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Impact of Option B+ on Uptake, Retention, and Transmission: a Pre/Post Study in Lilongwe, Malawi

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BACKGROUND AND METHODS

Background: In September 2011, Malawi implemented Option B+ (**B+**), lifelong antiretroviral therapy (**ART**) for pregnant and breast feeding women. The *Tingathe* program, started in 2009, two years prior to B+, is a service program utilizing dedicated community health workers (**CHWs**) as case managers to improve uptake and retention along the PMTCT cascade. The service is offered as part of routine care at participating government health centers. We assessed the impact of B+ on service uptake, retention, and vertical HIV transmission by comparing outcomes pre and post B+ implementation at 2 health centers in Lilongwe.

Methodology: PMTCT service utilization, program retention, and transmission outcomes at 1st DNA PCR (4-20 wks of age) were compared for HIV-infected (**HIV+**) pregnant women and their exposed infants followed in *Tingathe* 18 months pre (Oct 2009-Mar 2011) and post (Oct 2011-Mar 2013) B+. Chi-square and Fisher's exact test as well as two-sample t-test were used to compare proportions of events and continuous variables, respectively.

RESULTS

Table 1: Characteristics of HIV-Infected Pregnant Women at Enrollment

Characteristic	Pre Option B+ Total (n=1130)	Post Option B+ Total (n=1421)	P-value
Median maternal age, years (IQR)	26.9 (23.5 , 30.9)	27.8 (23.8 , 31.5)	0.019 (W)
Trimester of pregnancy: n(%)			
First (0- >13weeks)	42 (3.8)	74 (5.5)	<0.0001
Second (13- <28)	603 (54.1)	831 (62.3)	
Third (≥28 to 40)	470 (42.1)	430 (32.2)	
Unknown-missing	15	86	
HIV status at enrollment: n (%)			
Known HIV+	307 (27.4)	646 (45.6)	<0.0001
Newly diagnosed HIV+	815(72.6)	771(54.4)	
WHO stage: n (%)			
Stage 1 & 2	11 (1.0)	30 (2.1)	0.007 (F)
Stage 3	10 (0.9)	28 (2.0)	
Stage 4	2 (0.2)	6 (0.4)	
Not done	1107 (98.0)	1357 (95.5)	
Partner Disclosure status: n (%)[a]			
Partner involved and disclosed	278 (24.6)	565 (39.9)	<0.0001
Partner involved but not disclosed	791 (70.1)	816 (57.6)	
Partner not involved	60 (5.3)	36 (2.5)	
Missing data	1	4	

[a] Partner disclosed defined as partner having knowledge of maternal HIV status. Partner non-involved defined as a partner who is dead, or is otherwise separated from the mother.
Abbreviations: IQR (interquartile range); ART (antiretroviral treatment); W (Wilcoxon Rank-Sum test); F (Fisher's exact test)
Chi-square tests were used unless specified.

RESULTS

PRENATAL OUTCOMES:

•Post B+ a smaller proportion of women were HIV tested (98.9% pre vs. 83.4% post; p<0.001); attributed to test kit stock-outs.

•Among women testing HIV+ (1654-pre and 1535-post) a larger proportion were known to be HIV+ (18.8% vs. 41.2%; p<0.001) and already on ART (18.8% vs. 30.1%; p<0.001) post B+.

•Of those starting ART, median time to ART initiation (48 (19 - 140) vs. 0 (0 - 16) days; p<0.001) and duration on ART prior to delivery (62 (38 - 94) vs. 95 (61 - 130) days; p<0.001) improved significantly.

•However, post B+, despite a considerable increase in proportion of women who received ART (38.2 vs. 85.1%, p <0.001) over 15% of women continued to refuse ART . Common reasons cited by women included lack of partner disclosure, fear of potential side effects and religious reasons.

•Amongst recorded live births there was no change in proportion of women (95.8% vs. 95.4%; p=0.45) and infants receiving antiretrovirals for PMTCT (96.8% vs. 96.0%; p=0.34).

POSTNATAL OUTCOMES:

•Outcomes suggest improvements in infant care post B+: a greater proportion of infants received 1st DNA PCR (82.1% pre vs. 86.7% post; p=0.007); younger age at 1st DNA PCR (7.5 weeks (6.5 - 10.7) pre vs. 6.9 (6.4 - 8.0) post; p<0.001) and lesser proportion of infants testing 1st DNA PCR positive (4.6% pre vs. 2.6% post; p=0.028).

•There was no change in the proportion of HIV-infected infants initiated on ART.

Table 2: Steps of the PMTCT Cascade Completed by Mother-Infant Pairs: pre and post B+

STEP in PMTCT Cascade	Description	Pre Option B+ Oct 2009 - Mar 2011	Post Option B+ Oct 2011 – Mar 2013	P-Value
ACCESS Antenatal Care	**Pregnant women accessing antenatal care**	13,926	14,022	NA
TEST for HIV infection and ENROLL into PMTCT services	**Pregnant women tested for HIV infection**	13766/13926 (98.9)	11691/14022 (83.4)	<0.0001
	Pregnant women with HIV infection, *n/N (%)*	1654/14066 (11.8)	1535/12323 (12.5)	0.083
	Known HIV+	300/1654 (18.1)	632/1535 (41.2)	<0.0001
	Newly diagnosed HIV+	1354/1654 (81.9)	903/1535 (58.8)	
	Accepting PMTCT services at antenatal care *n/N (%)*	1130/1654 (68.3)	1421/1535 (92.6)	<0.0001
		N=1130	N=1421	
INITIATE ART	**ART status**, *n/N (%)*			
	On ART at enrollment	212/1130 (18.8)	428/1421 (30.1)	<0.0001
	Initiated ART after enrollment, *n/N (%)*	351/918 (38.2)	845/993 (85.1)	<0.0001
	Days to ART initiation, median (IQR)	48.0 (19.0, 140.0)	0 (0, 16.0)	<0.0001
PMTCT prophylaxis	**Number of live births recorded,** *n/N (%)*	844/1130 (74.7)	991/1421 (69.7)	0.006
	Mother received ART or PMTCT prophylaxis *n/N (%)*	N = 844	N = 991	
	ART	377/844 (44.7)	944/991 (95.3)	<0.0001
	PMTCT prophylaxis	423/844 (50.1)	1/991 (0.1)	
	None	44/844 (5.2)	46/991 (4.6)	
	Days on ART prior to delivery among those newly initiating, median (IQR)	62.0 (38.0, 94.0)	95.0 (61.0, 130.0)	<0.0001
	Infant received PMTCT prophylaxis, *n/N (%)*	817/844 (96.8)	951/991 (96.0)	0.341
TEST infant for HIV infection and INITIATE ART in HIV-infected infants	**Infant received HIV DNA PCR test** , *n/N (%)*	693/844 (82.1)	859/991 (86.7)	0.007
	Median age at 1st PCR test, weeks, median (IQR)	7.6 (6.6, 10.9)	6.9 (6.4, 8.0)	<0.0001
	First PCR test result available, *n/N (%)*	691/693 (99.7)	856 / 859 (99.7)	1.000 (F)
	Infants found to be HIV+ at 1st PCR (number positive/ number with 1st PCR results), *n/N (%)*			
	All PCR results available	32/691 (4.6)	22/856 (2.6)	0.028
	PCR done at 4-20 weeks of age	29/641 (4.5)	20/ 839 (2.4)	0.023
	PCR done at 4-16 weeks of age	27/609 (4.4)	20/827 (2.4)	0.034
	PCR done at 4-12 weeks of age	26/548 (4.7)	18/791 (2.3)	0.013
	HIV-infected children started on ART, *n/N (%)*	25/32 (78.1)	17/22 (77.3)	1.000 (F)

Unless specified, Chi-square tests and Wilcoxon tests were used to compare the categorical and continuous variables respectively.
Abbreviations: IQR (interquartile range); ART (antiretroviral treatment); F (Fisher's exact test)

CONCLUSIONS

•Patient level data from a CHW supported program in Lilongwe, Malawi demonstrate that B+'s simplified PMTCT approach has resulted in several improvements including improved ART use during pregnancy and more rapid initiation with longer duration of coverage for those newly initiating.

•However, although there was a significant increase in maternal ART initiation, over 15% of the post B+ cohort refused to initiate ART. It will be critical to explore the reasons for and develop initiatives to address maternal ART refusal.

•Early findings suggest improvements in infant care along the cascade.

•There was a decrease in the proportion of infants with a positive first DNA PCR result post B+. Although this is likely due to the impact of earlier and improved uptake of ART, including greater proportion of women likely on ART during conception, earlier median age at first DNA PCR post B+ may have contributed.

•Health systems issues like timely and reliable HIV testing for women and infants, continue to greatly impact implementation and will need to be addressed to ensure an AIDS-free generation.

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