The Structure and Outcomes of a HIV Postexposure Prophylaxis Program in a High HIV Prevalence Setup in Western Kenya

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Background: In 2001, HIV postexposure prophylaxis (PEP) was initiated in western Kenya.

Methods: Design, implementation, and evolution of the PEP program are described. Patient data were analyzed for reasons, time to initiation, and PEP outcome.

Results: Occupational PEP was initiated first followed by nonoccupational PEP (nPEP). Antiretroviral regimens were based upon national PEP guidelines, affordability and availability, and prevailing HIV prevalence. Emerging side effects data and cost improvements influenced regimen changes. Between November 2001 and December 2006, 446 patients sought PEP. Occupational exposure: 91 patients: 51 males; 72 accepted HIV testing; 48 of 52 source patients were HIV infected; median exposure—PEP time 3 hours (range: 0.3–96 hours). Of 72 HIV-negative patients receiving PEP, 3 discontinued, 69 completed, and 23 performed post-PEP HIV RNA polymerase chain reaction (all negative). Eleven follow-up HIV enzyme-linked immunosorbent assay tests have all turned negative. Nonoccupational exposure: 355 patients; 285 females; 90 children; 300 accepted HIV testing; median exposure—nPEP time 19 hours (range: 1–672 hours). Of 296 HIV-negative patients on nPEP, 1 died, 15 discontinued, 104 are on record having completed PEP, and 129 returned for 6-week HIV RNA polymerase chain reaction (1 patient tested positive). Eighty-seven follow-up HIV enzyme-linked immunosorbent assay tests have all turned negative.

Conclusions: It is feasible to provide PEP and nPEP in resource-constrained settings.

Key Words: health care worker, HIV, postexposure prophylaxis, sexual assault

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INTRODUCTION

The Center for Disease Control (CDC) estimates the risk of occupational transmission of HIV to range between 0.09% and 0.3% after exposure to HIV-infected blood and body fluids.[1] This risk varies with the type (percutaneous vs. mucous membrane) and severity (increasing volume of blood and high viral load) of exposure.[2] The CDC also estimates the risk of per-act transmission of HIV for nonoccupational exposures to HIV to range between 0.005% and 0.5%.[3] This risk is highest for blood transfusion, needle sharing among injection drug users, and such forms of sexual intercourse as penetrative anal and vaginal. The risk of occupational and nonoccupational HIV infection in sub-Saharan Africa could be higher considering the region's high HIV prevalence, the large number of untreated HIV-infected patients, and their delayed presentation to care.[4–7] Although data on the incidence and types of occupational injuries in Africa are limited, a cross-sectional survey of Kenyan hospitals found that 20% of health care workers (HCWs) had a recent potential HIV exposure related to their work, and among these, half had experienced multiple exposures.[8] In a report from South Africa, 13% of HCWs had sustained injuries where the source patient was documented to be HIV infected.[9] A multicenter study from West Africa reported that 46% of HCWs had been exposed to blood with the most common mode of exposure being percutaneous injuries. The majority of source patients in this study were untested (73%) with 13% of those tested being documented as HIV infected.[10]

Both nonoccupational exposure from sexual assault and occupational exposure are physically, psychologically, and emotionally distressing.[11–14] For HIV-exposed individuals, the knowledge that it is possible to minimize the risk of HIV transmission with the use of antiretrovirals (ARVs) may decrease psychological stress. Despite the absence of a randomized clinical trial on efficacy of HIV postexposure prophylaxis (PEP), there is significant evidence from animal transmission models,[15,16] perinatal HIV transmission prevention studies,[17–19] observational studies,[20] studies of PEP in

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HCWs,[21] and meta-analyses[22,23] indicating that PEP is effective in reducing HIV transmission. As such, there is a current consensus that HIV prophylaxis should be provided immediately after an exposure where there is judged to be risk of HIV acquisition.[1,3,22,23]

In late 2001, the Academic Model for Prevention and Treatment of HIV (AMPATH) initiated a trial occupational HIV PEP program at a public referral hospital in western Kenya to provide care to HCWs and gain operational experience in PEP implementation and management. This program was later rolled out to multiple sites across western Kenya and expanded to include nonoccupational postexposure prophylaxis (nPEP), which was provided largely to victims of sexual assault. In the study documented below, we describe the development and evolution of the PEP and nPEP treatment program and protocols since they were first introduced at the national referral hospital in western Kenya. We also present analysis of patient characteristics, exposures, and PEP outcomes.

METHODS

Study Design

The Moi Teaching and Referral Hospital (MTRH)/Moi University School of Medicine Institutional Review and Ethics Committee and the Indiana University School of Medicine Institutional Review Board approved the study. This retrospective cohort study used electronic medical records of patients enrolled for HIV PEP and nPEP between November 2001 and December 2006.

Study Site

This study was conducted at the MTRH in Eldoret, Kenya, which employs over 2000 HCWs. The US Agency for International Development–Academic Model for Prevention and Treatment of HIV (USAID–AMPATH) partnership provides HIV care to over 80,000 patients in western Kenya at within MTRH and 17 other clinic sites.[24] HIV PEP/nPEP programs are now incorporated into the care programs at all sites.

Structure of the HIV PEP/nPEP Program at MTRH

Occupational PEP is provided to HCWs who have been exposed to blood and body fluids in the course of their duties. nPEP is offered to individuals who have been sexually assaulted, have experienced condom malfunction, human bites, or have had contact with blood and body fluids of an individual who is either known or suspected of being HIV infected. At the beginning of this program in November 2001, all occupational exposures in our hospital were deemed to be "high risk" because the prevalence of HIV on the inpatient wards was extremely high (up to 50% in some wards). All nonoccupational exposures were also considered "high risk" for several reasons. First, it was anticipated, at the development of the nPEP protocols, that the majority of exposures would be from sexual assault given the increasing number of rape cases presenting to hospital casualty and the countrywide increase in sexual assault cases (Kenya Police Crime Reports, 1997–2003). Because of its association with genital trauma,[11] we assumed that sexual assault would increase the risk of contracting HIV. Second, we expected that a substantial number of nPEP seekers were caregivers exposed to blood and body fluids of HIV-infected patients. Third, all exposures occurred in the background of a national HIV prevalence estimated at 15% (Ministry of Health HIV sentinel surveillance data for 2000). By unifying both occupational and nonoccupational exposure risks into 1 "high-risk" category, we were able to use the only treatment regimen available to us at that time. This strategy also allowed us to introduce PEP at our emergency department without much resistance from an already overstretched workforce (as opposed to the extra workload of evaluating risk category, deciding on whether to treat and with what combination of ARVs). Also, because this regimen was similar to the one for antiretroviral therapy (ART) and for prevention of mother-to-child transmission of HIV, both of which had recently been introduced, we felt that confusion and prescription errors would be minimized. In 2007, after increasing financial and human resources at our site and new data from population-based HIV testing (HIV prevalence 6.7%[25]; less than half of that initially reported), the program shifted to performing more risk assessments and categorizing patients into 3 risk groups as: (1) low risk (no ART); (2) intermediate risk (dual ART); and (3) high risk (triple ART).

At the beginning of the HIV PEP/nPEP program, a triple combination of stavudine [40 mg (30 mg for patients $<$60 kg) twice daily], lamivudine (150 mg twice daily), and nevirapine (200 mg once daily for 14 days and escalated to 200 mg twice daily thereafter) was used as standard prophylaxis. The total duration of PEP was 28 days. The use of triple combination ARVs as prophylaxis for "high-risk" exposures was in accordance with the national ARV guidelines for PEP [National AIDS and Sexually Transmitted Infection Control Program, Ministry of Health, Government of Kenya, 2002]. The initial choice of ARVs was largely influenced by availability and cost. In 2005, we changed our standard PEP/nPEP regimen for "high-risk" exposures to combination zidovudine (300 mg twice daily), lamivudine (150 mg twice daily), and lopinavir/ritonavir (lopinavir 400 mg + ritonavir 100 mg twice daily). This change resulted from our experience with a fatal ARV-induced hepatitis in a patient receiving our initial nevirapine-based nPEP regimen. Emerging toxicity concerns and new black box warnings about the use of nevirapine in individuals with high CD4 cell counts also influenced this decision.[26,27] Similarly, concerns about stavudine-related toxicities[28] in healthy patients led to its substitution with zidovudine.

The goal of the program is to initiate ART within 15 minutes–2 hours of exposure and no later than 48 hours for occupational and 72 hours for nonoccupational exposures (Fig. 1). At the time of starting this program, the CDC recommended PEP initiation within 24–36 hours for occupational exposure.[29] Because there was not much evidence that PEP was ineffective thereafter, we opted for 48 hours. For nonoccupational exposures, we based our timing on an earlier CDC publication recommending nPEP within 72 hours.[30] HCWs are advised to swallow the first dose of combination antiretroviral therapy at the time the exposure occurs before

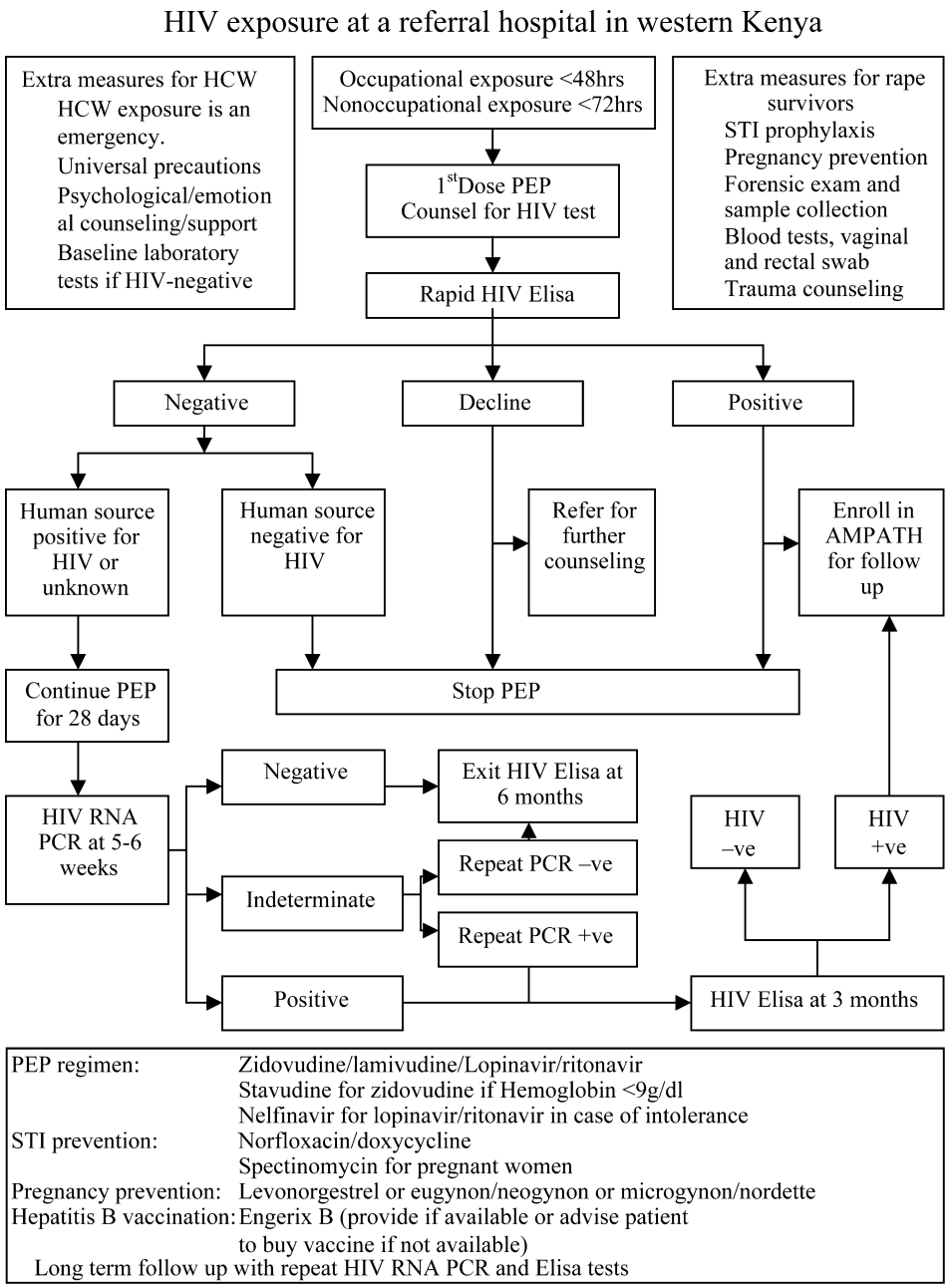

FIGURE 1. Algorithm for evaluation and treatment of occupational and nonoccupational HIV exposure at the MTRH in western Kenya.

seeking further treatment. For this reason, ARVs are kept at easily accessible locations within the hospital and are available 24 hours per day. Patients with nonoccupational exposure are given their first ART dose immediately upon presentation to the hospital casualty department.

We perform HIV testing in the majority of patients who come to our hospital under the Provider Initiated Counseling and Testing program. Therefore, HIV test results are usually available for source patients and, if not, it is mandatory for the patient to be approached immediately and counseled for HIV testing. All exposed individuals get a full clinical examination and laboratory evaluation that includes HIV rapid test, a complete blood count, liver enzymes (alanine aminotransferase and aspartate aminotransferase), renal function tests (urea and creatinine), and hepatitis B surface antigen. Because of resource constraints, laboratory tests are repeated only if there is clinical indication. Additional care for sexually assaulted patients include pregnancy test, collection of rectal and vaginal swabs for bacterial culture and sensitivity testing, prophylaxis against sexually transmitted infections, trauma counseling, and emergency contraception. If available, vaccination against hepatitis B is given to patients testing negative for hepatitis B surface antigen. Patients who agree to a HIV test and turn out to be negative are asked to continue ARVs to completion. These patients are seen after 2 weeks to assess side effects and adherence, at 4 weeks to confirm

TABLE 1. Demographic, Clinical and Risk Characteristics of Patients Seeking PEP At a National Referral Hospital in Western Kenya

Characteristic	Occupational Exposure (n = 91), No. (%)	Nonoccupational Exposure (n = 355), No. (%)
Demographic		
Male	51 (56)	70 (19)
Female	40 (44)	285 (81)
Adult	91 (100)	264 (75)
Children	—	90 (25)
HIV status of PEP seekers		
Negative	72 (79)	296 (83)
Positive	0 (0)	4 (1)
Declined test	19 (21)	55 (16)
HIV status of source	n = 52	n = 34
Negative	4 (8)	—
Positive	48 (92)	—
Occupational exposure		
Hollow-bore needle injury	61 (67)	—
Solid needle injury	13 (14)	—
Mucocutaneous exposure	12 (13)	—
Scalpel injury	4 (4)	—
Microscope slide injury	1 (1)	—
Nonoccupational exposure (%)		
Adult (female) rape	—	186 (52)
Child (female) rape	—	91 (26)
Rectal (male) rape	—	15 (4)
Adult	—	9
Children	—	6
Human bite	—	8 (2)
Other*	—	53 (15)
Identity of assailant	—	n = 276
Known related/unrelated	—	55 (20)
Known undisclosed	—	104 (38)
Unknown	—	117 (42%)
Time to PEP (hrs)	—	n = 320
Median (range)	3 (0.3–96)	19 (1–672)

*Other: unprotected consensual sex, condom malfunction, barber injury, contact with open wounds while nursing patient/relative.

PEP/nPEP completion, and at 5–6 weeks after PEP/nPEP initiation for a HIV RNA polymerase chain reaction (PCR) test. Exit HIV enzyme-linked immunosorbent assay (ELISA) testing is performed 3–6 months thereafter. Further details on management of the exposed patient are given in Figure 1.

Data Collection and Management

At the initial visit, demographic, risk characteristics, clinical, laboratory, and treatment data were entered in a structured initial encounter form. On subsequent visits, treatment adherence and side effects data, additional laboratory results, and any interventions such as further counseling were recorded on a return visit form. Data from both forms were entered into the AMPATH Medical Records System, a secure, fully electronic medical database whose quality is controlled by random assessment of 10% of all entries. These data were later abstracted and striped of all patient identifiers before analysis.

Statistical Analysis

Descriptive statistics such as median and range were generated for the continuous variables. Frequency tables were produced for categorical variables and these were compared via the χ^2 test. Patients were considered to have completed ARV prophylaxis only if this was confirmed on or after the 4-week follow-up appointment. Being on record as having a HIV RNA PCR test alone did not qualify patients to have completed prophylactic treatment. Similarly, patients who discontinued ARVs due to side effects were considered not to have completed PEP. Patients were considered lost to follow-up if they did not attend the 4-week follow-up appointment and did not perform RNA PCR or HIV ELISA tests at the designated times. Because the regimens used for PEP and nPEP were identical, the side effects reported by patients in both groups were summarized and analyzed jointly.

RESULTS

A total of 446 occupational and nonoccupational exposures were reported between November 2001 and December 2006. This figure represents all the patients who sought PEP in the period of this study. All patients were classified as having "high-risk" exposures (reasons explained in Methods section). The demographic, clinical, and risk characteristics of patients seeking PEP/NPEP are provided in Table 1. There were 91 HCWs (56% male) with occupational exposure. The cadres of exposed HCWs are as follows: 28% nurses, 22% medical and nursing students, 20% doctors (surgeons being the majority), 8% patient attendants, 7% clinical officers (equivalent of nurse practitioner), and the remaining (phlebotomists, laboratory technologists, public health officers, record clerks, and hospital security officers) accounted for 15%. The most frequent types of exposure were hollow-bore needle injury (67%), solid needle injury (14%), mucocutaneous exposure (13%), and scalpel injury (8%). Of the 72 HCWs (79%) who agreed to a baseline HIV test, all were negative. The HIV status of 52 source patients was known of which 48 (92%) were HIV infected. The median time from exposure to initiation of PEP was 3 hours (range: 0.3–96 hours) with 84% of HCWs presenting within the recommended 48 hours. No HCW refused the first dose of ARVs. The 4 HCWs whose source patient had a negative HIV test opted to continue PEP. Therefore, all (72) HIV-negative HCWs were expected to continue PEP to completion. Three (4%) HCWs discontinued PEP due to severe side effects and the remainder reported completing their ARV dosage. Even though all HCWs were and still are available and known individually to us, only 23 (32%) presented for HIV RNA PCR testing between weeks 5 and 6 of initiating PEP; all tested negative. To date, only 11 HCWs have had a follow-up HIV ELISA test; all were negative.

There were 355 nonoccupational exposures (81% female; 25% <13 years). Sexual assault was reported by 292 (82%) of exposed individuals with unprotected consensual sex, condom malfunction, human bites, exposure to body

fluids of individuals suspected to be HIV infected, and barber cuts accounting for the remainder. The cases of sexual assault were categorized as follows: 189 (64%) adult female rape; 91 (31%) child female rape; and 15 (5%) rectal rape (60% children; all male). The assailant(s) was/were known to the victim in 58% of cases. The majority (83%) of exposed individuals accepted baseline HIV –testing, and among those tested, the HIV prevalence was 1%. The median time from exposure to initiation of nPEP was 19 hours (range: 1–672 hours) with 86% of the patients presenting within 72 hours. No patient was reported to have refused the first dose of ARVs. ARVs were discontinued in 59 patients after the first doses because they either refused HIV testing (55) or were identified as HIV infected (4). Of the remaining 296 HIV-negative exposed individuals advised to continue nPEP to completion, 1 (0.3%) died, 15 (5%) discontinued because of side effects, 104 (35%) completed treatment, and 129 performed the 6-week HIV RNA PCR test. A total of 155 patients (52% of the 296 patients advised to complete nPEP) were lost to follow-up. Although patients lost to follow-up were predominantly female (82%), adult (57%), and on nevirapine-based nPEP (45%), none of these characteristics was statistically different from the entire cohort of patients with nonoccupational exposure. To date, 129 patients on nPEP have had a follow-up HIV RNA PCR test performed resulting in 1 positive test. This child was sexually assaulted, presented within 4 hours of assault, and completed nPEP. However, no follow-up HIV ELISA test result is available for her. Follow-up HIV ELISA tests have been performed on a total of 87 patients so far; all were negative.

With regard to ARV regimens prescribed to all patients (PEP and nPEP), 37% received stavudine/lamivudine/nevirapine and 63% received zidovudine/lamivudine/lopinavir–ritonavir. There were no statistically significant differences in the frequency of reported side effects between patients in the nevirapine arm (21%) and those in the lopinavir/ritonavir (14%) arm ($P = 0.44$). The most frequently reported side effects were epigastric pain, skin rash, and nausea in the nevirapine arm and diarrhea, dizziness, and epigastric discomfort in the lopinavir/ritonavir arm. There were no differences in ART completion rates between the 2 regimens ($P = 0.91$). The 1 death complicating the nevirapine treatment group was related to ARV-associated acute hepatitis after nPEP for sexual assault.

DISCUSSION

Though this is the largest documented public sector HIV PEP program in Kenya, based on the work of the Population Council on occupational injuries,[8] we feel that the number of HCWs presenting for HIV PEP is a fraction of those requiring it. We also suspect that sexual assault cases were underreported due to the culture of silence after rape.[25,31] In addition to lower than anticipated referral rates, this study raised other key issues with the provision of PEP/nPEP in our environment including the significant number of exposed individuals who declined HIV testing. It is unclear whether this is related to prior knowledge of their HIV status or fear of testing positive. Further exploration of this issue will need to be undertaken to ensure that all PEP-eligible individuals receive appropriate treatment. The same issues related to immediate postexposure testing may also be related to why a significant number of HCWs did not return for follow-up HIV RNA PCR and ELISA testing.

The sizeable proportion of exposed individuals presenting outside of the period during which prophylactic ARVs are recommended is of concern. Although in the formative stages of the program we allowed physicians to prescribe PEP at their discretion for such patients who presented late, this practice was stopped after availability of more data showing that initiating PEP after a certain period after exposure is ineffective.[1,3] We anticipate that with increased health care provider and community education, awareness of the need to present early after exposure will improve, resulting in fewer individuals presenting outside of the recommended treatment window.

The low rate of significant side effects in both the nevirapine-based and lopinavir/ritonavir-based treatment regimens was overshadowed by the death in the nevirapine group. Because of this death and pharmacosurveillance data indicating that individuals with high CD4 counts were more likely to have significant reactions to nevirapine,[26,27] we opted to provide a protease inhibitor–based regimen to our PEP clients. Because of these toxicity concerns, we strongly recommend that programs considering initiating a PEP protocol use either an efavirenz-based or protease inhibitor–based regimen.

The high prevalence of HIV infection in source patients raises significant concerns about the risk of occupational infection for HCWs and workplace safety standards. Protection of HCWs through limiting injections, safe needle and sharps disposal, continuing education on universal precautions, and HIV PEP availability are paramount in this and other similar settings. Health facilities need to have a well-defined emergency plan and system in place that allows for rapid assessment and initiation of PEP. In addition, in the unfortunate event that HIV PEP is unsuccessful, HCWs need to be assured of adequate compensation and uninterrupted medical care.

Weaknesses identified in this study include the relatively large proportion of individuals refusing baseline HIV testing and the high loss to follow-up rate. Other PEP programs have reported similarly high rates of losses to follow-up, implying that this problem is not unique to our program.[32–36] In a recent meeting between our program leadership and key personnel working directly with nPEP seekers, the following reasons were advanced as contributing to the high loss to follow-up rate. (1) Multiple stops at some of the scheduled clinic visits (emergency room/casualty, gynecology consultation, laboratory, legal clinic, and ART pharmacy; all of which are located in different places. (2) Non synchronization of clinic appointments. For instance, a patient might be scheduled to attend the legal clinic on a different day than ART pharmacy. (3) Charging patients for some of the services might be a deterrent to some patients. (4) Lack of an active follow-up program for patients who miss their appointments. (5) Confidentiality concerns including fear of stigmatization if the patients are seen collecting ARV medications from the

ART pharmacy. (6) Untoward effects of ART causing patients to decline their medications and subsequent clinic appointments. We would like to recommend centralization of PEP services (a one-stop shop) to improve coordination and supervision. Centralized services might also reduce the number of clinic visit. We also recommend introduction of active patient tracing programs. Greater efforts to educate the community, in general, and patients, in particular, regarding the importance of adhering to clinic appointments are also warranted.

The absence of data from those who were lost to follow-up makes it difficult to fully explore the toxicities of PEP and its effectiveness in preventing HIV acquisition. However, because our data are derived from a clinical program, it reflects the real life challenges of administering a HIV PEP program. Such data can identify potentially problematic issues related to PEP programs including the need to strengthen patient retention procedures.

CONCLUSIONS

Substantial rates of HIV testing refusal, delay to presentation, ARV discontinuation, and loss to follow-up are noted among patients seeking occupational and nonoccupational HIV PEP in western Kenya. Despite these issues, data from this program give us insight into the magnitude of the problem, the mechanics of providing care, and identifies areas for improvement with regard to HIV testing, PEP access, and delivery. Despite the identified logistical issues, this program has demonstrated that HIV PEP and nPEP can be provided in a high HIV prevalence resource-constrained setting. We advocate the expansion of such programs in sub-Saharan African as a means to protecting HCWs, a scarce and valuable resource within our region, and individuals from the community, the majority of who are victims of sexual assault.

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