

HPTN 071 (PopART)

Population Effects of Antiretroviral Therapy to Reduce HIV Transmission:

**IMPACT OF UNIVERSAL TESTING AND TREATMENT IN ZAMBIA AND SOUTH AFRICA:
RESULTS OF A COMMUNITY-RANDOMIZED TRIAL**

**SA HIV CONFERENCE
JUNE 2019**



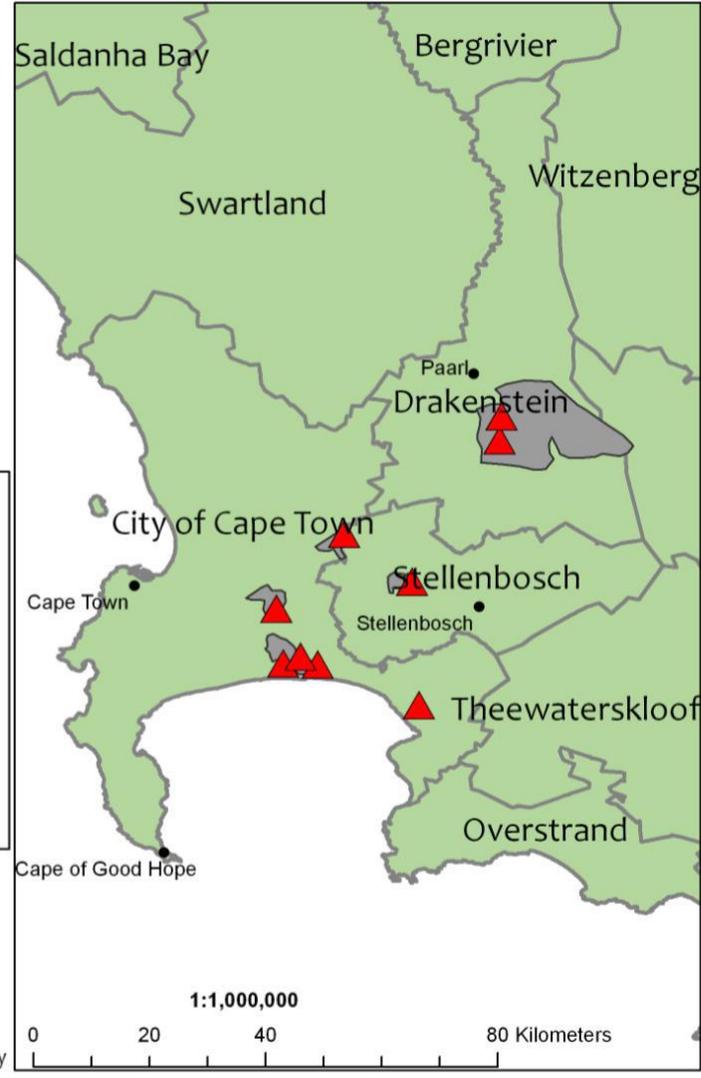
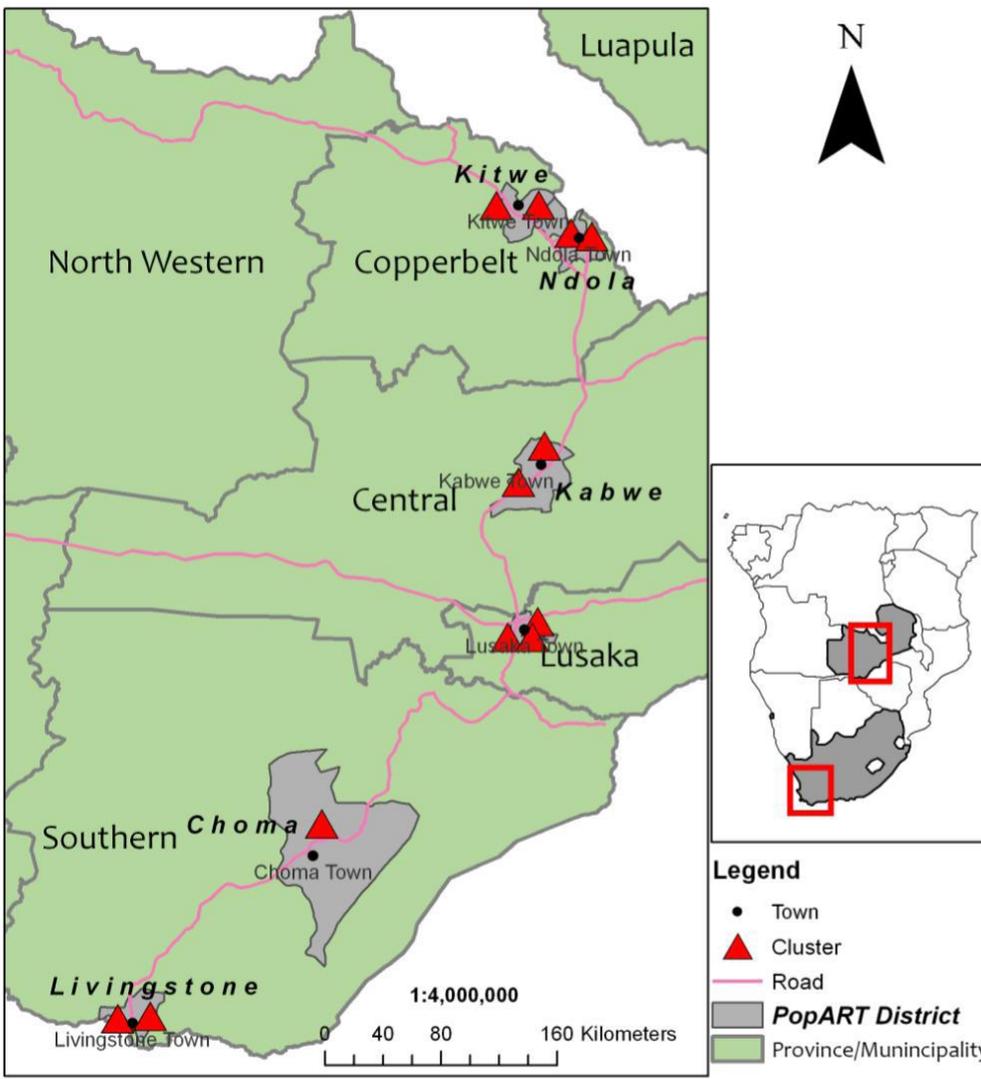
U.S. NATIONAL INSTITUTES OF HEALTH:
*National Institute of Allergy and Infectious Diseases
National Institute of Mental Health
National Institute on Drug Abuse*

Background

- Universal HIV testing and treatment (UTT) is proposed as a key strategy to reduce HIV incidence but evidence remains limited
- Previous UTT trials have shown inconclusive results
 - SEARCH & TasP trials found no impact
 - BCPP found 30% reduction although results were inconclusive (31% reduction in incident HIV in the primary analysis (IRR 0.69, $p=0.09$) and a 30% reduction in models adjusting for community cofactors (IRR, 0.70, 95% CI 0.50-0.99, $p=0.04$)

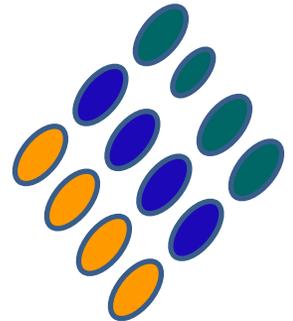
Study aims

- PopART Aims: To determine the impact of two community-level combination prevention packages, both including universal HIV testing and intensified provision of HIV antiretroviral therapy (ART) and care, on population-level HIV incidence
- We report primary results of HPTN 071 (PopART)



21 Communities

7 per arm (A, B or C)



12 in Zambia

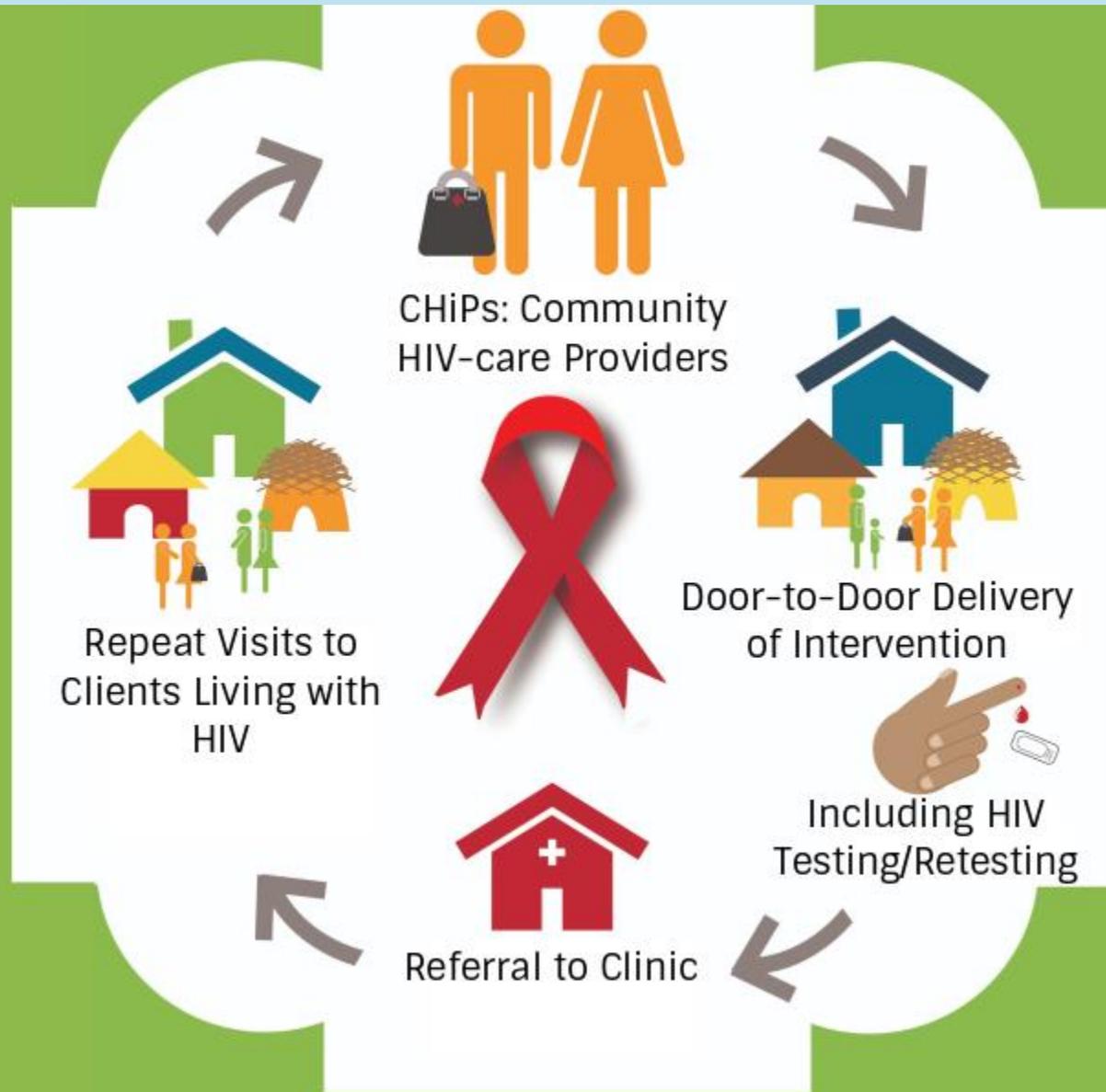


9 in South Africa

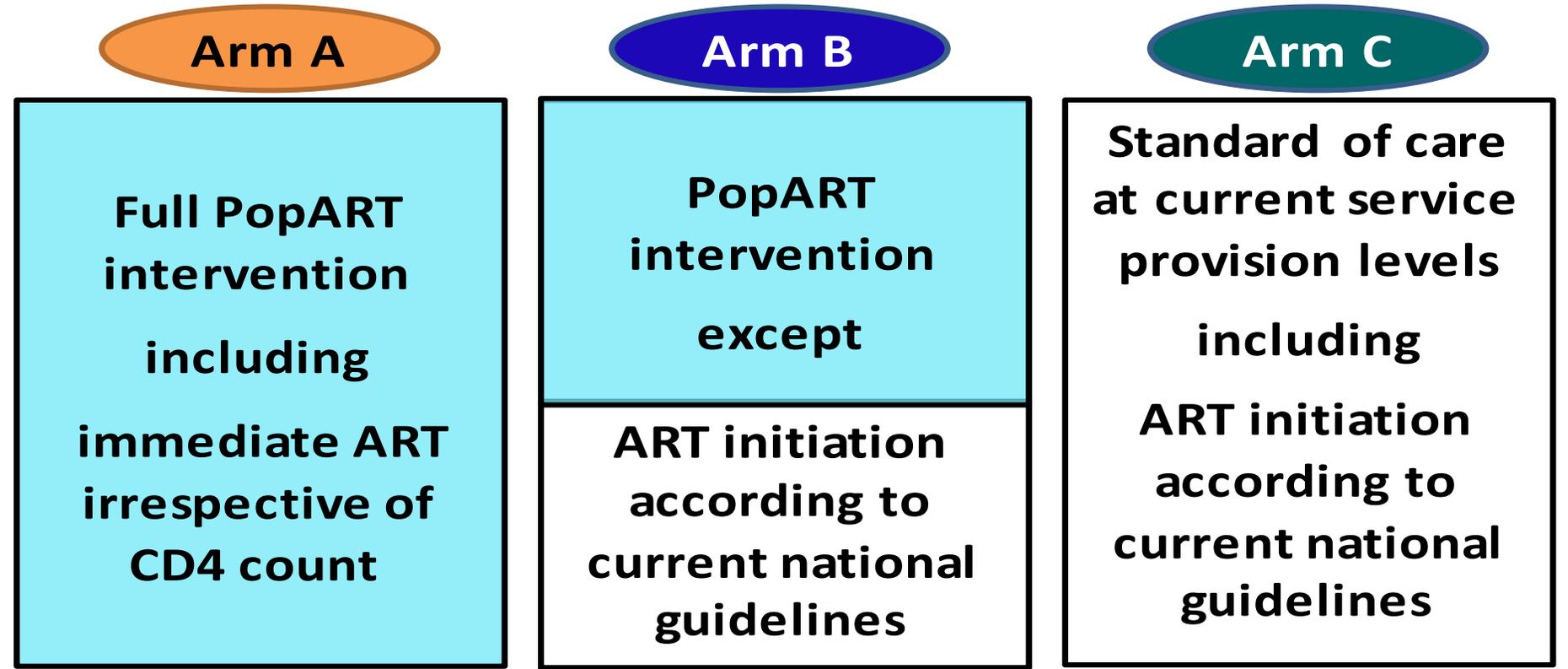
Total population ~1M

CHiPs Door-To-Door Intervention

- HIV counselling and testing
- VMMC referral
- PMTCT referral
- STI screening
- TB screening
- Condoms

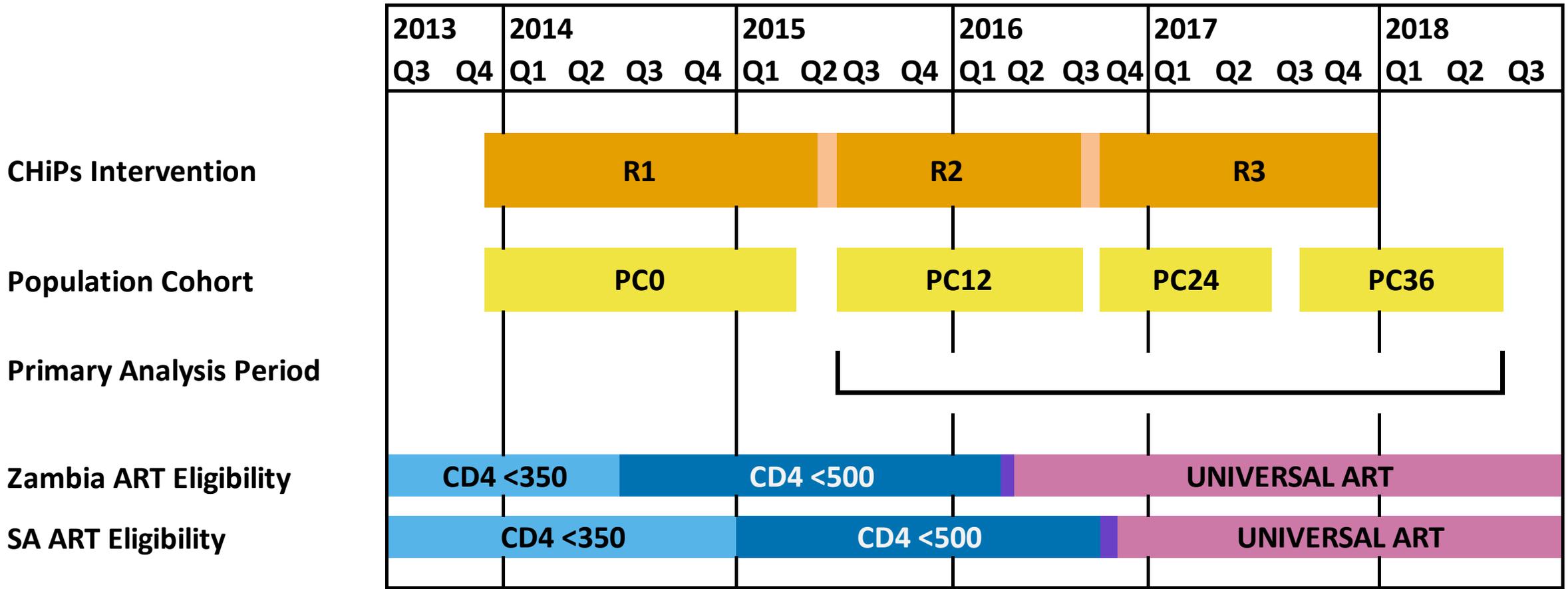


Study Design



2,500 random sample from each community =
Population Cohort (N=52,500)
Followed up annually for 36 months

Study Timeline



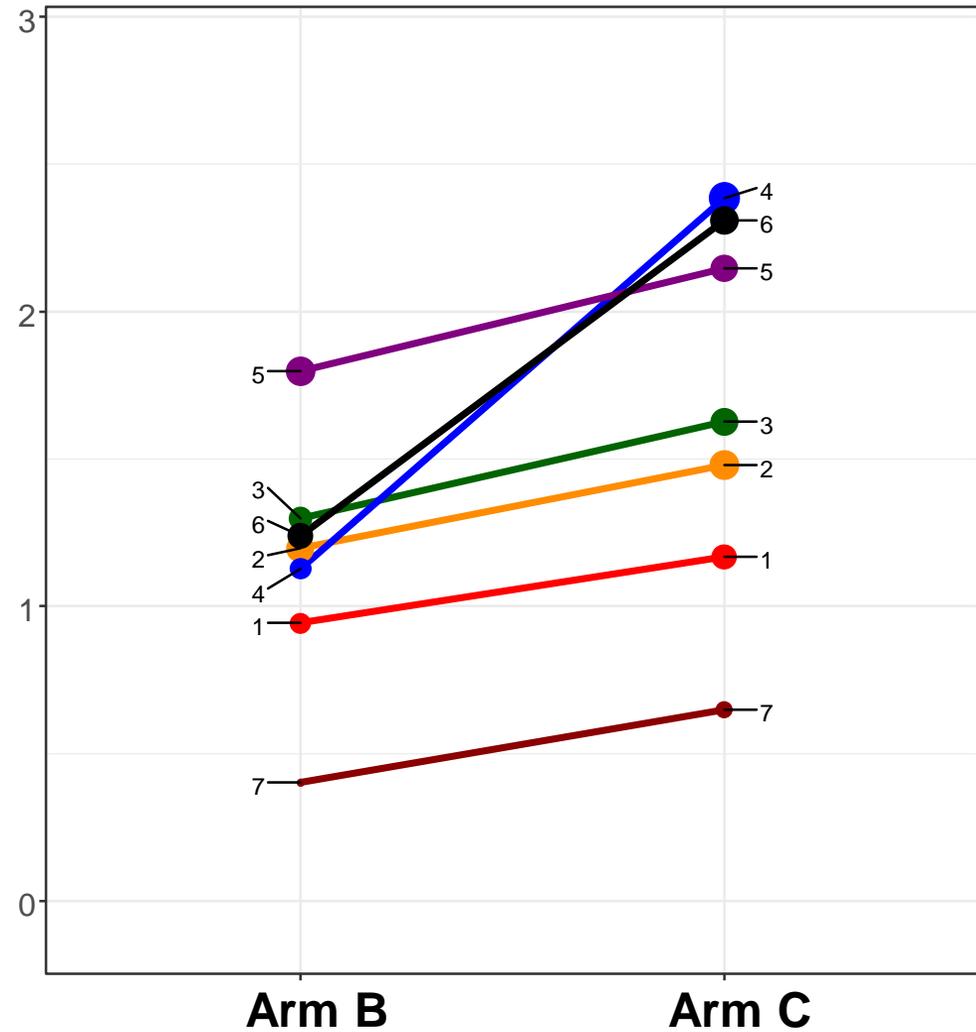
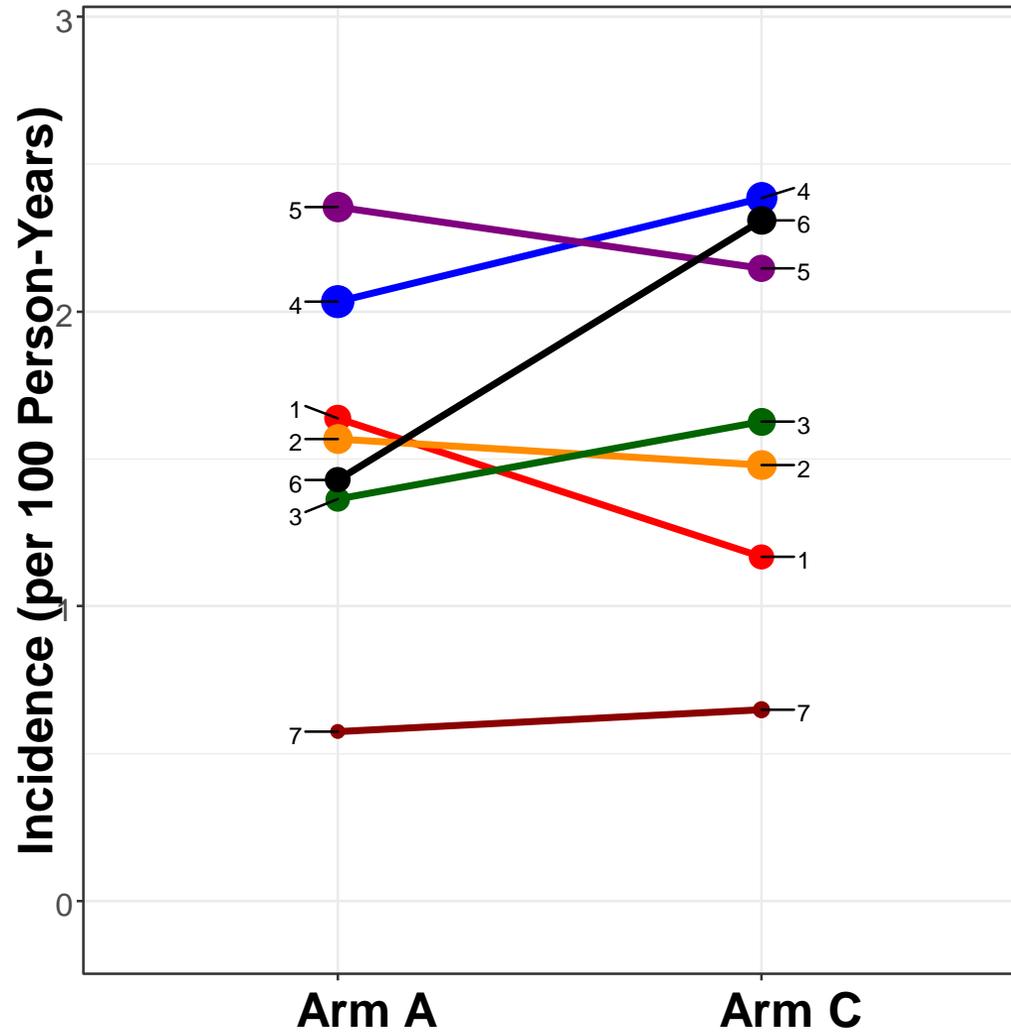
Key Methods

- Impact of PopART intervention on HIV incidence; when comparing Arm **A vs C** and Arm **B vs C**
- HIV incidence was measured in the **Population Cohort (PC)** between PC12 and PC36 (pre-specified in study analysis plan)
- PC enrolled a total of 38,474 (PC0)+5,014 (PC12)+4,813 (PC24)
= **48,301** participants
- Using established methods for CRT analysis methods

Baseline characteristics of Population Cohort (PC0)

	Arm A N = 12,671	Arm B N = 13,404	Arm C N = 12,399
Male	28%	29%	30%
Age: 18 – 24	40%	39%	40%
25 – 34	39%	39%	38%
35 – 44	21%	23%	22%
HIV Prevalence: Overall	21%	21%	22%
Men	12%	11%	12%
Women	25%	25%	27%
HSV2 Prevalence: Overall	44%	43%	46%
Men	26%	24%	23%
Women	54%	55%	54%
ART (self-reported coverage in HIV+)	33% (N = 2375)	41% (N = 2582)	35% (N = 2526)
Viral suppression (HIV+; 75/community)	56%	57%	54%
Medical Male Circumcision	17%	16%	19%

HIV Incidence by community (PC12-PC36)



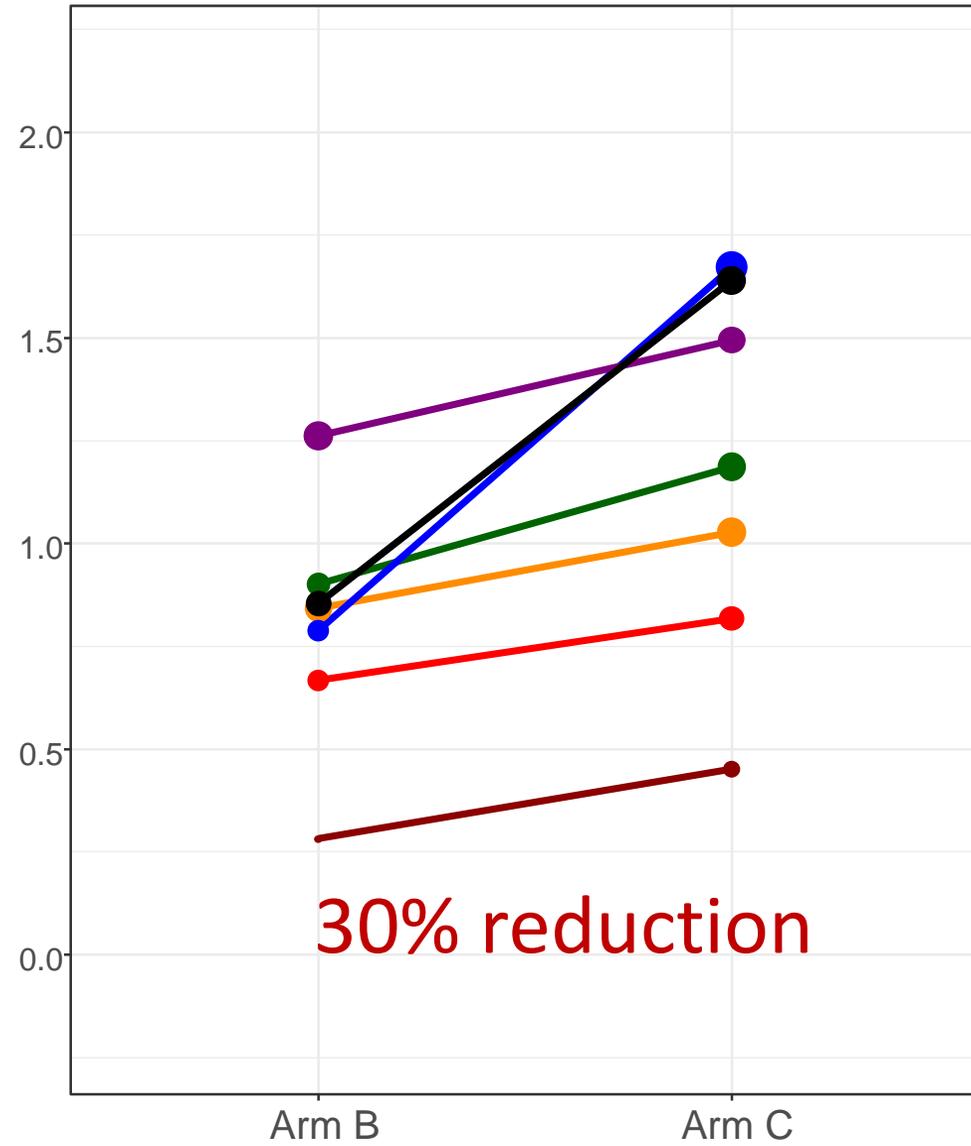
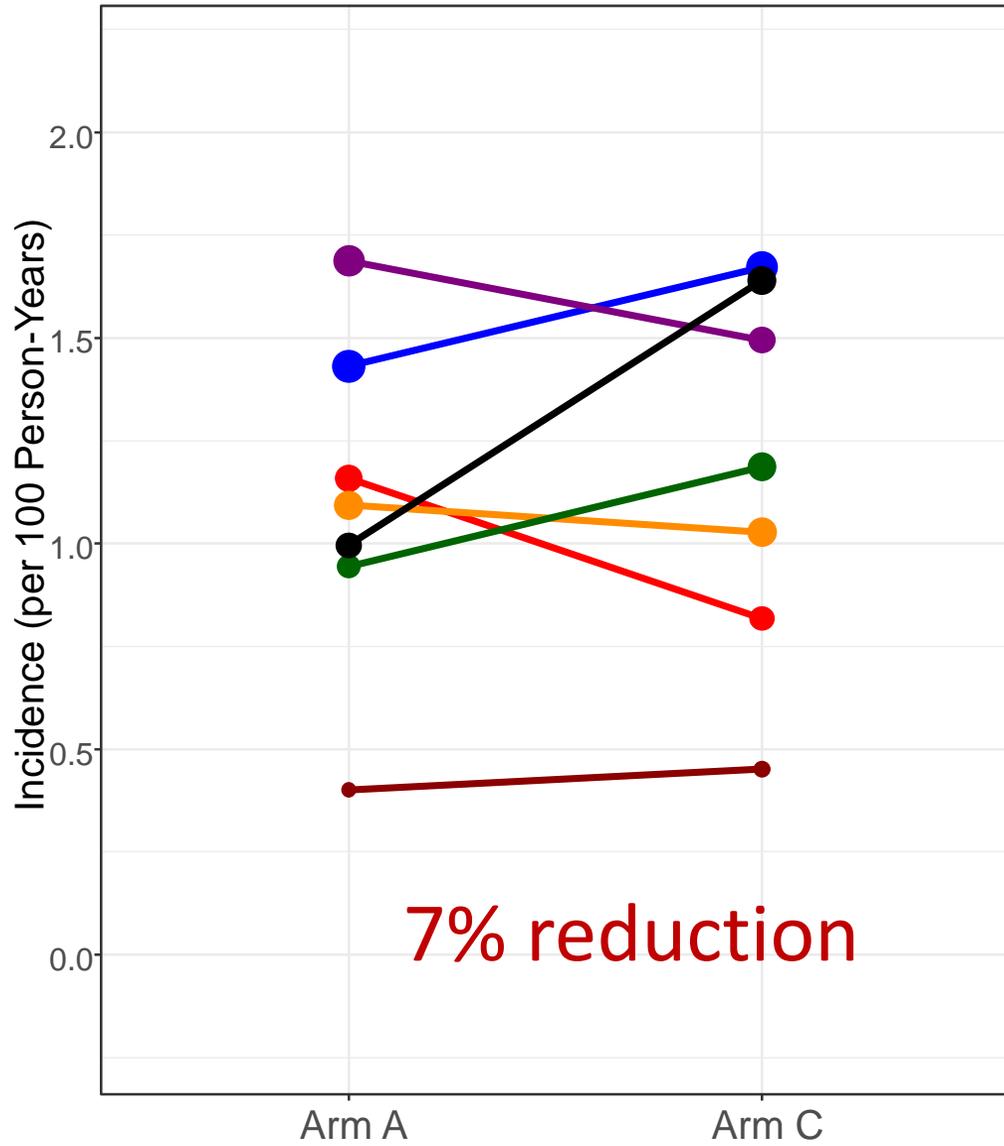
Triplets

- Z Triplet 1
- Z Triplet 2
- Z Triplet 3
- Z Triplet 4
- SA Triplet 5
- SA Triplet 6
- SA Triplet 7

Events

- 10
- 20
- 30
- 40

HIV Incidence by community (PC12-PC36)



Primary analysis: Incidence in PC12-PC36

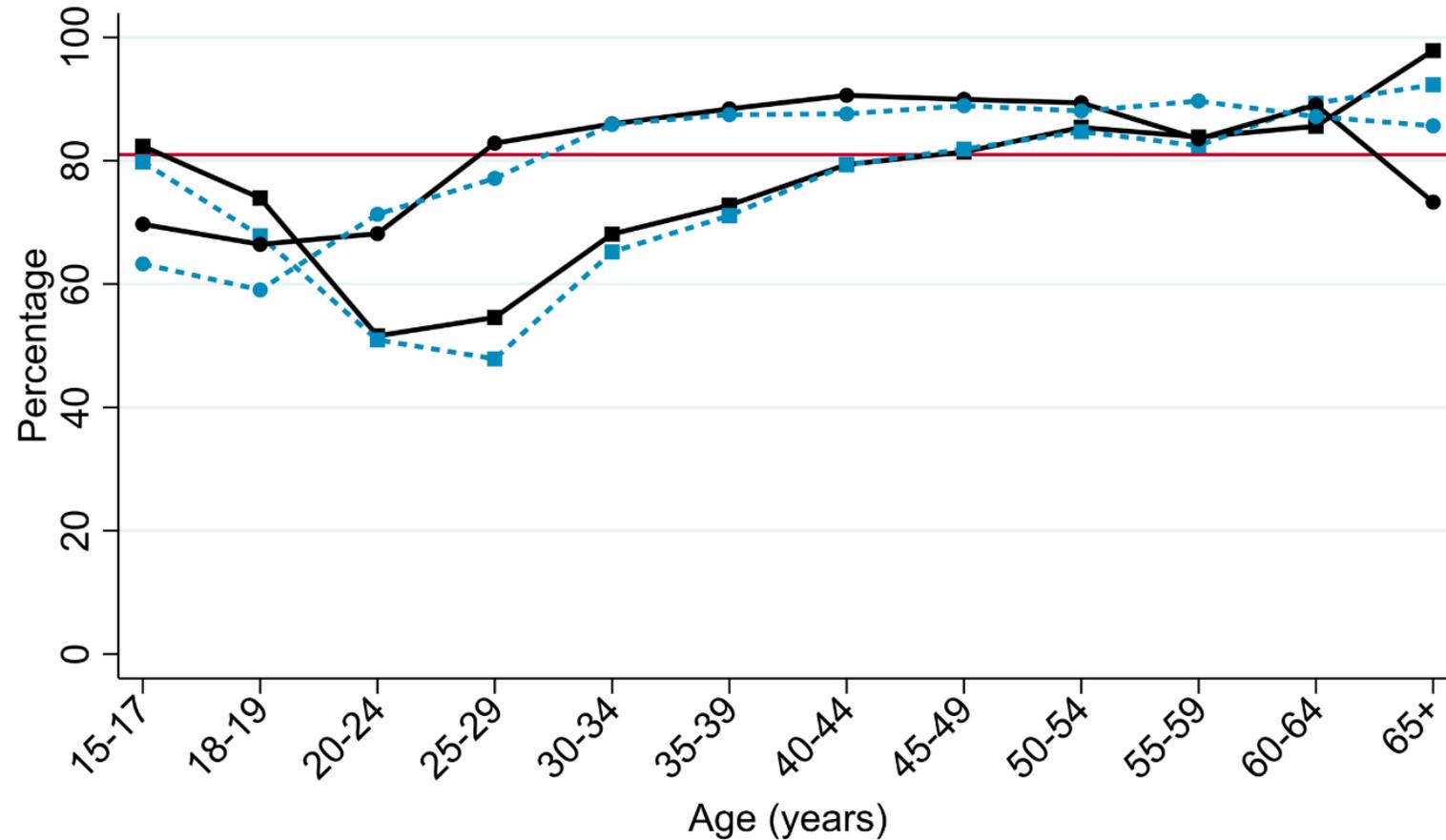
	Arm A	Arm B	Arm C
HIV Incidence (mean of community incidence rates)	198/12,990 (1.45%)	157/14,149 (1.06%)	198/12,563 (1.55%)
Adjusted Rate Ratio (95% CI)	0.93 (0.74, 1.18)	0.70 (0.55, 0.88)	
	7% reduction	30% reduction	
P value	0.51	0.006	

Adjusted for age category, sex and baseline community HIV prevalence.
Reported numbers include imputation for PC12 and PC24 missed visits

Subgroup analyses: Incidence in PC12-PC36

		Arm A	Arm B	Arm C
Men	Incidence	0.77%	0.45%	0.92%
	Adj RR	0.88 (0.41, 1.88)	0.52 (0.24, 1.12)	
Women	Incidence	1.71%	1.26%	1.79%
	Adj RR	0.96 (0.72, 1.28)	0.73 (0.55, 0.97)	
Younger (18-24)	Incidence	1.75%	1.50%	1.72%
	Adj RR	1.02 (0.79, 1.34)	0.92 (0.70, 1.20)	
Older (25+)	Incidence	1.31%	0.83%	1.46%
	Adj RR	0.90 (0.68, 1.20)	0.58 (0.43, 0.76)	

ART coverage at end of trial: CHiP data extrapolated to total population aged ≥ 15 years



90-90 target = 81%



Viral suppression at PC24

	Arm A	Arm B	Arm C
Viral suppression (Geometric mean of community %)	1531/2159 (72%)	1318/1891 (68%)	1480/2183 (60%)
Adjusted prevalence ratio (95% CI)	1.16 (0.99, 1.36)	1.08 (0.92, 1.27)	
	16% increase	8% increase	
P value	0.07	0.30	

Adjusted for age category, sex

Summary

- Achieved UNAIDS targets for ART coverage (81%)
- High rates of viral suppression achieved. (54-56% to 68-72%)
- There was no impact in the full intervention arm (Arm A) on HIV incidence, where ART regardless of CD4 count was delivered ahead of change in guidelines- this result was not explained by lower rates of viral suppression.
- PopART intervention with ART according to local guidelines (Arm B) reduced HIV incidence by 30% from 1.7% to 1.1%
- **Community-based services for HIV testing and linkage can be a key component of combination prevention in the global effort to achieve effective HIV control.**

Next steps

- Presentation of results at CROI on 6 March 2019, in country community dissemination of study results from 11 – 25 March 2019, publication of findings.
- Further analysis of quantitative, qualitative and phylogenetic data in progress to further explore and explain the PopART results.

Study partners

- Community members and representatives, community advisory boards, health committees etc..
- Western Cape Government Health Services
- City of Cape Town Health Services
- Kheth' Impilo
- ANOVA Healthcare Institute
- SACTWU Health Worker Programme
- TB HIV care
- Masincedane
- Supply Chain Management Services (SCMS)
- Stellenbosch University – Department of Paediatrics
- Stellenbosch University
- PEPFAR, CDC, USAID
- United Kingdom partners- LSHTM & Imperial College
- United States partners - HPTN, FHI 360

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The HPTN 071 Study Team, led by:

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Dr. Peter Bock

Zambart Project




Government Agencies:







Making progress possible. Together.

PEPFAR Implementing Partners:








PC enrolment and follow-up

PC0
Enrolled
38,474

PC12
Terminated
5,191 (13%)

Retained
25,289 (66%)

Missed
7,994 (21%)

PC12N
Enrolled
5,014

PC24
Terminated
5,043 (13%)

Retained
25,195 (66%)

Missed
8,059 (21%)

PC24N
Enrolled
4,813

PC36
Terminated
10,566 (28%)

Retained
27,501 (72%)

Subgroup analyses: Viral suppression at PC24

		Arm A	Arm B	Arm C
Men	VS	63%	61%	40%
	Adj RR	1.46 (0.86, 2.48)	1.41 (0.83, 2.41)	1
Women	VS	73%	68%	66%
	Adj RR	1.10 (1.00, 1.21)	1.03 (0.93, 1.13)	1
Younger (18-24)	VS	46%	42%	43%
	Adj RR	1.06 (0.70, 1.61)	0.94 (0.62, 1.43)	1
Older (25+)	VS	76%	71%	63%
	Adj RR	1.20 (0.96, 1.50)	1.12 (0.90, 1.40)	