	[1.44, 1.56]	20.43	< 0.001
Western	49.4	1.18	[1.12, 1.24]	6.47	< 0.001	1.18	[1.12, 1.24]	6.38	< 0.001
Age group									
15–19	37.1	Ref.				Ref.			
20–24	42.7	0.84	[0.79, 0.90]	−4.76	< 0.001	0.86	[0.80, 0.92]	−4.31	< 0.001
25–29	46.5	0.76	[0.71, 0.81]	−7.80	< 0.001	0.76	[0.70, 0.81]	−7.78	< 0.001
30–34	51.0	0.67	[0.63, 0.73]	−10.55	< 0.001	0.67	[0.62, 0.72]	−10.74	< 0.001
35–39	54.2	0.62	[0.57, 0.67]	−12.23	< 0.001	0.61	[0.57, 0.66]	−12.41	< 0.001
40–44	56.1	0.57	[0.53, 0.62]	−13.22	< 0.001	0.55	[0.51, 0.60]	−13.90	< 0.001
45–49	57.7	0.57	[0.52, 0.63]	−11.54	< 0.001	0.55	[0.50, 0.60]	−12.28	< 0.001
50+	58.3	0.58	[0.52, 0.63]	−11.39	< 0.001	0.53	[0.48, 0.58]	−13.04	< 0.001

PrEP pre-exposure prophylaxis; *CI* confidence interval

[a]Continuation probability from Kaplan–Meier estimates

[b]Multivariable Cox proportional hazard model adjusted for age group, province, and sex

reminders may facilitate PrEP continuation, and community dispensation may help remove access barriers [21–23]. These interventions may be tailored to the specific needs of individuals at risk. Long-acting PrEP methods may remove some barriers to PrEP continuation but are not widely available in Zambia.

This analysis has several limitations. First, the EHR captures only 29% of total PrEP clients and may not accurately represent the overall population accessing PrEP services. We observed lower EHR coverage among women and young people which may indicate that the SmartCare PrEP module is not being utilized at service delivery points where these populations are more likely to interact with the health facility, namely adolescent-friendly spaces and maternal and child health departments. This can be improved through scaled-up utilization of the PrEP SmartCare module in all facilities at all PrEP service delivery points. Second, SmartCare does not capture changes in risk behaviors which may affect PrEP initiation and continuation. Discontinuation could be overestimated because active PrEP clients may appear to discontinue in SmartCare if they transfer facilities or present under a different name. We could not measure PrEP adherence during active periods (when clients were expected to have pills in possession and take them as prescribed), but several other studies have shown that PrEP adherence declines over time [24–27]. Retesting results of PrEP clients were not available in the EHR, but aggregate DATIM reports from the provinces included in this analysis indicated that there were 548 seroconversions in 97,487 HIV retests among PrEP clients attending follow-up visits.

Despite the limitations, this analysis also has notable strengths. This report is the first large-scale analysis of programmatic data to measure PrEP continuation among the general population in Zambia. Second, this analysis identified several demographic groups with lower PrEP continuation that may benefit from enhanced counseling and differentiated service delivery models. Zambia's PrEP implementation approach uses risk-based criteria rather than population-based, which reduces the risk of stigmatizing PrEP but generalizes service delivery [28]. These results may help shape PrEP policy in Zambia to be more adaptable to individual client needs. Finally, this report demonstrates the feasibility of estimating PrEP continuation using EHR and the ability to measure additional indicators that are beyond the scope of paper-based registers currently in use in Zambia (i.e., active time on PrEP and restarts after discontinuation). The utility of PrEP monitoring through the EHR will increase as facilities nationwide transition toward real-time data entry into SmartCare.

Conclusions

PrEP continuation in Zambia is low, especially among young people. Zambia's EHR is a valuable resource for measuring individual-level PrEP continuation and identifying patterns in PrEP continuation which may be used to inform population-specific strategies to promote PrEP continuation. Adolescents and young people may benefit from PrEP reminder systems, support groups, and more frequent health facility interactions. Women may be supported through integrated sexual and reproductive health services and sensitization of their male partners. Men who tend not to visit health facilities often may be reached through community dispensation, longer prescriptions, and the use of HIV self-test kits for re-testing. Increased utilization of the PrEP SmartCare module and person-centered PrEP strategies are needed to monitor and sustain effective HIV prevention programs in Zambia to help achieve HIV epidemic control.

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Data Availability PEPFAR data are publicly available through data.pepfar.gov. SmartCare electronic health records are owned by the Zambia Ministry of Health and requests for data access can be submitted through moh.gov.zm.

Code Availability Analyses were completed using R version 4.0.4 (R Foundation for Statistical Computing) with *survival* and *survminer* packages. The code is available upon request through the corresponding author.

Declarations

Competing Interests The authors have no competing interests to declare.

Ethical Approval The protocol covering this project was approved by the ERES Converge IRB in Lusaka, Zambia (Ref. No. 2020-Mar-015, 2020-Jul-015). It was also reviewed in accordance with CDC human research protection procedures and was determined to be research, but CDC investigators did not interact with human subjects or have access to identifiable data or specimens for research purposes.

Consent to Participate Consent was waived as the project utilized data collected during routine health services and the authors had no access to personally-identifiable information.

Consent for Publication Not applicable.

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