Early Access to ART for All (EAAA) Implementation Study in Swaziland

Early experiences

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- Donna Spiegelman, Harvard T.H. Chan School of Public Health
Swaziland overview

- Projected Population (2015) ~1,119,375
- Stable HIV Prevalence (15-49 yrs) – 26%
- Declining HIV incidence 2.23 (2013) and 1.94 (2015) and 1.58 (2020)
- 90-90-90 Targets by 2030 possible in SD
  Even with CD4<500 eligibility
- Need to maintain current momentum:
  High ART uptake - 84% (CD4<350) – June 2015
  12 Months Retention rates - 91% (<15yrs) and 88% (>15yrs)

Source: HIV Annual Report 2014
**Objective**
- Understand the feasibility, affordability, acceptability, scalability and clinical outcomes of offering treatment to HIV-positive people regardless of CD4 and WHO clinical stage

**Design**
- Stepped wedge implementation conducted at 14 government health facilities over three year study period
- Open enrollment for all HIV+ adults ≥ 18 years of age, excluding pregnant and breastfeeding women already on Option B+

**Launched in September 2014, EAAA study designed to focus on critical unanswered implementation questions**

<table>
<thead>
<tr>
<th>Step 1:</th>
<th>Step 2:</th>
<th>Step 3:</th>
<th>Step 4:</th>
<th>Step 5:</th>
<th>Step 6:</th>
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<tr>
<td>2014</td>
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<td>2016</td>
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<td></td>
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<tr>
<td>Facility 1 + 2</td>
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**Primary Endpoints**
- Retention in care
- Viral suppression

**Secondary Endpoints**
- ART uptake
- Adherence
- Drug resistance
- Tuberculosis
- HIV disease progression
- Cost/patient per year
CD4 count at enrollment of 287 for newly diagnosed and 461 for pre-ART patients, consistent with national trends

EAAA Key Statistics
- Data from 1 Sept 2014 to 18 Sept 2015
- Total enrolment to date: 1,785
- 6 out of 14 study sites transitioned to intervention

CD4 Count at Enrolment
- Median CD4 (n=1456): 399 cells/mm³ (IQR: 243-569)
- Newly Diagnosed (n=571): 287 cells/mm³ (IQR: 159-446)
- Pre-ART (n=885): 461 cells/mm³ (IQR:332-617)
- Missing CD4 (n=329)

* Primary reasons for missing CD4 data include sample not processed, results not yet returned to facility, and data not entered in patient file. Some missing data will be retrieved
Acceptability: 70% of enrolled clients with CD4>350 attended to during the transition period initiated on the same day

- Clients report non-disclosure of HIV, use of traditional medicines, and inconvenience of timing as reasons to delayed ART initiation
- Social science research will further evaluate reasons for delayed initiation, non-adherence, and non-retention through in-depth qualitative interviews with clients
Social Science Objectives

- Describe how changes in health service delivery are impacting efforts to initiate ART before and after facilities transition to EAAA.
- Examine how early treatment initiation affects HIV testing and counselling services.
- Explore changes in social, economic and structural and determinants of delayed ART initiation, retention, adherence and disclosure before and after facilities have transitioned to EAAA.

→ Inform key behavioral parameters for the modelling team.
→ Triangulation of findings for key variables with the economic team.
**Social Science Research: Mixed Method Surveys**

- **Research objective:** Explore changes in and (social, economic and structural) determinants of delayed ART initiation, retention, adherence and disclosure, before and after facilities have transitioned to EAAA.
- **Mixed method approach:** Including questionnaires with open questions, observations of HIV services, and qualitative interviews

| Baseline | • ART clients initiated as per standard of care  
|          | • Target N=315 /380 across 9 facilities (as of 31st August 2015)  
|          | • 24% male and 76% female; 9.5% refusal rate |
| EAAA (1) | • EAAA clients initiated on ART during transition or intervention, CD4>350 and WHO clinical stage 1 or 2 or missing. Willing to be contacted at 6mo  
|          | • Target N=380 across 9 facilities |
| EAAA (2) | • Follow up of EAAA clients recruited in previous survey at 6 months |
Preliminary results show 85% self reported adherence and 81% of individuals are willing to disclose their HIV status to their partner.

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<th>Dose of ART missed last month</th>
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Economic evaluation: Patients’ out-of-pocket costs are considerable but not ‘catastrophic’: $3.18 USD/visit

- Despite provision of care being ‘free’ in Swaziland, clients bear a high out-of-pocket expense.
- EAAA is however unlikely to cause catastrophic health expenditure for Swazis, generally defined as >15% of monthly income, even for the poorest segment of Swazi society.
Economic evaluation: Preliminary modeling shows treatment for all is financially achievable in Swaziland

- Modeling projected a 30% increase in resources to move to national EAAA by 2020 – considerable but achievable, especially when considered with long-term health benefits.
Conclusion

- Implementation research studies are critical for getting the answers needed to achieve the ambitious 90-90-90 targets and successfully move towards a treatment for all approach.

- MaxART will offer answers for how to implement treatent for all in a government-managed health system and better understand the potential impact of this scientific breakthrough in a “real world” setting.

The MaxART Consortium would like to thank the clients, health workers, and community members who have actively participated in the implementation of the MaxART study.
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