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A Cluster-Randomized Controlled Trial of Antenatal Care and HIV Treatment Integration in Rural Kenya

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Study Background and Rationale

- In 2005, most antenatal care (ANC) services & HIV treatment services were offered in separate clinics
- We recognized missed opportunities and inefficiencies in referral-based systems
- **Hypothesis:** Integrating ANC and HIV treatment services for pregnant women in a single clinic may result in improved maternal outcomes and decreased mother-to-child transmission (MTCT).

SHAIP Study Design

Study Design	An operational study Prospective cluster randomized controlled trial
Intervention	Full integration of HIV care including highly active antiretroviral therapy (HAART) <u>into antenatal care clinics</u> (intervention), compared to referral for HIV care and treatment (control)
Major outcomes	• Vertical transmission of HIV • Uptake of infant HIV testing • Linkage and retention in care for mother-infant pairs • Maternal health outcomes (WHO stages, CD4 counts)
Study sites	12 facilities in 3 districts
Health facilities	District hospitals, sub-district hospitals, health centers, and dispensaries
Participants	1172 HIV-positive pregnant women (not yet enrolled in HIV care) and their exposed infants
Data sources	Electronic medical records and registers
Study Period	Women enrolled in pregnancy and mother-infant pairs followed for one year.

Separate Clinics at the Facility



ANC / MNCH Clinic

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Patient Support Center = HIV Clinic

The Control Clinics N=6



ANC / MNCH Clinic

Patient Support Center = HIV Clinic

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FANC=Focused Antenatal Care

The Intervention Clinics N=6



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ANC / MNCH Clinic



Patient Support Center = HIV Clinic

*Women transferred to PSC 18 months postpartum



Patient Characteristics at Enrollment

(N=1172 pregnant women)

	Intervention (n=569)	Control (n=603)	P value
Mean age in years (SE)	25.0 (0.19)	24.8 (0.18)	0.58
Education, n (%)			
None or Some Primary	481 (85%)	533 (89%)	0.37
Some Secondary or more	84 (15%)	68 (11%)	
Marital status, n (%)			
Married	472 (84%)	500 (84%)	0.99
Single/Separated/Divorced	49 (8%)	50 (8%)	
Widowed	43 (8%)	48 (8%)	

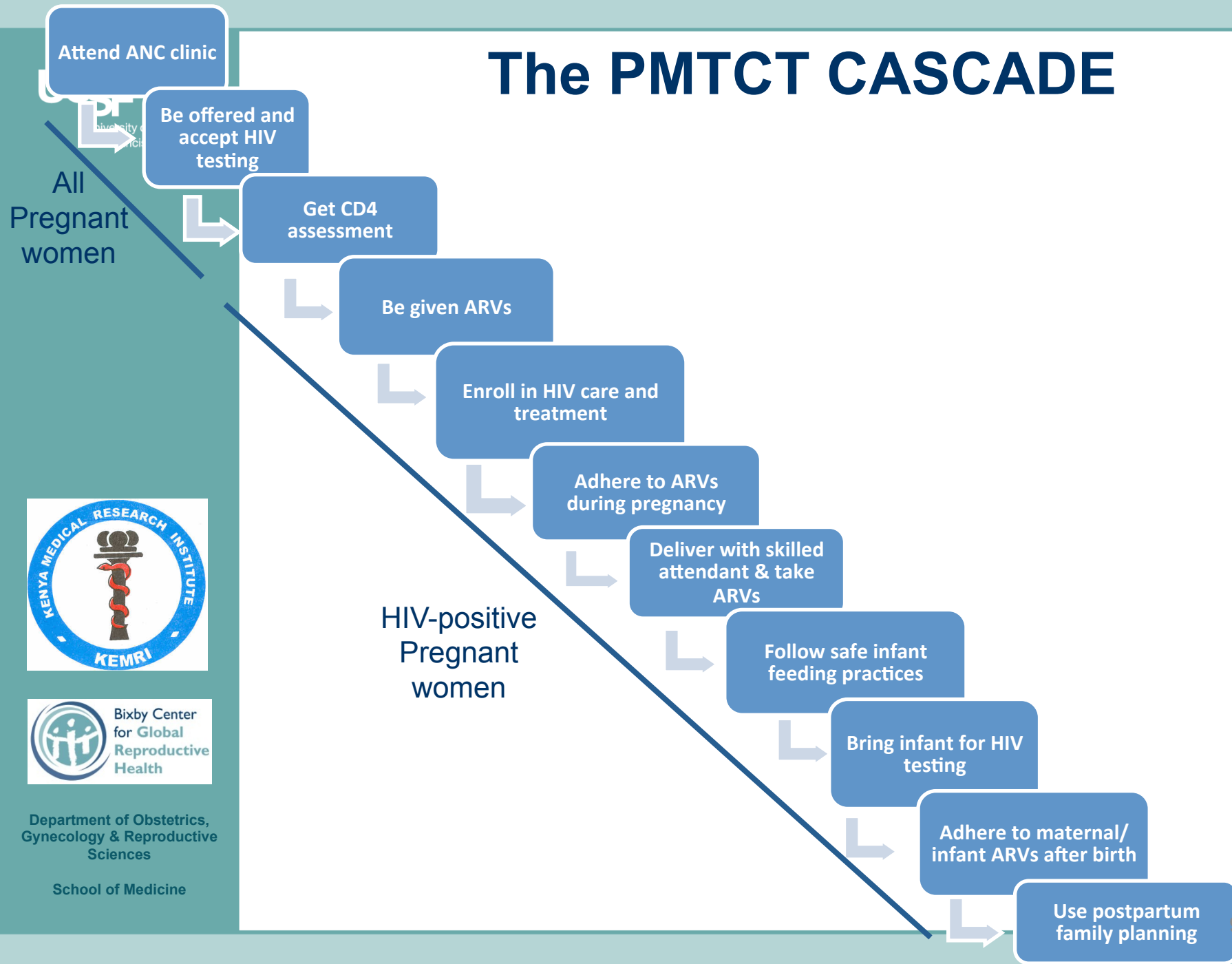


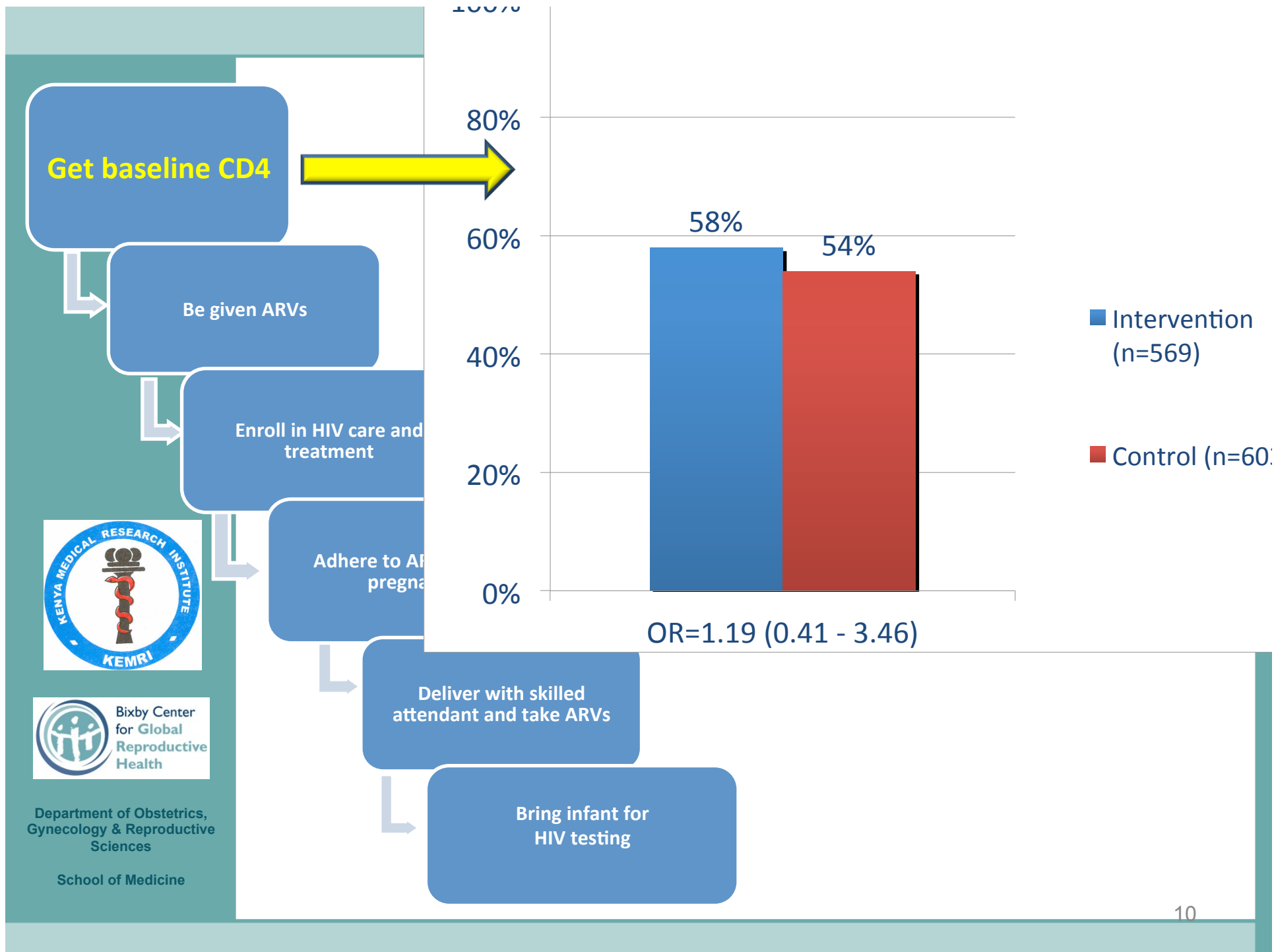
Patient Characteristics at Enrollment

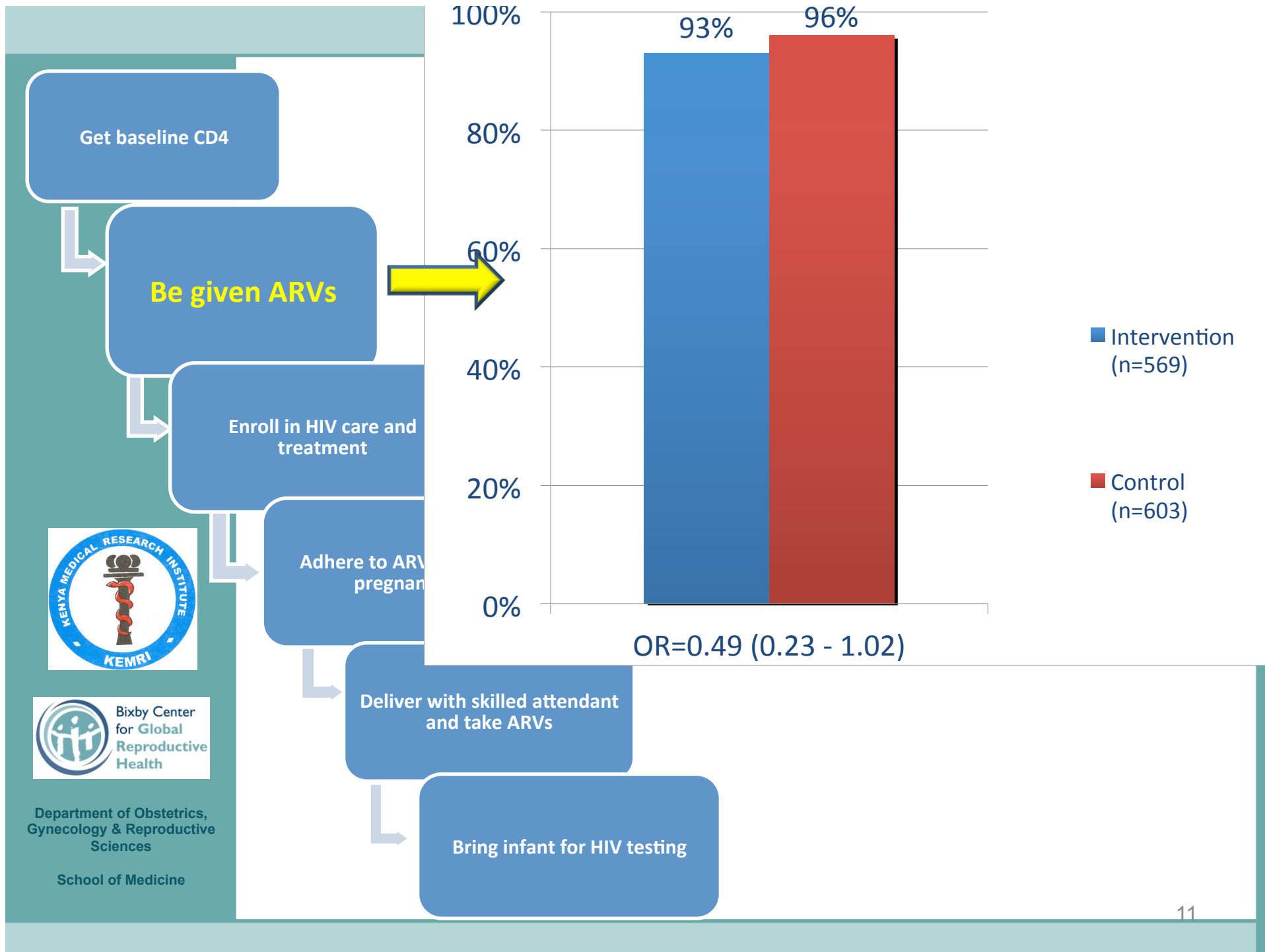
(N=1172 pregnant women)

	Intervention (n=569)	Control (n=603)	P value
Median Gravidae (IQR)	3 (2-4)	3 (2-4)	0.94
Median Parity (IQR)	2 (1-3)	2 (1-3)	0.92
Mean Gestational Age in weeks (SE)	26 (0.3)	25.2 (0.3)	0.10
WHO HIV stage n (%)			
WHO Stage 1	339 (63%)	455 (80%)	0.40
WHO Stage 2	79 (15%)	42 (7%)	
WHO Stage 3 or 4	31 (6%)	8 (1%)	
Not Staged	85 (15%)	67 (12%)	
Mean Baseline CD4 (SE)	495 (19.87)	523 (19.18)	0.34
Eligible for HAART	127 (22%)	87 (14%)	0.28

The PMTCT CASCADE







Get baseline CD4



Be given ARVs



Enroll in HIV care and treatment



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Adhere to ARVs during pregnancy



Deliver with skilled attendant
and take ARVs



Bring infant for HIV testing

100%

80%

60%

40%

20%

0%

69%

36%

■ Interventio
(n=569)

■ Control
(n=603)

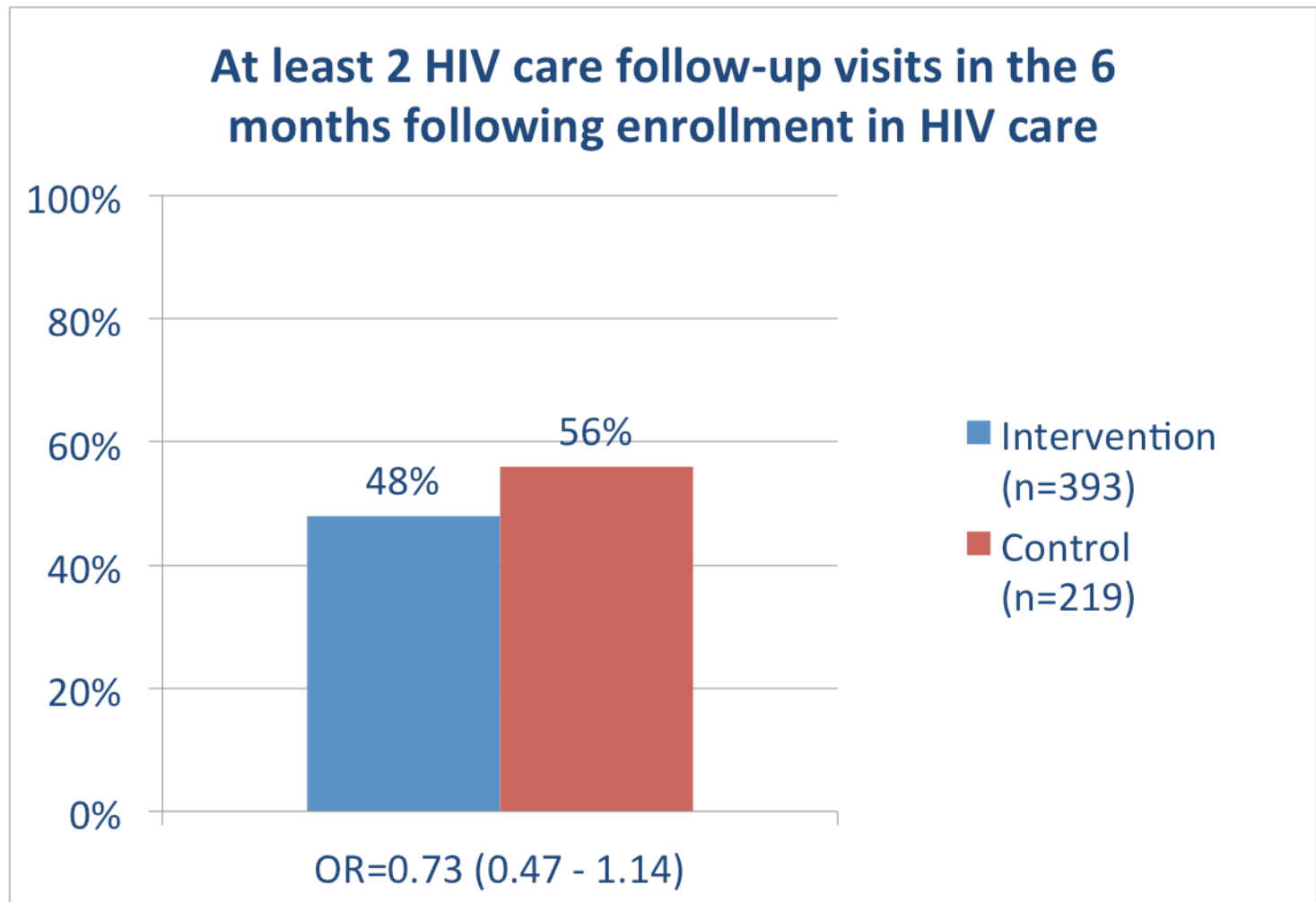
OR=3.94 (1.14 - 13.63)

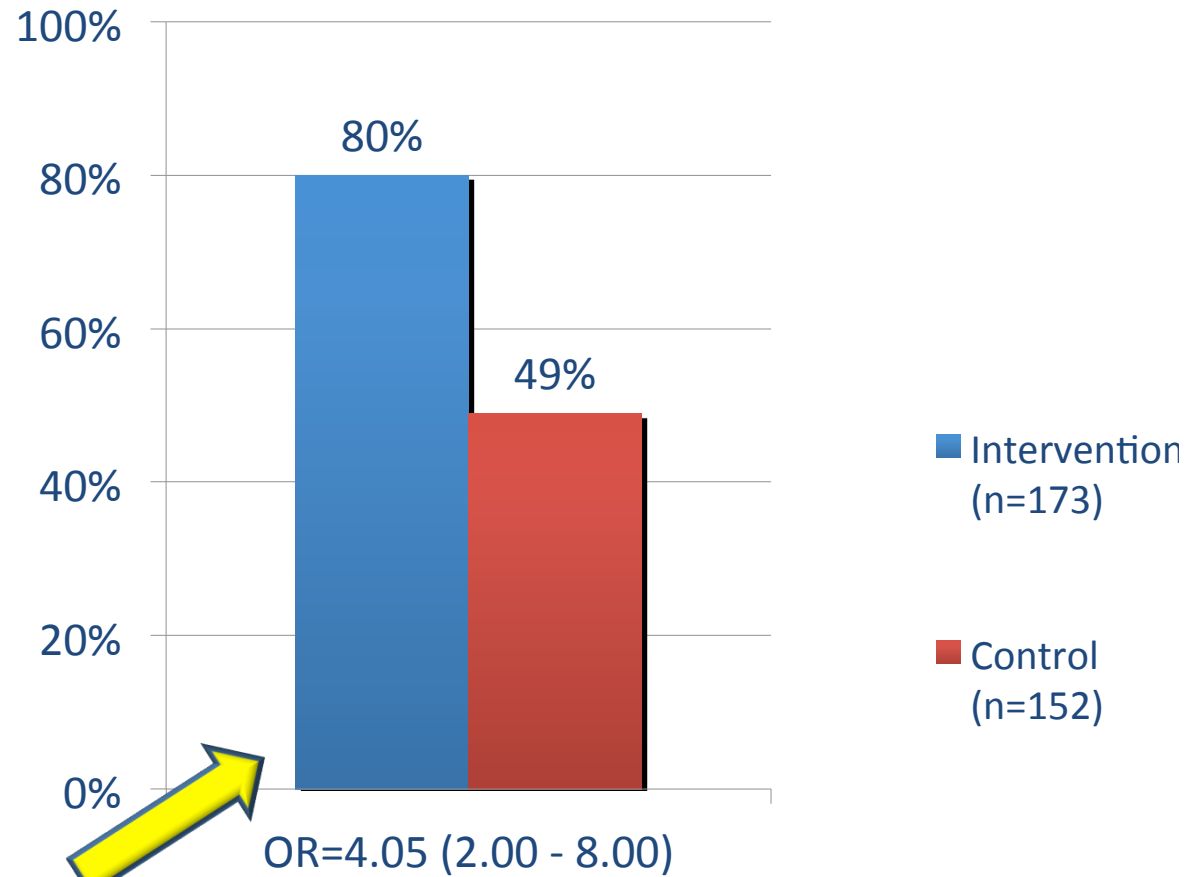
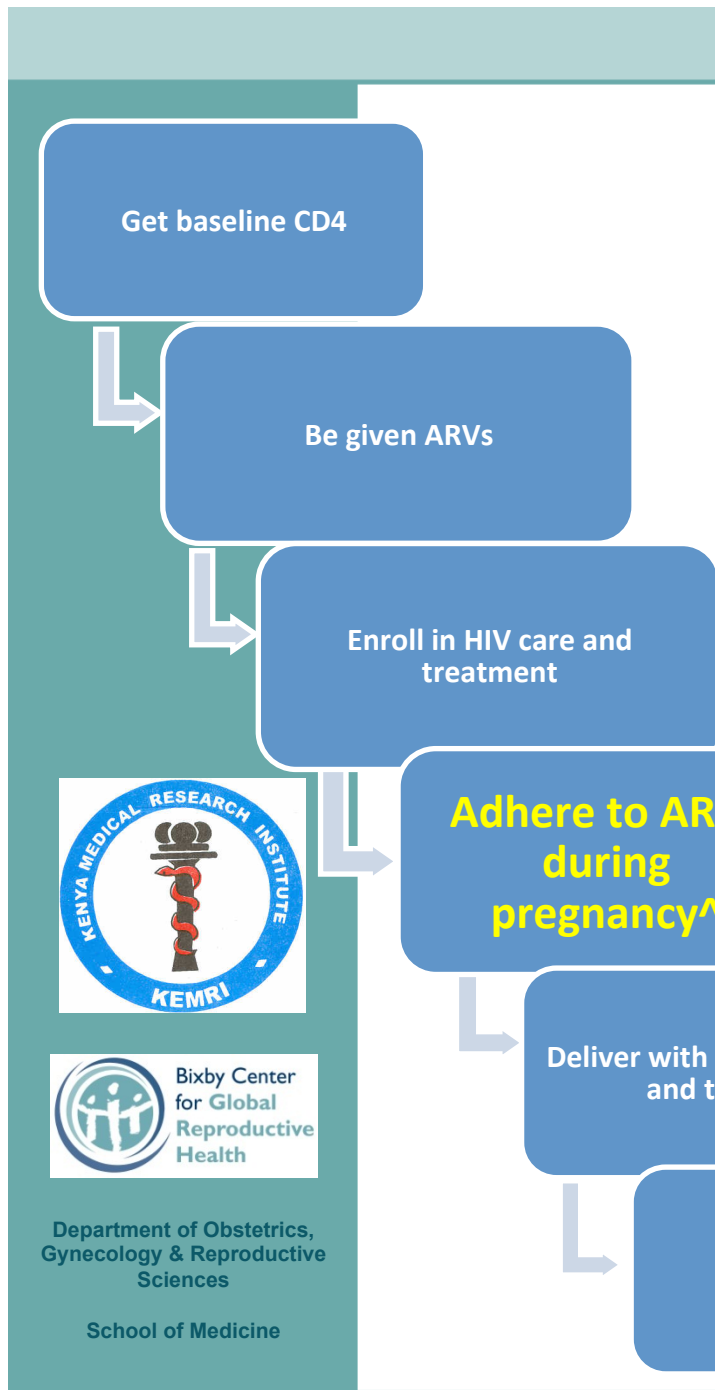
Median time to enrollment in
HIV care:

- Intervention sites: 0 days
- Control sites: 8 days
 - HR = 2.2 (1.62-3.01)

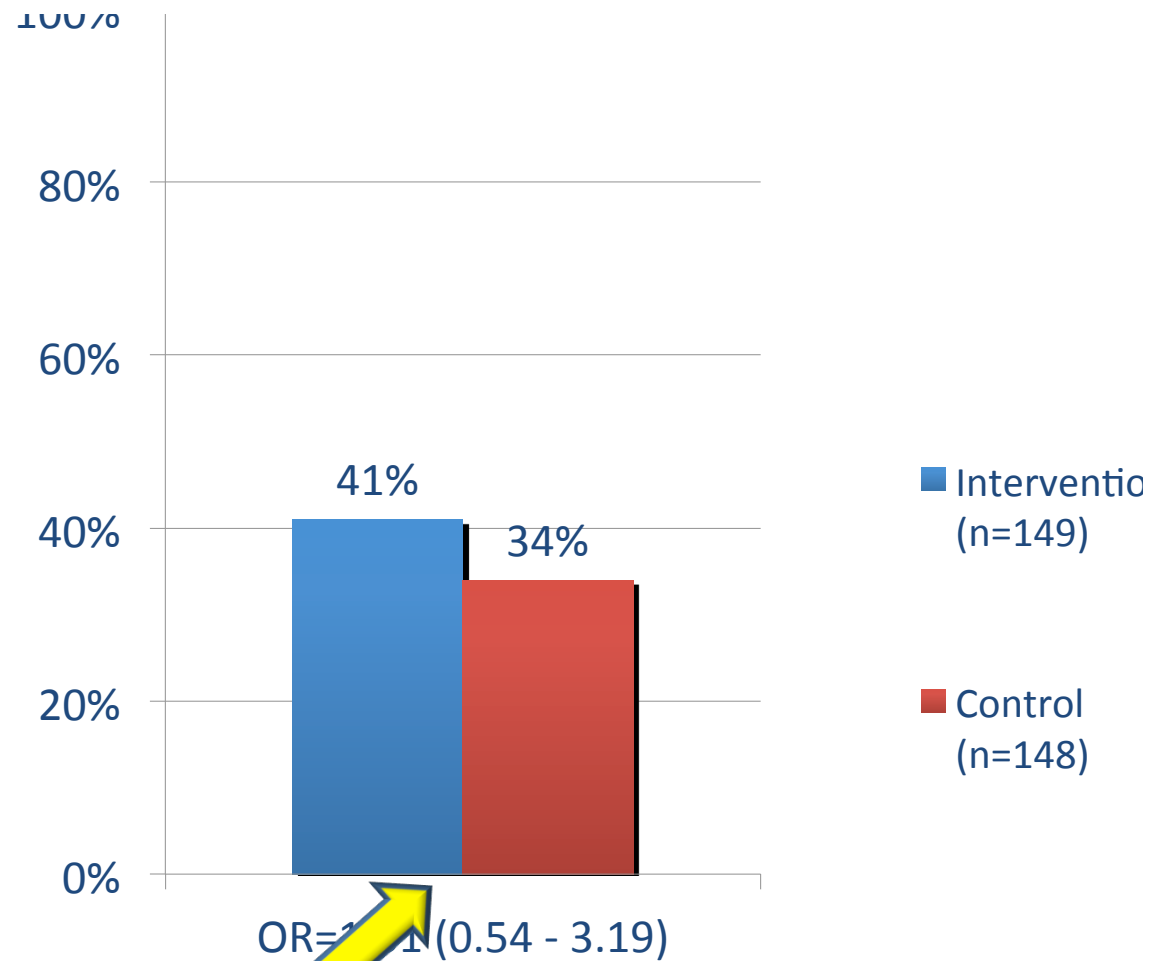
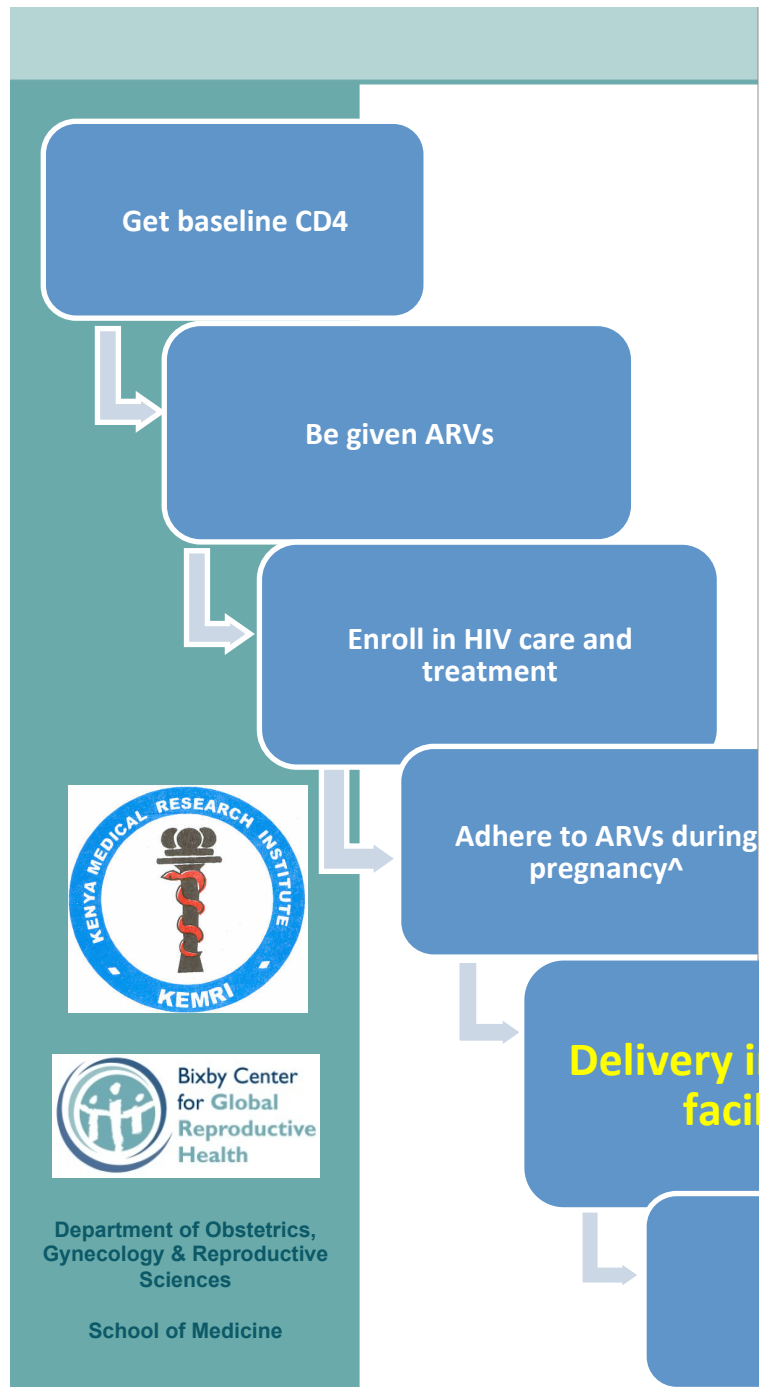


Retention in Care among Enrolled Women

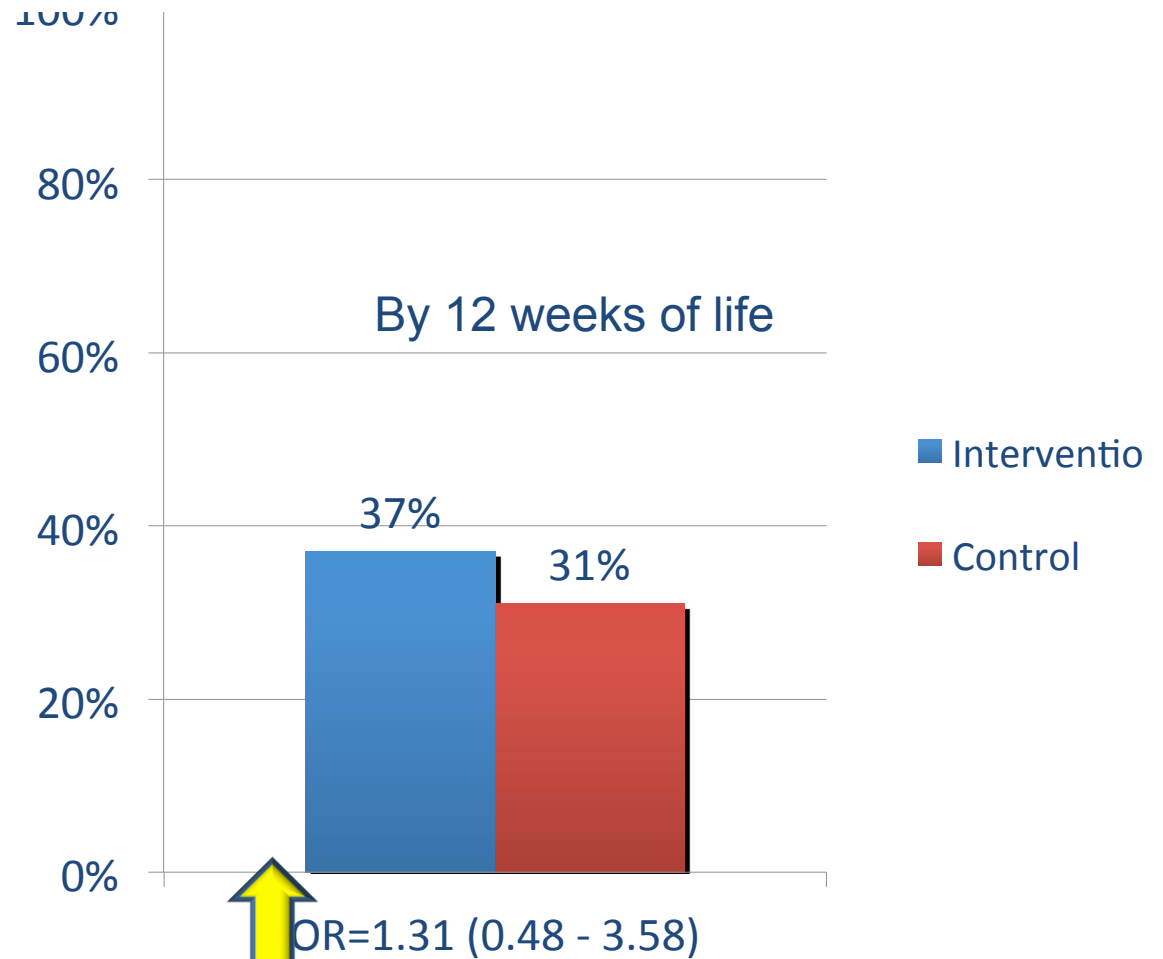
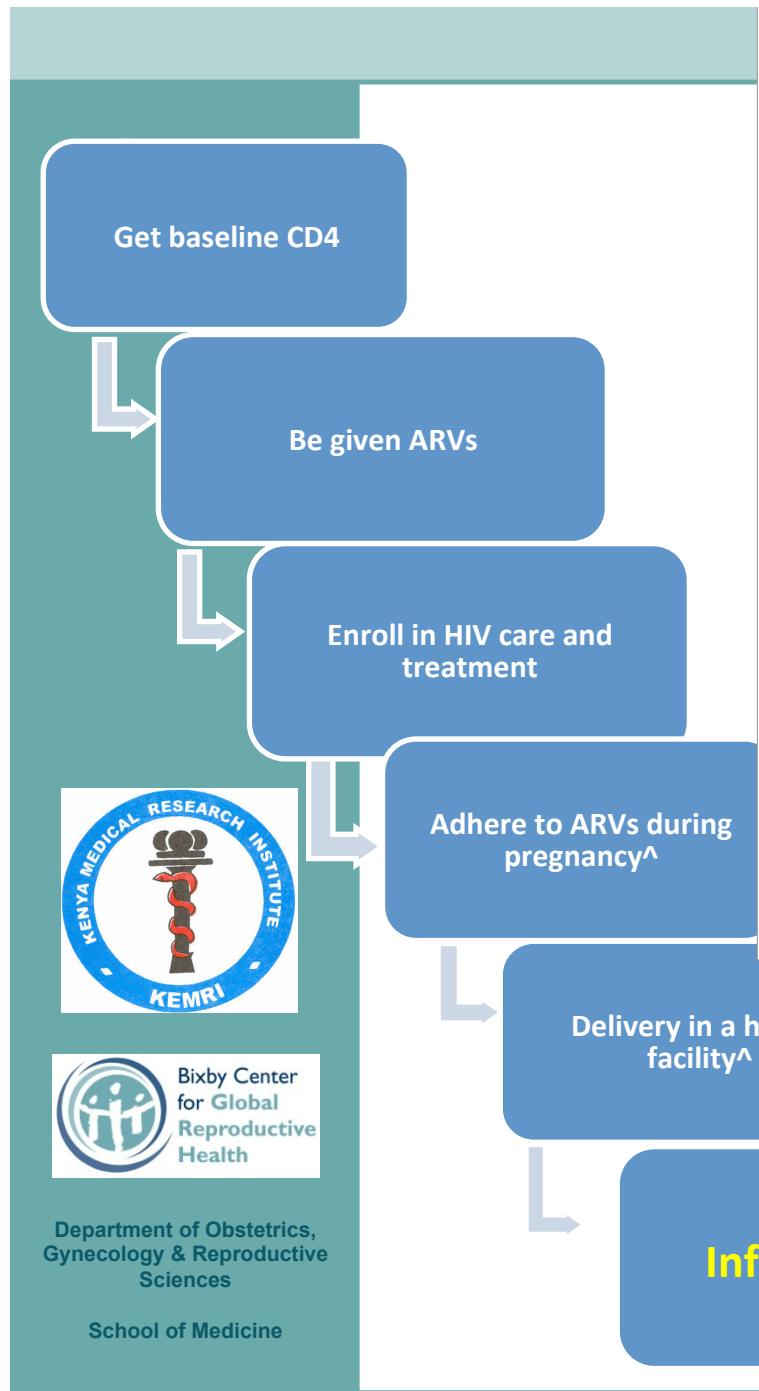




[^]Self report from women with postpartum forms (n=325)



^Self report from women with postpartum forms (n=325)



By close of study (around 9 months of age):

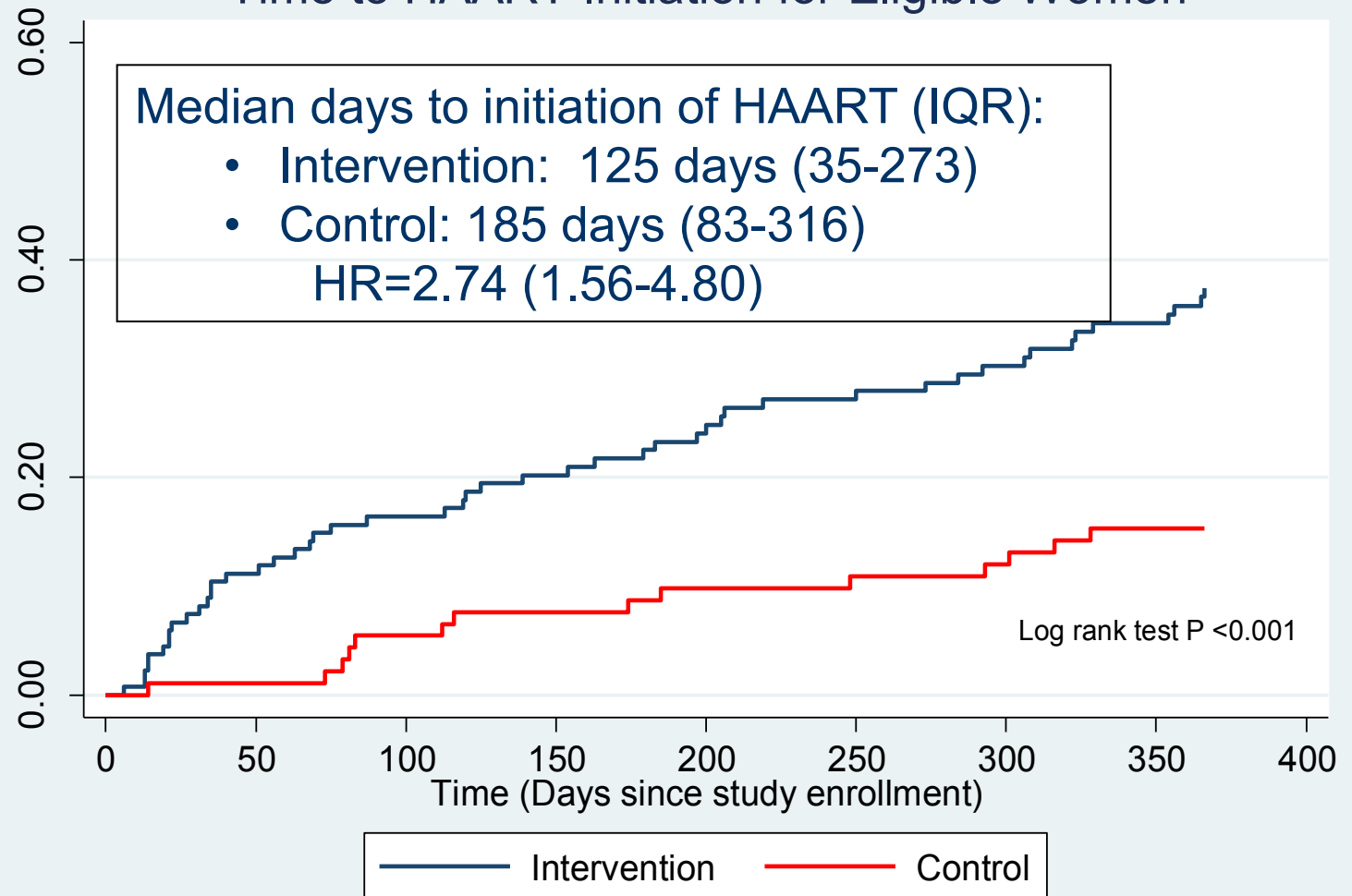
- Intervention: 67%
- Control: 56%

OR= 1.60 (0.75-3.39)



Time to HAART Initiation Among Eligible Women

Time to HAART Initiation for Eligible Women





Maternal Outcomes

	Intervention N (%)	Control N (%)	Adjusted OR	95% CI
Composite clinical or immunologic progression to AIDS	10 (4.9)	7 (5.1)	0.83	0.41-1.68
Lost to Follow up (LTFU)	147 (25.8)	200 (33.2)	0.74	0.37-1.51
Maternal Death – N (%)	9 (1.6)	8 (1.5)	1.19	0.43-3.29
Composite LTFU or Death	156 (27.4)	208 (34.5)	0.76	0.40-1.44

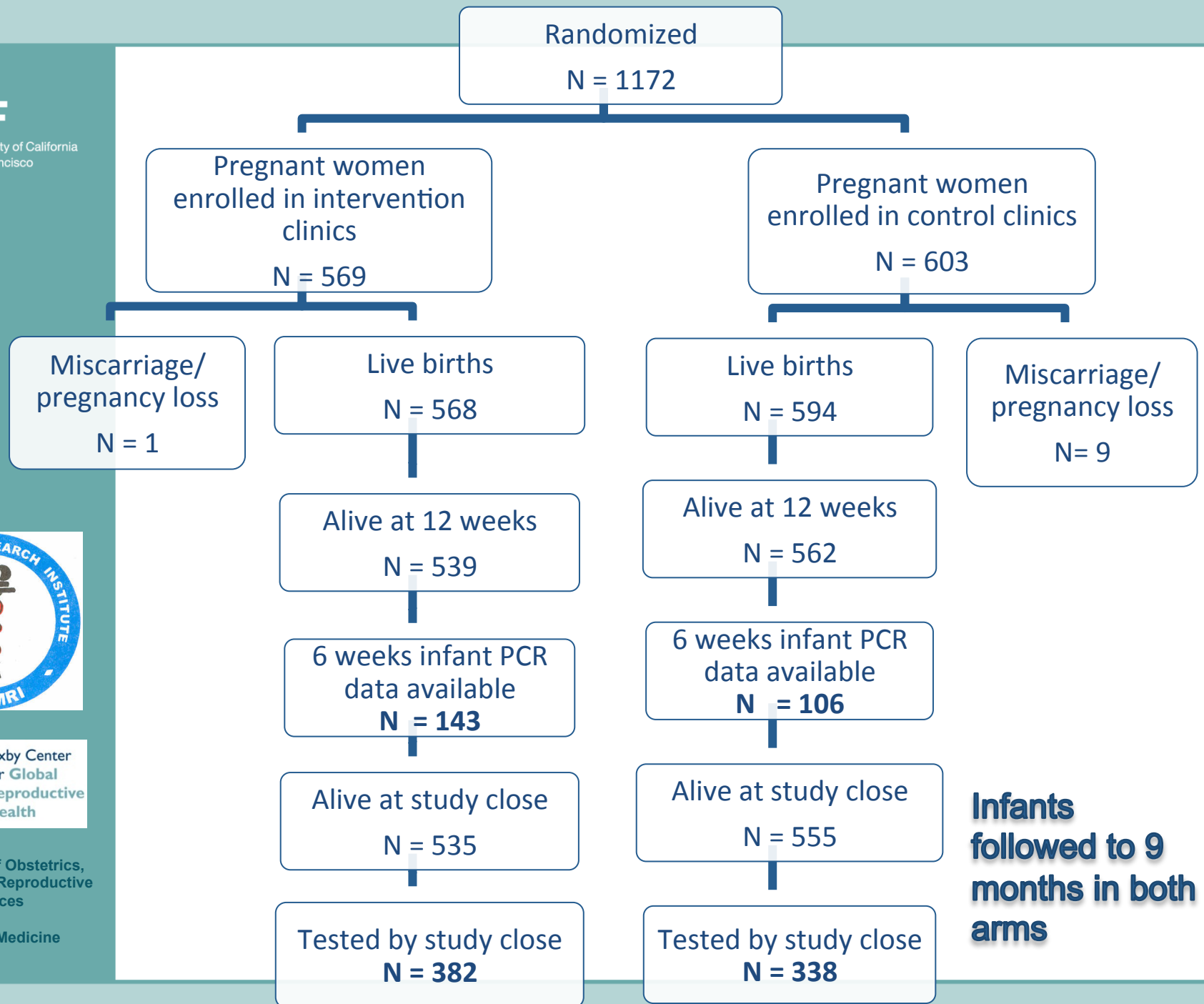


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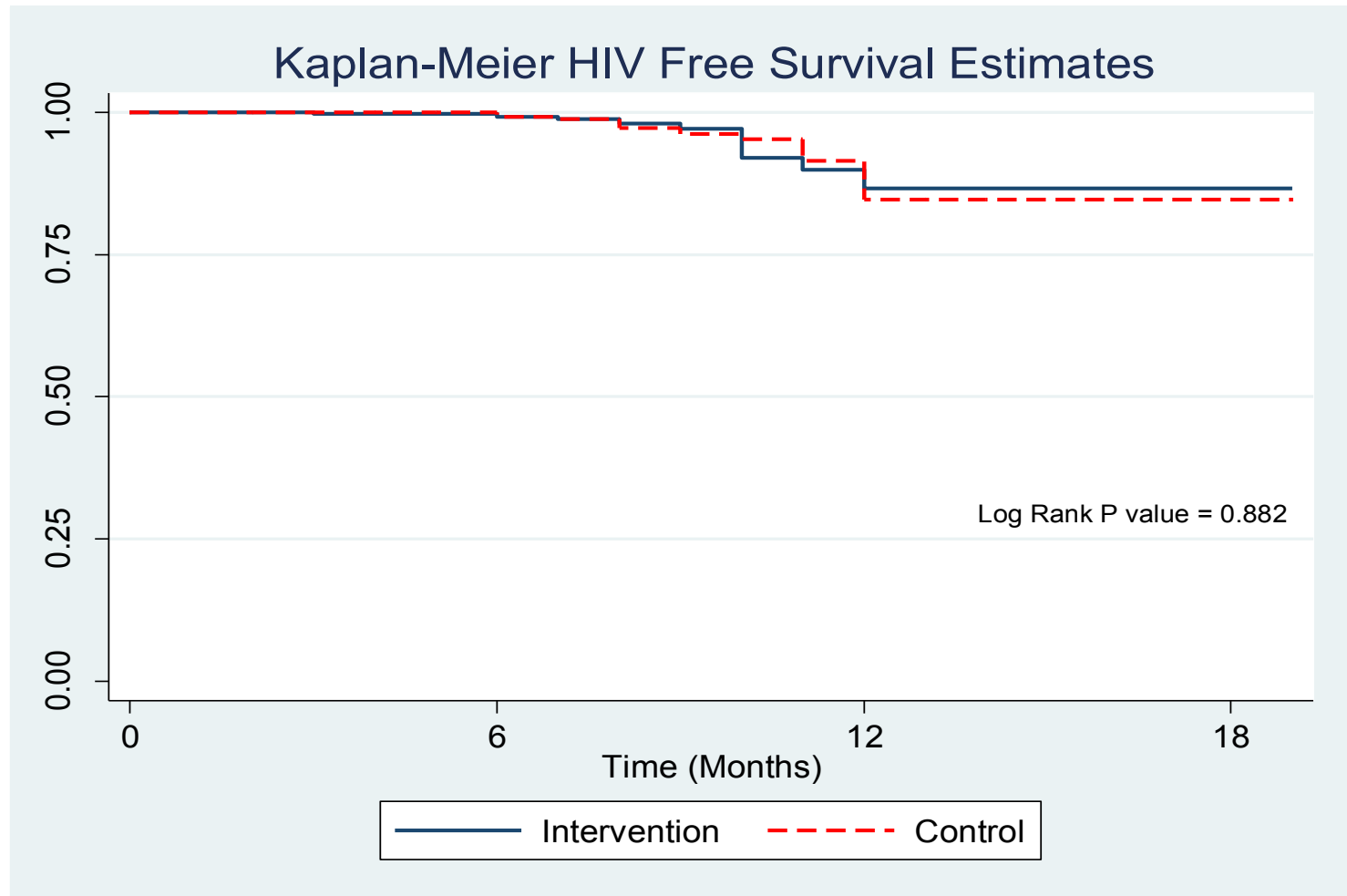
Infant Outcomes

	Intervention N (%)	Control N (%)	Adjusted OR	95% CI
Total exposed infants (All live births)	568 (99.8)	594 (98.5)	10.76	(1.14-101.85)
Infant Exclusively breastfed [^]	70 (58)	69 (58)	1.10	(0.61-2.01)
HIV infected at 6 weeks PCR test	6 (4.2)	7 (6.6)	0.62	(0.20-1.90)
HIV infected by end study period (by 9 months)	28 (7.3)	27 (8.0)	0.89	(0.56-1.43)

[^]Self report from women with postpartum forms (n=325)



HIV Free Survival Among Exposed Infants





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Conclusions

- Results indicate strong positive effects of integration on:
 - Women's timely enrollment in HIV care
 - Use of ARVs during pregnancy
- Early infant diagnosis remained a challenge in both study arms



Conclusions: Outcomes

- Integration was not associated with a reduced risk of MTCT
- In the short term, there was no difference in maternal health outcomes
- Integration of HIV services into the ANC clinic resulted in earlier initiation of HAART in eligible patients
- Important lessons for roll-out of WHO Option B+
 - Systems strengthening
 - Enrollment
 - Follow-up to support adherence and retention
 - Tracing and community linkages
 - Move towards immediate initiation of HAART models
 - Stigma reduction



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