Integrated strategies for Adolescents

Science Generation Breakout Session 2

27 September 2023

Linda-Gail Bekker (DTHF) & Lynda Stranix-Chibanda (UZ)



The task ahead



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

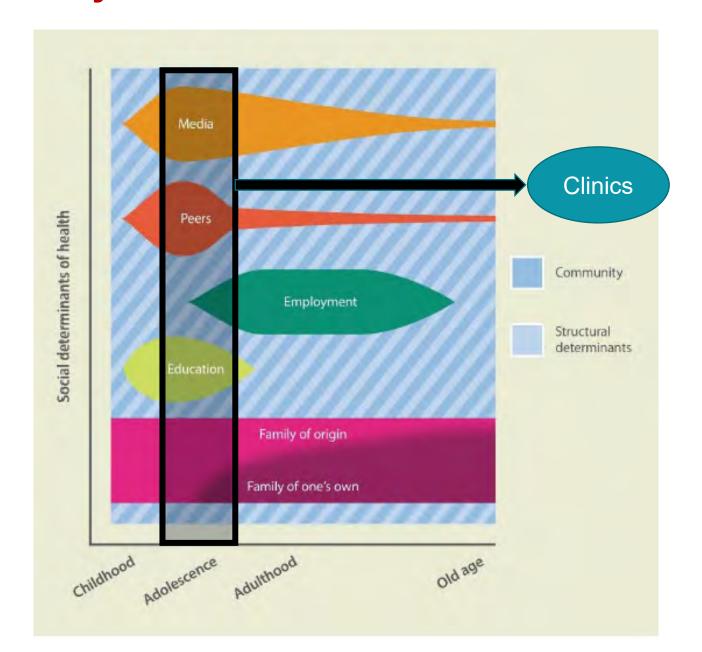
2 hours today + 1 hour tomorrow

what does integration mean?



- the *type* of integration (i.e. organisational, professional, cultural, technological);
- the level at which integration occurs (i.e. macro-, meso- and micro-);
- the process of integration (i.e. how integrated care delivery is organised and managed);
- the breadth of integration (i.e. to a whole population group or specific client group);
- the *degree* or *intensity* of integration (i.e. across a continuum that spans between informal linkages to more managed care co-ordination and fully integrated teams or organisations).

Points of entry for health interventions in adolescence



Barriers to services and care



Individual

Poor Education

Poor Knowledge

Poor risk perception

Social isolation

Stigma

Mental health

Financial Resources



Health care system

Designed for adults/Children

Discrimination

Poor knowledge

Judgmental attitudes

Lack of privacy

Lack of confidentiality

Lack of peer involvement

Overcrowding

Fragmentation

Transport

Clinic hours

Other structural barriers

Legal consent issues

Criminalization

Discriminatory laws or practices

Integrated care.....

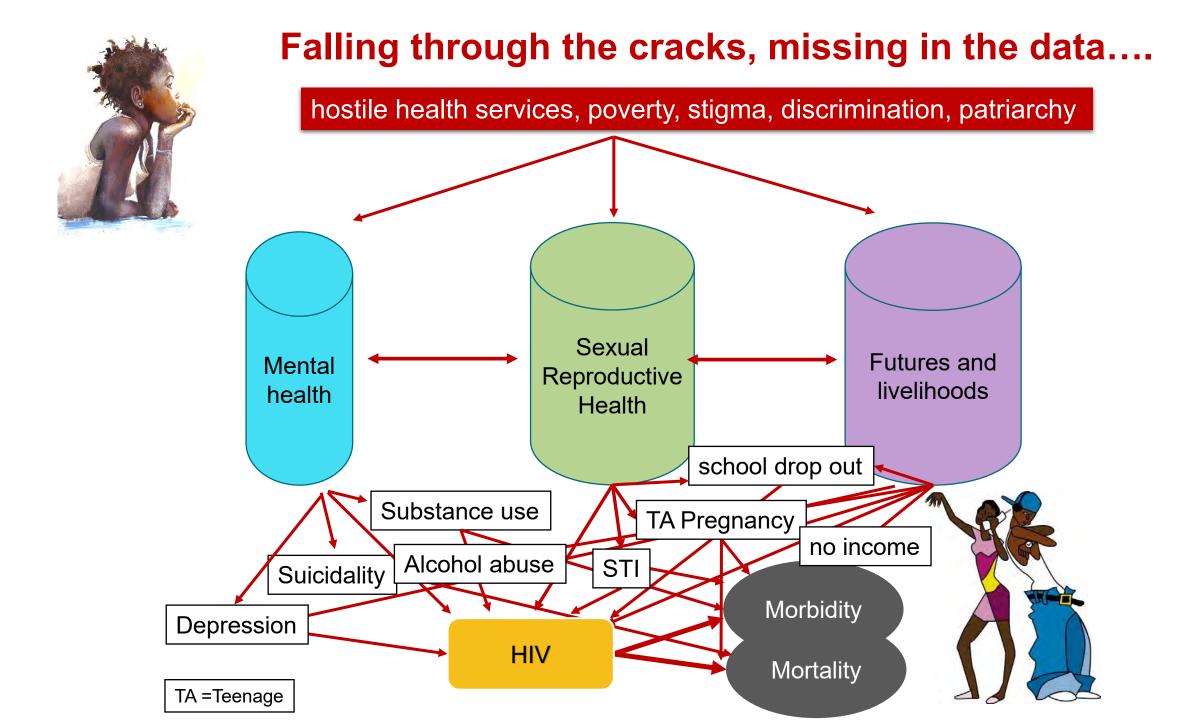


- Horizontal integration.
 - between health services, social services and other care providers that is usually based on the development of multi-disciplinary teams and/or care networks that support a specific client group (e.g. for older people with complex needs)
- Vertical integration.
 - across primary, community, hospital and tertiary care services manifest in protocol-driven (best practice) care
 pathways for people with specific diseases (such as COPD and diabetes) and/or care transitions between
 hospitals to intermediate and community-based care providers
- Sectoral integration.
 - within one sector, for example combining horizontal and vertical programmes of integrated care within mental health services through multi-professional teams and networks of primary, community and secondary care providers;
- People-centred integration:
 - between providers and patients and other service users to engage and empower people through health education, shared decision-making, supported self-management, and community engagement; and
- Whole-system integration:
 - that embraces public health to support both a population-based and person-centred approach to care. This is
 integrated care at its most ambitious since it focuses on the multiple needs of whole populations, not just to care
 groups or diseases.



Integration: ONE STOP!

There is huge potential for integrating SRH services with HIV services, mental health, and NCD screening.



Reaching AGYW through Differentiated Models of Care

A one size model does not fit all when it comes to HIV or other SRH services.

Differentiated care:

- Client-centred: takes different populations into account (e.g. HIV negative vs HIV positive, stable patients vs. unstable patients)
- Reflects the preferences and expectations of a specific population group
- Adapts SRH services for this group both treatment and prevention

For young women = Adolescent and Youth Friendly Services (AYFS) & Female Empowerment Programmes that tackle gender and power dynamics



Differentiated Prevention delivery:





Adolescent Health Interventions: Conclusions, Evidence Gaps, and Research Priorities

Delivery platforms utilised Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and Explana A. Salam, M.Sc.^a, Jai K. Das, M.D., M.B.A.^a, Zohra S. Lassi, Ph.D.^b, and D. College Control of the Control of the

JOURNAL OF
ADOLESCENT
HEALTH

www.jahonline.org

2016

COMMUNITYBASED	SCHOOL BASED	PRIMARY CARE FACIUTY/OUTREACH CUNICS	SOCIAL MEDIA	SOCIAL/FINAN CIAL PROTECTION
	The state of the s	SEXUAL HEALTH EDUCATION		
- 0	DATING VIOLENCE PREVENTION)N		
	MENTATION ESNANCY OBESITY			
PREVENTING FGM/C		PREVENTING FGM/C		
	TEENAGE PREGNANCY PREVENTION			
	PROMOTE HEALTHY NUTRITION/ PREVENT OBESITY VACCINATION PREVENTING EATING DISORDERS			
	SUICIDE PREVENTION PREVENTING SUBSTANCE ABUSE		PREVENTING SUBSTANCE ABUSE	
		TREATING DEPRESSION AND ANXIETY		

igure 1. Existing evidence of adolescent health—specific interventions according to the delivery platforms utilized, FGM/C = female genital mutilation/cutting; fMN = multiple micronutrient supplementation,

"Youth Friendly" care.....

- Non-judgmental
- Staff know-how
- Less fragmentation
- Staff continuity
- Flexi hours
- Affordable (free)
- Peer involvement
- Relaxed
- Psychosocial support
- Other services available





TAILORED, Client-Centred Treatment and Prevention Packages





Information and Education
Condoms
PEP(se), PrEP, ART
STI screening and treatment
Self Testing
Mental health support
Contraceptive choice
Antenatal care and Pverticalt
Empowerment and income
generation
Protection GBV



what about NCDs and adolescents?

NCDs now killing more South Africans than TB in major public health shift

Medical Brief, September 2022

DISEASES



Cardiovascular Disease



Chronic Respiratory Diseases



Cancer



Diabetes



Mental and Neurological Conditions

RISK FACTORS



Unhealthy Diet



Tobacco Use



Harmful Use of Alcohol



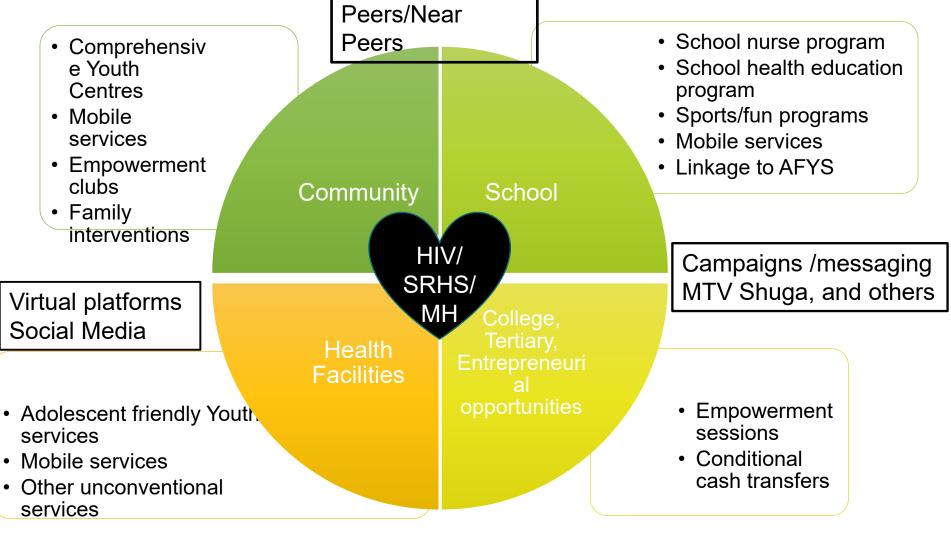
Physical Inactivity



Air Pollution

77% of all NCDs are in low and middle income countries – WHO report













OFFERING integrated care





Gaps in the prevention field



- Substance use and mental health among adolescents and youth.
 - Can SBIRT tools be effective for identification, brief intervention and referral? Can they be integrated with PrEP for adolescents?
- Uptake and adherence to HIV-self testing among at-risk adolescents.
- Stigma reduction behavioral intervention for PrEP among adolescents at high-risk of HIV (using drugs, engaged in sex work, MSM and transgender adolescents) in youth centers.
- DBT-like and/or life-skills building interventions.
- Structural interventions for adolescents (such as Cash Plus).
- Peer educators/supporters in schools.
- Others?

What has the HPTN already done?



• HPTN 068 - Effects of cash transfer for the prevention of HIV in young South African women

The task ahead



- 1. Review gaps in the research agenda,
- 2. Review the work that has already been done by the HPTN and in the larger HIV prevention field, and



3. Generate research proposals for leadership consideration and potential future protocol development.

2 hours today + 1 hour tomorrow



SCHEMA (1 OR 2)

- Title
- Purpose
- Design
- Population
- Region/Location
- Regimen/intervention
- Study duration
- Primary objectives (1 or 2)
- Endpoints



Strategies for prioritization



- Clearly define your primary objectives, endpoints and measurable data.
- Consider proposals that are inclusive of multiple sites.
- Ensure alignment with HPTN specific aims:
 - Long-acting antiretroviral (ARV) agents and novel delivery systems for pre-exposure prophylaxis (PrEP)
 - Multipurpose prevention technologies (MPTs) that concurrently prevent HIV and pregnancy, sexually transmitted infections (STIs) or opioid dependence
 - Broadly neutralizing antibodies (bnAbs), alone and in combination, for PrEP
 - Integrated strategies for HIV prevention
- Consider ideas consistent with the epidemiology of HIV and gaps in knowledge regarding HIV transmission.
- Consider ideas that advance research that would have impact on the HIV epidemic.
- Consider ideas that build on vanguard studies already conducted or ongoing by the HPTN.
- Consider large, multi-site studies or smaller pilot studies that lead to larger studies

Way of doing this.....



- Collaborative brainstorm
 - Everyone raises at least one possible idea- rapid brainstorm
 - See what ideas and rank in order of most feasible/preferred
 - Flesh out details in smaller groups
 - bring it all back asap



Thank you













Adolescents at Risk SC – Audrey Pettifor, Linda-Gail Bekker (Sinead Delany-Moretlwe)



- CHOICE: interventions and tools to help AGYW and providers choose the best method for them with the goal of improving PrEP persistence
- MEASUREMENT: how to better measurePrEP covered events for AGYW. Sex can be sporadic- how to measure use aligned with sexual activity better.
- IMPLEMENTATION: how to getPrEP out of clinics for healthy, uncomplicated cases- delivery out of clinic could improve persistence
- PLUS: combination prevention is not just putting PrEP in family planning clinics or STI clinics. Requires combining PrEp with interventions that address structural and behavioral barriers to HIV prevention (e.g. interventions focusing on GBV, poverty, adherence, etc.)

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.











Research Agenda



LA ARV agents and delivery systems

Long-acting systemic ARV agents will facilitate adherence with PrEP, a major limitation to PrEP effectiveness.

MPTs (pregnancy, STIs, dependence)

HIV prevention products are likely to achieve greater and more durable coverage with more significant health impact if they have a broader prevention profile for specific populations

AIMS 1-3
TEST <u>NEW</u>
PrEP
OPTIONS

bNAbs alone and in combination

A combination of bnAbs, if proven to be safe, effective and scalable, would be an additional option to ARV-based PrEP

THESE OPTIONS FEED INTO AIM 4 TO TEST DELIVERY APPROACHES (HOW, WHO, WHERE, WHEN, WITH WHAT ELSE)

Integrated Strategies

Effective HIV prevention requires an integrated package of interventions tailored to the needs of populations at risk

Specific Aims of the HPTN



1. To design and conduct studies of longacting antiretroviral (ARV) agents and delivery systems for pre-exposure prophylaxis (PrEP)

Rationale: Long-acting systemic ARV agents will facilitate adherence with PrEP, a major limitation to PrEP effectiveness.

- **1a.** To design and conduct Phase 1 and 2 studies to evaluate the safety, acceptability and pharmacokinetic/pharmacodynamic (PK/PD) characteristics of long-acting ARV agents and novel delivery methods.
- **1b.** To design and conduct Phase 3 studies to evaluate the safety and efficacy of novel long-acting ARV agents for HIV prevention. These may be delivered orally, by injection or infusion, or via devices such as implants or microneedle patches.
- **1c.** To design and conduct bridging studies to evaluate the safety and acceptability of long-acting ARV agents among specific populations such as adolescents and pregnant women.

2. To design and conduct studies to evaluate multipurpose prevention technologies (MPTs) that concurrently prevent HIV and pregnancy, sexually transmitted infections (STIs) or opioid dependence.

Rationale: HIV prevention products are likely to achieve greater and more durable coverage with more significant health impact if they have a broader prevention profile for specific populations.

- **2a.** To design and conduct Phase 1 and 2 studies to evaluate the PK/PD, drug interactions and safety of MPT candidates (e.g., injectable, implants, patches, rings) for HIV and contraception, STIs or opioid dependence.
- **2b.** To design and conduct Phase 3 studies to evaluate the safety and efficacy of an MPT for prevention of HIV and pregnancy which may be delivered by an injection, implant, microneedle patch or intravaginal ring.
- **2c.** To design and conduct studies to determine the acceptability and adherence with a co-formulated TDF/FTC-contraceptive oral agent; as an attractive option for women seeking contraception and HIV prevention. A Phase 3 study may not be required as efficacy of each component is known.

Specific Aims of the HPTN



3. To design and conduct studies in collaboration with the HIV Vaccine Trials Network to evaluate broadly neutralizing antibodies (bnAbs), alone and in combination, for PrEP

Rationale: A combination of bnAbs, if proven to be safe, effective and scalable, would be an additional option to ARV-based PrEP.

- **3a.** To design and conduct Phase 1 and Phase 2 studies to evaluate PK/PD, safety and the *ex vivo* viral neutralization activity of bnAbs with different specificities and binding sites.
- **3b.** To design and conduct Phase 3 studies of a multi-target bnAb or combinations of bnAbs to evaluate their efficacy and safety for PrEP.

4. To design and conduct integrated strategies for HIV prevention

Rationale: Effective HIV prevention requires an integrated package of interventions tailored to the needs of populations at risk

- **4a.** To design and conduct integrated strategies studies consisting of biomedical, socio-behavioral and structural interventions appropriate for priority populations at risk for HIV.
- **4b.** To use diverse designs for integrated strategies studies including cluster randomization, factorial, and step-wedge to evaluate the effectiveness of package and individual components for HIV prevention.
- **4c.** To identify geographic "hotspots" and clusters of HIV transmission using HIV recency testing, HIV molecular phylogeny and phylogeography, enabling focused HIV prevention interventions.
- **4d.** To include robust process measures to determine reasons for success or failure of integrated HIV prevention strategies.
- **4e.** To utilize mathematical modeling of data from integrated strategy studies to estimate impact at a population level