ANRS CO1/CO11 EPF – Information for researchers

Title: National prospective study on mother-to-child transmission of HIV-1 and/or HIV-2 and its prevention

In brief	Principal Investigator: Dr Josiane WARSZAWSKI
	Organisation/teams: INSERM-Université Paris-Saclay Joint Unit – CESP-INSERM U1018 – Clinical Epidemiology and Pharmacoepidemiology Team / AP-HP Health Service Public
	Date: The first participant was enrolled on 24 September 1984 End of mother enrolment: 28 June 2022 End of follow-up for newborns: 29 March 2023
	Average number of mother-child pairs expected: 900 to 1,000 annually, totalling total: 26,976 women living with HIV enrolled during pregnancy or at delivery (9,988 before 2005, 11,291 in CO1 and 5,687 in CO11).
	Research status: Completed
	Condition: HIV-1 and HIV-2
	Funding body: Inserm – ANRS MIE
	Funded by ANRS MIE
The project	The ANRS CO1 EPF study is a national prospective cohort study, launched in late 1984, aimed at estimating the rate of mother-to-child transmission of HIV-1 and/or HIV-2 (MTCT), assessing its trends, and subsequently evaluating the tolerability and efficacy of strategies to prevent this transmission (PMTCT), as well as identifying situations of vulnerability. From 2004 onwards, it comprised a detailed arm (CO1) and a simplified arm (CO11), drawing on a network of maternity units in France and the French overseas departments, including approximately 900 HIV-positive women each year who wished to carry their pregnancies to term, as well as their newborns. Newborns born to these mothers who were diagnosed as HIV-positive were included in the CO10 cohort for long-term follow-up until they reached the age of majority. The main objective, initially focused on assessing the effectiveness of PMTCT strategies, shifted from the 2000s onwards towards identifying the impact of antiretroviral treatments on the health of mothers and uninfected children in the short, medium and long term. Specific objectives include the study of PMTCT practices, risk factors for non-adherence to recommendations, the role of precarious living conditions, disclosure of HIV status, and co-infections. The study also examines the effects of treatment on pregnancy, preterm birth, congenital malformations and infant morbidity. Follow-up is based on clinical and biological data collected for up to 24 months in the child, with the period extended in the event of illness. Samples for biobanks were collected with the mothers' consent. Inclusion in the cohort is based on the collection of a 'no objection' declaration, except in the case of biobanks, for which explicit consent was sought. Since Amendment 15, no further samples have been collected for biobanks. The study has contributed to public health surveillance, the improvement of guidelines and the implementation of therapeutic trials.
Publication References	List of CO1/CO11 publications in the appendix
Study type	National, prospective, multicentre cohort study
Main objectives	Launched in 1985 (with a single enrolment at the end of 1984), the objectives of this cohort have evolved in line with advances in the prevention of mother-to-child transmission of HIV. From 2005 onwards, the was to assess the tolerability of strategies for the prevention of

	prevention of mother-to-child transmission of HIV (PMTCT), the efficacy of which has been demonstrated, both for the mother during pregnancy and the postpartum period and for the child in the short, medium and, where possible, long term. This observational study, conducted within the largest and longest-running national cohort, primarily involved describing the combined evolution of PMTCT strategies and the sustained effectiveness of these strategies in preventing transmission, alongside their impact on the course and outcome of pregnancy and their toxicity/tolerability in children not infected with HIV.
Specific objectives	• To investigate the frequency and risk factors associated with PMTCT strategies that do not comply with expert group recommendations, taking into account how these have evolved over time, • To analyse the role of precarious living conditions and the disclosure of HIV status on clinical management • To assess the impact of changes in clinical management over time on transmission rates, particularly in terms of the timing of cART initiation and the type of medicines, mode of delivery, perinatal and postnatal prophylaxis, as well as practices that are on the rise (assisted reproductive technology, amniocentesis, etc.) • To assess trends in the prevalence of breastfeeding amongst women living with HIV, which is not currently recommended in France • To study the immunovirological response during pregnancy according to the duration and type of antiretroviral treatment received • To investigate the relationships between preterm birth, modes of delivery and therapeutic strategies, and the associated morbidity • To estimate the incidence of conditions occurring during and following pregnancy, their association with preterm birth and their links to the antiretroviral treatments received • To investigate the prevalence, management and risk of transmission of maternal co-infections (HBV, HCV, CMV). • To assess the potential role of maternal HIV, social vulnerability, perinatal exposures or obstetric management with antiretrovirals on growth, perinatal and infant mortality, the occurrence of congenital malformations, haematological and biochemical abnormalities, serious infectious diseases, serious neurological disorders, cancers, endocrine disorders or conditions related to mitochondrial toxicity, and unexpected conditions in uninfected children • To assess the medium- and long-term health risks for children not infected with HIV
Inclusion criteria for inclusion	Any woman of legal age infected with HIV-1 and/or HIV-2 is eligible: - who wishes to carry her pregnancy to term and give birth in one of the maternity units participating in the study (list in the appendix). Inclusion takes place as soon as possible after conception, regardless of the outcome, if possible before the 28th week, - or who has had a pregnancy monitored at one of the maternity units participating in the study, regardless of the outcome, - or giving birth at one of the maternity units participating in the study, - and not having expressed any objection to taking part. In all three cases, HIV infection must have been known prior to this pregnancy or diagnosed during the pregnancy or within 7 days following delivery.
Exclusion inclusion	None
Main primary assessment	Mother-to-child transmission of HIV,

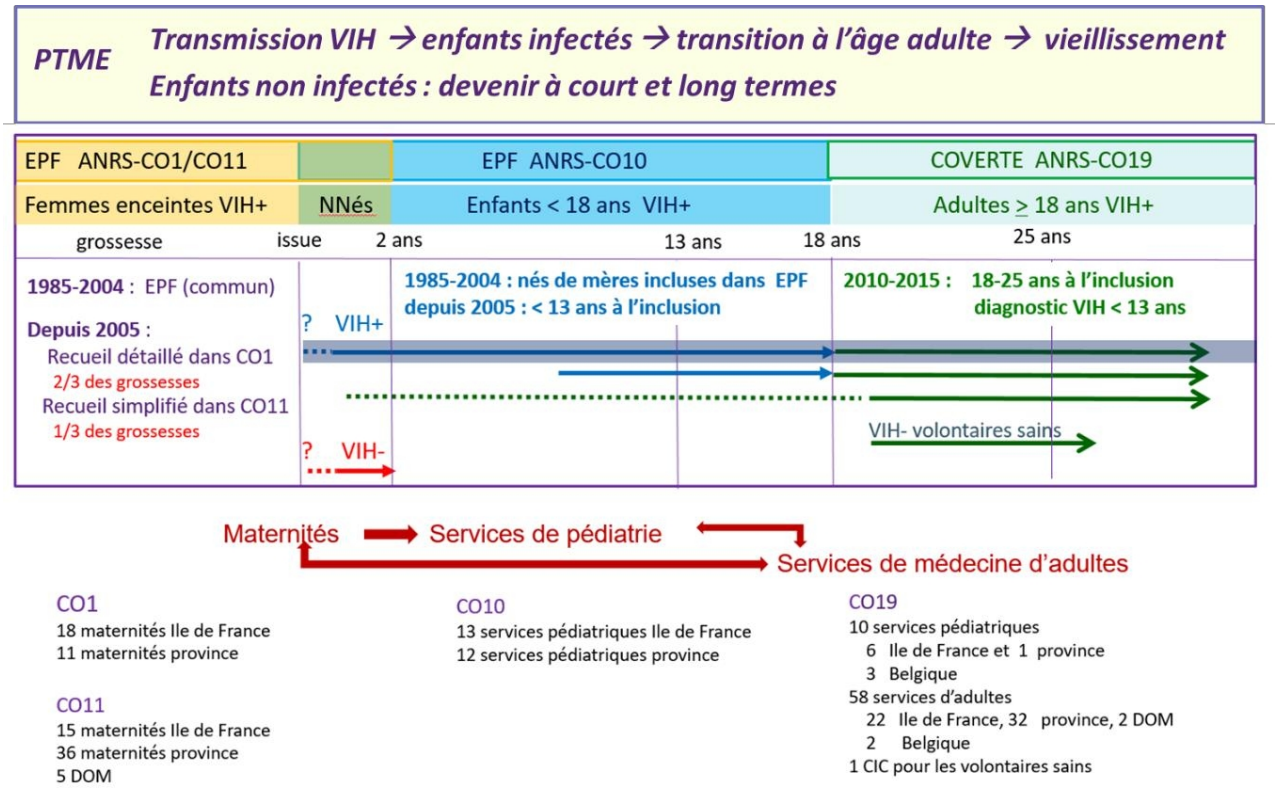
Secondary outcome measures	Mode of delivery Maternal and neonatal health indicators Infant development up to 24 months Adverse effects of PMTCT strategies

Summary

A – Study methodology and type of data and/or samples collected

Data and samples collected	**Biobanks**	For pregnant women included in ANRS-CO1 who have signed a written consent, a biobank is centralised at the National Centre for Perinatal Haemobiology Reference Centre at Saint-Antoine Hospital in Paris (in charge: A Mailloux, S Renoul), comprising aliquots of: 1°) **between 1989 and 2001**: cells initially stored in liquid nitrogen, subsequently transferred to -80°, plasma and serum from samples **taken from mothers and children** included in the EPF cohort *prior to it evolved into CO1/CO10/CO11 from 2005 onwards*. All samples were repatriated from the sites, including the serobank of the SEROGEST sub-study, stored at the Antoine Béclère Hospital in Clamart, was was also transferred in 2007 to the CNRHP in Saint-Antoine. 2°) **between 2005 and 2019:** whole blood and plasma from two 7-ml EDTA tubes collected at the end of pregnancy for the purpose of freezing three 1-ml aliquots of plasma and three 1-ml aliquots of whole blood **taken from the mothers at the end of pregnancy**, frozen and stored in the laboratories of the ANRS CO1 centres, then returned on average once a year, at –80°C by an approved courier, from the laboratories at the inclusion or follow-up sites to the CNRHP at Saint-Antoine Hospital in Paris (storage at -80°C). A complete blood count was to be ordered and collected on the same day. **This biobank is to be transferred to the ANRS biobank in Bordeaux**
	Data collected	The data collected have evolved since 1984 to keep pace with advances in knowledge and emerging issues. These detailed therapeutic, clinical and biological questionnaires were completed by doctors or medical assistants based on medical records: for mothers, at the end of pregnancy; for children: at birth, at 6 months (summarising the 1-, 3- and 6-month check-ups), 12 months and 18–24 months, and beyond 2 years via follow-up forms in the event of persistent clinical or persistent biological abnormalities. The sites participating in the ANRS-CO11 study – the 'National Observatory for Children Born to HIV-Positive Mothers' " prior to Amendment 15 continued, if they so wished, to complete a simplified case report form.

Research design: **ANRS EPFCO1/CO11/CO10 and COVERTE CO19 mother-child cohorts**



(*) Nnés: newborns

Sampling schedule: no samples were taken as part of the cohort, except for the biobank from pregnant women and children, provided signed consent was obtained.

Follow-up procedures: **standardised data collection based on routine medical follow-up. This data collection has varied over time to adapt to new research questions in line with advances in PMTCT strategies, with the following from 2005 onwards:**

- For mothers: detailed data in CO1 at the 1st,2nd and 3rd trimesters, and at the end of pregnancy in CO1; simplified data in CO11: at delivery with a summary of key pregnancy events
- For newborns not infected with HIV, for CO1 and CO11: at birth, at 1, 3 and 6 months, at 12 months, and at 18–24 months
- For children infected with HIV, follow-up ceases in CO1 upon diagnosis of the infection, and they are included in the cohort of infected children (CO10)

B – Procedures for accessing the collection

1- Project submission: **via the sample request form on the website**
2- Project assessment: by **the scientific committee or independent experts**
3- Provision of the collection**: final decision by ANRS MIE management or the scientific advisory board**
4- Contact email address for submitting your project: **biobanque@anrs.fr**

	EPF-CO1/CO11 PUBLICATIONS (>2005)
2023	Sibiude J, Le Chenadec J, Mandelbrot L, Hoctin A, Dollfus C, Faye A, Bui E, Pannier E, Ghosn J, Garrait V, Avettand-Fenoel V, Frange P, Warszawski J, Tubiana R. Update on perinatal human immunodeficiency virus type 1 transmission in France: zero transmission among 5,482 mothers on continuous antiretroviral Therapy From Conception and With an Undetectable Viral Load at Delivery. Clin Infect Dis. 8 February 2023;76(3)
2022	Dollfus C, Le Chenadec J, Mandelbrot L, Tubiana R, Faye A, Brossard M, Frange P, Blanche S, Warszawski J; ANRS CO1/CO11 study group. Improved haematological outcomes in HIV-1-exposed infants receiving nevirapine compared with zidovudine for postnatal prophylaxis in a high-resource setting. Pediatr Infect Dis J. 1 May 2022;41(5):420–423.
2022	Saint-Lary L, Diallo A, de Monteynard LA, Paul C, Marchand L, Tubiana R, Warszawski J, Mandelbrot L, Rekacewicz C, Petrov-Sanchez V, Faye A, Sibiude J, Dabis F, Sommet A, Leroy V. In utero exposure to antiretroviral drugs and pregnancy outcomes: Analysis of the French ANRS pharmacovigilance database. Br J Clin Pharmacol. March 2022;88(3):942–964
2021	Sibiude J, Le Chenadec J, Mandelbrot L, Dollfus C, Matheron S, Lelong N , Avettand Fenoel V, Brossard M, Frange P, Reliquet V, Warszawski J, Tubiana R, EPF study group Risk of birth defects and perinatal outcomes in HIV-infected women exposed to integrase strand inhibitors during pregnancy. AIDS 2 February 2021;35(2):219–226
2020	Zheng Y, Hirt D, Delmas S, Lui G, Benaboud S, Lechedanec J, Tréluyer JM, Chenevier-Gobeaux Elisa, Arezes E, Gelley A, Amri I, Urien S, Bouazza N, Foissac F, Warszawski J, Ghosn J. Effect of Pregnancy on Unbound Raltegravir Concentrations in the ANRS 160 RalFe Trial. Antimicrob Agents Chemother, 21 September 2020;64(10)
2020	Frange P, Tubiana R, Sibiude J, Canestri A, Arvieux C, Brunet-Cartier C, Cotte L, Reynes J, Mandelbrot L, Warszawski J, Le Chenadec J; ANRS EPF CO1/CO11 Study Group. Rilpivirine in HIV-1-positive women initiating pregnancy: to switch or not to switch? J Antimicrob Chemother. 11 March 2020
2019	Sibiude J, Warszawski J, Tubiana R, Le Chenadec J, Meier F, Faye A, Blanche S, Mandelbrot L; ANRS-French Perinatal Cohort Study Group. Elevated liver enzymes in pregnant women receiving antiretroviral therapy in the ANRS-French Perinatal Cohort. J Acquir Immune Defic Syndr. 1 May 2019;81(1):83–94.
2019	Peyronnet V, Warszawski J, Sibiude J, Dialla O, Bourgeois-Moine A, Bui E, Toulza CS, Peretti D, Brunet-Cartier C, Avettand-Fenoel V, Chenadec JL, Faye A, Tubiana R, Mandelbrot L. Does changing antiretroviral therapy in the first trimester of pregnancy for safety concerns have an impact on viral suppression? J Acquir Immune Defic Syndr. 15 April 2019;80(5):574–584.
2018	Warszawski J, Thomas C, Dialla O, Garrait V, Dollfus C, Reliquet V, Clech L, Dert C, Mandelbrot L, Audrain M, Blanche S; ANRS EPF Study Group. T-cell receptor excision circles in HIV-exposed, uninfected newborns Measured During a National Newborn Screening Programme for Severe Combined Immunodeficiency. J Pediatr. November 2018; 202:311–314.
2018	Benhammou V, Tubiana R, Matheron S, Sellier P, Mandelbrot L, Chenadec JL, Marel E, Khoshnood B, Warszawski J; ANRS CO1/CO11-EPF French Perinatal Cohort study group. HBV or HCV co-infection in HIV-1-infected pregnant women in France: prevalence and pregnancy outcomes. J Acquir Immune Defic Syndr. 15 April 2018;77(5):439–450.
2018	Hleyhel M, Goujon S, Sibiude J, Tubiana R, Dollfus C, Faye A, Mandelbrot L, Clavel J, Warszawski J, Blanche S; ANRS French Perinatal Cohort Study Group. Risk of cancer in children exposed to antiretroviral nucleoside analogues in utero: The French experience. Environ Mol Mutagen. June 2019; 60(5):404–409
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2016	Hleyhel M, Goujon S, Sibiude J, Blanche S, Warszawski J; on behalf of the ANRS French Perinatal Cohort Study Group. In-utero exposure to nelfinavir-ethyl methyl sulphone. AIDS. 13 November 2016;30(17):2729–2730
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2015	L Mandelbrot, R Tubiana, J Le Chenadec, C Dollfus, A Faye, E Pannier, S Matheron, MA Khuong, V Garrait, V Reliquet, A Devidas, A Berrebi, C Allisy, C Elleau, C Arvieux, C Rouzioux, J Warszawski, S Blanche; ANRS-EPF Study Group, "No perinatal HIV-1 transmission from women on effective antiretroviral therapy starting before conception," Clin. Infect. Dis., vol. 61, no. 11, pp. 1715–25, Dec. 2015.
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2015	J Sibiude, J Le Chenadec, D Bonnet, R Tubiana, A Faye, C Dollfus, L Mandelbrot, S Delmas, N Lelong, B Khoshnood, J Warszawski, S Blanche; French National Agency for Research on AIDS and Viral Hepatitis French Perinatal Cohort/Protease Inhibitor Monotherapy Evaluation Trial, "In utero exposure to zidovudine and heart anomalies in the ANRS French perinatal cohort and the nested PRIMEVA randomised trial," Clin. Infect. Dis., vol. 61, no. 2, pp. 270–80, July 2015.
2015	Sibiude J, Warszawski J, Blanche S. Tolerance of the newborn to antiretroviral drug exposure in utero. Expert Opin Drug Saf. 1 March 2015:1–12
2014	C. Taron-Brocard, J. Le Chenadec, A. Faye, C. Dollfus, T. Goetghebuer, V. Gajdos, J.-M. Labaune, A. Perilhou, L. Mandelbrot, S. Blanche, J. Warszawski, and EPF ANRS CO1/CO11 Study, "Increased risk of serious bacterial infections due to maternal immunosuppression in HIV-exposed uninfected infants in a European country," Clin. Infect. Dis. 1 November 2014;59(9):1332–45
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2012	J. Sibiude, J. Warszawski, R. Tubiana, C. Dollfus, A. Faye, C. Rouzioux, J.-P. Teglas, D. Ekoukou, S. Blanche, and L. Mandelbrot, "Premature delivery in HIV-infected women starting protease inhibitor therapy during pregnancy: role of the ritonavir boost?," Clin. Infect. Dis., vol. 54, no. 9, pp. 1348–60, May 2012.
2012	M. Burgard, S. Blanche, C. Jasseron, P. Descamps, M.-C. Allemon, N. Ciraru-Vigneron, C. Floch, B. Heller-Roussin, E. Lachassinne, F. Mazy, J. Warszawski, and C. Rouzioux, "Performance of HIV-1 DNA or HIV-1 RNA tests for early diagnosis of perinatal HIV-1 infection during antiretroviral prophylaxis," J. Pediatr., vol. 160, no. 1, pp. 60–6. e1, Jan. 2012.
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