Published in final edited form as:

J Acquir Immune Defic Syndr. 2012 October 1; 61(2): e13–e17. doi:10.1097/QAI.0b013e31825eec60.

Rapid point-of-care CD4 testing at mobile HIV testing sites to increase linkage to care: An evaluation of a pilot program in South Africa

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Abstract

Background—A mobile HIV counseling and testing (HCT) program around Johannesburg piloted the integration of point-of-care CD4 testing, using the Pima™ Analyzer, to improve linkages to HIV care. We report results from this pilot program for patients testing positive (n=508) from May–October 2010.

Methods—We analyzed three primary outcomes: assignment to testing group (offered POC CD4 or not; successful follow up (by phone); and completed the referral visit for HIV care within 8 weeks after HIV testing if successfully followed up. Proportions for each outcome were calculated and relative risks estimated using a modified Poisson approach.

Results—311 patients were offered the POC CD4 test, and 197 patients were not offered the test. No differences in patient characteristics were observed between the two groups. Approximately 62.7% of patients were successfully followed up 8 weeks after HIV testing, with no differences observed between testing groups. Among those followed up, 54.4% reported completing their referral visit. Patients offered the POC CD4 test were more likely to complete the referral visit for further HIV care (RR 1.25, 95% CI: 1.00–1.57).

Conclusions—In this mobile HCT setting, patients offered POC CD4 testing as part of the HCT services were more likely to visit a referral clinic after testing, suggesting rapid CD4 testing technology may improve linkage to HIV care. Future research can evaluate options for adjusting HCT services if POC CD4 testing were included permanently, as well as the cost-effectiveness of the POC CD4 testing compared to other approaches for improving linkage of care.

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Keywords

point-of-care CD4 testing; mobile HIV counseling and testing (HCT); linkage to care; South Africa

INTRODUCTION

Early identification of HIV-infected individuals and improved linkage from HIV testing to HIV care is a prerequisite for South Africa to achieve its goals for care and treatment.¹ Despite testing 13.5 million individuals during the HIV counseling and testing (HCT) campaign that began in April 2010, the numbers actually linked from HCT to an HIV care program are not known. Throughout South Africa, however, CD4 cell counts of those initiating antiretroviral therapy (ART) in South Africa have remained well below 200 cells/mm³ (the eligibility threshold until recently).²

By reducing barriers to accessing HIV counseling and testing (HCT) services, mobile HCT programs offer an opportunity to identify those with HIV infection while their CD4 counts remain high, before symptoms develop.^{3–6} Recent studies have demonstrated this strength of mobile HCT. While 50% of walk-in HCT patients to a hospital-based HCT site in Johannesburg diagnosed with HIV were already eligible for antiretroviral treatment (ART) on the day of HIV testing (CD4 cell > 200 cells/mm³), only 10% of patients diagnosed with HIV in a mobile HCT program in the same metropolitan area were treatment-eligible on the day of testing.^{7, 8} In a study from Cape Town, 33% of walk-in HCT patients diagnosed with HIV at fixed locations (hospital and clinic) were already eligible for antiretroviral treatment (ART) on the day of HIV testing (CD4 cell > 200 cells/mm³) and 20% had very low CD4 counts (< 100), but only 11% of patients diagnosed with HIV in a mobile HCT program were treatment-eligible on the day of testing.⁶

Patients who test positive in mobile HCT programs are referred to a clinic for CD4 testing to determine if they are eligible for ART or should instead be enrolled in pre-ART care. The existing limited evidence suggests that many patients fail to enroll in HIV care after referral from testing, however. A recent review of the literature found that a median of 59% of patients provided a blood sample for a CD4 count and returned for the results after testing positive for HIV.⁹ Some data suggest that patients with low CD4 counts are more likely than those with higher CD4 counts to return for their CD4 test results, perhaps because those with lower CD4 counts are already sick.^{8, 10, 11}

One solution for the failure of many HCT clients to return for their CD4 test results is to integrate rapid, point-of-care (POC) technologies into HCT service sites. Of particular note has been the Alere PIMA™ Analyzer, a small and portable device that generates a CD4 count result approximately 20 minutes from insertion of a cartridge containing a patient's blood sample.^{12, 13} Because it is rapid, portable, and usable outside a laboratory setting, this technology has created the possibility that a patient can receive both HIV and CD4 test results in a single visit to a testing site that is not based at a clinic or laboratory.¹⁴ Little evidence exists so far, though, about the effectiveness of a POC CD4 count in encouraging patients to enroll in HIV care, particularly if they volunteered for HIV testing in a non-clinic setting.

A mobile HCT program in Gauteng Province completed a pilot program in 2010 that included two components: (1) patients diagnosed with HIV in the mobile program were contacted by telephone 8 weeks (i.e. called 56 days later) after testing to ask if they completed their referral visit; and (2) to attempt to improve post-testing linkage to care, the mobile program integrated rapid POC CD4 testing into its HCT services using the Alere

PIMA™ Analyzer. Using information extracted from program records, the aim of this study is to assess the proportion of patients who completed their referral visit within 8 weeks of HIV testing in the mobile program under routine conditions and evaluate the impact of including POC CD4 testing on the proportion of patients completing the referral visit within 8 weeks of HIV testing.

METHODS

Study setting

The study was conducted using data generated by a pilot project implemented by Right to Care, a South African non-profit organization funded primarily by the U.S. Agency for International Development through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Right to Care provides HCT services to more 200,000 individuals annually. Its HCT services include a mobile HIV testing program operating in Gauteng Province called Access VCT.

Access VCT uses vehicles (2 mobile units) and tents/gazebos to conduct HCT. The vehicles carry materials and personnel to a location like a taxi rank or shopping mall for a day of testing. Nurses provide the counseling and testing services, and 6–10 nurses are present at each location on a testing day. Patients receive all services from one nurse and are assigned to a nurse on a first-come first-served basis. The standard sequence of events for HCT is: (1) pre-test counseling and consent for HIV testing; (2) rapid HIV testing; (3) post-test counseling for those with a negative result; (4) completing confirmatory HIV testing for those with a positive result; and (5) post-test counseling and referral to an HIV care and treatment site for those with a positive confirmatory HIV test result. As part of step 1 (pre-test counseling and consent), program staff obtain phone numbers and consent to contact HIV-positive patients by phone to inquire whether they completed their referral visit and, if not, to provide additional counseling to support completion of the referral.

In 2010, Right to Care acquired four Alere PIMA™ Analyzer units with assistance from USAID South Africa and Alere and designed a pilot project to integrate POC CD4 testing into its routine mobile HCT services in Gauteng Province. During the pilot, which ran from May to November 2010, Access VCT used up to four PIMA units in the same location, with each unit assigned to one nurse. Because of the “one-stop” structure of the program, where a patient sees one nurse for all services outlined above, only patients who were assigned to a nurse with a PIMA unit could be offered a POC CD4 test. With 6–10 nurses present during a day of testing at a mobile location and patients assigned on a first-come, first-served basis to nurses, this process created pseudo-randomization into two groups: those receiving the standard package of HCT services; and those receiving the standard package plus the opportunity to have a POC CD4 test. Those who were offered and accepted the POC CD4 test were asked for a blood sample, which was processed on site using the PIMA Analyzer. The same nurse then provided the results and referral to the patient. Those not offered the POC CD4 test, and those who were offered it but declined, received standard post-HCT counseling and referral to a clinic where a standard CD4 test could be done.

During the pilot project, all patients diagnosed with HIV were telephoned by an ACCESS VCT counselor eight weeks after their HIV test to ask if they had completed their referral visit to a clinic. Each patient was called up to three times, on different days and times of day.

Data collection and analysis

Data for this study were drawn from routinely collected medical records kept by the Access VCT program. For this analysis, we included all adult patients diagnosed with HIV by Access VCT between May and November 2010. A retrospective review of program records

was completed in late February 2011, which allowed 8 weeks of follow up for all patients diagnosed with HIV during the pilot period. For each patient, data collected included date of HCT, age, sex, previous HIV test(s), whether or not a POC CD4 test was offered and accepted, CD4 count result (if available), and self-reported completion of referral visit, based on the 8-week follow up phone call. The study received ethical approval from Boston University and the University of the Witwatersrand.

Data were analyzed using STATA (Version 11.1, Stata Corporation, College Station, TX, USA). We first evaluated whether the two study groups were comparable, based on assignment to testing technology (POC or standard) and probability of being reached by phone during the study follow up. In order to evaluate whether the pseudo-randomization to the two study groups was adequate to create balanced study populations we conducted two analyses. We started with a summary of available patient characteristics (age, sex, and tested previously for HIV) stratified by testing group. Relative risks of being offered the POC CD4 test were estimated using a modified Poisson approach and using age, sex, and whether the patient had tested previously for HIV as patient-specific covariates.¹⁵ We then estimated the proportion of patients successfully followed up by phone eight weeks after HIV testing. Relative risks of successful follow up were estimated using the modified Poisson approach, with testing group, gender, tested previously for HIV, and age as covariates.

For the subset of patients who were successfully contacted by the site, we next evaluated the proportion of patients who completed a referral visit eight weeks after their HIV test. We present the risk difference (RD) and corresponding 95% confidence intervals of completing the initial referral visit within eight weeks between testing groups. Relative risks of referral completion were also estimated using the modified Poisson approach, with testing group, gender, tested previously for HIV, and age as covariates. We provide intention-to-treat results, which uses the full sample of patients offered the POC test. We also provide per-protocol results, which exclude patients offered the POC CD4 test for whom the test was not completed, either because the patient declined the test or there was a technical failure preventing the nurse from giving the patient the results.

RESULTS

Assignment to testing group and probability of being reached by phone

A total of 508 adult patients were diagnosed with HIV in the mobile program during the pilot period. Their median age was 33 years [IQR: 25–40], 59.6% were women, and 39.9% reported having tested previously for HIV. Table 1 provides a summary of demographic characteristics, stratified by testing group. 311 patients (61%) were offered the opportunity to have a POC CD4 test, while 197 (39%) were not. Relative risks of assignment to testing group are also reported in Table 1. There were no large differences in age, gender, and previous HIV testing experience between those offered the POC CD4 test and those not.

The mobile program successfully contacted by phone 197 out of the 311 patients offered the POC CD4 test (63.4%) and 122 out of 197 not offered the test (61.9%). Relative risks of successful contact are reported in Table 2. We found no differences in successful contact between the testing groups or by age or previous HIV testing experience. Women were more likely to be contacted than men (RR 1.21; 95% CI 1.04–1.40).

Completed referral visit within 8-weeks of HIV testing (if patient reached by phone)

For the 197 patients offered the POC CD4 test who were successfully followed up by phone, 117 (59.4%) reported completing their referral visit within 8 weeks of HIV testing (Table 2). Among patients not offered the POC test, 57 out of 122 (46.7%) reported completing the referral visit within 8 weeks. The absolute risk difference between these two groups was

12.7% (95% CI: 1.5%–23.9%), equivalent to a 27.1% relative improvement in referral completion associated with the offer of the POC CD4 test. After controlling for age, gender, and previous HIV testing experience, patients offered the POC CD4 test also had a higher relative risk of completing their referral visit than those not offered the test (RR 1.23; 95% CI: 1.00–1.57).

Among the 311 patients offered the POC CD4 test, 32 patients (10.29%) declined the offer. An additional 16 patients who accepted the offer did not receive their POC CD4 results due to technical failure in performing the test. A total of 263 patients thus both accepted the POC CD4 test offer and received their CD4 test results. Among these 263 patients, 167 were successfully followed up 8 weeks after HIV testing, and 103 (61.7%) reported completing their referral visit within 8 weeks of HIV testing. Using this sub-sample for the treatment group, representing a treatment-on-treated analysis, the relative risk of completing the referral visit was 1.31 (95% CI: 1.04–1.64), slightly higher than in the intention-to-treat analysis.

Among the 263 patients who were offered the POC CD4 test and received a result, the median [IQR] CD4 cell count was 414 [251–586] cells/mm³. 17.1% had CD4 counts $\geq$ 200, the previous ART eligibility criterion, and 42.5% had CD4 counts $\geq$ 350, the new ART eligibility criterion. More than half (57.5%) had a CD4 count above 350 and were thus not yet eligible for ART. For this subsample of patients (offered and received POC CD4 test results, n=263), patients with CD4 counts $>$ 350 were somewhat less likely to complete their referral visit than those with CD4 counts $\leq$ 200 (RR 0.74; 95% CI: 0.55–0.97).

DISCUSSION

Early in 2011, South Africa announced an increase in the CD4 cell count threshold for initiating ART from 200 to 350 cells/mm³. To achieve the earlier treatment initiation target reflected in this policy, a large proportion of patients diagnosed with HIV, many of whom will obtain HIV tests at mobile and other non-clinic based testing facilities, will need to be successfully linked to an HIV care and treatment program. Neither mobile nor other community-based HCT testing programs, however, have found effective strategies for persuading a high proportion of patients to complete an initial CD4 count and enroll in an HIV care or treatment program.

Based on data extracted from routine medical records during a pilot project to integrate POC CD4 testing into a mobile HIV counseling and testing program, our findings suggest that integration of POC CD4 testing into mobile HCT programs can increase the proportion of patients who accept the referral provided and make at least one visit to an HIV clinic. In our study, 62% of patients who were offered and accepted the POC CD4 test reported having completed their referral visit within 8 weeks of HIV testing, compared to 47% of those not offered the POC CD4 test. While a sizable proportion of patients failed to enroll in care even among those who received POC results, the improvement was large enough to merit consideration of adopting this intervention on a larger scale. The study also demonstrated that when offered a rapid CD4 test in a routine mobile HCT setting, acceptance among patients is high—90% in the case evaluated here.

Our findings are roughly consistent with those of a handful of other studies that have evaluated rapid, POC CD4 technologies. In Mozambique, a study that used the PIMA Analyzer at the first referral visit, cutting the number of visits required to receive CD4 test results from two visits to one, showed an increase from 43% to 79% in the proportion of patients receiving CD4 results.¹⁶ Another study conducted in the same geographic area as ours (Gauteng Province, South Africa) found that incorporation of a POC CD4 count

increased the proportion of ART-eligible patients who initiated treatment (31% v 65%) but had no effect on uptake of pre-ART care for those not yet eligible for treatment.¹⁷ Both of these studies took place in clinics, rather than in non-clinical HCT settings. One study from Cape Town that investigated linkage to care after HIV testing in a mobile program that collected blood samples for standard CD4 testing for all patients as part of the mobile HCT service, allowing the program to provide patients with CD4 results by phone several days later, after laboratory-based processing.⁸ In this study, 57% of patients were successfully contacted by the program, and 53% were linked to care (mean time of 2.2 months after HIV testing).

The analysis presented here has several limitations that are typical of evaluations of routine practice. There was no explicit randomization of patients to the two testing groups (offered POC CD4 test or not), although the operating procedures of the mobile program a pseudo-random assignment to one of the two groups. Observable characteristics of the two groups were not significantly different, but we cannot rule out the possibility that the groups differed.

A second potential limitation is that follow up was limited to phone calls placed 8 weeks after HIV testing. Approximately 6 out of 10 patients were successfully followed up by the program. Although this is comparable to the 57.6% of patients newly diagnosed with HIV who were successfully reached by phone call or home visit by the mobile program in Cape Town mentioned above,⁸ it still leaves open the possibility that the patients not reached in our study differed from those who were contacted. In particular, we speculate that those who could not be reached by phone may have been less likely to complete a referral visit after their HIV test than those who were reached, due to a reluctance to admit this to the caller or to accept a call that pertained in any way to their HIV status. As reported in Table 2, however, assignment to study group was not a factor in successful follow up, suggesting that both groups were affected equally by this limitation.

A third limitation stems from the reliance of our study on self-reported completion of the referral visit. We had no way to verify participants' statements, and it is possible that some patients reported making a visit when they had not actually done so, to avoid any feared criticism from the caller. The previously mentioned study in Cape Town, which used medical records to confirm the self-reports of a subsample of its participants, however, found perfect agreement between self-reports and clinic records,⁸ however, suggesting that inaccurate reporting may not be a serious concern for our study.

Despite these limitations, the results of the pilot program were largely encouraging, suggesting that integration of POC CD4 testing into routinely offered, mobile HCT services can increase uptake of HIV care. Our findings also underscore the importance of mobile or community-based HIV testing. We found 42.5% of patients who tested in high-volume public settings that attracted a mobile testing service, and who were thus presumably not seriously ill at the time of testing, were already eligible for ART (based on the new South African guidelines). POC CD4 technology creates the opportunity to alert these patients to their treatment eligibility on the spot, and may thus make even those who do not enroll in HIV care immediately will seek care more promptly if they become ill.

The study also leaves open a number of important questions, however. These include patients' reasons for accepting or not accepting the POC test itself, which may range from simple practical considerations of not having time to wait while the test is processed to more complicated emotional barriers associated with fear of the results. It is also important to consider the affordability and cost-effectiveness of the POC technology, relative to both the absolute budget available for HIV care and to other potential interventions available to

improve linkage to care. The appropriate roles for point of care CD4 tests and other rapid, POC tests becoming available remain important research topics.

Acknowledgments

Funding for this study was provided by the South Africa Mission of the US Agency for International Development under the terms of Cooperative Agreement GHSA-00-00020-00, Country Research Activity (G/PHN/HN/CS). Dr. Fox was supported by Award Number K01AI083097 from the National Institute of Allergy and Infectious Diseases.

The authors thank Melinda Wilson, Busi Makhanya, Glynis Davis, as well as Access VCT, Right to Care, and Alere for their cooperation, support, and assistance during the completion of this study. This analysis could not have been completed without their generous support.

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Table 1

Characteristics of 508 subjects testing HIV-positive at a mobile HIV counseling and testing program in Johannesburg, South Africa by whether or not they were offered a rapid, point-of-care CD4 count test

Testing Group	Not offered POC CD4 test	Offered POC CD4 test	Relative risk of offered POC CD4 test [*]	95% CI
Sample Size	197	311		
Female - N (%)	109 (55.3)	194 (62.4)	1.14	0.99–1.32
Tested Previously for HIV – N (%)	92 (46.7)	185 (59.4)	0.87	0.75–1.00
Age [*] - Mean (Standard Deviation)	34.3 (11.8)	34.0 (10.7)		
Age < 30 Years – N (%)	78 (40.00)	116 (37.54)	1.00	
Age 30–39 Years – N (%)	58 (29.74)	112 (36.25)	1.15	0.98–1.35
Age 40–49 Years – N (%)	37 (18.97)	52 (16.83)	1.01	0.82–1.25
Age 49+ Years – N (%)	22 (11.28)	29 (9.39)	0.97	0.76–1.26

^{*} Age is missing for 4 patients total (2 patients in each testing group). These four patients are excluded from all multivariate analyses. Adjusted relative risks of being offered the POC CD4 test estimated using a modified Poisson approach (female, tested previously, and age categories as covariates).¹⁵

Table 2

Relative risks of successful follow up and completion of referral visit (if follow up successful) within 8 weeks of HIV testing

Outcomes*	Successful follow up (Yes/No)	Completed referral visit ITT analysis**	Completed referral visit (Yes/No) TOT analysis***	95% CI
Number of patients total in analysis	504	316	286	
Number with outcome (yes)	316	172	158	
	Relative Risk	Relative Risk	Relative Risk	95% CI
Offered POC CD4 test	1.01	1.25	1.31	1.04–1.64
Female	1.21	1.22	1.14	0.90–1.43
Tested Previously for HIV	1.01	1.14	1.09	0.88–1.35
Age < 30 Years	1	1	1	
Age 30–39 Years	0.97	0.87	0.94	0.72–1.22
Age 40–49 Years	0.95	1.26	1.26	0.97–1.64
Age 49+ Years	0.91	0.97	0.94	0.65–1.38

* Successful follow up means the patient was successfully contacted by phone 8 weeks after HIV testing.

** ITT is intention to treat, which uses the full sample of patients contacted and offered the POC CD4 test.

*** TOT is treatment on treated, which uses the full sample of patients contacted and offered the POC CD4 test and then excludes those who declined the test or the site experienced a technical failure with the test.

**** Relative risk is adjusted relative risks of successful contact using a modified Poisson approach (offered POC CD4 test, female, tested previously, and age categories as covariates).¹⁵