



EHP SA Adolescents Portfolio

EHPISA Adolescent research studies

- **Impact of HIV combination prevention interventions on HIV prevalence among young people in Zambia and South Africa (Adolescents in PopART)**
- **Evaluating a Combination HIV Prevention and Sexual and Reproductive Health Package for at-risk Young Women: A Demonstration Project – Malawi and South Africa**
- **The missing link in HIV prevention: Helping HIV-positive adolescents to reduce transmission in Southern and Eastern Africa – South Africa**
- **STRIVE to EMPOWER: Improved combination prevention (including PrEP) in Adolescent women in Tanzania and South Africa**

Unifying threads

- Operational research
- Looking at combination methods to improve uptake and adherence in an adolescent population
- Including PrEP
- Targetted at both HIV-negative and HIV-positive adolescents.
- All projects have at least one site in South Africa, with other sites in Zambia, Tanzania, and Malawi
- Policy implications

It is crucial that effective combinations of existing social and healthcare interventions should be adapted so that they are responsive to the unique needs of adolescents, those both HIV-positive and HIV-negative.



Timeframe: 30 months



Mzantsi Wakho: Social protection for HIV prevention among adolescents
University of Cape Town
Oxford University
Paediatric ART Clinic Software Development Project

Countries of Implementation:
 South Africa

Dr. Lucie Cluver
 Dr. Rebecca Hodes
 Craig Carty
 Elona Toska

Justification

- Over 600 new adolescent HIV-infections in Southern and Eastern Africa every day [UNICEF, 2013].
- Social and structural deprivation: key drivers of adolescent HIV infection and morbidity [Seeley et al, 2012].
- Growing body of evidence that ‘social protection’ can reduce risks of HIV-infection in Sub-Saharan Africa [UNICEF, 2012; Baird et al, 2012; Cluver et al, 2013; Handa et al, 2013].
- Aim: Provide high-quality evidence on combinations of existing social protection and healthcare interventions that are linked to reduced HIV-risk taking behaviour, and test feasibility and acceptability of a combination intervention to reduce HIV-risk behaviour.
- Mzantsi Wakho: Longitudinal study of HIV-positive adolescents in Eastern Cape. Largest community-based sample. Eastern Cape South Africa, 39 state health facilities

N=700 (+200) HIV+ adolescents

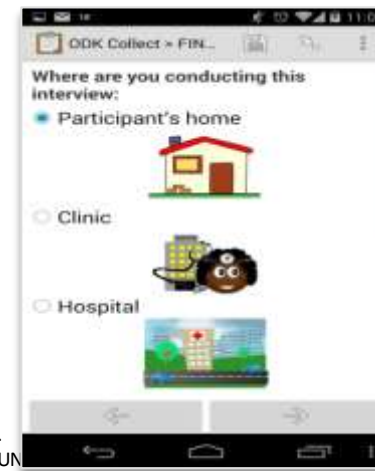
Every teen who ever started on ART

Community tracing: including lost-to-follow-up

Standardized interviews;

Biomarkers (VL/CD4);

In-depth qualitative and participatory research



UNICEF, *Towards an AIDS-Free Generation – Children and AIDS: Sixth Stocktaking Report*, 2013, UNICEF: New York.

Seeley, J., et al., *Addressing the structural drivers of HIV: a luxury or necessity for programmes?* J Int AIDS Soc, 2012. **15 Suppl 1**: p. 1-4.

Baird, S.J., et al., *Effect of a cash transfer programme for schooling on prevalence of HIV and herpes simplex type 2 in Malawi: a cluster randomised trial.* The Lancet, 2012. **379**(9823): p. 1320-9.

Department of Social Development, SASSA, and UNICEF, *The South African Child Support Grant Impact Assessment: Evidence from a survey of children, adolescents and their households*, 2012, UNICEF: New York.

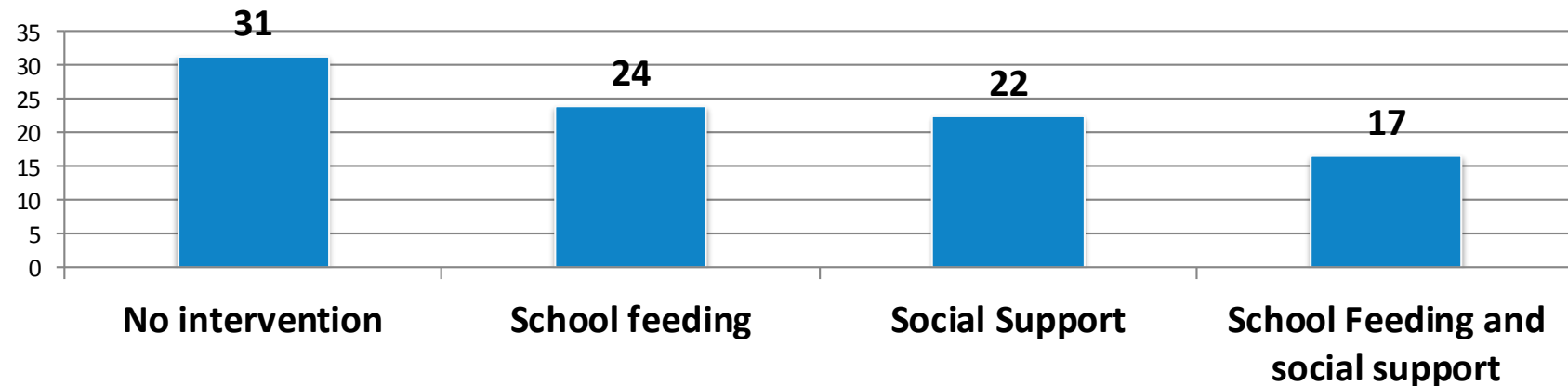
Handa, S., et al., *The government of Kenya's cash transfer program reduces the risk of sexual debut among young people age 15-25.* PLoS One, 2014. **9**(1): p. e85473.

Cluver, L., et al., *Child-focused state cash transfers and adolescent risk of HIV infection in South Africa: a propensity-score-matched case-control study.* The Lancet Global Health, 2013. **1**: p. e362-70.

Research Questions

- What combination of prevention approaches may reduce transmission risk behaviour among HIV-positive adolescents in the region?
- Do combinations of social protection ('cash plus care') and healthcare predict HIV-risk behaviour reduction among HIV+ teens?
- How do stakeholders: local leaders, experts, and adolescents themselves view combination HIV prevention interventions?
- How can adolescents be included in the design, implementation, monitoring and evaluation of programmes associated with reductions in risk behaviours?
- Are these programmes feasible and effective? (Pre- and post-testing & pro

% adolescents non-adherent:



Research Design and Methods

Mixed methods: systematic review, longitudinal quantitative research, in-depth and action-based qualitative research, and operational pre- and post-testing for feasibility and initial effectiveness of an intervention.

Stage	Research Component	Year 1 June 2015-May 2016	Year 2 June 2016-May 2017	Year 3 June-Nov 2017
1	Systematic review of interventions			
	Mzantsi Wakho baseline dissemination			
	Stakeholder mapping, consultations and network building			
	Preliminary qualitative research & community mapping			
2	Mzantsi Wakho one-year follow-up (T2) data collection			
	Longitudinal data analysis			
	Dissemination of longitudinal data analysis			
	Consultations with stakeholders on combination intervention to test			
	Participatory research with adolescents, families and providers on factors shaping HIV-transmission risk behaviour			
	Consultations with youth on longitudinal findings and combination intervention to test (qualitative)			
3	Pre-test data collection			
	Intervention design (youth-led qualitative workshops)			
	Intervention implementation			
	Youth consultations on intervention implementation			
	Process evaluation data collected during implementation			
	Post-test data collection			
	Mzantsi Wakho two-year follow up (T3) data collection ⁶			
	Longitudinal Mzantsi Wakho data analysis			
	Analysis of intervention feasibility data (quals & quants)			
	Write-up, policy engagement of intervention feasibility			

Research Outcomes



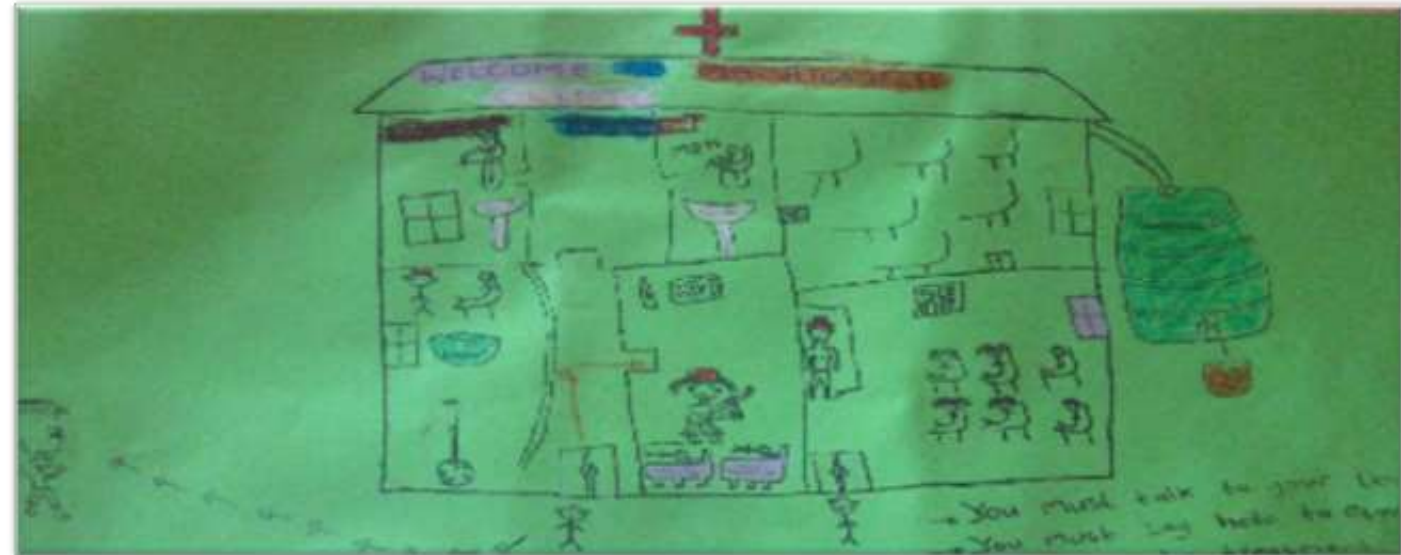
- **Stage 1:** Systematic review and a prevention ‘community audit’ will assess interventions successfully reduced HIV-transmission risk behaviour.
- **Stage 2:** Longitudinal analysis and qualitative research will measure and examine HIV-transmission risk behaviour as a composite of sexual behaviours linked to increased HIV transmission. Sexual behaviours to consider include inconsistent condom use, having an older partner, transactional sex, having multiple sexual partners and unwanted adolescent pregnancies.

Stage 3: Secondary outcomes will be assessed to determine the feasibility of a combination of interventions through process evaluation methodologies. The *secondary outcomes* for the intervention feasibility will include: participant enrolment, attrition, engagement, and satisfaction, as well as implementation fidelity and cultural acceptability.



Policy Implications

- Research gap identified by partners, including UNICEF, UNAIDS, ILO, UNDP, PEPFAR/USAID, Inter-agency Task Team for Social Protection, Care and Support (IATT) and Regional Interagency Task Team on Children and AIDS (RIATT-ESA).
- Consistent involvement of stakeholders (policy makers and implementing bodies) from design to dissemination.



Evaluating a Combination HIV/SRH Health Package for at-risk Young Women: A Demonstration Project

UNC Project/Lilongwe Medical Relief Fund Trust
Desmond Tutu HIV Foundation

Countries of Implementation:
Malawi and South Africa

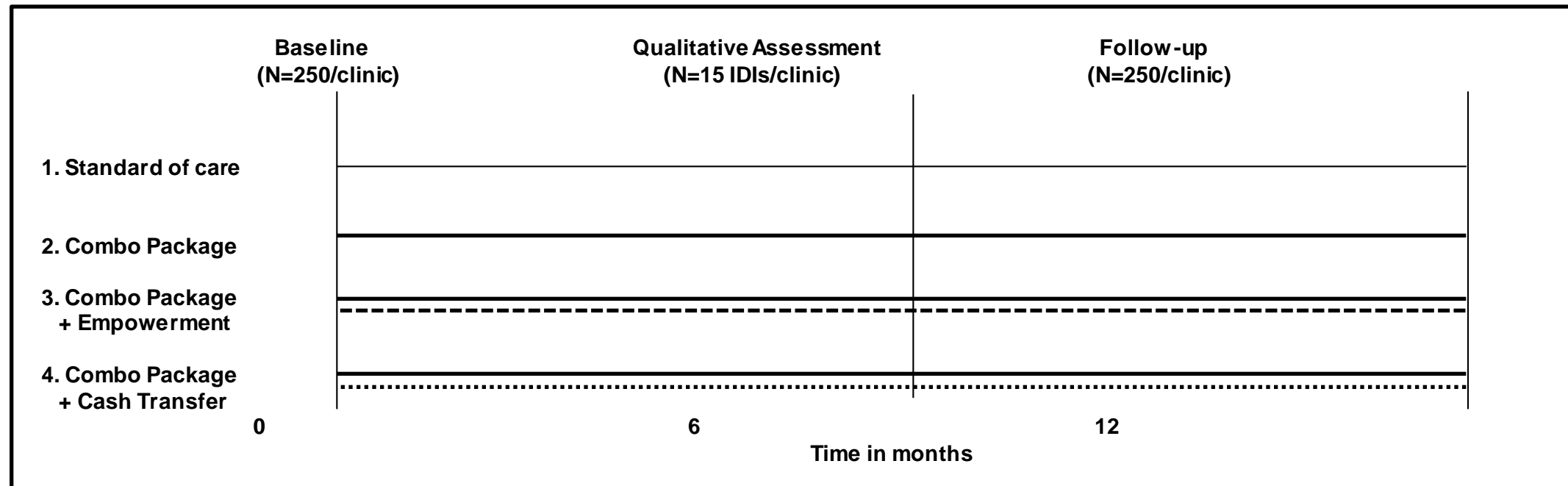
Presenter: Nora E. Rosenberg, PhD (PI)

Justification

	Malawi	South Africa
HIV prevalence among females 15-19	4.2%	5.6%
HIV prevalence among females 20-24	6.4%	17.4%
Marriage by age 18	49.6%	5.6%
Birth rate among girls 15-19 years (International Rank)	157.2/1000 (174/187)	59.2/1000 (118/187)
Proportion living on <\$1.25/day	61.6%	13.8%

- There is an unmet need for a “combo package” of integrated sexual and reproductive health services for adolescent girls and young women delivered by non-judgmental providers at convenient times and locations.
- It is not known whether empowerment sessions or economic incentives could enhance uptake and adherence of a combo package and reduce other sources of risk.

Research Design and Methodology



- Quasi-experimental design
- Enrol 250 young women in each clinic and follow for one year
- Sample Size: $N=250/\text{clinic} \times 4 \text{ clinics} \times 2 \text{ countries}=2000$ participants

Research Outcomes

- Describe **uptake** of the combo package and compare uptake between clinics.
- Describe **adherence** to each element of the combo package, and compare adherence between clinics.
- Describe **risk behaviours**, including age-disparate sex and intimate partner violence, and compare between clinics.
- Describe **barriers and facilitators** of uptake and adherence to the package and understand how the different packages operate to reduce risk.

Policy Implications

- South Africa and Malawi represent distinct, yet prototypical SSA settings. Findings will have broad generalizability across the region.
- Our ultimate goal is to have an evidence-based combination HIV prevention/SRH package that can be adapted and scaled up to a wide range of settings in the sub-Saharan African region.

Uptake and acceptability of a combination HIV prevention package among young people in Zambia and South Africa (Adolescents in HPTN 071/PopART Study)

Desmond Tutu TB centre, Stellenbosch University, Western Cape, South Africa;
London School of Hygiene and Tropical Medicine, London
Imperial College, London

Countries of Implementation: Zambia and South Africa

Mwate Joseph Chaila: MBChB, BSc.HB, Dip.Pal.Care

Adolescents in PopART Study Manager

On behalf of the HPTN 071/PopART Study Team



Justification

- Growing numbers of ALWH in SSA
- 430,000 new infections yearly occur among 15-24 year olds (UNAIDS, 2012)
- HIV prevalence among youth 15-24 in Zambia is 7% (ZDHS 2013-14)
- Uptake of HIV community-level combination prevention packages in young people in two of the most highly HIV-affected countries unknown
- Information on uptake of HIV testing and linkage to HIV care in young people limited

Research Questions

- Does being part of a community level combination HIV prevention strategy enhance HIV prevention, uptake of HIV testing and access to care amongst adolescents aged 15-20 years?
- Are additional specific youth targeted interventions necessary in the context of a community-wide combination HIV prevention strategy and, if so, what additional benefits and costs do they have?
- Will the PopART intervention be acceptable among adolescents and what will be the cost implication and the burden they will add on the existing health infrastructure?

Design of background trial HPTN071/PopART

3 arm cluster-randomised trial with 21 communities
(N ≈ 1.2million total population)

Arm A

Full PopART
intervention

including

immediate ART
irrespective of CD4
count

Arm B

PopART intervention

except

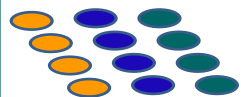
ART initiation
according to current
national guidelines*

Arm C

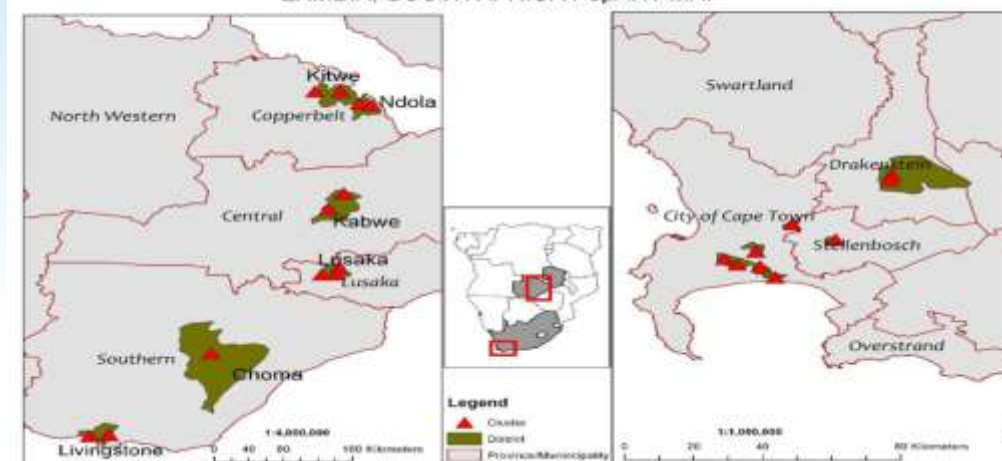
Standard of care at
current service
provision levels

including

ART initiation
according to current
national guidelines*



ZAMBIA, SOUTH AFRICA PopART MAP



Primary Objective

- To measure the impact of community-level HIV combination prevention packages (PopART intervention) in reducing HIV incidence
- Measured in a cohort of 52,500 adults over 3 years
- Average of population ~50,000 in each cluster (~ 50% adults and 18% adolescents)

Adolescent Study Design & Methodology

- Nested within the HPTN 071/PopART in 21 Communities in both Zambia and SA
- Study is a community randomised comparison of a combination prevention approach, combined with youth targeted interventions where necessary, in adolescents aged 15-20 years.
- Implemented in 3 phases
 1. *qualitative baseline studies and collection of process data from the second annual round of the ongoing the ongoing trial interventions*
 2. *addition of youth-targeted interventions where necessary*
 3. *cross-sectional survey in control arm communities plus ongoing collection and analysis of process and process and qualitative data after implementation of youth targeted intervention.*
- Sample size estimated at 5200 (15 – 20 yrs olds) and 3700 (10 -14 year olds) in each cluster

Research Outcomes

The primary outcome is the uptake of voluntary HIV counselling and testing, within the previous 12 months, amongst adolescents aged 15-20 years old.

Secondary outcomes-Quantitative:

- Acceptance of HIV testing and retesting
- Time between HIV diagnosis and initiation of care
- Linkage to care
- ART adherence and retention in care
- Unintended Pregnancy, Uptake of PMTCT
- Uptake of VMMC
- Uptake of condoms

Secondary outcomes-Qualitative

- Acceptability of PopART interventions and barriers to access in adolescents
- Acceptability of specific youth targeted interventions and barriers to access both in intervention and control communities
- Effect of the interventions on social networks, stigma, sexual behaviour, alcohol use, gender-based violence, HIV identity, other HIV prevention options and community morale
- Experiences of ALWH and affected by HIV over the course of the intervention period
- Particular needs and vulnerabilities of adolescent girls, especially ALWH

Policy Implications

- Individuals/organisations likely to influence policy from national line ministries and other stakeholders are involved
 - Study outcomes will influence local treatment guidelines
 - National community-level combination prevention packages will be implemented if proven cost effective
 - Recommendations to be made to the Adolescent Health Strategic Plan (ADH-SP) drafting committee in Zambia after the expiry of the current plan 2011-2015

Thank You!



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SCHOOL of
HYGIENE
& TROPICAL
MEDICINE



Research timeframe: 30 months

EMPOWER

Improved Combination Prevention (including PrEP) in Adolescent Women in Tanzania and South Africa

RHI, University of the Witwatersrand (SA)

Mwanza Intervention Trials Unit (Tz)

LSHTM (UK)

ICRW (USA)

Countries of Implementation:
South Africa and Tanzania

Deborah Baron, RHI
on behalf of
Sinead Delany-Moretlwe, RHI

Justification

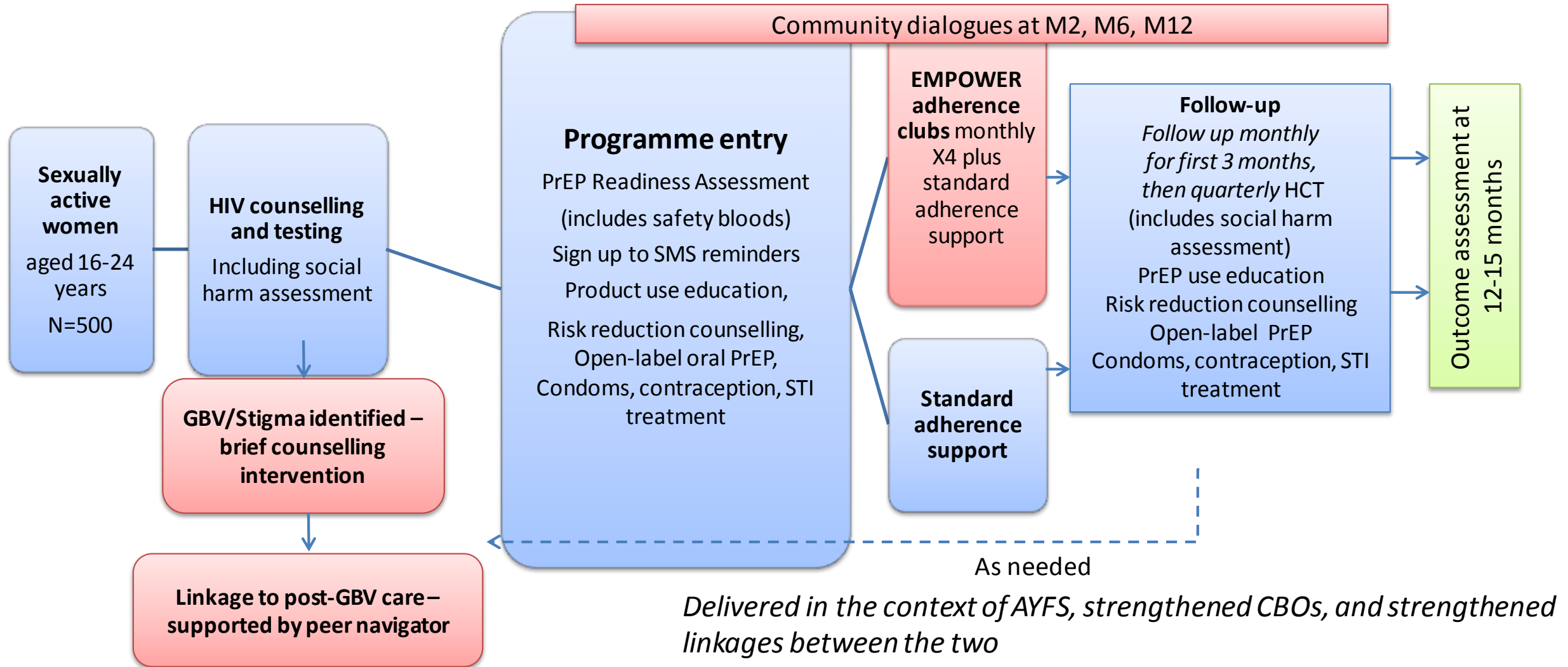
- PrEP, a potentially safe and effective HIV prevention method for women, is of particular importance in settings of high HIV transmission in eastern and southern Africa.
- Gender inequality, fear and experience of gender-based violence (GBV) and stigma are significantly associated with an increased risk of HIV acquisition in women in these regions .
- GBV and stigma may influence uptake and sustained use of biomedical HIV prevention.
- Limited evidence exists on how best to combine and coordinate HIV, GBV and stigma prevention interventions for Adolescent Girls and Young Women (AGYW) successfully within health systems

Research Questions

- What is the feasibility, acceptability and additional benefits of integrating GBV and stigma reduction interventions into HIV combination prevention services that include oral PrEP, for AGYW?

Research Design and Methods

Data collection – questionnaires, objective markers of adherence; qualitative data collection; program data



Those who are positive on violence screening will be referred to services and continued in follow-up if they desire

Research Outcomes

- Main outcomes of interest overall, and by intervention arm are:
 - The proportion of AGYW who
 - Accept PrEP
 - Are adherent based on drug levels, and
 - Retained in care by 12 months;
 - *Are there additional benefits for women attending empowerment support clubs?*
- Secondary outcomes:
 - No observed increase in social harms
 - Specifically participant experience of violence from a partner or other person; and internalized and anticipated stigma.
 - Proportion of AGYW who experience positive effects on partner communication, conflict and HIV testing;
 - *Are there additional benefits for women attending empowerment support clubs?*
- Process evaluation to demonstrate the feasibility and acceptability delivering an integrated

Policy Implications

- Provide important data on whether PrEP is acceptable to young women, and how best to deliver PrEP as part of a comprehensive HIV prevention response for young women.
- Provide additional data on how best to strengthen health system responses to GBV and stigma as part of a scalable package of interventions.