

HPTN 071 (PopART)

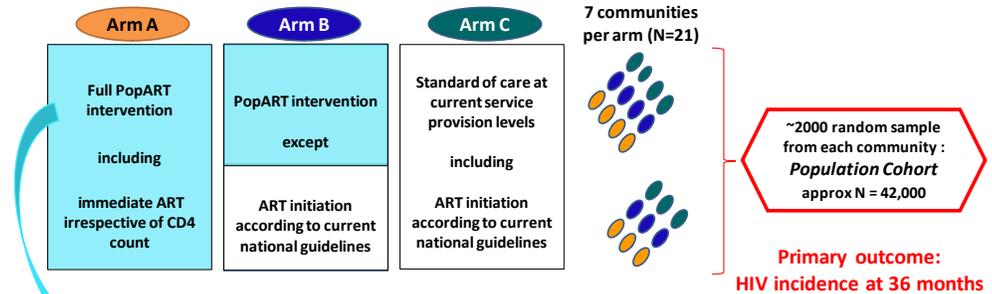
Key Findings After One Year of Intervention



The HPTN 071 (PopART) study is evaluating the impact of an HIV combination prevention strategy – utilizing universal household HIV testing and linkage to immediate antiretroviral treatment (ART) initiation – to reduce HIV incidence. Carried out in 21 communities (12 in Zambia and 9 in South Africa) divided among three study arms (A, B and C), this study will provide answers to questions regarding how best to combine HIV prevention interventions in different populations and settings for maximum impact at the lowest cost. Impact on HIV incidence at population level will be assessed through a research cohort of randomly-selected adults (the Population Cohort (PC)) from all study communities (approximately 42,000 individuals) to be followed for three years. UNAIDS targets specify that by 2020, 90% of those infected with HIV will know their status, 90% of those known to be HIV infected will have initiated antiretroviral therapy (ART) and 90% of those on ART will achieve viral suppression.

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3 arm cluster-randomised trial with 21 communities



PopART intervention package

- Annual rounds of Home Based Voluntary HIV Testing by Community HIV-care Providers (CHIPs)
- Health promotion, Active Referral and/or Retention in Care support by CHIPs for the following:
 - Voluntary Medical Male Circumcision (VMMC) for HIV negative men
 - Prevention of Mother to Child Transmission (PMCT) for HIV positive women
 - HIV treatment and care for all HIV positive individuals
 - Promotion of sexual health and TB services
 - Condom provision
- ART irrespective of CD4-count or immune-status provided at the local health centre in Arm A

http://www.hptn.org/research_studies/hptn071.asp

Protocol Version 2.0

How high were knowledge of HIV status and ART coverage before we started?

We measured pre-intervention uptake of HIV testing and ART in individuals recruited into the PC in all study communities. HIV prevalence was 12% in men and 27% in women.

In Zambia, 47% of HIV-positive men and 56% of HIV-positive women reported they were HIV-positive. In South Africa, 27% of HIV-positive men and 50% of HIV-positive women reported they were HIV-positive.

In Zambia, 32% of HIV-positive men and 37% of HIV-positive women reported they were on ART. In South Africa, 18% of HIV-positive men and 33% of HIV-positive women reported they were on ART.

Among HIV-positive men, overall around one-third knew their HIV-positive status and one-quarter were on ART, across the trial communities, but with considerably higher coverage in Zambia than South Africa. Among HIV-positive women, around half knew their HIV-positive status and one-third were on ART, with similar coverage in Zambia and South Africa.



It is possible these figures under-estimate knowledge of HIV-positive status, and uptake of ART, because some HIV-positive men and women may know they are HIV-positive but do not wish to disclose this to research interviewers. (Ayles, H. *HIV Testing and ART Coverage Before a UTT Intervention: Findings in HPTN071 (PopART)*. CROI 2016 (poster presentation). Boston, MA.)

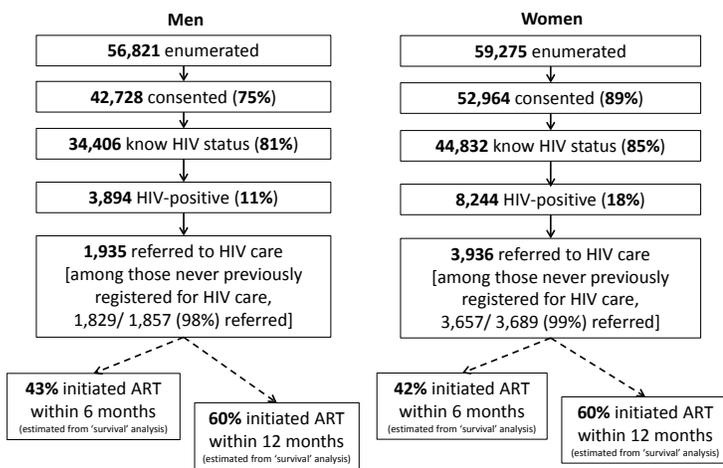
How close did we get to the 90-90-90 targets after the first year of the PopART intervention?

The PopART intervention involves annual rounds of household visits by Community HIV-care Providers (CHiPs) to provide HIV testing and counselling, with further visits to support linkage to care and provide other services. We used data collected by CHiPs to examine uptake of HIV testing and ART during the first year of the intervention in all four Arm A communities (out of 12 study communities overall) in Zambia.

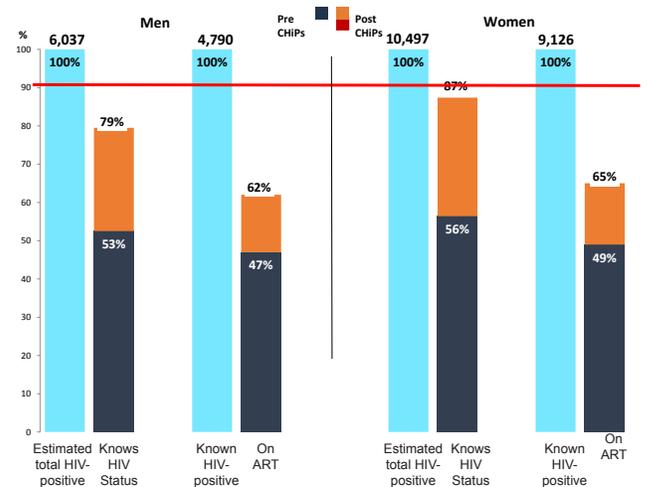
There were 47,000 households in these communities visited by CHiPs during the first round. Enumeration of household members was completed in 96% of households. During CHiPs visits to these households, 15% of men could not be contacted. Overall, of household members enumerated, 75% of men and 89% of women consented to participate. Eighty one percent of men and 85% of women accepted HCT, reported they were HIV-positive, or had tested for HIV in the previous three months and were HIV-negative.

Among HIV-positive individuals who had never previously registered for HIV care, 98% were referred. Of all those referred, approximately 40% and 60% initiated ART within six and 12 months respectively. In Arm A, among clients offered immediate ART outside national guidelines, 99% accepted and started ART.

Cascade of care from enumeration through ART initiation: First round

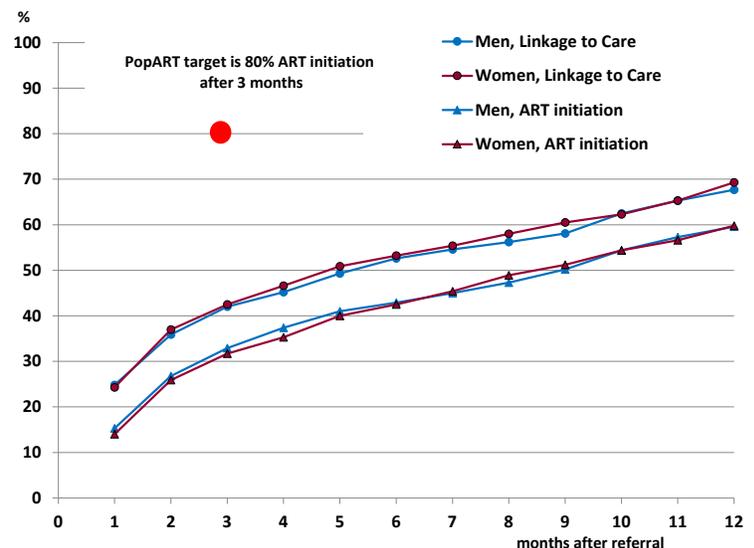


90-90: Estimated uptake in total adult population



Our baseline data indicate that prior to the PopART intervention, coverage was well below the 90-90-90 targets. However after one year of the intervention, we estimate in Zambia knowledge of HIV-positive status went up from about half to between 80% and 90% of the population, suggesting that the first '90' is achievable with a door-to-door home-based testing intervention. Among known HIV-positive individuals, ART coverage went up from about half to two-thirds of individuals. Continued annual rounds of intervention provide an opportunity for further increases in coverage over time. Achievement of the third 90 (retention on ART) will be assessed during year 2. (Hayes, R. *HPTN 071 (PopART): Uptake of first year of a combination HIV prevention intervention including universal HIV testing and treatment across 4 communities in Zambia*. IAS 2015 (poster). Vancouver, British Columbia and Hayes, R. *Reaching the 90-90-90 target: Lessons from HPTN 071 (PopART)*. IAS 2015 (oral presentation). Vancouver, British Columbia.)

Time from referral to linkage to care and ART initiation: First round



Further data on the coverage of the intervention during the first round were presented at the CROI 2016 conference in Boston. (Fidler, S. *Towards the second UNAIDS target: population level ART coverage in HPTN 071 (PopART)*. CROI 2016 (oral presentation). Boston, MA. and Shanaube, K. *Uptake of HIV testing in the HPTN 071 (PopART) trial in Zambia*. CROI 2016 (poster presentation). Boston, MA.)

Can a household intervention for HIV also help find tuberculosis?

TB case-detection is a secondary outcome of the HPTN 071 (PopART) study, which is being conducted in high TB/HIV co-infection settings. As part of the PopART intervention, CHiPs screened all household members they encountered for tuberculosis (TB) using a standard set of questions. Sputum samples were collected from individuals with any one of the TB symptoms shown in the box below. More than 200,000 individuals were screened in Zambia alone.

Symptoms

Is client coughing for two weeks or more?

Does client have drenching night sweats?

Has the client involuntarily lost weight of 1.5kg or more in the last month?

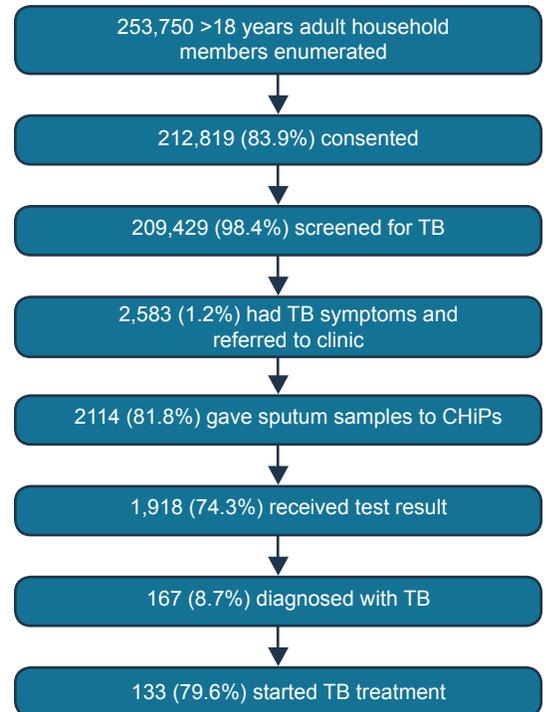
Is there a household member currently on TB treatment?

Approximately 1.2% of those screened in the eight intervention (Arm A and B) communities in Zambia reported TB symptoms. Of those referred, 6.5% were diagnosed with TB, cases that might not otherwise have been identified. This demonstrates that the household PopART intervention enabled TB case finding.

(Phiri, C. *Acceptability of large scale household based TB screening: HPTN 071 (PopART) trial. CROI 2016* (oral presentation). Boston, MA.)

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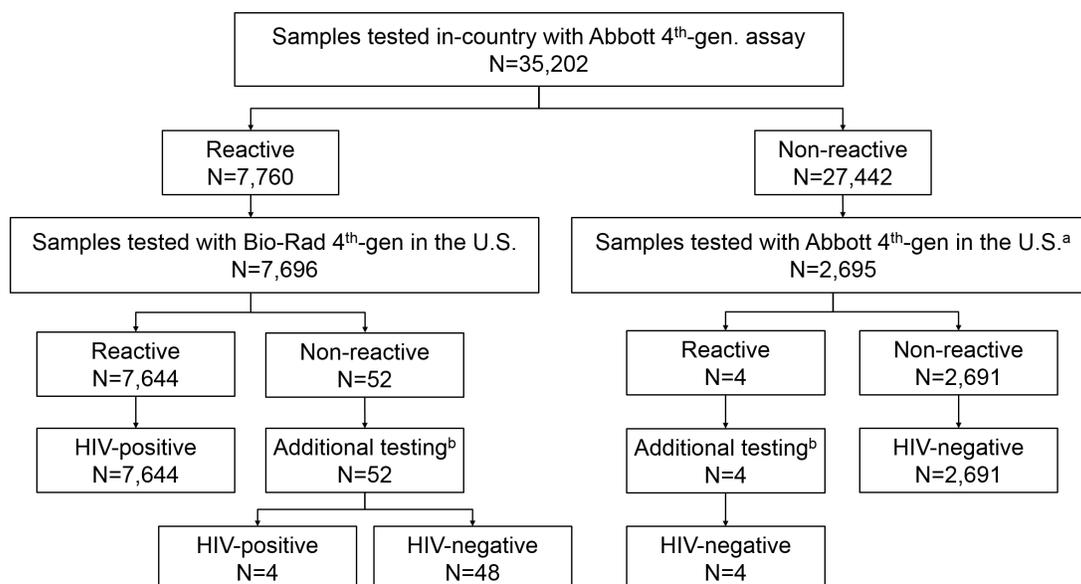
Results



Can we successfully screen for HIV in a large population-level survey?

The Abbott Combo test was used in Zambia and South Africa to screen samples from more than 30,000 PC study participants for HIV infection. HIV infection was confirmed in the U.S. at the HPTN Laboratory Center (LC) for all samples with a reactive in-country test result. Quality assurance testing was performed for 10% of samples with a non-reactive in-country test result. We evaluated performance of the Abbott Combo test as an HIV screening test in this large, African cohort. Overall, 48/7,695 (0.6%) Abbott POS samples had an initial false positive test result and 0/2,695 (0%) Abbott NEG samples had a false negative result.

The Abbott Combo test performed well when screening for HIV infection in a large, population-level survey in Africa. Special data and sample management procedures likely contributed to the high quality of initial HIV screening test results in this study. Quality assurance testing was helpful for confirming HIV infection status, especially for samples with an initial reactive Abbott Combo test result. (Piwowar-Manning, E. *Use of an Automated Assay to Identify HIV Infections in a Population Survey in Africa. CROI 2016* (poster presentation). Boston, MA)



^a 10% of the samples that had a non-reactive Abbott 4th-gen in-country test result were retested in the U.S.

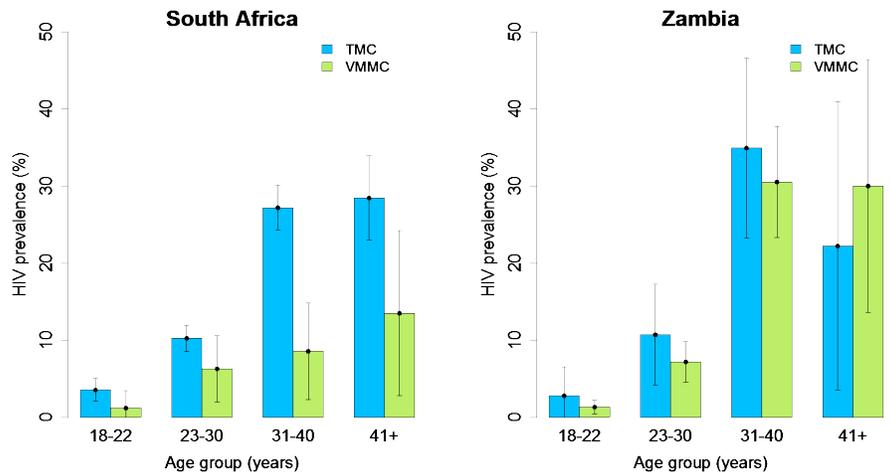
^b Additional testing was performed using a discriminatory assay and a HIV RNA assay

Does traditional male circumcision protect against HIV?

Across the PopART communities and beyond, there is a range of traditional practices which involve foreskin removal – referred to as traditional male circumcision (TMC). We explored whether TMC was as protective against HIV acquisition as voluntary male medical circumcision (VMMC).

In South Africa, men reporting TMC had almost three times higher HIV prevalence when compared to those reporting VMMC (after accounting for age and marital status). A similar analysis for men in Zambia did not show a statistically significant difference although the number of traditionally circumcised men in Zambia was limited. These findings are subject to the usual constraints of observational findings, but they suggest that TMC may not be protective against HIV. (*Pickles, M. Exploring the effectiveness of traditional circumcision practices in preventing HIV. CROI 2016 (oral presentation). Boston, MA.*)

HIV prevalence by circumcision type across age groups



Can we increase uptake of HIV testing in men by employing male CHiPs?

As data became available during the first round of delivery of the PopART intervention, uptake of home-based HIV testing was noted to be lower in men than women. Sixty-four percent of CHiP pairs in the intervention communities in Zambia were male-female pairs (N=107), 32% (N=53) were female-female pairs and 4% (N=6) were male-male pairs. The study team investigated (and continues to evaluate) new ways to reach men. One such assessment examined whether the deployment of male CHiPs to encourage HIV testing amongst men increased uptake by men. The findings showed that this did not significantly enhance male uptake. (*Phiri, M. Does a male CHiP increase uptake of HIV testing by men? Lessons from HPTN071 Study. CROI 2016 (poster presentation). Boston, MA.*)

	FF%	MM/FM%	Odds Ratio	95% CI
Males consenting to intervention	92.5	91.5	1	0.35-1.34
			0.66	
Uptake of HIV Testing	57.9	62.7	1	0.88-1.49
			1.14	

The PopART Social Science team has also presented on many studies during the past year:

Bond, V. The difference that makes a difference: Exposing and predicting the role of variable contexts in the uptake of Universal Test and Treatment within a HIV Prevention Community Randomised Trial (HPTN071/PopART) in 21 community sites in Zambia and South Africa. Association for Social Sciences and Humanities in HIV Conference to be held in Stellenbosch (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

Viljoen, L. A qualitative, discursive analysis of representations of women and HIV risk in 21 high-burden communities in Zambia and South Africa: the good, the bad and the vulnerable. Association for Social Sciences and Humanities in HIV Conference (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

Mathema, H. Healthcare workers as research participants in the context of an HIV prevention trial: Research imperative versus operational challenges. Association for Social Sciences and Humanities in HIV Conference (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

Hoddinott, G. Achieving 'universality' of HIV testing and treatment: social processes influencing men's access to clinic and home-based health services in Zambia and South Africa. Association for Social Sciences and Humanities in HIV Conference (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

Hoddinott, G. Disentangling 'context' in implementing public health interventions for HIV prevention at community-level; a case for using qualitative theory-generation in operational decision-making. Association for Social Sciences and Humanities in HIV Conference (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

Simwinga, M. Who is answerable to who? Exploring the complex relationship between researchers, the community and community representative organisations. Association for Social Sciences and Humanities in HIV Conference (oral presentation). July 6-9, 2015. Stellenbosch, South Africa.

