MaxART Immediate Access to ART for All Implementation Study

TasP in Africa Workshop, Gaborone

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Swaziland Context

- Population of Swaziland - ~1.1 million people
- Highest HIV prevalence and highest TB incidence in the world
- 31% prevalence among 18-49 year olds
- 2.38% incidence among 18-49 year olds
- 80% TB patients also HIV infected
- Strong National ART programme – national ART coverage > 80% of those eligible, 87% retention
- Very good PMTCT programme - >85% prophylaxis coverage
- Strong Government commitment – 100% ARV procurement for both PMTCT and ART
Adults and Paeds HIV Population, in need and receiving ART

- **Patients in Need of Treatment (Est.)**
- **Patients on Treatment**
- **Projected Patients on Treatment**
- **HIV+ Population (Est.)**
- **Extended Linear Growth (2011-2016)**
National TasP Framework

- Developed in 2012 by the Ministry of Health (MOH)

- To guide the MOH, partners, and individuals on development and implementation of interventions and operational research around TasP in Swaziland

- Articulates Swaziland’s readiness to implement TasP – for better health and reduction of new infections
Principles of TasP Framework

- Ensuring that people in need of ART according to current guidelines are provided with treatment and remain in care – plugging the “leaky cascade” - holistic approach

- Development of TasP study protocols that address the needs of the MOH – to make sound policy decisions on TasP

- Ensuring a rights based approach to implementation of TasP pilots – partnering with SWANNEPHA
Outline of TasP Pilots in Swaziland

MaxART—Immediate Access to ART for All (75,000 catchment population)

ICAP (Safe Generations) – Option B+

MSF – Option B+ and Immediate Access to ART for All
Overview *MaxART* Project

**Key 1**
Strengthening services and reaching all in need of testing and treatment based on current guidelines.

Strengthening the continuum of care and focusing on both communities and health facilities.

**Key 2**
Understanding the experiences of PLHIV, the needs on the ground, and ensuring dignity and human rights are maintained.

Research, modeling, and human rights monitoring.

**Key 3**
Assess the *feasibility, acceptability, scalability and affordability* of implementing Immediate Access to ART for All within the current health system, led by the MOH.
Overview of Key 1 and Key 2

- Male-focused health days
- Adolescent support initiative
- Engagement of traditional leaders

- POC CD4 testing
- Strengthening Treatment support
- Improved linkages, including referral system

- Strengthen provider-initiated testing and counseling
- Fast Track – community-solutions to mobilizing men and adolescents for testing

- SMS appointment reminder system
- Treatment support

- Nurse-led ART initiation
- Improved laboratory services (sample transportation)
# National Targets and Outcome

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<tr>
<th>Outcome</th>
<th>Target by 2014</th>
<th>Outcome December 13 (or most recent available data)</th>
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<tr>
<td>Number of people tested each year (adults and children)</td>
<td>250,000</td>
<td>294,000 tests (June 12-June 13) 227,000 estimated people tested</td>
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<tr>
<td>Number of people on treatment (adults and children)</td>
<td>101,734 (90% coverage based on 2013 need)</td>
<td>~ 100,000 (December 13)</td>
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<td>Proportion of patients on treatment lost to follow-up (adults and children)</td>
<td>10%</td>
<td>Estimated at 11% for 12-month follow up in 2011 initiation cohort.</td>
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Key 3 - Immediate Access to ART for All

Study Rationale and Significance

- Epidemiological rationale for offering treatment irrespective of CD4 is clear, but the behavioral and operational questions remain unanswered.

- Building on the promising clinical outcomes of recent trials, the proposed study is uniquely positioned to close the evidence gap by evaluating the realities of implementing IAAA through a government-managed health system in a high HIV prevalence and resource-limited setting.
Immediate Access to ART for All (IAAAA) Study Objectives

1. Determine the feasibility of implementing IAAA within Swaziland’s government-managed health system

2. Assess outcomes and estimated impact of IAAA within Swaziland

3. Assess the affordability and scalability of IAAA within Swaziland’s government-managed health system
IAAA - Study design

- Randomized stepped wedge, open enrollment, all HIV-positive adults ≥ 18 years of age across 15 sites in Hhohho Region.
- Illustrative design below; Sample size calculations in progress.
IAAA - Study Cohorts

Control Stage
(National Treatment Guidelines Eligibility)

Intervention Stage
(IAAA)

Group A: Eligible Individuals enrolled on ART (CD4<350)

Group B: Non-eligible Individuals – enrolled in PreART (CD4>350)

Group C: Individuals with CD4<350

Group D: Individuals with CD4>350
Primary Endpoints:
- Retention
- Viral suppression

Secondary Endpoints:
- ART uptake
- Adherence
- Drug resistance
- Tuberculosis
- HIV disease progression
- Cost per patient per year
IAAA - Social Science

- Ethnographic and mixed methods research in a sample of 6 sites, to answer 2 key research questions:

- **What are the differences in health service delivery before and after the implementation of a treatment for all intervention? How are these differences impacting ART initiation?**
  - Participant observation, before, during, and after transition to immediate access to ART for all
  - Semi-structured interviews with health providers after the transition

- **What are the differences in the social, economic, and structural factors between clients who have initiated on ART prior to and during the study? How do these differences impact adherence and retention?**
  - Quantitative survey of random sample of HIV-positive clients, before and after transition (sample size TBC with overall sample size)
  - Qualitative in-depth interviews among 30 diverse HIV-positive clients
IAAA - Cost Effectiveness and Modeling

Cost Effectiveness

- Conduct a cost-effectiveness and/or value for money analysis
- Estimate the per client lifetime cost to provide testing, treatment, and retain individuals
- Estimate the return (improved health outcomes and reduced infections) on investment of a TasP strategy in Swaziland

Mathematical Modeling

- Model the impact of an IAAA approach taken to a national scale on number of new adult infections
Sample size calculations in progress in line with the revised study design to a randomized stepped wedge

Finalization of partnerships with Mylan (donation of 1st and 2nd line drugs), MSF (VL testing), BC Centre for Excellence in HIV/AIDS (resistance testing) and Harvard School of Public Health (economic modeling)

Submission to Swaziland Ethics Committee expected in May 2014

Start of the IAAA study planned in June 2014
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More information on: www.stopaidsnow.nl/treatment-prevention

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The Swaziland Ministry of Health, STOP AIDS NOW!, and the Clinton Health Access Initiative (CHAI) initiated the MaxART project in Swaziland. The programme partners include the Swaziland Network of People Living with HIV and AIDS (SWANNEPHA) and the Global Network of People Living with HIV (GNP+), the National Emergency Response Council on HIV/AIDS (NERCHA), national and international non-governmental organisations including the Southern Africa HIV & AIDS Information Dissemination Service (SafaIDS), social scientists from the University of Amsterdam and researchers from the South African Centre for Epidemiological Modelling and Analysis (SACEMA).