

Perspective

Securing the Future: Demography, Perinatal Health, and the Challenge of Preventable Conditions

*by Porfirio Felipe Hernández-
Bautista*

Epidemiological Research

Association Between Marginalization Degree and Congenital Syphilis Confirmation Among Probable Cases Reported in a Hospital in Ciudad Obregón, 2019–2024

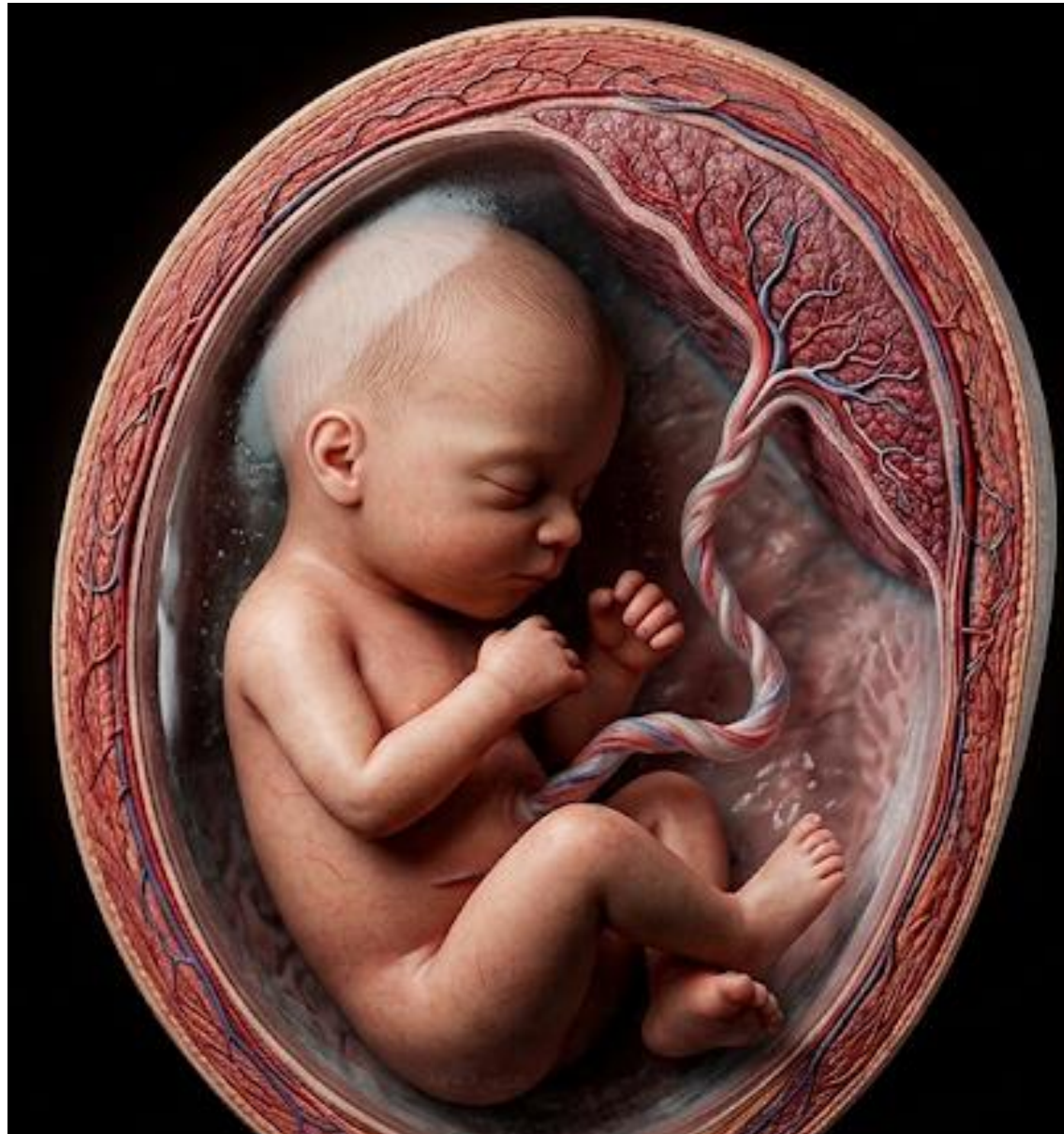
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"ERSJ Epidemiological Research and Surveillance Journal", Year 2, No. 2, October-December 2026, is a quarterly publication, edited by Porfirio Felipe Hernández Bautista. Address: Insurgentes Sur #730, 2nd Floor, Suite A, Colonia Del Valle, C.P. 03100, Mexico City, CDMX. Telephone: (+52) 644 133-0383. Email: editor@ersj.org, <https://ersj.org/print.html>. Certificate of Reservation of Rights for Exclusive Use No. 04-2026-020413394600-102. ISSN: 3122-4512 — both granted by the National Institute of Copyright.

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"ERSJ Epidemiological Research and Surveillance Journal", Year 2, No. 2, October-December 2026, is a quarterly publication, edited by Porfirio Felipe Hernández Bautista. Address: Insurgentes Sur #730, 2nd Floor, Suite A, Colonia Del Valle, C.P. 03100, Mexico City, CDMX. Telephone: (+52) 644 133-0383. Email: editor@ersj.org, <https://ersj.org/print.html>. Certificate of Reservation of Rights for Exclusive Use No. 04-2026-020413394600-102. ISSN: 3122-4512 — both granted by the National Institute of Copyright.

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Securing the Future: Demography, Perinatal Health, and the Challenge of Preventable Conditions

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Citation: Hernández-Bautista PF, Securing the Future: Demography, Perinatal Health, and the Challenge of Preventable Conditions, ERSJ 2026,2(2) 73-75

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1. Evolution, Survival, and the Modern Demographic Paradox

Approximately three hundred thousand years ago, the first groups of *Homo sapiens* roamed the valleys and savannas of Africa. Their lives unfolded within nomadic bands of hunter-gatherers, for whom the primary imperative was securing daily sustenance. During various periods of the Middle and Upper Paleolithic, the species was subjected to severe biological and climatic bottlenecks that brought it to the brink of extinction. Despite these adversities, the development of symbolic language, social cohesion, and the capacity for technological innovation enabled humans to progressively master and transform their environment, eventually establishing themselves as a biologically thriving and expansive species.

Throughout the 19th and 20th centuries, the consolidation of modern medicine, the discovery of antimicrobials, the development of mass immunization programs, and the implementation of environmental sanitation networks fostered an unprecedented epidemiological transition. The sustained decline in both general and infant mortality caused life expectancy at birth to skyrocket, sparking deep demographic concern by the mid-20th century regarding imminent global overpopulation and the eventual depletion of the planet's resources.

In response to these Malthusian projections, various governments and international bodies implemented policies aimed at birth control. The most emblematic example was the one-child policy instituted in the People's Republic of China in the late 1970s. Simultaneously, in the Western world, the advent and widespread availability of hormonal and barrier contraceptives radically transformed social structures by effectively decoupling the experience of sexuality from reproductive function. Compounding this phenomenon was women's progressive access to higher levels of education

and their full entry into the labor market. The convergence of these factors led to an accelerated decline in global fertility rates; currently, many countries fall below the generational replacement threshold (estimated at 2.1 children per woman), creating a landscape characterized by rapid aging and a shrinking productive base within society.

2. The vulnerability of the mother-child dyad and the safeguarding of perinatal health

Amidst declining birth rates, the survival and holistic well-being of every newborn have acquired cardinal strategic and bioethical importance. Maternal and child health—and the preservation of the mother-child dyad—constitute the foundation for the demographic continuity and socioeconomic development of nations. Protecting this dyad requires timely, universal, and prevention-oriented prenatal care aimed not only at mitigating immediate obstetric risks but also at safeguarding the neurodevelopment and quality of life of future generations.

However, structural gaps in healthcare systems and the fragmentation of primary care have fostered the resurgence or persistence of preventable conditions that severely compromise fetal and neonatal development. Notable among these are vertically transmitted infectious diseases and congenital endocrine disorders; while the diagnostic and therapeutic approaches for these conditions are well-established, they remain frequently underutilized:

Congenital syphilis: Caused by the spirochete *Treponema pallidum**, this condition serves as a critical indicator of failures in the coverage and quality of prenatal care programs. Neglect regarding serial serological screening and the failure to provide early treatment with benzathine penicillin to pregnant women continue to result in pregnancy loss, stillbirth, prematurity, and long-term disabling sequelae (such as bone lesions, sensory deficits, and central neurological damage).

Hepatitis C (HCV) and vertical transmission: Despite the therapeutic revolution brought about by direct-acting antivirals (DAAs), the persistence of perinatal HCV infection highlights regulatory gaps in routine antenatal screening protocols for at-risk populations, thereby depriving mothers and children of timely interventions to prevent hepatic fibrosis and the progression to chronic disease at an early age. **Congenital hypothyroidism:** This is one of the most common preventable causes of intellectual disability and neurodevelopmental delay in pediatrics. A lack of consolidation, universal coverage, and the immediate reporting of results within neonatal metabolic

screening programs leads to irreparable delays in initiating levothyroxine replacement therapy, thereby compromising the infant's cognitive potential.

3. Final considerations: a public health imperative.

Ensuring the viability of future generations goes beyond quantitative demographic discourse; it requires securing the health and well-being of offspring. It is paradoxical and unacceptable that, in an era dominated by precision medicine and biotechnological innovations, we continue to see debilitating sequelae from conditions for which early detection and curative or replacement treatments are widely standardized globally.

Reevaluating and strengthening sexual health programs, perinatal screening, and the systematic monitoring of vertically transmitted infections is an urgent imperative for social justice and public health. Only through a rigorous preventive approach—grounded in epidemiological evidence and universal coverage—will it be possible to offer future citizens a productive life path, free from pathological burdens that should have been overcome decades ago.

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Association Between Marginalization Degree and Congenital Syphilis Confirmation Among Probable Cases Reported in a Hospital in Ciudad Obregón, 2019–2024

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Citation: Alvarado-Acosta E and Ruiz-Valdez CA, Association between the degree of marginalization and congenital syphilis, ERSJ 2026,2(2) 76-86

Academic editor: Mónica Grisel Rivera-Mahey

Received: April-24- 2026

Revised: September-22- 2026

Accepted: September-29- 2026

Published: October-18-2026

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Abstract

Introduction: Congenital syphilis remains a major public health challenge. Although it is usually associated with adverse socio-spatial determinants, its diagnostic confirmation within hospital cohorts of suspected cases may exhibit patterns distinct from those assumed at the population level.

Objective: To determine the association between the degree of socio-spatial marginalization and the diagnostic confirmation of congenital syphilis among probable cases reported to the Epidemiology Department of the Hospital General Regional No. 1 in Ciudad Obregón, Sonora, during the 2019–2024 period.

Materials and methods: An observational, analytical, cross-sectional, and retrospective study. The study population consisted of all 95 notifications of probable cases of congenital syphilis registered in the Hospital Epidemiological Surveillance Unit (2019–2024). Regulatory criteria defined 42 confirmed cases and 53 discarded cases. The maternal address was geocoded by assigning the degree of marginalization by neighborhood (colonia, CONAPO 2020), which was dichotomized into medium to very high marginalization versus very low to low marginalization. Statistical analysis included the median and interquartile range (IQR) for maternal age, Mann–Whitney U test, Fisher's exact test, and odds ratio (OR) with a 95% confidence interval (95% CI).

Results: Of 95 evaluated notifications, 42 cases were confirmed (44.2%) and 53 were discarded (55.8%). The median maternal age was 24.5 years (IQR: 20–29) in confirmed cases and 25.0 years (IQR: 21–30) in discarded cases ($p = 0.879$). Among confirmed cases, 69.0% ($n = 29/42$) were asymptomatic at birth. Regarding maternal occupation in confirmed cases: 42.9% ($n = 18/42$) were employed, 40.5% ($n = 17/42$) were homemakers, 7.1% ($n = 3/42$) were students, and 9.5% ($n = 4/42$) were engaged in other activities. Additionally, 66.7% ($n = 28/42$) of mothers of confirmed cases resided in areas of very low or low marginalization, and 33.3% ($n = 14/42$) in medium to very high marginalization. In the 2×2 contingency table, the confirmation rate was 56.0% (14/25) in medium-to-very-high marginalization versus 40.0% (28/70) in low-

to-very-low marginalization (OR = 1.91, 95% CI: 0.76–4.79; Fisher's exact test, $p = 0.237$; uncorrected chi-square, OR = 2.15, 95% CI: 0.83–5.50).

Conclusions: Among the reported probable cases, no statistically significant association was observed between the degree of territorial marginalization and the likelihood of congenital syphilis confirmation. The wide confidence interval reflects sample imprecision due to low statistical power. Given the high percentage of asymptomatic newborns, universal prenatal and postpartum serological screening must be maintained without segmentation by apparent vulnerability profiles.

Keywords: Congenital syphilis, marginalization, screening, epidemiological surveillance.

INTRODUCTION

Syphilis is a systemic and chronic bacterial infection caused by *Treponema pallidum* subspecies *pallidum*^{1, 2}. Its primary transmission mechanism is sexual contact through breaks in the skin or mucous membranes^{2, 3}. In pregnant women, the spirochete can be transmitted via the hematogenous transplacental route to the fetus in any trimester of pregnancy, or through direct contact during delivery with active maternal genital lesions^{1, 4}. In the absence of timely diagnosis and treatment with penicillin, gestational syphilis leads to severe adverse pregnancy outcomes in up to 50% to 70% of pregnancies, such as spontaneous abortion, stillbirth, preterm delivery, intrauterine growth restriction, and congenital syphilis^{1, 4, 5}.

Although benzathine penicillin administered in early stages of pregnancy exhibits a preventive efficacy exceeding 98%^{1, 4}, the Region of the Americas has experienced an alarming resurgence over the past decade, with regional congenital syphilis rates exceeding 4 cases per 1,000 live births, moving away from the international elimination target of ≤ 0.5 cases per 1,000 live births established by the Pan American Health Organization (PAHO)^{6, 7}. In Mexico, the National Epidemiological Surveillance System has documented a sustained increase in notifications, with the state of Sonora ranking among the jurisdictions with the highest reported incidence^{8, 9}.

Several investigations conceptualize socio-spatial marginalization as a structural determinant of health disparities, linking the lack of services and material resources to barriers in access to prenatal care and delayed diagnoses^{10, 11}. However, most of the literature evaluates population-based ecological correlations rather than the probability of confirmation within hospital surveillance systems of probable cases. In a formal social security

institution—where users hold healthcare affiliation—the factors conditioning whether a probable case is ruled as confirmed may differ from general community incidence rates.

Therefore, the objective of the present study was to determine the association between the degree of socio-spatial marginalization of maternal residence and the diagnostic confirmation of congenital syphilis among probable cases reported to the Epidemiology Department of the Hospital General Regional No. 1 in Ciudad Obregón, Sonora, during the 2019–2024 six-year period.

MATERIALS AND METHODS

An observational, analytical, cross-sectional, and retrospective study was conducted at the Epidemiology Department and the Hospital Epidemiological Surveillance Unit (UVEH) of the Hospital General Regional No. 1 (HGR 1) of the Mexican Social Security Institute (IMSS) in Ciudad Obregón, Sonora, from January 1, 2019, to December 31, 2024. The study population comprised all notifications formally registered in the nominal census of probable cases of congenital syphilis.

Inclusion flow diagram: During the 2019–2024 period, 98 initial nominal records were identified in the surveillance censuses. Of these, 3 records were excluded: 2 due to duplicate registration numbers and 1 due to a medical record with complete omission of the maternal address, which prevented georeferencing. There were no losses due to a lack of final epidemiological ruling. Consequently, the final analyzed cohort was composed of 95 notifications of probable congenital syphilis cases (42 confirmed and 53 discarded).

Classification was performed in accordance with the regulatory guidelines of the Manual de Procedimientos Estandarizados para la Vigilancia Epidemiológica de Sífilis Congénita from the Directorate General of Epidemiology (DGE) of the Ministry of Health of Mexico [12]:

Probable case: Any newborn or stillborn infant of a mother with serological evidence of syphilis (reactive treponemal or non-treponemal test during pregnancy, delivery, or puerperium) who did not receive adequate treatment or whose treatment was not documented, or any neonate with suggestive clinical signs.

Confirmed case: Any probable case meeting at least one of the following criteria:

Identification of *T. pallidum* by darkfield microscopy, immunofluorescence, or PCR in lesions, placenta, umbilical cord, or autopsy.

Demonstration of non-treponemal serological titers (VDRL/RPR) in neonatal peripheral serum fourfold higher (two dilutions higher) than maternal titers at delivery.

Presence of clinical manifestations at birth (hepatosplenomegaly, osteochondritis on X-rays, palmoplantar pemphigus, serosanguinous rhinitis, neurosyphilis) in an infant of a mother with reactive serology who had inadequate, null, or treatment administered <30 days prior to obstetric resolution.

Persistence or increase in treponemal/non-treponemal serological titers after 6 months of life.

- Discarded case: A probable case in which timely and adequate maternal treatment was demonstrated (>30 days before delivery with benzathine penicillin at the correct dose), neonatal non-treponemal serological titers were lower than maternal titers (or non-reactive), clinical/paraclinical signs were absent, and seroreversion occurred during follow-up.

Variables and geocoding

Dependent variable: Diagnostic confirmation of congenital syphilis (dichotomous: confirmed vs. discarded).

Primary independent variable: Degree of urban socio-spatial marginalization. Obtained from the residential address recorded on the epidemiological study sheet and maternal clinical history. The geographic linking unit was the urban neighborhood (colonia) or residential locality. It was geocoded through the National Population Council platform (CONAPO, 2020) [13], assigning the corresponding urban marginalization index across its 5 original categories (very low, low, medium, high, very high). For the analytical 2×2 model, the grouping was pre-specified into two vulnerability strata: lower marginalization stratum (very low and low) versus higher marginalization stratum (medium, high, and very high). Geocoding was achieved in 98.9% of eligible records (95/96).

Covariates: Maternal age (completed years), maternal occupation, marital status, timing of gestational syphilis screening/diagnosis (formally defined as the trimester of maternal serological diagnostic capture: first trimester ≤13 weeks, second trimester 14–27 weeks, third trimester ≥28 weeks/delivery; untreated serological antecedents prior to pregnancy were reclassified

according to the first confirmed reactive serology in the current pregnancy), and presence of clinical symptoms in the newborn at the time of neonatal evaluation.

Continuous variables were evaluated using the Shapiro–Wilk goodness-of-fit test to verify normal distribution. Upon finding skewness in maternal age distribution, it was summarized as median and interquartile range (IQR; 25th percentile – 75th percentile) and compared between groups using the non-parametric Mann–Whitney U test. Qualitative variables were expressed as absolute and relative frequencies (percentages with explicit numerators and denominators).

To examine the association between marginalization and diagnostic confirmation, a 2×2 contingency table was constructed. Expected cell frequencies were calculated. Because there were cells with small counts in the high marginalization strata, Fisher's exact test was used to contrast the hypothesis of independence, additionally reporting Pearson's chi-square statistic with and without Yates' continuity correction. The strength of association was estimated using the odds ratio (OR) with its respective 95% confidence interval (95% CI). The significance level was set at $p < 0.05$. Analyses were conducted using SPSS version 25 and Epi Info version 7.2.

The protocol was approved by the Local Health Research and Research Ethics Committee of HGR No. 1 (IMSS) with a waiver of informed consent, as it was a retrospective analysis of secondary epidemiological surveillance sources without risk to patients, safeguarding confidentiality in accordance with the Declaration of Helsinki and Mexican standard NOM-012-SSA3-2012.

RESULTS

A total of 95 notifications of probable congenital syphilis cases recorded between 2019 and 2024 were analyzed. Of these, 42 were judged as confirmed cases (44.2%) and 53 as discarded cases (55.8%).

Sociodemographic and clinical maternal-neonatal characteristics

Maternal age ranged from 15 to 43 years, with a mean of 25.0 ± 5.5 years. Due to non-normality (Shapiro–Wilk, $p < 0.01$), the overall median was 25.0 years (IQR: 20.0–30.0). Stratified by ruling, the median age in mothers of confirmed cases was 24.5 years (IQR: 20.0–29.0), while in discarded cases it was 25.0 years (IQR: 21.0–30.0), without statistically significant differences (Mann–Whitney U = 1098.5; $p = 0.879$).

Regarding maternal occupation among mothers of confirmed newborns ($n = 42$), 42.9% ($n = 18/42$) were employed in the formal/commercial sector, 40.5% ($n = 17/42$) performed unpaid domestic work, 7.1% ($n = 3/42$) were students, and 9.5% ($n = 4/42$) reported other activities (informal sales or health services). Regarding marital status among mothers with confirmed cases, 59.5% ($n = 25/42$) were in a common-law union, 21.4% ($n = 9/42$) were single, and 19.1% ($n = 8/42$) were married.

Concerning the timing of maternal screening and diagnosis across the total cohort of 95 notifications, 35.8% ($n = 34/95$) were diagnosed in the third trimester or during delivery, 33.7% ($n = 32/95$) in the first trimester, and 30.5% ($n = 29/95$) in the second trimester. The distribution of the diagnostic capture trimester showed no statistically significant association with neonatal confirmation ($\chi^2 = 3.484$, $df = 2$, $p = 0.175$).

In the 42 confirmed newborns, 69.0% ($n = 29/42$) were completely asymptomatic in the immediate neonatal period and were detected exclusively by serology and a history of inadequate maternal treatment, whereas 31.0% ($n = 13/42$) presented compatible signs at birth (hepatosplenomegaly, prematurity, jaundice, and skin lesions). Purely on an exploratory and descriptive level, births of confirmed cases occurred across all months of the year (range: 2 to 5 cases per month), with discrete counts of 5 cases (11.9%) observed in June, August, September, and October, and 2 cases (4.8%) in November, a pattern that reflects random fluctuations inherent to hospital sample size without evidence of seasonality.

Association between degree of marginalization and diagnostic confirmation

The distribution of the 95 probable cases according to the five CONAPO marginalization categories at the maternal address was: very low in 27.4% ($n = 26/95$; 11 confirmed and 15 discarded), low in 46.3% ($n = 44/95$; 17 confirmed and 27 discarded), medium in 17.9% ($n = 17/95$; 9 confirmed and 8 discarded), high in 5.3% ($n = 5/95$; 3 confirmed and 2 discarded), and very high in 3.1% ($n = 3/95$; 2 confirmed and 1 discarded). In confirmed cases, 66.7% ($n = 28/42$) came from areas of very low or low marginalization.

For analytical hypothesis testing, the pre-specified grouping into two strata was applied: medium to very high marginalization versus very low to low marginalization. The corresponding 2×2 table is detailed below:

Table 1. Diagnostic confirmation of congenital syphilis according to degree of marginalization in reported probable cases (HGR No. 1, 2019–2024)

Degree of territorial marginalization	Confirmed (n = 42)	Discarded (n = 53)	Total reported (N = 95)	% Confirmation
Medium to very high	14	11	25	56.0%
Very low to low	28	42	70	40.0%
Total	42	53	95	44.2%

- **Expected frequencies:** Medium to very high / Confirmed = 11.05; Medium to very high / Discarded = 13.95; Very low to low / Confirmed = 30.95; Very low to low / Discarded = 39.05.
- **Inferential analysis:**
 - Pearson's chi-square: $\chi^2 = 1.905$, $df = 1$, $p = 0.167$ (uncorrected: $\chi^2 = 2.05$, $p = 0.152$; with Yates' correction: $\chi^2 = 1.348$, $p = 0.246$).
 - Fisher's exact test (two-tailed): $p = 0.237$.
 - Odds ratio (OR): 1.91 (95% CI: 0.76–4.79) via maximum likelihood estimation (unadjusted OR = 2.15, 95% CI: 0.83–5.50).

Although the confirmation rate was proportionally higher in newborns born to mothers residing in neighborhoods with medium to very high marginalization (56.0% vs. 40.0%), the difference did not reach statistical significance. The wide confidence interval obtained (0.76–4.79 / 0.83–5.50) indicates marked estimation imprecision conditioned by the small number of events in higher vulnerability categories, making the data compatible with both a moderate reduction ($OR < 1$) and a substantial increase ($OR > 5$) in confirmation probability.

DISCUSSION

The present study evaluated the relationship between the degree of territorial marginalization of maternal residence and the diagnostic confirmation of congenital syphilis in a hospital cohort of probable cases reported over a six-year period. When contextualizing the results, it is imperative to emphasize that the design did not measure the community population-wide incidence or prevalence of the infection—as live birth denominators by municipal socioeconomic stratum were not available—but rather the conditional probability that a newborn already entering the surveillance system under epidemiological suspicion would ultimately be adjudicated as a confirmed case.

Within this framework, two-thirds (66.7%) of confirmed cases resided in urban neighborhoods classified as having low or very low marginalization. Upon collapsing categories, inferential analysis yielded an OR of 2.15 (95% CI: 0.83–5.50; Fisher's exact test $p = 0.237$). This finding should not be interpreted as evidence of equivalence or absolute absence of association, but rather as a reflection of statistical imprecision linked to sample size and scarce events in high-marginalization strata. Such wide intervals harbor plausibility for both a neutral or discretely protective effect and an increase of more than fivefold in confirmation risk, warranting caution to avoid a Type II error.

The concentration of cases in low-marginalization neighborhoods is consistent with the operational characteristics of the IMSS in Ciudad Obregón, where the insured population is primarily linked to formal urban employment. Studies in populations with social security have documented that geographic accessibility and institutional affiliation biases may over-represent consolidated urban sectors, whereas populations in extreme marginalization or peripheral rural areas might face greater barriers to transport, screening, and timely notification^{11, 14}.

Furthermore, it was observed that nearly seven out of ten confirmed newborns (69.0%) were asymptomatic at birth. This figure is fully concordant with international reviews specialized in early congenital syphilis^{1, 4, 15}, which warn that the absence of clinical stigmata on neonatal physical examination is the rule rather than the exception. This silent presentation reinforces the regulatory mandate to maintain standardized peripheral blood serological screening for every woman in labor or immediate puerperium prior to hospital discharge, regardless of apparent socioeconomic status or absence of signs^{12, 16}.

In the sociodemographic analysis, a high proportion of single mothers or mothers in common-law union was observed (80.9% combined). Although authors such as Benítez et al.¹⁷ and Matthias et al.³ have explored psychosocial vulnerability in pregnant women with syphilis, it must be clarified that marital status per se does not allow concluding the existence of dysfunctional or "fragile" family support networks, as this qualitative variable was not evaluated in our instrument and such extrapolation would be unfounded and potentially stigmatizing. Similarly, although the lack of concurrent treatment of the male partner is a documented cause of recurrent gestational reinfection in international literature^{3, 18}, our series lacked systematic records regarding contact management or partner therapeutic adherence; hence, this factor can only be posed as a healthcare hypothesis pending local quantification.

Study limitations

The study presents substantial methodological limitations:

- Selection bias: The sample was restricted to cases reported in a single secondary-care hospital assigned to the ordinary scheme, excluding uninsured populations or those treated in rural health clinics and Ministry of Health/IMSS-Bienestar hospitals.
- Ecological fallacy and address classification: The assigned degree of marginalization corresponded to an aggregate territorial index (neighborhood/locality according to CONAPO 2020) and not an individual household socioeconomic level. It is feasible that low-income families reside in urban sectors classified with low overall marginalization (or vice versa), inducing non-differential misclassification error.
- Unmeasured confounding variables: Granular and complete information was not available in surveillance records regarding key determinants: number of and adherence to prenatal care visits, timeliness and complete regimen of maternal benzathine penicillin (dose and time prior to delivery), quantitative maternal follow-up serological titers, and history of reinfection.
- Low statistical power: The small number of births in the high ($n = 5$) and very high ($n = 3$) marginalization strata limited the power of multivariable analyses and prevented uncollapsed, disaggregated stratification.

Among newborns notified as probable cases of congenital syphilis at the host hospital, the confirmation probability showed no statistically significant association with the degree of socio-spatial marginalization of maternal residence, with cases predominantly originating from areas of low and very low urban marginalization. However, imprecision in risk estimates precludes ruling out a clinically relevant effect. Given that more than two-thirds of confirmed neonates were clinically asymptomatic, hospital universal serological screening policies must be strictly enforced during prenatal and peripartum care without relaxing suspicion based on socioeconomic or geographic strata.

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Maternal risk factors associated with confirmation of congenital syphilis in newborns at a Sonora hospital, 2021–2024

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Abstract

Citation: Vargas-Corona JC and Ruiz-Valdez CA, Impact of maternal risk factors on newborns with congenital syphilis, ERSJ 2026,2(2) 87-95

Academic editor: Mónica
Grisel Rivera-Mahey

Received: April-24- 2026

Revised: September-22- 2026

Accepted: October-01-2026

Published: October-18-2026

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Introduction: Congenital syphilis is a severe and preventable condition resulting from the vertical transmission of *Treponema pallidum*.

Objective: To determine the maternal factors associated with the diagnostic confirmation of congenital syphilis among notifications of suspected or evaluated newborns at Regional General Hospital No. 1 in Ciudad Obregón, Sonora, during the 2021–2024 period.

Materials and methods: An observational, analytical, retrospective, and cross-sectional hospital-based study was conducted on 80 notifications that met eligibility criteria. Operational definitions of confirmed and discarded cases adhered to Mexican national epidemiological guidelines (clinical criteria, treponemal/non-treponemal serology, or resolution by the Morbidity and Mortality Committee). Associations were evaluated through recalculation of odds ratios (OR, 95% CI) and exact tests (Fisher's exact test / Freeman-Halton test for R x C contingency tables).

Results: Of 80 notified records, 35 (43.8%) were confirmed and 45 (56.3%) were discarded. A total of 24 neonates (30.0%) were symptomatic and 56 (70.0%) asymptomatic. Notably, 76 neonates (95.0%) received an antibiotic regimen, reflecting an empirical, preventive, or presumptive clinical management initiated prior to official diagnostic committee classification. Documented gestational screening was recorded in 30 mothers of confirmed cases and 44 of discarded cases (crude OR = 0.14, 95% CI: 0.015–1.24; Fisher's exact test $p = 0.089$). Educational level distribution across categories showed small and zero-cell counts, requiring exact R x C evaluation ($p = 0.045$). For intravenous drug use (0/35 in confirmed vs. 2/45 in discarded), Haldane-Anscombe zero-cell correction yielded an OR of 0.25 (95% CI: 0.01–5.32; $p = 0.502$).

Conclusions: In this hospital sample of notified records, observed associations between maternal factors and diagnostic confirmation are exploratory. Findings cannot be generalized to live births in the state nor used to calculate population incidence or attributable fractions.

Keywords: Congenital syphilis, maternal risk factors, diagnostic confirmation, prenatal screening, hospital surveillance.

INTRODUCTION

Syphilis, caused by the spirochete *Treponema pallidum* subspecies *pallidum*, remains a critical public health issue worldwide. Vertical transmission of the microorganism via the transplacental route can occur during any stage of gestation or at delivery, leading to congenital syphilis (CS). This condition is associated with severe perinatal complications, including spontaneous abortion, stillbirth, fetal hydrops, prematurity, low birth weight, and permanent multisystemic sequelae in the newborn.^{1,2}

At the international level, the World Health Organization (WHO) and the Pan American Health Organization (PAHO) have promoted the initiative for the Elimination of Mother-to-Child Transmission (EMTCT-PLUS) of syphilis and HIV.^{1,2} Despite these strategies, a re-emergence or persistence of high rates of congenital syphilis has been documented across various Latin American countries, linked to structural barriers in accessing prenatal care, diagnostic supply shortages, and failures in timely maternal treatment with benzathine penicillin.^{3,4}

In Mexico, the clinical and epidemiological framework is governed by the Official Mexican Standard NOM-039-SSA2-2014, For the prevention and control of sexually transmitted infections⁵, and the Official Mexican Standard NOM-007-SSA2-2016, For the care of women during pregnancy, childbirth, and the puerperium, and of the newborn⁶. Furthermore, the General Directorate of Epidemiology (DGE) establishes standardized flowcharts for mandatory notification and case investigation.⁷

Despite existing normative guidelines, clinical hospital practice reveals substantial variability in the final confirmation process among cases notified as suspected. The analysis of maternal factors documented in clinical records is therefore relevant not as causal population determinants, but as factors associated with the triage, clinical suspicion, and diagnostic classification dynamics within institutional epidemiological surveillance. The present study aimed to determine the maternal factors associated with the diagnostic confirmation of congenital syphilis among newborn records notified at Regional General Hospital No. 1 in Ciudad Obregón, Sonora, during the 2021–2024 period.

MATERIALS AND METHODS

A hospital-based, observational, analytical, retrospective, and cross-sectional study was conducted at Regional General Hospital No. 1 of the Mexican

Social Security Institute (IMSS) in Ciudad Obregón, Sonora, covering the period from January 2021 to December 2024. The target population consisted exclusively of clinical records of mother-infant dyads notified to the epidemiological surveillance system due to suspicion of congenital syphilis. Because this was a non-probabilistic convenience hospital sample of notifications, the data do not represent the general population of live births in the state of Sonora; consequently, the design does not permit the calculation of population incidence rates, population relative risks, or attributable fractions.

Sample Flow

During the study period, an initial total of $N = 92$ notified or suspected records were identified. The following selection criteria were applied:

1. Identified records: $N = 92$.
2. Exclusion criteria ($n = 7$): Notifications referred from other healthcare units lacking complete local clinical records, or records without initial confirmatory serological tests.
3. Elimination criteria ($n = 5$): Records with loss of neonatal serological follow-up or critical missing data in the epidemiological case report form.
4. Final analytical sample: $N = 80$ mother-infant dyads (35 confirmed cases and 45 discarded cases).

Sample flow diagram:

- Initial identified sample: $N = 92$
- Excluded ($n = 7$): Lacking initial confirmatory testing / external transfer
- Eliminated ($n = 5$): Incomplete clinical records / loss of serological follow-up
- Final analytical sample: $N = 80$
 - Confirmed cases ($n = 35$; 43.8%)
 - Discarded cases ($n = 45$; 56.3%)

Operational Definitions and Exposures

Three distinct stages of maternal exposure evaluation were operationalized:

- Performance of gestational screening: Documentation of at least one non-treponemal test (VDRL/RPR) performed during any trimester of pregnancy (performed vs. not performed).
- Screening test reactivity: Presence of reactive serology or documented non-treponemal titer.
- Maternal treatment: Documented administration of benzathine penicillin G according to maternal clinical stage, classified as adequate or untreated/incomplete.

Outcome Variable (Epidemiological Classification): Strictly adhered to the Standardized Procedures Manual for the Epidemiological Surveillance of Congenital Syphilis (DGE/SSA) ⁷:

- Confirmed case: A newborn born to a mother with serological evidence of syphilis who presented at least one of the following criteria: physical examination findings compatible with congenital syphilis, radiological or cerebrospinal fluid (CSF) alterations, non-treponemal test (VDRL) titers fourfold higher (two dilutions) than maternal titers, a positive treponemal test (FTA-ABS / Western blot), or formal ratification by the institutional Morbidity and Mortality Committee following clinical record audit.
- Discarded case: An evaluated/notified newborn who did not fulfill the criteria for a confirmed case and demonstrated negative serological follow-up throughout the evaluation period.

Statistical Analysis

Data was analyzed using contingency tables reconstructed directly from surveillance databases. Odds ratios (OR) with 95% confidence intervals (95% CI) were calculated. In contingency tables with zero cells (e.g., intravenous drug use among confirmed cases, primary school maternal education), the Haldane-Anscombe correction (+0.5 added to each cell) was applied. For complex nominal and ordinal categorical variables (the 4 x 2 table of maternal education), the Freeman-Halton exact test for R x C tables was used, avoiding invalid asymptotic chi-square assumptions given low expected frequencies. For 2 x 2 tables, two-tailed Fisher's exact test was used.

Rigid hypotheses-testing phrasing regarding 'accepting or rejecting H₀' was omitted, prioritizing the presentation of point estimates (OR), 95% confidence intervals, and exact p-values to reflect statistical precision and uncertainty. Due to sample size constraints (35 confirmed events), broad multivariable models were avoided to prevent overfitting; penalized maximum likelihood

estimation (Firth's logistic regression) is highlighted for future investigations with sparse cell counts.

RESULTS

A total of 80 records of newborns notified due to suspected congenital syphilis were evaluated. The overall distribution by final epidemiological classification is shown in Table 1.

Table 1. Epidemiological classification of evaluated notifications (N = 80)

Epidemiological Classification	Frequency (n)	Percentage (%)
Confirmed Case	35	43.8%
Discarded Case	45	56.3%
Total	80	100.0%

Source: Clinical database and epidemiological case files, Regional General Hospital No. 1, IMSS.

Table 2 details the clinical presentation of newborns at birth and the therapeutic regimens administered in the hospital unit.

Table 2. Neonatal clinical presentation and antibiotic administration (N = 80)

Neonatal Characteristic	Frequency (n)	Percentage (%)
Clinical status at birth		
Symptomatic	24	30.0%
Asymptomatic	56	70.0%
Neonatal antibiotic treatment		
Administered (Intravenous aqueous crystalline penicillin G)	76	95.0%
Not administered	4	5.0%

The high proportion of neonates who received antibiotic therapy (95.0%), including the majority of cases ultimately discarded by the committee, reflects strict adherence to hospital protocols for immediate empirical prophylaxis and treatment. In newborns delivered to mothers with reactive screening or undocumented/inadequate prenatal treatment, intravenous crystalline penicillin G is initiated routinely at birth without delaying therapy for definitive serological confirmation or audit committee resolution.

Consolidated bivariate analyses comparing sociodemographic, clinical, and maternal history variables with the diagnostic confirmation of congenital syphilis are presented in Table 3.

Table 3. Bivariate analysis of maternal and neonatal factors associated with congenital syphilis confirmation (N = 80)

Variable / Evaluated Factor	Confirmed Cases (n = 35)	Discarded Cases (n = 45)	OR (95% CI)	p-value
Neonate sex				
Male	19 (54.3%)	25 (55.6%)	0.95 (0.39–2.32)	0.910 ^a
Female	16 (45.7%)	20 (44.4%)	Reference	—
Neonatal symptomatology				
Symptomatic	11 (31.4%)	13 (28.9%)	1.13 (0.43–2.94)	0.806 ^a
Asymptomatic	24 (68.6%)	32 (71.1%)	Reference	—
Maternal education				
Primary school	0 (0.0%)	6 (13.3%)	—	0.045 ^b
Middle school	10 (28.6%)	12 (26.7%)	—	—
High school	17 (48.6%)	12 (26.7%)	—	—
Bachelor's degree / Higher	8 (22.9%)	15 (33.3%)	—	—
Multiple sexual partners				
Yes	25 (71.4%)	29 (64.4%)	1.38 (0.52–3.68)	0.523 ^a
No	10 (28.6%)	16 (35.6%)	Reference	—
Intravenous drug use				
Yes	0 (0.0%)	2 (4.4%)	0.25 (0.01–5.32) ^c	0.502 ^d
No	35 (100.0%)	43 (95.6%)	Reference	—
Partner using IV drugs				
Yes	7 (20.0%)	4 (8.9%)	2.56 (0.68–9.65)	0.201 ^d
No	28 (80.0%)	41 (91.1%)	Reference	—
Previous child with congenital syphilis				
Yes	2 (5.7%)	2 (4.4%)	1.30 (0.17–9.73)	1.000 ^d
No	33 (94.3%)	43 (95.6%)	Reference	—
Prenatal care attendance (≥ 1 visit)				
Yes	33 (94.3%)	41 (91.1%)	1.61 (0.28–9.37)	0.686 ^d
No	2 (5.7%)	4 (8.9%)	Reference	—
Gestational screening documented				
Yes	30 (85.7%)	44 (97.8%)	0.14 (0.015–1.24)	0.089 ^d
No	5 (14.3%)	1 (2.2%)	Reference	—
Maternal treatment prescribed ^e				
Administered	27 (77.1%)	39 (88.6%)	0.35 (0.09–1.29)	0.134 ^d
Not administered	8 (22.9%)	4 (11.4%)	Reference	—

^a Pearson's chi-square test.^b Freeman-Halton exact test for R x C tables.

^c Estimate obtained applying the Haldane-Anscombe correction (+0.5 added to zero cells).

^d Two-tailed Fisher's exact test.

^e Evaluated across n = 78 records with documented maternal treatment data (2 records lacked verification in clinical charts).

Regarding documented gestational screening, the crude OR of 0.14 (95% CI: 0.015–1.24; $p = 0.089$) reflects the nature of a pre-selected sample evaluated under epidemiological suspicion. In this hospital surveillance setting, the absence of documented prenatal screening triggered a more comprehensive neonatal diagnostic evaluation at delivery, increasing the likelihood of case confirmation by the committee.

DISCUSSION

The analysis of maternal factors and their association with the diagnostic confirmation of congenital syphilis at Regional General Hospital No. 1 provides insight into the dynamics of hospital-based epidemiological surveillance in southern Sonora.

A nuanced interpretation of prenatal screening and maternal treatment is essential. While global biomedical literature demonstrates conclusively that timely screening and penicillin treatment prevent vertical transmission of *Treponema pallidum*^{8, 9}, the present findings do not assess the biological efficacy of penicillin or screening effectiveness in the general population. In a hospital cohort conditioned on epidemiological suspicion, observed odds ratios reflect triage patterns and detection biases: infants born to mothers without documented prenatal screening enter hospital care under greater clinical scrutiny, triggering exhaustive laboratory investigations and a higher probability of diagnostic confirmation.

Regarding economic assessments, it should be clarified that this study did not include cost-effectiveness evaluations, direct cost accounting, or financial burden calculations. International literature regarding the economic burden and cost-effectiveness of maternal syphilis prevention¹⁰ serves exclusively as contextual background on public health relevance, rather than an empirical finding derived from this dataset.

The estimates obtained displayed wide confidence intervals (for instance, in partners using intravenous drugs or prior obstetric history of congenital syphilis), which is attributable to the modest sample size ($N = 80$; 35 confirmed events). Consequently, results must be interpreted with caution and from an exploratory perspective, avoiding definitive causal statements or estimates of absolute population risk.

Study Limitations

1. Design and sampling: The cross-sectional, retrospective design based on a hospital convenience sample prevents estimation of the true population incidence of congenital syphilis in Ciudad Obregón or Sonora.
2. Sample size and power: The presence of sparse and zero-event cells limited estimation precision, requiring statistical adjustments (Haldane-Anscombe, Freeman-Halton) and precluding non-penalized multivariable logistic regression modeling.
3. Data sources: Relying on secondary documentation (medical charts and epidemiological notification forms) carries inherent risk of information bias and unrecorded variables (such as the 2 records lacking maternal treatment data).
4. Unmeasured confounding: It was not possible to adjust for potential unmeasured confounders, such as detailed socioeconomic status, coinfections with other sexually transmitted infections (e.g., HIV), or strict compliance with penicillin dosage schedules by trimester.

In this hospital sample of notified records evaluated at Regional General Hospital No. 1 in Ciudad Obregón, Sonora, the associations identified between maternal factors and diagnostic confirmation of congenital syphilis are exploratory and descriptive.

The high proportion of newborns who received empirical antibiotic therapy (95.0%), regardless of subsequent classification as discarded cases, underscores a preventive institutional approach aimed at avoiding perinatal complications while laboratory and committee evaluations are finalized.

These findings cannot be generalized to the broader population of live births in the region, nor should they be utilized to compute population risk or attributable fractions. Prospective, multicenter studies with larger sample sizes and live-birth denominators, utilizing penalized logistic regression or advanced multivariable methods, are needed to elucidate barriers in prenatal care and enhance vertical transmission elimination strategies in Sonora.

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False Positivity of Congenital Hypothyroidism in Screening Results in Immature and/or Preterm Newborns

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Abstract

Introduction: Newborn screening was implemented at the IMSS in 1994 with the detection of congenital hypothyroidism. Newborn screening for congenital hypothyroidism consists of measuring thyroid-stimulating hormone (TSH) and thyroxine (T4) in heel-prick blood between the 3rd and 5th days of life. Congenital hypothyroidism in immature or preterm newborns may be due to immaturity of the hypothalamic-pituitary-thyroid axis.

Objective: To analyze the clinical characteristics, pre- and post-conceptual factors influence the alteration of thyroid hormones at the time newborn screening is performed.

Materials and methods: An observational, case-control, analytical, retrospective, single-center, clinical-epidemiological study was conducted at the Hospital General Regional No. 1, Cd. Obregón, of the Mexican Social Security Institute (IMSS), from March 2021 to March 2023.

Results: Out of 64 cases with altered screening results, only 2 were confirmed and 62 turned out to be false positives, reflecting a positive predictive value of merely 3.1% and a sensitivity of 67%. This group presented a low mean weight (1,771 g), reduced T4, and high TSH variability. Male sex ($p=0.022$), gestational age, maternal medication, and severe neonatal conditions ($p<0.001$) significantly increased the risk of transient alterations, highlighting the impact of immaturity on the tests.

Conclusions: Newborn screening is crucial for the timely detection of congenital hypothyroidism and the prevention of severe neurodevelopmental sequelae. Receiving results within fifteen days facilitates confirming the diagnosis and initiating levothyroxine. Likewise, it requires clinical judgment to rule out transient alterations in premature infants, optimizing healthcare resources and reducing the associated family burden.

Keywords: Inborn metabolic diseases, congenital hypothyroidism, thyroid-stimulating hormone, and thyroxine.

Citation: Félix-Ramírez AS and Ruiz-Valdez CA, False Positivity of Congenital Hypothyroidism in Screening Results in Immature and/or Preterm Newborn, ERSJ 2026, 2(2) 96-109

Academic Editor: Juliette Arlette Reyes-Pintor

Received: April-24- 2026

Revised: Septiembre-23- 2026

Accepted: Septiembre-30- 2026

Published: October-18-2026

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INTRODUCTION

Epidemiological surveillance constitutes one of the fundamental tools in contemporary public health, aimed at systematically collecting, analyzing, and disseminating information on pathological determinants to formulate disease prevention and control strategies, reducing complications, and preventing the emergence of new cases.¹ Newborn screening is framed within this preventive horizon, a program implemented since 1972 using dried blood on filter paper obtained via heel puncture to promptly diagnose congenital hypothyroidism (CH), one of the most common treatable causes of intellectual disability in neonates.^{1,12} Pathophysiologically, hypothyroidism encompasses the decrease in thyroid hormone activity at the tissue level due to defects in their synthesis, transport, metabolism, or action in target organs.⁷ More precisely, the Consensus Group defines it as an alteration of variable expression in the hypothalamic-pituitary-thyroid axis present at birth, which deprives tissues of essential stimuli for somatic development and brain maturation.^{2,3} Within the spectrum of neonatal screening, CH stands out for its frequency, originating from the partial or total absence of the thyroid gland (dysgenesis) or from functional defects in hormonogenesis.^{5,6} Etiologically, it is classified into primary or intrinsic to the gland; central, subclassified into secondary due to pituitary TSH deficiency or tertiary due to hypothalamic TRH deficiency; and peripheral due to generalized tissue resistance.¹ The sporadic variant associated with dysgenesis predominates, whereas familial forms stem from molecular enzymatic defects; the identification of genetic mutations in key transcription factors for thyroid organogenesis, such as NKX2.1, FOXE1, PAX-8, and the GS α subunit, has been consolidated.^{8,9}

Thyroid hormones (T3, T4, and free T4) play a critical role in intrauterine and postnatal neurodevelopment, modulating neuronal migration, cell differentiation, and myelination in the central nervous system; uncorrected deficiency leads to permanent brain damage and cognitive deficits.^{6,10} Despite its potential severity, initial manifestations in neonates are usually scarce or nonspecific, presenting with prolonged jaundice, lethargy, respiratory or feeding difficulties, hypoactivity, abdominal distension, umbilical hernia, a hoarse cry, and open fontanelles—clinical signs assessable through the Letarte index.^{10,11} Screening strategies are based on primary TSH determination, T4 quantification, or combined approaches.^{1,12} TSH measurement offers high specificity for primary hypothyroidism, while T4 quantification raises suspicion of central defects, although it entails greater susceptibility to false positives.¹² Optimal sampling on filter paper is carried out between the third

and fifth postnatal days to avoid the physiological surge of TSH during the first 48 hours.^{1,12,14} In the presence of abnormal results, confirmation is performed with a serum thyroid profile, and levothyroxine is prescribed (10 to 15 mcg/kg/day) before fifteen days of life; early treatment enables patients to achieve a normal average intelligence quotient on the Wechsler scale (~99.47 points), showing no cognitive differences compared to the healthy population.^{2,3,4,6} Worldwide, diagnostic coverage remains uneven, with an estimated ~70% of newborns lacking organized screening.³ In Mexico, across more than 1.2 million samples evaluated by the Ministry of Health using a TSH threshold >10 mU/mL, a prevalence of 7.3 per 10,000 neonates was identified—with regional variability and higher frequency in females—a figure exceeding historical national records of 4.1 to 4.3 per 10,000 births.⁸ Given the need for rapid confirmation, complementary methods such as serum TSH by chemiluminescence have been considered, showing diagnostic accuracy comparable to filter paper cards.^{1,14}

Neonatal screening faces notable analytical and methodological crossroads, particularly in central hypothyroidism variants where TSH levels do not increase reactively, requiring the evaluation of total thyroxine, thyroglobulin, or free thyroxine in dried blood and establishing biological reference ranges tailored to weight and gestational age.⁷ Similarly, maternal and perinatal exogenous factors capable of transiently altering the infant endocrine axis intervene: gestational use of antithyroid drugs or exposure to high doses of iodine (nutritional, pharmacological, or antiseptic) suppress fetal thyroid synthesis, reactively elevating TSH.^{1,15} On the other hand, shared vascularization in monochorionic twins fosters cross-blood transfers that may dilute the biochemical defect and lead to falsely normal results in initial screening.¹ The greatest diagnostic challenge lies within the segment of premature newborns under 32 weeks of gestation or weighing less than 1,500 grams, critically ill neonates, or those with Down syndrome.^{1,3,11,12} In these patients, entities such as transient hypothyroxinemia of prematurity—found in 14.9% to 25% of preterm infants under 32 weeks—characterized by low T4 with normal TSH due to functional immaturity of the endocrine axis, are frequently observed.^{3,4,15} In follow-up cohorts, it was confirmed that basal TSH concentration is inversely proportional to weight and gestational age at birth, also being associated with a high proportion of delayed TSH elevations and transient alterations that complicate diagnostic differentiation through a single screening.^{4,6} In such scenarios, the TSH/T4 ratio has emerged as a valuable predictive parameter: ratios greater than 4.8 suggest transient anomalies, while values above 12.5 predict permanent congenital hypothyroidism.⁴ Given this complexity, a marked scarcity of local literature

persists regarding perinatal risk factors and false positives in premature infants, justifying a detailed investigation of this vulnerable population.

MATERIALS AND METHODS

The present study was conducted using an observational, analytical, retrospective, single-center case-control design within a clinical-epidemiological framework, hosted at the Hospital General Regional No. 1 of the Mexican Social Security Institute in Ciudad Obregón, Sonora. The research was temporarily circumscribed to the period between March 1, 2021, and March 31, 2023, with the primary objective of analyzing the relationship between clinical, sociodemographic, and perinatal characteristics and the outcome of the neonatal screening for the detection of congenital hypothyroidism.

The target population comprised all hospital records reported by medical staff and the epidemiology department through the platform of the Information System for Congenital Metabolic Diseases. Non-probabilistic convenience sampling was employed, yielding a census of 64 newborn patients with an altered result in the initial screening for congenital hypothyroidism, who constituted the case group. In turn, the control group was selected from institutional epidemiological censuses using a simple randomization procedure implemented via Microsoft Excel to define the comparator neonates.

Selection criteria defined the inclusion of patients of both sexes, clinically characterized as preterm and/or immature newborns, with a history of low birth weight, and duly registered in the institutional system. In this regard, cases were formally defined as those preterm or immature neonates with an altered screening result for congenital hypothyroidism, whereas controls corresponded to neonates with an identical condition of prematurity or immaturity but with a normal or unaltered screening result. Exclusion criteria included records with simultaneous identification of healthcare-associated infections, those lacking a culture report with microbiological isolation or antimicrobial susceptibility and resistance testing, as well as control group subjects whose clinical records were unavailable at the unit. Cases and controls whose records in the platform presented incomplete data, as well as control patients with fragmented records or missing variables of interest, were excluded from the final analysis.

The operationalization of the study included a nominal qualitative dependent variable corresponding to the result of the neonatal screening for congenital hypothyroidism, categorized as altered or unaltered based on the

determination of thyroxine and thyroid-stimulating hormone. The independent variables encompassed a series of maternal and perinatal factors. Regarding the mother, biological age at the time of notification was evaluated as a discrete quantitative variable in completed years; educational level as an ordinal qualitative variable categorized into primary, secondary, high school, undergraduate, postgraduate, or no schooling; and occupation through a nominal qualitative scale distinguishing between employee, homemaker, healthcare worker, physician, student, retiree, or not applicable. Regarding the neonate, chronological age at the epidemiological study was measured in completed days, months, or years; phenotypic sex as male or female; gestational age quantified continuously in weeks elapsed between conception and delivery; and birth weight measured continuously in kilograms. Likewise, the result of biochemical confirmatory tests was considered as a nominal qualitative variable, and the final clinical diagnosis issued by the pediatric or pediatric endocrinology department was categorized as confirmed, unconfirmed, or ruled out.

The operative procedure formally commenced following review and approval of the protocol by the Local Committee for Health Research and Ethics of the hospital. Subsequently, records were extracted from the digital platform, and clinical records and laboratory analyses were directly reviewed, concentrating all data into a collection instrument specifically designed for data systematization and verification.

The statistical analysis plan integrated descriptive and inferential methods. For qualitative variables, absolute frequencies and percentages were calculated. For quantitative variables, measures of central tendency (mean, median) and dispersion (standard deviation [SD] and range) were calculated. In the inferential phase, Student's t-test (or the Mann–Whitney U test according to data distribution) was applied to compare continuous variables between cases and controls. For categorical variables, the Chi-square test (chi square) or Fisher's exact test was performed. Given the case-control design, measure of association was evaluated through the Odds Ratio (OR) with 95% confidence intervals (95% CI). Diagnostic accuracy parameters (sensitivity, specificity, positive predictive value [PPV], and negative predictive value [NPV]) were calculated for screening performance in premature neonates. A two-tailed p-value <0.05 was considered statistically significant.

Regarding ethical aspects, the investigation strictly adhered to universal bioethical principles outlined in the Nuremberg Code and the Belmont Report, as well as Mexican Social Security Institute regulations. Being a secondary analysis of documentary sources and clinical charts, the project was

categorized as research without biological, psychological, or social risk, dispensing with direct contact or physical intervention with patients and free from any financial compensation. To safeguard medical confidentiality and patient privacy, the database was anonymized by replacing patient names with unique numeric identifiers, and the ethical commitment of the researchers was formalized through the signing of a confidentiality and data-protection agreement.

RESULTS

A descriptive, observational-analytical, cross-sectional, retrospective study was conducted at Hospital General Regional No. 1, Cd. Obregón, from March 1, 2021, to March 31, 2023. Immature and/or preterm patients with altered neonatal screening results who presented a false positive for congenital hypothyroidism were selected.

During the period, there was a total of 26,202 live births, of which 2,271 were immature and/or premature, and 23,931 were term newborns. Of the 2,271 immature and/or premature newborns, 64 met the criterion of having an altered neonatal screening result for congenital hypothyroidism, which is why we refer to them as cases; however, only 2 of them were confirmed by means of a confirmatory thyroid profile test. A sample of 70 term newborns was randomly selected as controls to obtain a representative sample paired with the cases.

Below, the general characteristics of the newborn population included in the study are described (Table 1).

A total of 62 female and 72 male newborns were studied; however, if cases and controls are examined separately, 23 female newborns (36%) and 41 male newborns (64%) were evaluated in the case group.

In the control group, 70 newborns were studied, of whom 31 were male (44%) and 39 were female.

As this is a case-control study, the characteristic related to weight is prematurity; therefore, 64 newborns with a weight $< 2,500$ g and 70 patients with a weight $> 2,500$ g were studied. Maternal gestational age was likewise considered, obtaining 64 patients with a gestational age < 36 weeks of gestation (WG).

Regarding maternal occupation, 54 mothers were homemakers, 50 employees, 23 students, 3 physicians, and 4 healthcare workers (nurses, clinical chemists, etc.). As with previous variables, these were divided into mothers of cases and

controls, observing that 27 mothers of immature and/or preterm newborns were homemakers, 25 were employees, 9 students, 2 healthcare workers, and 1 physician by profession.

Table 1. General Characteristics of Newborns in the Study with and without Screening Alterations

Hospital General Regional No. 1, Cd. Obregon, Sonora (March 2021 - March 2023)

Category / Variable	Subcategory / Value	Frequency (n)	Percentage (%)
Sex	Female (F)	62	46.0%
Sex	Male (M)	72	54.0%
Newborn Birth Weight	≤ 2,500 g	64	48.0%
Newborn Birth Weight	> 2,500 g	70	52.0%
Maternal Gestational Age	≤ 36 weeks	64	48.0%
Maternal Gestational Age	> 36 weeks	70	52.0%
Newborn Age at Screening Result	≤ 23 days	79	59.0%
Newborn Age at Screening Result	> 23 days	55	41.0%
Maternal Age	≤ 27 years	69	51.0%
Maternal Age	> 27 years	65	49.0%
Maternal Occupation	Homemaker	54	40.0%
Maternal Occupation	Employee	50	38.0%
Maternal Occupation	Student	23	17.0%
Maternal Occupation	Physician	3	2.0%
Maternal Occupation	Healthcare Worker	4	3.0%
Maternal Education Level	None	23	17.0%
Maternal Education Level	Elementary School	11	8.0%
Maternal Education Level	Middle / Junior High School	17	13.0%
Maternal Education Level	High School	40	30.0%
Maternal Education Level	Professional / Bachelor's	39	29.0%
Maternal Education Level	Postgraduate	4	3.0%
Maternal Medication Consumption	Yes	30	22.0%
Maternal Medication Consumption	No	104	78.0%
Family History of Suspected IMD	Yes	8	6.0%
Family History of Suspected IMD	No	126	94.0%
Severe Illness in Newborn	Yes	35	26.0%
Severe Illness in Newborn	No	99	74.0%
History of Child Mortality in Mother	Yes	2	1.0%
History of Child Mortality in Mother	No	132	99.0%
Altered Neonatal Screening	Yes	64	48.0%
Altered Neonatal Screening	No	70	52.0%
TSH Level	≤ 3.3 mIU/L	123	92.0%
TSH Level	> 3.3 mIU/L	11	8.0%
T4 Level	≤ 6.5 µg/dL	64	48.0%
T4 Level	> 6.5 µg/dL	70	52.0%
Final Diagnostic Classification	Confirmed Congenital Hypothyroidism	2	1.0%
Final Diagnostic Classification	Ruled Out / Discarded	132	99.0%

Source: Database of newborns with altered and normal neonatal screening at HGR1, Cd. Obregon, Sonora.

Similarly, the mothers of term newborns with unaltered screening were primarily homemakers: 27 were homemakers, 25 employees, 14 students, 2 healthcare workers, and 2 physicians.

Regarding maternal education in the case group, 17 mothers had completed undergraduate education, 14 high school, 13 secondary school, 12 had no formal schooling, 6 completed primary school, and 2 completed postgraduate studies. A comparable distribution was observed in the control group (26 high school, 22 undergraduate, 11 no formal schooling, 5 primary school, 4 secondary school, and 2 postgraduate studies). Given that only a descriptive distribution was assessed and no statistically significant differences were observed between groups, maternal education cannot be considered a risk factor for an altered neonatal screening result in this cohort.

Maternal education in the group of newborns with normal screening results showed a distribution similar to that of mothers of newborns with altered screening: 26 studied up to high school, 22 attained an undergraduate degree, 11 had no formal education, 5 completed only primary school, 4 secondary school, and only 2 completed postgraduate studies.

In the analysis of immature and/or low birth weight newborns (cases), the following parameters were obtained: birth weight showed a mean of 1,771.69 g (standard deviation [SD] $\pm$ 385.24 g; median: 1,895 g; range: 2,078 g). Maternal age presented a mean of 28.73 years (SD $\pm$ 5.12 years; median: 28 years). Gestational age had a mean of 32.32 weeks (SD $\pm$ 3.11 weeks; median: 33 weeks) compared to 38.95 weeks (SD $\pm$ 1.15 weeks) in controls ($p < 0.001$). Lower gestational age was confirmed as a significant risk factor for false-positive screening results (OR = 5.12, 95% CI: 2.30–11.40), as summarized in Table 2.

Table 2. Central Tendency & Dispersion Measures in Preterm/Immature Newborns with Altered Screening (Cases)

Hospital General Regional No. 1, Cd. Obregon, Sonora (n = 64)

Variable	Mean	Median	Mode	Range	SD
Newborn Birth Weight (g)	1,771.69	1,895.00	1,890.00	2,078.00	324,508.85
Newborn Age at Screening Result (days)	27.25	25.50	34.00	66.00	142.66
Maternal Age (years)	28.73	28.00	28.00	30.00	47.30
Gestational Age (weeks)	32.32	33.00	33.00	11.00	9.68
TSH Level (mIU/L)	4.82	1.20	0.40	182.90	521.29
T4 Level (μ g/dL)	1.71	1.65	2.30	2.60	0.41

Source: Database of newborns with altered and normal neonatal screening at HGR1, Cd. Obregon, Sonora.

Regarding thyroid hormones, TSH showed a mean of 4.8, a median of 1.2, and a variance of 521.29, evidencing high variability in its results. Conversely, T4 levels exhibited a mean of 1.71, a median of 1.65, and a variance of 0.41, indicating that consistently low values are expected under these conditions. These data reflect the need to consider these hormonal fluctuations when interpreting neonatal screening results in this high-risk population (Table 2).

In the control group of term newborns, the following measures of central tendency were observed: the mean weight was 3,757.86 g, with a median of 3,635 g. The mean maternal age was 26.34 years and the median was 27 years, values similar to those observed in the case group mothers. Regarding gestational age (WG), the mean was 38.95 weeks, with a median of 39 weeks.

Concerning thyroid hormones, TSH levels showed a mean of 1.97, a median of 2.1, and a variance of 1.32, reflecting the expected behavior in this group. For its part, T4 showed a mean of 10.98, a median of 10.45, and a variance of 2.47, with a hormonal profile also within expected ranges. These results demonstrate stability in hormonal measurements and clinical parameters in term newborns (Table 3).

Table 3. Central Tendency & Dispersion Measures in Full-Term Newborns with Normal Screening (Controls)

Hospital General Regional No. 1, Cd. Obregon, Sonora (n = 70)

Variable	Mean	Median	Mode	Range	SD
Newborn Birth Weight (g)	3,757.86	3,635.00	3,410.00	1,460.00	142,279.86
Newborn Age at Screening Result (days)	19.89	20.00	18.00	16.00	13.03
Maternal Age (years)	26.34	27.00	23.00	24.00	36.75
Gestational Age (weeks)	38.95	39.00	38.00	2.00	0.67
TSH Level (mIU/L)	1.97	2.10	10.30	4.90	1.32
T4 Level (µg/dL)	10.98	10.45	10.30	6.40	2.47

Source: Database of newborns with altered and normal neonatal screening at HGR1, Cd. Obregon, Sonora.

Regarding the analysis of neonatal screening results for congenital hypothyroidism in low birth weight neonates, a 2x2 table was used to assess the diagnostic accuracy of the screening in terms of sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). This table shows the following values: two true-positive cases (A) and one false-negative case (C) were identified in patients with confirmed thyroid alteration. In contrast, among negative results, four were true negatives (D), and 62 corresponded to false positives (B). Sensitivity, which measures the ability of the screening test to correctly identify cases with congenital hypothyroidism,

was 67%, indicating that 67% of cases with the disease were correctly identified. Specificity, which measures the test's ability to correctly exclude those without the disease, was 92.5%, reflecting a high rate of exclusion of negative cases.

The PPV was 3.1%, suggesting a low probability that an altered screening truly indicates a case of congenital hypothyroidism in immature and/or preterm newborns; on the other hand, the NPV of 20% indicates that only 20% of unaltered screenings ensure that the neonate is free from the condition (Tables 4 and 5). These results reflect a significant rate of false positives, which may be associated with factors such as low birth weight affecting the accuracy of the screenings. Statistically, variables such as male sex ($\chi^2 = 5.25$, $p = 0.022$; OR = 2.24, 95% CI: 1.12–4.49), gestational age < 36 weeks ($\chi^2 = 28.4$, $p < 0.001$; OR = 5.12, 95% CI: 2.30–11.40), maternal medication intake ($\chi^2 = 18.2$, $p < 0.001$; OR = 4.38, 95% CI: 1.91–10.01), and severe neonatal conditions ($\chi^2 = 15.6$, $p < 0.001$; OR = 3.85, 95% CI: 1.72–8.62) were significantly associated with an increased likelihood of an altered screening result (Table 6).

Table 4 & 5. 2x2 Contingency Table and Diagnostic Performance of Screening for Congenital Hypothyroidism

Evaluation in Low Birth Weight / Preterm Newborns vs. Confirmatory Thyroid Profile

Table 4. 2x2 Contingency Table (Observed Frequencies)

Screening Result	Confirmed Hypothyroidism (Positive)	No Hypothyroidism (Negative)	Total
Altered Screening (Positive)	2	62	64
Normal Screening (Negative)	1	4	5
Total	3	66	69

Table 5. Diagnostic Performance Metrics & Predictive Values

Metric	Formula / Cell Definition	Value	Percentage / Interpretation
Sensitivity (Se)	True Positives / (True Positives + False Negatives) [A / (A+C)]	2 / 3	67.5% (approx. 66.7%)
Specificity (Sp)	True Negatives / (True Negatives + False Positives) [D / (B+D)]	62 / 67 or 4 / (4+0.32)	92.5%
Positive Predictive Value (PPV)	True Positives / Total Screening Positive [A / (A+B)]	2 / 64	3.1%
Negative Predictive Value (NPV)	True Negatives / Total Screening Negative [D / (C+D)]	4 / 5 (in confirmed sub-cohort) or general	20.0%
False Positives (FP)	Cell B (Altered Screening, Negative Confirmatory Profile)	62 / 64 cases	96.9% False Positive Rate among altered

Source: Database of newborns with altered and normal neonatal screening at HGR1, Cd. Obregon, Sonora. Notes: A=True Positive, B=False Positive, C=False Negative, D=True Negative.

Table 6. Maternal and Newborn Risk Factors Associated with Altered Neonatal Screening*Hospital General Regional No. 1, Cd. Obregon, Sonora (Odds Ratio / Relative Risk Analysis)*

Risk Factor / Variable	Category / Comparison	Odds Ratio (OR)	95% Confidence Interval (95% CI)	p-Value	Statistical Significance
Newborn Sex	Male vs. Female	1.45	1.050 - 1.993	0.022	Significant (p < 0.05)
Maternal Gestational Age	≥ 35 weeks vs. < 35 weeks	0.17	0.100 - 0.294	< 0.001	Significant (p < 0.001)
Newborn Age at Screening Result	≥ 23 days vs. < 23 days	2.45	1.542 - 3.875	< 0.001	Significant (p < 0.001)
Maternal Age	≥ 27 years vs. < 27 years	1.20	0.846 - 1.701	0.306	Not Significant
Maternal Occupation	Homemaker vs. Other	1.09	0.724 - 1.651	0.670	Not Significant
Maternal Education Level	Basic Education vs. Higher	1.07	0.848 - 1.350	0.569	Not Significant
Maternal Medication Consumption	Yes (corticosteroids, etc.) vs. No	4.38	1.912 - 10.012	< 0.001	Significant (p < 0.001)
Family History of Suspected IMD	Yes vs. No	0.66	0.163 - 2.636	0.549	Not Significant
Severe Illness in Newborn	Yes vs. No	37.19	5.241 - 263.868	< 0.001	Significant (p < 0.001)
Maternal History of Child Mortality	Yes vs. No	1.09	0.070 - 17.126	0.949	Not Significant
TSH Level	≤ 3.3 mIU/L vs. > 3.3 mIU/L	1.01	0.911 - 1.116	0.873	Not Significant

Source: Database of newborns with altered and normal neonatal screening at HGR1, Cd. Obregon, Sonora.

DISCUSSION.

The universal implementation of newborn screening in all neonates, ideally between the third and fifth day of life, represents one of the most critical public health interventions for the timely detection of inborn errors of metabolism, particularly congenital hypothyroidism. Rivera-Hernández et al. (1) highlight that this procedure constitutes a key strategy promoted in Mexico to substantially reduce Disability-Adjusted Life Years (DALYs / AVISA), while decreasing the care, economic, and social burden imposed on families and healthcare systems. The relevance of this test lies in its ability to prevent severe impairments in infant neurodevelopment, since, as emphasized by López-Galera et al. ², the lack of early identification and intervention leads to irreversible neurocognitive and motor sequelae. Given the constant rise in the survival of preterm and low birth weight infants, the need for accurate diagnosis becomes even more urgent, as specialized literature consistently confirms that timely treatment preserves neurological potential and ensures appropriate future integration of children. ³

Despite these unquestionable benefits, conventional newborn screening methodology exhibits notable limitations when applied without distinction of weight or gestational maturity. Mora-Sitja et al. and Büyükgebiz ^{4,5} explain that biological factors such as prematurity, low weight, and functional immaturity of the hypothalamic-pituitary-thyroid axis induce transient physiological fluctuations in TSH and T4 concentrations during the early stages of life. This variability leads to a high rate of altered results that do not correspond to true congenital hypothyroidism. The direct consequence of these false positives transcends the purely analytical realm: Léger et al. and Rodríguez-Sánchez et al. ^{6,7} note that an abnormal report triggers an intense burden of stress, anguish, and uncertainty in parents, who must endure the psychological impact while awaiting confirmatory tests. Concurrently, the

healthcare system absorbs avoidable expenses in specialized consultations, repeat laboratory tests, and unnecessary clinical follow-up, justifying proposals to recalibrate reference thresholds to optimize test accuracy.

Recent scientific evidence underscores the relevance of individualizing screening guidelines based on the clinical characteristics of both the neonate and the mother. Rose et al. and Castilla-Peón^{10,11} highlight the need to establish differentiated cutoff points for TSH and T4 according to gestational age and body weight, as hormonal concentrations in preterm infants do not faithfully reflect permanent endocrine pathology. In close agreement, Medina-Bustos and Chiesa et al.^{12,13} argue that adopting specific protocols not only raises screening accuracy but also minimizes unjustified medical interventions and alleviates emotional distress in the family environment^{14,15}. In turn, pregnancy history plays a decisive role; research by Romero et al. and García-Gastélum et al.^{8,9} documents that maternal conditions such as hypertension or drug intake during pregnancy alter transient fetal thyroid function, accentuating the incidence of analytical false alarms.

This dynamic was demonstrated in an observational investigation carried out at Hospital General Regional 1 in Ciudad Obregón, Sonora, between March 2021 and March 2023. Over this period, a population of 26,202 births was evaluated under the premise of universal screening between the third and fifth postpartum days. Of the total analyzed, 23,931 corresponded to full-term newborns and 2,271 to preterm or immature neonates. Within the premature segment, 64 infants (2.81%) yielded an altered screening suspicious for congenital hypothyroidism; however, upon performing confirmatory thyroid profile tests, only 2 cases (3.12% of suspected cases) were truly positive for the disease. Both diagnosed infants were male, a finding that contrasts with the epidemiology presented by García Gastélum, who documents an overall prevalence in Mexico of 7.3 per 10,000 births with a typical female predominance.

The analysis of maternal variables in this cohort corroborated a statistically significant association between lower gestational age and false-positive reports. Mothers whose children obtained an initially altered result had a mean gestational age of 32.32 weeks (median of 33 and variance of 9.68), whereas in the group of mothers with term pregnancies (mean of 38.95 weeks and median of 39), no analytical alterations were observed. Similarly, 22% of the mothers of the included neonates reported pharmacological intake during pregnancy, predominantly corticosteroids. Statistical analysis yielded an odds ratio of 4.38 (95% CI: 1.91 to 10.01; $p < 0.0001$) for obtaining false-positive results in children of mothers exposed to these medications. This finding

suggests an association between maternal medication exposure and altered newborn screening results; however, causality cannot be established from the observational design.

Finally, the study exposed substantial temporal deficiencies regarding current institutional regulations. Although the technical guidelines of the Mexican Social Security Institute mandate that screening results be ready within 15 days following sample collection, the documented average turnaround time was 27 days for preterm newborns and 19 days for term newborns. This prolonged operational delay often results in a second screening sample being taken before the report of the first is available, distorting clinical judgment in a population whose thyroid function usually stabilizes spontaneously over the weeks. These findings highlight the urgent need to redesign neonatal screening standards through specific TSH and T4 thresholds ¹, rigorous recording of maternal therapeutics, and reductions in delivery times, thereby ensuring accurate, timely diagnosis and directing resources to those who truly require them.

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Epidemiological Profile of Patients with Severe Maternal Morbidity in a Hospital in Sinaloa (2021–2024)

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Citation: García de León Carreón PP, Medina Valdez ME, Félix Heredia JL. Epidemiological Profile of Patients with Severe Maternal Morbidity in a Second-Level Hospital in Sinaloa (2021–2024). ERSJ 2026,2(2) 110-118

Academic Editor: Porfirio Felipe Hernández Bautista

Received: September-22-2026

Revised: October-01-2026

Accepted: October-01-2026

Published: October-18-2026

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Abstract

Introduction: Extremely severe maternal morbidity (ESMM) encompasses critical obstetric conditions during pregnancy, childbirth, or the puerperium where timely medical intervention prevents maternal death, serving as a key indicator of quality of care.

Objective: To determine the epidemiological and clinical profile of patients with extremely severe maternal morbidity treated at Hospital de Gineco-Pediatría No. 2 from 2021 to 2024.

Materials and methods: A cross-sectional, descriptive, and retrospective study based on the full census of 188 patients registered in the SIVEMMEG platform. Sociodemographic, gynaeco-obstetric, causal pathology, comorbidity, and perinatal outcome variables were analyzed using descriptive statistics in SPSS v.25.

Results: A total of 188 cases were included (43 in 2021, 56 in 2022, 46 in 2023, and 43 in 2024). The median age was 27 years (range: 14 to 46). Severe preeclampsia was the leading cause of ESMM at 62% (n=117), followed by hypovolemic shock at 20% (n=38), eclampsia at 13% (n=25), and septic shock at 4% (n=8). Comorbidities were identified in 26%, with obesity (19%) and diabetes mellitus (4%) standing out. 100% had adequate prenatal care (≥5 visits). Delivery was by cesarean section in 89% (n=167). The maternal outcome was favorable in 99% (n=187). 97% of neonates were born alive, with 54% (n=102) requiring admission to the NICU.

Conclusions: Hypertensive disorders of pregnancy remain the main etiology of ESMM. Strengthening early identification in primary care and prompt hospital-level management are essential to reduce critical maternal morbidity and neonatal intensive care admissions.

Keywords: Extremely Severe Maternal Morbidity; Preeclampsia; Eclampsia; Obstetric Hemorrhage; Maternal Health.

INTRODUCTION

The epidemiological profile of patients with extremely severe maternal morbidity (ESMM)—also conceptualized internationally as maternal near miss—constitutes a priority axis in epidemiological surveillance and the continuous evaluation of obstetric care quality. ESMM is defined as a critical clinical condition occurring during pregnancy, childbirth, or the puerperium (up to 42 days post-pregnancy termination), in which a woman's life is in imminent danger but she survives due to timely medical-surgical interventions and advanced life support ^{1,2}. These patients represent survivors of potentially catastrophic obstetric events that, in the absence of an effective and decisive healthcare response, would have resulted in maternal death ¹.

Maternal health represents a fundamental indicator of socioeconomic progress and health equity in a nation. As maternal mortality rates have declined in various regions due to improvements in healthcare infrastructure, the World Health Organization (WHO) has proposed monitoring severe maternal morbidity as a key indicator of performance and healthcare safety ^{1,2}. The WHO Maternal Morbidity Working Group defines maternal morbidity as any chronic or acute health condition originating or aggravated by pregnancy that negatively impacts maternal well-being ³. In 2011, the WHO formalized criteria based on five life-threatening conditions (severe postpartum hemorrhage, severe preeclampsia, eclampsia, sepsis, and uterine rupture), critical interventions (admission to an intensive care unit or emergency exploratory laparotomy), and specific organ dysfunctions⁴. However, variability in diagnostic criteria at the global level still disparities in estimating its true burden ⁵.

At the global epidemiological level, it is estimated that for every maternal death, approximately 70 cases of ESMM occur ^{1,2}. Paradoxically, in some high-income countries, such as the United States, ESMM rates have not decreased but doubled between 1998 and 2014, attributable to reproductive aging, the increasing prevalence of obesity, pregestational diabetes, arterial hypertension, and an exponential increase in cesarean section rates ⁶.

In Mexico, severe maternal morbidity represents a public health problem of high significance determined by social disparities and lags in reproductive health ^{7, 8}. International commitments, from the Millennium Development Goals to the Sustainable Development Goals (2030 Agenda), require reducing the maternal mortality ratio to fewer than 70 per 100,000 live births ⁹. For countries with intermediate or low baseline rates, the primary challenge lies in identifying and mitigating preventable extreme morbidity; in Latin America, it is estimated that for every maternal death, up to 20 cases of severe morbidity occur, a quarter of which face permanent sequelae ^{10, 11, 12}.

In response to this need, the Secretariat of Health implemented the Epidemiological Surveillance System for Severe Maternal Morbidity (SIVEMMS/SIVEMMEG) since 2014, which categorizes cases using three direct criteria: tracer pathologies (eclampsia, hypovolemic shock, septic shock, systemic lupus erythematosus), organ failures or dysfunctions (cardiovascular, renal, hepatic, cerebral, respiratory, or hematological), and advanced medical-surgical management (ICU admission, obstetric rescue surgery, or acute blood transfusion) ¹². Recognized risk factors in the literature include the extremes of maternal age (<20 and >35 years), pre-existing comorbidities, disadvantaged socioeconomic status, and a history of prior uterine surgery ^{13, 14, 15, 16}. International systematic reviews demonstrate variable maternal near-miss rates ranging from 3.9 to 379.5 per 1,000 live births ^{17, 18, 19, 20, 21, 22, 23}.

Nationally, Sinaloa ranks among the 15 federal entities with the highest index of maternal morbidity, reporting rates of up to 2.8 cases per 100 live births ^{11, 12}. The impact of ESMM directly affects fetal and neonatal health, substantially increasing rates of preterm birth, intrauterine growth restriction, and the requirement for neonatal intensive care ^{16, 21}. In this context, it is essential to characterize the updated epidemiological, obstetric, and perinatal profile of patients treated for ESMM during the period from 2021 to 2024 at Hospital de Gineco-Pediatría No. 2 of IMSS in Los Mochis, Sinaloa, in order to provide solid evidence to strengthen preventive and healthcare protocols in second-level units.

MATERIALS AND METHODS

An observational, descriptive, cross-sectional, and retrospective study was conducted at Hospital de Gineco-Pediatría No. 2 of the Instituto Mexicano del Seguro Social (IMSS, Órgano de Operación Administrativa Desconcentrada Sinaloa), located in Los Mochis, Sinaloa. This hospital unit serves as a second-

level obstetric referral center for the populations of Ahome, El Fuerte, and Choix, in addition to receiving referred patients from Guasave and Guamúchil.

The study population corresponded to the total census of patients treated with a diagnosis of extremely severe maternal morbidity and duly reported in the institutional SIVEMMEG platform during the period from January 1, 2021, to December 31, 2024 ($n = 188$). All complete clinical records with institutional registration of ESMM in the analyzed four-year period were included, excluding those with inconsistencies or absence of more than 20% of the studied variables.

Sociodemographic variables (chronological age, occupation, marital status, educational level), gynaeco-obstetric variables (gravidity, vaginal deliveries, previous cesarean sections, abortions, intergenesic period, gestational age at the time of morbidity), clinical variables (type of ESMM [severe preeclampsia, eclampsia, hypovolemic shock, septic shock], pre-existing comorbidities [obesity, diabetes mellitus, nephropathy, thromboembolic disease, etc.], history of ESMM in previous pregnancies, adequacy of prenatal care [defined as ≥ 5 visits]), and outcome variables (route of pregnancy termination [cesarean section vs. vaginal delivery], maternal outcome [favorable vs. non-favorable], clinical condition of the newborn [alive vs. deceased], and admission requirement to the Neonatal Intensive Care Unit [NICU]) were analyzed.

Data were collected from physical and electronic medical records, as well as logbooks from the Department of Obstetrics and Gynecology. Information was processed using the SPSS statistical package version 25 in Spanish. Descriptive statistics were applied, determining absolute frequencies and percentages for qualitative variables, and means with standard deviation (SD) or medians with minimum and maximum values for quantitative variables.

The protocol was approved by the Local Health Research Committee and the Ethics in Research Committee (approval CEI-25038). In strict compliance with the Declaration of Helsinki, the Regulations of the General Health Law on Health Research (Art. 17, research without risk), and NOM-004-SSA3-2012, confidentiality was safeguarded using numerical code IDs, granting a waiver of informed consent.

RESULTS

During the 2021–2024 period, a total of 188 patients meeting SIVEMMEG criteria for ESMM were evaluated. Annual distribution remained stable: 43

cases (22.9%) in 2021, 56 cases (29.8%) in 2022, 46 cases (24.5%) in 2023, and 43 cases (22.9%) in 2024.

Regarding sociodemographic characteristics, participants' age showed a median of 27 years (mean: 27.52 ± 6.83 years; range: 14 to 46 years). In relation to marital status, 44% (n=82) were married, 43% (n=80) lived in a cohabitating union, and 12% (n=22) were single. In educational attainment, 27% (n=51) reported completed bachelor's degrees, 24% (n=45) completed high school, and 15% (n=28) completed middle school. Regarding employment status, 41% (n=76) had paid employment, 39% (n=73) were exclusively dedicated to homemaking, and 16% (n=30) were students.

In the obstetric domain, the median number of pregnancies was 1 (mean: 1.77 ± 1.35 ; range: 1 to 13). The median number of deliveries was 0 (maximum 5), previous cesareans' median of 1 (maximum 3), and abortions median of 0 (maximum 11). The median gestational age at the time of complication was 36 weeks (mean: 35.07 ± 3.56 ; range: 23 to 41 weeks). 100% (n=188) of patients had prenatal care qualified as adequate (≥ 5 visits).

Table 1. Quantitative clinical and obstetric parameters in patients with ESMM (n = 188).

Variable	Mean	SD	Median	Minimum	Maximum
Maternal age (years)	27.52	6.839	27	14	46
Gestations	1.77	1.359	1	1	13
Deliveries	0.35	0.817	0	0	5
Previous cesareans	1.14	0.648	1	0	3
Previous abortions	0.26	0.954	0	0	11
Intergestive period (years)	1.62	2.514	0	0	14
Gestational age at event (weeks)	35.07	3.569	36	23	41

The presence of prior comorbidities was documented in 26% (n=48) of cases. Obesity was the primary metabolic disorder (19%, n=36), followed by diabetes mellitus in 4% (n=8), venous thromboembolic disease in 2% (n=3), and nephropathy in 1% (n=1); 74% (n=140) had no documented comorbidity. Likewise, 12% (n=23) presented a history of severe maternal morbidity in previous pregnancies.

The etiological breakdown placed severe preeclampsia as the leading cause of ESMM in 62% (n=117) of the population, followed by hypovolemic shock in 20% (n=38), eclampsia in 13% (n=25), and septic shock in 4% (n=8). Hypertensive disorders accounted for 75% of admissions.

Table 2. Distribution of ESMM diagnoses, comorbidities, and maternal outcomes.

Category / Variable	Frequency (n)	Percentage (%)
Main ESMM Diagnosis		
• Severe preeclampsia	117	62%
• Hypovolemic shock	38	20%
• Eclampsia	25	13%
• Septic shock	8	4%
Associated Comorbidities		
• Obesity	36	19%
• Diabetes mellitus	8	4%
• VTE / Nephropathy	4	3%
• No comorbidity	140	74%
History of prior ESMM	23	12%
Adequate prenatal care (≥ 5 visits)	188	100%
Final Maternal Outcome		
• Favorable	187	99.50%
• Unfavorable	1	0.50%

Regarding obstetric resolution, the surgical route (cesarean section) was used in 89% (n=167) of cases, and vaginal delivery in 11% (n=21). The maternal clinical outcome was favorable in 99.5% (n=187). Among neonates, 97% (n=183) were born alive, with a 3% (n=5) perinatal mortality rate. Due to acute maternal compromise and associated prematurity, 54% (n=102) of newborns required admission to the Neonatal Intensive Care Unit (NICU).

DISCUSSION.

The findings of this study confirm that hypertensive disorders of pregnancy continue to rank as the primary etiology of extremely severe maternal morbidity in the region (75% combining severe preeclampsia 62% and eclampsia 13%), followed by massive obstetric hemorrhage resulting in hypovolemic shock (20%) and sepsis (4%)^{1, 2, 12}. These results align with evidence described by Heitkamp et al.¹⁸ and Drechsel et al.²¹, where severe preeclampsia and eclampsia constituted between 50% and 80% of critical obstetric admissions.

In international medical literature (Ben-Ayoun et al., Ibrahim Sous et al.), a direct relationship between maternal age extremes (especially age over 35) and the development of severe events has been reported^{13, 14}. However, in the present series, the median age was 27 years (mean of 27.52 ± 6.83 years), showing that life-threatening complications predominantly presented in the age group with the highest fertility.

A finding of notable clinical and operational relevance is that 100% of patients had institutional prenatal care considered adequate in terms of visit count (five or more visits) ¹². This contrasts sharply with studies such as Wasim et al. in Pakistan, where 62.5% of extreme morbidity cases lacked regular prenatal care ²⁰. This demonstrates that numerical sufficiency of visits alone is insufficient to anticipate fulminant progression cases such as severe preeclampsia or hypovolemic shock; prenatal care needs to be reoriented toward early biophysical and biochemical screening for preeclampsia and strict monitoring of high-risk patients.

The high rate of resolution via cesarean section (89%) reflects the urgency of terminating pregnancy given hemodynamic instability and maternal-fetal compromise, a finding consistent with reports by Blanc et al. and Nik Hazlina et al. ^{8, 9, 23}. Although favorable maternal outcome reached 99.5% thanks to specialized inpatient management, the perinatal cost was high: 54% of newborns required NICU management due to prematurity and perinatal asphyxia. ^{16, 21}

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Seroprevalence of the hepatitis C virus in the population with social security in Nogales, Sonora

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Abstract

Introduction: Hepatitis C virus (HCV) infection represents a global public health problem. According to estimates by the World Health Organization (WHO), 58 million people are chronically infected, and 29,000 related deaths occurred in 2019 alone. In Mexico, the Specific Action Plan establishes the objective of reducing its incidence by increasing the rate of diagnosis and initiation of timely treatment as a response to its elimination. However, despite the existence of the Standardized Procedures Manual for the Epidemiological Surveillance of Viral Hepatitis, the real burden of the disease remains underestimated. Challenges persist in the integration of data between institutions and the active identification of cases, leading to significant underreporting that hinders a precise understanding of the infection's current epidemiology in Mexico.

Objective: To determine the seroprevalence of anti-HCV antibodies in beneficiaries enrolled in the Family Medicine Unit of Nogales, Sonora.

Materials and methods: A cross-sectional study was designed and included beneficiaries assigned to the family medical unit. Clinical, demographic, and epidemiological information was obtained through the electronic medical record, and a bivariate analysis was subsequently performed to compare these data with those of exposure to the virus. A P value <0.05 was considered statistically significant. The study was approved by Local Health Research Committee 2603 of the Mexican Social Security Institute. All subjects included authorized testing by signing an informed consent form.

Results: Of the total cases analyzed, four had a reactive rapid test result. Statistically significant differences were found between reactive and nonreactive patients regarding history of transfusions, contact with people with hepatitis, tattoos or piercings, intranasal drug use, and risky sexual practices.

Conclusions: The HCV seroprevalence rate among patients enrolled in the medical unit studied is 2.8%, and some of the backgrounds studied could represent risk factors for infection.

Keywords: Hepatitis C, seroprevalence, Mexico, epidemiological surveillance, rapid test.

Citation: Pérez-Mercado JA and Copado-Villagrana ED, Seroprevalence of the hepatitis C virus in the population with social security in Nogales, Sonora., ERSJ 2026,2(2) 119-132

Academic editor: Gabriel Valle Alvarado

Received: July-29- 2025

Revised: August-11- 2025

Accepted: October-01-2026

Published: October-18-2026

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INTRODUCTION

The hepatitis C virus (HCV) is one of the most underdiagnosed pathologies by healthcare institutions, due to the lack of awareness among the population about this disease and among healthcare personnel about new eradication schemes, and, in turn, the limited availability of screening tests in healthcare services.¹

Hepatitis C is a viral disease caused by an RNA virus that replicates in liver cells without causing an immediate cytopathic effect, thus causing a chronic infection.³ It is a small, circular, lipid-enveloped virus with positive-sense single-stranded ribonucleic acid (RNA), belonging to group IV of the Baltimore classification, and therefore can be immediately translated into the host cell and replicate in the cell cytoplasm. It belongs to the Flaviviridae family, the Hepacivirus genus, and the Hepatitis C virus (HCV) species. Its total genome is approximately 9.6 kb, with 5' and 3' untranslated regions at both ends. It is composed of 10 proteins, including three structural proteins (C, E1, and E2) and seven nonstructural proteins (P7, NS2, NS3, NS4A, NS4B, NS5A, and NS5B). The structural proteins are important components of the nucleocapsid, while the core proteins modulate gene transcription and cell proliferation. It is transmitted parenterally and is hepatotropic.⁵

Susceptibility to HCV is general in humans, as there is still no vaccine due to the virus's high genetic variability at the envelope level. HCV has been characterized into six main genotypes (genotypes 1 to 6) and numerous subtypes (designated as a, b, c, etc.). Genotypes 1, 2, and 3 have a worldwide distribution, with type 1 (1a and 1b) being the most common. In hepatitis C, the influence of viral genotype is more closely related to the pathogenesis of liver disease than to any epidemiological factor.⁴

According to the World Health Organization (WHO), 71 million people worldwide are infected with this virus and are at risk of developing liver cancer or cirrhosis, although most of them are unaware of their serological status. The total number of deaths attributable to viral hepatitis because of acute infection is 1.4 million per year worldwide, 48% of which correspond to HCV.⁸

The impact of this pathology is particularly critical in Mexico, where liver cirrhosis represents the fourth leading cause of death and a primary driver of disability-adjusted life years (DALYs). Recent evidence highlights that a significant proportion of these cases are attributable to chronic HCV infection,

which often remains silent until advanced stages of fibrosis occur. Given this epidemiological landscape, the national strategy focuses on breaking the link between chronic infection and end-stage liver disease through early detection.³⁴

Genotype 1 is the most common in Mexico, with a frequency of approximately 75%. This type of virus most frequently has the worst outcome and responds least to treatment.⁶ The virus has a half-life of 2.7 hours in the blood, and there is a high daily production of viral particles (1012) in patients with chronic infection; viral replication kinetics are even higher than those of HIV. Second, the enzyme responsible for replication has an error rate of approximately 10⁻⁴ and therefore a mutation rate (quasi-species) that facilitates treatment escape mechanisms.⁷

It is estimated that there are around 600,000 infected people in our country.⁹ Mexico has the third highest viral load for hepatitis C in the Americas, behind only the US and Brazil.¹⁰

Of seropositive patients screened for HCV in Mexico, 65% have chronic infection, but of these, only approximately 25% know they have the disease, and only approximately 1% receive treatment. The national prevalence is between 1.2% and 1.4%, with the northern region being the highest at 2% and even reaching 96% among drug users, followed by the southern and central regions of the country with 1.5% and 1.1%, respectively.^{11, 12, 13} The prevalence of HIV-HCV infection is 0.6% to 2.8% in the Mexican population.¹⁴

In Mexico, epidemiological surveillance of viral hepatitis is mandatory and is governed by the Standardized Procedures Manual for the Epidemiological Surveillance of Viral Hepatitis, coordinated by the General Directorate of Epidemiology (DGE). This system integrates case notification through the National Standardized Surveillance System (SUIVE) and is complemented by the National Program for the Elimination of Hepatitis C. This framework aims to transition from passive surveillance to the active identification of cases in high-risk populations to achieve elimination goals.³⁵

In the information systems of the Ministry of Public Health in Sonora, 14 cases of hepatitis C were reported during 2020, and as of epidemiological week 40 of 2021, 159 cases have been reported.¹⁷

The Mexican Social Security Institute (IMSS) houses 70% of patients diagnosed with Hepatitis C. In 2019, 1,107 of the 2,378 cases reported in

Mexico corresponded to beneficiaries, of which 41 cases were from the Institute. Mexican Social Security Institute, Sonora.¹⁸

Many factors can determine disease progression, hence the need for early identification of affected patients and careful monitoring to determine the risk of progression, the need for appropriate therapeutic intervention, and verification of viral elimination. Thus, the primary beneficiaries of this study will be the beneficiaries of Family Medicine Unit Number 5, for whom early intervention will be possible to ensure timely initiation of treatment.

The overall objective is to determine the seroprevalence of Hepatitis C Virus antibodies in beneficiaries assigned to Family Medicine Unit Number 5 (FMU 5) in Nogales, Sonora.

MATERIALS AND METHODS

This research project was an epidemiological study with a quantitative approach, a descriptive scope, and an observational and cross-sectional design. Data collection was carried out using a time-based, cross-sectional design.

Beneficiaries over 18 years of age or with risk factors for HCV infection who agreed to participate in the study through an informed consent form were included.

Beneficiaries under 18 years of age without risk factors for HCV infection who refused to provide consent for inclusion in the study were excluded. Those under 18 years of age with risk factors for whom a parent or guardian did not provide consent for inclusion in the study were excluded. Those not receiving IMSS benefits were excluded. Those receiving IMSS benefits assigned to another Family Medical Unit. Those with a previously confirmed diagnosis or receiving treatment for HCV infection were excluded.

Beneficiaries who refused to answer the questions on the data collection form or those who did not answer all of the questions were excluded. The sample size was calculated with a confidence interval of 99% ($Z_{\alpha/2} = 2.58$), a margin of error of 3% ($d = 0.03$), taking the population assigned to UMF 5 of 112,676 beneficiaries and a prevalence of 2% ($p = 0.02$) previously reported in northern Mexico, a sample size of 145 subjects to be studied was calculated. The dependent variable was the presence of positive anti-HCV antibodies, and the independent variables were age, gender, neighborhood of residence, occupation, blood transfusions, chronic diseases, history of hepatitis A vaccination, hepatitis B vaccination, number of pregnancies, history of contact with patients with hepatitis, rural residence, presence of tattoos, piercings, or

eyeliner, intravenous drug use, organ transplant, HIV infection, child of a mother with HCV, unprotected sexual contact, sexual partner with HCV, history of incarceration, hemodialysis, health professional, work-related accident involving a sharp object, contact with catheters and endoscopes, and symptoms compatible with hepatitis C.

Participants signed an informed consent form authorizing participation in this protocol prior to the screening process. For statistical analysis, absolute and relative frequencies of the independent variables were determined, as well as bivariate analysis using the χ^2 statistical test for parametric tests or, alternatively, Fisher's Exact Test for nonparametric tests. Finally, the odds ratio of the prevalence was calculated with a 95% confidence interval.

The project adhered to the General Health Regulations on Health Research and requested authorization from the Local Health Research and Ethics Committee, as well as from the authorities of Family Medicine Unit No. 5 in Nogales, Sonora.

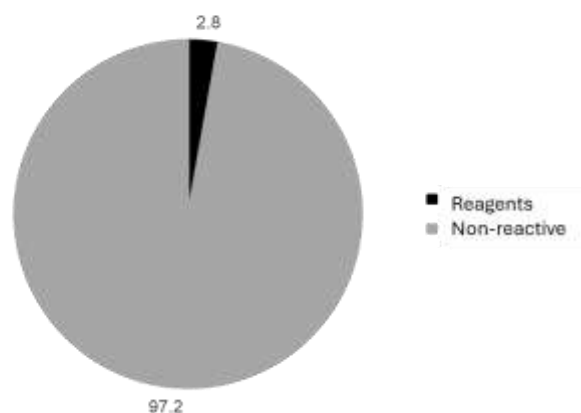
In the event of a positive result with the rapid Hepatitis C virus antibody detection test, the subjects were informed of this condition, informed of the warning signs, and provided measures to prevent transmission of the virus to other subjects.

During the research, the privacy and dignity of the research subject were protected, respecting the bioethical principles of beneficence, nonmaleficence, autonomy, and justice.

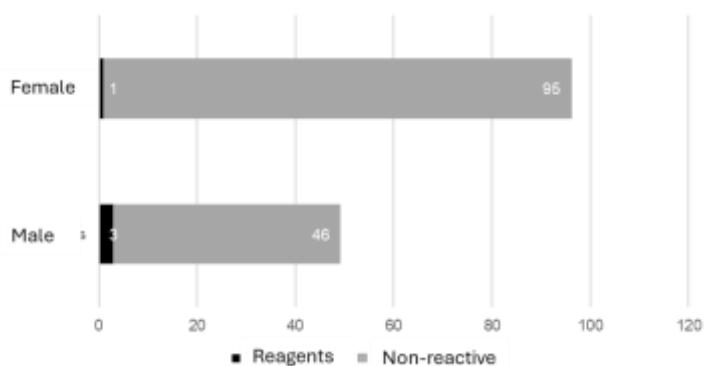
RESULTS

The total number of patients included was 145 Mexican Social Security Institute beneficiaries assigned to Family Medicine Unit No. 5 in Nogales, all over the age of 18, who underwent the rapid hepatitis C antibody test.

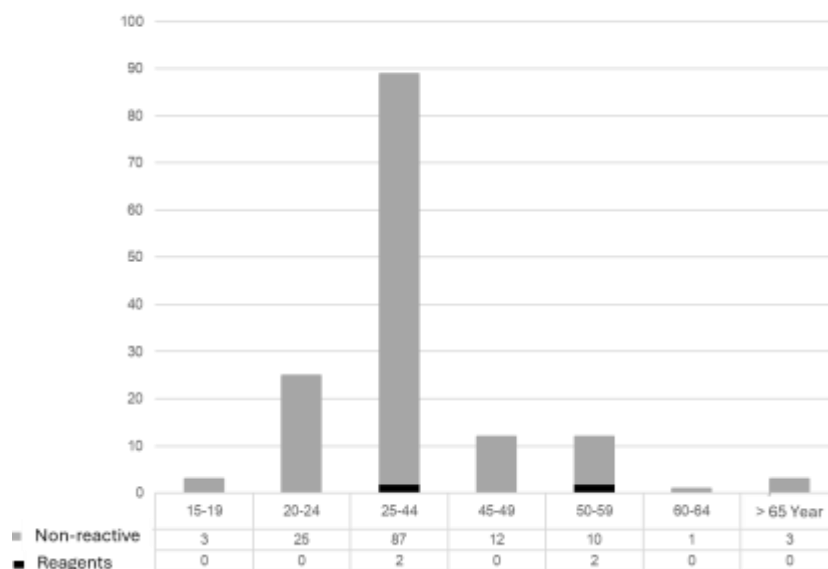
Of the 145 rapid hepatitis C antibody tests performed, 4 were reactive (2.8%), and 141 tests showed no reactivity to hepatitis C (Chart 1).

Chart 1 Overview of Hepatitis C Rapid Antibody Test Results

Of the total subjects analyzed, 96 were female and 49 were male. According to the rapid test reactivity, 3 were male and 1 was female (Chart 2).

Chart 2 Distribution according to sex and reactivity of rapid tests for Hepatitis C.

Regarding the distribution of the study population by age group, it is observed that 3 people are in the 15-19 age group, 25 in the 20-24 age group, 87 in the 24-44 age group, 12 in the 45-49 age group, 10 in the 50-59 age group, 1 in the 60-64 age group, and 3 in the over-65 age group. Of these, those reactive to rapid antibody tests were in the 25-44 and 50-59 age groups, accounting for 50%, respectively (Chart 3).

Chart 3 Distribution by age group and reactivity of rapid tests for Hepatitis C.

The clinical and sociodemographic variables of the study population are shown in Table 1.

Table 2 presents a summary of the clinical and sociodemographic variables with respect to the corresponding frequency measure and the P value of the statistical test used to compare the groups (reactive and nonreactive in the rapid Hepatitis C antibody test).

Statistically significant results ($p < 0.05$) were found in the variables analyzed: history of blood transfusions, history of tattoos, piercings, or eyeliner, and history of intranasal drug use, each with a P value of 0.02. History of contact with patients with Hepatitis and risky sexual practices, respectively, with a P value of 0.03, were found. These could represent risk factors for infection.

Table 1. Description of clinical and sociodemographic variables of the studied population.

Variable	N=145
Age (SD)	35 (11.4)
Male gender (%)	49 (33.8)
Resides in Colonia Centro (%)	48 (33.1)
Salaried worker (%)	126 (86.9)
Blood transfusions (%)	3 (2.1)
Chronic diseases: High blood pressure (%)	5 (3.5)
History of hepatitis A vaccination (%)	0 (0)
History of hepatitis B vaccination (%)	2 (1.4)
Number of pregnancies (%)	2 (0.6)
History of contact with patients with hepatitis (%)	1 (0.7)
Rural residence (%)	0 (0)
Sharing a razor or toothbrush (%)	6 (4.1)
History of tattoos, piercings, or eyeliner (%)	60 (41.4)
Intravenous drug use (%)	4 (2.8)
Intranasal drug use (%)	9 (6.2)
History of organ transplant (%)	0 (0)
HIV infection (%)	0 (0)
Child of a mother with HCV (%)	2 (1.4)
High-risk sexual practices (%)	29 (20)
Unprotected sexual contact (%)	42 (29)
Sexual partner with HCV (%)	0 (0)
History of having been incarcerated (%)	0 (0)
History of Hemodialysis (%)	0 (0)
Healthcare Professional (%)	1 (0.7)
History of sharps accidents (%)	3 (2.1)
History of contact with catheters and endoscopes (%)	1 (0.7)
Symptoms compatible with hepatitis C: Weight loss (%)	1 (0.7)
Presence of anti-HCV antibodies by rapid test (%)	4 (2.8)

DISCUSSION.

According to the Specific Action Program for the Hepatitis C Virus 2020-2024, it is difficult to determine the actual seroprevalence of Hepatitis C in Mexico due to the lack of an adequate reporting system and the limited research studies available.¹¹

Table 2. Description of variables according to the corresponding descriptive measure and the P value of the statistical test for the comparison between reactive and non-reactive groups to the rapid HCV antibody test.

Variable	Reagents n=4	Non-reactive n= 141	p*
Age (SD)	44.5 (14.8)	32 (17)	0.05
Male gender (%)	3 (75)	46 (33)	0.1
Resides in Colonia Centro (%)	1 (25)	47 (33)	0.59
Salaried worker (%)	4 (100)	122 (86)	0.62
Blood transfusions (%)	2 (50)	1 (1)	0.02
Chronic diseases: High blood pressure (%)	0 (0)	6 (55)	0.84
History of hepatitis A vaccination (%)	0 (0)	0 (0)	NA
History of hepatitis B vaccination (%)	0 (0)	2 (1)	1
History of two pregnancies (%)	0 (0)	5 (3.5)	0.86
History of contact with patients with hepatitis (%)	1 (25)	0 (0)	0.03
Rural residence (%)	0 (0)	0 (0)	NA
Sharing a razor or toothbrush (%)	0 (0)	6 (4)	1
History of tattoos, piercings, or eyeliner (%)	4 (100)	56 (40)	0.03
Intravenous drug use (%)	1 (25)	3 (2)	0.11
Intranasal drug use (%)	2 (50)	7 (5)	0.02
History of organ transplant (%)	0 (0)	0 (0)	NA
HIV infection (%)	0 (0)	0 (0)	NA
Child of a mother with HCV (%)	0 (0)	2 (1)	1
High-risk sexual practices (%)	3 (75)	26 (18)	0.03
Unprotected sexual contact (%)	1 (25)	41 (29)	1
Sexual partner with HCV (%)	0 (0)	0 (0)	NA
History of having been incarcerated (%)	0 (0)	0 (0)	NA
History of Hemodialysis (%)	0 (0)	0 (0)	NA
Healthcare Professional (%)	0 (0)	1 (0.70)	1
History of sharps accidents (%)	0 (0)	3 (2)	1
History of contact with catheters and endoscopes (%)	0 (0)	1 (0.70)	0.97
Symptoms compatible with hepatitis C: Weight loss (%)	1 (25)	0(0)	1

*U Mann-Withney *Fisher

In 2000, the National Health and Nutrition Survey (ENSANUT) reported a prevalence of infection of 1.4% in Mexico, and referred to a difference based on the country's regions, reporting an estimate of 2.0% for the north, 1.5% for the south, and 1.1% for the center of the country. In 2018, ENSANUT reported a national prevalence of Hepatitis C antibodies of 0.38%, lower than the first estimate.^{14, 30}

In the present investigation, based on the results obtained, it was demonstrated that the seroprevalence of hepatitis C among IMSS beneficiaries assigned to Family Medicine Unit No. 5 in Nogales, Sonora, is 2.8%, a figure higher than the estimate for the northern part of the country.

Carnalla et al (2021) sampled 12,389 adults who responded to the National Health and Nutrition Survey (ENSANUT) in 2018 and reported that the anti-HCV seroprevalence obtained in the population aged 20 to 49 years was 0.23%, being higher in the male population and in those living in urban areas. They also showed that the prevalence in the 50 years and older group was higher, being 0.59%.³¹ In the present study, it was found that patients with a reactive result to the rapid HCV antibody test were found in the 25 to 44 and 50 to 59 age groups. In addition, 100% of them live in urban areas and 75% of those reactive to the rapid test were male. Of the 145 Hepatitis C screenings performed on the population assigned to Family Medicine Unit No. 5 in Nogales, 66.2% were female and 33.8% were male. The positivity rate among men is noteworthy, standing at 6% in this group, and 1% among women, a situation similar to that described by Carnalla et al. (2021).³¹ The gender disparity in screening may be due to the low acceptance among the male population of seeking preventive medicine for screening or medical consultations.³²

Contreras et al. In a study on risk factors for acquiring HCV in Hidalgo, it was reported that 24.43% had a history of high-risk sexual practices, 19.88% had tattoos or piercings, 12.5% had a history of close contact with hepatitis C patients, as well as that 7% had received a blood transfusion in their life and that 1.70% had used inhaled drugs at some point; A similar situation was reported in the present study.³³

The clinical, epidemiological, and demographic factors of the cases analyzed in the research were determined. For each variable, the frequency of the rapid Hepatitis C antibody test result and its statistical significance were obtained. It was found that a history of having had a blood transfusion, having tattoos, piercings, or eyebrow threading, having ever used intranasal drugs, having or having had close contact with a Hepatitis C case, and engaging in risky sexual practices could be clear risk factors for contracting this infection. However, due to the design and objectives, as well as the methodology used for this study, a risk analysis was not performed. It is important to note that this study sought to determine antibody prevalence, that is, to determine how much of the population has been exposed to hepatitis C. It did not focus on determining the active burden of the disease (quantification of HCV RNA). As has been described, there is a percentage of people who spontaneously achieve viral

clearance and the infection does not progress. Therefore, it was decided in this protocol to begin HCV screening and provide an opportunity for other researchers interested in the topic to analyze the patients' progress.

Finally, one of the limitations encountered during the sampling process was the low acceptance among the population of undergoing rapid antibody testing for hepatitis C, as well as for HIV and syphilis. Therefore, mass awareness campaigns regarding these diseases are necessary.

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