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Obtaining informed consent from HIV infected pregnant women, Abidjan, Côte d'Ivoire.

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The Helsinki declaration is the reference statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects [1]. The main principle imposes to a physician to obtain an informed consent document from the research candidate before participating in a clinical research. However, this declaration did not take into account the socio-cultural context of developing countries where the majority of the patients are illiterate. Indeed, obtaining the consent of study participants is difficult and complex in resource poor settings especially in the context of HIV [2-3]. We initiated in March 2001 in Abidjan, the ANRS 1201 DITRAME PLUS open-label study to assess the field efficiency of a short-course combined regimen of Zidovudine and Nevirapine to prevent mother-to-child transmission of HIV (PMTCT). We studied the level of understanding of the informed consent document in the HIV-1 infected women enrolled in this project.

We conducted a cross-sectional survey within the DITRAME PLUS study in October and November 2001. The study sample comprised all HIV-infected women included in this study after having signed the informed consent document and been seen at least once by the team during the study period. A specific questionnaire was completed through interviews by social workers. After the interview, the consent document was checked to verify how it had been signed by the participants and countersigned by the research representative.

Overall, 55 HIV-1 infected women were interviewed during the study period in median 136 days (Interquartile range [52–188]) after having signed the informed consent document corresponding to their inclusion in the project. The interview was conducted in local language “Dioula” for 26 (47.3%) women. Their median age was 26 years, 26 (47.3%) women were illiterate, 21 (38.2%) had primary school education and 8 (14.5%) had college or high school education level.

All women had signed the document and the name of patients and doctors had been collected. However, about half (27/55) of the consent documents had been signed by fingerprints including all illiterate women. All physicians had countersigned the consent form.

Only 44 women (81.5%) remembered that they had signed the informed consent form (Table). Among them, 95% remembered that they had been given an information sheet and only 48% declared to have understood the information given after the physician's explanation. Only seven of them remembered having read in detail the information sheet. Among the 35 women who said they had not read the information sheet, 71% declared that they could not read. However, all these HIV-infected women were fully aware that they were followed in the research project on PMTCT at the time of the interview. Ten (18%) women declared that during the inclusion visit they had asked questions to the attending physician about the project to know the risks and benefits for themselves and their children.

This study confirms that obtaining informed consent is difficult and complex in illiterate women especially in developing countries [2-4]. The most important weakness observed was the misunderstanding of all the information given to them before they signed the consent form. Subsequently, these women could not fully exercise their rights during the research process. A similar observation was reported in Bangladesh where 65% of the 105 women interviewed did not know that they were free to stop their participation in the study at any moment [4]. In Haiti, it was found that only 3/15 HIV-infected women advised by the attending physician participants understood the message [3]. However, our study shows that the majority of HIV-infected women knew they were followed for a PMTCT study with active drugs.

The Helsinki declaration also proposes that a witness assists the illiterate patient before signing the informed consent form, but this cannot be systematic in the context of HIV because of the confidentiality issue and the high risk of stigmatization.

In conclusion, it appears necessary to improve the process to obtain a consent allowing a better comprehension of their participants in clinical trials. Languages problem and lack of familiarity with scientific terminology often limit understanding. In this context, WHO department of HIV/AIDS proposed in June 2003 the best practices for informed consent like: to offer choice of multiple language, to make oral “forms” available, to realize discussion groups for explaining the protocol and finally to allow participants to discuss their possible participation with others before making a final decision [5]. These propositions could help scientists in giving clear explanations concerning the rights of the patients before and also during the time of the ongoing clinical research.

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Table. Perception and understanding of information sheet by HIV-1 infected women participating to the ANRS 1201/1202, Ditrame Plus study in Abidjan, Côte d'Ivoire (2001).

	Number	Percentage
Process to obtain consent document		
Remember to have signed a consent document	44/55	81.5
Remember to have received an information sheet	42/55	76.5
Remember to have received explanations of project*	39/42	95.1
Declare having understood the explanation given by the physician*	20/42	47.6
Remember having read the information sheet*	7/42	16.7
Rights of the patient during project		
Know about the possibility for them to withdraw freely from participation at any time in the project	15/55	27.3
Possibility to stop the treatment at any time	9/55	16.4
Possibility to see the doctor at any time	50/55	90.9
Computerization of data	3/55	5.5

* Among women who have received information sheet