Opt-out provider-initiated HIV testing and counselling in primary care outpatient clinics in Zambia
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Objective To increase case-finding of infection with human immunodeficiency virus (HIV) in Zambia and their referral to HIV care and treatment by supplementing existing client-initiated voluntary counselling and testing (VCT), the dominant mode of HIV testing in the country.

Methods Lay counsellors offered provider-initiated HIV testing and counselling (PITC) to all outpatients who attended primary clinics and did not know their HIV serostatus. Data on counselling and testing were collected in registers. Outcomes of interest included HIV testing coverage, the acceptability of testing, the proportion testing HIV-positive (HIV+), the proportion enrolling in HIV care and treatment and the time between testing and enrolment.

Findings After the addition of PITC to VCT, the number tested for HIV infection in the nine clinics was twice the number undergoing VCT alone. Over 30 months, 44 420 patients were counselled under PITC and 31 197 patients, 44% of them men, accepted testing. Of those tested, 21% (6572) were HIV+; 38% of these HIV+ patients (2515) enrolled in HIV care and treatment. The median time between testing and enrolment was 6 days. The acceptability of testing rose over time.

Conclusion The introduction of routine PITC using lay counsellors into health-care clinics in Lusaka, Zambia, dramatically increased the uptake and acceptability of HIV testing. Moreover, PITC was incorporated rapidly into primary care outpatient departments. Maximizing the number of patients who proceed to HIV care and treatment remains a challenge and warrants further research.

Introduction
The World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the United States Centers for Disease Control and Prevention (CDC) recommend provider-initiated testing and counselling (PITC) as a cost-effective and ethical way of improving access to HIV testing during general epidemics. Nevertheless, client-initiated, or opt-in, voluntary counselling and testing (VCT) remains the dominant form of testing in many sub-Saharan African countries, including Zambia. While VCT has been effective in identifying substantial numbers of HIV-positive (HIV+) individuals, in 2007 it was estimated that as many as 80% of HIV-infected adults in sub-Saharan Africa were unaware of their HIV serostatus and only 2.2% of all adults were tested annually. The introduction of routine opt-out PITC would offer an additional point of entry to HIV care and treatment for affected individuals.

In routine opt-out PITC, HIV testing and counselling are recommended as standard components of medical care at healthcare facilities. The term “opt-out” means that patients must explicitly refuse an HIV test. Routine opt-out PITC encourages a streamlined approach to HIV testing that involves simplified pretest counselling and verbal rather than written consent. Despite lingering ethical concerns about patients feeling coerced into being tested, there is a burgeoning body of evidence suggesting that routine opt-out PITC can play an important part in scaling up access to HIV testing, care and treatment in places where infection is highly prevalent.

This paper describes findings obtained during the first 30 months of a programme designed to introduce PITC for HIV infection into the outpatient departments of nine primary health-care clinics in Lusaka, Zambia, as part of an initiative to integrate primary care for patients with and without HIV infection. The programme had two primary objectives: (i) to improve uptake of HIV testing by offering an accessible and acceptable alternative to VCT and (ii) to improve HIV case-finding among patients attending outpatient departments who may be independently seeking outpatient medical care but not HIV care and treatment.

Methods
Setting
In April 2004, a large-scale public sector HIV care and treatment programme was established in Lusaka by the Zambian Ministry of Health with implementation assistance from the Centre for Infectious Disease Research in Zambia (CIDRZ) and funding from the President’s Emergency Plan for AIDS Relief (PEPFAR). Details of the Lusaka programme have been described previously.

Between July 2008 and June 2010, an integrated approach to outpatient care for individuals with and without HIV infection was introduced in a staggered fashion into nine urban primary health-care clinics in Lusaka. Clinical and administrative services at each clinic were harmonized for patients with and without HIV infection in three key ways: (i) the physical space used by patients and patient flows were amalgamated; (ii) medical records were standardized and (iii) routine PITC was introduced. All patients attending outpatient departments were referred for...
pretest counselling under the PITC programme unless they were already receiving HIV care and treatment or had evidence of being tested for HIV within the last 6 months (e.g., the test was reported in medical records or a test slip was available from a recognized external test provider).

Counselling and testing at each clinic were provided by two lay counsellors who were trained in psychosocial and provider-initiated counselling techniques. They worked in 5-hour shifts. Counselling was carried out in accordance with WHO and Zambian national guidelines and the presence of HIV was initially detected using the rapid Determine HIV-1/2 test (Abbott Laboratories, Abbott Park, United States of America). Positive HIV test results were confirmed using the Uni-Gold HIV test (Trinity Biotech, Bray, Ireland) and any conflicting results were resolved using the Bioline test (Standard Diagnostics Incorporated, Suwon City, Republic of Korea). Patients underwent pretest counselling either individually or in groups. However, they were always seen in private when deciding whether to opt in or out of HIV testing, while undergoing testing and during post-test counselling. Patients who opted out continued to follow normal outpatient procedures. Those who opted in proceeded to testing and underwent post-test counselling, regardless of the test result. Patients found to be HIV+ could enrol in the HIV care and treatment programme immediately or on a predetermined date.

Lay counsellors were supervised by the individuals in charge of the health centres and received group mentoring at quarterly review meetings facilitated by a CIDRZ nurse. Lay counsellors at the five clinics first involved in the integrated primary care programme and the introduction of PITC were hired on a renewable contract by the Lusaka District Health Management Team using funds from PEPFAR. Donor funding for these positions was being maintained in early 2011 but it was expected that counsellors would be transferred permanently onto the Zambian Ministry of Health payroll. Lay counsellors at clinics subsequently involved in the PITC programme were trained and hired by the Ministry of Health. Clinics that provided VCT continued to do so after the introduction of PITC. Community awareness programmes, which involved drama performances and door-to-door visits by neighbourhood health committees, took place in clinic catchment areas 4–6 weeks before and after the implementation of PITC and provided information about the integration of care for patients with and without HIV infection and the introduction of PITC.

Data collection and analysis

Registers kept in counselling rooms were used to record patients’ personal details, including gender and age, whether HIV testing was accepted or refused and, where appropriate, the reason for refusal. For patients who accepted, details of the test result, the date it was received and, for those who were HIV+, the date of enrolment in the HIV care and treatment programme were also recorded. The registers were reviewed each month by the individuals in charge of the clinics to evaluate how systems were functioning, to gauge counsellors’ performances and to ensure that orders for test kits and reagents were accurate. The registers were stored in a locked drawer in a locked room when not in use.

For this study, anonymous data on the number of patients counselled, tested and found to be HIV+ were collated monthly and entered manually into an electronic database. Data were checked for accuracy and completeness by the CIDRZ project coordinator. Details of patients who tested HIV+ during PITC were cross-referenced with entries on the national SmartCare electronic medical database to track those who enrolled in HIV care and treatment. Operational constraints prevented patients’ records being harmonized at two clinics, which meant that patients who tested HIV+ during PITC could not be tracked to determine if they enrolled in HIV care and treatment. The rate of enrolment in the HIV care and treatment programme was calculated by dividing the total number of patients who enrolled at the seven clinics with harmonized patient records by the total number of patients who tested HIV+ at all nine clinics taking part in the PITC programme. Consequently, the enrolment rate was probably underestimated.

The time to enrolment in the HIV care and treatment programme was defined as the number of days between the date of the patient’s test recorded in the PITC register and the date of enrolment recorded in the patient’s SmartCare electronic record. Although both mean and median times to enrolment were calculated, the median was considered the better measure because there was a small number of extreme outliers. Data analyses were performed using Microsoft Excel 2007 (Microsoft, Redmond, USA). The study protocol was approved by the institutional review boards of the University of Zambia in Lusaka, Zambia, and the University of Alabama at Birmingham, United States of America.

Results

Over 30 months, the staggered introduction of PITC at nine primary health-care clinics, as part of the programme to integrate care for patients with and without HIV infection, resulted in 44,420 patients receiving counselling. After subtracting patients who should not have undergone counselling because they knew and could prove their HIV status, the number counselled for the first time was 41,861. Of these patients, 31,197 (75%) agreed to be tested. Subsequently, 6,572 (21% of those tested) were found to be HIV+ and 2,515 (38% of HIV+ patients) enrolled in the HIV care and treatment programme. Overall, 44% of individuals who accepted testing were male, as were 41% of the HIV+ patients who enrolled in the care and treatment programme.

Over time, the percentage of individuals who accepted testing increased at all sites, as did the proportion who refused testing because their HIV status was known (Fig. 1). Fig. 1 shows that the overall rate of acceptance of HIV testing increased from 52% in the first 3 months of the programme (i.e., July to September 2008) to 83% in the last 3 months reported (i.e., October to December 2010). Full details of the number of patients who underwent counselling, accepted testing and were found to be HIV+ at the nine clinics in each month during the PITC programme are shown in Table 1 (available at: http://www.who.int/bulletin/volumes/89/5/10-084442). The clinics are numbered 1 to 9 according to the date of entry into the programme, such that Clinic 1 was involved first. The mean percentage of patients who accepted testing at individual clinics ranged from 47% in Clinic 9 to 99% in Clinic 8, while the mean percentage found to be HIV+ each month ranged from 13% to 26%. The rate of enrolment in the HIV care and treatment programme among HIV+ patients was low overall (38%), although it was higher in clinics with longer experience: Clinic 1: 47%; Clinic 2: 59%; Clinic 3:
50%; Clinic 4: 44%; Clinic 5: 43%; Clinic 8: 14% and Clinic 9: 25%. As noted earlier, patients in Clinics 6 and Clinic 7 could not be tracked from PITC to HIV care and treatment.

Six of the nine clinics provided VCT for HIV infection before the introduction of PITC, while the other three (Clinics 5, 6 and 7) started VCT along with PITC using the same lay health-care workers. Across the six clinics that previously offered VCT, the mean uptake of VCT increased from 48 patients per month in July 2007 to 190 patients per month in December 2010. Across the three clinics without pre-existing VCT, the mean number of patients who received VCT reached 117 per month following the introduction of PITC. Fig. 2 plots the total number of clients at all nine clinics who received VCT and PITC each month before and after the introduction of PITC. The introduction of PITC directly increased the number of patients who underwent HIV testing by between 11% and 207% compared with the number tested under VCT in the same month. The mean monthly increase across all sites during the 30-month study period was 97%, an almost twofold increase in clinic-based testing. At all clinics, the rate of case-finding of HIV+ individuals was consistently higher among VCT clients (mean: 33%) than PITC clients (mean: 22%), which suggests that VCT continued to be used by people who knew or suspected they had an HIV infection.

Among all patients who enrolled in HIV care and treatment, the median time between HIV testing and enrolment was 6 days (interquartile range, IQR: 13). The median time between HIV testing and enrolment at the clinics individually was: Clinic 1: 4 days (IQR: 14); Clinic 2: 6 days (IQR: 6); Clinic 3: 1 day (IQR: 5); Clinic 4: 4 days (IQR: 8); Clinic 5: 15 days (IQR: 20); Clinic 8: 13 days (IQR: 32.5); and Clinic 9: 3 days (IQR: 5).

**Discussion**

In countries like Zambia where there is a general HIV epidemic, case-finding of HIV+ patients must be effective to ensure universal access to care and treatment. Yet the rate of HIV testing often remains far too low. One solution is to provide tests that are more readily available and acceptable for specific population groups.

To date, evidence that PITC can improve case-finding of HIV+ patients and increase the number who proceed to HIV treatment and care has come primarily from controlled studies and from specific intervention programmes: for example, studies targeting patients with tuberculosis or sexually transmitted infections or programmes to prevent mother-to-child transmission of HIV. Although data from Botswana suggest that introducing PITC into primary care clinics increased the uptake of HIV testing, the country’s small population and status as a middle-income country make the findings difficult to generalize. Additional supporting evidence for the effectiveness of PITC in outpatient settings in sub-Saharan Africa comes from experience in tertiary health-care in Uganda and South Africa.

The present study adds to the literature on PITC in sub-Saharan Africa and provides support for WHO’s recommendations on the routine use of PITC in primary care. The study demonstrates that access to and uptake of HIV testing were improved by incorporating routine PITC into a programme of integrated primary care in urban and periurban populations in a country with a high prevalence of HIV infection and limited resources.

**Coverage of HIV testing**

In the 30 months during which PITC was introduced into nine urban clinics in Zambia, an additional 31 197 individuals underwent HIV testing. This equates to 9% of the aggregate catchment population of the clinics (i.e. approximately 400 000) and 2.6% of the total population of Lusaka. With PITC and changes in the uptake of VCT taken into account but routine testing for the prevention of mother-to-child transmission excluded, the introduction of PITC resulted in a mean increase of 97% in monthly clinic-based HIV testing above that associated with VCT alone; the increases at the individual clinics ranged from 57% to 408%.

The demand for client-initiated VCT generally increased following the introduction of PITC, which suggests that PITC was providing an additional route to testing rather than replacing VCT. The increase in the uptake of VCT occurred partly because staff were guaranteed to be available for testing after the introduction of PITC. Previously, testing was carried out...
Acceptability of HIV testing

The percentage of individuals who agreed to HIV testing was comparable to that reported in other controlled settings.\textsuperscript{2,23,35,41} The initially lower rates of acceptance seen in all but one clinic demonstrate that patients were able to exercise free choice. Thereafter, the rate of acceptance increased over time, supporting the view that routine PITC can help “normalize” HIV testing and remove a key structural barrier to accessing care and treatment.\textsuperscript{2,17} Patients at outpatient departments may have been willing to undergo HIV testing because they suspected that their presenting illness could be related to HIV infection but were afraid or unwilling to volunteer for testing.

In the past, opt-out testing has been criticized for being open to coercion by providers and because there is a risk that patients may not fully understand the purpose of testing. Consequently, monitoring whether patients have complete freedom to choose HIV testing is an ethical imperative. In the PITC programme, patient registers established at the inception of the study were reviewed each month to determine whether the rate of acceptance of HIV testing by patients seeing any individual counsellor was particularly high or low, and counsellors attended refresher courses on informed consent and counselling.

**HIV infection case-finding**

More than one in five patients tested in the PITC programme were found to be HIV+. This figure is consistent with the known prevalence of HIV infection in Lusaka District at the time of writing.\textsuperscript{43} Case-finding among VCT clients was higher (mean: 33%), which suggests that more of these individuals had symptoms that they themselves recognized as being related to HIV infection. Nonetheless, a preliminary analysis of HIV+ patients who proceeded to HIV care and treatment at the first four clinics that were involved in the integrated primary care programme and that incorporated PITC demonstrated that more than 50% had advanced-stage disease (i.e. CD4+ T-cell count: < 200/μL) and were eligible for antiretroviral therapy.\textsuperscript{29} Consequently, although the case-finding rate was lower with PITC, the programme still provided an important point of entry to care for patients with advanced immune suppression who were either asymptomatic or unable or unwilling to seek care themselves. In high-prevalence settings, therefore, PITC can lead to additional case-finding and increase the chance that HIV infection can be identified and treated early. As a result, patients could start antiretroviral therapy with lower viral loads, with substantial benefits for clinical outcomes in individuals and for disease prevention at the population level.\textsuperscript{44,45}

**Sex differences**

Due to constraints on data collection, the study findings could only be analysed partially by sex. Men made up 44% of those who accepted testing in the PITC programme and 41% of HIV+ patients who enrolled in HIV care and treatment. Although anecdotally more women than men attended outpatient departments, the study findings indicate that HIV testing in clinics in Lusaka may also have been more acceptable to women than men and that, in this setting, HIV+ women were more likely to access care and treatment. Consequently, while more research is needed, the indications are that strategies other than clinic programmes may be required to improve men’s access to HIV care and treatment.

**Enrolment in treatment programmes**

The median time between HIV testing and enrolment in the HIV care and treatment programme was 6 days, which we regarded as acceptable. The immediate enrolment of patients found to be HIV+, although ideal, is often impractical because of a shortage of health-care workers or because patients need to think about their situation since many will have attended the clinic for reasons other than HIV infection. However, the large number of patients who do not progress from HIV testing to HIV care and treatment poses a greater challenge. In this study, only 38% of HIV+ patients enrolled in the HIV care and treatment programme. Implementers of the PITC programme were able to work with clinic managers to improve the system for enrolment in HIV care and treatment, and this led to better average rates of enrolment at clinics that integrated primary care and initiated PITC services first. However, the pattern of enrolment was often erratic and the average enrolment rates at clinics that joined the PITC programme later were lower. The referral systems appeared to be weak and were affected disproportionately by changes in leadership, staff rosters and other unanticipated factors.

**Limitations**

The study was limited by being a non-randomized study of data collected routinely at nine urban clinics. Moreover, the analysis included data collected from clinics
that entered the primary care integration programme, including the introduction of PITC, at very different times because the programme had to be implemented according to a predetermined schedule. A further limitation is that the study was not designed to enable a rigorous comparison of VCT and PITC. Consequently, the study’s findings on trends in HIV testing should be interpreted with caution. In addition, the study did not include a cost-effectiveness analysis, which would be important for a full assessment of the feasibility of scaling up HIV testing programmes. For these reasons, the study’s results may not be generalizable beyond its particular setting.

Further research

The study’s findings highlight gaps in our understanding of HIV testing in Zambia and the following could provide topics for future studies: (i) differences in the clinical and demographic characteristics of patients undergoing VCT and PITC; (ii) the clinical and demographic characteristics of patients who refuse PITC; (iii) features of the clinic, community or culture that act as barriers to HIV testing and enrolment in care and treatment programmes; and (iv) whether undergoing PITC rather than VCT before enrolment in an HIV care and treatment programme influences clinical outcomes. Moreover, since patients undergoing PITC are less likely to be prepared for a positive HIV test result than those undergoing VCT, it would also be helpful to determine whether more extensive counselling or a different form of counselling about enrolment in HIV care and treatment would be beneficial.

Conclusion

Improving diagnosis and treatment for HIV+ individuals is an important public health goal. This study demonstrates that introducing PITC using lay health-care workers in busy urban primary health-care centres can double HIV testing and substantially increase case-finding of HIV+ individuals, which is vital for those with advanced disease. Critically, these gains were achieved without disrupting existing HIV or other health-care services. Nonetheless, scaling up HIV testing and treatment has substantial foreseeable implications for the health-care system: more health-care workers and drugs will be needed and infrastructure must be improved. In this study, increasing HIV testing involving supervised lay health-care workers who transferred from short-term contracts to the Zambian Ministry of Health payroll and used general Ministry of Health funds to pay for the additional test kits required. This approach works over the short to medium term. Ultimately, however, universal access to HIV testing and treatment in Zambia and similar countries depends on real increases in funds and human resources and requires a higher level of commitment from both national governments and the international community.

Competing interests: None declared.
Вывод

Рутинное внедрение системы ТКИМУ с использованием услуг непрофессиональных консультантов в медицинских клиниках Лусаки (Замбия) привело к резкому повышению отклика больных и увеличению численности согласившихся на прохождение тестирования на ВИЧ-инфекцию, в девяти клиниках превысило вдвое численность охваченных системой ДКТ. В течение 30 месяцев 44 420 больных получили консультации в рамках ТКИМУ, а 31 197 больных (из них 44% – мужчины) согласились пройти тест. Из общего количества прошедших тестирование 21% (6572) были ВИЧ-положительными; из этого числа 38% ВИЧ-положительных больных (2515) получили медицинскую помощь и лечение по поводу ВИЧ. Медианное время между тестированием и обращением к специалисту превысило шесть дней. Доля больных, согласившихся на прохождение тестирования, со временем возросла.

Резюме

Добровольное тестирование и консультирование амбулаторных больных по поводу ВИЧ, проводимое по инициативе поставщиков услуг в учреждениях первичной медико-санитарной помощи в Замбии

Цель

Повысить число диагностируемых случаев заражения вирусом иммунодефицита человека (ВИЧ) в Замбии и количество больных, направляемых к врачам-специалистам для получения медицинской помощи и лечения по поводу ВИЧ, благодаря дополнению существующей системы добровольного консультирования и тестирования (ДКТ) по инициативе пациента (основного механизма тестирования на ВИЧ в этой стране).

Методы

Общественные (непрофессиональные) консультанты предложили проводить тестирование и консультирование по инициативе медицинского учреждения (ТКИМУ) для всех амбулаторных пациентов, которые посещали клиники первичной медицинской помощи, но не знали своего серостатуса по ВИЧ-инфекции. Данные о консультировании и тестировании фиксировались в реестре. Исходы, представляющие интерес, включали в себя: охват тестированием на ВИЧ; согласие на тестирование; доля ВИЧ-положительных (ВИЧ+) результатов тестирования, доля больных, охваченных медицинской помощью и лечением, и время между тестированием и обращением к специалисту.

Результаты

После того, как система ДКТ была дополнена ТКИМУ, количество больных, прошедших тестирование на ВИЧ-инфекцию, в девяти клиниках превысило вдвое численность охваченных системой ДКТ. В течение 30 месяцев 44 420 больных получили консультации в рамках ТКИМУ, а 31 197 больных (из них 44% – мужчины) согласились пройти тест. Из общего количества прошедших тестирование 21% (6572) были ВИЧ-положительными; из этого числа 38% ВИЧ-положительных больных (2515) получили медицинскую помощь и лечение по поводу ВИЧ. Медианное время между тестированием и обращением к специалисту превысило шесть дней. Доля больных, согласившихся на прохождение тестирования, со временем возросла.

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Resumen
Realización de pruebas para el VIH y asesoramiento iniciados por el proveedor y con exclusión voluntaria en las clínicas ambulatorias de atención primaria en Zambia

Objetivo Aumentar la detección de casos de infección por el virus de la inmunodeficiencia humana (VIH) en Zambia y su remisión para la asistencia y el tratamiento del VIH complementando la realización de pruebas y asesoramiento voluntarios iniciados por el paciente (AVP), con pruebas para el modo de VIH dominante en el país.

Métodos Los asesores no científicos ofrecieron la realización de pruebas para el VIH y asesoramiento iniciados por el proveedor (PITC) a todos los pacientes ambulatorios que acudieron al centro de atención primaria y desconocían su seroestado de VIH. Los datos sobre asesoramiento y pruebas se obtuvieron de los registros. Los resultados de interés incluyeron la cobertura de las pruebas del VIH, la aceptabilidad de las pruebas, la proporción de pruebas VIH-positivas (VIH+), la proporción de inscritos en la asistencia y el tratamiento del VIH y el período de tiempo entre las pruebas y la inscripción.

Resultados Tras la incorporación de las PITC a las AVP, el número de personas que se sometieron a las pruebas para la infección por el VIH en las nueve clínicas duplicó el número de los que se sometieron exclusivamente a las AVP. Durante 30 meses, 44 420 pacientes recibieron asesoramiento a través de las PITC y 31 197 pacientes aceptaron someterse a las pruebas, siendo el 44% de los mismos varones. De los que se sometieron a las pruebas, un 21% (6572) resultaron VIH+; el 38% de estos pacientes VIH+ (2515) se inscribieron en el tratamiento y asistencia del VIH. La media de tiempo entre las pruebas y la inscripción fue de 6 días. La aceptabilidad de las pruebas fue creciendo con el tiempo.

Conclusión La introducción de PITC rutinarias empleando asesores no científicos en las clínicas de atención primaria de Lusaka, Zambia, aumentó de manera espectacular la acogida y la aceptabilidad de las pruebas de VIH. Además, las PITC se incorporaron rápidamente a los departamentos ambulatorios de atención primaria. Maximizar el número de pacientes que se sometan a la asistencia y el tratamiento del VIH sigue siendo todo un reto y exige realizar investigaciones en mayor profundidad.

Referencias
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Research
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