

# BMJ Open Audit of HIV counselling and testing services among primary healthcare facilities in Cameroon: a protocol for a multicentre national cross-sectional study

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## ABSTRACT

**Introduction** HIV testing is an invaluable entry point to prevention, care and treatment services for people living with HIV and AIDS. Poor adherence to recommended protocols and guidelines reduces the performance of rapid diagnostic tests, leading to misdiagnosis and poor estimation of HIV seroprevalence. This study seeks to evaluate the adherence of primary healthcare facilities in Cameroon to recommended HIV counselling and testing (HCT) procedures and the impact this may have on the reliability of HIV test results.

**Methods and analysis** This will be an analytical cross-sectional study involving primary healthcare facilities from all the 10 regions of Cameroon, selected by a multistaged random sampling of primary care facilities in each region. The study will last for 9 months. A structured questionnaire will be used to collect general information concerning the health facility, laboratory and other departments involved in the HCT process. The investigators will directly observe at least 10 HIV testing processes in each facility and fill out the checklist accordingly.

**Ethics and dissemination** Clearance has been obtained from the National Ethical Committee to carry out the study. Informed consent will be sought from the patients to observe the HIV testing process. The final study will be published in a peer-reviewed journal and the findings presented to health policy-makers and the general public.

## INTRODUCTION

HIV is a major cause of morbidity and mortality worldwide particularly in low/middle-income countries (LMIC).<sup>1</sup> Sub-Saharan Africa (SSA) inhabits just 12% of the global population, yet it bears almost three quarters (71%) of the global HIV burden.<sup>2</sup> In 2016, there were approximately 26 million people living with HIV in SSA, with 1.2 million new HIV infections and 700 000 AIDS-related deaths.<sup>3</sup> HIV testing is an invaluable entry point to prevention, care and treatment services for people living with

## Strengths and limitations of this study

- This is the first study to assess the quality of HIV testing services in Cameroonian primary care facilities. The study will provide insights to the current standards of HIV testing services.
- Our findings could go a long way to improve the quality of point-of-care testing in primary healthcare facilities where the majority of Cameroonian people seek for medical attention.
- The multicentric design with samples from each of the 10 regions will ensure representative and generalisable findings.
- The direct observation of the HIV counselling and testing (HCT) process will facilitate identification of loopholes and provide practical solutions to improve on the quality of these services.
- The inability to carry out further testing (nucleic acid tests and antigen/antibody tests) especially on indeterminate test results could wrongly index shortcomings of the overall HCT process instead of the individual rapid diagnostic tests.

HIV and AIDS.<sup>4</sup> In 2014, about 150 million children and adults underwent HIV testing in LMIC.<sup>5 6</sup> Most of these tests were carried out using rapid diagnostic tests (RDTs). These tests have the merits of being relatively less expensive, easy to use, less time consuming for testing and do not require extra laboratory equipment or expertise.<sup>7</sup> Furthermore, they constitute a pivotal diagnostic tool for HIV screening and testing in resource-limited settings.<sup>7-9</sup> Though invaluable for HIV screening, their diagnostic accuracy in clinical practice remains an unresolved debate.<sup>7</sup> In a bid to improve on their accuracy, health professionals are recommended to adhere to WHO guidelines and to other externally validated national testing protocols.<sup>10 11</sup> Unfortunately, only 8% of African countries

adhere to the current WHO recommendations.<sup>4</sup> Barriers to this adherence include poor quality testing services, suboptimal quality assurance, inaccurately implemented HIV testing guidelines, understaffed and underskilled health systems.<sup>5 10 11</sup> These barriers reduce the performance of RDTs and could result in misdiagnosis of HIV seroprevalence, most commonly leading to false positive results.<sup>5 7 10 12</sup>

This is particularly worrisome because a false positive HIV result is associated with adverse psychological and social impacts such as social stigmatisation, discrimination, abandonment, divorce, domestic violence, severe depression and suicide.<sup>7 8</sup> These ultimately destabilise family relationships and can reduce the credibility of HIV tests and the whole health system.<sup>5</sup> Likewise, antiretroviral therapy (ART) exposes misdiagnosed individuals to toxic medications with numerous side effects.<sup>6</sup> Moreover, placing an HIV-negative person on ART for life incurs extra costs as high as US\$6300 on the health system, and this siphons the already limited resources to fight against HIV.<sup>8 13</sup> There have been several cases of misdiagnoses over the last couple of years, mostly false positive results in resource-challenged settings using RDTs.<sup>6 10–12</sup> In Malawi, 4.6% of people referred for ART initiation were subsequently found to be HIV negative on retesting.<sup>8</sup> RDTs in the Democratic Republic of Congo had a false positive rate of 10.5%.<sup>6</sup> Likewise, 129 out of 295 Ugandans were falsely tested HIV seropositive using RDT.<sup>14</sup> To this effect, an analysis of the HIV counselling and testing processes in Malawi highlighted the following reasons for the poor quality of HIV testing; omission of some portions of the process such as counselling, inadequate personnel, lack of standard operating procedures (SOP) in many testing sites and lack of quality control of the testing process.<sup>15 16</sup> More still, an analysis of the HIV voluntary counselling and testing process in 38 South African health facilities revealed an overall process compliance of 3.4%.<sup>17</sup> They identified erroneous specimen collection methods, lack of staff training, poor quality assurance services and short incubation times for HIV testing as the main reasons for the poor compliance.<sup>17</sup>

After an extensive literature search on PubMed, Medline and other grey literature sources, no study has assessed the quality of HIV testing services in Cameroonian primary healthcare facilities, particularly the adherence to recommended HIV counselling and testing (HCT) process. With the recent adoption of the provider-initiated testing (opt out) strategy in Cameroon, whereby all patients are routinely proposed an HIV test, and those who consent are tested while those who do not wish to be tested voluntarily 'opt out'.<sup>18</sup> HCT now constitutes a standard component of medical care.<sup>18 19</sup> In this context, given the predominance of RDTs in our setting, emphasis has to be laid on the quality of HCT services in primary healthcare facilities, most especially the adherence to recommended HCT procedures and the impact this may have on the reliability of HIV test results. The overall research goal is to contribute to the global HIV

response and correctly diagnose 90% of people with HIV by 2020.<sup>1</sup>

## OBJECTIVES

The general objective is to assess the adherence of primary healthcare facilities in Cameroon to recommended procedures for HCT. Specifically, we seek to evaluate the proportion of primary healthcare facilities possessing national HIV testing algorithms and SOPs for different HIV tests, determine the proportion of these primary healthcare facilities which completely adhere to the recommended process for HCT and assess the prevalence of indeterminate results during the study period.

## METHODS AND ANALYSIS

### Study setting

The study will be carried out in selected primary healthcare facilities in Cameroon. Cameroon is a Central African country, with a total population of about 23 million inhabitants. It consists of 10 regions, 360 districts, 360 municipalities and 14 major city councils. In 2016, there were 560 000 people living with HIV in Cameroon, of which 330 000 (58%) knew their HIV status, 210 000 (37%) were on treatment and 110 000 (19%) were virally suppressed.<sup>3</sup>

### HIV testing algorithm in Cameroon

Cameroon makes use of a serial HIV testing strategy with two RDTs used in series. The first line test is the highly sensitive Determine HIV1/2 (Alere test, USA). The second line test is either OraQuick HIV-1/2 or Shanghai HIV (1+2) Antibody test or Uni-Gold HIV Rapid Test which all have a high specificity (see online supplementary file 1 for test characteristics). A negative result on the first line test is considered negative for HIV antibodies. A positive result on the first test warrants a second line testing. A negative result on the second line test leads to an indeterminate test result and the patient is retested in 3 weeks. A positive result on the second test leads to an HIV-positive diagnosis. Most primary healthcare facilities possess a laboratory where all HIV testing are carried out by trained laboratory technicians. Semesterly, external quality validation, using pre-established forms, of all HIV testing materials provided by the Ministry of Public Health are done by the national reference laboratory (Centre Pasteur du Cameroun).

### Study design, duration and participants

This hospital-based cross-sectional analytical study will span from 1 August 2017 to 31 April 2018, a period of 9 months (see online supplementary file 2 for proposed timeline).

Primary healthcare facilities which carry out HCT and which consent to participate will be included in the study. Otherwise they will be excluded.

Participants older than 15 years who consent to participate will be included in the study, otherwise, they will be excluded.

Hospitalised patients for whom HIV tests have been requested will be excluded from the study.

### Sample size and sampling

Primary healthcare facilities will be selected from all the 10 regions of Cameroon by a multistage random sampling of facilities in each region. In each region, two health districts will be randomly chosen from the total number of health districts. From each health district, three health areas will be randomly selected, from which two primary healthcare facilities will be randomly selected for inclusion in the study.

Using the following formula :

$$n = \frac{Z^2 P (1-P)}{d^2}$$

Where n=sample size (number of hospitals), P=expected proportion of hospitals with an overall process compliance. Assuming the algorithm for HCT in primary healthcare facilities in Cameroon is similar to that in South African primary healthcare clinics, the value of P would be 0.034, based on a report from the Strategic Evaluation, Advisory and Development Consulting in South Africa<sup>17</sup>; d=precision (if 5%, d=0.05); Z statistic (Z): for the level of confidence of 95%, which is conventional, Z value is 1.96 for a 95% CI.

A minimum of 50 primary healthcare facilities will be required for this study.

### Study procedure

Data will be collected using two separate questionnaires. The first questionnaire will be a structured questionnaire which collects data on each healthcare facility. This will include general information on the HCT services of the facility, staff qualification, laboratory equipment, quality control measures, HCT algorithms and SOPs (see online supplementary file 3 for questionnaire). The directors and personnel in charge of the HCT services of each healthcare facility will be approached to fill out the aforementioned questionnaire where appropriate. In the case where there exists more than one testing service, the laboratories of the health facility will be the point of entry of interest in our study. We believe laboratories will be more representative of the HIV testing quality in each healthcare facility and this will ensure uniformity in the entry points included in the study. A detailed mapping of the 'recommended' HIV counselling and testing process will be outlined in the form of a list, adapted from the 'Analysis of Point of Care Testing/Voluntary Counselling and Testing performed at South African primary healthcare clinics'<sup>17</sup> (see online supplementary file 4 for recommended HCT test process). The second questionnaire will assess the adherence to the recommended HCT process (see online supplementary file 5 for questionnaire). The investigators will directly observe at least 10

HIV testing processes in each health facility. The HIV test process will be incorporated in the questionnaire. Each step in the process will be checked off accordingly by the investigator.

### Definitions of terms

1. SOP adherence will be defined as the proportion of primary healthcare facilities which displays SOPs and national algorithms for HIV testing. Displaying these procedures provides a reference for those involved in the HCT process whenever the need arises. The number of these primary healthcare facilities with displayed SOPs and national HIV testing algorithms will be reported as a percentage of the total number of facilities.
2. Overall process adherence will be defined as complete adherence to the recommended HCT process. It provides a direct assessment of the quality of the HCT process in each health facility. The number of items checked on the checklist will be divided by the total number of items and reported as a percentage. The resulting percentage will permit a dichotomous categorisation into total adherence (100% adherence to checklist) and non-adherence (<100% adherence to checklist). The number of facilities who check all the items on the recommended checklist will be divided by the total number of facilities and reported as a percentage to give the overall facility adherence.
3. Requirement availability adherence will be defined as the presence in each primary healthcare facility of the required equipment to reliably carry out HIV testing. It will provide a measure of the shortcomings of health facilities in terms of requirements for HIV testing. The number of items checked on the requirements checklist will be reported as a percentage of the total number of recommended items.
4. Turnaround time will be defined as the amount of time taken to carry out the overall test, compartmentalised as pretest counselling duration, specimen collection, test incubation period and post-test counselling duration.
5. Indeterminate results will be defined as a positive result on the first test and a negative result on the second test. It will seek to assess the effect of the quality of the HCT process on the individual HIV test results. The total number of indeterminate results will be expressed as a percentage of the total number of tests carried out. The proportion of indeterminate results will then be compared with the above four outcomes for each health facility.

### Data management and analysis

Collected data will be entered into Microsoft Excel 2013 spread sheets and exported to the Statistical Package for Social Sciences (SPSS) V.20.0 for analysis. Five per cent of entered questionnaires will be double checked by the principal investigator to detect and correct errors. Results will be presented as frequencies, proportions

and percentages for qualitative variables, while quantitative variables will be presented as mean or median where appropriate. Primary healthcare facilities will be categorised as completely adherent or non-adherent. Factors associated with adherence will be determined using bivariate analysis. Fisher exact test and  $\chi^2$  test will be used as appropriate when examining the relationship between variables. Statistical significance will be achieved at  $P < 0.05$ .

To determine independent predictors of adherence, a multivariate logistic regression analysis will be performed on a model built using variables that have  $P$  values  $< 0.25$  according to Bursac *et al*<sup>20</sup>

### Ethics and dissemination

Ethical clearance has been granted by the National Ethical Committee after submission of the complete protocol. Each regional delegation has been approached to provide administrative authorisation to carry out the study. The directors of the selected health facilities will be approached for authorisation to carry out the study in their institutions. Informed written or verbal consent will be sought from the patients to observe their HIV testing process. The final study will be published in a peer-reviewed journal and the findings presented to health policy-makers and the general public.

### DISCUSSION

With the absence of yearly refresher courses on the HCT processes, we expect primary healthcare facilities in Cameroon to adhere poorly to the recommended guidelines. Between 25% and 50% of facilities will possess displayed SOPs and national algorithms for HIV testing. This finding will inform public health authorities on the need to intensify training of all primary healthcare facilities on the SOPs and guidelines for HCT, in a bid to improve the quality of HIV testing in Cameroon.

We expect less than 10% of primary healthcare facilities to completely adhere to the recommended process for HCT. This will inform public health authorities on the need for these facilities to adhere to these recommended guidelines as this has been proven to improve the performance of RDTs and the reliability of HIV test results.

We expect more than 1% of indeterminate test results. This will lay emphasis on the need to improve adherence to recommended HCT processes, adherence to WHO HIV testing guidelines and improving quality assurance measures for RDTs in Cameroon. Worth noting, indeterminate results could reflect inherent shortcomings of RDTs. To avert these drawbacks, further testing with nucleic acid tests and antigen/antibody tests could help to differentiate between inherent shortcomings of RDTs and shortcomings in the overall HCT process. The inability to carry out the aforementioned sophisticated laboratory testing, owing to our limited resources, may falsely index the HCT as being the cause of the indeterminate results. Our findings will be presented to the Ministry of Public

Health in Cameroon and at the regional delegations of Public Health. We shall also disseminate our findings in conferences and seminars on HCT.

**Contributors** FLT: initial conception and design of the study. JNT, VNA, BMK: critical revision of protocol. All authors have read and approved the final manuscript.

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