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Background: Nearly half of HIV-infected children worldwide are born in West and Central African countries where access to prevention of mother-to-child transmission of HIV (PMTCT) programmes is still limited. WHO recommends reinforced antiretroviral prophylaxis for infants at high risk of mother-to-child transmission of HIV (MTCT) but its implementation needs further investigation in the field.

Methods: The prospective ANRS 12344-DIAVINA study evaluated the feasibility of a strategy combining early infant diagnosis (EID) and reinforced antiretroviral prophylaxis in high-risk infants as identified by interviews with mothers at Ignace Deen Hospital, Conakry, Guinea.

Results: 6493 women were admitted for delivery, 6141 (94.6%) accepted HIV testing and 114 (1.9%) were HIV positive. Among these, 51 high-risk women and their 56 infants were included. At birth, a blood sample was collected for infant EID and reinforced antiretroviral prophylaxis was initiated in 48/56 infants (86%, 95% CI 77%–95%). Iron supplementation was given to 35% of infants for non-severe anaemia. Retrospective measurement of maternal plasma viral load (pVL) at delivery revealed that 52% of women had pVL < 400 copies/mL attributable to undisclosed HIV status and/or antiretroviral intake. Undisclosed HIV status was associated with self-stigmatization (85% versus 44%, $P = 0.02$). Based on the results of maternal pVL at delivery, 'real' high-risk infants were more frequently lost to follow-up (44% versus 8%, $P < 0.01$) in comparison with low-risk infants, and this was associated with mothers' stigmatization (69% versus 31%, $P < 0.01$).

Conclusions: Reinforced antiretroviral prophylaxis and EID at birth are widely feasible. However, mothers' self-disclosure of HIV status and antiretroviral intake do not allow adequate evaluation of MTCT risk, which argues for maternal pVL measurement near delivery. Furthermore, actions against stigmatization are crucial to improve PMTCT.

Introduction

Despite progress in the prevention of mother-to-child transmission of HIV (PMTCT), about 150 000 children were born with HIV in 2019. Worldwide, 85% of pregnant women living with HIV are receiving antiretroviral therapy (ART), however, regional disparities remain (58% in West and Central Africa; 95% in East and South Africa). In Western and Central Africa, the MTCT rate was 20% (16%–24%) in 2019: 42% of child infections occurred in children whose mothers never received ART during pregnancy and 18% occurred among breastfeeding children.[1]

The 2016 WHO guidelines recommended differentiated antiretroviral prophylaxis in infants according to their risk of MTCT. High risk of MTCT is defined by a maternal HIV plasma viral load (pVL) of >1000 copies/mL in the 4 weeks before delivery; or, if pVL measurement is not available, a duration of <4 weeks

of maternal ART at delivery; or a first time diagnosis of HIV infection at delivery or during breastfeeding. The recommended antiretroviral prophylaxis regimens for breastfed infants are: nevirapine for 6 weeks if there is a low risk of MTCT or, if there is high risk of MTCT, zidovudine/nevirapine dual prophylaxis for 6 weeks, followed by 6 weeks of either nevirapine single prophylaxis or nevirapine/zidovudine dual prophylaxis.[2]

WHO recommends the early diagnosis of HIV infection (EID) in HIV-exposed infants at 4–6 weeks after birth. This enables HIV-infected infants to initiate ART before 8 weeks of life, resulting in reduced HIV related morbidity and mortality in childhood.[2,3] Indeed, without ART, 50% of infants infected during the perinatal period (*in utero* and *per partum*) die during the first 2 years of life.[4] However, this WHO recommendation is poorly implemented in resource-constrained countries. In 2019, the proportion of HIV-exposed infants receiving HIV testing within 8 weeks was 60% worldwide, and it was only 33% in Western and Central Africa.[1] In addition, delays within the cascade of paediatric HIV diagnosis and management (from offering and accepting tests, transporting and processing samples to returning results to caregivers and families) adversely affect retention in care. The average time taken for the return of EID results is 2–3 months, and it is estimated that 34% to 75% of children exposed to HIV die or are lost to follow-up.[5]

In Guinea, HIV prevalence is 1.7%. Despite significant decentralization of PMTCT care (323 PMTCT sites in 2016 serving a population of 10 628 972), antenatal consultation is offered to only 56% of pregnant women, of whom 66% are tested for HIV (37% of all pregnant women). In this setting, Solidarité Thérapeutique et Initiatives pour la Santé (Solthis) in collaboration with the Programme national de Lutte contre le VIH SIDA et les Hépatites (PNLSH) conducted a pilot project from July 2013 to March 2014 implementing systematic HIV screening among pregnant women delivering at two university Hospitals in Conakry, Guinea. Among 7113 women admitted to the delivery rooms, 6188 (87%) had not been tested for HIV during pregnancy. Despite a transient shortage in the supply of HIV tests, HIV testing was offered to 3706 women, 3631 (98%) consented and were tested, and 141 were diagnosed with HIV (3.9%) (Solthis and PNLSH, unpublished data). These findings later encouraged the PNLSH to implement systematic HIV screening in the delivery rooms (Plan for Accelerating Paediatric HIV Care in Guinea 2017–2020). In addition, access to EID and antiretroviral prophylaxis for HIV-exposed infants remains poor. In 2015, only 246/2214 (11%) of HIV-exposed infants were tested within 2 months. Among them, 43/246 (21.5%) were HIV positive and only 17/43 (39.5%) initiated antiretroviral therapy (PNLSH data).

The ANRS 12344-DIAVINA study aimed to evaluate the feasibility of reinforced antiretroviral prophylaxis and EID in infants born to women identified as at high risk of MTCT in delivery rooms.

Patients and methods

The ANRS 12344-DIAVINA study (NCT 03642704) was a prospective non-comparative study.

Main objectives

These were: (1) to assess the cascade of HIV testing in the delivery room; (2) to assess the feasibility of a strategy combining EID at birth and initiation of reinforced antiretroviral prophylaxis within 48 h of birth in infants with a high-risk of MTCT. The strategy was defined as successful if the proportion of infants receiving EID and reinforced antiretroviral prophylaxis was ≥80%; (3) to assess the safety of the reinforced antiretroviral prophylaxis (combining zidovudine/lamivudine and nevirapine) particularly regarding rates of haematologic side effects; and (4) to assess the cascade of care in the management of HIV infected mothers and their infants.

Participants

Enrolment was conducted between February 2017 and March 2018; follow-up was completed in September 2019. Women were recruited through the maternity ward of the Ignace Deen Hospital in Conakry, Guinea. HIV testing was offered to all pregnant women presenting for delivery according to national recommendations. All HIV-infected pregnant women were invited to enrol if they had not initiated ART or had received <4 weeks of ART before delivery. Enrolment criteria included: age >18 years old, admission for delivery; high risk of HIV MTCT defined by an established HIV infection in women who have received <4 weeks of ARV at the time of delivery or a new diagnosis of HIV infection during delivery, according to the WHO definition.

Procedures

All participants provided written informed consent. They underwent screening evaluations, which included a medical history, a physical examination, and laboratory testing including complete blood count, pVL, CD4 cell count, creatinine, and ALT. All laboratory testing was done at the Institut National de Santé Publique (INSP) laboratory in Conakry, Guinea. pVL was quantified using the Generic HIV-1® (Biocentric). Women newly diagnosed with HIV were initiated on a tenofovir/lamivudine/efavirenz regimen at delivery as recommended by the PNLSH. Women were counselled to exclusively breastfeed their infants for the first 6 months with complete cessation of breastfeeding at 12 months. Infants initiated zidovudine/lamivudine/nevirapine prophylaxis within 48 h of birth, and trimethoprim/sulfamethoxazole from 6 weeks of age until they were confirmed to be HIV negative by HIV serology at 18 months. Infant HIV testing was performed by PCR at birth, at 14 weeks, and at 6, 9, 12 months of age. The PCRs were performed at the INSP laboratory (Conakry, Guinea) before September 2017 using a homemade real-time PCR based on Generic HIV-1® (Biocentric); then between September 2017 and April 2018, at the Virology laboratory of Necker Hospital (Paris, France) using Generic HIV-1® and Generic DNA® (Biocentric), and, finally at the Virology laboratory at Donka Hospital (Conakry, Guinea) from April 2018, using Xpert® HIV-1 qual (Cepheid). HIV serology was performed at 9 and 18 months using Alere Determine® rapid test. HIV infection was based on two positive PCR tests obtained from two different blood samples. Every infant who tested positive for HIV initiated the zidovudine/lamivudine/lopinavir + ritonavir regimen immediately according to WHO guidance from 2016.[6]

We graded adverse events according to the 1992 adult and 1994 paediatric toxicity tables of the Division of AIDS (DAIDS), NIH.[7] Serious adverse events (SAEs) were defined as grade 3 or 4 toxicity confirmed on a repeat visit or as illness resulting in death or hospitalization. Causes of death were determined by review of hospital records (if available) and/or by interviewing the mother or the caregiver (verbal autopsy).

Women and infants were followed for 72 weeks: study visits were scheduled at delivery (day 0), 2, 4, 8, 12, 14, 24, 36, 48 and 72 weeks. During study visits, we assessed adherence to drugs and feeding recommendations, performed clinical evaluations, and provided psychosocial counselling. Haemoglobin was measured in infants by colorimetry at 4 and 8 weeks. Criteria for discontinuation of zidovudine were blood haemoglobin ≤7 g/dL at week 4 or blood haemoglobin ≤6 g/dL at week 8. In women, pVL was measured at 4, 12, 24, 36, 48 and 72 weeks; blood count, creatinine and ALT were measured at 4, 12, 24, 48 and 72 weeks; and CD4 count was measured at 48 weeks. The study reimbursed

transport costs for both scheduled and unscheduled visits, and it also contributed to the cost for all outpatient and inpatient care for the study participants. The ARVs were supplied by PNLSH.

Additional substudy

In September 2017, because of unexpected results of pVL measurement in some women (see results), mothers' plasma samples were tested with Western Blot at the virology laboratory of Necker Hospital (Paris, France) and screened for antiretrovirals at the Pharmacology laboratory of Bichat Hospital (Paris, France). This substudy was conceived when the first 10 participants who had not reported taking antiretrovirals were found to have pVL <400 copies/mL at delivery. The discovery of antiretrovirals in plasma assays of participants who had not reported taking antiretrovirals led us to carry out a survey using self-administered questionnaire on the factors associated with non-disclosure of HIV status and antiretroviral use. Adequate disclosure of HIV status was defined by a pVL >400 copies/mL at delivery in women disclosing a newly diagnosed HIV status or by a disclosure of established HIV infection irrespective of ART status and pVL at delivery. This substudy was conducted in December 2017 among all women included at the time of this survey ($n=40$, 43 included, 2 pVL at delivery unavailable, 1 lost to follow-up).

Statistical analysis

χ^2 and Fisher exact tests were used.

Ethics

This study was approved by the ethics committee of Guinea, CNERS (Comité d'Ethique pour la Recherche en Santé) (Study number: 139/CNERS/16). Each participant provided written informed consent.

Results

HIV testing at delivery room and HIV prevalence

Among 6493 pregnant women admitted for delivery between February 2017 to February 2018, HIV counselling and testing was proposed to 6431 subjects (99.0%), of whom 6141 agreed to be tested (95.5%). HIV testing was positive in 114 cases (HIV prevalence = 1.9%; 95% CI 1.5%–2.2%).

Inclusion

Among 114 women diagnosed with HIV at the time of delivery, 57 (50%) were considered at low risk of MTCT because they reported knowing their HIV status and having been on ART for >4 weeks. 57 (50%) were considered at high risk of MTCT because they declared to be newly diagnosed with HIV or to have received ART for <4 weeks. A total of 51 'high-risk' mothers (89% of eligible patients) and 56 infants (including 5 twin pairs) were included (Figure 1). The reasons for non-inclusion were: neonatal death ($n=2$), maternal and neonatal death ($n=1$), refusal ($n=1$), situation threatening the respect of anonymity (health care worker) ($n=1$), mother–child pair left the maternity ward before receiving information from the investigators ($n=1$).

Characteristics of mothers at inclusion

Among the 51 'high-risk' mothers, 38 declared that they discovered their HIV status at delivery. The rest knew their HIV statuses but declared that they had not received antiretroviral therapy. Median age was 30 years (IQR 26–36) and median CD4 cell count was 411 cells/mm^3 (IQR 315–490). Among the 48 'high-risk' women included in the study with blood samples available at delivery, pVL was <400 copies/mL in 25 participants (52%). We retrospectively tested plasma samples obtained at delivery in the 10 first women who declared unknown HIV status ($n=6$) or no ARV intake ($n=4$) but had pVL <400 copies/mL. HIV-1 infection was confirmed by Western blot and ARVs were detected in the plasma in all cases indicating that 10/10 women were virologically suppressed on ART but did not disclose their HIV status and/or ARV treatment at delivery (Table 1).

Subsequently a quantitative substudy of 40 women (43 included at the time of this substudy, 2 pVL at delivery unavailable, 1 lost of follow-up) was performed to assess the factors associated with the non-disclosure of HIV status to healthcare workers at delivery. In this substudy, non-disclosure of HIV status was defined by a pVL <400 copies/mL at delivery in women declaring to be newly diagnosed with HIV ($n=13$). Non-disclosure of HIV status was associated with difficulties in talking about HIV (85% versus 44%, $P=0.02$). Socio-demographic characteristics, understanding of the study or indirect benefit from participation in the study were comparable irrespective of HIV disclosure status (Table 2).

Feasibility of the strategy and follow-up

Overall, 86% (95% CI 85%–100%) of infants received EID and initiated reinforced antiretroviral prophylaxis at birth and 79% (95% CI 68%–90%) completed the 12 weeks antiretroviral prophylaxis. 16/52 (31%, 95% CI 18%–43%) infants were lost to follow-up at 72 weeks. Based on the results of maternal pVL at delivery, we classified infants as having 'real' high-risk of MTCT (maternal pVL ≥ 400 copies/mL) or low risk of MTCT (maternal pVL < 400 copies/mL) (Table 2). High-risk of MTCT infants completed the 12 week ARV prophylaxis (64% versus 96%, $P=0.01$) less frequently; were more frequently lost to follow-up at 72 weeks (48% versus 8%, $P<0.01$); and were more likely to be HIV-infected from birth to 18 months (27% versus 11%, $P=0.02$) (Table 3) as compared with low risk of MTCT infants.

The main reason of loss to follow-up was stigma, in the form of maternal self-stigmatization and stigmatization by their relatives (in 11 cases), according to the psychosocial counsellors. Stigma (69%) was significantly more frequent than economic constraints $n=2$ (12%) and travel outside Conakry $n=3$ (19%), $P=0.002$.

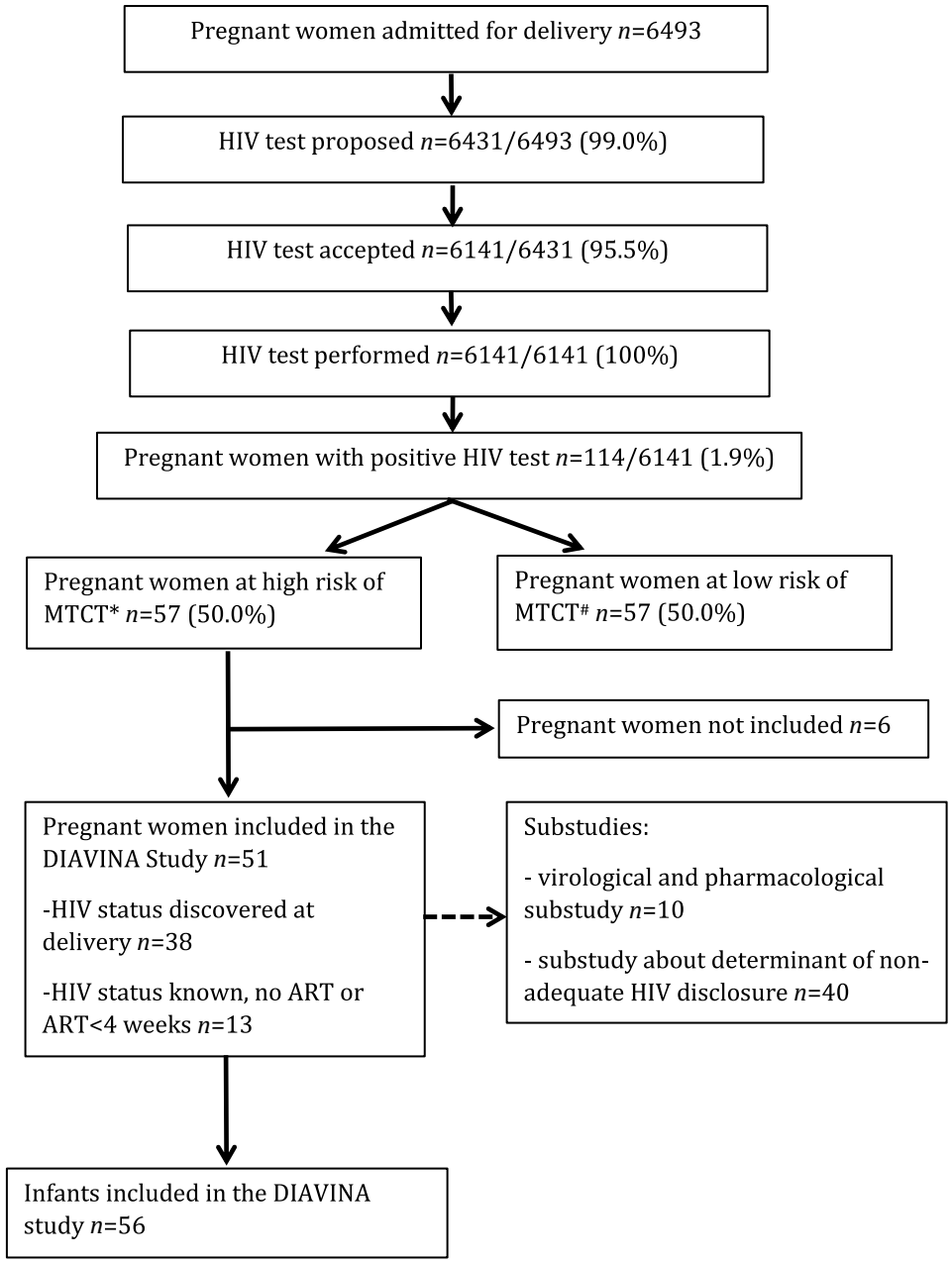
Virological outcome

Among 25 women with VL < 400 copies/mL at inclusion, 45% (95% CI 25%–66%) experienced virological failure defined by at least one pVL > 400 copies/mL during follow-up. Among 23 women with pVL > 400 copies/mL at inclusion, 31% (95% CI 8%–54%) experienced virological failure defined by at least one pVL > 400 copies/mL after 6 months of follow-up ($P=0.50$).

Overall, four HIV infections were diagnosed in infants and in all cases, they were born to mothers with pVL >6 $\log_{10}$ copies/mL at delivery. Three newborns were diagnosed with HIV at birth and one was diagnosed with HIV at 6 months (Table 4).

Adverse events

Among the infants, 81 adverse events occurred in 37 infants. Fourteen serious adverse events (SAEs) including 4 deaths



*High risk of mother-to-child transmission (MTCT): HIV diagnosis at delivery or HIV status known before delivery with no antiretroviral therapy (ART) initiated or ART initiated less than 4 weeks before delivery.

#Low risk of MTCT: HIV status known before delivery and ART initiated (and not interrupted) for more than 4 weeks before delivery.

Figure 1. Flow chart.

occurring before the age of 3 months were reported in 12 infants; these SAEs were pneumopathy, *n*=2; malaria, *n*=4; diarrhoea and dehydration, *n*=4; early neonatal infection, *n*=1; severe acute malnutrition, *n*=2; staphylococcus sepsis, *n*=1; candidiasis, *n*=1 and unexplained death, *n*=2. Cause of death included: diarrhoea, dehydration and severe acute malnutrition in one

Table 1. Virological and pharmacological results of women with HIV-RNA <400 copies/mL at inclusion ($n=10$)

			ARV plasma concentration (ng/mL)					
HIV status and ARV intake disclosure	Western blot	HIV-RNA (copies/mL)	TDF	ZDV	FTC	3TC	EFV	NVP
HIV diagnosed at delivery								
Patient 1	HIV-1	<400	21		<10		180	
Patient 2	HIV-1	<400	59		466		3646	
Patient 3	HIV-1	<400	69		39		2393	
Patient 4	HIV-1	<400	46		14		737	
Patient 5	HIV-1	<400	31		<10		167	
Patient 6	HIV-1	<400	51		82		834	
HIV-infected, no ART								
Patient 7	HIV-1	<400		67		331		9271
Patient 8	HIV-1	<400	216		209		2733	
Patient 9	HIV-1	<400		<10		87		6173
Patient 10	HIV-1	<400	116	1551				669

Abbreviations: ARV, antiretroviral; TDF, tenofovir disoproxil fumarate; ZDV, zidovudine; FTC, emtricitabine; 3TC, lamivudine; EFV, efavirenz; NVP, nevirapine.

child, and respiratory distress at birth in one child. In two children, death occurred at home with diarrhoea reported in one and no information in one.

No treatment-related SAEs associated with reinforced antiretroviral prophylaxis were reported.

Among mothers, a total of 16 adverse events were reported in 11 women. Three SAEs were reported in two women, and one of them died (tenofovir disoproxil fumarate-related acute renal failure, liver failure, coma and death).

Haematological tolerance of reinforced antiretroviral therapy in infants

Haemoglobin measurements were available in 46/56 infants. Median haemoglobin was 10 g/dL (IQR 9.5–10.5) at week 4 and 9.5 g/dL (IQR 8.5–11) at week 8. Overall, 16/46 (35%) infants required iron supplementation due to minor to moderate anaemia (10 infants at week 4, 6 at week 8). No infant required zidovudine interruption due to anaemia.

Discussion

These results highlight the feasibility, the acceptability and the value of HIV testing of pregnant women at delivery since a quarter of HIV-infected women discovered their infection at delivery. This project increased HIV screening in the delivery room of Ignace Deen Hospital (Conakry, Guinea); HIV testing was performed in 94.6% of women at delivery (6141/6493) during the study versus 65% (3071/4757) of women delivering during the previous 12 months ($P<0.01$). Improving access to HIV testing at delivery is even more necessary in rural areas because of high rural–urban inequalities in access to prenatal care coverage in West and Central Africa regions.[8] Early infant diagnosis at birth and reinforced ARV prophylaxis seems feasible and it contributed to the wide adoption of breastfeeding, which is recommended in this context.[9] The tolerance of 12 weeks of reinforced zidovudine, lamivudine and nevirapine-based prophylaxis was acceptable.

However, we were surprised by the high proportion of women who were reluctant to disclose their HIV status or ART intake to health care workers despite the better conditions offered by this research as compared with the routine conditions in Guinea. Indeed, we provided access to a consultation office that allowed for confidentiality, and support from a psychosocial counsellor who was a member of a civil society organization for people living with HIV (PLWH). Non-disclosure of HIV status does not appear to be related to misunderstanding of the study or to indirect benefits of the protocol, but rather to a reluctance to speak about HIV with health care workers, which suggests self-stigmatization. Non-disclosure of HIV status and/or ART intake has been previously reported at 21% and 36% from PLWH household surveys conducted in Kenya and in South Africa, respectively.[10,11] Similarly, in a population-based health campaign in rural Uganda, 10% of people who declared they were not on ART were virologically suppressed.[12] In a retrospective study of the databases of two Parisian hospital laboratories, antiretrovirals were detected in the plasma of 74% of patients with undetectable pVL. These patients declared they were unaware of their HIV infection, and most of them were African immigrants.[13] Among pregnant women, 5% of those initiating ART had pVL < 400 copies/mL in Kenya and 30% had pVL < 1000 copies/mL in Uganda, also suggesting concealed ART intake.[14,15] The high rate of non-disclosure observed in our study could be linked to the high level of HIV stigma reported by 80% of PLWH in Guinea[1] and to the fear of HIV disclosure to relatives, which are key barriers to PMTCT in Africa.[16] The weight of the stigma is considerable, and over time significantly contributes to high rates of HIV vertical transmission.[17]

WHO recommends the use of pVL to better estimate the MTCT risk, however, access to pVL testing for pregnant women remains a challenge in sub-Saharan Africa, especially at the end of pregnancy.[18] In case of unavailable pVL testing, WHO recommends estimation of the risk of MTCT based on mother interview. Our results suggest that such a recommendation may overestimate the risk of MTCT in some women, leading to unnecessary

Table 2. Factors associated with non-disclosure of HIV status to health care workers (HCW) at delivery ($n=40$)

Characteristics	Non-disclosure of HIV status to HCW ($N=13$)	Adequate disclosure of HIV status to HCW ($N=27$)	*P* value
Sociodemographics			
Age (median)	28	31	NS
Marital status	92%	70%	NS
Non-disclosure of HIV status to relatives (retrospective assessment)	92%	78%	NS
Primiparity	38%	48%	NS
Secondary and university education	69%	59%	NS
Understanding of the interest of the study			
Correct understanding of the protocol	69%	63%	NS
Main reason to participate in the study declared by women			
Access to the best care for their children	31%	52%	NS
Access to the best care for themselves	38%	19%	NS
Access to early infant diagnosis	31%	19%	NS
Access to free care and free transportation for follow-up visit	0%	4%	
Main concern about HIV care in the hospital			
Difficulty to speak about HIV with health care workers	85%	44%	0.02
Fear of loss of confidentiality	15%	44%	NS

NS, not significant.

reinforced antiretroviral prophylaxis for their child. Additionally, in cases where women declared to have received >4 weeks of ART before delivery, low-risk classification of MTCT based on mother interview could lead to offering suboptimal prophylaxis to children in case of virological failure in their mother, which would remain undiagnosed in the absence of viral load measurement. Virological failure is frequent in pregnant women; in South Africa, 22% of pregnant women receiving ART had pVL> 1000 copies/mL at delivery.[19] This high rate of virological failure was most frequently associated with non-adherence rather than to resistance to ART.[20] To conclude, implementation of pVL testing close to delivery at scale is urgently needed in order to objectively estimate the risk of MTCT, and then adapt the ARV neonatal prophylaxis and the care of the mother/child pair.

In this study, although sampling for the EID was easily performed, testing using the homemade real-time PCR in Guinea based on Generic HIV-1® (Biocentric) was not feasible. Therefore, samples were transported and analysed in a virology laboratory in France. This caused a considerable delay in reporting the results and initiating ART for infected infants. We later used Xpert® HIV-1 qual, but it was too late to offer timely EID for majority of the infants included. WHO recommendations have changed over time and the benefit of point-of-care testing for EID is now recognized.[21] Point-of-care EID allows for a considerable reduction in the turnaround time of results and an increased number of infected infants receiving ART before the sixtieth day of life. An observational study of 1793 infants in Malawi compared the use of point-of-care EID with the reference diagnostic test in a centralized laboratory. The use of point-of-care EID increased the proportion of HIV-infected infants who initiated ART before 60 days from 41.9% to 91.1%.[22] One of the advantages of the GenXpert platforms is their versatility, which allows efficient multidisease testing including COVID-19, hepatitis B and C, TB, and HIV (pVL and EID).[23] The use of the GenXpert platforms widely deployed for TB diagnosis to carry out EID and viral load measurements for pregnant women in the third trimester or in the delivery room would be an interesting option to consider. Such an intervention would make it possible to apply not only the WHO recommendations for improved access to EID, but also those concerning differentiated prophylaxis with a real assessment of the risk of MTCT based on maternal pVL.

Our study also revealed that a high number of infants were lost to follow-up (16/52 during the 72 weeks follow-up), especially among infants born to mothers with high pVL who have the greatest need for reinforced antiretroviral prophylaxis and for follow-up. Maintenance in care and adherence to ART in pregnant and breastfeeding women remains a considerable challenge in sub-Saharan Africa,[24] with consequences for both mother and infant, since it is estimated that half of the infants with confirmed HIV infection at birth are lost to follow-up.[5] In our study, HIV stigmatization and self-stigmatization were more often declared by women whose children were later lost to follow-up. Previous studies identified that close follow-up and appointments by phone or SMS may improve the postnatal retention in care.[25] However, the financing of transport, the support by the psychosocial counsellors, and telephone reminders did not prevent the loss to follow-up of one-third of mother/child pairs in our study, suggesting that this proportion could be higher in Guinea in the absence of these enablers.

Our study suffers from many limitations, including the monocentric study design and the low number of inclusions. This feasibility study was not designed to demonstrate the efficacy of reinforced ARV prophylaxis, so the low numbers of inclusion do not allow us to draw any conclusions on efficacy. This study was also not designed to study the impact of stigma on EID and reinforced antiretroviral prophylaxis. Also, the definition of stigma, which was based on interpretation by psychosocial counsellors, may be questionable. The definition of non-HIV status disclosure and/or non-ART intake disclosure, based on the pVL measurement rather than plasma ARV levels, may have contributed to underestimation of the proportion of women who did not report ART intake to health care providers. Finally, the difficulties in developing the EID sample testing procedure required the use

Table 3. Comparison of early infant diagnosis (EID) and reinforced antiretroviral prophylaxis at birth, clinical and virological outcome between children at 'real' high-risk and low-risk of mother-to-child transmission (MTCT) (based on the results of maternal VL at delivery)

Characteristics	High-risk MTCT children (maternal VL >400 copies/mL at delivery)	Low-risk MTCT children (maternal VL <400 copies/mL at delivery)	Total	*P* value
Number of children	*N*=27	*N*=26	*N*=56	
Exclusive breastfeeding	23/25 (92%, 81%–100%)	21/24 (88%, 74%–100%)	47/52 (90%, 82%–98%)	NS
Breastfeeding duration, months (median, IQR)	9.9 (7.8–10.8)	10.6 (7.9–12.9)	10.2 (7.7–12)	NS
EID collected and reinforced ARV prophylaxis prescribed at birth, *n*/*N* (%, 95% CI)	23/27 (85%, 72%–99%)	23/26 (88%, 76%–100%)	48/56 (86%, 85%–100%)	NS
Completion of 12 weeks reinforced ARV prophylaxis, *n*/*N* (%, 95% CI)	16/25 (64%, 45%–82%)	23/24 (96%, 88%–100%)	41/52 (79%, 68%–90%)	0.01
Loss of follow-up at birth, *n*/*N* (%, 95% CI)	6/27 (22%, 7%–38%)	1/25 (4%, 0%–12%)	8 (14%, 5%–23%)	NS
Loss of follow-up between birth and Week 72, *n*/*N* (%, 95% CI)	12/25 (48%, 28%–68%)	2/24 (8%, 0%–19%)	16/52 (31%, 18%–43%)	0.004
Death *n*/*N* (%, 95% CI)	2 (7%, 0%–17%)	2 (8%, 0%–18%)	4 (7%, 0%–14%)	NS
HIV infection diagnosed at birth, *n*/*N* (%, 95% CI)	3/18 (17%, 0%–34%)	0/24 (0%, 0%–13%)	3/44 (7%, 0%–14%)	NS
HIV infection from birth to 18 months, *n*/*N* (%, 95% CI)	4/15 (27%, 4%–49%)	0/22 (0%, 0%–14%)	4/37 (11%, 1%–21%)	0.02

NS, not significant.

Table 4. Maternal plasma HIV-RNA, timing of ART initiation and follow-up of HIV-infected children

	Patient			
Characteristics	009	011	020	023
Maternal plasma HIV-RNA (log_{10} copies/mL)				
Day 0 (birth)	6.17	6.54	6.70	7.53
Week 4	4.09	4.25	3.76	4.77
Week 12	<2.60	3.71	<2.60	ND
Week 24	6.12	<2.60	<2.60	ND
Date of collection of the first positive EID	Week 24	Day 0	Day 0	Day 0
Delay between EID sample and ART initiation (days)	148	434	98	46
Follow-up	LTFU at 12 months	In care at 18 months	In care at 18 months	Death at 53 days of life

EID, early infant diagnosis; ART, antiretroviral therapy; LTFU, lost to follow-up; ND, not done.

of all available samples and did not allow us to perform additional analyses to document ART adherence with systematic pharmacological data or to document HIV resistance.

Conclusions

These results highlight the value of HIV testing at delivery, since at least one-quarter of HIV-infected women discovered their infection at delivery. This could be even more useful in rural areas where PMTCT programmes are less implemented. EID at birth and reinforced antiretroviral prophylaxis seem feasible, and the tolerability of 12 weeks of zidovudine/lamivudine/nevirapine reinforced prophylaxis is acceptable.

However, the high level of HIV stigma observed in Guinea may jeopardize the evaluation of the risk of MTCT based on mother interview at delivery, and increase the risk of postnatal loss to follow-up of mother–infant pairs at high risk of MTCT. In this context, the implementation of pVL testing close to delivery at scale and the development of interventions to fight stigma are urgently needed to eliminate MTCT in Guinea.

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