

# Community Engagement in a large Community Randomised Trial

The case of the HPTN 071 (PopART) Study

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On behalf of the HPTN 071 CWG



### **Presentation Outline**

- HPTN 071 Trial Description
- Community Engagement Team Responsibilities
- Challenges of Home-based Testing
- Successes in Community Engagement
- Lessons Learnt



# HPTN 071 (PopART)

 Population effect of universal HIV testing and immediate ART to Reduce HIV
 Transmission



## PopART Research Questions

- What is the impact of the PopART combination HIV prevention package (including Universal Test and Treat -- UTT) on HIV incidence at population level?
- Can the PopART package be delivered to scale and with high coverage and retention?
- What are the challenges in delivering the package and how can these be addressed?
- What are the adverse effects of the intervention and what is the balance of harms and benefits?
- What is the cost-effectiveness of the PopART intervention?



#### 3 arm cluster-randomised trial with 21 communities

Arm A

**Full PopART intervention** 

including

immediate ART irrespective of CD4 count

Arm B

PopART intervention

except

ART initiation according to current national guidelines

Arm C

Standard of care at current service provision levels

including

ART initiation according to current national guidelines

7 communities per arm (N=21)

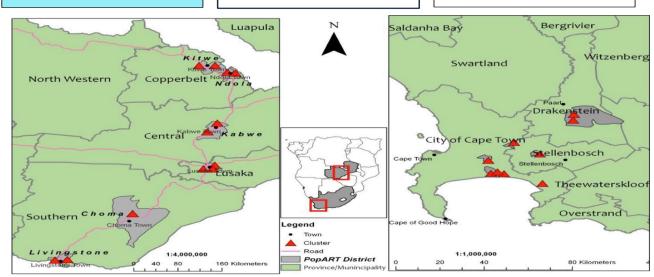


12 in Zambia 9 in S. Africa 2,000 random sample from each community:

Population Cohort

N = 42,000

Primary outcome:
HIV incidence at 36 months



Zambia

**South Africa** 

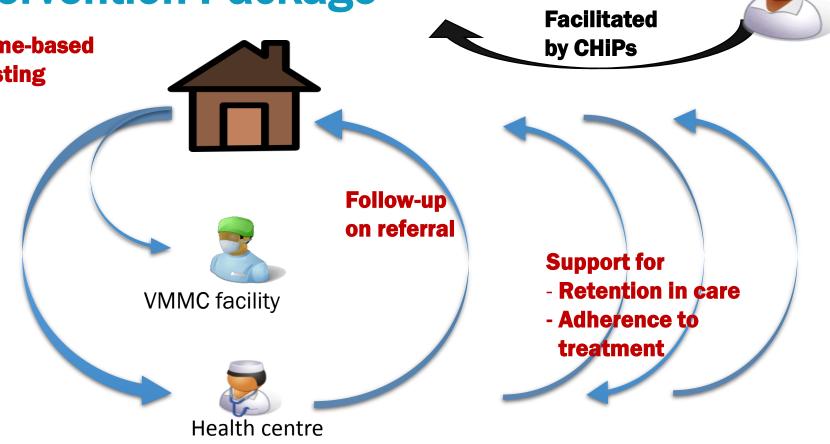




Annual Rounds of Home-based Voluntary HIV Testing

#### **Service promotion and referral for**

- VMMC
- PMTCT
- HIV treatment and care
- **TB**
- STI



Universal treatment for HIV+ irrespective of CD4 count

**CHiPs: Community HIV-care Providers** 

**PMTCT: Prevention of Mother to Child Transmission** 

**VMMC: Voluntary Medical Male Circumcision** 

**TB: Tuberculosis** 

**STI: Sexually Transmitted Infections** 



# 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

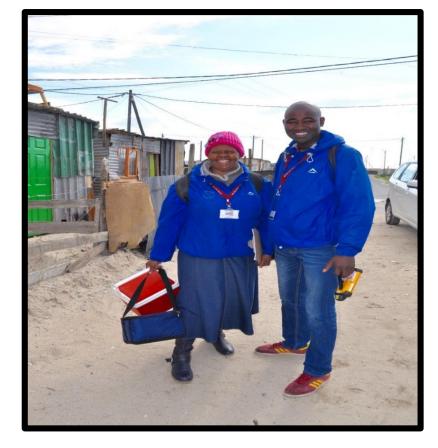


# **Intervention Teams**

#### Zambia



#### South Africa





# Population Cohort (PC) Team

- Census conducted to determine number of households in each community
- Households selected randomly
- Individuals enrolled into cohort, randomly selected by electronic data capture device
- Individuals in cohort followed for 36 months (collect blood sample at every visit)
- Individuals answer a series of questions at every visit (12 sections: quality of life, overall health, members of household, etc.)
- The PC will help measure the impact of the home-based testing (CHiPs)



# **PC Teams**

#### Zambia



#### South Africa





## Community Engagement (CE) Experiences in PopART Study

- Intrinsic goal of CE: building respect and trust of the communities we work with
- Instrumental goal of CE: helping to improve the quality of research; maintain community interest



### Intrinsic Community Engagement

- Community members were invited to contribute to the protocol
  - Zambia: working with established CABs from previous study
  - Zambia: National consultative meeting with various stakeholders
  - South Africa: working with government departments and City of Cape Town
- Dialoguing with Civil Society
  - "Nothing for us without us"
  - There were strong and well established civil society organizations (CSOs) in SA from the onset
  - Zambia created an umbrella association to coordinate CSO effort



#### Intrinsic Community Engagement

- Social Science/Qualitative research to obtain baseline information
  - Enabled CE to identify possible intervention/engagement areas
  - Messaging areas were also identified (prevention and treatment concepts)
  - Major stakeholders for possible representation on the CABs were identified



- Informed consent: working with entire communities requires that entire geographical communities are reached with same information; also specific communities are targeted with specific information
- Ensuring communities accept different study teams/ components (PC, Intervention, Case Control, Adolescents, Phylogenetics). Communities were often confused leading to misconceptions
- Mobilising and creating awareness for specific causes
  - Entry into a new section of the community
  - Creating general awareness responding to community concerns
  - Helping in locating participants who have moved



#### Messaging

- Keeping ahead with changes in the study and informing communities
- Keeping ahead in government guidelines and informing communities
- Developing IEC material that support CE efforts and inform communities
- Improving recruitment of difficulty to reach groups
  - Mobile communities ('fishers of men programme in Zambia)
  - Engaging men (Man Up Campaign in Zambia and Jamboree in South Africa)
- Motivating control communities
  - Keeping CAB members motivated and stakeholders informed



- Effective CE strategies
  - Community meetings
  - Work place activities
  - Following men where they are found
  - Stakeholder meetings



- Expanded role of the CAB
  - CABs involved in resolution of incidents (social harms)
  - CABs providing protection to study staff
  - CABs suggesting strategies to improve uptake of study intervention and research
    - HCT
    - VMMC



### Challenges of Home-based Testing

- Study staff safety
- Relocations
  - People moved to newly built houses
- Mobile populations
  - Seasonal farm workers
  - Truck drivers
- Cultural Barriers especially in MMC
  - Xhosa culture against VMMC



### Challenges of Home-based Testing

- Middle class attitude in Home Based Testing
- Myths around blood collection
  - Luminathi
  - Witchcraft



#### Successes in Community Engagement

- Engaging CABs helps to get their support in communities in issues related to the safety of our teams in the community
- Good relationships with other NGOs, advocacy groups (TAC) and the community at large
- Campaigns
  - Man up (Zambia)
  - Jamborees (SA)
  - Mass mobilisation (SA)



#### Successes in Community Engagement

- Capacity-building opportunities
  - How to Review a Protocol and Provide Feedback training by FHI 360
  - Basic HIV Knowledge
  - Minute Writing



#### **Lessons Learnt**

- Safety should be a combined effort between community members and the researchers for the safety of the employees
- Making sure that all official operational systems are there before the study begins (Health Committees in SA) as they are a very important link between the researchers and the community
- CE coupled with all kinds of consultations to all stakeholders and the community at large can reduce myths about research
- Cultural sensitivity is very important when doing CE



# Thank You