Linkage to HIV Care Following HIV Self-testing: Results From a Cluster-Randomised Trial of Community-Based Distribution of Oral HIV Self-Test Kits Nested in Four HPTN 071 (PopART) Communities in Zambia

Sian Floyd[1], Kwame Shanaube[2], Ab Schaap[1,2], Mwelwa Phiri[2], Bernadette Hensen[1], Chama Mulubwa[2], Virginia Bond[1,2], Bwalya Chiti[2], Musonda Simwinga[2], Richard Hayes[1], Sarah Fidler[3], Alwyn Mwinga[2], Helen Ayles[1,2]

[1] London School of Hygiene & Tropical Medicine, United Kingdom; [2] ZAMBART, University of Zambia, Lusaka, Zambia; [3] Imperial College, London, United Kingdom

BACKGROUND

- Evidence has accumulated that HIV self-testing (HIVST) will contribute towards achieving the first 90 target.
- However, for those who self-test and the result is HIV-positive, there is limited evidence about how to ensure linkage to confirmatory testing and linkage to HIV care (LTC).
- HPTN 071 (PopART) is a 3-arm cluster-randomized trial (CRT) in 21 large peri-urban/urban communities in Zambia and the Western Cape of South Africa, with high HIV prevalence and a total study population of ~1 million.
- The study is testing the impact on HIV incidence of a household-based combination HIV prevention approach (Arms A and B) provided by community HIV care providers (CHiPs) – the "PopART" intervention – compared with standard-of-care (Arm C).
- In December 2016, 4 of the PopART intervention communities in Zambia were included in a nested cluster-randomized trial of adding oral HIV self-testing (HIVST) to the standard PopART intervention.
- Here we report findings about the impact of the HIVST intervention on linkage to HIV care, among individuals who were newly diagnosed with HIV during the HIVST trial period. This was a secondary outcome of the HIVST trial.

Photographs of CHiP teams in Zambia who deliver the PopART intervention:
(a) Offering HIVST as a testing option; (b) providing rapid HIV testing using a fingerprick blood sample

METHODS (1)

PopART INTERVENTION

- The PopART intervention was delivered during 2014-2017.
- In Arm A, from the start of the study universal ART (irrespective of CD4 count) was offered through routine government services to all individuals with an HIV-positive diagnosis. In Arm B, ART was provided according to national guidelines.
- Universal ART became part of national guidelines for HIV care in Zambia in 2016, and from May/June 2016 was offered in Arm B communities as well as in Arm A.
- Before the start of the study, each of the intervention communities was divided into "zones" with ~500 households per zone. In each zone, a pair of CHiPs (a "CHiP team") was responsible for delivering a combination HIV prevention package that included a universal offer of home-based HIV testing with a rapid diagnostic test using fingerprick blood (RDT), referral of HIV-positive individuals to HIV care, and re-visits to HIV-positive individuals to support LTC.
- CHiPs delivered the intervention over three annual "rounds" of intervention; the third was from September 2016-December 2017. In each round, they aimed to offer intervention services to all individuals who were resident in their zone.

HIVST TRIAL – SETTING AND DESIGN

- Four of the PopART intervention communities in Zambia, 2 in Arm A and 2 in Arm B, were included in the HIVST trial. The total population across the 4 communities was ~160,000, and the total number of CHiP zones was 66.
- Half of the 66 zones were randomised to receive the HIVST intervention, and half to continue to receive the standard intervention.
- The HIVST intervention was delivered in the 33 zones that were randomised to receive it from January 18 2017 to June 30 2017. Follow-up visits to support LTC continued to September 30 2017.
- Following the HIVST trial analysis plan, analyses were restricted to individuals who were enumerated as a household member during February 1 to April 30 2017.

METHODS (2)

HIVST TRIAL INTERVENTION

- All individuals who were aged ≥16 years, and did not self-report to CHiPs that they already knew they were HIV-positive, were eligible to be offered HIV testing.
- HIVST was offered as an alternative to testing with a rapid diagnostic test (RDT) on a fingerprick blood sample.
- HIVST was offered in person, and also via secondary distribution.
- When offered in person, CHiPs demonstrated how to use the test kit, and then the individual could choose to test either with, or without, CHiP supervision
- For individuals aged ≥18 years, CHiPs offered to provide an HIVST kit for later use by an absent partner = "secondary distribution".
- **CHiPs explained that if the HIVST result was positive, it was important to confirm this test result with an RDT.**
- For individuals who chose unsupervised self-testing, or those who tested via secondary distribution, CHiPs were expected to conduct a follow-up visit within 7 days.
- CHiPs asked permission to read the result of the self-test. **An individual's self-test result was determined by the CHiP reading, if this was done, and otherwise according to the individual's self-report of the test result.**
- For individuals who first tested via secondary distribution, the test result could be received by CHiPs either from the individual themselves or from the partner who distributed the test kit.

CONFIRMATORY TESTING AND LINKAGE TO HIV CARE (LTC)

- **For individuals with a positive HIVST result, and who the CHiPs met in person following this test result, CHiPs offered confirmatory testing with an RDT.**
- For individuals who did not accept the initial offer of confirmatory testing, CHiPs tried to contact individuals again, to make another offer of confirmatory RDT.
- **Individuals were "diagnosed HIV-positive" if they accepted the offer of RDT and the test result was HIV-positive.**
- **For individuals who were diagnosed HIV-positive, CHiPs were expected to make follow-up visits to support LTC.**

DATA COLLECTION, AND TWO MAIN OUTCOMES

- At follow-up visits for LTC support, CHiPs recorded whether the individual was still resident in the CHiP zone, and if the individual was contacted they collected information on registration for HIV care and ART initiation
- **Our two main outcomes on LTC were:**

1) the **time from CHiP referral to LTC**, estimated using the Kaplan-Meier method
2) the **percentage of individuals who had LTC by the end of the study period**, i.e. by September 30 2017, among all who remained resident according to the last information collected.

RESULTS AND CONCLUSIONS

UPTAKE OF HIV TESTING, AND NUMBER TESTED HIV+

- **In the 33 non-HIVST zones**, 7,800 individuals aged ≥16 years tested for HIV with an RDT, and **204 (2.6%) tested HIV+.**
- In the 33 HIVST zones, 7,757 individuals tested for HIV after meeting the CHiPs in person; for 216 (2.8%) the first test result was HIV+.
- In addition, 323 individuals in HIVST zones first tested for HIV via secondary distribution, and for 21 this first test result was HIV+.
- Overall, **in the 33 HIVST zones**, for **237 individuals the first test result was HIV+**

UPTAKE OF CONFIRMATORY TESTING IN HIVST ZONES

- **13 individuals who tested HIV+ following secondary distribution were not contacted in person by CHiPs**
- **Of those contacted in person, 20 did not accept the offer of confirmatory RDT.**
- Overall, 190 of the 237 individuals (83%) whose first test result was HIV+ were confirmed HIV+ on an RDT (Fig 1).
- In addition, there were 5 individuals whose first HIVST result was HIV-, but on a subsequent RDT they were diagnosed HIV+.
- **In total, 195 individuals were newly diagnosed HIV+ on an RDT in HIVST zones**

Fig 1. Flow chart from a first HIV+ test result, to RDT confirmation, in HIVST zones

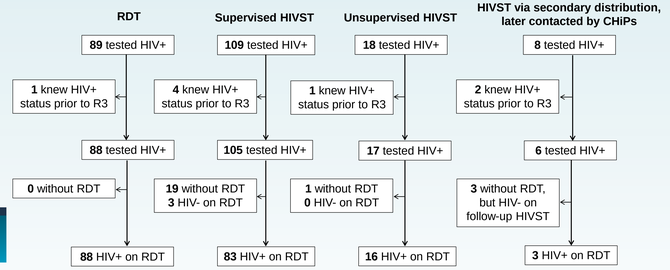


Table 1: Referral to HIV care, time to LTC, and LTC by September 30 2017

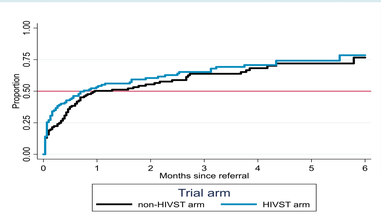
	Overall		Option chosen for first HIV test, HIVST zones			
	Non-HIVST zones	HIVST zones	RDT	Supervised self-test	Unsupervised self-test	Secondary distribution, then contacted in person
Number diagnosed HIV+	N=204	N=195	N=88	N=86	N=16	N=5
Referred to care	98% (n=199)	94% (n=184)	97% (n=85)	93% (n=80)	87% (n=14)	100% (n=5)
Followed up after referral	65%	68%	61%	70%	93%	80%
LTC by 3 months (3M) after referral[1]	64%	65%	71%	69%	46%	25%
Hazard ratio, 95% CI[2]	Ref (1.0)	1.12 [0.8-1.6]	Ref (1.0)	1.13 [0.7-1.8]	0.49 [0.2-1.2]	0.25 [0.03-1.9]
Still resident as of Sep 30 2017	74% (152/204)	78% (153/195)	69% (61/88)	84% (72/86)	94% (15/16)	100% (5/5)
LTC by September 30 2017	51% (78/152)	55% (84/153)	56% (34/61)	57% (41/72)	53% (8/15)	20% (1/5)

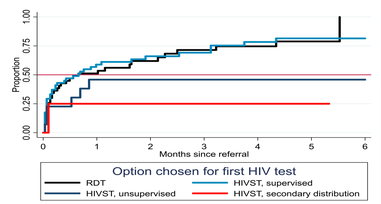
1 estimated using Kaplan-Meier method; 2 Estimated from Cox regression, adjusted for community, gender, and age group

LINKAGE TO HIV CARE (LTC)

- **The estimated percentage of individuals who were LTC by 3 months after referral was 65% in HIVST zones and 64% in non-HIVST zones (Table 1, Fig 2).**
- In HIVST zones, there was a **suggestion that LTC was slower for individuals who first tested with unsupervised self-testing or via secondary distribution, compared with those who first tested with an RDT or supervised self-testing** (Table 1, Fig 2).
- The percentage who were recorded by CHiPs as LTC by 30 September 2017, among all who remained resident in the same CHiP zone, was 55% in HIVST zones and 51% in non-HIVST zones (p=0.78).

Fig 2. Time to linkage to care (LTC), after referral to HIV care (a) by trial arm (b) by choice of first testing option, HIVST zones





CONCLUSIONS

- Linkage to HIV care (LTC) following an HIV-positive diagnosis and referral to HIV care was not undermined by offering HIVST as a testing option, in the context of LTC support.
- Strategies are needed to facilitate confirmatory RDT following an HIV-positive self-test result, and LTC following unsupervised self-testing and secondary distribution

ACKNOWLEDGMENTS

HPTN 071 is sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) under Cooperative Agreements UM1-AI068619, UM1-AI068617, and UM1-AI068613, with funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). Additional funding is provided by the International Initiative for Impact Evaluation (3ie) with support from the Bill & Melinda Gates Foundation, as well as by NIAID, the National Institute on Drug Abuse (NIDA) and the National Institute of Mental Health (NIMH), all part of the U.S. National Institutes of Health (NIH). We also wish to acknowledge implementing partners in South Africa (City of Cape Town and Western Cape Government health departments, Kheth' Impilo, ANOVA Healthcare, SACTWU Worker Health Programme and Supply Chain Management Services) and Zambia (Zambian Ministry of Health, CIDRZ, ZPCT II and JSI).

The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIAID, NIMH, NIDA, PEPFAR, 3ie, or the Bill & Melinda Gates Foundation.

For more information, visit **hptn.org** and follow us:
Facebook: **HIVptn** | Twitter: **@HIVptn** | Youtube: **HIVptn**

Presented at the
22nd International AIDS Conference
Amsterdam, Netherlands
23-27 July 2018
Poster Number: THPDC01