



KPIS Implementation Study

Key Population Implementation Science

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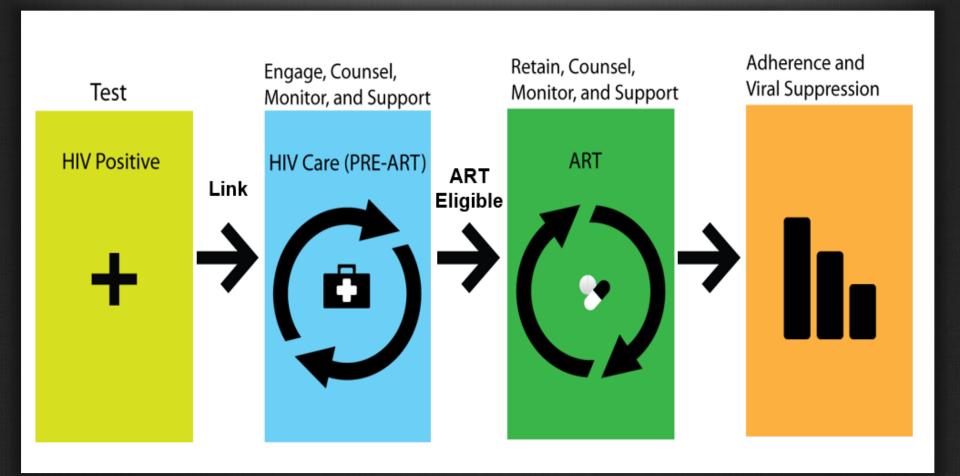


Overview

- Objectives and Aims
- Interventions and Study Design
- Sites and Recruitment
- Next Steps

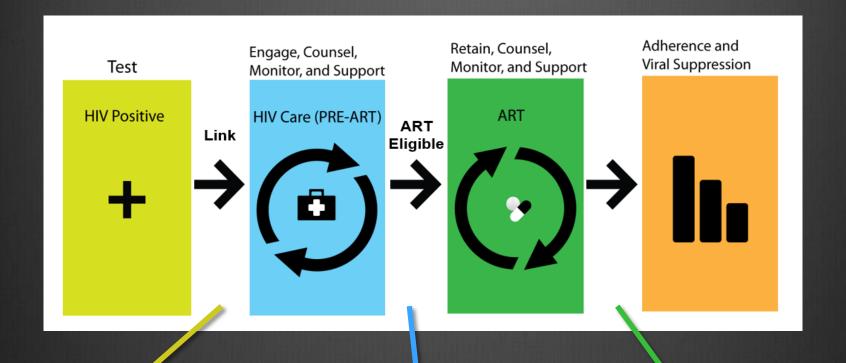
Objectives

- Optimize continuum of HIV care
- Capacity building for MSM services
- Using an implementation science framework



HIV testing and treatment cascade

(credit W El-Sadr)



Aim 1: diagnose MSM unaware of HIV status

Aim 2: use POC CD4 testing to return results and improve determination of ART eligibility

Aim 3: assess utility of peer-based adherence support for achieving/sustaining VL suppression

Aim 1 test and diagnose

- 1 nurse to work in community based sites
- survey men testing HIV positive
 - testing practices, status awareness, barriers to testing
- in-depth interviews (IDIs) with those who:
 - HIV+ and never before tested
 - HIV+ at baseline and do not enter care

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- equipment and training for POC CD4
- ART-eligible offered immediate treatment
- ART-ineligible offered Peer Health Navigator (PHN) for pre-ART care
 - rest CD4 in 6 months
- pre-intervention receive SOC
- IDIs for those ART-eligible but don't accept treatment

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Adherence support and decentralized care for improving treatment outcomes

- peer-based adherence support from PHNs
 - 1:20
 - SMS system
- viral load lab results obtained clinic/NHLS records
 - baseline, 6 and 12 months
- IDIs with men who lose VL suppression

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Intervention

- decentralized HIV testing & counseling
 - promote study enrollment

- POC CD4 and creatinine testing
 - EVALUATE: completion CD4 staging and return of results, POC versus clinic-based

- PHN for adherence support
 - EVALUATE: viral load suppression (proportion ART-eligible VL-suppressed at end of follow-up period)

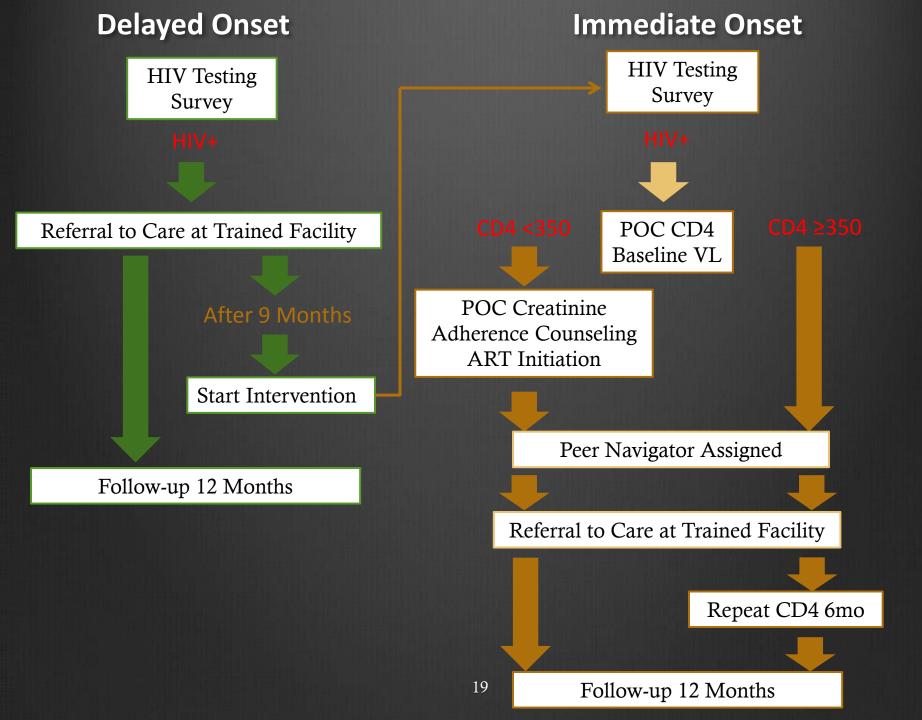
Delayed Onset Design

one-step, stepped wedge

baseline assessment in all clusters

- half clusters receive intervention full 18 months

- other half clusters start receiving at 9 months



Proposed Sites

- 1. Nelson Mandela Metro Bay (Eastern Cape Province)
- Pietermaritzburg (KZN Province)
- 3. Vhembe and Mopani (Limpopo Province)
- 4. Soweto (Gauteng Province)
- Nelspruit and Mapulaneng (Mpumalanga Province)
- 6. Khayelitsha and Gugulethu (Western Cape Province)

Primary Outcome

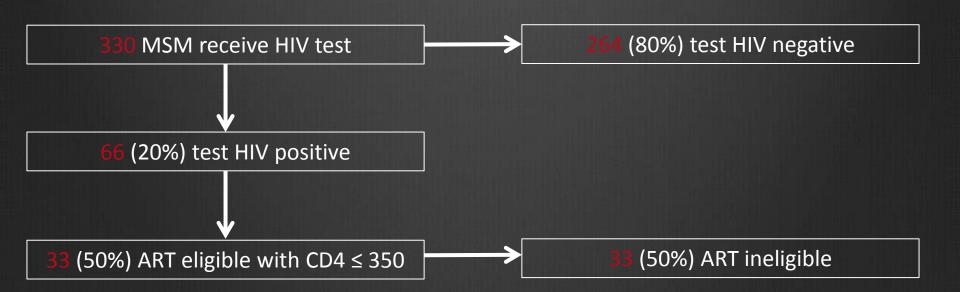
Primary outcome = viral suppression

defined as undetectable VL within 6 months of ART

 proportion treatment eligible enrolled who achieve viral suppression at end of follow-up period

Total Enrollment

- To reach 33 tx-eligible HIV+ MSM per cluster, need to test 330 MSM per cluster
- HIV test ~2000 total across all sites



Next Steps

- Protocol review and corrections

- IRB requirements

- Collaborate with NHLS

- Site preparation

Comments?

