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)

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

Support for
- Retention in care
- Adherence to treatment

Universal treatment for HIV+
Irrespective of CD4 count

Facilitated by CHiPs

VMMC: Voluntary Medical Male Circumcision
PMTCT: Prevention of Mother to Child Transmission
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
Instrumental Community Engagement

• 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
Instrumental Community Engagement

• Effective CE strategies
  • Community meetings
  • Work place activities
  • Following men where they are found
  • Stakeholder meetings
Instrumental Community Engagement

• 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