STI Online First, published on October 10, 2014 as 10.1136/sextrans-2014-051625

SHORT REPORT

Home-based counseling and testing for HIV and syphilis – an evaluation of acceptability and quality control, in remote Amazonas State, Brazil

Luciana Viana da Costa Ribeiro,[1] Meritxell Sabidó,[1,2] Enrique Galbán,[3,4] Jorge Augusto de Oliveira Guerra,[1] David Mabey,[5] Rosanna W Peeling,[5] Adele Schwartz Benzaken[1,3]

ABSTRACT

Objective Home-based, voluntary counselling and testing (HBCT) can help scale up early diagnosis. We aimed to evaluate the acceptance of HBCT for HIV and syphilis, estimate the prevalence among home-tested individuals and assess the performance of point-of-care testing by health staff using dried tube specimens (DTS) in a remote municipality of the Amazon region.

Methods Community health teams conducted door-to-door outreach in the urban area of São Gabriel da Cachoeira, Amazonas. HBCT for HIV and syphilis was offered to all residents aged ≥15 years. To provide an external quality assurance (EQA) of the healthcare workers' (HCW') ability to perform testing, DTS panels of reference samples were reconstituted and tested by the workers.

Results HBCT was offered to 1752 individuals and accepted by 1501 (85.6%). Those tested had a median age 32.0 years, 64.4% were women and 85.1% were indigenous; none were previously tested using a rapid test. The prevalence of HIV was 0.37% in men and 0.0% in women; the prevalence of syphilis was 1.12% in men and 2.69% in women. Eleven HCW tested 44 DTS samples for HIV and 44 for syphilis. EQA testing revealed that workers interpreted 55.8% and 90.7% of HIV and syphilis reference samples correctly.

Conclusions HBCT was acceptable and successful in reaching untested individuals. However, there were concerns with the quality of test performance, highlighting the need for continual evaluation and retraining of community HCW. As Brazil scales up HIV and syphilis testing, our findings highlight how HBCT can maximise coverage in similar remote areas and improve knowledge about prevalence of these infections.

INTRODUCTION

In the Amazon, gaps in access to healthcare and in meeting the increasing need for testing challenge efforts to broaden the testing coverage. Home-based, voluntary counselling and testing (HBCT) can be an alternative testing model for HIV and syphilis to overcome the shortcomings of an underserved area and reach individuals unaware of their HIV status.[1] The expansion of point-of-care (POC) testing needs to be coupled with external quality assurance (EQA) programmes to ensure reliable test performance.[2] In Brazil, a new approach for POC HIV and syphilis testing based on dried tube specimens (DTS) is being scaled up after its feasible application was demonstrated.[3]

We evaluated the effectiveness of the introduction of HBCT for HIV and syphilis using rapid testing together with EQA in a remote municipality in the Brazilian Amazon. In particular, we described the acceptability of POC testing for HIV and syphilis, estimated the prevalence of these infections and evaluated testing performance by health staff using DTS.

METHODS

Study setting

The study was conducted from December 2011 to May 2012 in the urban area of the municipality of São Gabriel da Cachoeira. It is a remote region only accessible by boat or plane and characterised by dispersed indigenous settlements.

HBCT was introduced as part of the National Family Health Program, which operates through multidisciplinary family health teams at basic primary healthcare sites. The urban area of the municipality has four of these teams that cover 93.3% of its population (17 775 inhabitants).

Sampling

To establish the sampling frame, we used the population that was presumed sexually active based on age (≥15 years) residing within the catchment area assigned to the four teams (11 399 inhabitants). The primary sampling unit was the family health team, and the number of participants in each one was proportional to the size of their population covered. Participants were selected randomly from all community residents by cluster sampling based on households. Participating households were selected by simple random sampling from the list of all households in the community. If nobody within a household agreed to participate, the household was replaced also randomly. Anyone who was sexually active, ≥15 years old and resided in the community at the time of the household visit was eligible for inclusion.

Data collection

We trained 11 healthcare workers (HCW (4 nurses and 7 nurse practitioners)) involved in testing and EQA. Overall, 41 community health

▶ Additional material is published online only. To view please visit the journal online (http://dx.doi.org/10.1136/sextrans-2014-051625).

[1]Fundação de Medicina Tropical Doutor Heitor Vieira Dourado (FMT-HVD), Manaus, Amazonas, Brazil
[2]TransLab. Departament of Medical Sciences, Universitat de Girona, Girona, Catalunya, Spain
[3]STI/AIDS Department, Fundação Alfredo da Matta, Manaus, Amazonas State, Brazil
[4]Facultad de Medicina Calixto García, La Habana, Cuba
[5]Department of Clinical Research, London School of Hygiene and Tropical Medicine, London, UK

Correspondence to
Dr Meritxell Sabidó, Fundação de Medicina Tropical Doutor Heitor Vieira Dourado, Avenida Pedro Teixeira 25, Manaus, AM CEP: 69040-000, Brazil; xellsabido@gmail.com

Received 5 April 2014
Revised 12 September 2014
Accepted 19 September 2014

To cite: Ribeiro LV da C, Sabidó M, Galbán E, *et al*. *Sex Transm Infect* Published Online First: [*please include* Day Month Year] doi:10.1136/sextrans-2014-051625

agents helped identify households and announced the testing through a campaign using radio advertisement and leaflets. At each home, they sought permission from the head of household and explained the study. Subjects signed written consent and received individual or group pretest counselling by the nurses or nurse practitioners. In a private room, participants were interviewed using a structured questionnaire, tested and post-test counselled.

Home-based, voluntary counselling and testing

A nurse practitioner collected samples by a finger prick and performed HIV testing using the DPP HIV-1/2 rapid test Bio-Manguinhos (Oswaldo Cruz Foundation, Rio de Janeiro, Brazil) and syphilis testing using the SD Bioline Syphilis 3.0 (Standard Diagnostics, Kyonggi-do, Korea). Participants received their results within 15 min and free condoms. Those with a reactive test result were referred for confirmatory testing and treatment.

External quality assurance

EQA procedures were performed in May 2012 separately from the HBCT. HCW involved in testing were provided with a proficiency testing panel that included DTS with sera that were well characterised as positive or negative. DTS was prepared by the reference laboratory of Fundação Alfredo da Matta in Manaus according to the method of Parekh *et al*[2] with some modifications described by Benzaken *et al*.[4] Dried sera were reconstituted with phosphate buffered saline-Tween 20 on site.[2]

Each HCW evaluated four samples for syphilis and four samples for HIV, all previously selected at random from their respective panel. HCW were asked to interpret a sample on the basis of the intensity of reactivity (strong positive, weak positive, very weak positive or negative) and to give their final interpretation of the results as positive or negative, depending on the observed reactivity pattern. An invalid result could also be reported when the rapid test did not show the control line. Data were collected on a worksheet and were sent to the reference laboratory for scoring. Individualised on-site retraining was indicated when necessary. Testing personnel responded on the difficulties of rapid test performance and DTS panels' reconstitution. The quality control system included standard operating procedures and weekly monitoring visits.

Data analysis

Testing acceptance was defined as undertaking testing together with counselling and receiving test results at home. To assess the performance of HCW, their rapid test interpretations on site were compared against the expected results of the samples prepared by the reference laboratory. We considered an interpretation to be correct when the test result reported by the HCW (positive or negative) corresponded with the DTS result in the reference lab. For each test, we calculated kappa coefficient between the results of the samples tested on site and those obtained in the reference lab.

The ethical review committee of Fundação de Medicina Tropical approved the study. A parental informed consent was not necessary for individuals <18 years of age.

RESULTS

Acceptance of HBCT

The home-based screening team visited 1861 households that had a total of 1752 potential participants aged ≥15 years. Of these, 1501 individuals (85.6%) agreed to both HIV and syphilis testing and received the test results. Non-responders (n=251) were either not at home at the time of the study visit or refused to participate. Most (92.3%) preferred individual precounselling.

Median age of participants was 32 years (IQR: 22–47), 535 were men (35.6%) and most (88.9%) were indigenous.

HIV and syphilis prevalence

The prevalence of HIV (n=2) was 0.13% (95% CI 0.02 to 0.48), and in men (n=2) was 0.37% (95% CI 0.05 to 1.34). HBCT identified 32 cases of syphilis, 6 in men, 26 in women, and 2 out of 68 pregnant women. The prevalence of syphilis was 2.13% (95% CI 1.46% to 2.99%), in men 1.12% (95% CI 0.41% to 2.42%), in women 2.69% (95% CI 1.76% to 3.91%) and in pregnant women 2.94% (95% CI 0.36% to 10.22%).

External quality assurance

Eleven HCW evaluated four sample (DTS) tubes for HIV and four DTS for syphilis. Of those, nine (81.8%) interpreted at least one test result incorrectly for HIV and three (27.3%) did for syphilis. For each test, 44 DTS were provided to HCW (table 1). Overall, 24 (54.5%) of the HIV readings and 40 (90.9%) of the syphilis readings were correct, resulting in a kappa coefficient of 0.34, and of 0.77, respectively. Overall, 16 HIV DTS (43.8%) and 3 syphilis DTS (6.8%) were falsely

Table 1 Results of the DTS-based EQA programme in São Gabriel da Cachoeira, Amazonas

	Overview of DTS results from the reference lab							
	Expected positive result				Expected negative result			
Result reported by HCW	Number of DTS	Reported positive	Reported negative (FN)	Reported invalid	Number of DTS	Reported positive (FP)	Reported negative	Reported invalid
HIV								
Nurse	18	8 (44.4%)	9 (50.0%)	1 (5.6%)	5	0 (0.0%)	5 (100%)	0 (0.0%)
Nurse practitioner	15	5 (33.3%)	7 (46.7%)	3 (20.0%)	4	0 (0.0%)	4 (100%)	0 (0.0%)
Total	33	13 (39.4%)	16 (48.5%)	4 (12.1%)	11	0 (0.0%)	11 (100%)	0 (0.0%)
Syphilis								
Nurse	18	15 (83.3%)	3 (16.7%)	0 (0.0%)	6	1 (16.7%)	5 (83.3%)	0 (0.0%)
Nurse practitioner	15	15 (100%)	0 (0.0%)	0 (0.0%)	5	0 (0.0%)	5 (100%)	0 (0.0%)
Total	33	30 (90.9%)	3 (9.1%)	0 (0.0%)	11	1 (9.1%)	10 (90.9%)	0 (0.0%)

For each test, 11 HCW tested four DTS for HIV and four for syphilis. Expected DTS results from the reference lab and results reported by HCW are shown.
DTS, dried tube specimens; EQA, external quality assurance; FN, false negative; FP, false positive; HCW, healthcare workers.

reported as negatives (36.4%). For HIV DTS, 7 of which were very weak positives (43.8%), 6 were weak positives (37.5%) and 3 were strong positive samples (18.7%), whereas for syphilis DTS all of which were very weak positive samples.

Nurses reported a slightly higher proportion of false HIV-negative results (50.0%) than nurse practitioners (46.7%), and all the incorrect readings for syphilis. None of the HCW reported facing difficulties in performing POC testing or in handling the reconstitution of the DTS for HIV or syphilis.

DISCUSSION

The study suggests that the testing strategy was very well received in the community, which might be related to the sensitisation campaign and the involvement of health agents who were well known by the community.[5] Studies from five African countries show that 83% of the population accepts HBCT for HIV.[5]

HBCT was successful in identifying syphilis cases, especially among pregnant women. Community screening of 45 226 sexually active indigenous people from the Amazon region showed a lower syphilis prevalence both overall (1.62%) and in pregnant women (1.36%) than that in our study.[6]

The kappa coefficient showed excellent (>0.75) and poor (<0.40) agreement for syphilis and HIV, respectively. HCW reported a substantial proportion of false-negative results for HIV test with very weak positive samples, which were expected to be up to 5.8% of samples.[7] The performance of the HIV kits might be a source of some misinterpretations. The HIV-1/2 rapid test Bio-Manguinhos showed 99.3% sensitivity and 100% specificity, and HCW classified only 36.0% of DTS panel samples correctly.[8]

False-negative results occurred even though HCW considered both POC testing and DTS easy to use, which suggests the need for remedial actions to improve testing performance.[3] These actions may include closer examination of testing practices, record keeping, refresher training and periodic supervisory site visits.[4 9] Results reported by nurse practitioners were more often correctly interpreted than those reported by nurses, most likely due to practitioners being more experienced with malaria and dengue rapid tests.[10]

The main study limitations are that we did not address unintended consequences of HBCT, and that the study does not provide a useful estimate of HIV prevalence due to challenges observed with test performance for HIV.

Our findings highlight how HBCT can maximise testing coverage and can be used as a tool to improve baseline prevalence data of both infections in remote areas with similar characteristics. HBCT could also be integrated with tuberculosis and malaria community programmes. However, efforts should be made to ensure the quality of test performance.

Handling editor Jackie A Cassell

Acknowledgements We thank the community health team of São Gabriel da Cachoeira/Amazon for their efforts to enrol participants in their homes. We thank the Project Saúde e Condições de Vida de Povos Indígenas na Amazônia, Programa de Apoio a Núcleos de Excelência (PRONEX) of the Fundaçao de Amparo à Pequisa do Estado do Amazonas (FAPEAM), with the collaboration of the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

Contributors ASB conceived the study and coordinated fieldwork. LVdCR conducted fieldwork. EG conducted preliminary data analysis. MS wrote the article and conducted the data analyses. All authors contributed to the discussion of the results and critical revision of the manuscript.

Funding The study was partially funded by the Bill & Melinda Gates Foundation through a grant (#47697) to RWP at the UNICEF/UNDP/World Bank/WHO Special Program for Research and Training in Tropical Diseases and subsequently at the London School of Hygiene and Tropical Medicine. The Amazonas Division of the National Program on AIDS, Sexually Transmitted Infections, and Viral Hepatitis donated the HIV tests. The study was also supported in part by the Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq) of the Ministério da Ciência, Tecnologia e Inovação (MCTI), Brazil, and the Programa Estratégico de Ciência, Tecnologia & Inovação nas Fundações Estaduais de Saúde—PECTI/AM SAÚDE, Government of the Amazonas State, Brazil.

Competing interests None.

Patient consent Obtained.

Ethics approval Ethical review committee of Fundação de Medicina Tropical. Approval number: 2061.

Provenance and peer review Not commissioned; externally peer reviewed.

REFERENCES

1 Bateganya MH, Abdulwadud OA, Kiene SM. Home-based HIV voluntary counseling and testing in developing countries. *Cochrane Database Syst Rev* 2007;(4):CD006493.
2 Parekh BS, Anyanwu J, Patel H, *et al*. Dried tube specimens: a simple and cost-effective method for preparation of HIV proficiency testing panels and quality control materials for use in resource-limited settings. *J Virol Methods* 2010;163:295–300.
3 Mabey DC, Sollis KA, Kelly HA, *et al*. Point-of-care tests to strengthen health systems and save newborn lives: the case of syphilis. *PLoS Med* 2012;9:e1001233.
4 Benzaken AS, Bazzo ML, Galban E, *et al*. External quality assurance with dried tube specimens (DTS) for point-of-care syphilis and HIV tests: experience in an indigenous populations screening programme in the Brazilian Amazon. *Sex Transm Infect* 2014;90:14–18.
5 Sabapathy K, Van den Bergh R, Fidler S, *et al*. Uptake of home-based voluntary HIV testing in sub-Saharan Africa: a systematic review and meta-analysis. *PLoS Med* 9:e1001351.
6 Benzaken AS, Pinto NV, Carvalho CH, *et al*. Increasing access to HIV and syphilis screening in remote areas using rapid tests. *Sex Transm Infect* 2011;87(Suppl 1):A2.
7 Gray RH, Makumbi F, Serwadda D, *et al*. Limitations of rapid HIV-1 tests during screening for trials in Uganda: diagnostic test accuracy study. *BMJ* 2007;335:188.
8 da Motta LR, Vanni AC, Kato SK, *et al*. Evaluation of five simple rapid HIV assays for potential use in the Brazilian national HIV testing algorithm. *J Virol Methods* 2013;194:132–7.
9 Yao K, Wafula W, Bile EC, *et al*. Ensuring the quality of HIV rapid testing in resource-poor countries using a systematic approach to training. *Am J Clin Pathol* 2010;134:568–72.
10 Learmonth KM, McPhee DA, Jardine DK, *et al*. Assessing proficiency of interpretation of rapid human immunodeficiency virus assays in nonlaboratory settings: ensuring quality of testing. *J Clin Microbiol* 2008;46:1692–7.

Home-based counseling and testing for HIV and syphilis – an evaluation of acceptability and quality control, in remote Amazonas State, Brazil

Luciana Viana da Costa Ribeiro, Meritxell Sabidó, Enrique Galbán, Jorge Augusto de Oliveira Guerra, David Mabey, Rosanna W Peeling and Adele Schwartz Benzaken

Sex Transm Infect published online October 10, 2014