HPTN 071



Key Findings As Study Nears Completion

HPTN 071 (PopART) is a community-based, randomized study evaluating the impact of a combination HIV prevention package on HIV incidence. This study is the largest community-randomized trial testing the universal HIV test and treat strategy and is being conducted across 21 high HIV burden, resource-limited urban settings in the Western Cape of South Africa and Zambia, with a total estimated population of 1 million.

Study communities were randomly assigned to one of three study arms (A, B and C). In the original study design, Arm A received a household intervention package with an offer of HIV treatment irrespective of CD4 count, Arm B received the household intervention package, but with HIV treatment offered per national guidelines, and in Arm C there was no household intervention and treatment followed national guidelines. The household intervention comprises annual rounds of home-based HIV counseling and testing delivered by Community HIV-Care Providers (CHiPs) who also support linkage to care, antiretroviral therapy (ART) retention and other HIV-related services.









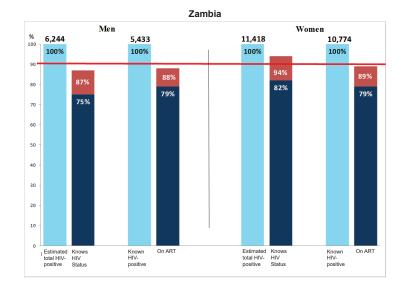
Achieving the First Two UNAIDS 90-90-90 Targets On Completion of a Three-Year Universal Testing and Treatment (UTT) Intervention in the HPTN 071 (PopART) Randomised Trial in Zambia and South Africa

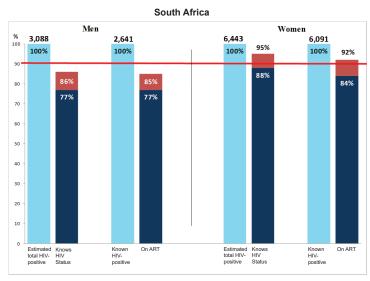
AIDS 2018, Richard John Hayes Poster, Programme #THPEC289, 26 July 2018

How close did the HPTN 071 trial get to achieving the first and second "90"s? Estimates show that after three rounds of delivery of the PopART intervention, the first two of the UNAIDS 90-90-90 targets were reached overall in adults aged 15 and over in the 7 PopART intervention communities in Zambia and South Africa receiving the full intervention from the start of the trial. Of an estimated 9,332 HIV-positive men and 17,861 HIV-positive women, 87% of men and 94% of women knew their HIV+ status following R3 (first-90) in Zambia, and 86% of men and 95% of women in South Africa. Among these, 88% of men and 89% of women were estimated to be on ART (second-90) by the end of R3 in Zambia, and 85% of men and 92% of women in South Africa. Estimates displayed by gender and age show that both indicators were achieved or exceeded in older adults, but gaps remained in men aged 18-34 years and women aged 15-29 years. After three rounds of intervention in these urban communities with high mobility and migration, we estimated that the first and second 90 targets were reached overall among women and almost reached among men. Continuing efforts are needed to reach the remaining HIV+ adults not yet diagnosed or on ART, particularly among younger adults where important gaps remain.

First and Second 90 estimates for South Africa and Zambia, overall in the total population

Navy blue = at time of Round 3 visit Red = by end of Round 3

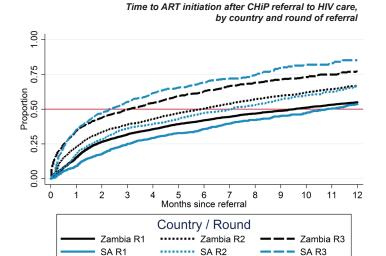




Dramatic Reductions in Time to ART Initiation Among HIV+ Individuals Referred to HIV Care Following Home-Based Testing Services: Experiences From the HPTN 071 (PopART) Trial Between 2014 and 2017

AIDS 2018, Sarah Fidler Poster, Programme #THPEC276, 26 July 2018

How did 'time to start' for ART change over the course of the PopART intervention? After 3 annual rounds of delivering a community-wide combination HIV prevention package to 7 communities in Zambia and South Africa, dramatic reductions were seen in the time from HIV testing to ART initiation. The median time to ART initiation after CHiP referral to care was ~10 months, ~6 months, and ~3 months in R1, R2, and R3 respectively, with a reduction overall and for both men and women over successive rounds of the PopART intervention. Implementation of a universal HIV test and treat strategy with support within the community to link to care and initiate ART was highly acceptable and effective in improving time to ART initiation.



Median time to ART initiation after referral to HIV care: R1: ~10 months: R2: ~6 months: R3: ~3 months

Linkage to HIV Care Following HIV Self-Testing: A Cluster Randomised Trial of Community-Based Distribution of Oral HIV Self-Test Kits Nested in Four HPTN 071 Communities in Zambia

AIDS 2018, Sian Floyd Poster Discussion, Programme #THPDC0102, 26 July 2018

If people self-test for HIV, does that create difficulties in their linking to care? In December 2016, 4 of the PopART intervention communities in Zambia, comprising 66 zones, were included in a cluster-randomized trial of adding oral HIVST to the standard intervention. Self-testing was offered in-person, supervised or unsupervised, and to absent partners via secondary distribution. Among 13,267 individuals in 33 HIVST zones, 195 were diagnosed HIV-positive; additionally 20 tested HIV-positive with supervised/unsupervised self-testing but did not have confirmatory RDT, and 13 tested HIV-positive following secondary distribution but were not contacted in-person by CHiPs. Among 13,706 individuals in 33 non-HIVST zones, 204 were diagnosed HIVpositive. Among those diagnosed, 94% (184/195) in HIVST and 98% (199/204) in non-HIVST zones were referred to care. We estimated that 65% in HIVST, and 64% in non-HIVST, zones were LTC by 3 months after referral (hazard ratio 1.11, 95%CI 0.78-1.58). In HIVST zones, there was a suggestion that LTC

Months since referral

Trial arm

non-HIVST arm

HIVST arm

Time from Referral-to-HIV-Care to Linkage-to-Care

was slower for individuals who tested with unsupervised self-testing or via secondary distribution, compared with those who tested with RDT. Linkage to HIV care (LTC) following an HIV-positive diagnosis and referral to HIV care was not undermined by offering HIV self-testing as a testing option compared to provider-delivered HIV testing, in the context of LTC support. However, strategies are needed to (1) facilitate LTC when self-testing is done without supervision, including following secondary distribution, and (2) facilitate confirmatory testing, following an HIV-positive self-test result.

Retention on ART Within the HPTN 071 (PopART) Universal Testing and Treatment Programme in Zambia and South Africa

AIDS 2018, David Macleod Poster, Programme #THPEC323, 26 July 2018

What do ART clients say about their ability to remain on treatment in the context of a large universal test and treat trial? Estimates of retention on ART were calculated based on self-reported data from people living with HIV in the seven HPTN 071 (PopART) study communities in Zambia and South Africa that received the full intervention from the start of the trial. Our data indicate that at the round three visit at the end of the PopART intervention, approximately 95% of individuals known to be on ART self-reported taking ART within the last month and not missing pills in the last three days. That is, they reported being retained on ART. In the absence of routine viral load testing, these results provide some indication that retention on ART within the study was high, a necessary component in order to meet the "third 90" of the UNAIDS 90-90-90 targets.

HIV Care Cascade Among Adolescents in a "Test and Treat" Community-Based Intervention in Zambia and South Africa: HPTN 071 (PopART) for Youth Study

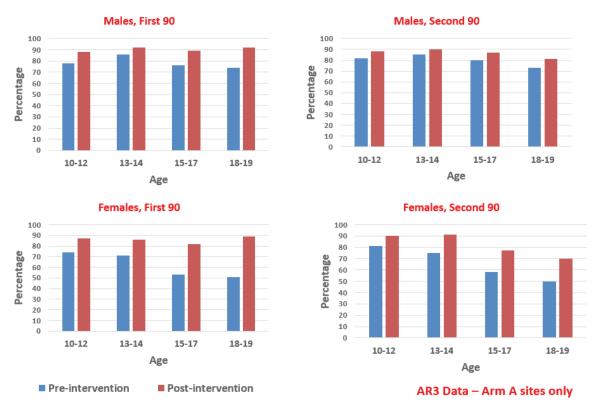
Evidence for HIV Prevention in Southern Africa (EHPSA) Satellite Session, Graeme Hoddinott Presentation, 23 July 2018

AIDS 2018, Kwame Shanaube Non-Commercial Satellite Presentation, Programme #MOSA34, 23 July 2018

AIDS 2018, Kwame Shanaube Poster, Programme #THPEC247, 26 July 2018

When a community-level HIV intervention is offered to every household, how do youth fare? Prior studies have shown that adolescents continue to have worse health outcomes than adults throughout the HIV cascade of care. The PopART for Youth (P-ART-Y) study was nested within HPTN 071 (PopART) and measured the acceptability and uptake of the PopART HIV prevention package among adolescents and young adults. The PopART intervention came close to achieving both the first and second UNAIDS 90-90-90 targets for all adolescent males. However, gaps still remain for older adolescents for the second 90, especially in adolescent girls.

The first and second UNAIDS 90s estimated for the total population in the PopART sites

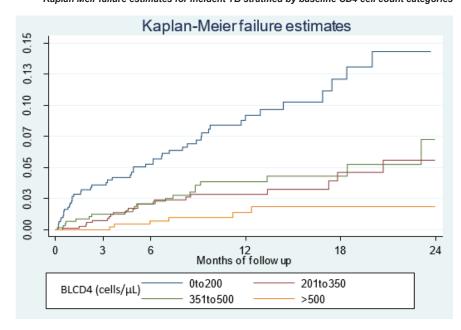


Incidence of Tuberculosis Among HIV-Positive Individuals Initiating Antiretroviral Treatment at Higher CD4 Counts in the HPTN 071 (PopART) Trial in South Africa

JAIDS, Peter Bock et al, January 2018

Will early ART initiation lower TB incidence? We followed HIV-positive individuals starting ART with CD4 counts above 500 cells/µL and found that TB incidence was significantly lower among these individuals than among those with lower CD4 counts. Scale-up of ART, regardless of CD4 count, along with other TB prevention strategies, has the potential to significantly reduce TB incidence.

Kaplan Meir failure estimates for incident TB stratified by baseline CD4 cell count categories



Attrition When Providing Antiretroviral Treatment at CD4 Counts >500cells/µL at Three Government Clinics Included in the HPTN 071 (PopART) Trial in South Africa

PlosONE, Peter Bock et al, April 2018

What are the rates of attrition when providing ART in South Africa? Loss to care, or attrition, in this study was high, especially during the first six months of treatment, and was highest among clients starting ART at higher baseline CD4 counts. Improved monitoring of clients moving in and out of ART care and between clinics, along with other strategies to improve retention, will help to better understand attrition and improve retention in countries with high rates of HIV.

Individual and Community-level Risk Factors for HIV Stigma in 21 Zambian and South African Communities: Analysis of Data from the HPTN 071 (PopART) Study

AIDS, James Hargreaves et al, February 2018

How does stigma, whether internalized or experienced, affect HIV treatment? We evaluated clients during Year 1 in healthcare settings and in the community and concluded that HIV stigma remains unacceptably high in South Africa and Zambia and may act as a barrier to HIV prevention and treatment. However, stigma appeared lower in the healthcare settings. Further research is needed to understand its determinants.

Responses from People Living with HIV to items on internalised and experienced stigma items (n=3859)

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Internalised stigma	Strongly Disagree	Disagree	Agree	Strongly Agree	
I have lost respect or standing in the community because of my HIV status	1296 (33.6%)	2093 (54.2%)	316 (8.2%)	154 (4.0%)	
I think less of myself because of my HIV status	1224 (31.7%)	2138 (55.4%)	340 (8.8%)	157 (4.1%)	
I have felt ashamed because of my HIV status	1295 (33.6%)	2046 (53.0%)	364 (9.4%)	154 (4.0%)	
"Current internalised stigma": Responding Agree or Strongly Agree to any of	868/3859 (22.5%); South Africa (18.2%) vs Zambia (25.9%), p<0.001;				
the above	Cronbach's alpha (0.82); cluster range (1.9%-35.4%); outlier 80.0%				
Frequency of experienced stigma (any setting)	Never	Not disclosed	Once	A few times	Often
People have talked badly about me because of my HIV status	2908 (75.4%)	356 (9.2%)	233 (6.0%)	272 (7.0%)	90 (2.3%)
Someone else disclosed my HIV status without my permission	3119 (80.8%)	258 (6.7%)	277 (7.2%)	163 (4.2%)	42 (1.1%)
I have been verbally insulted, harassed and/or threatened because of my HIV status	3304 (85.6%)	234 (6.1%)	131 (3.4%)	156 (4.0%)	34 (0.9%)
I have been physically assaulted because of my HIV status	3455 (89.5%)	230 (6.0%)	66 (1.7%)	86 (2.2%)	22 (0.6%)
I have felt that people have not wanted to sit next to me, for example on public	3387 (87.8%)	330 (8.6%)	76 (2.0%)	49 (1.3%)	17 (0.4%)
transport, at church or in a waiting room because of my HIV status					
"Experienced any stigma in past year": Responding Once, A few times or Often	853/3859 (22.1%); South Africa (18.8%) vs Zambia (24.7%), p<0.001;				
("ever") to any of the above	Cronbach's alpha (0.92); cluster range (6.4%-36.8%); outlier 80.0%				
Frequency of experienced stigma (health setting)	Never	Not disclosed	Once	A few times	Often
I have been denied health services because of my HIV status	3627 (94.0%)	114 (3.0%)	55 (1.4%)	51 (1.3%)	12 (0.3%)
Healthcare workers talked badly about me because of my HIV status	3558 (92.2%)	121 (3.1%)	101 (2.6%)	66 (1.7%)	13 (0.3%)
A health worker disclosed my HIV status without my permission	3593 (93.1%)	103 (2.7%)	90 (2.3%)	64 (1.7%)	9 (0.2%)
"Experienced healthcare setting stigma in last year": Responding Once, A few	280/3859 (7.3%); South Africa (8.7%) vs Zambia (6.1%), p=0.002;				
times or Often ("ever") to any of the above	Cronbach's alpha (0.90); cluster range (1.0%-21.8%); outlier 60.0%				
"Any stigma last year": Yes to current internalised stigma, experienced any or	1271/2050/25 50/ cluster range /11 40/ 55 90/ outlier 100.00/				
healthcare setting stigma in last year"	1371/3859 (35.5%); cluster range (11.4%-55.8%); outlier 100.0%				







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