A step-wedge simple randomized trial to assess the use of Case Managers to Increase Linkage to HIV Care and Early retention of Newly Diagnosed HIV-positive Persons at a regional Referral Hospital in Western, Kenya

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Abstract- Linkage of newly diagnosed HIV positive individuals to HIV care and treatment services is essential to initiate lifesaving antiretroviral therapy and thereby reduce HIV transmission. However, program data has shown that only 38% of newly diagnosed HIV patients in Kenya are linked to care. Case management model, a model with proven efficacy, uses case managers to provide strength based counseling that enable individuals identify their internal strengths and assets needed to facilitate linkage and enhance retention. This evaluation seeks to test the efficacy of using case managers in increasing linkage and early retention to HIV care among newly diagnosed HIV positive individuals at a referral hospital in Western Kenya within one year and including a six month follow up period by comparing linkage and retention rates among HIV infected persons who receive case managers to those who did not. A step-wedged design will be employed at 12 of the 24 hospital departments. This will be done by introducing the intervention in a phased approach by testing site. A minimum of 672 HIV infected persons will be recruited. Linkage to care will be defined as a recorded encounter at the HIV clinic's enrolment registry. Participants will be considered retained in care after attending two or more visits over a six month period. Data on participant characteristics, linkage and retention proportions and their associated factors will be analyzed in the early and late intervention groups. Results from this evaluation will provide information on improving linkage and retention rates among HIV infected patients.

Index Terms- HIV, Phased-approach, engagement in HIV care

I. BACKGROUND

A. Introduction

In 2014, 36.9 million people were living with HIV globally; there were 2.0 million new infectiosn and 1.2 million deaths [1]. In 2015, 2009 indicated that only around 49% of PLHIV in low and middle income coutnries who are in need of ART are actually on ART [2]. According to the Kenya Demographic and Health Survey of 2012, the national HIV prevalence among persons aged 15-64 years was 5.6%. In the same survey, Kisumu County of Kenya had a HIV prevalence of 18% [3].

In Africa, linkages rates among newly diagnosed HIV patients range from 23%-50% [4-6]. HIV treatment programs from Low and Middle Income Countries have an attrition rate of 21% six months after enrolment into HIV care [7]. In Kenya, 53% of HIV infected persons are not aware of their HIV infection. About 89% persons country-wide aged 15-64 years who were aware of their HIV infection were on care, 88% of those eligible for Antiretroviral Therapy (ART) were on ART; only 43% of those who initiated care remained in care [8]. At the Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH), a regional referral hospital in Western Kenya, only 38% of HIV infected persons are linked HIV care, and 83% of them are retained in care within 1-2 months, 76% within 3-4 months, and 61% within a one year period (L.Nguti, personal communication, October 22, 2014).

HIV test and treat strategies aim to mitigate the effects of HIV by increasing the coverage of HIV testing services, linking those tested to relevant HIV prevention, care and treatment services and ensure those linked to these services are managed appropriately [9]. This has been emphasized in UNAIDS' recent 90-90-90 treatment targets that aims to eliminate HIV by 2030 [10]. HIV testing is postulated to decrease HIV transmission by decreasing risky sexual behavior among all persons tested and decrease viral load among those who test HIV positive after ART initiation [11]. Delayed presentation or non-retention in HIV care places HIV-infected clients at risk for elevated morbidity and mortality [12] and reduces the long term benefits of ART as prevention [13].

Linkage to care has been defined as 'attending one or more clinic visits' [14], "documented CD4 T- cell counts results' or [15] or 'a scheduled visit with a health care provider who can manage ART' [16, 17] all within 6 months of HIV diagnosis. HIV biomarkers (CD4 count and plasma HIV viral load) are often evidence of a completed visit at a HIV clinic [18] . Other measures include, records of missed visits [17, 19], appointment adherence [20], visit constancy [19] and gaps in care [21].

Strength-based counseling, a strategy that includes building patient-provider relationships, improving family-patient relationships, identifying clients strengths, providing information and education, [22] and use of patient navigators [23], has been successfully used to improve linkage to HIV care after diagnoses [24]. JOOTRH which has low linkage and retention rates does not routinely use case managers. There is a need to test the efficacy of using case managers to improve linkage and early retention of newly diagnosed HIV-infected patients at JOOTRH.

B. Study Objectives

General objectives

To compare linkage and retention rates in care among newly diagnosed HIV-infected persons who have received case managers versus those who have not received case managers.

Specific objectives

1. To compare time from HIV diagnosis to first encounter (presentation at the HIV clinic registry) for newly diagnosed HIV-infected persons who have received case managers versus those who have not yet received case managers.
2. To compare proportion of patients enrolled to HIV care at the JOOTRH PSC among newly diagnosed HIV-infected persons who have received case managers versus those who have not yet received case managers.
3. To compare the attrition rates at enrolment, months two, four and six among newly diagnosed HIV-infected persons who have received case managers versus those who have not yet received case managers at the JOOTRH PSC.
4. To describe factors predictive of linkage among newly diagnosed HIV-infected patients and retention among newly diagnosed HIV-infected patients enrolled in care at JOOTRH PSC within the implementation period of the case manager's intervention.
5. To describe barriers to enrolment into HIV care for newly diagnosed HIV-infected patients and barriers to retention among newly diagnosed HIV-infected patients enrolled in care at JOOTRH PSC within the implementation period of the case manager's intervention.

II. METHODOLOGY

A. Study design and setting

A step-wedge design will be used to implement and evaluate the efficacy of using case manager's to improve linkage and early retention to HIV care and treatment at JOOTRH. The intervention will be implemented sequentially to participants over a specified time period. By the end of the implementation period, all the participants will have received the intervention [25]. The step-wedge design was chosen due to ethical, logistical and financial concerns. Since the intervention has been proven to work elsewhere, it would be unethical to deny some patients the intervention. Additionally, it was difficult to identify an alternative health facility to act as a control that would be comparable to JOOTRH in terms of support service package e.g. phone reminders on appointment dates, phone/home tracing of clients who fail to honour appointments, use of community health workers to monitor ART and to provide daily observed treatment for special populations (people of unsound mind), group therapy before and after enrolment,. Financial constrains also prevented the implementation of the intervention across all departments all at once. This thus justified the phased-approach to introducing the intervention at JOOTRH.

JOOTRH is a regional HIV referral facility accessible to Western Kenya and parts of Rift Valley regions. The hospital is located in the Southwest region of the country bordering Lake Victoria. It serves a population in excess of 5 million people and has a bed capacity of 457 with occupancy of approximately 95% [8]. Annually, it offers outpatient services to over 250,000 persons and inpatient services to approximately 21,000 persons. HTC services are offered to both patients and visitors at all service delivery points in the hospital. In 2011, approximately 6,000 persons were tested for HIV at the JOOTRH; 6.3% of persons never tested before they tested HIV positive [26].

JOOTRH has 24 departments where HIV testing is conducted. Only 12 of these departments will be used as evaluation sites, although all the 24 departments shall eventually implement the patient-linkage intervention. The 12 'evaluation-departments' shall be matched according to whether they are ambulatory or inpatient, and also whether the majority of the clients are men or women (Table 1). We shall purposively select one member of each pair into an early intervention group while the other will be in the midterm intervention group. The remaining departments, which do not form part of the 12 evaluation sites, will comprise the late-intervention group; data from the late-intervention group shall not be used in this evaluation.

Table 1: Assignment of departments into intervention phases

	PHASE 1	**PHASE 2**	**PHASE 3**
OPD	Consultant clinic	Children OPD	TB/HIV
	ANC	Post natal clinic	Dental
	Clinical room 8	VCT	FP
			Clinical room 9
			GBVRC
			Mortuary
			ENT
IPD	Male Surgical	Male Medical	Gynecology ward
	Maternity	Eye Clinic	Female Surgical
	Children IPD	Casualty	Female Medical

			Eye Ward
			Oncology ward

The intervention will implemented every three months until full coverage of all hospital units is achieved over a nine month period. Implementation will start in six units while 18 units continue to provide routine services. After a three month period, the units will be increased to 12 units and the remaining 12 units will continue to provide routine services. Finally, the intervention will be scaled to the remaining 12 units over a three month period. The intervention will continue to be implemented in the whole facility even after the end of the study period. All clients will be followed up for a period of 6 months. (Table 2).

Table 2: The step wedge design phases

		TIME IN MONTHS														
		Pre-implementation Months 0-2			Phase I enrolment Months 3-6			Phase II enrolment (phase I follow up) Months 6-8			Phase III enrolment (phase I & ii follow up) Months 9 onwards					
ARM	**CLINIC**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**
Phase I Early arm 6 clinics	**A**	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
	B	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
	C	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
	D	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
	E	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
	F	0	0	0	X	X	X	X	X	X	X	X	X	X	X	X
Phase ii arm 6 Middle clinics	**G**	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
	H	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
	I	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
	J	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
	K	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
	L	0	0	0	0	0	0	X	X	X	X	X	X	X	X	X
Phase iii Late intervention 12 clinics	**M**	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	N	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	O	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	P	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	Q	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	R	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	S	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	T	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	U	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	V	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	W	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X
	X	0	0	0	0	0	0	0	0	0	X	X	X	X	X	X

B. Study population

Participants will be;

1) Patients, visitors or persons accompanying patients who are drawn from the hospital's catchment area and opt to access HIV care and treatment services at JOOTRH.

i. Criteria for inclusion of subjects

Newly diagnosed HIV positive clients will be eligible for inclusion in the study if;

- Aged 18 years and above.
- Mature minors aged 15-17 years.
- Reside in the JOOTRH catchment area.
- Selected JOOTRH as their preferred referral hospital for HIV care.
- Able to speak English, Kiswahili, or Dholuo.
- Willing and able to provide informed consent for participation.
- Was attending the facility as an outpatient/visitor or had accompanied a patient to the facility.

ii. Criteria for exclusion of subjects

- Patients and persons who are unable to understand or provide informed consent.
- If it is observed that the person giving consent is possibly under the influence of alcohol and drugs, since participants' judgment and behavior may impair the validity of consent.
- Persons not drawn from the catchment area.
- Person who opts to access HIV care and treatment services elsewhere.
- In patients, some of whom may be drawn from outside Kisumu (and may prefer to access HIV care at other facilities) since JOOTRH is a referral hospital. The length of hospital stay may also be a hindrance to their inclusion.

C. Sample size determination

This was computed based on methods for sample size computation for stepped-wedge cluster randomized trials [27-30] . This entailed obtaining a standard sample size for an individual-randomized trial and multiplying it by the design effect to yield the required sample size.

The current linkage rate is 58% (control arm). The intervention is expected to increase the linkage rate by 20% (intervention arm). Using a power of 80%, a two-sided level of significance of 5% and a standard sample size equation for an individual-randomized trial on using STATA version 13.1, this yielded a sample size of 85 patients per arm.

From JOOTRH data, under standard care, the inter-department (inter-cluster) variation in rates $\left(\sigma_b^2\right)$, is 0.1042. The mean of linkage rates ($\overline{p}$) between the control (58%) and intervention (78%) groups is 68%. The intra-department variance $\left(\sigma_w^2\right)$, given as, $\overline{p}$ (1- $\overline{p}$), is 0.2176.

The intra-cluster correlation coefficient (ICC) calculated using the formula below is 0.3239.

$$\rho = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_w^2}$$

To obtain the desired sample size for our stepped-wedge cluster randomized trial, we multiply the standard sample size estimate by a design effect (*Deff*). Where *m* is the average number of individuals per departments (assuming all departments are of equal size) is 10 and ρ is the intra-cluster correlation coefficient.

$$Deff = 1 + (m-1)\rho$$

The design effect is 3.9.

The design effect (3.9) will be multiplied by the standard sample size per arm (85) to yield a sample size of 331.5 per arm. A sample size of 331.5 implies a total of 27.6 patients per department per arm since the study will be conducted in 12 departments. This is rounded off to a minimum of 28 patients per department. We will then have 56 in each department (28 in the control/pre-implementation arm and 28 in the intervention arm/implementation arm) giving a minimum sample size of 672 patients.

D. Sampling techniques

In the intervention arm, in each department, the 28 patients will consecutively be recruited. In the control arm, the 28 patients per department will consecutively be recruited too. Approximately 2-5 patients will be recruited daily in each department depending on the patient-volume.

E. Study Procedures

Standard procedures for HIV management at JOOTRH for the control arm

Standard procedures for HIV diagnosis at the HTC point

At JOOTRH, patients who have sought outpatient services and hospital visitors are usually offered HTC services by individuals certified by the National AIDS and STI Control Programme (NASCOP) to offer HIV testing and counseling.

Newly diagnosed HIV positive persons (patients/ visitors/ or people accompanying patients to the hospital) then undergo the following procedures in order to facilitate their linkage to care;

1. Obtaining their contact details which indicate their residence and directions to their workplace and and how the patient could be reached.Contact details also included a phone number.
2. An inquiry on where they wish to obtaing HIV care and treatment services. If the person is drawn from JOOTRH's catchment area, he or she has an option to also attend the HIV clinic at JOOTRH.
3. HIV infected persons are then referred to the HIV clinics of their choice and are advised to go there within 2-4 weeks. Those who do not return for subsequent visits are called 'no show'.

4. A follow-up phone call and/or home visit is made for persons who opted to receive HIV care and treatment services at JOOTRH who fail to turn up at the HIV clinic for enrolment within 4 weeks of a positive HIV diagnosis. This is done by peer educators and Community Health Workers (CHWs) with a view to determine reasons for "no show'and to further encourage linkage to care.

Standard procedures for HIV care and treatmetn at the HIV clinic

1. Upon arrival at the JOOTRH clinic, newly diagnosed HIV-infected persons presents referral forms at the reception, their names are entered in the pre-enrolment register, and cards with a pre-enrolment identity (ID) numbers are issued. These cards are then used in subsequent appointments.
2. The newly-diagnosed HIV-infected persons are then asked to attend a group counseling session where they are briefed on the clinic procedures and HIV care and treatment.
3. HIV infected persons are then requested to return for a second group counseling session within seven days when an enrolment ID number is issued and baseline laboratory tests (including CD4 counts) are ordered; they are then asked to return to pick results within 3- 5 days.
4. When they return, they are seen by a clinician and results of the laboratory tests are reviewed. Subsequently, they are initiated on the appropriate treatment and appointments are scheduled for the next visit. Those who do not return for any subsequent visits after the initial visit are called 'no return'.
5. If an appointment during the pre-enorlment phase is not honored, follow-up phone calls and/or home visits are made by peer educators and CHWs using the contacts provided at registration. This is done to determine the reasons for 'no return' and to further encourage 'return to care'. Tracing outcomes are then documented and patient clinic records updated.
6. Client exit interviews and patient flow analysis are periodically carried out as quality assurance measures.

The intervention arm: Case Managers' Intervention at the JOOTRH Patient Support Centre

Strength based case management uses of trained personnel to enable clients identify their internal strengths and barriers to successful linkage to HIV care [24]. Peer educators, who already have basic knowledge on HIV and trained in HIV counseling, will be recruited as case managers. They will receive refresher training on basic HIV counseling and on the study procedures. They will then be responsible for the following;

- Assisting newly diagnosed HIVinfected persons who select to attend the JOOTRH HIV clinic to navigate the hospital system.
- Providing strength-based counseling to identify and mitigate risk factors for non-enrolment/missed appointments. These factors, which will be identified during the counseling sessions, include disbelief of HIV serostatus, discomfort or negative perceptions of health care system or health care provider [31], feeling of wellness [32] lack of transportation [33], limited social support [34], alcoholism [35] and HIV stigma [36].
- Escorting the patient to ensure enrolment at the PSC.
- Maintaining contact with the client from HIV diagnosis up to six months post enrolment to provide continuous education on HIV related issues such as the basics on HIV disease, HIV disease progression, HIV care/ART, adherence, nutrition, and address the client's HIV and health related concerns such as disclosure and stigma.
- Conducting follow up for 'no show' to determine reasons for presenting at the HIV clinic, and 'no return' to determine reasons for not attending the next scheduled appointments. A maximum of 8 telephone attempts over a four week period will be made before concluding a 'no return'. Up to three home follow up attempts will be made to conclude a home visit for persons who could not traced by phone.

Implementation of the Case Managers' Intervention at the JOOTRH HIV Clinic

Patients enrolling in HIV care shortly after HIV diagnosis (within 4 weeks)

1. All newly diagnosed HIV positive persons will be assigned to a case manager who will be responsible for supporting them unitl enrolment at the HIV clinic and at months one, three and six after enrolment.
2. Immediately following HIV diagnosis, the case manager will assist newly diagnosed HIV positive persons who were referred to the JOOTRH HIV clinic, to navigate the hospital and to have the clinical issues that brought them addressed.
3. The Case manager will then provide strength based counseling to identify and mitigate risk factors for non-enrolment/missed appointments.
4. The Case manager will guide the newly diagnosed HIV infected person for pre-enrolment counseling (as described in the standard procedure) and ensure the patients is registered at the pre-enrolment registry
5. The Case manager is responsible for all tracking all subsequent follow up visits through telephone calls and home follow up (if necessary) until all scheduled visits within a 6 months period after enrolment have been honored.
6. The case manager will maintain contact with the newly diagnosed HIV infected person from time of HIV diagnosis up to six months post enrolment, provide continuous education on HIV related issues and address the client's HIV and health related concerns.
7. The case manager will conduct phone follow up for clients who fail to return for appointments ('no return') after enrolment to determine reasons for no return. He will attempt to contact the participants on phone on eight different days over a four week period for a missed appointment. He will also conduct home visits to clients not traced by phone; up to three home follow up

attempts over a four week period will be made to conclude a home visit.

Patients who delay enrolling in HIV care after HIV diagnosis (after 4 weeks) 'no show'

1. The case manager assigned to a newly diagnosed HIV infected person will conduct phone follow up for clients who fail to enroll for HIV care within four weeks after HIV diagnosis ('no show') to determine reasons for not initiating care after enrolment. The case manager will attempt to contact him/her on eight different days over a four week period. Homevisits to will be carried out for persons not traced by phone; up to three home follow up attempts over a four week period will be made to conclude a home visit. Procedures 1-7 will be followed for persons who opt to enroll at the JOOTRH HIV clinic who are found on tracing.

F. Randomization

Upon diagnosis, newly diagnosed persons will be systematically randomized to either the 'standard of care' or 'Case managers' intervention'. The sampling interval will be two i.e. every second person diagnosed with HIV at each department is assigned to the intervention while the other gets the standard of care [37].

G. Outcome

The core-primary outcomes will be:

1) Documented linkage to HIV care. Linkage to HIV care will be defined as established encounter with the JOOTRH PSC at the pre-enrolment registry with the first initial CD4 result collected.

2) Documented retention to HIV care. Early retention in HIV care will be defined as attending two or more HIV clinic visits over a six month period.

3) Time-to-enrollment at PSC. Time-to-enrollment is defined as the difference between date of diagnosis and date of first presentation at the PSC.

H. Statiscial methods

Data collection

Quantitative data

The study data will consist of the information present in the registers that health providers routinely collect at each patient encounter using a set of pre-existing standardized forms or other type of medical record. These forms and data are based on the Kenyan national guidelines on HIV testing and counseling (HTC) and HIV care and treatment.

Initially, data on linkage and retention rate within a two month period during which routine services are offered will provide baseline information on which to compare subsequent phases of the study. Evaluation of linkage and early retention will be made through a 6-months follow up period for patients enrolled during the early and mid-term intervention groups. This will be compared among patients in the case managers group and those receiving routine services.

Data will be collected from all the 12 evaluation departments for a period of 13 months. The month at which we will begin data collection, shall be considered month-one.

Information deemed relevant to the study's objectives that will be abstracted will include records of HIV diagnosis, HIV care/ART initiation. These will include patient demographics (e.g. name, date of birth, occupation, etc), data of HIV diagnosis, referral source, date of enrolment into HIV care or treatment, date of first CD4 count, date of subsequent care/ART visit, health services they are receiving (including ART, prophylaxis, diagnosis, treatment of opportunistic infections, etc), CD4 count values and data from patient satisfaction surveys and patient flow analysis. This information will be collected using either scannable forms or sourced directly from the EMR system.

Each participant will be assigned a unique identifier. Any time the participant shows up for a visit and is part of the study, his/her unique identifier will indicate that they are part of the study.

Additional data will be collected from 'no show/no return' study participants using structured questionnaires which will be administered by trained case managers.

Qualitative data

Study interviews will be conducted by case managers for;

- Persons who selected JOOTRH as their preferred referral HIV clinic but failed to show up within 4 weeks of testing at the intervention sites; also known as no-show clients
- Persons who initiated HIV care at JOOTRH and missed any appointment within six months of enrolment at the intervention sites; also known as no-return

Data analysis

Data will be exported into STATA 13.1/SAS 9.2 Software for analysis. The explanatory variables will include patients' age, gender, date of HIV diagnosis, CD4 count at enrolment, and location of residence amongst others. Socio-demographic and clinical characteristics of the study participants will be described using descriptive statistics. Categorical variables will be compared using chi-square test and, where appropriate, the Fisher exact test. Continuous variables will be compared using t-test and, where applicable, the Wilcoxon test. The primary analysis will be at the individual-level and the secondary analysis will be at the department-level.

We will employ data analysis methods for stepped-wedge cluster randomized design [38-40]. For the individual-level analysis in the "linkage to HIV care" outcome, we will compare proportion linked to HIV care between the two arms using Mixed Effects Regression Models. The departments and calendar-time will be considered as the random effects variables the other covariates will be fixed effects. This model, in essence, will account for clustering within departments and time effects. We will also explore potential interaction between department and calendar-time. Potential factors predictive of linkage to care will be assessed from the model. For the department-level analysis, weighted t-test will be employed. The t-test will be weighted by the number of patients per department since we anticipate the number of participants per departments will vary. The intention-to-treat analysis will be employed. Analysis of "retention to HIV care" outcome will be analogous to the "linkage to HIV care" outcome.

For the "time-to-enrollment" outcome, Kaplan Meier curves will be used to describe time-to-enrollment at the PSC. The Log rank test will be used to determine differences in time-to-enrollment between comparison groups. Cox proportional hazards regression model will be used to evaluate the association between time-to-enrollment at the PSC and covariates such as patients' age, gender, date of HIV diagnosis, CD4 count at enrolment, and location of residence. Statistical analysis will be performed using STATA version 13.1 (StataCorp, College Station, Texas, USA) and p-value of less than 0.05 will be used to define statistical significance.

To evaluate factors influencing linkage to HIV care for the qualitative data, content analysis of the transcripts will be coded and thematically analyzed using NVIVO version 8 software. Deductive and inductive codes will be used. Ranking of identified factors will be performed using participants' response density as well as the Delphi process of investigator assessment.

I. Ethical considerations

Informed Consent of Participants

After a HIV positive diagnosis and prior to recruitment to the study, the Counselor and participant will go through the informed consent process. An informed oral consent will be required for participation in the study. The informed consent process will be administered in the language the participant feels most comfortable, in English, Kiswahili or Dholuo. The participant will be informed of the new referral procedures as described in the intervention. A detailed description of all procedures including period of study will be explained.

Confidentiality of data

No personal identifiers will be collected for the data analysis. The study team will take measures to ensure that all the information collected remain private. All data collected will be kept secured, in locked storage spaces or in password-protected files and computers for the digital files. Furthermore, all staff will be trained in ethical procedures and measures to protect confidentiality; they will be required to sign confidentiality agreements.

Institutional Review Board oversight

Ethical approval for the conduct of this study will be sought and obtained from the KEMRI and JOOTRH ethical review committees. A request will be made to CDC for reliance as per the KEMRI-CDC blanket reliance agreement.

III. DISCUSSION

A. Potential risk to participants

Primarily, participants risk loss of privacy. This loss of privacy may result from disclosing personal information before and after HIV testing procedures or simply from being seen participating in the study. The choice of preferred referral site will not alter the services to be offered at during HIV testing.

B. Potential benefits to study participations

Participants will have the opportunity to access HTC services and to be referred to relevant HIV health services. All the participants who opt to initiate HIV care and treatment at JOOTRH will be assigned a case manager to support them in navigating the health care system until care is initiated. This participant will also benefit from regular phone follow up to ensure he/she is retained in care.

The main benefit for participants in this study will be their contribution to informing, and improving HIV prevention, care, and treatment interventions among HIV-positive clients. In addition to the direct benefits from their participation, participants may indirectly benefit from the improvement of HIV prevention, care, and treatment services within their communities. As such, the potential risks of participating in this assessment are offset by the benefits to the individual participants and the wider community.

C. Study limitations and potential sources of bias

There is a probability of contamination between patients in the intervention arm (case managers) and patients in the control arm (standard care) during the conduct of the study when these patients meet at the HIV clinic, support group meetings and outside the hospital. We will attempt to mitigate this by a large sample size based on within and between cluster differences and the design effect.

The step wedge design is biased due to different lengths of duration allocated to the control and intervention arms of each unit/participant in the study. We will control for this by doing a contemporaneous analysis across clusters (see data analysis section).

There is a possibility of selection bias in the units that are selected for implementation of the intervention. We have attempted to reduce this via stratification of the units in order to have an equal representation of ambulatory and in patient units and both genders.

The data analysis method may overestimate or underestimate standard errors; to counteract this, analysis will be done at the individual level and the cluster level (departmental).

D. Expected application of results

The primary purpose of this intervention is to increase linkage and early retention in care of newly positive HIV persons. In addition, data concerning the barriers to accessing HIV care will enable improvement of service. Findings from the study will be presented to JOOTRH and personnel providing care to the population. Findings may also be disseminated through conference presentations, abstracts, and/or peer-reviewed journal publications. The data will be owned by KEMRI/CDC. Data will available to other organizations upon request. No identifying information will be collected; therefore, all of the disseminated results will be anonymous.

We anticipate demonstrating the efficacy of using case managers in improving linkage and retention in HIV care among newly diagnosed HIV- infected persons**.** The intervention will be scaled up to other departments within JOOTRH should it realize the desired results.

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Competing interests: None

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