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Low Prevalence Rate of Indeterminate Serological Human Immunodeficiency Virus Results among Pregnant Women from Burkina Faso, West Africa▽

Dramane Kania,[1,2] Paulin Fao,[2] Diane Valéa,[1,2] Clarisse Gouem,[2] Thérèse Kagoné,[1] Hervé Hien,[2] Paulin Somda,[2] Patrice Ouédraogo,[2] Aly Drabo,[1] Sandrine Gampini,[1] Nicolas Méda,[2] Serge Diagbouga,[2] Philippe Van de Perre,[3] and François Rouet[1,2]* for the WHO/ANRS 1289 Kesho Bora Study Group in Burkina Faso

Laboratoire de Virologie, Centre Muraz, Bobo-Dioulasso, Burkina Faso[1]; Essai Kesho Bora, Centre Muraz, Bobo-Dioulasso, Burkina Faso[2]; and Université Montpellier 1, EA 4205, Transmission, Pathogenèse, et Prévention de l'Infection par le VIH, and CHU Montpellier, Laboratoire de Bactériologie-Virologie, Montpellier, France[3]

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Rapid human immunodeficiency virus (HIV) antibody tests have been adopted into national guidelines for HIV testing in many countries in sub-Saharan Africa. One goal of HIV rapid testing is to minimize the occurrence of indeterminate results. From January 2005 to December 2007, plasma (or serum) samples from pregnant women in Bobo-Dioulasso (Burkina Faso, West Africa) were screened for HIV by using two rapid tests (the Determine HIV1/2 test [Abbott] and Genie II HIV-1/HIV-2 [Bio-Rad]) through a sequential algorithm prior to enrollment of HIV-1-infected women in a prevention of mother-to-child transmission (PMTCT) trial (WHO/ANRS 1289 Kesho Bora trial). Samples exhibiting indeterminate results (Determine positive and Genie II negative) were further tested with a fourth-generation HIV enzyme immunoassay (EIA) (Murex HIV Ag/Ab combination in 2005 and 2006 and Vironostika HIV Uni-Form II Ag/Ab in 2007). If positive, they were finally assessed for HIV-1 RNA (Generic HIV-1 RNA viral load assay; Biocentric). From a total of 44,653 samples tested, 597 (1.3%) showed indeterminate results. Of these, 367 could be analyzed by EIA. Only 15 (15/367, 4.1%) samples were found EIA reactive. Of these, 11 could be tested for HIV-1 RNA. All were HIV-1 RNA negative. In our clinical practice, pregnant women with such indeterminate results are now reassured during posttest counseling that they are very unlikely to be infected with HIV-1. As a consequence, such women with indeterminate results can reliably be considered negative when urgent clinical decisions (such as providing PMTCT prophylaxis) need to be taken.

In sub-Saharan Africa, rapid testing for human immunodeficiency virus (HIV) is the most efficient and sometimes the only feasible way to quickly provide information about HIV status among adults and children ≥18 months of age (6, 29). In contrast to enzyme immunoassays (EIAs) and Western blot assays (WBs), HIV rapid tests are relatively cheap, easy to use, and fast to perform. Most of them do not require refrigeration, sophisticated laboratory equipment, skilled technicians, and an electricity supply. Results from serum, plasma, whole-blood, urine, or saliva samples are obtained by visual reading after a few minutes. Some of the rapid tests can distinguish HIV type 1 (HIV-1) from HIV type 2 (HIV-2). They are also accurate and reliable as a result of applying a quality system approach recommended by the World Health Organization (WHO) (36). Due to their low cost and technical advantages, they have been adopted into national HIV voluntary counseling and testing (VCT) guidelines in many African countries. Their sensitivity and specificity have been studied in Kenya (12), Tanzania (22), Uganda (15), Zambia (30), South Africa (25), Cameroon (1), Central African Republic (24), Democratic Republic of Congo (19), Ghana (2), Ivory Coast (32), and Burkina Faso (23, 28).

One objective for rapid HIV testing is to minimize the occurrence of indeterminate results (i.e., discordant results when using at least two different rapid tests). It is often quite difficult for HIV counselors and health care providers to disclose such indeterminate results. In the context of interventions for prevention of mother-to-child transmission (PMTCT) of HIV-1 (which can require immediate decisions, notably during labor), medical staff need to know rapidly the HIV status of the woman from the laboratory in order to provide her, or not, antiretroviral (ARV) prophylaxis (5, 26, 27). The prolonged delay in the decision (by performing additional tests or by retesting women 14 days later) can be inappropriate in the clinical routine since women may deliver before obtaining definitive results.

The aims of this study conducted among pregnant women from Burkina Faso (West Africa) with a low risk of early HIV-1 seroconversion were (i) to determine the prevalence rates of indeterminate results by using two rapid tests in a sequential algorithm, as recommended in Burkina Faso, and (ii) to assess, using additional tests, the biological significance of indeterminate results in order to define a more rational strategy at the individual and public health levels.

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* Corresponding author. Present address: 2 Place de la Chaine, 17000 La Rochelle, France. Phone: 226.20.97.01.02. Fax: 226.20.97.04.57. E-mail: franrouet@yahoo.fr.

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TABLE 1. Prevalence rates of indeterminate and positive serological HIV results obtained with the Determine and Genie II rapid assays according to a sequential algorithm[a]

HIV rapid testing result	No. of results (%)				*P*
	2005 (n = 12,592)	2006 (n = 15,725)	2007 (n = 16,336)	Total (n = 44,653)	
Indeterminate (Determine positive, Genie II negative)	152 (1.21)	213 (1.35)	232 (1.42)	597 (1.34)	0.29
Positive (Determine positive, Genie II positive)[b]	554 (4.40)	623 (3.96)	726 (4.44)	1,903 (4.26)	0.07
HIV-1	519 (4.12)	576 (3.66)	681 (4.17)	1,776 (3.98)	0.04
HIV-2	19 (0.15)	22 (0.14)	17 (0.10)	58 (0.13)	0.50
HIV-1 + 2	16 (0.13)	25 (0.16)	28 (0.17)	69 (0.15)	0.63

[a] Prevention of mother-to-child transmission (PMTCT) Kesho Bora trial, Bobo-Dioulasso, Burkina Faso (2005–2007).
[b] The differentiation between HIV-1 and HIV-2 was achieved by using the Genie II test (see Materials and Methods).

MATERIALS AND METHODS

Studied population. The studied population consisted of ARV-naïve pregnant women from Bobo-Dioulasso (Burkina Faso, West Africa) screened for HIV from January 2005 to December 2007 in order to participate in the multicenter PMTCT Kesho Bora trial (10), which evaluated the impact of highly active antiretroviral therapy (HAART) during pregnancy and breastfeeding on mother-to-child transmission (MTCT). During VCT, HIV screening was performed by two rapid assays (see "Laboratory methods" below). In Bobo-Dioulasso (the second city of Burkina Faso, located in the western part of the country), it was carried out in 18 antenatal clinics. A written informed consent was obtained from all participants. The study protocol was reviewed and approved by the WHO ethics committee and the Institutional and National Ethical Review Boards in Burkina Faso.

Laboratory methods. (i) On-site rapid HIV testing. As recommended by the WHO for countries with limited resources and with a relatively low HIV prevalence (~4% in Burkina Faso) (9, 29), on-site rapid HIV testing was performed by using two distinct rapid assays according to a sequential testing algorithm. We used a sensitive test first and followed it by a second specific test, allowing the confirmation of initial positive results and the discrimination between HIV type 1, type 2, and type 1 + 2 infections. All plasma (or serum) samples were first tested by the immunochromatographic Determine HIV1/2 test (Abbott Laboratories, Wiesbaden, Germany). Samples found nonreactive by the Determine assay were considered true HIV-negative results. No further serological test was performed. Women were thus given negative results. If reactive, they were further assessed by the immunofiltration Genie II HIV-1/HIV-2 assay (Bio-Rad Laboratories, Marnes-la-Coquette, France). If the two assays were concordantly positive, women were given positive results. Discordant specimens, meaning positive by the Determine test but negative by the Genie II, were considered indeterminate and submitted to supplemental assays. All assays were interpreted according to manufacturer's specifications. One day of training for nonlaboratory personnel (such as midwives, nurses, nursing auxiliaries, and ward orderlies) was provided at each site by the reference laboratory (Virology Laboratory, Centre Muraz, Bobo-Dioulasso, Burkina Faso). Quality assurance programs, including refrigerator temperature monitoring as well as regular follow-up visits to check on specimen collection, laboratory procedures, and records, were conducted at least once a month during the first 6 months and at a lower frequency thereafter. After testing, all samples with indeterminate results were stored for a median time of 2.5 days (range, 1 to 5) on sites, mostly at −20°C (~80% of cases) or 4°C, depending on the capacities of each site. According to trial-specific procedures, women with indeterminate results were asked to return for HIV testing in 3 months (after their initial testing) in order to identify seroconverters. During the Kesho Bora trial, even if this meant overtreating some participants, all women with indeterminate results were given 200 mg of nevirapine (NVP) at labor. Their newborn babies received a single dose of NVP within 72 h after birth.

(ii) Supplementary assays. All available specimens showing indeterminate HIV results were systematically sent once a week to the reference virology laboratory of Centre Muraz (Bobo-Dioulasso), stored at −20°C, and further tested with a fourth-generation (G4) EIA, the Murex HIV Ag/Ab combination (Abbott, Dartford, Kent, United Kingdom), from January 2005 to December 2006, and then the Vironostika HIV Uni-Form II Ag/Ab (bioMérieux Laboratories, Boxtel, The Netherlands) till January 2007. No additional consent was required for further testing by EIAs. All assays were interpreted according to the manufacturer's instructions. If negative, no additional test was further performed and the woman was given a negative result. If positive (signal/cutoff [S/C] ratio of ≥1), samples were finally assessed for HIV-1 RNA by using the quantitative real-time PCR Generic HIV viral load assay (Biocentric, Bandol, France) (31). The low detection limit of this assay was 300 copies/ml using 0.2 ml of plasma. A low positive control (LPC; target value, 3.8 $\log_{10}$ copies/ml; accepted ranges, 3.5 to 4.1 $\log_{10}$ copies/ml), included in the kit, was used to validate each run. As previously documented for other HIV-1 RNA assays (20), with the Generic HIV viral load assay, serum (versus plasma) samples produced differences in $\log_{10}$ HIV-1 RNA levels that were not statistically significant (unpublished data). If HIV-1 RNA was detectable (>300 copies/ml), the woman was considered HIV positive and received relevant posttest counseling. If the HIV-1 RNA level was <300 copies/ml, she was considered HIV negative.

Statistical analysis. Statistical analysis was performed using Epi Info version 6.0 software (Centers for Disease Control and Prevention, Atlanta, GA). HIV prevalence rates of indeterminate and positive results were expressed in percentages, with 95% confidence intervals (95% CI). Indeterminate and positive prevalence rates were compared according to the study period by using the Pearson chi-square test.

RESULTS

On-site results. Between 2005 and 2007, 51,983 pregnant women attended one of the 18 antenatal clinics. Their mean age was 24.6 ± 6.1 years. Eighty-eight percent were married. A total of 44,653 (85.9%) were accepted to be screened for HIV antibodies by rapid HIV testing during the 3 years (2005, n = 12,592; 2006, n = 15,725; and 2007, n = 16,336) (Table 1). Among these, a total of 597 specimens were found Determine positive but Genie II negative, yielding an overall 1.3% prevalence of indeterminate results (95% CI, 1.2 to 1.4). No significant difference was obtained in terms of the rates of the prevalence of indeterminate results according to the three studied years (χ^2 test, P = 0.29). In addition, 1,903 (4.3%; 95% CI, 4.1 to 4.4) samples were found concordantly positive, mostly (>90%) represented by HIV-1 monoinfections.

Among the 597 indeterminate women, 110 were retested from 15 days to 3 months after their initial screening. All of them maintained the same indeterminate profile. No case of HIV-1 seroconversion could be documented.

Additional assays results. Among the 597 samples found indeterminate, 367 (61.5%) could be further analyzed for either Murex (n = 228) or Vironostika (n = 139) G4 EIA results. It must be pointed out that all 597 samples were tested by EIA. However, 230 results were missing in our database because they were directly transmitted to women without being recorded. Overall, a vast majority (352/367, 95.9%; 95% CI, 93.5 to 97.6) of samples were found negative by EIA. Only 15 (15/367, 4.1%; 95% CI, 2.4 to 6.5) specimens were found EIA

reactive, with no significant difference according to the EIA used (8/228, 3.5% with Murex versus 7/139, 5.0% with Vironostika, χ^2 test, $P = 0.47$). Eight of them had low S/C ratios (<2) (range, 1.04 to 13.66).

Out of these 15 samples, 11 could be assessed for the presence of HIV-1 RNA. All of them were found strictly negative for HIV-1 RNA, including all specimens exhibiting high S/C ratios. The four results missing were due to specimens that were not available (insufficient volume). Results obtained for the LPC were strictly within the accepted ranges.

DISCUSSION

Our study conducted in Burkina Faso demonstrated that the prevalence rate of indeterminate HIV results obtained with the Determine and Genie II assays through a sequential algorithm was relatively low (~1%) and stable over a 3-year period. This estimated prevalence of indeterminate results compares very closely to prevalence rates previously documented with the same rapid tests and algorithms for African pregnant women living in Ivory Coast (32) (where the CRF02_AG and CRF06_cpx strains are predominant, as in Burkina Faso) (35) and South Africa (where subtypes C represent almost all circulating strains) (25). However, Aghokeng et al. (1) reported higher rates (9.0%) of indeterminate results in Cameroon, probably related to the higher HIV genetic diversity found in this country. In fact, the comparison between studies is difficult due to differences in study design, study period, population selection, and assays/testing algorithm approaches.

Based on a large sample size, our survey also revealed that indeterminate results were false-positive reactivities. Indeed, in a very large (~96%) proportion, these false-positive results were not confirmed by EIA results, which remained negative. Gray et al. (15) in Uganda obtained similar results (94.1%), notably due to weak positive bands not confirmed as positive by EIAs and WBs. The WHO recommends that if two tests (rapid tests or EIAs in our context) out of three are negative, the result can be interpreted as presumptively HIV negative. False-positive reactions in HIV serological tests have been documented widely for both rapid tests (2, 15, 19, 33) and EIA techniques (8, 11, 13). The causes of false-positive reactions are many and include cross-reactive epitopes (7, 13, 18, 34) (as seen, for instance, in malaria, schistosomiasis, tuberculosis, or human T-cell leukemia virus type 1 [HTLV-1] infections), general immune activation due to multiple concomitant infections, nonspecific IgG binding, or contaminating proteins. Finally, for the remaining 4 percent of samples exhibiting a positive EIA result, we were not able to identify early seroconversions by HIV-1 RNA testing.

Our study has several limitations. The intensity of positive bands obtained with the Determine assay was not recorded. In fact, weak bands were considered positive results, as recommended by the manufacturer. It has been shown by Gray et al. that HIV-negative sera can exhibit weak bands (15). Since HIV prevalence is low in Burkina Faso, the probability of having seroconverters in our studied population is low. The conclusions of our study may not apply to subjects harboring very diverse HIV-1 strains (such as in Cameroon), for which inaccurate diagnosis of HIV-1 groups M and O is challenging (1). Further, given that only 367 indeterminate samples (out of a total of 567) could be analyzed in our database for G4 EIAs and only 11 (out of a total of 15) with a positive EIA result could be assessed for HIV-1 RNA, our survey was not able to fully investigate all potential HIV seroconversions. However, we think that missing data for EIAs did not introduce bias in the results obtained. More importantly, under our field conditions, some specimens were stored at 4°C 5 days before HIV-1 RNA testing. One can argue that these storage conditions had a negative impact on HIV-1 RNA stability, yielding HIV-1 RNA undetectability (equivalent to false-negative results). However, it has been reported that samples can maintain their HIV-1 RNA concentrations for at least 14 days at 5°C and around 3 years at −20°C (14, 16). Amellal and colleagues also demonstrated that 1 week of storage of plasma specimens at 4, 22, and 30°C did not significantly affect HIV-1 RNA viral load levels (3, 4). In contrast, they obtained reduced median HIV RNA concentrations for samples stored at 37°C. These authors concluded that in resource-constrained settings, plasma samples can be saved for up to 1 week at these temperatures before shipping to a reference laboratory. Also, it is well known that early seroconversions in adults are associated with very high HIV-1 RNA levels (21) and therefore unlikely to become fully undetectable under the storage conditions of our study. Furthermore, it was not possible to identify during follow-up HIV seroconversions among women with such indeterminate results. Finally, among those indeterminate samples, no HIV-2 molecular assay was performed. However, in Burkina Faso, the HIV-2 infection prevalence rate is much lower than that reported for HIV-1, as shown in our survey.

In conclusion, the national policy and guidelines for HIV screening in Burkina Faso, recommending the use of Determine and Genie II assays through a sequential algorithm, yield a relatively low frequency of indeterminate false-positive results EIA negative. In our setting, with relatively low genetic HIV-1 diversity and a moderate HIV prevalence rate, when a third rapid test is not available and/or when there is a very short time window between HIV testing in the labor ward and PMTCT intervention, pregnant women with such indeterminate test results are now individually reassured during posttest counseling that they are very unlikely to be infected with HIV-1. If possible, they are also counseled to be retested after 14 days. In community-based clinic settings, given the potential clinical risks and the cost of unnecessary ARV prophylaxis for women and infants, as well as the potential stigma resulting from considering wrongly a subject HIV positive, clinicians can reliably decide not to provide PMTCT prophylaxis to these women showing nearly exclusively nonspecific reactions.

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