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# Better adherence to pre-antiretroviral therapy guidelines after implementing an electronic medical record system in rural Kenyan HIV clinics: a multicenter pre–post study☆

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SUMMARY

*Introduction:* The monitoring of pre-antiretroviral therapy (pre-ART) is a key indicator of HIV quality of care. This study investigated the association of an electronic medical record system (EMR) with adherence to pre-ART guidelines in rural HIV clinics in Kenya.
*Methods:* A retrospective study was carried out to assess the quality of pre-ART care using three indicators: (1) the performance of a baseline CD4 test, (2) time from enrollment in care to first CD4 test, and (3) time from baseline CD4 to second CD4 test. A comparison of these indicators was made pre and post the introduction of an EMR system in 17 rural HIV clinics.
*Results:* A total of 18 523 patients were receiving pre-ART care, of whom 38.8% in the paper group had had at least one CD4 test compared to 53.4% in the EMR group ($p < 0.001$). The adjusted odds of performing a CD4 test in clinics using an EMR was 1.59 (95% confidence interval 1.49–1.69). The median time from enrolment into HIV care to first CD4 test was 1.40 months (interquartile range (IQR) 0.47–4.87) for paper vs. 0.93 months (IQR 0.43–3.37) for EMR. The median time from baseline to first CD4 follow-up was 7.5 months (IQR 5.97–10.73) for paper and 6.53 months (IQR 5.57–7.87) for EMR.
*Conclusion:* The use of the EMR system was associated with better compliance to HIV guidelines for pre-ART care. EMRs have a potential positive impact on quality of care for HIV patients in resource-constrained settings.


## 1. Introduction

Nearly two-thirds of the 34 million persons infected with HIV globally live in Sub-Saharan Africa (SSA).[1] As of December 2011, 70% of the 1.7 million HIV-related deaths occurred in SSA.[2] The high volume of patients in an environment that lacks adequate skilled human resources and equipment, adds to the dire need to invent ways to improve the quality of care for those infected with HIV. Despite the availability of diagnostic testing for HIV and the availability of highly active antiretroviral therapy (ART) since the mid 1990s, early mortality remains high among patients who access ART with advanced symptomatic disease and low baseline CD4.[3,4] Effective pre-ART patient monitoring and timely initiation of ART can potentially reduce HIV-related mortality.[5] The 2010 revision of the World Health Organization (WHO) guidelines on ART for HIV infection recommend using CD4 cell counts to monitor pre-ART care and determine patient eligibility for ART initiation.[6] Although the 2013 revision of the WHO guidelines recommending the use of viral load for patient monitoring were released in July 2013,[7] many countries are yet to adopt them.

Various studies have shown the benefits of electronic medical record (EMR) systems in delivering quality health care for chronic illnesses.[8–10] EMRs can be integrated into clinical practice to enhance guideline adherence. Despite the evidence of the benefits of EMRs, many health facilities that offer HIV care and treatment in SSA use paper-based records for patient data.[11] As the number of enrolled patients increases against a relatively fixed number of overworked health workers, the paper records become more prone

☆ *Disclaimer:* The findings and conclusions in this paper are those of the authors and do not necessarily represent the official position of the US Centers for Disease Control and Prevention or the Government of Kenya.

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to error, less efficient, and ineffective in managing the complex longitudinal patient data. This situation can potentially compromise the quality of information used for patient care and thereby negatively affect patient outcomes. Due to these considerations, a number of health facilities in SSA are transitioning practice from the use of paper records to EMRs in order to improve patient monitoring and hence quality of care.[10]

The Kenyan Ministries of Health (MOH) and the US President's Emergency Plan for AIDS Relief (PEPFAR) have provided resources for the national rollout of EMRs at HIV, tuberculosis, and maternal and child health (MCH) clinics to improve data management for clinical decision-making and reporting.

The aim of this study was to assess the effect of the change from a paper-based to an electronic-based medical record system on CD4 testing among HIV-infected persons in the pre-ART care period.

## 2. Methods

We conducted a retrospective study to compare quality of care indicators before and after the introduction of an EMR system at 17 health facilities providing HIV care and treatment services in Nyanza Province, western Kenya. Study participants were patients aged 2 years and older receiving HIV care at the participating clinics, since the Kenyan HIV guidelines require that all children under 2 years of age should initiate ART irrespective of their immunological status. All the clinics had used paper-based records before transitioning to electronic records at varying times from January 2009 to February 2012.

### 2.1. Study setting

Nyanza Province has the highest HIV burden among Kenya's eight provinces, with a prevalence of 14.9%; it is home to about a third of all HIV-infected persons in Kenya.[12] EMRs were installed at 17 health facilities that had electricity and adequate security for computers. The 17 clinics, which were providing HIV care and treatment to about 39 203 active patients as of September 2012, (PEPFAR semi-annual report for Kenya) are all located in rural settings and encounter common challenges including inadequate staffing and weak infrastructure; the latter includes frequent electric power interruptions and unreliable Internet access. The studied facilities fall into three categories, as established by the Government of Kenya, namely: district hospitals ($n = 4$), which are level 4 (headed by a physician and providing both inpatient and outpatient services); health centers ($n = 11$), which are level 3 (headed by a clinical officer who is equivalent to a physician assistant; these provide a limited number of services compared to district hospitals); and dispensaries ($n = 2$), which are level 2 (headed by a nurse and providing only limited outpatient services).

### 2.2. Pre-ART care

Pre-ART care is provided during the period between a confirmed HIV-positive test and eligibility for ART initiation based on Kenyan ART guidelines. Pre-ART care is offered at no cost to the patient in many SSA countries. During the pre-ART care period, HIV-infected patients receive a range of clinical services, including the provision of co-trimoxazole prophylaxis, multivitamins, screening for TB and other opportunistic infections, and routine laboratory monitoring; key among these are CD4 cell count measurements every 6 months and viral load tests. The CD4 cell count serves as the most important laboratory indicator of the degree of immunosuppression among HIV patients and is the most important prognosis indicator for patients starting ART.[3,4,13] The CD4 test is now widely available in health facilities in SSA for the routine monitoring of HIV disease progression and response to treatment.

### 2.3. Paper-based patient monitoring system

The paper-based system entailed the recording of patient details on an MOH-approved Comprehensive Care Clinic Card (MOH 257) (Appendix). MOH 257 holds demographic and contact details of the patient, treatment support data, HIV testing and treatment history, allergies, HIV treatment eligibility and regimen (first- or second-line), vital signs, treatment outcomes, laboratory results including CD4, co-infections, and an appointment date for the next visit. Observations for each visit are recorded in a single column on a paper chart (see Appendix).

Scheduling patient visits for each clinic day was done manually from the MOH 257 where the follow-up visit date was recorded. Analyses such as tracking of patient clinic visit appointments, trends in measurements such as vital signs and treatment progress including CD4 cell counts, statistical summaries for hospital administration use, and MOH reporting were all conducted manually. Clinicians reviewed the individual patient's treatment history based on filed paper notes during routine clinic visits.

### 2.4. Electronic medical record (EMR) system

The EMR system rolled-out in the 17 facilities is called the Comprehensive Care Centre Patient Application Database (C-PAD) and was developed in 2007.

Data management entails clinicians recording information on paper forms (MOH 257), as was the case for the paper-based system, followed by data entry by a data clerk into the EMR on the same day as the clinic visit or the next day. Mandatory variables such as demographic data, vital signs, medications, and key laboratory measurements must be entered into the computer for the continuation of system operation. It takes about 10 min to enter the records of a new patient and about 5 min to update the records of a revisit patient if all required information is available. Data clerks make immediate follow-up with the clinicians to provide any missing data. Weekly reviews of EMR-generated patient summary reports are used to flag patients with conditions that need follow-up – for example, patients with no baseline CD4 result or those whose follow-up CD4 tests are overdue. Data entry by data clerks is common practice in many SSA countries as clinics transition from the use of paper to electronic systems. Clinicians interact with the EMRs through the weekly patient summary reports or by directly reviewing individual patient data on the EMR in addition to the paper records.

For this study, pre-EMR data from the paper forms (MOH 257) were entered retrospectively for all patients who initiated treatment prior to the installation of the EMR system, and compared to electronic data for patients enrolled in HIV care after the installation of the EMR.

### 2.5. Outcome measures

We assessed the effect of EMR use on the following factors, which are key in pre-ART care: (1) performing a baseline CD4 test, (2) time from enrolment into HIV care to the first (baseline) CD4 test, and (3) time from the first to the second CD4 test.

Each patient enrolled in HIV care should undergo baseline CD4 testing. The shorter the time from enrolment into HIV care to baseline CD4 testing, the better the compliance with HIV treatment guidelines.[13] According to the HIV treatment guidelines, a repeat CD4 test should be performed for every patient at least once every 6 months. For each site, the date of C-PAD installation was used to

compare the outcome measures during the paper-based vs. the EMR-based data management.

### 2.6. Statistical analysis

Data for each visit were ordered by visit date; records with a CD4 count but with no CD4 date, had the CD4 date imputed using the clinic appointment date prior to that corresponding to the CD4 result in the database.

We used descriptive statistics to summarize continuous variables using the median and interquartile range (IQR). Logistic regression was used to calculate the odds ratio (OR) and the adjusted odds ratio (aOR) to test for any association between EMR use and the performance of baseline CD4 tests. Cox proportional hazards regression was used to calculate hazard ratios (HR) and adjusted hazard ratios (aHR) to test the associations between EMR use and the time-based outcomes (time from enrolment in HIV care to first CD4 test, and time from first to second CD4 test). In the multivariate analyses (Cox proportional hazard and logistic regression), we adjusted for age and sex of the patient, year of change of treatment guidelines, and the level of the health facility, and used the paper system as the reference group. Kaplan–Meier survival graphs were used to visually present the comparison of time to event for the two time-based outcomes. For time-based outcomes, records that did not have a CD4 test result were censored on the date of the last visit. The log rank test of equality was used to test for statistical differences in the rate of occurrence of the time-based outcomes in the paper and EMR groups. The survivor function measurement was used to calculate the median time to event and the IQR. Pearson's Chi-square test was used to compare proportions and to calculate associated *p*-values. The generalized estimating equations (GEE) method was used to adjust for intra-facility correlation. Statistical analysis was conducted using Stata version 12.1.

### 2.7. Ethical considerations

The study was approved by the US Centers for Disease Control and Prevention (CDC) and Kenya Medical Research Institute (KEMRI) institutional review boards. Prior to analysis, individual patient data were de-identified by the KEMRI staff responsible for primary data collection.

## 3. Results

A total of 37 851 patients aged 2 years and older were enrolled at the clinics, of whom 18 523 (48.9%) were receiving pre-ART care as they were not yet eligible for ART based on the national guidelines. This excluded 2414 patients who had transferred in from other clinics. The pre-ART care patients consisted of 12 529 females (67%) and 5994 males (33%). Overall, 15 476 patients were enrolled in HIV care before the implementation of the EMR (paper group), while 3047 were enrolled after EMR implementation (EMR group). The median age of patients at enrolment in the paper group was 28.9 years (IQR 22.8–37.2) and in the EMR group was 28.1 years (IQR 23.0–35.9). Table 1 shows the characteristics of the pre-ART patients.

**Table 1**
Characteristics of pre-ART patients receiving HIV care during the paper and EMR phases at 17 health facilities in Siaya County, western Kenya

| | Paper, *n* (%) | EMR, *n* (%) | Total |
|---|---|---|---|
| Number of patients (*n*) | 15 476 | 3047 | 18 523 |
| Sex | | | |
| Male | 4938 (31.9%) | 1056 (34.7%) | 5994 |
| Female | 10538 (68.1%) | 1991 (65.3%) | 12529 |
| Median age, years | 28.9 | 28.1 | 28.7 |
| WHO stage | | | |
| 1 | 4408 (29.9%) | 1239 (46.3%) | 5647 |
| 2 | 4197 (28.5%) | 852 (31.8%) | 5049 |
| 3 | 5763 (39.1%) | 527 (19.7%) | 6290 |
| 4 | 371 (2.5%) | 58 (2.2%) | 429 |
| Recorded CD4 results | 6001 (38.8%) | 1626 (53.4%) | 7627 (41.2%) |
| MOH level (clinic type) | | | |
| 2 | 664 (4.3%) | 98 (3.2%) | 762 |
| 3 | 2799 (18.1%) | 460 (15.1%) | 3259 |
| 4 | 12 013 (77.6%) | 2489 (81.7%) | 14502 |
| Mean duration of data collection (months) | 55.3 | 14.1 | 35.2 |

Pre-ART, pre-antiretroviral therapy; EMR, electronic medical records; WHO, World Health Organization; MOH, Ministries of Health.

### 3.1. Association between EMR use and performance of the baseline CD4 test

Among the 18 523 patients receiving pre-ART care, 7627 (41.2%) had at least one CD4 test result recorded, while 10 896 (59%) did not have any CD4 test results. Among the pre-ART care patients, 6001 (38.8%) in the paper group had at least one CD4 test, while 1626 (53.4%) in the EMR group had at least one CD4 test. These included 15.7% (*n* = 1195) and 9.2% (*n* = 150) of patients with imputed CD4 test dates in the paper and EMR groups, respectively (patients who had a CD4 result recorded but missing the date of CD4 test). In the bivariate analysis, the odds of performing the baseline CD4 test was 57% higher using the EMR compared to the paper system (OR 1.57; 95% confidence interval (CI) 1.49–1.66). After adjusting for patient age and sex, level of health facility, and year of change of treatment guidelines, the use of EMR was independently associated with 59% higher odds of ever performing the baseline CD4 test compared to the paper system (aOR 1.59, 95% CI 1.49–1.69).

### 3.2. Time from enrolment into HIV care to first CD4 test among pre-ART patients

Among the pre-ART patients who had at least one CD4 test, the median time from enrolment into HIV care to first CD4 test was 1.40 months (IQR 0.47–4.87) for paper vs. 0.93 months (IQR 0.43–3.37) for EMR. Figure 1 shows the time from enrolment in HIV care to baseline CD4 test. The proportion of patients with baseline CD4 tests conducted within 3 months of enrolment was 64.8% (95% CI 63.1–66.5) for the paper-based system vs. 74.1% (95% CI 70.5–77.5)

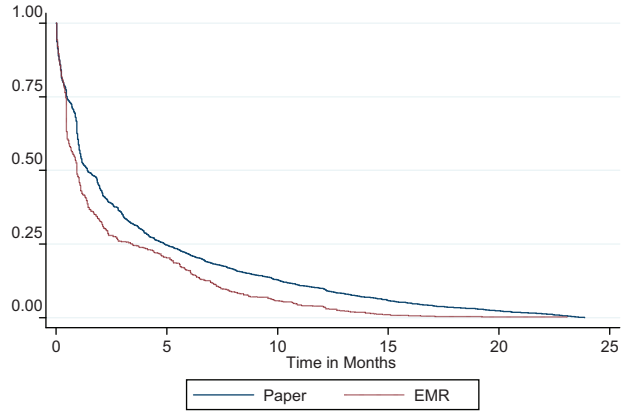


**Figure 1.** Time from enrolment into HIV care to first CD4 test among pre-ART patients.

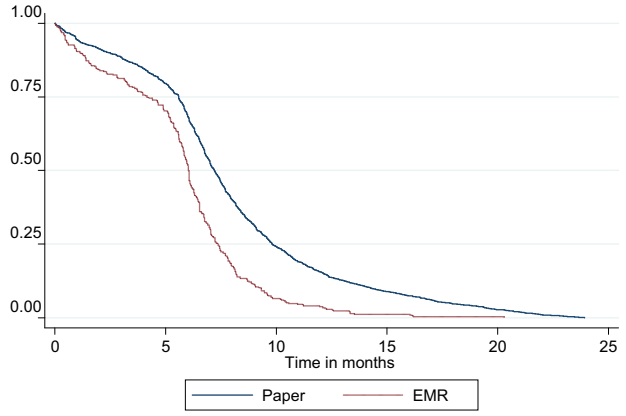


**Figure 2.** Time from first to second CD4 test among pre-ART HIV care patients.

for the EMR system. The unadjusted analysis using Cox regression indicated that EMR use was associated with a 57% higher hazard of conducting a CD4 test compared to the paper system (HR 1.57; 95% CI 1.26–1.95). After adjusting for age and sex of the patient, level of health facility, and year of change of treatment guidelines, EMR use was associated with a hazard ratio of 1.49 (95% CI 1.17–1.88).

### *3.3. Time from first CD4 test to second CD4 test among pre-ART patients*

Among the 18 523 pre-ART patients, 2863 (15.5%) had had at least two CD4 tests done; 2295 (14.8%) were in the paper group, while 568 (18.6%) were in the EMR group. The median time from baseline to first follow-up CD4 test was 7.5 months (IQR 5.97–10.73) for paper and 6.53 months (IQR 5.57–7.87) for EMR. Figure 2 shows the Kaplan–Meier curves for the time from first to second CD4 test. Six months after the first CD4 test, 25.7% (95% CI 24.0–27.5) of patients had had a second CD4 test for the paper-based system compared to 35.0% (95% CI 31.2–39.1) using the EMR system. The hazard ratio of conducting a second CD4 test was 1.78 (95% CI 1.30–2.46). After adjusting for patient age and sex, level of health facility, and year of change of treatment guidelines, EMR use was associated with a 49% higher hazard of conducting a second CD4 test (aHR 2.09; 95% CI 1.41–3.09).

Among the patients enrolled on pre-ART HIV care, 1591 (8.6%) and 914 (4.9%) had at least three and four CD4 tests, respectively. The intervals between the successive tests were comparable to the time from first to second CD4 test.

## 4. Discussion

EMR use was associated with better adherence to the pre-ART care guidelines in all three of the outcome measures. The clinical guidelines[13] require that a baseline CD4 test be conducted at enrolment; however, only 41% of the patients had a baseline CD4 recorded. Among those with a recorded baseline CD4, two-thirds of patients in the paper system and three-quarters in the EMR had a baseline CD4 test 3 months after enrolment into pre-ART care. The EMR was associated with a 59% increase in the odds of performing a baseline CD4 test. There was a significant reduction in time from enrolment into pre-ART care to the first CD4 test. EMR use was associated with a 47% higher hazard of conducting a baseline CD4 test. The proportion of patients who had had a second CD4 test 6 months after the first one was low. Only 26% (paper) and 35% (EMR) of patients had had a second CD4 at 6 months as required in the ART guidelines. The median time from first to second CD4 test using the EMR was closer to the recommended 6 months compared to the paper system.

Although not reported in the results section, we found data quality to be better in the EMR compared to the paper system. For example, key data elements such as date of CD4 test and CD4 results were three times more likely to be missing in the paper system compared to the EMR. This could be attributed to the fact that the EMR contains mandatory fields that must be entered, resulting in fewer missing values. Data clerks also add a layer of data quality checking during data entry into the EMR and consult with clinicians when they encounter missing values. In some cases, results are lost between the laboratory and the data entry room. In such cases, even the EMR was not able to improve the completeness of recorded data and this could have contributed to the missing CD4 results as reported in this paper. Some CD4 tests, mainly in the EMR group, were conducted earlier than the 6 months stipulated in the guidelines. An earlier CD4 test can be ordered if a clinician suspects HIV treatment failure or if a previous CD4 test was conducted when a patient had an acute illness.

The findings of our study are consistent with those of studies by Williams and Boren,[10] Alamo et al.,[14] and Were et al.,[15] which were also conducted in resource-constrained settings. These studies showed that EMR use was associated with a reduction in time to various events such as patient waiting time, time spent by clinicians attending to patients, and time to order a laboratory test in HIV clinics. The three studies above were each conducted in a single clinic, with a relatively small sample size compared to our study.

One of the key strengths of the present study is that the data were collected from 17 clinics thereby providing a large and general patient population. All the clinics use the same guidelines[13] and the same EMR, hence the patient management procedures, administrative procedures, drug regimens, and laboratory investigations are standardized.

Our study was limited by some factors. EMRs are still not fully used at the point of care, mainly due to infrastructure problems such as a lack of reliable electric power. The clinics have, however, made every effort to ensure that the time between the consultation and the entry of the records into the computer is as short as possible so that clinical staff can provide any missing data or act on incorrect data promptly. We also dropped records that did not have an enrolment date recorded and imputed CD4 dates in cases where CD4 results were recorded but the CD4 test date was missing. Nearly 60% of the patients did not have a CD4 test result recorded. This was due to a combination of data quality problems, missed orders, and missing or lost results from the laboratory. Other contributing factors could be limited access to CD4 tests in rural areas, where the study sites are located, equipment breakdown, stock out of test reagents, inadequate staff in the laboratory, and clinicians being unaware of the guidelines. Due to the retrospective nature of our study, we were not able to pinpoint the contribution of each of the aforementioned reasons to missing CD4 test results. We were also unable to quantify the fraction of missing data that required additional consultation between the data clerk and clinician. However, the data clerks and clinicians indicated that the missing information that required consultations reduced with time. Additionally, due to the retrospective, observational, before-and-after design of this study we were not able to determine a cause and effect relationship between the use of the EMR and the outcome variables. Some of the outcomes could have been effected temporal changes, such as improved practice, delivery of supplies, and improved laboratory equipment. Further investigations on the strength of associations between EMR use and the outcomes described in this study need to be assessed through a prospective randomized controlled trial.

With regard to the implications of the study, the EMR seems to have improved quality of patient care. As many health care systems in developing countries increase investment in these technologies in order to provide quality care to the increasing volumes of HIV patients, there is need for the quantification of

empirical evidence of the impact of such interventions on quality of care. In a competitive funding environment, only technologies that have been shown to be positively associated with adherence to guidelines and better quality of care justify funding. This study therefore adds to the body of knowledge that will inform the deployment of EMRs in resource-limited settings like Kenya. Additionally, the data presented in this study show that there is need to improve the timeliness of conducting CD4 tests.

Further work on evaluation of the use of clinical decision support functionality of an EMR on compliance with pre-ART guidelines is needed to provide a more complete picture of the effect of EMRs. Specifically, there is need to assess whether the benefits of point-of-care use of EMRs with decision support systems in resource-limited settings can be similar to those documented in developed countries.[16,17]

In conclusion, our study demonstrated the use of the EMR to be positively associated with enhanced compliance with key quality indicators for pre-ART care, as required by the HIV treatment guidelines. EMRs have a potential positive impact on quality of care for HIV patients in the resource-constrained setting. However, there is still the need for much greater improvement.

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*Conflict of interest*: None.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijid.2014.06.004.

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