



**HPTN**

HIV Prevention  
Trials Network

# **HIV Prevention Trials Network Community Working Group Plenary**

## **LESSONS LEARNED IN HPTN 077**

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# Overview

- Background
- Community engagement – in research
- Community engagement – long term
- Working together for change
- Understanding context
- Ringing the changes
- Recruitment and accrual plans
- Time to cohort accrual
- Retention rates
- Challenges and lessons learned
- Conclusion

# Community Engagement- In Research

- Work with communities to build an understanding of the importance of research, making it locally responsive
- Build capacity and relationships with important stakeholders
- Building awareness of important health problems to encourage community responsibility for participation in solutions to these problems
- Collaborate and consult with communities to ensure that the purpose and importance of the research is understood
- Create a common understanding of how the research will help to answer scientific questions and knowledge generation
- Encourage ownership of the research studies amongst CSRGs, participants and researchers
- Get input into research materials from CSRG

# Community Engagement – Long Term

- Build communities that understand the importance of research – create communities that engage meaningfully with research
- Improve communication skills and capacity of local health professionals, other researchers, interventionists and community stakeholders.
- Create communities that work towards breaking stigma, and act as peer educators, agents of change and supporters of research
- Aim to have community engagement that equitably shares power amongst the researchers and community to improve retention, recruitment efforts and improve intervention success and sustainability.
- Foster transdisciplinary collaborations
- Empower communities to be advocates for building public support and political will to implement and roll-out effective large-scale interventions.

# CAPRISA-Vulindlela: Working together for Change


- Engaging in community dialogue and collaboration since 2002
- Fully informed and voluntary participation in new investigational drugs trials
- Build a strong research literacy foundation
- Community education programmes
  - -General information sessions
  - -Recruitment tools
- Appropriate cohorts

# Understanding Context: Formative research

Initial studies were conducted to inform new research ideas:

- The temporal trends in HIV/AIDS
- A case mix at the Primary Health Care clinic
- Demographic Health Survey which included the establishment of stigma prevalence associated with HIV/AIDS in the community
- HIV-sero prevalence and incidence in preparation for efficacy studies

## Antenatal survey data-2001 to 2013



Age Group (Years)	HIV Prevalence (N=4818)
≤16	11.5%
17-18	21.3%
19-20	30.4%
21-22	39.4%
23-24	49.5%
>25	51.9%

## Ringling the changes

- HPTN 077 was the first network multi-centre trial at VCRS
  - First time enrolling a low risk cohort
  - long acting injectable with oral lead-in phase
  - This trial product falls under a new class of drugs and has a long half life
  - The trial site team ensures participants' safety during trial
- CRSG/CAB consultations conducted
  - to discuss protocol, possible recruitment, retention strategies and study documents

# Recruitment and accrual plans

- A pre-screening tool was developed to be used in the community during recruitment (based on the definition of low risk and inclusion/exclusion criteria)
  - Most women in the community do not perceive themselves being at risk of acquiring HIV.
  - They do not see themselves at risk because they are faithful to partners who are not always faithful
- Innovative strategies to pre-screen
  - Mobile wellness services provided by COMOSAT were crucial to identify low risk individuals, based on health screening results



## Time to cohort accrual

### **Cohort 1 – 7.3 weeks**

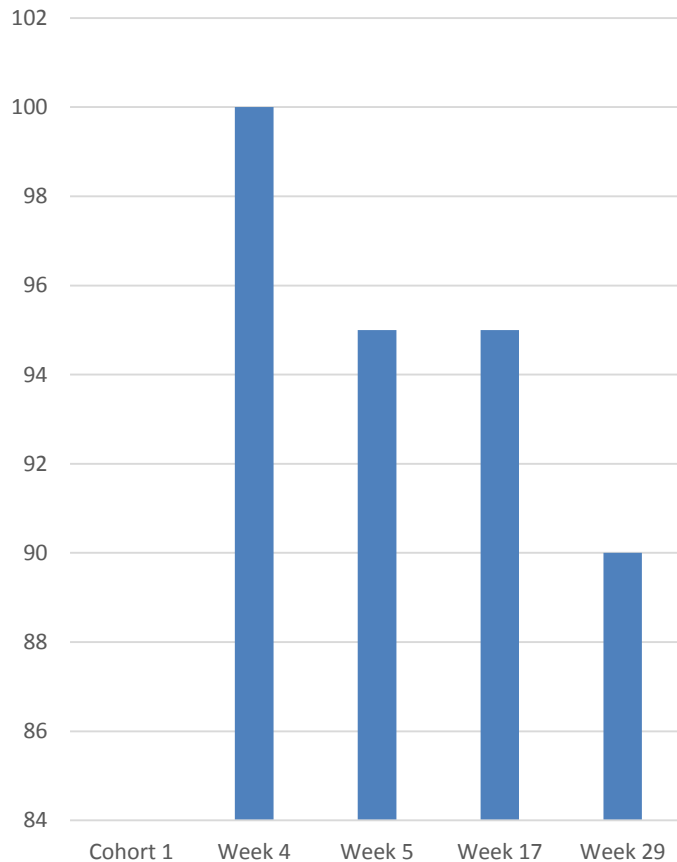
- Activated – 18 Jun 15 and last enrolled on 25 Aug15 (22 in total)
- The recruitment team had to modify original strategies by changing recruitment areas
- Delays in obtaining regulatory approvals

### **Cohort 2 – 7.9 weeks**

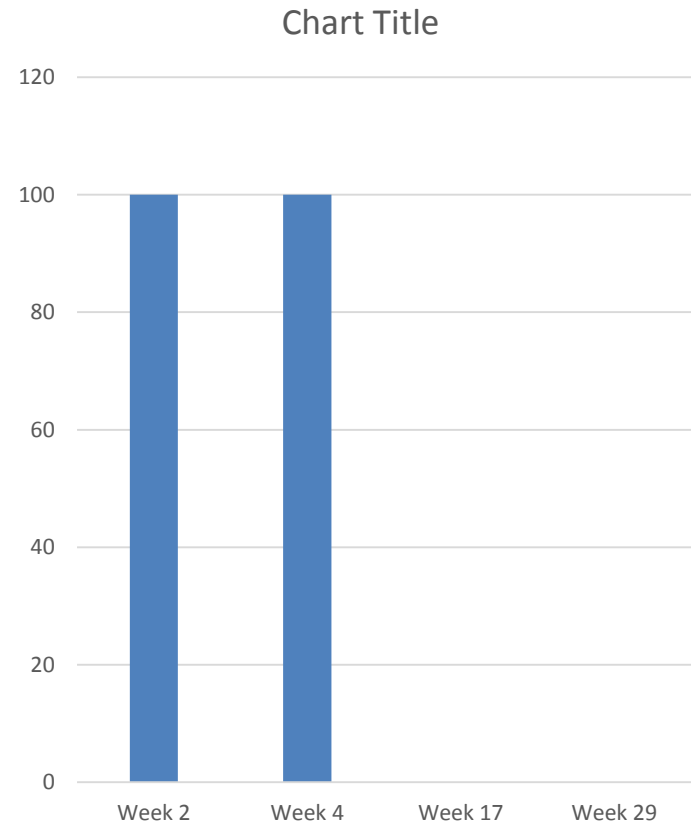
- 2 participants enrolled on 4<sup>th</sup> and 13<sup>th</sup> April 2016
- Multi-trial general information sessions
- Matching participants to a trial product
- Screened out rate is very high and reasons are based on safety and retention
- The site was more cautious and experienced

# Retention rates (%)

## Cohort 1



## Cohort 2



# Challenges and lessons learned

- Recruiting low cohorts within a high prevalence rate population poses a challenge of slow accrual
  - A wellness clinic was set up to prepare for HPTN 077
- A strategy of recruiting door-to-door did not work
  - Recruitment plan was evaluated and revised to add other areas of recruitment and implemented regular meetings to review recruitment targets

## Challenges and lessons learned

- A large number of potential participants would be recruited and enrol a few
  - Pre-screening activities are important to exclude those ineligible before they screen for a trial
- Community members raised a concern over an injectable investigational drug, being painful
  - Community education on new studies and forms of investigational drugs should be done thoroughly and promote acceptability of a drug
- Retention became a challenge
  - The clinic operated on flexible hours, provided transport and conducted split visits

## Conclusion

- Community engagement is an ongoing cycle of information, consultation, collaboration with the aim to empower communities with knowledge
- Experiences in HPTN 077 prepared the CRS to conduct other network trials
- Enrolling appropriate cohorts is enhanced by pre-enrolment activities which include wellness clinics, field pre-screening and ongoing dialogue between researchers and research communities

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