LEVERAGING COMMUNITY & PEER-BASED APPROACHES TO IMPACT THE HIV TREATMENT CASCADE AMONG MSM IN SOUTH AFRICA

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Background

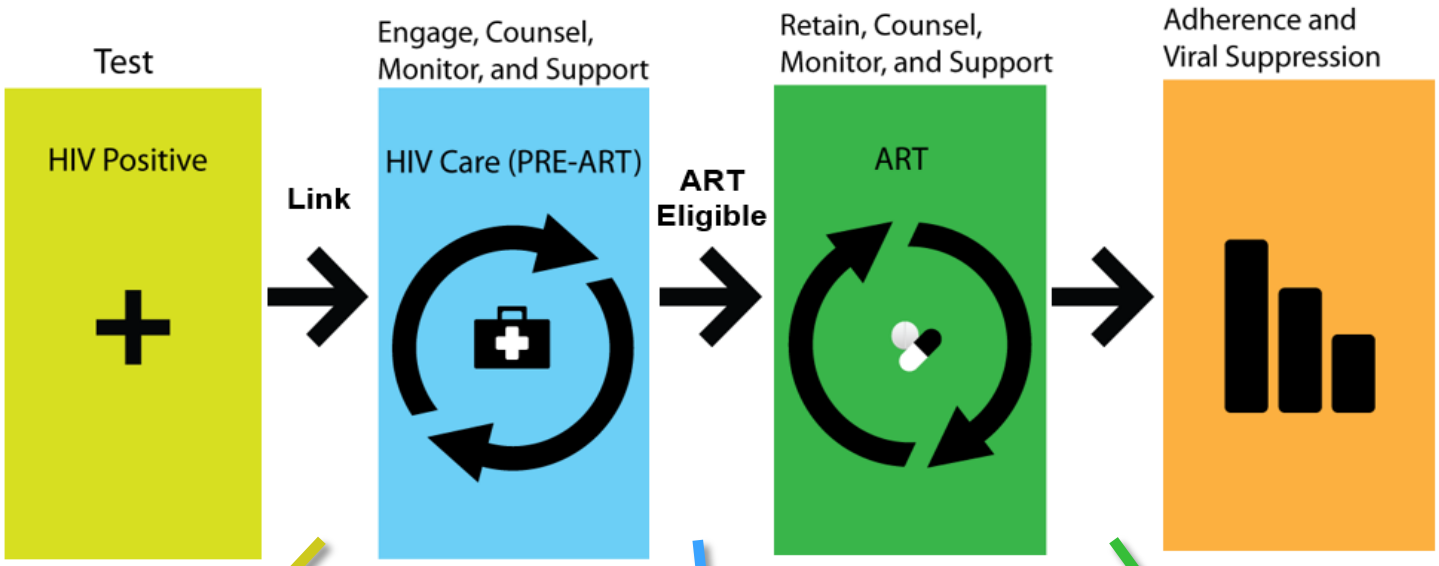
- SA MSM high risk of HIV acquisition/transmission - SA NSP on HIV, STIs & TB 2012-2016 acknowledge MSM as key population
- There is a disproportionate burden of HIV among MSM wherever studied - In SA, HIV prevalence estimates among MSM range from 13% to 49% with 9.2% of new infections being attributable to MSM (UCSF, 2015; McIntyre et al, 2013; SANAC, 2012)
- Although SA has the largest ART program in the world (Shisana et al, 2008) <40% of ART-eligible patients were on treatment at the previous national guidelines of CD4 <350 cells/mm^3(UNAIDS, 2010)
- MSM face high levels of stigma and discrimination and experience barriers to accessing health care (Lane et al, 2008)
- Optimizing the continuum of HIV care for MSM is a crucial component of comprehensive HIV prevention, treatment, and care programs (Rebe, K., et al)
- Reducing HIV transmission by expanded, early and consistent use of ART is key to ending the HIV epidemic (Cohen et al, 2011; Padian et al, 2011)
- Rates of testing, linkage to care, and treatment in South Africa must improve significantly to decrease new infections (Lane, et al, 2008)

Primary Research Questions

- **Research Question 1:** Can community driven, non-clinic based HIV testing approaches successfully identify MSM with newly diagnosed HIV and MSM with previously diagnosed HIV who are not on ART?
- **Research Question 2:** Can the use of community-implemented POC CD4 and linkage interventions increase the extent of determination of eligibility for and early initiation of ART among MSM living with HIV in South Africa?
- **Research Question 3:** Does increased support provided by peer health navigators improve treatment outcomes among MSM living with HIV?
- **Research Question 4:** Does increased community support for linkage to care for a stigmatized population such as MSM living with HIV result in improved implementation outcomes with a focus on acceptability, feasibility, fidelity, implementation costs, and sustainability?

Study Purpose

- We aim to improve treatment initiation, clinic retention, and ART adherence for treatment-eligible MSM, and improve monitoring of CD4 count among treatment-ineligible men.
- Launch an effectiveness-implementation trial to Investigate the effectiveness (fidelity, feasibility, applicability, acceptability) of a package of community, individual, & peer-based innovative interventions
- To optimize continuum of care for difficult-to-reach MSM – essential for comprehensive HIV prevention, treatment, and care programs
  - Implement community-driven strategies to find and diagnose MSM who are unaware of their HIV status
  - Increase linkage to care and early treatment initiation
  - Achieve viral suppression among treatment initiators through adherence support - retain MSM living with HIV in care and support adherence
  - Improve program delivery and uptake of services
- Capacity building in South African cities with little MSM services; build on existing programs in other sites
- Implementation science: test package of interventions that can be reasonably implemented and scaled up if effective
  - Measure utility (acceptability, feasibility, & uptake) of: POC CD4 vs standard clinic-based CD4 testing; utility of peer-based adherence support for achieving VL suppression; decentralization of ART programs and ideally establish best practices



HIV testing and treatment cascade (credit W El-Sadr)

Aim 1: Diagnose MSM unaware of their status -HIV testing – HCT is entry point for continuum of prevention, treatment, care & support

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

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

Study Population

- Inclusion Criteria
  - ≥18 years of age
  - Male sex at birth
  - Anal sex with another man in the past 12 months - Do not have to self-identify as gay, bisexual or transgender
  - Resident of the study site area
  - Able to complete study instruments, with or without assistance, in local languages (English, Xhosa, Tshivenda, Xitsonga, Isiswati, IsiZulu or Afrikaans)
  - Access to private messages via a mobile phone
  - Willing to provide contact information, including mobile phone number
  - Willing to have study staff abstract clinic records and access laboratory results for up to 24 months after enrollment
  - Not currently on ART; Not virally suppressed
- Exclusion Criteria for Follow Up
  - Men who test negative for HIV and Men diagnosed with HIV and already on ART
  - Persons who are screened, but not study-eligible, will have the opportunity to receive HIV testing and referral to HIV care

Recruitment Methods

Recruitment will occur through multiple methods depending on what is feasible and appropriate at each study site, including:

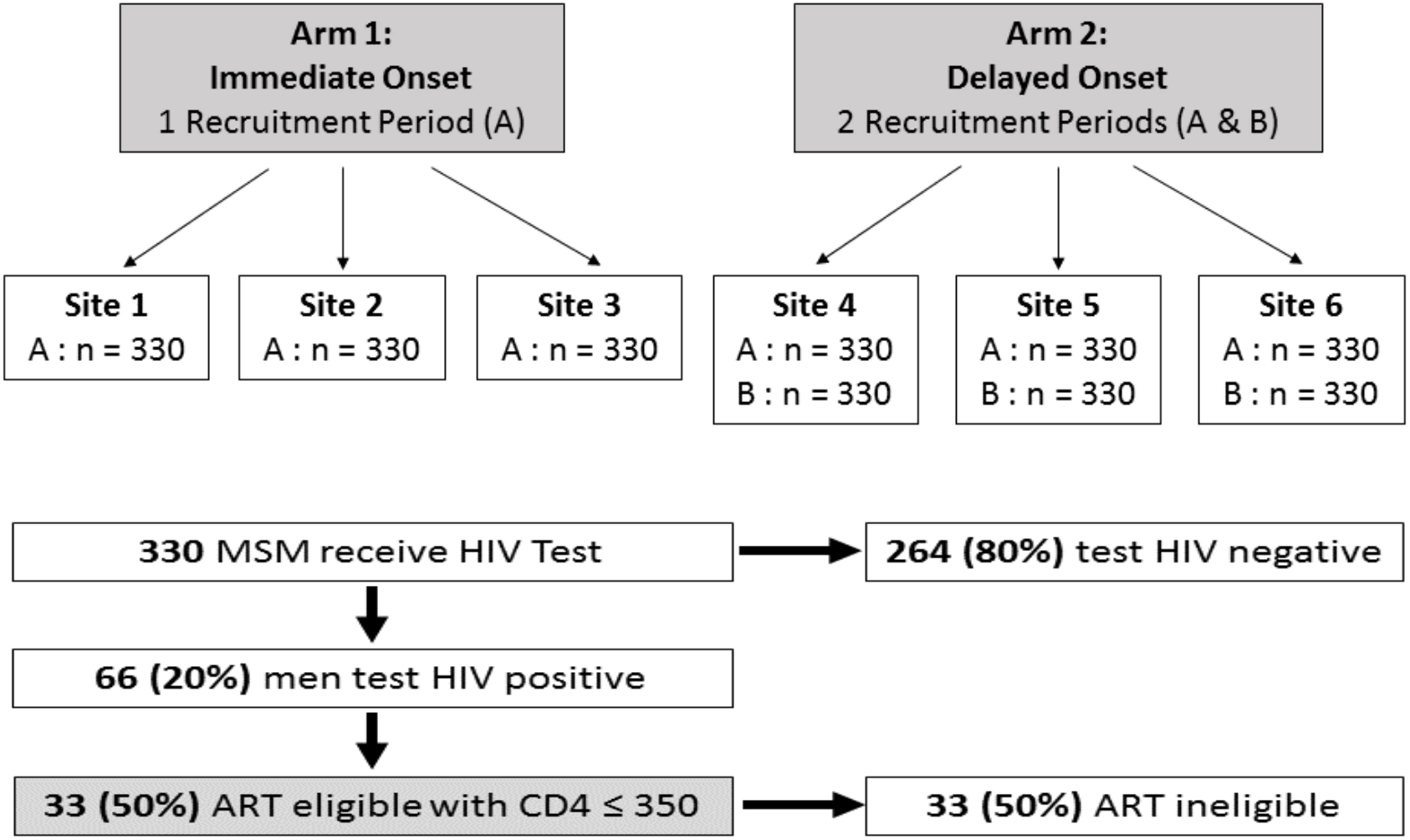
- **RDS:** RDS-like peer referral recruitment strategies to reach MSM who may have less access to HIV testing and linkage services - Seeds from community will receive referral coupons, without limits to the number of coupons per person, to distribute to peers.. Men who receive coupons will be directed to attend testing events where they will be screened for eligibility. Seeds and participants will receive no compensation for distributing referral coupons.
- **Social networks:** Facebook advertisements, Twitter, Whatsup user groups, and other social media advertisements on MSM-specific social media sites.
- **Online and print advertisement**: Advertise study through media campaigns, media and television ads, newspapers ads, flyers, ads in taxi and buses, and other media ads.
- **Time and location sampling: Recruit at** Gay and MSM events and venue hotspots , **e.g.** pride festivals, Mr. Gay modeling events, braai's, bars and dance clubs.
- **Mobile units**: Organizations like ANOVA and ICAP in some sites use mobile units to recruit, test, and treat MSM. Study staff will collaborate with these organizations to recruit MSM for the study.
- **Outreach events and meetings:** Conduct outreach events and meetings with local MSM activist organizations, e.g. Eastern Cape Gay and Lesbian Association in Port Elizabeth.
- **Referrals from other projects:** Other research studies may refer men for screening, including the Sibanye Health Project (MP3).

All methods will include balanced partnerships with CBOs led by or serving MSM in the area

Study Sites Identified

- Site specific circumstances relating to current research and programmatic activities were taken into consideration to ensure synergy, avoid duplication and participant fatigue
- Study site selection took place in JULY and August 2015
- Study sites were selected in consultation with local authorities, MSM Community and stakeholder engagements
- Multiple partners at different levels – CBOs, DOH, service providers
- Ensured robustness of venues using site feasibility assessment form, i.e. MSM numbers, accessibility, affordability, regular water, power supplies, biosafety, etc.
- Potential venues identified; heterogeneity of sites; Hotpots identified; surrounding clinics identified; local stakeholders identified; Community Advisory Boards established
- Provincial approvals and buy in received
  - Nelson Mandela Metro Bay in Eastern Cape Province
  - Pietermaritzburg (Ugugumdlovu) District in KZN Province
  - Mopani District (Greater Tzaneen-Maake/Lenyenye) in Limpopo Province
  - Ekurhuleni (Springs) in Gauteng Province
  - Nkangala District (beginning of Thembisile Hani Sub-District) in Mpumalanga Province
  - Cape Town CBD in Western Cape Province

Sample Size Calculation: 2,900 MSM



Sample Size Assumptions

The following assumptions were made when calculating sample size using STATA 12:

- 20% HIV prevalence and 50% ART eligibility
- 10% Annual LTFU
- Intra-cluster correlation of 0.05
- Coefficient of variation of cluster size is 0.25
- Power of 80%
- Statistical significance of 0.05
- All calculations were conducted with a starting proportion of 0.50.
- We used this conservative proportion to ensure we account for a large enough sample size.
- Magnitude of effect of intervention between 20 and 40% over standard of care

Site Staffing

- Appoint local people
- Consistent within each site – Appoint 9 staff:
  - 1 coordinator,
  - 1 NIMART trained nurse,
  - 3 Peer Health Navigators,
  - 2 Community Mobilizers,
  - 2 counsellors
- Interviews completed first week of September 2015

Training Grid

Training	Counselors	Nurses	Peers	Coordin-ators	Lead Provider
Research ethics	X	X	X`	X	HSRC
HIV Prevention Counseling	X				Emory or ANOVA
Peer navigation			X		JHU
Study specific procedures	X	X	X	X	HSRC
Data procedures		X	X	X	Emory
Lab procedures HIV Rapid testing, CD4, Creatinine	X	X		X	NHLS/NICD
Sensitization	Clinics in all study cities				ANOVA

Study Design: 1step, stepped wedge

- These designs involve sequential roll-out of an intervention to groups of participants over a number of time periods. By the end of the study, all participants (immediate and delayed) will have received the intervention, but the delayed group will serve as the "control" group.
- Comparability of effects across groups and time periods - control vs intervention sites e.g.
  - compare completion of CD4 staging & return of CD4 results among HIV-infected MSM staged by POC CD4 vs standard clinic-based CD4 testing;
  - compare time to ART initiation among ART-eligible MSM receiving the intervention vs those receiving the standard of care
- Allows for 2 different comparison effects
  - Between immediate vs Delayed Onset
  - Delayed Onset: Before and After Implementation
- Retains focus on implementation science
  - All groups that receive intervention and durability of the intervention can be assessed
  - Determines how feasible it was to roll-out the intervention
  - Determines how much time was observed from the intervention to the effect
- Ability to Measure Implementation Outcomes
- Addresses issues of a larger stepped-wedge design that viral suppression outcomes would not occur within one individual step.

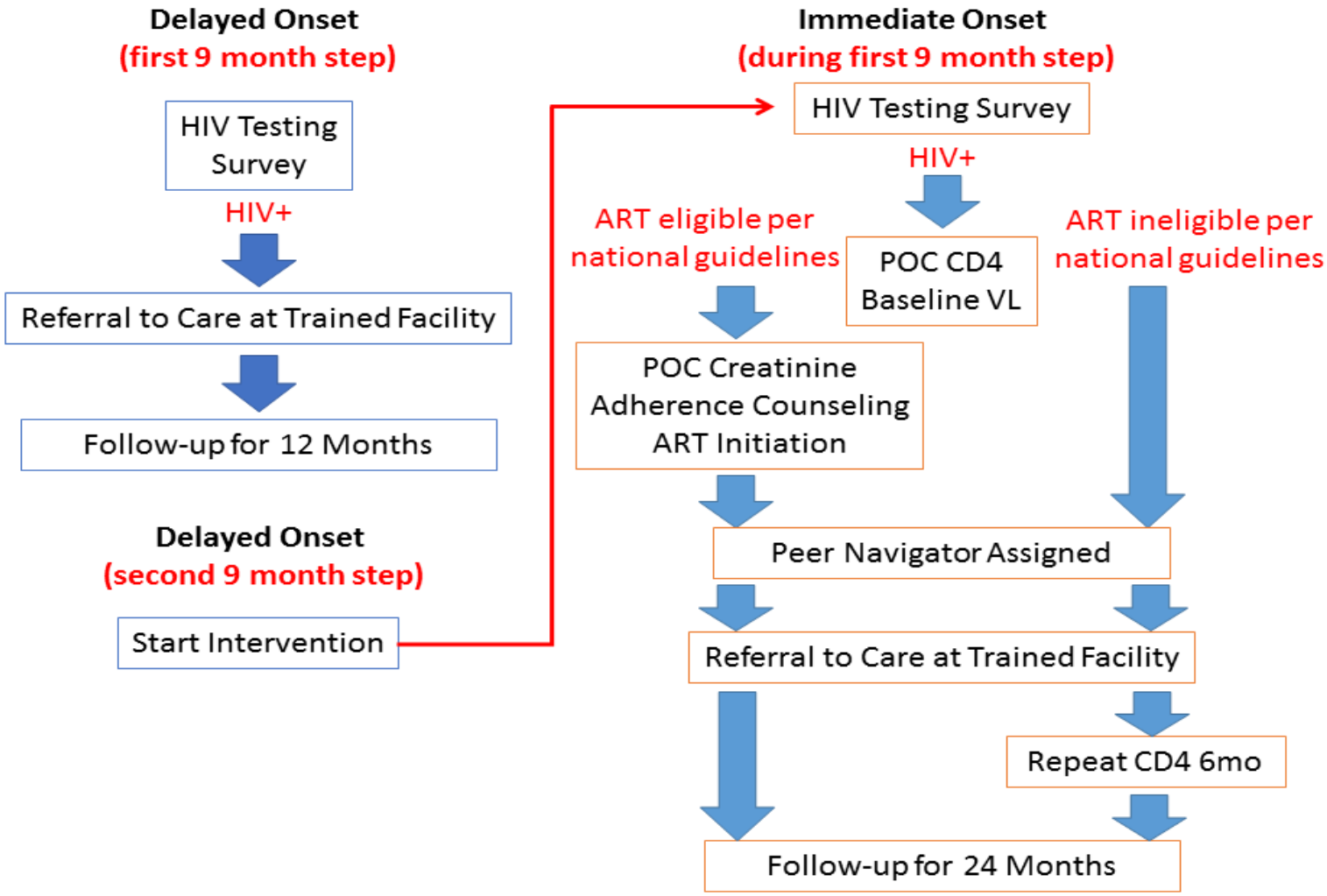
Study Design – Immediate Onset Arm

- Three sites will be randomized to immediate onset sites - logistical and financial limitations
- Immediate onset sites will initiate following interventions at study start
- LGBT sensitization training in clinics for provision of health care for MSM prior to enrollment
- Study staff training - Combination of administrative training and training in study procedures
- PHN training on treatment adherence and support
- POC HIV testing - Men attend a one-time study visit with HIV decentralised HIV counseling and testing at month 0
- POC VL testing - specimen collected & sent for baseline VL
- POC CD4 testing - specimen collected & sent for baseline CD4 to assess treatment eligibility at time of diagnosis to encourage treatment initiation
- POC creatinine - for eligible men: men with low CD4 - CD4<500 cells/mm^3
- POC treatment initiation - testing for ART presence; on-site treatment initiation for eligible men - NIMART nurse to initiate treatment if eligible
- SMS Behavioural surveys for men who test HIV+ - uptake and acceptability of the study interventions; adherence checks for men who initiate ART, peer navigator feedback
- PHN - HIV-infected men linked to study participants to encourage adherence & retention in care
- HIV-positive men followed for 24 months – abstract clinic records, access laboratory results & SMS surveys for up to 24 months after enrollment. Additional 12 months to assess long-term effects of the intervention

Study Design – Delayed Onset Arm

- Three sites will be randomized to delayed onset sites (control arm)
- First 9 months
  - Decentralized HIV testing and counseling at month 0 and survey, no other specimen collection
  - Referral to care per standard guidelines if HIV-positive
  - Follow up HIV positive MSM for 12 months – abstract clinic and lab records
  - LGBT sensitization training in clinics for provision of health care for MSM prior to enrollment
  - Study staff training - Combination of administrative training and training in study procedures
  - Follow up/interventions will be provided for those who are found not to be living with HIV.
- Second 9 months
  - Initiate intervention at 9 months to allow the effect of the intervention package to be assessed during months 1-9
  - Implement all POC interventions administered in the immediate onset arm including PHN training on treatment adherence and support

Study Design: Summary



Primary Outcomes

- Viral suppression is the ultimate outcome the package of interventions intends to impact
  - undetectable HIV viral load within 6 months of initiating treatment.
  - We will measure the proportion of ART eligible men enrolled in the study who achieve viral suppression within 6 months of initiating ART at the end of the 12-month follow-up period.

Secondary & Implementation Outcomes

Secondary Outcomes
Proportion of HIV-positive men who enter care
Proportion of men who receive CD4 results
Proportion of ART-eligible men who initiate ART
Time to ART initiation for ART-eligible men
Proportion of ART-eligible men who initiate ART and are retained in care
Proportion of treatment ineligible HIV-infected men who receive a CD4 test within 6 months following their study visit CD4

Implementation Outcomes
Acceptability of outreach/CBO-based testing intervention
Relative advantages of non-clinic-based ART initiation & retention package compared to standard of care
Perceived credibility of CBOs to initiate ART as compared to standard ART clinics
Utility of decentralized NIMART-trained nurse initiated ART and peer navigator based support
Implementation costs associated with experimental condition
Maintenance and routinization of using clinic-based approaches and peer-navigators for retention as indicators to describe potential sustainability of the interventions

KPIS Timelines for Key Milestones

- Lets discuss
- Staff appointment
- Staff training
- Clinic training
- Site activation
- Launch/Enrolment


THANK
YOU