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Site identification and development for microbicide trials in resource-poor setting: the experience of Nestra Klinical/Access to health

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Introduction: The need for novel method to prevent human immunodeficiency (HIV) infection has become an urgent global publich health priority. In sub-saharan Africa (SSA), 57% of all people infected with HIV are women and girls. The need for new female-initiated microbicides that prevent HIV infection could provide an important tool to control the HIV/AIDS epidemic. Regions heavily affected include those of low income with already stretched scarce resources for clinical management. These areas are often lacking in research experience and microbicides expertise.

Materials and methods: Criteria used by Access/Nestra Klinikal to identify sites are: HIV prevalence and incidence; population and community characteristics: investigator interest: ability to develop physical research infrastructure; ability to conduct research according to internationally approved guidelines; regulatory and ethical environments; and the availability or the ability to build clinical support structures for trial participants.

Results: Selection and development of sites for clinical trials should be undertaken in a comprehensive fashion to create an effective research environment that includes regulatory, scientific and political/community concerns. Site selection and development for large muilti-center efficacy varies.

Conclusions: Site selection by sponsors is best archieved in collaboration with local researchers familiar with the communities who can provide comprehensive strategic plans for individual site development. Early involvment of host country representatives may enhance product registration following pivotal efficacy trials.

5. Prevention

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Maternal and infant age, feeding options, ART use and singlet/multiple pregnancy affect rates of mother-to-child transmission of HIV in Cameroon, 2004–2013

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Introduction: Transmission rate of HIV from mother to child transmission (MTCT) is reducing in many countries. While it is the case in Cameroon, risk factors should be identified to further reduce this transmission. We aimed to evaluate the risk factors associated with MTCT HIV in Cameroon from 2004 to 2013.

Materials and methods: We conducted a retrospective study based on early infant diagnosis results as well as the clinical data collected from their mothers. Data collected from 2004 to 2013 were analyzed using Stata software and the Pearson's chi-square and Fisher's exact tests.

Results: A total of 15,233 HIV infected mothers and their 15,404 exposed infants aged 6 weeks to 18 months were recruited. Mean age of infants was 16.7 weeks, and 34.8% were breastfed. Mean age of mothers was 27.5 years. The overall rate of transmission was 9.4%. No gender was associated to MTCT. Only 3.8% of infants were HIV infected when their mothers underwent ART treatment compared to 25.9% when they did not. As well, only 4.1% of infant were infected under Nevirapine prophylaxis, compared to 26.4% when no Nevirapine was given to the infant. Infection rate increased with infant 'age at testing. The younger age of the mother also favors the transmission ($p=0.003$). There were more infected children in singlet pregnancies compared to multiple pregnancies, $p<0.001$. The order of delivery in twin's pregnancies did not impact MTCT. There were more HIV infected children in male-female twins' sets ($p=0.037$)

Conclusions: In our setting, taking altogether much effort is needed to reduce vertical transmission of HIV. Our results prove the efficiency of ART in mothers as well as ARV prophylaxis in infants in the reduction of MTCT. The mother and infant age and the feeding option also impact the transmission of HIV. These findings suggest that many parameters contribute to MTCT of HIV-1. Interventions to decrease MTCT of HIV through family planning and regular pre/post natal consultations and good clinical practices should be re-enforced.

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PrEP in the CeGIDD of the Departemental Council 13: local data (June 2016–January 2018)

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Introduction: This retrospective study assesses the impact of Pre-Exposure Prophylaxis/HIV in patients included in the free centers of extra-hospital screening and Diagnosis information on CD13, examining HIV seroconversions, treatment tolerance and the prevalence of sexually transmitted diseases (Syphilis, Chlamydiae, Lymphogranuloma Venereal, hepatitis).

Materials and methods: The ANSM order of June 07, 2016, authorizes extra-hospital CeGIDD to prescribe the association Emtricitabine/Fumarate of Tenofovir Disoproxil in HIV PrEP. This analysis covered a period of 20 months, from June 2016 to January 2018. 228 individuals were included, for which a compendium of behavioral and epidemiological data was carried out. A clinical and biological follow-up at 1 month and every 3 months including an STD and renal assessment was prescribed.

Results: 228 males and MSM were included in the study. 30% were under the age of 29, 61% were between 30 and 49 years old and 9% over 50 years old. 75% declared that they did not use any psycho-active substances. The side effects of PrEP were limited to 7% digestive disorders and 1% cephalgias. No HIV or hepatitis B seroconversions were observed. 2 patients had acute hepatitis C, including 1 with a co-infection hepatitis A that required the cessation of PrEP. 4 acute hepatitis A were diagnosed. Among the 228 MSM, 17 showed Syphilis, 40 had Gonorrhea, 33 Chlamydiae and 10 with a Lymphogranuloma Venereal. There were a total of 123 episodes of treated STDs (17 Syphilis, 56 Gonorrhea, 40 Chlamydiae, 10 LGV). It was also noted that PrEP increased immunization coverage for hepatitis A (0/33%) and hepatitis B (64/83%).

Conclusions: PrEP-HIV is a well-tolerated prophylaxis. No HIV seroconversion was detected over this period. The prevalence of STDs in PrEP is difficult to compare to the pravalence of STDs in non-PrEP, due to different behavioral and sexual practices. The challenge of extra-hospital CeGIDD will be to reduce the number of STDs to come, to insist again and again on prevention and screening with close follow-up.

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Knowledge regarding human immune deficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) in a French hospital

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