

# Maternal retention and early infant HIV diagnosis in a prospective cohort study of HIV-positive women and their children in Malawi

International Journal of STD & AIDS  
2023, Vol. 34(1) 54–61  
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DOI: 10.1177/09564624221136647

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Marina Giuliano<sup>1</sup> , Stefano Orlando<sup>2</sup>, Mauro Andreotti<sup>1</sup>, Bryan Mthiko<sup>3</sup>, Robert Mphwere<sup>3</sup>, Thom Kavalo<sup>3</sup>, Fausto Ciccacci<sup>4</sup>, Maria Cristina Marazzi<sup>5</sup> and Marco Florida<sup>1</sup> 

## Abstract

**Background:** Post-partum loss to follow-up and lack of early HIV infant diagnosis (EID) can significantly affect the efficiency of programs for the prevention of mother-to-child transmission.

**Methods:** In a prospective observational study 167 women were enrolled at week 36 of gestation and followed with their infants up to one year after delivery. Retention was defined as the proportion of women who attended the 12 months visit and EID as an HIV PCR test performed within 2 months. Determinants for retention and EID were assessed in univariate analyses and in multivariable logistic regression models.

**Results:** Women lost to follow-up (24/167 or 14.4%) had a shorter duration of antiretroviral therapy (ART) at enrolment in comparison to women retained in care ( $p = 0.025$ ). Lack of EID (occurring in 18.9% of the cases) was directly correlated, although not significantly, with a history of child death ( $p = 0.071$ ), a higher educational level ( $p = 0.083$ ), and female infant gender ( $p = 0.064$ ).

**Conclusions:** Longer duration of ART at enrolment significantly predicted a better post-partum retention, suggesting that specific counselling interventions should be targeted to recent ART initiators. A low proportion of infants did not receive an EID, but predictive factors were difficult to identify.

## Keywords

HIV, prevention of mother-to-child transmission, retention, postpartum, early infant diagnosis, Malawi

Date received: 3 August 2022; revised: 14 October 2022; accepted: 17 October 2022

## Background

Access to antiretroviral therapy (ART) has greatly increased in the last years in HIV-positive women, and in 2020 an estimated 85% of pregnant women globally received effective antiretroviral drugs for prevention of mother-to-child transmission (PMTCT), compared to only 17% in 2010.<sup>1</sup> However, lack of retention in care (which can be considered a proxy for adherence to ART) can both impair women's health and increase the risk of HIV transmission. Several studies have reported variable rates of retention and assessed its possible determinants, but different definitions of retention were used, precluding direct comparisons and complicating the interpretation of results.<sup>2–6</sup> One important issue in evaluating retention in care is that loss to follow-up often includes silent transfers to other clinics, changes of

residence, treatment interruptions, and deaths.<sup>7</sup> Documenting real outcomes among patients lost to follow-up is therefore important but may be difficult unless tracing strategies are implemented.

<sup>1</sup> National Center for Global Health, Istituto Superiore di Sanità, Rome, Italy

<sup>2</sup> Department of Biomedicine and Prevention, University of Rome Tor Vergata, Rome, Italy

<sup>3</sup> DREAM Program, Community of S. Egidio, Blantyre, Malawi

<sup>4</sup> UniCamillus, Saint Camillus International University of Health Sciences, Rome, Italy

<sup>5</sup> Department of Human Sciences, LUMSA University, Rome, Italy

## Corresponding author:

Marina Giuliano, National Center for Global Health, Istituto Superiore di Sanità, Viale Regina Elena 299, Rome 00161, Italy.

Email: [marina.giuliano@iss.it](mailto:marina.giuliano@iss.it)

Early infant diagnosis (EID) among HIV-exposed infants, allowing to initiate antiretroviral treatment in a timely manner, is also a critical component of the PMTCT programs, because risk of death in untreated HIV-positive infants has been estimated to reach 35% in the first year of life and 50% in the second year.<sup>8</sup> In 2020, only 63% of infants born to mothers with HIV in high-burden countries were tested within the first 2 months of life, and only 54% of children living with HIV were on antiretroviral therapy.<sup>9</sup> To address this treatment gap, infant testing coverage must be improved. There are limited data on factors associated with lack of EID and further information would be helpful to design targeted strategies.

In this study we analyzed data from a cohort of HIV-positive women and their infants followed up to one year after delivery focusing on the above important steps of the PMTCT cascade with two specific objectives: (1) to assess rates and determinants of maternal retention at 12 months in a setting that included tracing strategies; (2) to define the factors associated with the suboptimal coverage of HIV infant diagnosis within the first 2 months of life.

## Methods

The GF-ISS (Global Fund-Istituto Superiore di Sanità) study, a prospective cohort study conducted in Malawi between January 2019 and August 2021, aimed to evaluate post-partum retention in care of HIV-positive ART-treated women and infant HIV testing rates, and to compare the health and growth of HIV-exposed infants with that of a parallel cohort of HIV-unexposed infants (this second objective will be reported in a separate paper).

HIV-positive women attending the antenatal clinics of three clinical sites (the urban DREAM Center, in Mandala, Blantyre, and the two peri-urban sites of Chileka and Machinjiri, all in the Blantyre area) were enrolled between January 2019 and March 2020, with the following inclusion criteria: at least 18 years of age, gestational age between 32 and 36 weeks, being on ART or starting treatment during pregnancy, willingness to have home visits. After baseline enrolment, women and their children were followed with monthly visits up to 1 year after delivery. At each visit, information about ART intake was collected. Women were discontinued from the study if they experienced a miscarriage or a stillbirth and in case of a neonatal death as the study was designed for mother-child pairs. The study was conducted within the structures of the DREAM (Disease Relief through Excellent and Advanced Means) Program of the Community of S. Egidio, an Italian faith-based non-governmental organization.<sup>10,11</sup>

## Tracing activity for women not attending study visits

If a mother missed two consecutive study visits after enrolment, a home visit was requested, and a trained counsellor attempted, as soon as possible, to trace the woman at the address collected at enrolment. If the woman was not found, the counsellor was instructed to obtain information by relatives found at the address or from the neighbours.

## Early infant diagnosis

The first HIV test was performed in infants 6 weeks after delivery, when a follow-up visit was scheduled for mothers and infants. At this visit a dried blood spot (DBS) was collected and sent on the day of collection to the laboratory of the DREAM program in Blantyre to perform HIV-DNA PCR.

## Study outcomes

Retention in care was defined as the proportion of women who had a visit 12 months after delivery ( $\pm 30$  days). This outcome was selected according to the results of a recent study of different measures of retention, that showed that a simple indicator such as attendance or non-attendance at a single time point (12 months postpartum) reflected the woman's attendance over the preceding 12 months.<sup>12</sup> Early infant diagnosis (EID) was defined as an HIV PCR test performed within 2 months of birth (60 days).

## Statistical analysis

Variables were summarized as medians with interquartile range (IQR), frequencies and percentages. Differences between groups were evaluated using the  $\chi^2$  test or Fisher's exact test, as appropriate, for categorical variables, and by the Mann-Whitney U test for quantitative variables. To determine predictors of loss to follow-up and of EID testing, we used univariate analyses and multivariable logistic regression models that included all the variables that were associated to the above outcomes at a significance level  $< 0.25$  in univariate analysis. Differences were considered statistically significant at  $p$  levels  $< 0.05$ . For all data management and analyses, the SPSS software, version 27 (IBM Corp, 2017, NY, USA) was used.

## Ethics approval

Ethical approval was obtained from the National Health Sciences Research Committee in Malawi (approval number #2085), and written informed consent was obtained from all women participating in the study.

## Results

### Population characteristics

A total of 170 HIV-positive pregnant women were enrolled. Two women had a stillbirth and one pregnancy ended with a neonatal death (infant death on the day of birth). These three cases were excluded from the analyses since these conditions represented predefined exclusion criteria. The analyses were therefore conducted on 167 women. One-hundred and forty-three women completed follow-up (12 months after delivery) while 24 (14.4%) were lost to follow-up. Their characteristics are reported in [Table 1](#). Median length of follow-up was 372 days (IQR 365–383) for retained women and 113 days (IQR 56–228) for women lost to follow-up ( $p < 0.001$ ). Median number of postpartum visits attended was nine (IQR 1–9) for retained women and two (IQR 2–5.75) for women lost to follow-up. All women were in WHO stage I. Only five women were not on ART at enrolment (all completed follow-up). Regular ART intake was reported in 98.9% of the visits performed (1577/1595). Antiretroviral therapy was modified during follow-up in 63.5% (106/167) of women at a median of 6 (IQR 3–9) months after delivery. In all women but one, these changes reflected the modified national guidelines for antiretroviral therapy, which included after February 2020 dolutegravir in the place of efavirenz. The remaining woman was switched because of treatment failure.

### Tracing activity

The tracing of patients lost to follow-up was strongly affected by the COVID pandemic, due to the reduced activity of counsellors. In fact, in Malawi policies of SARS-COV-2 containment were implemented since March 2020 and although there was no official restriction on internal movement, the Government recommended the closure of workplaces for non-essential staff.<sup>13</sup>

Fifteen home visits were performed to trace women who had missed two consecutive visits. In six cases re-engagement occurred. For the other nine cases, the counsellors reported that four women had transferred to another facility, one woman had died (and no other information was available), two were not found at the address that was given at enrolment, one had a stillbirth that was not reported to the Clinical Center, and one was not willing to continue the study.

### Factors associated with retention

The characteristics of women retained in care and lost to follow-up are reported in [Table 1](#). Compared to women who completed the study, women lost to follow-up were younger (median 25 vs 30 years,  $p = 0.017$ ), had a lower BMI at enrolment (24.1 vs 25.6,  $p = 0.028$ ), had more frequently no

other children at home (29% vs 11.2%,  $p = 0.061$ ), and had a shorter duration of antiretroviral therapy at enrolment (3.5 vs 25 months,  $p = 0.011$ ). Women lost to follow-up were also less likely to live in urban areas (20.8% vs 33.6% of retained women,  $p = 0.22$ ) and to have previous dead children (12.5% vs 26.6% in retained women,  $p = 0.20$ ). In a multivariable logistic regression model that included all the factors reported above, only the duration of ART before enrolment retained statistical significance, with an ART duration below 14 months (median previous ART duration in the sample) associated with an adjusted odds ratio of loss to follow-up of 3.7 (95% C.I. 1.2–11.7),  $p = 0.025$  ([Table 2](#)).

### Early infant diagnosis

This analysis included women who were seen at the delivery visit with documented presence of an infant ( $n = 159$ ), excluding women who were only seen at enrolment ( $n = 8$ ). A total of 30 infants from these 159 mothers (18.9%) did not receive an EID, although all these mothers, but four, completed follow-up. The four women who did not complete follow-up were lost after the 6-week visit when PCR was scheduled. Among the 30 infants who did not receive an EID, 18 were never tested until 12 months (all tested HIV-negative at this time) and 12 were tested later than scheduled (after 2 months, all tested HIV-negative). The characteristics of the mother/infant pairs according to the presence of an EID are reported in [Table 3](#).

Among the infants that received an EID, only one tested HIV-positive. EID was performed at a median of 42 (IQR 40–45) days from birth. In a multivariable logistic regression model that included all factors associated with missed testing at a significance level  $< 0.25$  in univariate analysis (infant gender, presence of previous dead children, educational level, maternal BMI, first pregnancy), none of these variables was significantly associated with missed testing for EID although some associations approached significance (AOR 2.23 95% C.I. 0.95–5.22,  $p = 0.064$  for female infant gender, AOR 2.26, 95% C.I. 0.93–5.52,  $p = 0.071$  for a history of child death, and AOR 2.25, 95% C.I. 0.90–5.61,  $p = 0.083$  for a higher educational level, respectively) ([Table 2](#)).

## Discussion

In this cohort of HIV-positive women and their children, maternal retention at 12 months post-partum was relatively high at 85.6%, and was associated to a longer time on ART before enrolment. Testing for early HIV infant diagnosis was missed in a low but non insignificant proportion of infants, and predictive factors remained difficult to define.

Retention in care by HIV-positive women has been reported in several studies, and different factors were found to be implicated. In a systematic review and meta-analysis of studies up to 2017 in Africa,<sup>5</sup> the pooled estimate of

**Table 1.** Characteristics of HIV-positive women who completed follow-up or were lost to follow-up. Values are expressed as medians with IQR or percentages.

	All	Completed follow-up	Lost to follow-up	p Value
N. (%)	167	143 (85.6%)	24 (14.4%)	
Age (years)	30 (25–34)	30 (25–34)	25 (21.8–32)	0.017
Body mass index at enrolment (kg/m <sup>2</sup> )	25.3 (23.5–28.3)	25.6 (23.7–28.7)	24.1 (22.5–25.8)	0.028
Hemoglobin at enrolment (g/dl)	11 (9.9–11.9)	11 (9.9–11.9)	11.1 (9.8–11.8)	0.598
Marital status				
Married/cohabitating	158 (94.6%)	135 (94.4%)	23 (95.8%)	1.000
Single/separated/divorced	9 (5.4%)	8 (5.6%)	1 (4.2%)	
N. of previous dead children				
0	126 (75.4%)	105 (73.4%)	21 (87.5%)	0.200
1–3	41 (24.6%)	38 (26.6%)	3 (12.5%)	
First pregnancy, N. (%)	24 (14.4%)	19 (13.3%)	5 (20.8%)	0.348
N. Children in the household				
0	23 (13.8%)	16 (11.2%)	7 (29.2%)	0.061
1–2	84 (50.3%)	74 (51.8%)	10 (41.6%)	
3–6	60 (35.9%)	23 (37.0%)	7 (29.2%)	
Residence				
Rural	23 (13.8%)	21 (14.7%)	2 (8.3%)	0.220
Semirural	91 (54.5%)	74 (51.7%)	17 (70.8%)	
Urban	53 (31.7%)	48 (33.6%)	5 (20.8%)	
Distance from the clinical center				
1–2 km	60 (35.9%)	49 (34.3%)	11 (45.8%)	0.358
>2 km	107 (64.1%)	94 (65.7%)	13 (54.2%)	
Electricity at home				
Yes	83 (49.7%)	71 (49.7%)	12 (50.0%)	1.000
No	84 (50.3%)	72 (50.3%)	12 (50.0%)	
Water at home				
Yes	94 (56.3%)	83 (58.0%)	11 (45.8%)	0.265
No	73 (43.7%)	60 (42.0%)	13 (54.2%)	
Education				
None/primary	67 (40.1%)	56 (39.2%)	11 (45.8%)	0.344
Secondary or above	100 (59.9%)	87 (60.8%)	13 (54.2%)	
Employment				
Yes	57 (34.1%)	49 (34.3%)	8 (33.3%)	1.000
No	110 (65.9%)	94 (65.7%)	16 (66.7%)	
ART at enrolment				
TDF/XTC/EFV	138 (82.6%)	120 (83.9%)	18 (75.0%)	0.536
TDF/3TC/DTG	13 (7.8%)	10 (7.0%)	3 (12.5%)	
Other	16 (9.6%)	13 (9.1%)	3 (12.5%)	
Time on ART at enrolment (months)	14 (3–84)	25 (3–89)	3.5 (3–13)	0.011
HIV-RNA at enrolment (% <40 copies/mL)	88.2% (n. 68)	87.3% (n. 63)	100% (n. 5)	0.648
Gestational age at delivery (weeks)	40 (38–42)	40 (38–42)	40.5 (35.5–42.7)	0.760
Place of delivery				
Hospital	63 (39.6%)	57 (39.9%)	6 (37.5%)	0.267
Health center	96 (60.4%)	86 (60.1%)	10 (62.5%)	
Mode of delivery				
Caesarean section	21 (13.2%)	19 (13.3%)	2 (12.5%)	0.359
Vaginal	138 (86.8%)	124 (86.7%)	14 (87.5%)	
Infant gender (% female)	49.0%	47.5%	62.5%	0.299
Infant birth weight <sup>a</sup>	3.6 (3.2–4.0)	3.6 (3.2–4.0)	3.55 (2.9–4.0)	0.854
Infant birth length <sup>a</sup>	50 (48–51)	50 (48–52)	49 (48–50)	0.306

IQR: interquartile range; ART: antiretroviral treatment; TDF: tenofovir; XTC: lamivudine or emtricitabine; 3TC: lamivudine.

<sup>a</sup>Within 15 days of birth.

**Table 2.** Multivariate logistic regression analysis for risk factors associated with retention and early infant diagnosis.

Variable	Category	AOR (95% CI)	p value
<b>Retention</b>			
Age	≥30	Reference	0.798
	<30 years	1.15 (0.39–3.40)	
Body mass index	>25.3	Reference	0.125
	<25.3	2.13 (0.81–5.63)	
Duration of ART at enrollment	>14 months	Reference	<b>0.025</b>
	≤14 months	3.71 (1.2–11.7)	
Residence	Urban	Reference	0.935
	Rural/Semirural	1.050 (0.32–3.37)	
Previous dead children	Yes	Reference	0.310
	No	2.01 (0.52–7.83)	
Presence of other children in the household	Yes	Reference	0.150
	No	2.27 (0.74–6.97)	
<b>Early infant diagnosis</b>			
Maternal body mass index	<25.3	Reference	0.594
	>25.3	1.26 (0.53–2.96)	
Previous dead children	No	Reference	0.071
	Yes	2.26 (0.93–5.52)	
First pregnancy	Yes	Reference	0.251
	No	2.51 (0.52–12.02)	
Education level	None/Primary	Reference	0.083
	Secondary or above	2.25 (0.90–5.61)	
Infant gender	Male	Reference	0.064
	Female	2.23 (0.95–5.22)	

retention in care during pregnancy and postpartum in the Option B+ era was 74.5% (ranging from 42 to 97%) at 12 months after ART initiation (loss to follow-up was defined as more than 90 days without attending an appointment), and younger age and late ART initiation were associated with a higher loss to follow-up. More recent studies reported variable retention rates, ranging from only 67.4% 6 weeks postpartum in Ghana<sup>6</sup> to 85.6% at 12 months in Kenya, a rate similar to the one observed in our study.<sup>14</sup> Young age, no education, lack of disclosure, recent HIV diagnosis have all been shown to be associated with higher rates of loss to follow-up (LTFU) in studies focusing on determinants of retention.<sup>4,14,15</sup> In our study, although younger women were at higher risk of LTFU, the only independent predictor of loss to follow-up in a multivariable analysis was a short time on ART at enrolment, a factor significantly associated with LTFU also in a large meta-analysis<sup>5</sup> and in one recent study in China.<sup>16</sup> These findings suggest that a more extensive intervention such as specific counselling, active tracing, and home-based assistance should be targeted to the population of recent ART initiators to improve retention.

Low retention in pregnant women may reflect a specific vulnerability of this population due to difficulty in maintaining HIV care during pregnancy and postpartum. However, few studies have traced women LTFU from PMTCT programs to assess real rates of retention-in-care

and outcomes after being lost. In a study on Option B plus<sup>4</sup> in Uganda, 46% were retained in care at 25 months after ART initiation, but after successful tracking of 55% of the women, the real retention rate was estimated at 71.3% (36% of those traced had self-transferred). In a study conducted in South Africa<sup>17</sup> the evaluation of outcomes after being lost to follow-up showed that pregnant/postpartum women were less likely to have died (3.6%) and more likely to have migrated (7.5%) compared to the general population, while the majority had transferred to other facilities (29.3%). These findings suggest that transfers may become more common as treatment programs expand and patients can find ART centers close to their homes, and that participants in longitudinal studies may require frequent communications to update contact information, particularly in settings where mobility is common.<sup>18</sup> The very few data that we collected with the tracing activity (strongly affected by the COVID pandemic) are in line with that reported above, since several silent transfers were documented and in some cases no information was found at the address given. We cannot exclude that, in this last case, because of the stigma still associated with HIV infection, women may have given a wrong address at the enrolment visit.

Some heterogeneity in retention-in-care rates reported in the literature could be attributed to differences in the definitions used. We decided to use a simple measure to define retained women (attendance to the 12-month visit),

**Table 3.** Characteristics of mother/infant pairs according to the presence of testing for EID. Values are expressed as medians with IQR or percentages.

	All	EID testing within 2 months	No EID	p value
N. (%)	159	129 (81.1%)	30 (18.9%)	
Maternal age (years)	30 (25–34)	30 (25–34)	31 (25–34)	0.650
Body Mass index at enrolment (kg/m <sup>2</sup> )	25.3 (23.5–28.5)	23.1 (23.1–28.4)	25.8 (24.7–28.8)	0.190
Hemoglobin at enrolment (g/dl)	11 (9.9–11.9)	11 (9.9–11.9)	11.1 (10.1–12.0)	0.933
Marital status				
Married/cohabitating	150 (94.3%)	122 (94.6%)	28 (93.3%)	0.534
Single/separated/divorced	9 (5.7%)	7 (5.4%)		
N. of previous dead children				
0	120 (75.5%)	101 (78.3%)	19 (63.3%)	0.072
1–3	39 (24.5%)	28 (21.7%)	11 (36.7%)	
First pregnancy, N. (%)	22 (13.8%)	20 (15.5%)	2 (6.7%)	0.167
N. Children in the household				
0	21 (13.2%)	18 (14.0%)	3 (10.0%)	0.837
1–2	80 (50.3%)	64 (49.6%)	16 (53.3%)	
3–6	58 (36.5%)	47 (36.4%)	11 (36.7%)	
Residence				
Rural	23 (14.5%)	18 (14.0%)	5 (16.7%)	0.446
Semirural	84 (52.8%)	66 (51.2%)	18 (60.0%)	
Urban	52 (32.7%)	45 (34.9%)	7 (23.3%)	
Distance from the clinical center				
<2 km	58 (36.5%)	47 (36.4%)	11 (36.7%)	0.569
>2 km	101 (63.5%)	82 (63.6%)	19 (63.3%)	
Electricity at home				
Yes	81 (50.9%)	63 (48.8%)	15 (50.0%)	0.535
No	78 (49.1%)	66 (51.2%)	15 (50.0%)	
Water at home				
Yes	92 (57.9%)	53 (41.1%)	14 (46.7%)	0.360
No	67 (42.1%)	76 (58.9%)	16 (53.3%)	
Education				
None/primary	63 (39.6%)	55 (42.6%)	8 (26.7%)	0.078
Secondary or above	96 (60.4%)	74 (57.4%)	22 (73.3%)	
Employment				
Yes	53 (33.3%)	43 (33.3%)	10 (33.3%)	0.590
No	106 (66.7%)	86 (66.7%)	20 (66.7%)	
ART at enrolment				
TDF/XTC/EFV	131 (82.4%)	108 (83.7%)	23 (76.6%)	0.409
TDF/3 TC/DTG	12 (7.5%)	8 (6.2%)	4 (13.3%)	
Other	16 (10.1%)	13 (10.1%)	3 (10.0%)	
Time on ART at enrolment (months)	19 (3–85)	24 (3–86)	5 (3–78.5)	0.689
HIV-RNA at enrolment (% <40 copies/mL)	88.2% (n. 68)	87.7% (n. 57)	90.9% (n. 11)	0.617
Gestational age at delivery (weeks)	40 (38–42)	40 (38–42)	39 (37–41.25)	0.291
Place of delivery				
Hospital	63 (39.6%)	50 (38.8%)	13 (43.3%)	0.397
Health center	96 (60.4%)	79 (61.2%)	17 (56.7%)	
Mode of delivery				
Caesarean section	21 (13.2%)	17 (13.2%)	4 (13.3%)	0.591
Vaginal	138 (86.8%)	112 (86.8%)	26 (86.7%)	
Infant gender (% female)	78 (49.1%)	59 (45.7%)	19 (63.3%)	0.062
Infant birth weight <sup>a</sup>	3.6 (3.2–4.0)	3.5 (3.1–4.0)	3.65 (3.22–4.27)	0.487
Infant birth length <sup>a</sup>	50 (48–51)	50 (48–51)	49 (48–52.5)	0.831

IQR: interquartile range; ART: antiretroviral treatment; TDF: tenofovir; XTC: lamivudine or emtricitabine; EFV: efavirenz; DTG: dolutegravir; 3TC: lamivudine.

<sup>a</sup>Within 15 days of birth.

a common and simple definition that may allow comparability of the data reported.

In our cohort early infant diagnosis was performed in more than 80% of infants, in line with data reported in the last UNAIDS report for the country (79% in 2020).<sup>9</sup> Although this represents a high percentage (compared to a rate of testing in the country of only 21% in 2015), it would be important to identify associated factors to be able to address them with targeted interventions. However, in our study, independent predictive factors for a lack of EID were not clearly identified. Other studies have investigated on this topic: lack of maternal ART or infant prophylaxis,<sup>17–19</sup> lack of maternal ANC attendance,<sup>20,21</sup> new maternal HIV diagnosis,<sup>18</sup> lack of information about the importance of early testing<sup>22</sup> have all been identified as possible predictors of the lack of an EID. In one study in rural Malawi (2013–2016) it was also shown that receiving an infant HIV test result was associated to a reduced infant study retention, especially an infant's positive result.<sup>23</sup> Indeed, in our study, in the only case of HIV transmission, the mother/infant pair left the study soon after diagnosis. Also, one of the factors that were associated (although not significantly) with the lack of EID in our study was represented by a history of a previous child death, suggesting that a possible previous HIV infant diagnosis could prevent testing in a second infant.

All these findings indicate the critical role of providing specific counselling about the importance of timely infant testing and of the efficacy of early antiretroviral treatment in HIV-positive children.

Limitations of our study include the relatively small sample size, and that its generalizability can be affected by the fact that the study was conducted during the pandemic era. Strengths of this study can be considered the availability of detailed information of maternal socio-demographic characteristics, and of maternal HIV history and treatment.

## Conclusions

Adherence to all the steps of the PMTCT cascade is crucial, and model-based analyses have shown that elimination of vertical transmission could be reached by >90% adherence to each step.<sup>24</sup>

Efforts should be concentrated to improve counselling strategies both to address the issue of retention and to stress the importance of EID. Tracing may be recommended, especially for recent ART initiators.

## Acknowledgements

We thank Alessandra Mattei and Stefania Donnini for providing secretarial help, We also wish to thank Sangwani Salimu for contribution in the set-up of the study in Malawi.

## Authors' contributions

M.G., S.O., M.A. and M.F. were responsible for the design of the study, M.G. and M.F. drafted the manuscript, M.G. was responsible for conducting the statistical analysis, S.O. supervised the implementation and conduction of the project, B.M. was responsible for assessing maternal retention, R.M., and T.K. were responsible for clinical activities and data collection at the clinical sites, M.A., F.C., and M.C.M. contributed to interpretation of data and critically revised of the manuscript for important intellectual content.

## Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

## Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by a grant to the Istituto Superiore di Sanità from the Italian Agency for Cooperation and Development through the Global Fund 5% Initiative (Grant No. AID 011141/03/04) and is an Italy Independent Activity in the scope of EDCTP2 recorded as Participant State Initiated Activity-PSIA 2019-2072.

## ORCID iDs

Marina Giuliano  <https://orcid.org/0000-0003-2789-7797>

Marco Floridia  <https://orcid.org/0000-0003-3971-0141>

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