Development of a screening tool to improve the yield of HIV testing in Provider Initiated HIV testing and counseling for family-members of HIV infected persons and patients at JaramogiOgingaOdinga Teaching and Referral Hospital

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Abstract- The prevalence of undiagnosed HIV infection among the Kenyan population was approximated to be 2%in 2012 and with the maturing of the epidemic, there is a need to focus resources on ensuring those who are HIV positive are on ART, andto identify the undiagnosed HIV infected persons. With an average cost per test estimated to be between USD 2-8, the present cost-benefit ratio ofuniversal HIV Testing and Counselling (HTC) programs are close to intolerable limits. However, HIV infected persons who are unaware of their status continue to unknowingly transmit HIV to their sexual partners who may also in-turn infect other partners and propagate the spread of the infection. We propose to develop a screening interview (prior to HIV testing) that would have the highest yield in identifying new HIV diagnoses among ambulatory and in patients at the JaramogiOgingaOdinga Teaching and Referral hospital (JOOTRH) and families of HIV infected persons enrolled at the JOOTRH HIV Clinic. A mixed methods study design will be employed. A retrospective medical record review will be conducted at JOOTRH to describe the yield of HIV testing among various patient categories and family members of HIV infected persons at the HIVclinic. We will review records of 1500in patients and out patients who were seen at JOOTRH between January-December 2014 and HIV testing records of approximately 400family members of HIV infected persons enrolled at the JOOTRH HIV clinic. From this, a screening interview to increase the yield of HIV testing will be developed.Prospectively we will operationally compare the yield of the newly developed algorithm to routine testing. This will be conductedamong 831patients in 24 hospital departments and among family members of 277index cases at the JOOTRH HIV clinic.

Variables to be collected include patient demographics (age , gender, occupation, residence), clinical characteristics including presenting complaint, medical history, physical examination findings, vital signs, admission notes, diagnoses, treatment, whether it is a new or repeat visit and date of last visit. Variables collected for index clients at the JOOTRH HIV clinic will include all their clinical information, data on family size, age of family members, history of previous testing of family members and knowledge of HIV status, health status of family members. Data from the JOOTRH HIV clinicpatient databases will then be linked to the Provider Initiated Testing and Counseling, PITC database. The JOOTRH HIV clinic database contains all clinical information for the patient who are enrolled at the HIV clinic; this will be merged to family members' database.

Analysis of the prediction model will be performed using a multivariable logistic regression model. Selection of the variables will largely follow sequential manual steps based on knowledge of the HIV epidemiology and hypothesized associations between patient characteristics and HIV infection. We will then develop the risk score by multiplying the final prediction model's regression coefficients by 10. A 10-fold cross-validation method will be used to evaluate the internal validity of the model. Receiver operating characteristic (ROC)curve will be constructed and area under the curve calculated to assess discrimination. The predicted HIV positivity with the observed HIV positivity will be plotted fitting a linear regression line and calculating the slope and $R^2$to assess calibration.

We anticipate developing a screening interview that would have a high sensitivity, specificity, negative predictive value and positive predictive value in identifying persons who are in need of a HIV test result. Consequently, HIV programs can achieve a higher yield for HTC with a more cost-effective method.

Index Terms- Focused HIV testing, High yield approache,Screening for HIV testing,

I. INTRODUCTION

A.Background

Knowledge of HIV status forms a key entry point for access to the HIV cascade of care (i.e. the relevant HIV prevention, care and treatment services). For this reason, in 2006 the UNAIDS recommended in its 'universal access to knowledge of HIV status' goal that at least 80% of populations should be aware of their HIV status by 2010[1 2]. Later, in December 2013, UNAIDS recommended that 90% of all PLHIV should know their HIV status[3].Kenya committed to the UNAIDS goal of 'universal access' to knowledge of HIV status by providing HTCservices at different settings(including hospitals) and using various approaches e.g. Provider Initiated Testing and Counseling (PITC) at health facilities for both patients and visitors and targeting families of HIV infected persons enrolled

in care as well as providing referrals and linkages of those tested to relevant HIV health services[1].

By 2012, 72% of persons who participated in a nationwide survey in 2012had ever been tested for HIV; among the HIV positive, 47% were aware of their correct HIV statusand 90% of them were enrolled in HIV clinics[4]. In 2012, the prevalence of undiagnosed HIV infection among the general Kenyan population was approximated to be 2%[4 5]. Consistent with this, HTC among family members of HIV infected persons in Nyanza province where despite the HIV prevalence being triple that of national levels (15.2% against the country's average of 5.6%), testing 48,000 family members of HIV infected persons over a 3 month period in 2014 only yielded 2% HIV positive persons(Mutai, H, CDC Kenya Branch Chief Western Kenya, personal communication, December 2014).At JOOTRH, between September and December 2014, the HIV prevalence rate among family members ofHIV infected persons enrolled at the JOOTRH HIV clinic was 9% (ManaseAmolloh, personal communication, January 2015).Among patients seen at JOOTRH between July and October 2014, the HIV prevalence ranged from 4-6% (Audo, C, HIV Counseling and Testing Coordinator, JOOTRH, personal communication, January 2015).

The proportion of positive tests from HTC programs has been diminishing. With an average implementation cost of 2-8 USD per test, the cost-benefit ratio of these programs is negatively skewed. More efficient methods for identifying the undiagnosed HIV population are urgently needed[6]. With an increase in knowledge of HIV status and linkages to HIV care services among those infected, contemporary strategies such as family testing which maybeuseful where HIV incidence is low or the yield of HIV screening is likely to be very low or close to zero, no longer seem to be useful[1]. Even in high HIV prevalent regions like Nyanza province where blanket approaches to HTC (like PITC) are advocated for, the yield of testing has been diminishing (6% in 2012, 4% in 2014) (Audo, C, HIV Counseling and Testing Coordinator, JOOTRH, personal communication, January 2015).HIV programs therefore need to redirect their focus to search for the 'undiagnosed' population' rather than increase HTC coverage.

In Kenya, the HIV burden is borne by those in the reproductive age group (i.e. 15-49 years, particularly females, persons with TB, persons who engage in anal sex, widowed persons, uncircumcised men, persons living in urban regions, persons with multiple and concurrent sexual partnerships, persons who engage in transactional sex, non-prescription drug use and persons in the fishing industry because they disproportionately engage in the aforementioned risk behaviours[4].

Screening programs are designed to assess persons at risk of disease in a population using repeated measurements or large numbers of people and a screening test that is low cost, simple, safe and acceptable. This is a substantial and demanding task and for this reason screening programs are not perfect[7]. The fact that 2% of the Kenyan population who are HIV positive do not know their status[4], translates to screening approximately 50 persons to yield one new HIV diagnosis (assuming they are evenly spread out through the community); a costly venture for HIV programs. Despite the low rates of undiagnosed infection, HIV infected persons who are unaware of their status continue to

unknowingly transmit HIV to their sexual partners who may also in-turn infects other partners and propagates the spread of the infection. Screening programs are only useful if the human and financial resources to operate the screening system are available, and the cost-benefit ratio of the screening program is acceptable. Screening programs should therefore be periodically reviewed to determine the need to modify, or contextualize them to prevailing logistical, political and epidemiological situations [7]. The current HTC guidelines recommend HIV testing for individuals who have not been tested in the past three months, do not know their HIV status, and are at risk of HIV[1].However, among persons whom knowledge of HIV status is vital to key HIV prevention interventions e.g. pregnant mothers and infants born to HIV positive mothers, screening for HIV among all persons is still recommended[8].Screening does not always have to be diagnostic, but it should identify people who require further diagnostic testing.Interviewing a patient about a set of criteria is an affordable and practical way to screen, and would be ideal if it helps determine those who require further testing and those who can safely defer HIV testing[9]. Targeted HIV testing makes maximum use of resources and gives a higher yield[10].

In the literature, Targetted HIV testing among high risk populations has aided in the identification of new HIV diagnosis[11]. Interview questions should be somewhat selective (i.e. should have a high positive predictive value), so not everyone will "screen positive" – this will save resources by limiting the number of people who require additional diagnostic testing.We propose to develop a screening interview to be used prior to HIV testing that would increase yield in identifying new HIV diagnosis.

B.Study objectives
Main Objective

To improve the yield of PITC testing approaches for families of HIV infected personsand ambulatory/in patients at JOOTRH through the implementation of an HIV screening interview prior to HIV testing

Specific objectives

1. To describe socio-demographic and clinical characteristics associated with HIV infection among persons tested at JOOTRH from the retrospective data review
2. To develop/propose a screening interviewbased on patient characteristics that would provide the highest yield in HIV testing, using the retrospective data review.
3. To determine the sensitivity, specificity, negative and positive predictive value of a HIV screening toolfor patients and family members of HIV infected patients at JOOTRH by prospectively testing the newly developed algorithm.

II. METHODS

A.Study design and setting

JOOTRH is located in Kisumu county, a region with a population of approximately 1,000,000; 40% are aged >15 years and 51 % are female.[5]This hospital, a regional referral hospital to the former Nyanza province and parts of Rift Valley and Western Kenya has a bed capacity of 457 and a bed occupancy

rate of 95%.Annually, it offers outpatient services to over 250,000 persons and inpatient services to approximately 21,000 persons.[12] The JOOTRH HIV clinic incepted in 2003 has a cumulative patient enrolment of 23,000 and approximately 6,000 currently on care(Awuor, A, HIV Care and Treatment Coordinator, JOOTRH, personal communication). Seventy-five percent of patients are eligible for testing using the current HTC guidelines) (Audo, C, HIV Counseling and Testing Coordinator, JOOTRH, personal communication)[1].

A mixed methods study design will be employed to conduct a two part study in each of the study populations (out patients and in patients at the JOOTRH and family members of HIV infected patients at the JOOTRH HIV clinic). The two parts of the study will include

1. Development of the HIV testing screening tool: A retrospective medical record review of 4000 patient records for patients seen at JOOTRH between January 2014 to December 2014 and 3000 records of family members of HIV infected patients who are currently enrolled at the JOOTRH PSC will be conducted at the JOOTRH to describe the yield of HIV testing and a develop an algorithm to increase the yield of HIV testing.

2. Validating of the newly developed HIV testing screening tool; we will operationally compare the yield of the new screening tool versus routine testing by prospectively assessing the utility of the newly developed algorithm in increasing the yield of HIV testing.

B.Development of the HTC screening tool: the retrospective arm of the study
Study population

Patient testing arm: Medical records of Allin patients and out patients aged 2 years or older who were seen at the JOOTRH between January-December 2014. HIV testing is recommended for **all children** aged less than 18 months using HIV DNA PCR and Antibody testing as per the Kenya National HIV testing guidelines. For these reasons, chart review for this age-group will not be done[1].

Family testing arm: HIV testing records of Family members of an index client aged 2 years andoldernewly diagnosed with HIV and enrolled at the JOOTRH PSC.HIV clinic.
Criteria for inclusion of participants
- Out patientsand in patients (regardless of HIV status) seen at the JOOTRH between January and December 2014
- Family members of HIV infected persons enrolled at the JOOTRH HIV clinic
- Persons aged 2 years and older
- Complete patient and HIV testing records

Criteria for Exclusion of participants
- Persons aged less than 2years
- Was not tested for HIV or has Indeterminate or unresolved HIV test results
- Incomplete or missing patient or HTC records

Sample size for the retrospective data abstraction

Patient testing arm:For the retrospective data, we purpose to develop a risk score to accurately identify persons at risk for HIV infection using the 'case-control' approach.The ratio of cases to controls for the retrospective data abstraction will be 1:4, since, there is no further gain of power above four controls per case[13]. The sample size is estimated for the derivation of a risk model to minimize the possibility of over-fitting the multivariable logistic regression model[14]. A "rule of thumb" of a multivariable logistic regression analysis is an event-to-predictor ratio of 10:1[2]. Since, the review of charts doesn't come with a significant cost; we chose a conservative event-to-predictor ratio of 15:1 to yield greater power. We anticipate evaluating at least 20 candidate predictor variables (e.g.age, gender, presenting complaints, marital status, examination findings, results of laboratory tests etc), implying an estimate of 300cases of HIV in the sample. With a case to control ratio of 1:4, it implies we will need 1200 controls yielding a total sample size of approximately 1500 screened charts to develop the screening risk score.

Family testing arm: For the family testing, we will take a third of the above computation. This implies that we will take 100 index clients and approximately400screened family members of index clients at the PSC to develop the screening risk score for HIV infected clients.

The controls will be matched to the cases based on; age, gender, inpatient oroutpatient, diagnosis and number of hospital visits within the year.

Data collection

Informed consent to access the hospital's medical records will be sought from the hospital's administration and from KEMRI HISS administration to access the PITC databases.

Patient testing arm: A retrospective review of patient records at the JOOTRH (both electronic and paper) for patients who were seen at the hospital between January and December 2014 will be conducted. The 1500patient records will be proportionally allocated to in-patients and out-patient departments commensurate to patient volumes; i.e. approximately 10% of records (150) will be from the inpatient departments. Variables collected include patient demographics (age , gender, occupation, residence), clinical characteristic including presenting complaint, medical history, physical examination findings, vital signs, admission notes, diagnoses, treatment, whether it is a new or repeat visit, date of last visit, etc. JOOTRH outpatient medical records are currently in an electronic format. The inpatient data at JOOTRH is in paper format and will be abstracted by study assistants and entered into the study databases. The PITC electronic database contains patient identifiers, TB screening outcomes, new or repeat testing, new or repeat visit at JOOTRH, HIV test results, sexual behavior etc.

Data from the JOOTRH out-patient electronic database and from the abstracted in-patient database will then be linked to the PITC electronic data base using the hospital's patient number that is available on both databases. This will then be merged with the PITC electronic database to create a HTC patients database from which a screening interview will be developed

Family testing arm: We will review medical information about index clients at the JOOTRH HIV clinic database which

contains all clinical information for the patient who are enrolled at the HIV clinic. We will also conduct a retrospective review of data on family testing. Data on family testing and outcomes of family testing is currently available on paper format. We will collect all data on approximately 400family members. Variables collected for index clients at the JOOTRH HIV clinic will include all their clinical information, e.g. duration of HIV diagnosis, duration on ART, data on family size, age of family members, history of previous testing of family members and knowledge of HIV status, health status of family members (see Enrolment, follow up forms, family members testing card). Family members will be assigned (if not already assigned) a unique identifier that will identify them with the family member enrolled at the clinic. These identifiers will be used to link the family member to the participant enrolled at the clinic. Variables that will be collected from the family members will include age, relationship to index member.

Data from the PSC electronic database will then be linked to the family testing data to create a family members database from which a screening interview will be developed

Data storage

Electronic data will be collected from the JOOTRH patient databases using external hard drives and entered into a computer database at KEMRI CRC. Here, the patient data will be merged with existing PITC databases using patient unique identifiers.

Electronic data will be uploaded into electronic databases at CRC. Participant forms will be scanned into an electronic database and merged with the PITC databases. The external hard-drives will be password protected and the paper forms will be stored in a lockable cabinet. Merged datasets will be stored on password protected computers with only members of the study team being privy to the dataset. Data will be stored for a minimum period of 5 years after the completion of the study and will be destroyed five years after the last publication.

Data analysis

Development of a screening questionnaire will be based on risk factors for HIV, natural history of the disease and clinical features. [9]Analysis of the prediction model will be performed using a multivariable logistic regression model. Selection of the variables will largely follow sequential manual steps based on knowledge of the HIV epidemiology and hypothesized associations between patient characteristics and HIV infection. [14]We will then develop the risk score by multiplying the final prediction model's regression coefficients by 10.[15]Patients will then be grouped distinctively into categories generated from cut-points of their risk scores based on HIV prevalence. [14]

Associations among proportions of categorical variables will be assessed using the Chi-square or Fisher's exact tests, where appropriate. T-test or Wilcoxon rank-sum test will be used to compare differences in in mean/medians of continuous variables, as appropriate. Analysis will be done using Stata version 13.0 (StataCorp, College Station, Texas, USA) .[16]

C.Validating of the newly developed screening interview: the prospective arm of the study
Study population

Patient testing arm: Medical records of All in patients and out patients aged 2 years or older who were seen at the JOOTRH between January-December 2014

Family testing arm: HIV testing records of Family members of an index client aged 2 years and older, newly diagnosed with HIV and enrolled at the JOOTRH PSC.

Criteria for inclusion of participants
- All Out patientsand in patients seen at the JOOTRH between January and December 2014 irrespective of HIV status
- Family members of HIV infected persons enrolled at the JOOTRH HIV clinic
- persons who have consented to join the study
- Persons aged 2 years and older

Criteria for exclusion of participants
- Persons aged less than 2years
- Declines HIV testing or has Indeterminate or unresolved HIV test results
- Those who have not consented to participate in the study

Sample size for the prospective arm of the study

We computed sample size for validation of the newly development algorithm using theBuderer'sformulain order to be 95% confident that the sensitivity/specificity of the Criteria is within plus or minus 5% of the population estimated sensitivity/specificity:[17]

Sample size (*n*) based on sensitivity=
$$\frac{Z_{1-\alpha/2}^2 \times S_N \times (1 - S_N)}{L^2 \times \Pr evalence}$$

Sample size (*n*) based on specificity=
$$\frac{Z_{1-\alpha/2}^2 \times S_P \times (1 - S_P)}{L^2 \times (1 - \Pr evalence)}$$

Where

n = required sample size,

S_N= anticipated sensitivity,

S_P= anticipated specificity,

α = size of the critical region ($1 - \alpha$ is the confidence level),

$Z_{1-\alpha/2}$ = standard normal deviate corresponding to the specified size of the critical region (α),

L = absolute precision desired i.e. level of accuracy

The prevalence chosen should be selected with caution, lest the sample size adopted results in a loss of precision or confidence or both[18].The prevalence of HIV in Kisumu County where JOOTRH lies is 18.7%[19]. Since the sensitivity and specificity of the Targeted HIV screening algorithmis unknown, a conservative estimate of 50% that would protect the precision of the maximum width would be ideal.However, we want a screening tool that will be able to identify almost everyone with HIV among the HIV undiagnosed persons. We therefore adopted a sensitivity and specificity of 97% for our sample size computation. The standard normal deviate corresponding to 95% confidence interval is 1.96 while the absolute precision desired, L, is ±3%.

Implementing the formulas above in RVersion 3.1.3[20]program yielded

$$n(sensitivity)=665$$

$$n(specificity)=153$$

Ideally, the preferred minimum sample size that will give a precision of 3% or less for both sensitivity andspecificity is 665 patients.

Adjusting for 20% non-response or missing data yields

$$n = \frac{665}{0.80} = 831, subjects$$

We will therefore use a sample size of 831patients to validate the screening algorithm.

We will validate our screening algorithm for the family testing as well. The sample size of the index patients will be 277(approximated a third of the sample size computed above).

Data collection

Individual patients and their family members will be recruited into the study after consenting to participation. All patients (or family members of HIV infected persons), consenting for the study, will be administered the newly developed algorithm and tested for HIV.. Written informed consent (and assent for persons aged 12-17 years) to conduct a screening interview will only be sought from those assigned to the targeted testing arm.Verbal consent to perform HIV testing as per the national HTC guidelines will be sought from all those who consent to HIV testing whether they are assigned to routine testing or targeted testing.

Prospectively, we will validate the newly developed algorithms for HIV testing in families of HIV infected persons enrolled at the JOOTRH PSC and patients by operationally comparing the yield of HIV testing in routine testing to that from targeted testing. All participants will be administered the newly developed screeningalgorithm and undergo HIV testing; consent will be sought as per the Kenyan National HIV testing guidelines .We will use stratified probability proportional to size (PPS) methodto obtain the number of patients to be sampled per department among the twenty-four departments of JOOTRH. This will be based on proportions of patients counselled and tested in each department from the PITC data of 2014. Each department will get a sample proportional to its size. The patients will be interviewed conveniently until the desired sample size per department is attained.

For the prospective arm of the study for family testing, 277index cases will be randomly selected from the PSCdatabase. The newly developed screening algorithm will be administered and HIV testing done for all the family membersconsenting for the study.

The newly developed screening algorithm will be entered into scannable paper or electronic data collection tools which will be used by the HTC counselors prior to HIV testing. The routinely used PITC data collection tools will be used to collect data on results of HIV testing. The two databases will be linked using the unique patient identifiers assigned to patients at the hospital's records department upon arrival (for patients) and a unique identifier derived from the JOOTRH HIV clinic that is linked to the index case for the family members of HIV infected persons enrolled at the JOOTRH PSC.

Data storage

Electronic data will be collected from the JOOTRH patient databases using external hard drives and entered into a computer database at KEMRI CRC. Here, the patient data will be merged with existing PITC databases using patient unique identifiers.

Electronic data will be uploaded into electronic databases at the JOOTRH CRC. Participant forms will be scanned into an electronic database and merged with the PITC databases. The external hard-drives will be password protected and the paper forms will be stored in a lockable cabinet. Merged datasets will be stored on password protected computers with only members of the study team being privy to the dataset. Data will be stored for a minimum period of 5 years after the completion of the study and will be destroyed five years after the last publication.

Data analysis

Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) with their 95% confidence intervals (CI) will be reported. A 10-fold cross-validation method will be used to evaluate the internal validity of the predictive model. Receiver operating characteristic (ROC)curve will be constructed and area under the curve calculated to assess discrimination. The predicted HIV positivity with the observed HIV positivity will be plotted fitting a linear regression line and calculating the slope and R^2 to assess calibration[14].

D.Ethical considerations
Informed consent

This will be sought from the hospital administration and prior to accessing patient records.

Individual informed consent will be sought from individual participants for the prospective arm of the study (see consent and assent forms).

Confidentiality

All study staff will be trained in ethical procedures asked to sign confidentiality agreements. All study documents will be stored under lock and key and electronic files will be stored in password protected computers. All data will be anonymized prior to analysis and only the PI will have access to participant link log that contains information that can identify participants by their study identifiers.

Institutional Review Board oversight

This will be sought from relevant institutional review boards.

III.   DISCUSSION

A.Potential risks to participants

There is the risk of accidental disclosure of participants' private medical information; to mitigate this, we will take the utmost precautions to protect participant confidentiality including aksing study staff to sign confidentialty agreement forms.

Possible undue pressure for index client to disclose HIV status to the family; persons who have not disclosed their HIV status to their family members will be excluded from the study but still referred for on-going counseling to assist them with the process of disclosure which is recommended.

B. Potential benefits to participants

There will be no direct benefit to participants. However, consequent to development of a screening interview, the undiagnosed PLHIV will still benefit from early diagnosis and HIV program will achieve the highest yield for their investment in HTC programs.

C. Limitations

Those who have not consented to join in the study may differ from those who do not. We intend to collect minimal demographic information on those who do not consent to join the study to determine whether they differ from those who consent to join the study.

D. Expected application of results

We anticipate developing a HIV screening interview that would have a high sensitivity, specificity, negative predictive value and positive predictive value in identifying persons who are in need of a HIV test result. Consequently, HIV programs can achieve a higher yield for HTC with a more cost effective method.

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Competing interests: None

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