

UCT Clinical Trial Unit Groote Schuur Hospital CRS Update for MTN-017



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Programme Manager

MTN Annual Meeting
15 March 2015



DESMOND TUTU
HIV FOUNDATION



Overview

- Study Progress
- Best Study Practices
- Study Challenges
- Lessons Learned

Study Progress: Milestones

11 March 2014

Screening

20 Oct 2014

10 April 2014

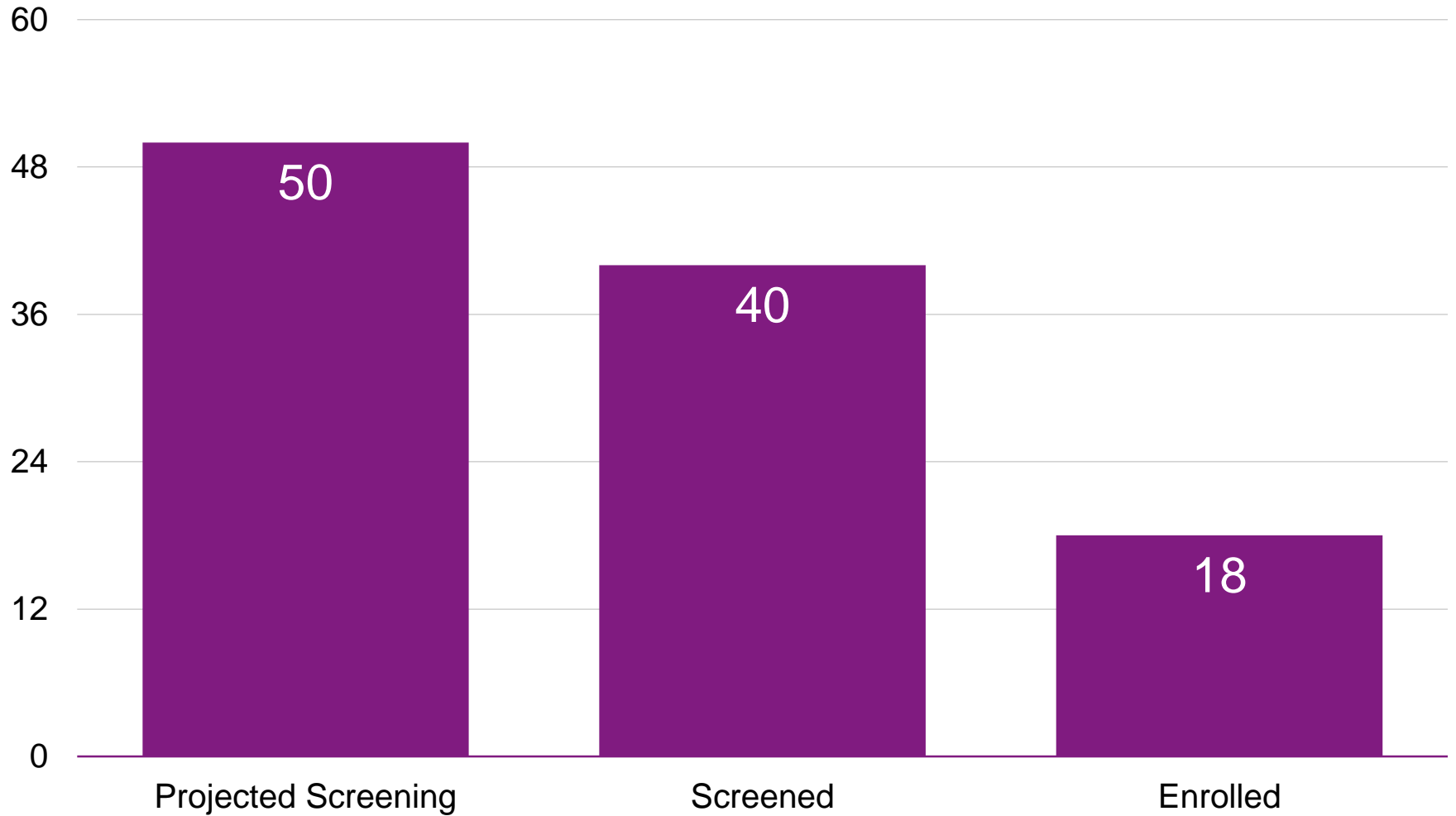
Enrollment

30 Oct 2014

Final Follow Up

30 April 2015

Study Progress: Accrual



Study Progress: Accrual and Retention

7

Months

Total Duration of
Accrual

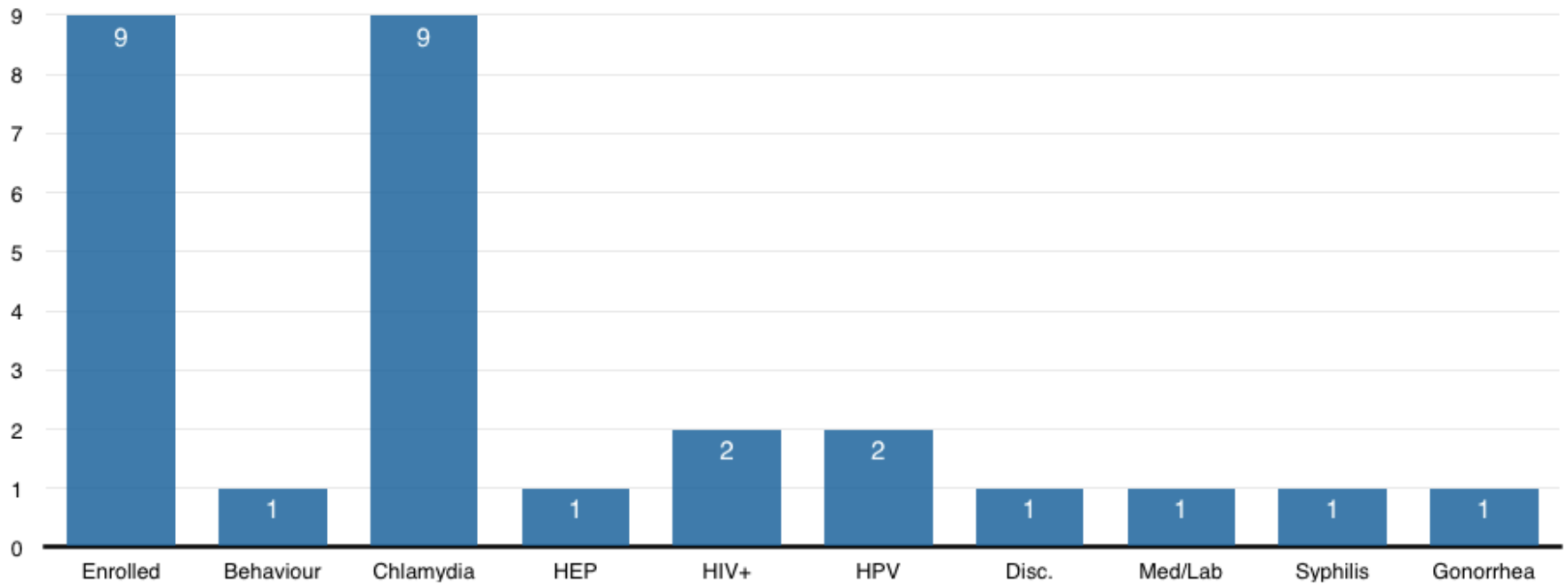
2.2 : 1

Enrollment
Ratio

9

Total Missed
Visits

Best Practices



Initial Screening Results

All HIV/STI + participants were referred to care



Best Practices

We developed an anal STI pre-screening protocol to address the prevalent asymptomatic STIs that were increasing our screening to enrollment ratio.

Anal Pre-Screening Protocol

Complete basic demographic form and contact information



Receives HIV test from study counselor



Visual and Digital Anal Exam

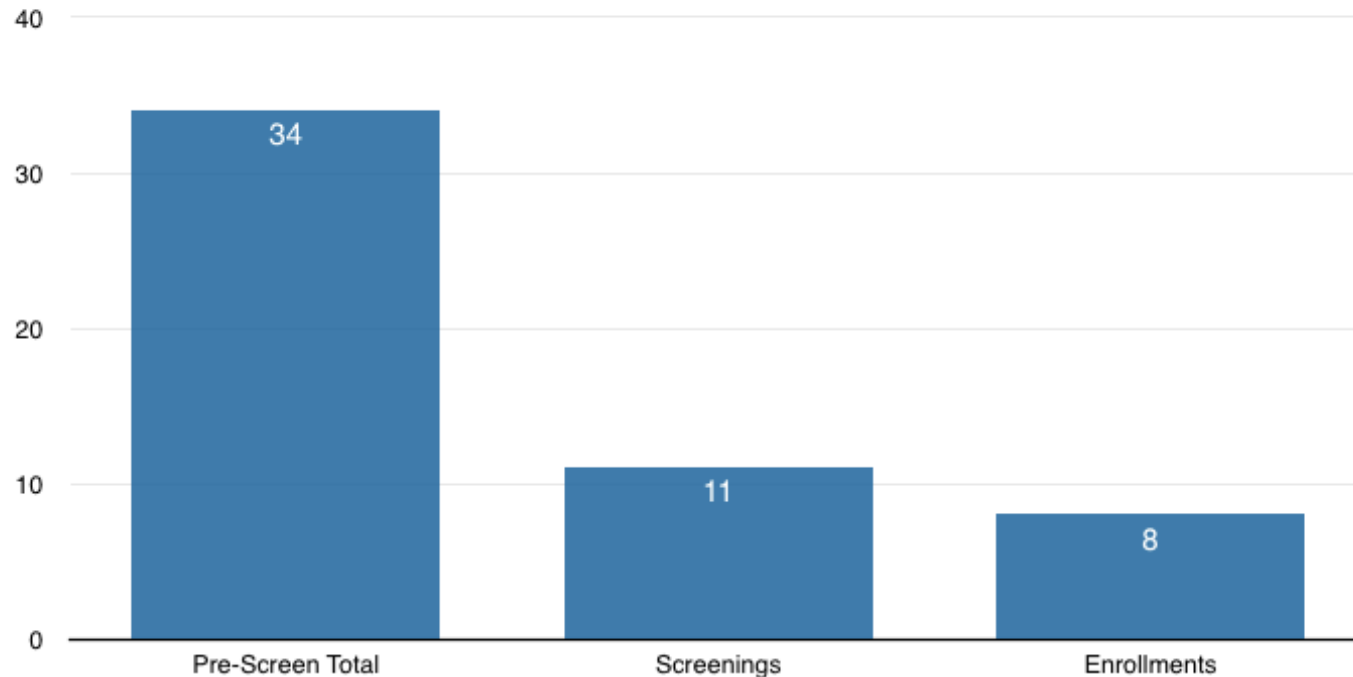


Anoscopy and Sample Collection



Return in +/- 1 week for results

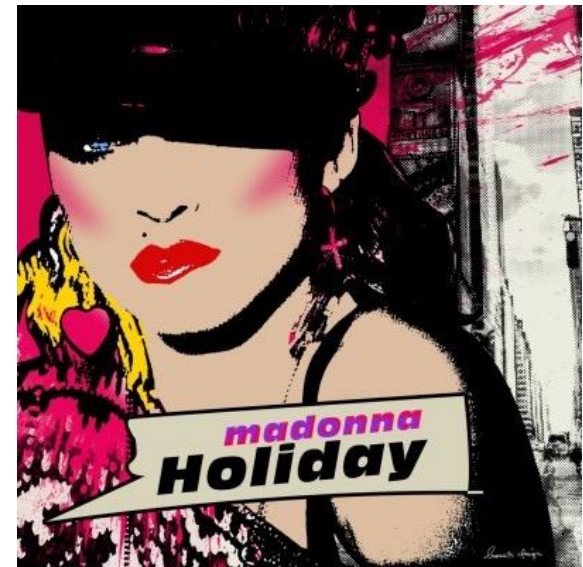
Anal Pre-Screening Protocol



Pre-Screening, Screening, and Enrollments
August - October 2014

Retention Challenges

- Extended holidays to the Eastern Cape during the Dec - Jan Festive Season.
- Our team coordinated visits around these expected travel dates.
- Still resulted in missed visits due to participants unable to organize transport back to Cape Town





Retention Strategies

**Bi-weekly/Weekly
Meetings in each
community group**

**Dissemination of HIV prevention
information and supplies**

Events across different communities

**Monthly activities in
each community
including sports and
debate**

Full community programme events

Adherence

- Challenges: using and storing product in family settings when disclosure has not occurred.
- Strategies: client centered approaches developed with experienced counselors. Participants valued alarms and visual reminders including the study SMS message.



Research Assistants in charge of adherence counseling, Daniel Ndzuze and Lindsay Gcwabe



Lessons Learned

Additional Pre-Screening Procedures were required

Extensive Education was needed to introduce microbicides

Recruitment benefited from having strong community-led strategies in place

**Comprehensive education about microbicides
and phase II studies was required to
successfully reach participants.**

Barriers to engagement

- Participants had not been exposed to microbicides previously.
- Some participants were skeptical of the microbicide application.
- Other participants were nervous or afraid of the anoscopy procedure



Education
Activity

2011

2012

2013

**RM
Discussions**



RM Video



**Outreach
Worker Info
Sessions**



Opportunities for Education

Community Outreach

Meet with Outreach worker at event

Meet with senior outreach worker one on one

Pre Screening

Discussion with Counselor

Discussion with Doctor

Screening and Enrollment

Discussion with Counselor

Discussion with SCO

Discussion with Doctor



**Recruitment had to be a comprehensive
community-driven process lead by MSM
peers**

Community Engagement Structure

Outreach Staff

Community Interns

Community Leaders

C1

C2

C3

C4

C5

C6

C7

C8



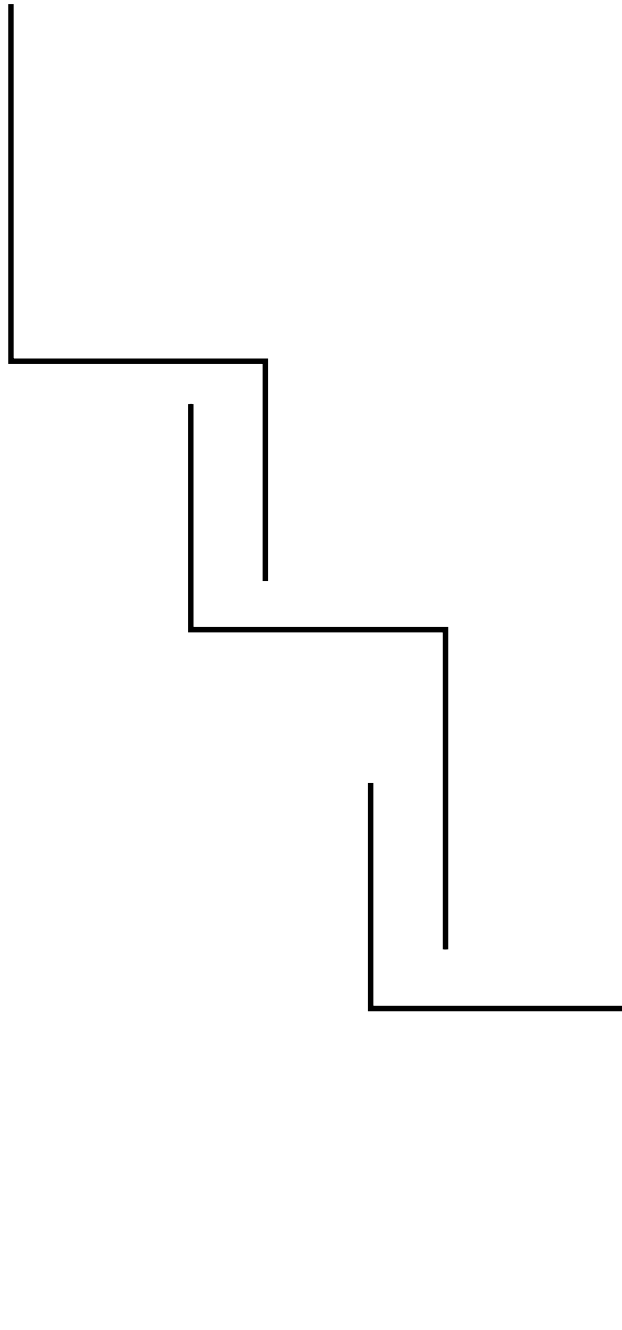
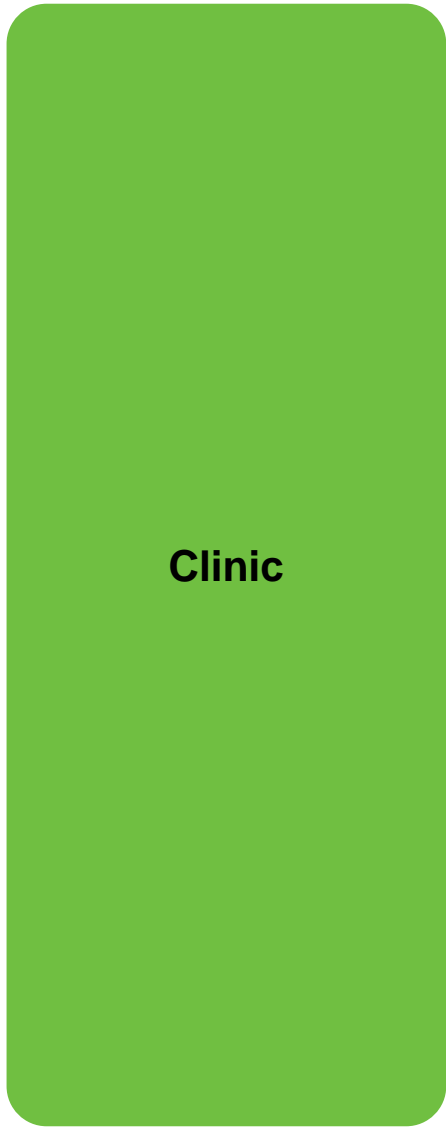
Outreach

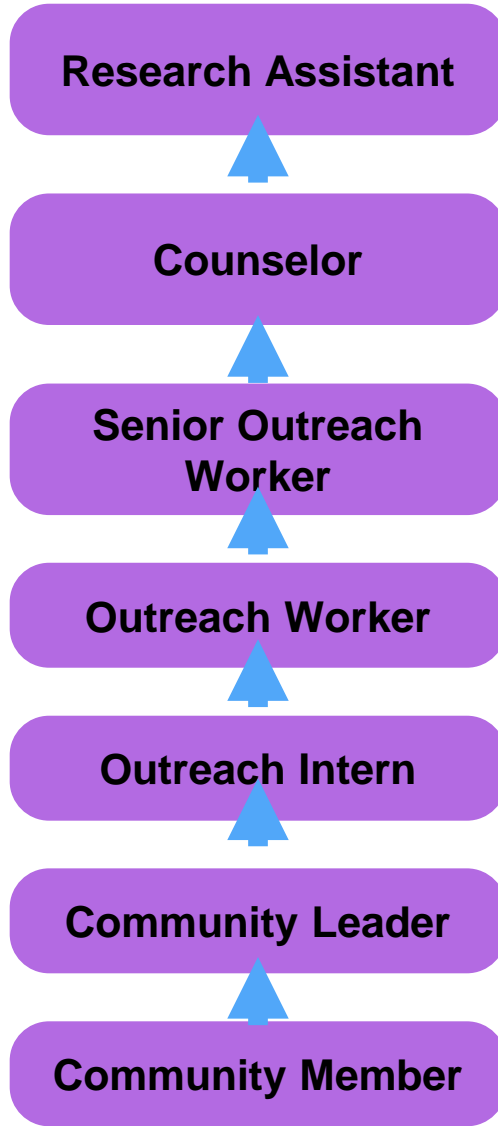
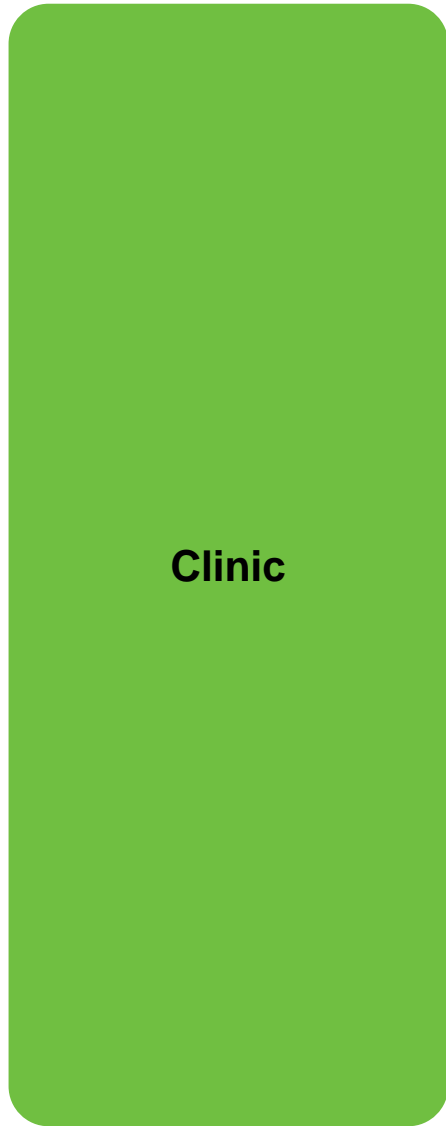
**Community
Engagement**

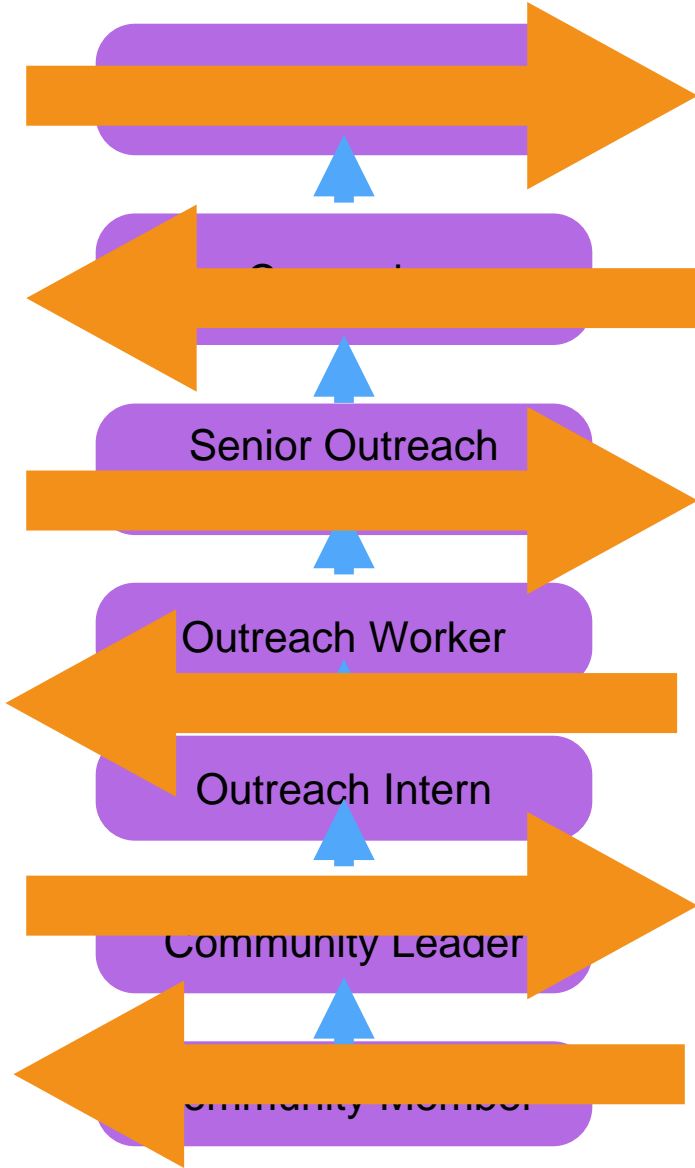
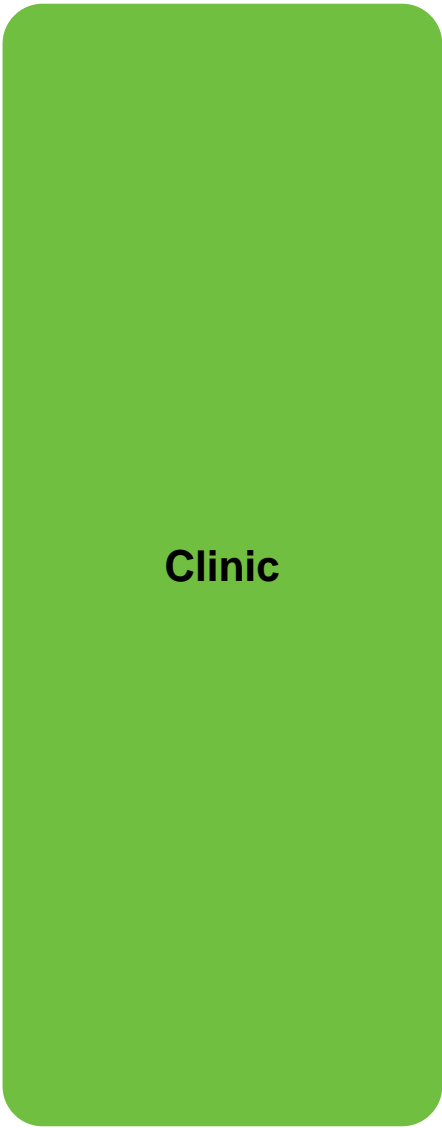
Recruitment

Team Structure and Capacity Building









Going Forward

- Ensuring high data quality and strong retention is an important goal for our site.
- Driven by a strong integrated team approach.
- Each file is reviewed for QA
- Monitor for trends from data queries and address through staff refresher trainings.



Senior outreach worker, Xolani Mvula; Research Assistant, Daniel Ndzuze; SCO Karen Dominguez; Research Assistant Brian Kanyemba; Research Nurse, Jo Sage

Going Forward

- Everyone on our team is involved in participant retention.
- Clinic team build meaningful relationships with participants and outreach team implement regular visits to sustain contact between visits
- Adherence is driven by counseling team and enforced outside of the clinic with retention officers.



Senior outreach worker, Xolani Mvula; Research Assistant, Daniel Ndzuze; SCO Karen Dominguez; Research Assistant Brian Kanyemba; Research Nurse, Jo Sage



Any Questions?
