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

## Early experiences

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Knowledge for action: The power to make a difference!



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# Swaziland overview

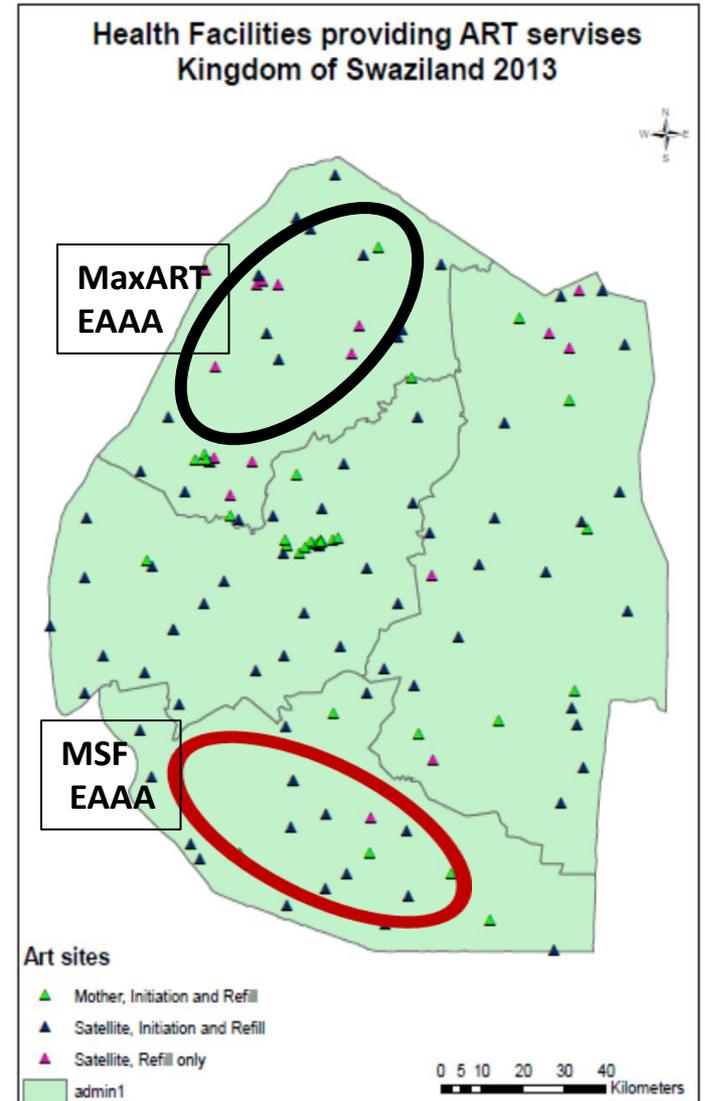
Projected Population (2015) ~1,119,375

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)



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

## 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  $\geq 18$  years of age, excluding pregnant and breastfeeding women already on Option B+

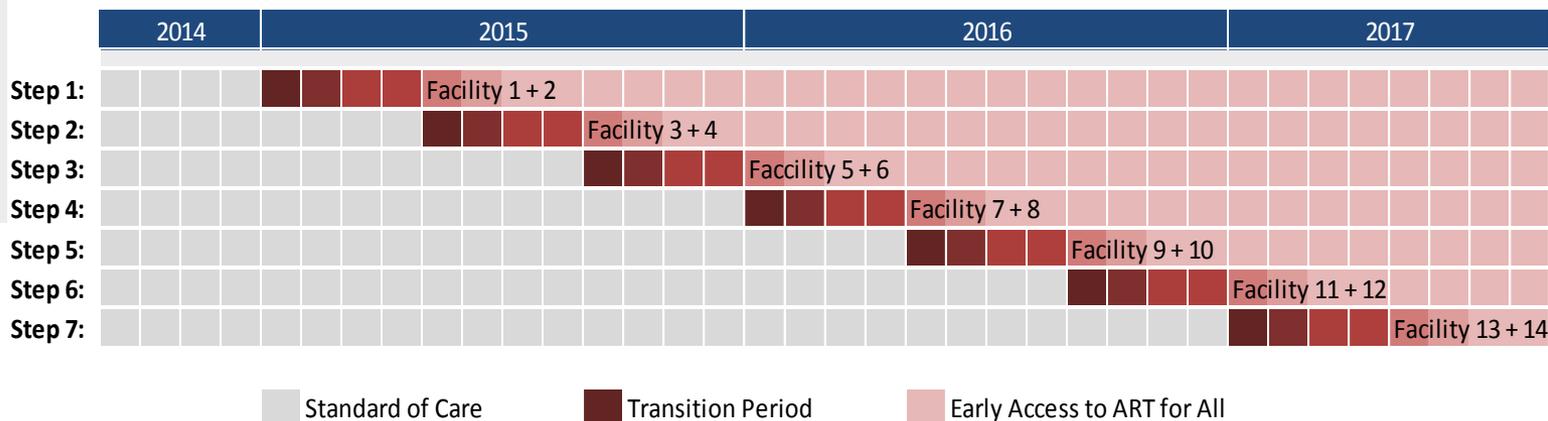
### Primary Endpoints

- Retention in care
- Viral suppression

### Secondary Endpoints

- ART uptake
- Adherence
- Drug resistance
- Tuberculosis
- HIV disease progression
- Cost/patient per year

Stepped Wedge Study Design



# CD4 count at enrollment of 287 for newly diagnosed and 461 for pre-ART patients, consistent with national trends

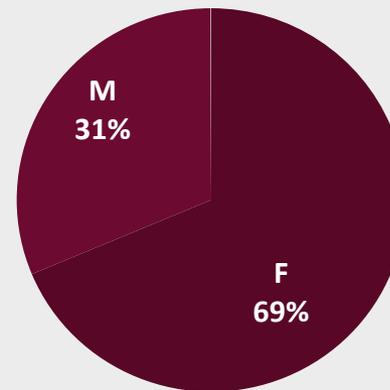
## EAAA Key Statistics

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

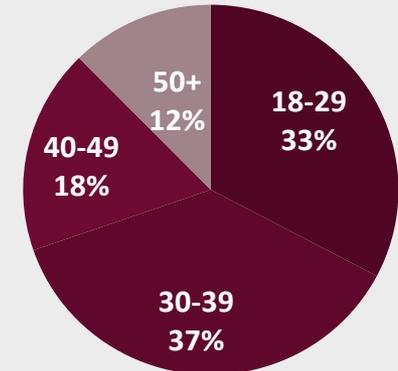
## CD4 Count at Enrolment

- Median CD4 (n=1456): 399 cells/mm<sup>3</sup> (IQR: 243-569)
- Newly Diagnosed (n=571): 287 cells/mm<sup>3</sup> (IQR: 159-446)
- Pre-ART (n=885): 461 cells/mm<sup>3</sup> (IQR:332-617)
- Missing CD4 (n=329)

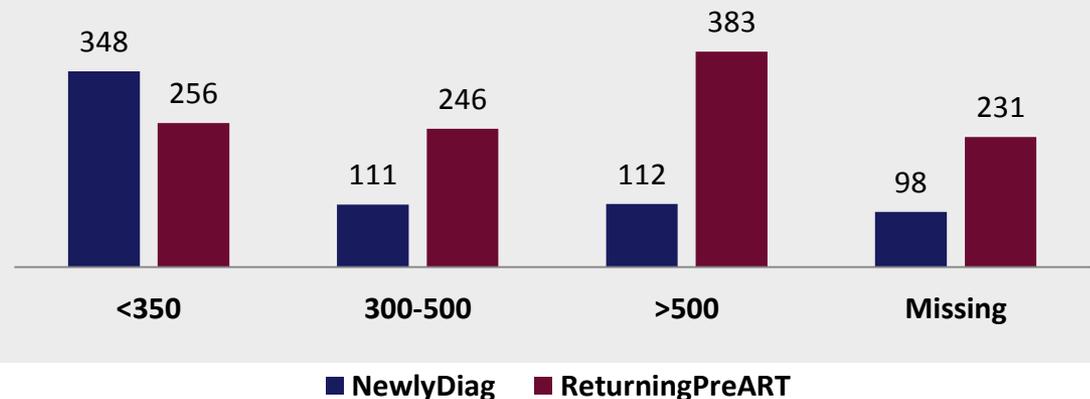
Gender



Age Category

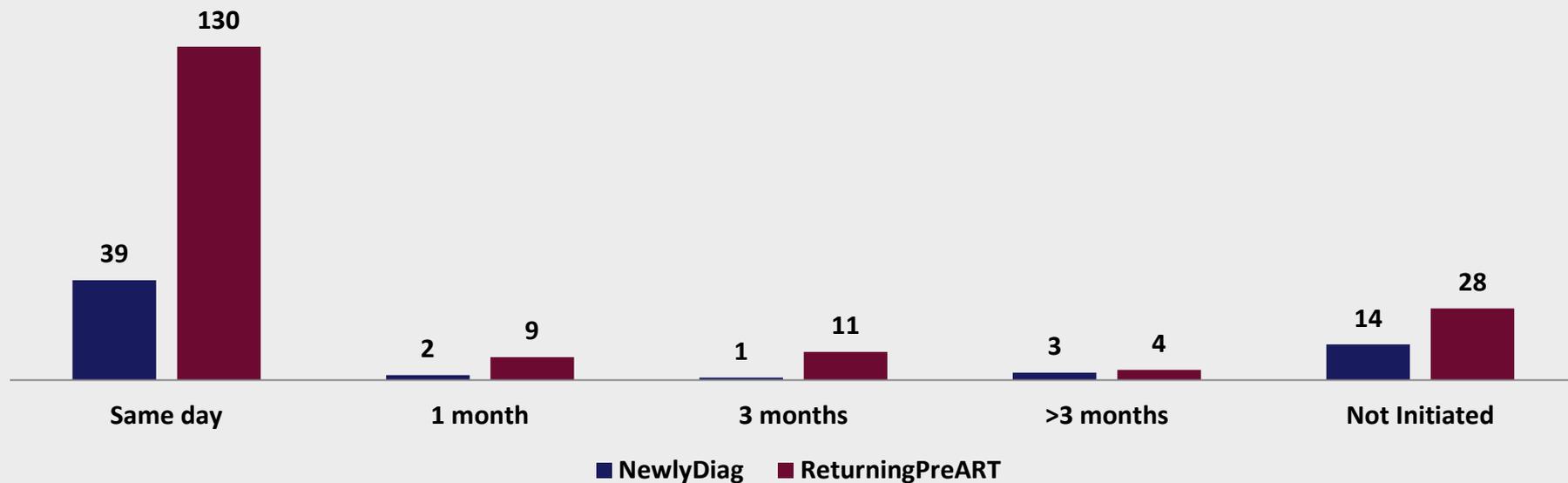


Client enrolment by CD4 Category



\* 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 31<sup>st</sup> 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

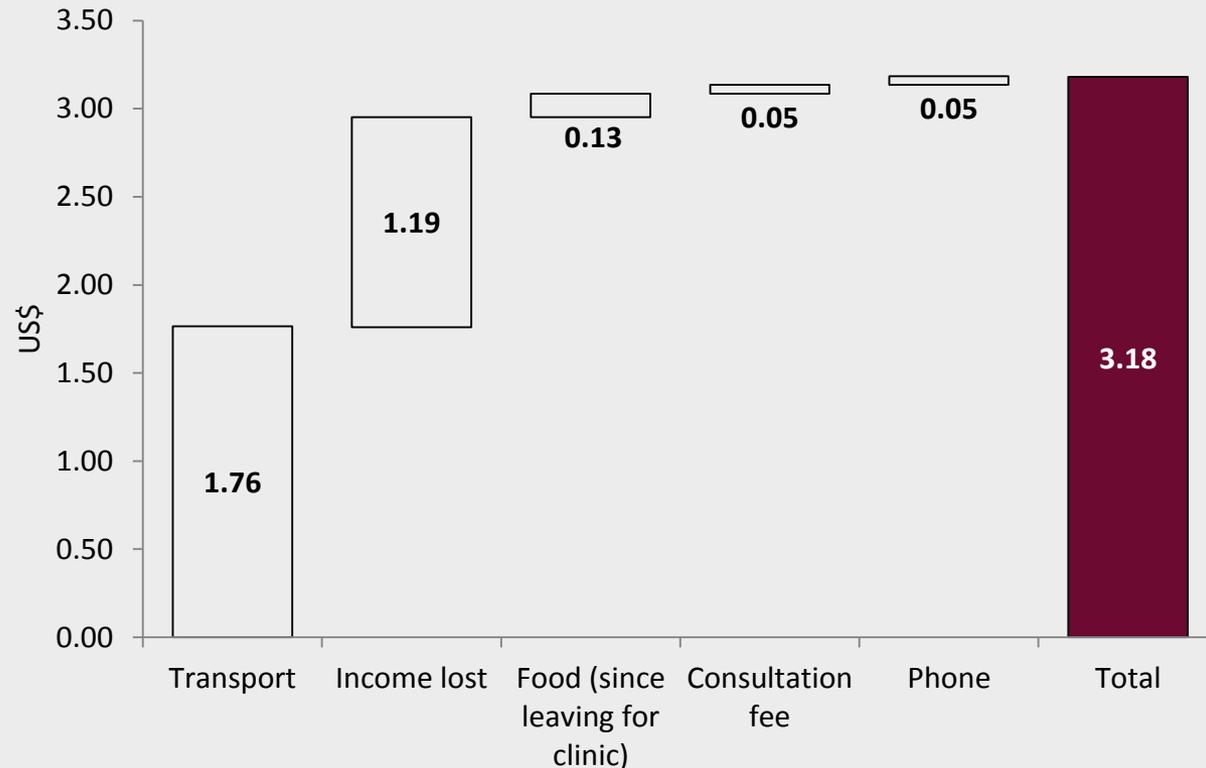
# Preliminary results show 85% self reported adherence and 81% of individuals are willing to disclose their HIV status to their partner

Dose of ART missed last month		N=314
No	266	85%
Yes	48	15%
Due to no food	11	23%
Disclosure of HIV status		N=314
No	5	2%
Yes	309	98%
Disclosure to partner	249	81%
Guilt about HIV status		N=314
No	217	69%
Yes	94	30%
Unsure	3	1%

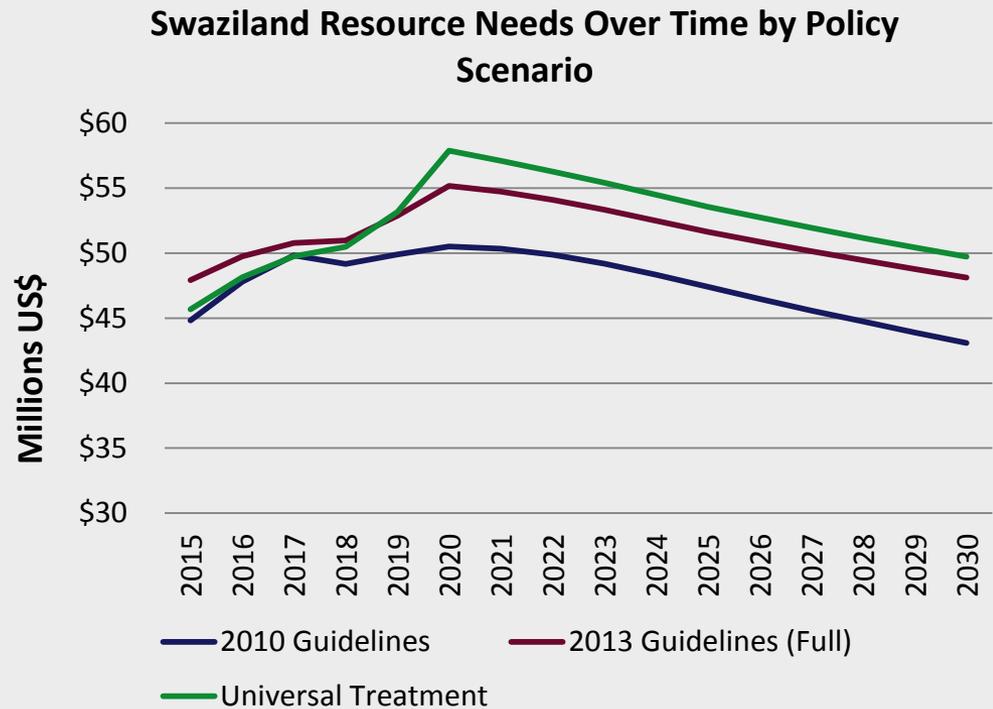
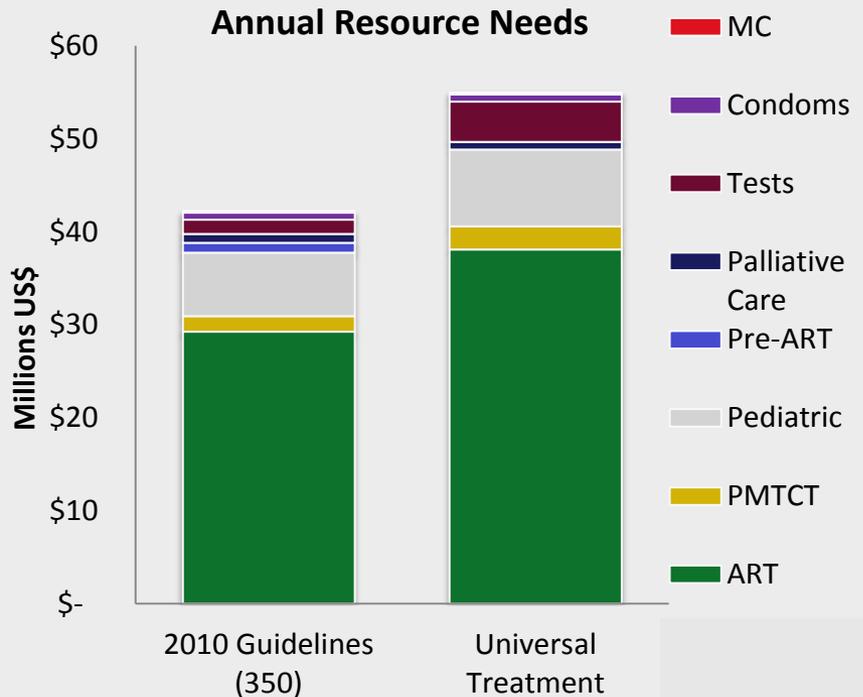
# Economic evaluation: Patients' out-of-pocket costs are considerable but not 'catastrophic': \$3.18 USD/visit

- 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.

Out-of-pocket expenditure for one ART visit  
(assuming 5 ART visits per year)



# 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 treatment 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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