Status-Neutral HIV Services for Sexual- and Gender-Minority Africans in SSA

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HPTN Regional Meeting

September 2023

Goals of Breakout Sessions

HPTN Regional Meeting

- Review gaps in the research agenda
- Review the work that has already been done by the HPTN and in the larger HIV prevention field
- Generate ideas for research proposals for leadership consideration and future concept and protocol development.

Format

- Our role as moderators: Review the current research landscape and facilitate a science generation discussion. Theresa's role: capture key ideas presented and start to populate schema as-we-go

- **Day 1 (Wed):** Brainstorm research ideas/questions; prioritize the top 1-3 most likely to fill an existing knowledge/service gap (most likely to attract enthusiasm from reviewers/funders); draft the purpose and intervention sections of the schema.

- **Day 2 (Thrs):** Fill-in the remainder of Schema for 1-2 prioritized ideas

Part of the HPTN Agenda is Discovery

New Prevention Tools and Methods

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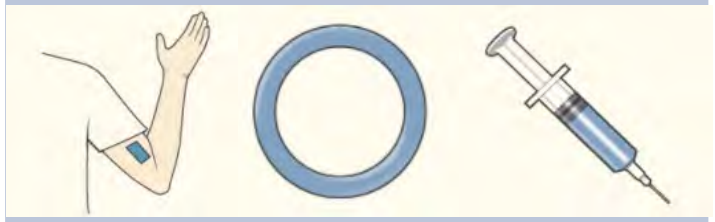
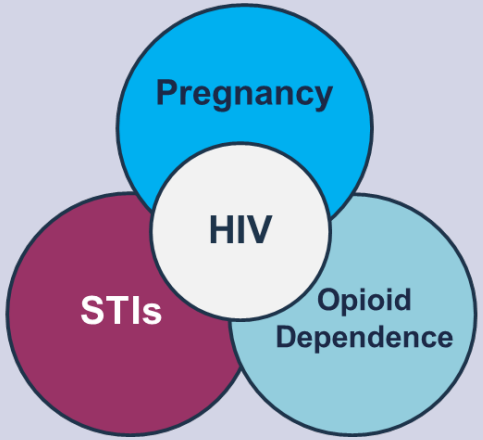
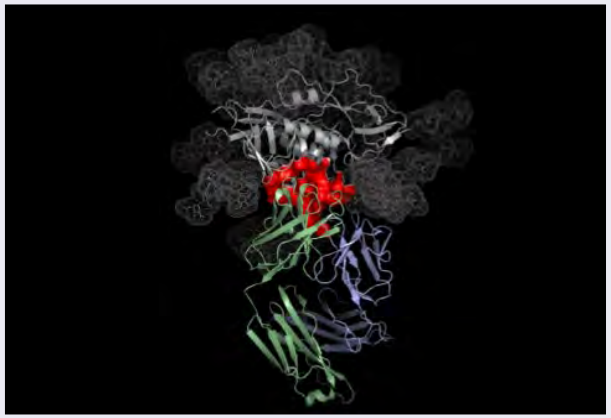


Novel ARV Methods and Delivery Systems



Multi-Purpose Prevention Technologies (MPTs)



Broadly Neutralizing Antibodies (bNabs)

Integrated Strategies Implement Discoveries for Population Impact

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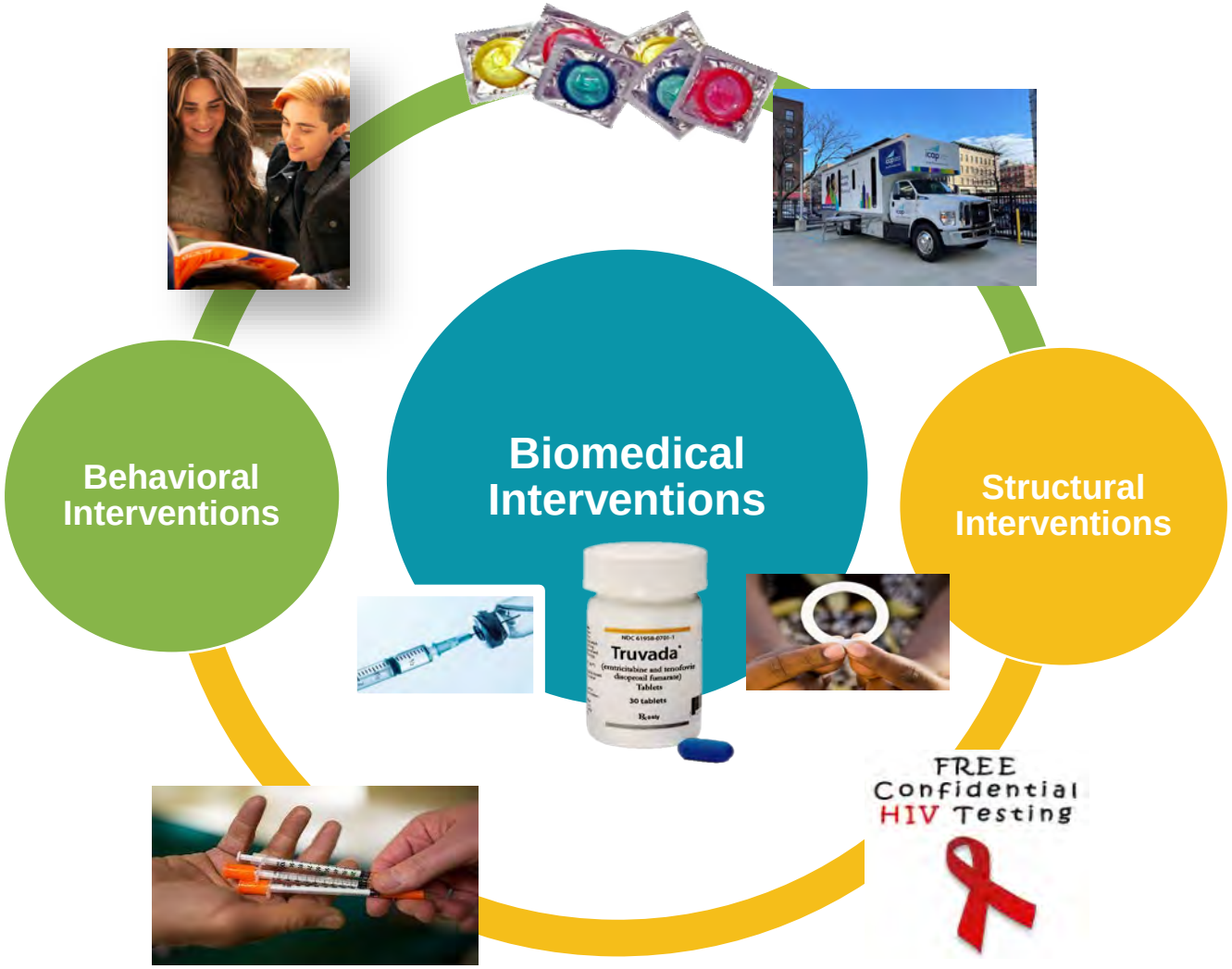
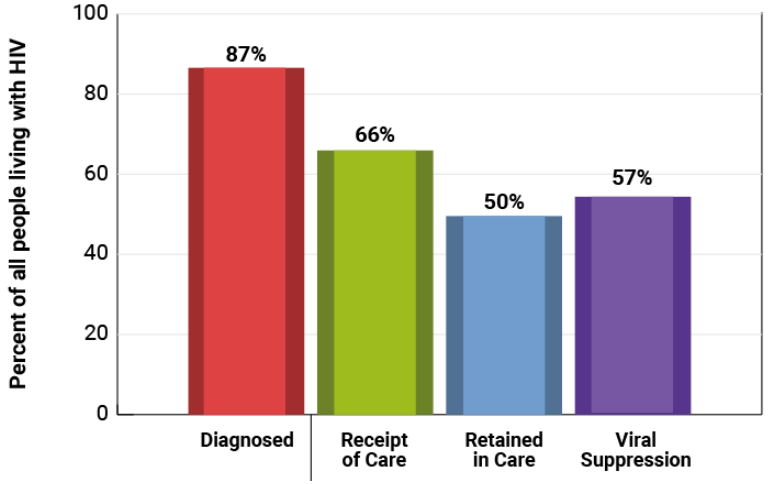


What is a “Status-Neutral” Approach?

First, let’s think about how we have long-envisioned HIV services…



HIV.gov

Usually when we say retention/adherence, referring to only PLWH.

Current thinking: step-by-step, disease-specific, **linear** approach.

What is a “Status-Neutral” Approach?

Status-neutral approach represents a paradigm shift:

Regardless of the clients’ HIV status, continuous, quality services and engagement are the foundation of a successful national HIV strategy.

- Both prevention and treatment, are part of the same **multidirectional cycle/continuum (non-linear)**

- Goals is to stay healthy, whether that means sustained VLS or sustained PrEP, re-testing, lapsing on ART or PrEP and needing to start the cycle again

- De-stigmatize testing, re-testing, PrEP, VMMC, treatment

- Introduced in New York City, USA (2018?)

What is a Status-Neutral Approach?

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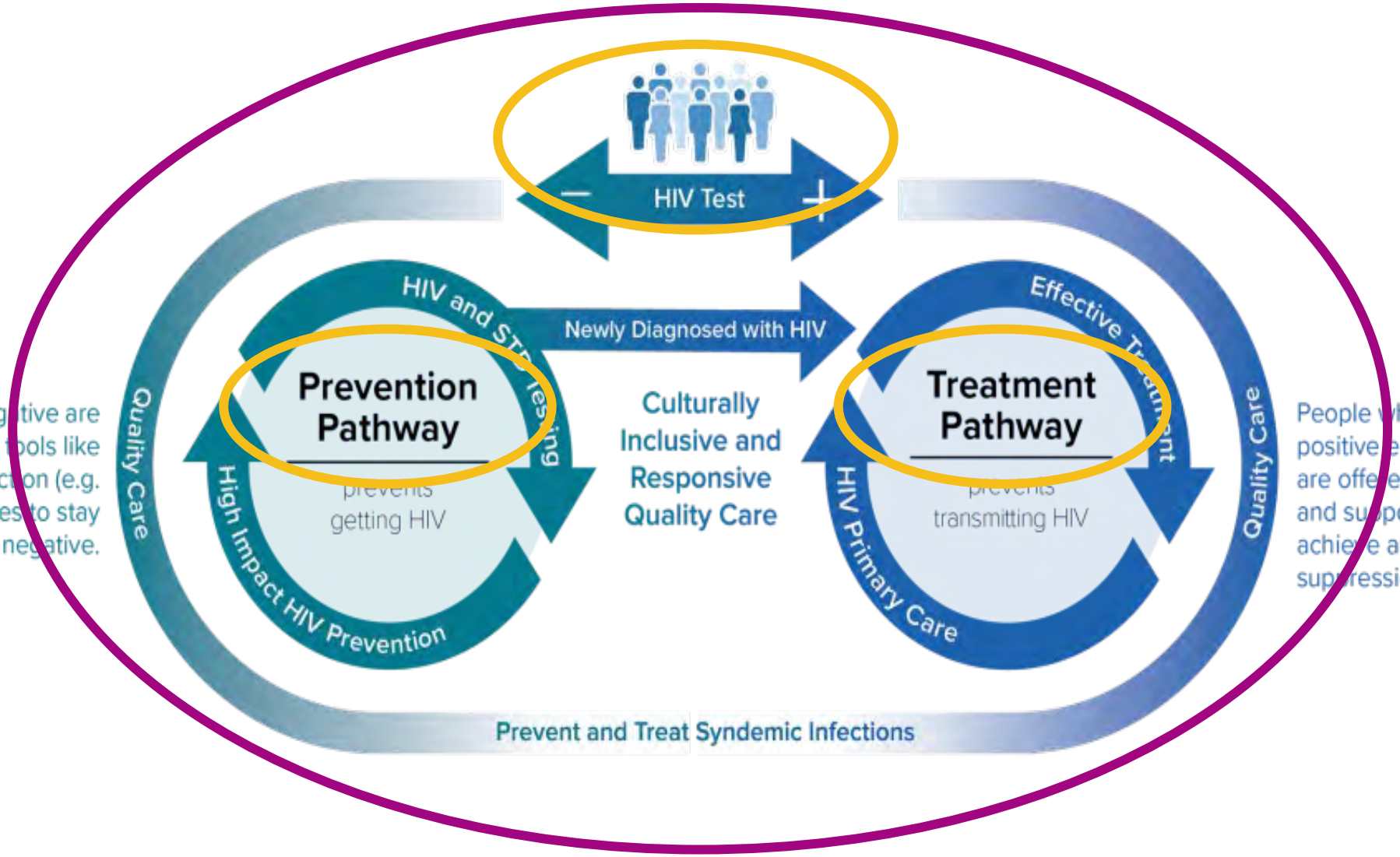
People whose HIV tests are negative are offered powerful prevention tools like PrEP, condoms, harm reduction (e.g. SSPs), and supportive services to stay HIV negative.



People whose HIV tests are positive enter primary care and are offered effective treatment and supportive services to achieve and maintain viral suppression.

Integrated Strategies: What has HPTN already done?

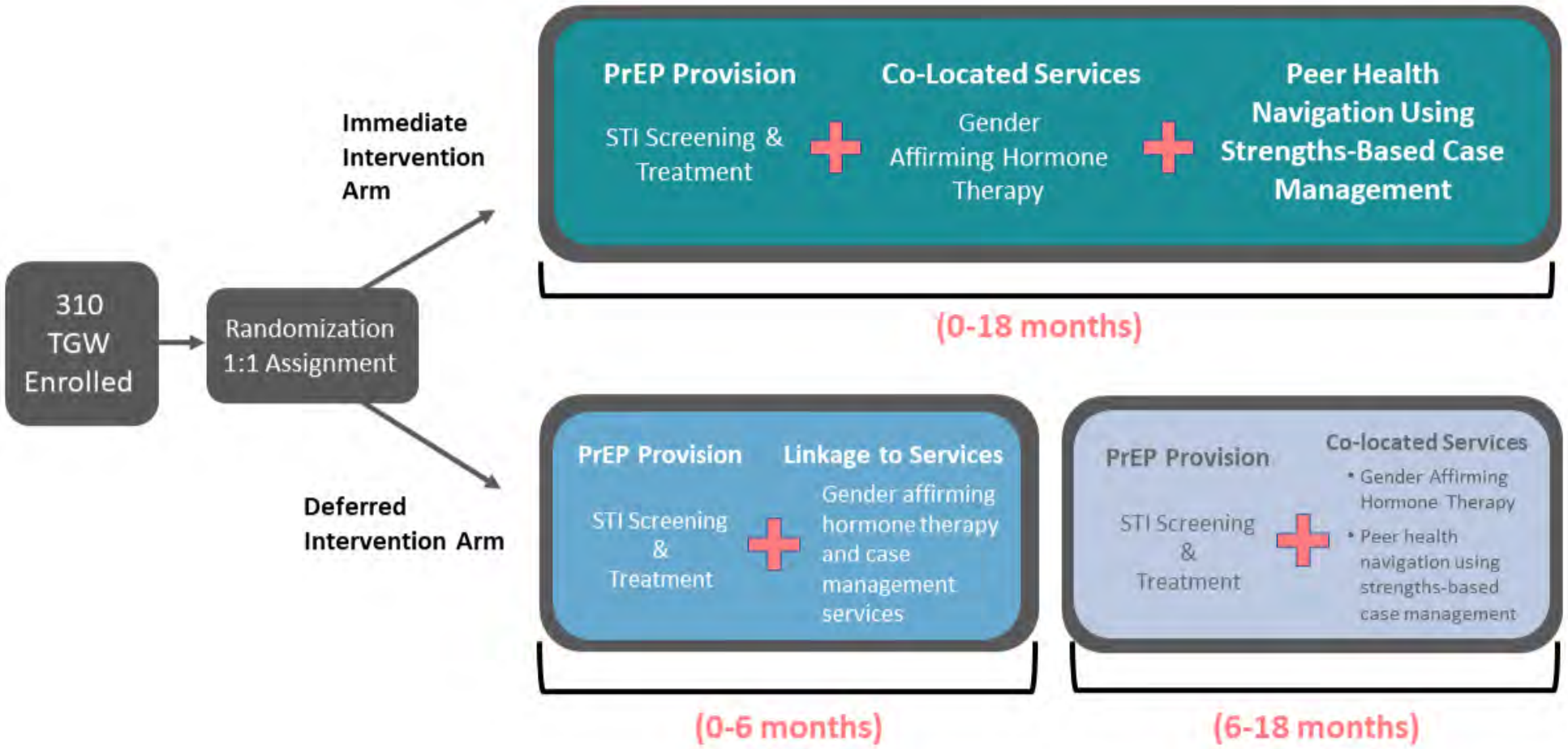
- Current Agenda: Three studies focused on US epidemic priority populations:
    - Men who has sex with men in US South (HPTN 096) – status neutral design
    - Transgender women (HPTN 091)
    - People who inject drugs (HPTN 094) – status neutral design

- HPTN 075 determined the feasibility of recruiting and retaining men who have sex with men (MSM) in SSA (Malawi, Kenya, and South Africa).

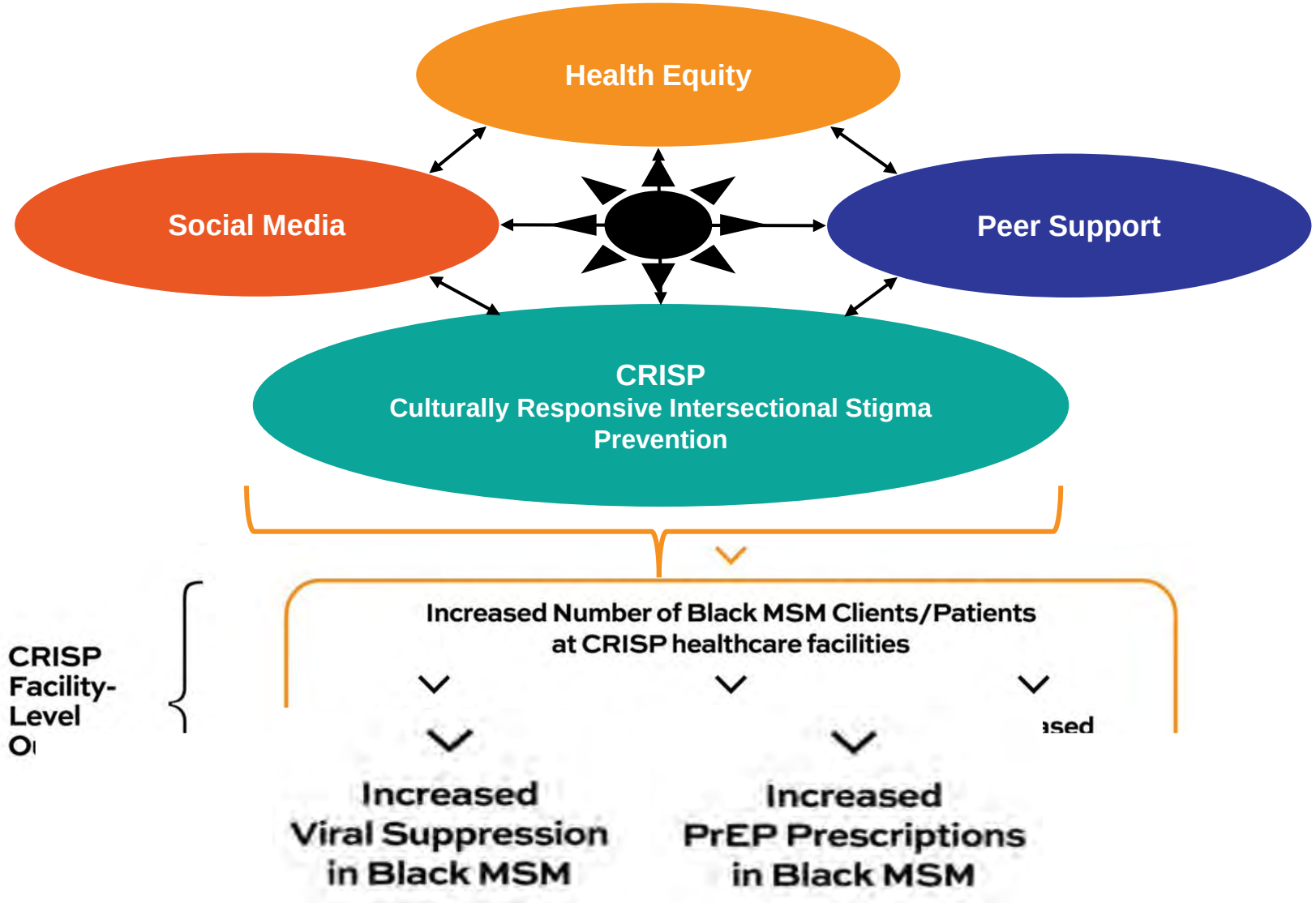
- HPTN 078 tried to identify and recruit HIV-infected MSM in the US who were not virally suppressed, through deep-chain respondent driven sampling (DC-RDS).

- HPTN 091 is assessing the feasibility, acceptability, preliminary impact of a multi-component strategy that provides HIV prevention services, gender-affirming hormone therapy, and Peer Health Navigation to improve pre-exposure prophylaxis (PrEP) uptake and adherence.

HPTN 091: Study Design



HPTN 096: Evaluating Integrated Strategies



Protocol Co-Chairs: Chris Beyrer, LaRon Nelson & Bob Remien

Examples of status-neutral research or services in SSA?

Feedback from the audience…

Some gaps in HIV prevention

- Addressing stigma, discrimination, and community/partner violence.
- Addressing internalized stigma and mental health.
- Adapt relevant components of the HPTN 096 model to the SSA context (e.g., building coalitions, provider training, etc.).
- Treatment/prevention literacy
- Integrated strategy studies with CAB-LA in international settings with high HIV incidence
    - Build on HPTN 084 and HPTN 084-01 for AGYW
    - **Build on lessons learned from HPTN 075 for African MSM and transgender women**
    - Build on HPTN 094 for PWID in countries with high HIV incidence (e.g. India)
    - Explore status neutral approach in these studies

Types of Studies

- Vanguard/pilot studies
- Definitive studies

Schema Template

TITLE	
Purpose	
Design	
Population	
Location/ Region	
Description of Regimen/ Intervention	
Study Duration (estimated time for accrual and follow-up)	
Primary Objective(s) (no more than two)	
Endpoints (should address and parallel the objectives)	

Guidelines for the Group

- Does a status neutral approach make sense in the African context?
- If yes, does it make sense to aim for one protocol that includes MSM, transgender and nonbinary people, or are separate protocols best different populations?
- What are the key components needed to be evaluated?
- Should this start with one or more vanguard studies

Acknowledgments

- Overall support for the HIV Prevention Trials Network (HPTN) is provided by the National Institute of Allergy and Infectious Diseases (NIAID), Office of the Director (OD), National Institutes of Health (NIH), National Institute on Drug Abuse (NIDA), the National Institute of Mental Health (NIMH), and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) under Award Numbers UM1AI068619-17 (HPTN Leadership and Operations Center), UM1AI068617-17 (HPTN Statistical and Data Management Center), and UM1AI068613-17 (HPTN Laboratory Center).

- The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Extra slides from HPTN guidance doc

Strategies for Prioritization

- Consider proposals that are inclusive of multiple sites.
- Consider large, multi-site studies or smaller pilots that lead to larger studies.
- Ensure alignment with HPTN specific aims:
  - Long-acting ARV agents and novel delivery systems for PrEP
  - Multipurpose prevention technologies (MPTs), concurrently prevent HIV and pregnancy, STIs or opioid dependence
  - Broadly neutralizing antibodies (bnAbs), alone/in combination, for PrEP
  - Integrated strategies for HIV prevention
- Consider ideas that…
  - Are consistent with the epidemiology of HIV and gaps in knowledge regarding HIV transmission.
  - Advance research that would have impact on the HIV epidemic.
  - Build on HPTN vanguard studies, completed or ongoing

Lower priority areas

- Surveys without a proposed intervention.
- Studies dependent upon the initiation of other experimental structural programs.
- Studies with interventions that are not sustainable in public health settings (e.g. cash transfers).
- Proposals primarily focused on addressing broad societal issues (e.g. partner violence, poverty) without a well-defined HIV prevention component.
- Broad ideas without well-defined hypotheses.
- Expanding existing interventions in different populations without clearly identifying/ addressing important differences in contexts or behaviors.
- Early first in human trials that are being done by other research groups.