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Anthropology and Clinical Trial Emerging Reproductive Issues in Cambodia

Pascale Hancart Petitet, *Senior member, IEDRC*

Abstract—At the Institut Pasteur du Cambodge, existing links among researchers involved in programs funded by the National Agency for Research on AIDS and Hepatitis led principal investigators of clinical trial and social scientists to work together. This paper presents how we framed this research that aims to document, from an anthropological point of view, various issues related to procreation and contraception for people living with HIV within the clinical trial "Camelia" (ANRS 1295–CIPRA KH001). Indeed, in the CAMELIA clinical trial a total of 661 patients (236 women) were enrolled. Despite the strong requirement stated in the informed consent form, 19 women enrolled in the trial became pregnant. The anthropological research was helpful to bring insights into how the clinical trial deal with various social forms related to reproductive practices produced globally, reinterpreted locally and negotiated by patients. It provides body rich stories of lived bodies and various insights on how HIV/Aids mostly combines to poverty challenge both the reproductive norms and "choices" and the "emic" notion of « couple » and « family ». For example, we describe why CAMELIA patients do not always disclose their HIV status to their partner and the social construction and social implications of such decision. We explored the reasons and strategies they mobilized to maintain a couple relationship. We analyzed how CAMELIA team deals within those complexities and pointed out the individual and structural intertwined logics behind discourses and facts. Thus we illustrate also how reproductive bodies are enacting and being enacted when medical things travel in poor Cambodian settings and where medicine and biological risks figure only as a reduced part of daily life.

Index Terms—Anthropology, reproduction, Clinical trial camellia, Cambodia

I. WHEN ANTHROPOLOGY MEETS CLINICAL TRIALS

The implementation of clinical trials in developing countries has mainly been developed over the last 20 years. It raises various questions for anthropologists that a laboratory team UMI 233 at the Institut de Recherche pour le Développement try to analyze for several years and mainly in three geographical areas: in West Africa (Burkina Faso and Senegal), in South India (Pondicherry) and China (Beijing) [1], [2]. The objectives of these research programs are especially to identify and describe the various local actors involved in the implementation of clinical trial. It also aims to document the perception, experience and impact of the clinical trial for patients included in the trial. Finally, these programs intend to analyze the interpretations and discourses produced about clinical trials and their social

uses. More recently, Petryana [3] documents how experiments travel in approaching social, political and economical conditions that shape research objects and subjects.

My research conducted in Cambodia since 2008 led me to approach various issues at the intersections of reproduction politics and the global flows of medical technologies. Indeed, at the Institut Pasteur du Cambodge, existing links among researchers involved in programs funded by the National Agency for Research on AIDS and Hepatitis led principal investigators of clinical trial and social scientists to work together. From April 2010 to December 2011, my research aimed to document, from an anthropological point of view, various issues related to procreation and contraception for people living with HIV within the clinical trial "Camelia" (ANRS 1295–CIPRA KH001). This clinical trial was launched in January 2006 by the French National AIDS Research and Viral Hepatitis - ANRS 1295/12160 - and the National Institute of Health (NIH) - DAIDS-ES ID 10425- It is a prospective, randomized, multi- center, « open-label superiority » trial (with no placebo) designed to measure the effect of earlier versus later initiation of antiretroviral therapy on mortality among HIV-infected adults with no previous exposure to antiretroviral drugs who had a CD4+ T-cell count of 200 per cubic millimeter or less and had received a new diagnosis of tuberculosis. Inpatients and outpatients were recruited between January 31, 2006, and May 27, 2009, from five hospitals in Cambodia [4].

II. THE "MEDICALLY NON-RECOMMENDED PREGNANCIES" ISSUE

In the CAMELIA clinical trial a total of 661 patients (236 women) were enrolled. All women were requested first to undergo pregnancy test which had to be negative to insure their inclusion in the trial and then to use a double contraceptive method including condoms as they were given treatment non compatible with pregnancy. In addition to free access to condoms in all outpatient clinics of the CAMELIA study sites, VCCT and other places, spermicidal gel stocks were available at the pharmacy level of the 5 hospitals participating to the trial. Despite the strong requirement stated in the informed consent form, 19 women enrolled in the trial became pregnant. The CAMELIA operational team decided to start a comprehensive process on reproductive health issues in HIV-infected women treated at the study sites whether or not included in the trial. This comprehensive process included investigation on training of health staffs, information given to patients and health workers, patients' access to appropriate contraceptive

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methods. Since March 2009, we exchanged with the operational CAMELIA team about the *medically non-recommended pregnancies* issues. We shared our knowledge on birth spacing, contraception practices, and contraception means and reproductive health focused services available for HIV patients in Cambodia. Various activities were implemented (group discussion, evaluation of available reproductive health services, identification of an existing referral system, collaboration with Reproductive Health Association Cambodia and organization of trainings). These activities took place in a context where, at country level, issues relating to reproductive health for people living with HIV are still not much taken into consideration. In Cambodia, the first antiretroviral drugs (ARVs) were officially introduced in 2000 and many actions led by the Ministry of Health contributed to a decrease in HIV prevalence (among 15 to 49 year old adults) down to 0.9% in 2006 and 0,8% in 2010 [5]. In 2010, Prevention of Mother To Child Transmission (PMTCT) sites scaled-up significantly and 57,3% of HIV infected pregnant women receive ARV. However, besides isolated initiatives, there is no specific program related to the gynecological follow-up of women living with HIV. At the international level and according to the WHO's medical eligibility criteria related to the use of contraceptives, most methods are considered as healthy and efficient for women living with HIV, asymptomatic or at the stage of AIDS [6]. Yet, practices in the field often seem very far from the proposed objectives. Until recently in Cambodia, government policy wish to limit the births of children born from mothers LWH; a lack of training was observed among caregivers and social workers on these issues. In such context, our objectives were to explore how contraceptive use is constructed in terms of discourse and action for people living with HIV. We describe and analyze how women living with HIV are adapting their practices, or inventing new strategies of access to reproductive health care.

Within this research project specifically, we discussed with some CAMELIA patients, team and caregivers and observed consultations and counseling activities related to birth control and to the HIV Prevention of Mother to Child Transmission. The data collection activities were conducted from November 2010 to April 2011. We observed counseling sessions and conducted interviews with women included in the trial and some partners (8 women and 3 men in Phnom Penh and the surrounding area, 11 women and 6 men in Svay Rieng), and among caregivers (doctors, nurses) in charge of monitoring these patients to the hospital Khmer Soviet Friendship Hospital (9) and the referral hospital of Svay Rieng (5). We also met with representatives of patient groups (7 in Phnom Penh and 4 in Svay Rieng) and discussed at length with eight CAMELIA's coordinators and PI. We wonder about the process of informed consent and how patients understood it. Our main objective was to examine the socio cultural dimensions of reproductive health (or on birth control and procreation) among women in childbearing age enrolled in the CAMELIA clinical trial. What was at stakes during counseling sessions performed in routine care? What are the complex configuration between

the requirements of trial stakeholders and caregivers and the patients' conditions, demands and desires?

III. INFORMED CONSENT: SOCIAL CONSTRUCTION AND LOCAL REINTERPRETATIONS

The drafting of the consent form raised various discussions amongst partners involved in the CAMELIA clinical trial implementation. Indeed, for the NIH representatives (National Health Institute) the objectives of the consent form are numerous and have to include "*description of any foreseeable risks or discomforts to the subject, an estimate of their likelihood, and a description of what steps will be taken to prevent or minimize them*" [7]. According to the CAMELIA team in Cambodia, reading and signing an extensive informed consent was irrelevant and impractical for very sick patients. Various actions were launched to make the informed consent understandable by patients: collaborative work on the information sheet and consent form with PLWHIV associations, involvement of one ethnologist linguist in this documents writings, team training on the consent form process.

According to CAMELIA Coordinators, addressing the issue of contraception with patients involved in the trial appeared irrelevant as on that time their physical condition was very critical and the initial duration of follow-up during the study was 50 weeks. However, later on the duration of follow-up in the CAMELIA trial was extended up to the week 50 for the latest included patient. This led to a longer duration of follow-up for many patients. After several months of treatment, many people recovered and returned to normal life and sexuality. Also, during a staff meeting in May 2009, the issue related to the occurrence of pregnancy among CAMELIA patients was discussed. The CAMELIA team established a referral system for patients to existing reproductive health and PMTCT services and organized formal training for staff. However, impacts of these activities were limited. Indeed, Cambodian doctors working in public hospital in Phnom Penh relate their own experiences in this regard. According to them, women do not actually address reproductive issues with their physician. Indeed, the relationship between caregiver/patient and man/woman leaves little room for this kind of interaction.

Before examining the patient representations related to informed consent, let's see how counselors in charge of delivering prevention messages faced the medically not recommended pregnancy issue in their daily practice. The CAMELIA patients underwent to counseling sessions organized for every regular patient undergoing ARV therapy in public hospitals. As we observed, the counseling session follows a standard model of which objectives are to assess and reinforce adherence to ARV treatment. Counselors give advice on lifestyle and nutrition, and recall the messages on prevention by condom use. If a patient raise the issue of pregnancy desire, the role of the counselors consist in assessing the social condition and decide to what extent the patient will be able to handle the arrival of a child. If the clinical and social criteria are considered favorable, informative messages on the prevention of vertical transmission of HIV were given. If not, counselors tent to show to the patient the unrealistic and the irresponsibility of

a parenthood project.

Let us examine the difficulties to deal with birth control recommendations from the CAMELIA patient perspectives. Our data confirm, if necessary, that Cambodian women often have limited decision power in matters of reproduction. They have to buy the condoms, to provide them to their husbands, and insert it during sexual intercourse. However, many men refuse to use condom. In addition, resorting to abortion seems frequent for people living with HIV. But the decision making process for an abortion and the way it is done in practice often remain part of the “unspoken”. In a context where people living with HIV are supposed either not to have sex, or to conform to condom use, the occurrence of a pregnancy shows the absence of respect of the rules and has to be silenced. HIV non-disclosure among couple is also another issue faced by CAMELIA patients. This leads them to do not follow the medical recommendation related to birth control. Indeed, many women depend on men income and they do not dare to tell the truth to their partners. The last issue we need to approach is related to CAMELIA patients’ child desire. Indeed, in urban areas, and among the middle and upper classes, traditional rules related to marriage are often subject to rapid change and many couple can delay the arrival of a child in their family. However, according to several of our informants mostly belong to extremely poor backgrounds the relationships between a man and a woman, inside or outside marriage, are conditioned by the arrival of a biological child. It is often reported in Cambodia that the encounter between a man and a woman or between two individuals is related to the fact that both had good *nisai* from their previous life. The *nisai* is a component of the person who marks his attraction and its “compatibility” with another individual, an activity, or a place. These people have done good deeds (good = *tver* together in a previous life). In such context, having a baby appears as a normal and expected event among couple. In addition, other issues lead people to bear children. In some cases, giving birth to a child is considered as a mean to access to resources like rice, milk for the baby, various domestic items, scholarship for elder children, incentives to go to the hospital. Also, having a newborn to feed is often a criteria selected by various AID organizations to obtain their support. In various circumstances, giving birth to a child is also used as commercial transaction in the informal markets of adoption.

IV. PERSPECTIVES

The non-medically recommended pregnancies issue in clinical trial is not a new topic. An interesting point made by Le Gac et al. in Senegal [8] and Watts et al. in US [9] is that the proportion of women who got pregnancies during a trial is lower than in the general population of PLWA in both countries. This would be interesting to calculate also in Cambodia. Our previous study was describing the many reasons that lead people living with HIV not to evoke contraception related issues with caregivers. On the one hand, the topic of sexuality is difficult to address with doctors. Besides, these people are often supposed not to have a sex life and they have to comply with the use of condoms if they have sexual intercourses [10]. What we

show here is how CAMELIA patients construct their birth control practices outside medical recommendations, according to information taken from their social network and collected during the received healthcare, the demand of their partner or various difficulties to cope with pregnancy prevention. Thus this research brings insight into how the clinical trial deal with various social forms related to reproductive practices produced globally, reinterpreted locally and negotiated by patients. It provides body rich stories of lived bodies and various insights on how HIV/AIDS mostly combines to poverty challenge both the reproductive norms and “choices” and the “emic” notion of « couple » and « family ». Also this ethnography provides various insights to reconsider the notion of alliance, kinship and parenthood as previously explored by Nepote [11], Ledgerwood [12] and Crochet [13]. For example, we describe why CAMELIA patients do not always disclose their HIV status to their partner and the social construction and social implications of such decision. We explored the reasons and strategies they mobilized to create and/or to maintain a couple relationships and various aspects related to the social construction of “child desire” in context of social vulnerability. Thus, we bring new ethnographical insights relevant to address various social forms of human reproduction in Contemporary Cambodia. Finally, we analyzed how CAMELIA team deals within those complexities and pointed out the individual and structural intertwined logics behind discourses and facts. Thus in recalling Mol concepts [14], we illustrate also how reproductive bodies *are enacting* and *being enacted* when medical objects, technologies and concepts travel in poor Cambodian settings and where medicine and biological risks figure only as a reduced part of daily life.

Before ending, we need to add that the field surveys lead us to meet CAMELIA patients at home and revealed their extremely precarious living conditions. Many of them were among the evicted population of Phnom Penh. Indeed, in Cambodia since 1990 in several provinces and in the capital Phnom Penh problems related to urban planning needs, poor informal settlements, land grabbing and land speculation are recurrent. Poor people are routinely evicted from their living areas and national and international organizations are implementing various projects for resettlement. However, in many of these “gray areas”, no sanitation, no water, no system of primary health care is available and people suffer from extreme poverty, lack of educational opportunities and employment. These people targeted by various development programs aiming to achieve various public health objectives. One’s aims to reduce the maternal mortality and focus on issues related to safe abortion access and male sterilization, for example. Others can luckily be involved in various treatment access programs, like CAMELIA clinical trial, which provide a form of guaranteed access to health care. It appears that in the Cambodian context combining autocratic management of resources and liberalization of economic markets, the access to care is the only legitimate, socially and politically acceptable demand. People that we met were mostly worried and concerned by the daily management of their survival. In such context, the *non-recommended pregnancy* was neither an issue for them as they had to deal with their precarious social conditions, neither for caregivers

as they faced various difficulties in their daily professional activity. It was mostly an issue for the CAMELIA team aiming to provide the best level of care and for me researching in the field of anthropology of reproduction.

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Pascale's research concerns the body, illness and medicine in connection with cultural, social and political reproduction. She has interests in both applied and theoretical anthropology (medical systems, gender, reproductive technologies). She published various scientific chapters and articles included two books issued from her doctoral thesis in anthropology related to the social dimension of birth in South India *Maternités en Inde du Sud* (Edilivre, 2008), 2011 & *L'art des matrones revisité. Naissances contemporaines en question* (Faustroll Descartes, 2011). Since 2008, her research, addresses issues related to the social construction and social production of family planning in the context of HIV. This research stands at the intersections of reproduction politics, global flows of medical technologies, and social form and outcomes of inequalities. (<http://ird.academia.edu/PascaleHancartPetitet/About>).