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REVIEW ARTICLE

Findings in the use of the dual rapid test for detection of HIV and syphilis in pregnant women in Mexico

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Abstract

Although dual rapid tests for HIV/Syphilis screening were introduced in our country in 2012, an evaluation of the use of these tests has not been carried out to date. The objective of the study was to know the progress in the use of the rapid dual test for the detection of HIV/Syphilis in the population of pregnant women in Mexico. A descriptive cross-sectional study was carried out to know the situation of the use of the test as a screening for pregnant women in the two main health institutions: the Secretary of Health in the states and the Mexican Social Security Institute ordinary regime for the year 2023. It was found that despite having sufficient dual tests in the states, the percentages of application of the test are less than 50% in most of them and the percentage of patients for whom it is confirmed their test when it is reactive for HIV/Syphilis is less than 20% in the case of the Secretary of Health. A more in-depth study is required to determine the causal agents.

Keywords: *Dual test. Syphilis/HIV. Screening.*

Hallazgos en la utilización de la prueba rápida dual para detección de VIH y sífilis en embarazadas en México

Resumen

A pesar de que en nuestro país se introdujeron en el 2012 las pruebas rápidas duales para el tamizaje de VIH/Sífilis, no se ha realizado hasta el momento una evaluación de la utilización de estas pruebas. El objetivo del estudio fue conocer los avances en el uso de la prueba dual rápida para la detección de VIH/Sífilis en la población de mujeres embarazadas en México. Se realizó un estudio transversal descriptivo para conocer la situación de la utilización de la prueba como tamiz para las mujeres embarazadas de las dos principales instituciones de salud: la Secretaría de Salud en los estados y el Instituto Mexicano del Seguro Social, régimen ordinario para el año 2023. Se encontró que los porcentajes de aplicación de la prueba en los estados, a pesar de contar con las suficientes, son menores al 50% en la mayoría de ellos y el porcentaje de pacientes a los cuales se les confirma su prueba cuando resulta reactiva para VIH/Sífilis, es menor al 20% en el caso de la Secretaría de Salud. Se requiere realizar un estudio más profundo para determinar los agentes causales.

Palabras clave: *Pruebas duales. Sífilis/VIH. Tamizaje.*

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Introduction

The availability of rapid screening tests for HIV and other STIs is a key strategy to facilitate the diagnosis of vertical transmission in pregnant women. The World Health Organization (WHO) recommends that pregnant women be tested for HIV, syphilis, and Hepatitis B (HbsAg) at least once during pregnancy preferably in the first trimester. The dual rapid test for HIV infection and syphilis can be used as a first test for pregnant women in prenatal care. The dual rapid test for HIV and syphilis detects antibodies to both Treponema pallidum (the cause of syphilis) and HIV. Like other rapid tests used only for HIV, it does not require refrigeration. At present, available products do not discriminate between active and past syphilis infections. Therefore, if a person has had syphilis that was treated or resolved and anti-treponemal antibodies persist, the HIV rapid dual test for HIV infection and syphilis may be positive for syphilis[1].

These simple tests can be used in the care setting and save costs compared to tests usually done in prenatal care. They enable more women to be diagnosed with HIV and syphilis so that they can access treatment and avoid passing the infection on to their children.

Successful implementation of dual rapid HIV and syphilis tests in prenatal care would increase the rates of syphilis detection to match those of HIV in countries such as India, where rates of syphilis screening in prenatal care increased by 195%, Uganda 119% and 117% in Nigeria, without affecting HIV testing rates[2].

Although many countries have policies for prenatal syphilis screening, more than 350,000 adverse pregnancy outcomes due to untreated maternal syphilis are reported each year despite the low cost of treatment[3]. To achieve current targets, efforts have been made to accelerate the elimination of maternal and child transmission of syphilis and HIV.

A study in China assessed the acceptability and feasibility of dual HIV/Syphilis testing in pregnant women at primary health care centers and increased acceptance of tests especially in rural areas[4].

Prevention of maternal and child transmission of HIV, initially introduced as a vertical program, has also been increasingly integrated into routine prenatal care. Therefore, in many countries and regions, services for the prevention of maternal-child transmission of HIV and syphilis are now provided simultaneously; dual elimination of maternal and child transmission of HIV and syphilis is now a regional strategy in the Americas, Asia-Pacific, Africa, and Europe, and at least 60 countries have integrated strategies for the prevention and elimination of maternal and child transmission of HIV and syphilis[5].

In general, rapid diagnostic tests (RDTs) are highly sensitive and specific. The WHO compared the performance of eight rapid syphilis tests with a combined treponemal test reference standard and found sensitivities of 84.5-97.7% and specificities of 92.8-98.0%. Comparison of the results of rapid tests among patients at the US STD clinic showed that capillary puncture samples are as good as venous blood samples for detection[6].

Countries have started using dual HIV and syphilis RDTs in various settings. Many studies have shown satisfactory clinical performance in diagnosing both HIV infection and syphilis-causing infection. The WHO evaluation of this RDP performance as part of the prequalification process showed a final sensitivity of 100% (95% CI 98.2-100%) for HIV antibodies and specificity of 99.5% (95% CI 97.2-100%) compared to the reference analyses. In the case of antibodies against Treponema pallidum, the final sensitivity was 87% (95% CI 81.5-91.3%), with a specificity of 99.5% (95% CI 97.2-100%)[7].

The advantages of the dual rapid HIV and syphilis test in prenatal care offer the possibility of detecting both infections with a single digital puncture. Results are available quickly, allowing antiretroviral treatment against HIV infection to be started, penicillin treatment benzathine for syphilis, or both if necessary. In addition to increasing the coverage of screening and treatment for syphilis, the dual rapid test can simplify training by providing one test instead of two, and reduce storage space and transport costs, as well as waste disposal. Countries should review the HIV and syphilis rapid dual-test as part of their control and prevention strategy.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimated a prevalence of 0.2/100,000 inhabitants aged 15-49 years, with regard to syphilis, has been reported as a prevalence of 0.014/100,000 inhabitants, however, this disease is considered as a reemerging disease among the priority public health problems.

A study conducted in three Instituto Mexicano del Seguro Social (IMSS) delegations demonstrated the validity of the dual rapid test for HIV/Syphilis as a screening test, due to its high sensitivity and specificity found during the study[8]. In Mexico, the incidence of HIV in pregnancy is 0.067%[9]. Screening for HIV during pregnancy is part of routine testing during prenatal monitoring. The offer of testing during pregestational consultation and prenatal monitoring is set out in NOM-007/SSA2-2016 for the care of women during pregnancy, childbirth and puerperium, and of

newborns. However, HIV screening coverage in 2016 within the Ministry of Health (SS) was just over 50%, according to estimates by the Censida[10].

The NOM-039-SSA2-2014 for the prevention and control of sexually transmitted infections states that every pregnant woman should be tested for VDRL or RPR and immunofluorescence for Treponema pallidum during the first prenatal visit, regardless of the trimester of pregnancy in which they are, and those in which no tests have been performed, these should be offered before or immediately after delivery, to detect syphilis in pregnant women and to prevent congenital syphilis[11].

In the Specific Action Programme under Priority Objective 4, it considers the elimination of vertical transmission of HIV and syphilis with a prevention, timely treatment, and non-discrimination approach (Ministry of Health, 2022). It should be noted that, according to the information reported by the conventional epidemiological surveillance system, during 2022 only 15 cases of vertical transmission of HIV per year of birth were reported, out of a total of 46 cases of vertical transmission[12]. In our country, the dual test was started in 2012 at the Mexican Health Department and the Social Security Institute. To use these dual tests, it is required that this be authorized by the Federal Commission for the protection against health risks and included by the Council of General Health in its National Compendium of Health Inputs[13]. The objective of the review was to describe the findings from the application of the dual test for HIV/syphilis (Neogen Dual) the test most frequently used in 2023 in pregnant women who attended health services (SSA and IMSS) of the states and to analyze the frequency and percentage of reactivity and positivity of the test.

Methodology

This is a retrospective, cross-sectional descriptive study of the results found in the application of the dual test for HIV/Syphilis in pregnant women from state health services (health centers) and the Mexican Social Security Institute, ordinary regime (Units of family medicine) FMU by 2023. The population under study were pregnant women who attended prenatal consultation in first-level units of these two institutions during this year. The variables under study were number of rapid duplex tests distributed, tests applied, reactive tests, and confirmed tests. The test most frequently used was the so-called Neogen Dual (HIV and syphilis), reagent for the qualitative chromatographic determination of antibodies against HIV 1 and 2 and Treponema pallidum in serum, plasma or whole blood. With a sensitivity of 99% or more and a specificity of 98% or more for HIV and a sensitivity of not < 95% and a specificity of not < 98% for syphilis, according to the certificate of diagnostic evaluation from the Institute of Epidemiological Diagnosis and Reference.

Information is requested through the National Institute of Information Transparency to the National Centre for Equity and Gender and Reproductive Health of the SSA, and the Medical Benefits Directorate of the Mexican Social Security Institute on the number of dual tests applied during 2023 and how many of these were found to be reactive to the rapid test and were confirmed for HIV and syphilis, respectively.

In parallel, 15 randomly selected states were also asked for the number of reactive tests they had and how many of these were confirmed according to the standard. Only seven states sent information regarding confirmed tests.

The analysis includes calculation of the frequency of application of the duplex test by state and its reactivity rates and confirmation of possible positive cases to HIV/syphilis. We also calculate the prevalence rate found in seven of the 15 states from which we request information on confirmation of diagnosis (STROBE Statement).

Results

According to the National Center for Equity and Gender and Reproductive Health of the Federal Secretariat of Health, 2,004,058 dual tests were distributed throughout the country for the Maternal and Perinatal Health Program in all 32 states. Those tests included in the National Compendium of Health Inputs 2023 with a sensitivity equal to or > 99% and a specificity equal to or > 98% for HIV and a sensitivity not < 95% and a specificity not < 98% for syphilis.

Out of 2,004,058 tests distributed in the states, a total of 728,742 HIV tests (36.4%) and 698,083 (34.8%) for syphilis were applied, the difference observed between the number of HIV/syphilis tests is due to the application of some individual tests. The states of Tamaulipas, Tabasco, Aguascalientes, Hidalgo, Morelos, and Quintana Roo have rates of application or use of tests above 50% for HIV/Syphilis (Table 1). Not being so for the rest of the states.

Of the 728,742 tests applied for HIV, 1,803 cases were detected in the country (0.25%), and the states of have the highest percentage of reactive cases were Veracruz (1.72), Tamaulipas (0.89), Sonora (0.77), San Luis Potosí (0.62), Zacatecas (0.56), Colima (0.51), Baja California Sur (0.49), and Chihuahua

Table 1. Percentage of rapid dual test for HIV/Syphilis distributed and applied by state, 2023

State	Distributed testing	Applied HIV testing	%	Applied syphilis testing	%
Aguascalientes	15,000	8,772	58.5	8,761	58.4
Baja California	51,300	14,881	29.0	14,620	28.5
Baja California Sur	9,240	4,933	53.4	4,180	45.2
Campeche	16,870	6,306	37.4	6,146	36.4
Coahuila	40,700	11,216	27.6	10,191	25.0
Colima	13,170	5,080	38.6	5,013	38.1
Chiapas	137,970	50,373	36.5	47,592	34.5
Chihuahua	51,650	16,951	32.8	16,107	31.2
Mexico City	100,000	23,197	23.2	21,444	21.4
Durango	33,980	4,750	14.0	4,544	13.4
Guanajuato	130,580	57,663	44.2	57,547	44.1
Guerrero	87,480	35,786	40.9	33,312	38.1
Hidalgo	43,640	24,833	56.9	24,104	55.2
Jalisco	146,120	40,499	27.7	39,563	27.1
State of Mexico	300,000	105,699	35.2	102,260	34.1
Michoacán	70,000	25,540	36.5	25,280	36.1
Morelos	35,760	20,867	58,3	19,936	55.7
Nayarit	17,820	6,099	34.2	6,037	33.9
Nuevo León	83,950	21,202	25.3	21,135	25.2
Oaxaca	82,390	8,764	10.6	7,173	8.7
Puebla	106,884	40,971	38.3	38,360	35.9
Querétaro	43,820	16,764	38.3	16,519	37.7
Quintana Roo	27,250	14,082	51.7	13,906	51.0
San Luis Potosí	46,490	21,575	46.4	21,038	45.3
Sinaloa	45,800	9,951	21.7	9,586	20.9
Sonora	31,550	13,667	43.3	12,694	40.2
Tabasco	63,350	39,946	63.1	37,705	59.5
Tamaulipas	20,000	16,661	83.3	15,060	75.3
Tlaxcala	29,450	2,127	7.2	2,118	7.2
Veracruz	92,364	40,453	43.8	37,527	40.6
Yucatán	32,740	12,923	39.5	12,904	39.4
Zacatecas	31,490	6,211	19.7	5,721	18.2
Total	2,004,058	728,742	36.4	698,083	34.8

Source: National Center for Gender Equity and Reproductive Health. SSA, SINBA consolidated cube, 2023.

Table 2. Percentage of HIV/Syphilis tests administered and reactive cases by state in pregnant women

State	Applied HIV testing	Reactive HIV cases	%	Applies syphilis testing	Reactive syphilis cases	%
Aguascalientes	8.772	8	0.09	8.761	114	1.30
Baja California	14.881	13	0.09	14.620	91	0.62
Baja California Sur	4.933	24	0.49	4.180	26	0.62
Campeche	6.306	14	0.22	6.146	16	0.26
Coahuila	11.216	26	0.23	10.191	155	1.52
Colima	5.080	26	0.51	5.013	56	1.12
Chiapas	50.373	127	0.25	47.592	186	0.39
Chihuahua	16.951	71	0.42	16.107	165	1.02
Mexico City	23.197	54	0.23	21.444	78	0.36
Durango	4.750	18	0.38	4.544	30	0.66
Guanajuato	57.663	68	0.12	57.547	146	0.25
Guerrero	35.786	73	0.20	33.312	230	0.69
Hidalgo	24.833	23	0.09	24.104	33	0.14
Jalisco	40.499	64	0.16	39.563	360	0.91
State of Mexico	105.699	158	0.15	102.260	493	0.48
Michoacán	25.540	17	0.07	25.280	99	0.39
Morelos	20.867	23	0.11	19.936	131	0.66
Nayarit	6.099	7	0.11	6.037	72	1.19
Nuevo León	21.202	20	0.09	21.135	188	0.89
Oaxaca	8.764	3	0.03	7.173	3	0.04
Puebla	40.971	59	0.14	38.360	146	0.38
Querétaro	16.764	3	0.02	16.519	32	0.19
Quintana Roo	14.082	22	0.16	13.906	77	0.55
San Luis Potosí	21.575	133	0.62	21.038	96	0.46
Sinaloa	9.951	31	0.31	9.586	127	1.32
Sonora	13.667	105	0.77	12.694	226	1.78
Tabasco	39.946	136	0.34	37.705	215	0.57
Tamaulipas	16.661	149	0.89	15.060	151	1.00
Tlaxcala	2.127	4	0.19	2.118	6	0.28
Veracruz	40.453	697	1.72	37.527	697	1.86
Yucatán	12.923	12	0.09	12.904	27	0.21
Zacatecas	6.211	35	0.56	5.721	71	1.24
Total	728.742	1803	0.25	698.083	4317	0.65

Source: National Center for Gender Equity and Reproductive Health. SSA, SINBA consolidated cube, 2023.

Table 3. Percentage of dual rapid tests applied in pregnant women, reactive and confirmed for HIV in seven states, 2023

State	Applied testing	HIV reactive test	%	Confirmed HIV test	%
San Luis Potosí	21,575	133	0.6	72	54.1
Nayarit	6,099	7	0.11	1	14.2
Guanajuato	57,663	68	0.11	10	14.7
Aguascalientes	8,772	8	0.09	1	12.5
Coahuila	11,216	26	0.23	2	7.6
Veracruz	40,453	697	1.7	113	16.2
Nuevo León	21,202	20	0.09	1	5.0
Total	166,980	959	0.57	200	20.8

Prevalence: 1.19 × 1000 pregnant women. Source: the states.

Table 4. Percentage of dual rapid tests applied in pregnant women, reactive and confirmed for syphilis in seven states, 2023

State	Applied testing	Syphilis reactive test	%	Confirmed syphilis test	%
San Luis Potosí	21,038	96	0.45	SI	SI
Nayarit	6,037	72	1.19	1	1.38
Guanajuato	57,547	146	0.25	42	28.6
Aguascalientes	8,761	114	1.30	114	100.0
Coahuila	10,191	155	1.52	SI	SI
Veracruz	37,527	697	1.85	113	16.2
Nuevo León	21,135	188	0.88	2	1.06
Total	162,236	1468	0.90	272	18.5

Prevalence: 1.6 × 1000 pregnant women. Source: the states.

(0.42). In the case of syphilis, 4,317 reactive cases (0.65%) were detected from 698,083 tests applied and the states with the highest percentage of reactivity were Veracruz (1.86), Sonora (1.78), Coahuila (1.52), Sinaloa (1.32), Aguascalientes (1.30), Zacatecas (1.24), Nayarit (1.19), Colima (1.12), Chihuahua (1.02), and Tamaulipas (1.0) (Table 2).

Only seven states; San Luis Potosí, Nayarit, Guanajuato, Aguascalientes, Coahuila, Veracruz, and Nuevo León reported on the number of confirmatory tests the percentage of confirmation of reactive tests in these states was 20.8% for HIV and 18.5% for syphilis. (Tables 3 and 4).

The estimated prevalence in the seven states that shared their confirmed test information was 1.19 for HIV and 1.6 for syphilis per 1,000 pregnant women.

In the case of the Mexican Institute of Social Security under the ordinary regime during 2023, 516,916 rapid tests were performed, of which 169 reactive tests were found 0.03%; the states with the highest number of reactive tests were: Tamaulipas (0.23), Nuevo León (0.06), Baja California (0.04), Sinaloa (0.07), Quintana Roo (0.07), and Oaxaca (0.14). A total of 79 reactive tests were confirmed (46.7%), in the states of de Aguascalientes, Michoacán, Puebla, Querétaro, Quintana Roo, Veracruz (South),

Table 5. Dual rapid tests applied percentage of reactivity and confirmatory tests by state, Mexican Social Security Institute, ordinary regime 2023

States	Applied test	Reactive test	%	Confirmed test	%
Aguascalientes	9,361	2	0.02	2	100.0
Baja California	27,307	10	0.04	9	90.0
Baja California Sur	8,413	0	0.00	0	0.0
Campeche	4,117	4	0.10	2	50.0
Coahuila	22,159	3	0.01	1	33.3
Colima	4,185	4	0.10	3	75.0
Chiapas	6,000	0	0.00	0	0.0
Chihuahua	17,080	1	0.01	0	0.0
Durango	9,422	0	0.00	0	0.0
Guanajuato	34,765	0	0.00	0	0.0
Guerrero	6,923	1	0.01	0	0.0
Hidalgo	8,839	5	0.06	1	20.0
Jalisco	37,499	6	0.02	2	33.3
State of Mexico, East	29,627	3	0.01	3	100.0
State of Mexico, West	16,842	3	0.02	3	100.0
Michoacán	13,097	2	0.02	2	100.0
Morelos	6,947	6	0.09	1	16.7
Nayarit	6,631	4	0.06	0	0.0
Nuevo León	41,833	25	0.06	14	56.0
Oaxaca	6,451	9	0.14	4	44.4
Puebla	16,228	2	0.01	2	100.0
Querétaro	11,512	1	0.01	1	100.0
Quintana Roo	13,514	9	0.07	9	100.0
San Luis Potosí	15,528	1	0.01	0	0.0
Sinaloa	13,839	9	0.07	2	22.2
Sonora	26,358	0	0.00	0	0.0
Tabasco	7,024	4	0.06	3	75.0
Tamaulipas	16,633	39	0.23	5	12.8
Tlaxcala	5,585	0	0.00	0	0.0
Veracruz, North	11,623	6	0.05	3	50.0
Veracruz, South	7,882	1	0.01	1	100.0
Yucatán	14,266	3	0.02	2	66.7
Zacatecas	5,956	1	0.02	1	100.0
Mexico City, North	11,444	1	0.01	1	100.0
Mexico City, South	21,576	4	0.02	2	50.0
Total	516,916	169	0.03	79	46.7

Source: Coordination of first level units of the directorate of medical benefits, IMSS 2023.

Zacatecas and Mexico City. They had confirmation rates of 100% (Table 5).

Discussion

If we consider that the calculations for the acquisition of rapid dual tests are based on the request of the states regarding the number of probable annual pregnancies, these figures would indicate that the application of dual rapid tests for the detection of HIV and Syphilis in pregnant women in the country is very low regardless of the availability of tests in the states, this situation could be due to a low offer of the benefit to pregnant women in first level care units such as this one within the NOM-007/SSA2-2016 and factors such as state distribution, staff training, conviction to accept the test among other causes.

The sensitivity and specificity of rapid tests performed in pregnant women are generally adequate; However, a certain number of false positives and negatives persists, which varies according to the prevalence of HIV infection in the population, so the characteristics of the diagnostic equipment, the handling of rapid tests, the type of sample used, and the procedures must be considered health conditions of people. It is recommended that in prenatal care services that have many patients, screening be done through laboratory methods such as the enzyme immunoassay. However, due to the heterogeneity in the supply processes of supplies, laboratory equipment, human resources, and geographical access to the health services of the federal entities of our country, the use of rapid tests should be prioritized.

In the case of the Mexican Institute of Social Security ordinary regime, the results observed are more optimistic than for the state health secretary, since their percentages of reactivity to the test are lower, 0.25 versus 0.03%, this may be because the maternal and child health program control system works better and has greater resources. However, 14 states also did not have desirable confirmatory testing rates.

Another variable that is of utmost importance is the confirmation of reactive tests with confirmatory tests such as Elisa, PCR, Wester Blood, and in the case of syphilis, fluorescent antibody tests against Treponema (FTA ABS) which may not be available. In state laboratories, their installed capacity for processing all dual samples is insufficient. Public health authorities will need to accelerate HIV and syphilis maternal and child care programs, requiring multi-level commitment to promote them, provide adequate resources and reliable procurement systems, and improve training and supervision.

Conclusion

The findings in this study allow us to observe that the Maternal and Child Health program in Mexico, despite having RDTs in sufficient quantities to cover the needs of the states, both in the Ministry of Health and the Mexican Institute of Social Security (IMSS), are no longer used in 50% of pregnant women when they go to the health unit, health center, Hospital or Family Medicine Unit (FMU).

A field study is required to determine what factors prevent these rapid duplex tests from being offered to all pregnant women who come for prenatal care. Likewise, determine if there are resources in these states to confirm those tests that are reactive to Syphilis/HIV to begin comprehensive treatment of one or both diseases according to regulations.

The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the National Center for Equity and Gender and Reproductive Health of the Secretary of Health and to the Directorate of Medical Benefits of the Mexican Institute of Social Security ordinary regime.

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Ethical disclosures

Protection of humans and animals. The author declares that no experiments were performed on humans or animals for this research.

Confidentiality of data. The author declares that no patient data appear in this article. In addition, the author has acknowledged and followed the recommendations according to the SAGER guidelines depending on the type and nature of the study.

Right to privacy and informed consent. The author declares declare that no patient data appear in this article.

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