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Electrophysiological diagnostic process in neonates after failure in Universal Newborn Hearing Screening (UNHS)

Processo de diagnóstico eletrofisiológico em neonatos após falha na Triagem Auditiva Neonatal Universal (TANU)

Proceso de diagnóstico electrofisiológico en neonatos tras un fallo en la prueba de cribado auditivo neonatal universal (UNHS, por sus siglas en inglés)

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Abstract

Introduction: Universal Newborn Hearing Screening is an important public health strategy to identify and diagnose hearing loss early in newborns. Adherence to the stages of screening, diagnosis, and rehabilitation within recommended timeframes is essential to ensure adequate development of auditory and language skills. Therefore, it is crucial to investigate the diagnostic pathway of these children, considering the time of initiation and completion, the factors involved, and the audiological findings, as a basis to improve care pathways and ensure effectiveness of actions in pediatric hearing health. **Objective:** This study aims to investigate the electrophysiological diagnostic process in neonates who failed Universal Newborn Hearing Screening. Method: A descriptive-exploratory study with quantitative and qualitative approaches. Medical records of infants up to 12 months old who attended audiological assessment following failure in Universal Newborn Hearing Screening or lack of screening were analyzed. Statistical analysis included Pearson correlations, Kruskal-Wallis test, and multiple linear regression models with a

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significance level of 5%. **Results:** The sample consisted of 24 children referred after failure in universal newborn hearing screening. The mean age at diagnosis initiation was 78 days, with 25% of children beginning the process at 90 days or older. Of the 24 children, 79.2% completed the diagnosis. **Conclusion:** The results emphasize the importance of coordination between screening and diagnosis, family support, and efficient organization of care pathways to ensure the full development of children with hearing loss.

Keywords: Neonates; Infants; Risk; Hearing; Hearing loss; Electrophysiology.

Resumo

Introdução: A Triagem Auditiva Neonatal Universal é uma importante estratégia de saúde pública para identificar e diagnosticar precocemente a deficiência auditiva em recém-nascidos. O cumprimento das etapas de triagem, diagnóstico e reabilitação dentro dos prazos recomendados é essencial para garantir o desenvolvimento adequado das habilidades auditivas e da linguagem. Diante disso, torna-se fundamental investigar o percurso diagnóstico dessas crianças, considerando o tempo de início e conclusão, os fatores envolvidos e os achados audiológicos, como subsídio para aprimorar os fluxos assistenciais e garantir a efetividade das ações em saúde auditiva infantil. **Objetivo:** O objetivo da presente pesquisa é estudar o processo de diagnóstico eletrofisiológico em neonatos que falharam na Triagem Auditiva Neonatal Universal. **Método:** Estudo descritivo-exploratório, com abordagem quantitativa e qualitativa. Foram analisados prontuários de lactentes com até 12 meses de idade, que compareceram para avaliação audiológica após falha na Triagem Auditiva Neonatal Universal ou ausência de realização da triagem. A análise estatística incluiu correlações de Pearson, teste de Kruskal-Wallis e modelos de regressão linear múltipla, com nível de significância de 5%. **Resultados:** A amostra foi composta por 24 crianças encaminhadas após falha na triagem auditiva neonatal universal. A idade média de início do diagnóstico foi de 78 dias, com 25% das crianças iniciando o processo aos 90 dias ou mais. Das 24 crianças, 79,2% finalizaram o diagnóstico. **Conclusão:** Os resultados reforçam a importância da articulação entre triagem e diagnóstico, do acolhimento familiar e da organização eficiente dos fluxos de atendimento para garantir o desenvolvimento pleno da criança com deficiência auditiva.

Palavras-chave: Neonatos; Lactentes; Risco; Audição; Perda auditiva; Eletrofisiologia.

Resumen

Introducción: El cribado auditivo neonatal universal es una importante estrategia de salud pública para identificar y diagnosticar la pérdida auditiva precozmente en recién nacidos. El cumplimiento de las etapas de cribado, diagnóstico y rehabilitación dentro de los plazos recomendados es esencial para garantizar un desarrollo adecuado de las habilidades auditivas y lingüísticas. Por lo tanto, es crucial investigar la vía diagnóstica de estos niños, considerando el momento de inicio y finalización, los factores implicados y los hallazgos audiológicos, como base para mejorar las vías de atención y garantizar la eficacia de las acciones en salud auditiva pediátrica. **Objetivo:** Este estudio tiene como objetivo investigar el proceso diagnóstico electrofisiológico en neonatos que no superaron el cribado auditivo neonatal universal. **Método:** Estudio descriptivo-exploratorio con enfoques cuantitativos y cualitativos. Se analizaron los expedientes médicos de lactantes de hasta 12 meses de edad que acudieron a una evaluación audiológica tras no superar el cribado auditivo neonatal universal o la falta de cribado. El análisis estadístico incluyó correlaciones de Pearson, la prueba de Kruskal-Wallis y modelos de regresión lineal múltiple con un nivel de significación del 5 %. **Resultados:** La muestra consistió en 24 niños derivados tras no superar el cribado auditivo neonatal universal. La edad media al inicio del diagnóstico fue de 78 días, y el 25 % de los niños comenzó el proceso a los 90 días o más. De los 24 niños, el 79,2 % completó el diagnóstico. **Conclusión:** Los resultados destacan la importancia de la coordinación entre la detección y el diagnóstico, el apoyo familiar y la organización eficiente de las vías de atención para garantizar el desarrollo integral de los niños con pérdida auditiva.

Palabras clave: Neonatos; Lactantes; Riesgo; Audición; Pérdida auditiva; Electrofisiología.

Introduction

Universal Newborn Hearing Screening (UNHS) is a public health strategy for early identification of hearing loss in newborns. Conducted within the first days of life, UNHS enables identification of neonates with a higher probability of presenting hearing loss, as well as the implementation of early interventions, ensuring better development of language and auditory and communicative skills[1,2].

However, neonates who fail UNHS require additional tests to confirm or rule out the presence of hearing loss. A newborn failing the screening does not by itself indicate a definitive diagnosis of hearing loss; it is essential that these infants undergo a more detailed diagnostic evaluation. In this context, the speed of diagnostic tests is crucial to avoid delays in intervention. According to guidelines by the Joint Committee on Infant Hearing (JCIH), the 1-3-6 stages are recommended, which stipulate that hearing screening should be completed by the first month of life, diagnosis concluded by the third month, and therapeutic intervention begun by the sixth month at the latest. Additionally, the JCIH introduced the 1-2-3 timeline, suggesting an even earlier approach to identify and intervene in cases of hearing loss. In this model, hearing screening must be completed by the first month, audiological diagnosis by the second month, and intervention initiated by the third month. Following these stages ensures infants with hearing loss receive intervention within the critical period for language development[3,4,5].

To ensure that the diagnosis is accurate and reliable, it is fundamental to adopt the Cross-checking principle. This approach recommends the use of different complementary diagnostic methods, avoiding reliance on a single test, and ensuring greater precision in confirming hearing loss. This principle is applied in recommendations and guidelines such as those from the British Society of Audiology[6], ensuring the results of different tests are consistent and complementary, minimizing errors, and maximizing the efficiency of diagnosis and early intervention[7].

The Auditory Brainstem Response (ABR) Protocol of 2022, developed by Jennifer L. Hatton, Anna Van Maanen, and David R. Stapells, is a comprehensive guide for performing the Brainstem Evoked Response Audiometry (BERA), designed for the British Columbia Early Hearing Program (BCEHP). This protocol is used for early screening and diagnosis of hearing loss in children, aiming for rapid detection and intervention in at-risk infants. The document guides the use of equipment, training, and quality control standards to ensure accuracy and reliability of results. Among the topics covered, the protocol defines who is qualified to perform the tests, describes the audiologists' role in clinical support and protocol adherence, and establishes detailed operational parameters for different types of hearing loss, including conductive and sensorineural[8].

The Screening Protocol and the Surveillance Protocol, both from 2019, developed by the Ministry of Children, Community, and Social Services of Ontario (MCCSS), are protocols for early identification of permanent hearing loss in newborns and young children, intended for the Ontario Infant Hearing Program (IHP), which is the hearing screening and surveillance program. In the screening protocol[9], all newborns undergo universal hearing screening, usually using otoacoustic emissions (OAE) and/or automated auditory brainstem response (AABR), which are fast and effective tests to detect possible hearing loss. If the initial screening is not successfully completed, further attempts are made, and if necessary, the child is referred for more detailed diagnostic audiological evaluation[9].

Simultaneously, the surveillance protocol[9] is applied to children with risk factors for progressive or late-onset hearing loss, such as family history of hearing loss, specific neonatal infections, or other medical conditions associated with hearing loss. In this protocol, children are periodically monitored for early detection of any hearing loss that may manifest during the first years of life. This monitoring involves ongoing audiological assessments and allows early and appropriate interventions.

In addition to the mentioned protocols, there is also the "Recommended Procedure Auditory Brainstem Response (ABR) Testing in Newborns," developed by the British Society of Audiology[6]. This document updates the "Recommended Procedure Auditory Brainstem Response (ABR) Testing in Babies," created in 2019 (adapted from the "Guidance for Auditory Brainstem Response testing in babies," created in 2013). The recommended procedure document was created by members of the Electrophysiology Special Interest Group (EPSIG)

and developed according to the BSA Processing Documents (2003). The procedure guide was created to enable uniformity and improvements in test performance, as well as in wave interpretation. This document contains information about patient preparation, stimulus, data collection and analysis, decision criteria for results at each stimulus level, calibration, artifacts, among other guidelines. It is worth noting that BSA procedural documents are used in the United Kingdom, a country considered to have one of the most efficient UNHS and Neonatal Hearing Health programs[6].

The BSA recommendation includes a systematic approach that combines different audiological examinations aiming to ensure a comprehensive assessment of auditory function. Among the examinations used are electrophysiological tests, such as Auditory Brainstem Response (ABR) and Auditory Steady-State Response (ASSR), and electroacoustic tests such as Otoacoustic Emissions (OAE) and Acoustic Immittance Measures[6].

The Auditory Brainstem Response test (BERA, Brainstem Evoked Response Audiometry) is an objective evaluation used to measure electrical responses generated along the auditory pathway up to the brainstem in response to sound stimuli. This procedure is performed by applying surface electrodes fixed to the forehead and mastoid regions of the patient, associated with equipment that emits acoustic stimuli, such as clicks or pure tones, through headphones or bone vibrators[10].

The responses captured by BERA reflect the synchronized electrical activity of neural structures, such as the auditory nerve and brainstem nuclei, at specific latencies (waves I to VII). Each wave represents activation of different segments of the auditory pathway, with wave I associated with the distal portion of the auditory nerve, wave III with the cochlear nucleus region, and wave V with the inferior colliculus region, the most robust and frequently analyzed[2,10].

BERA is widely employed in the identification and characterization of sensorineural, conductive, or retrocochlear hearing losses, especially in populations unable to undergo subjective exams, such as newborns, young children, and patients with cognitive impairments. The test also assists in diagnosing auditory neuropathy and retrocochlear lesions, such as auditory nerve schwannomas[10].

As a non-invasive evaluation, BERA is performed either during natural sleep or light sedation, when necessary, to minimize movement and artifacts that could interfere with recording quality. This test is recognized for its high sensitivity and specificity, being an essential tool for screening, diagnosis, and monitoring of auditory conditions across different age groups[2,10,11].

Auditory Steady-State Response (ASSR) testing is an objective evaluation that measures electrical responses of the central auditory system generated in response to acoustic stimuli modulated in frequency or amplitude, presenting continuous and periodic characteristics. This technique uses surface electrodes placed on the head, similar to those used in BERA, and is conducted with stimuli delivered via headphones, such as modulated pure tones, allowing simultaneous evaluation of different frequencies[12].

Responses obtained in ASSR correspond to synchronized activity of multiple neuronal populations along the auditory pathway, mainly in the brainstem and auditory cortex. These responses are analyzed according to the modulation frequency, which determines the rhythm of the acoustic stimulus and, consequently, the electrical response[12].

The main advantage of ASSR is the ability to estimate auditory thresholds at different frequencies (usually between 500 Hz and 4000 Hz), being especially useful in cases of severe to profound hearing loss, where BERA responses may be limited. Furthermore, its objective nature and capacity for simultaneous bilateral measurements make ASSR an efficient clinical test, especially in pediatric populations and patients with collaboration difficulties[12].

This test is widely used for hearing aid fittings and pre-cochlear implant assessments due to its precision in estimating frequency-specific auditory thresholds. Like BERA, ASSR is preferably conducted during natural sleep or light sedation to minimize movements that could affect recording quality[12,13].

Otoacoustic Emissions (OAE) testing is an objective evaluation that measures sound responses emitted by the outer hair cells of the cochlea, either spontaneously or in response to acoustic stimuli. Conducted using a probe placed in the external auditory canal containing a stimulus generator and a microphone, the test can detect spontaneous or evoked emissions, the latter subdivided into transient evoked otoacoustic emissions (TEOAE), generated by brief stimuli, and distortion product

otoacoustic emissions (DPOAE), produced by the interaction of two tones of different frequencies. OAEs assess frequencies from 500 Hz to 8000 Hz, covering different cochlear regions, and are sensitive to detecting early cochlear changes before clinical symptoms of hearing loss appear[14].

Acoustic Immittance Measures, or immittance testing, is an electroacoustic procedure employed in middle ear evaluation, analyzing the tympano-ossicular system and acoustic reflexes[15,16]. This test includes analysis of stapedius reflexes and tympanometric curves, which are classified into different types: type «A» curve representing normal mobility of the tympano-ossicular system; type «Ad» curve reflecting hypermobility; type «Ar» curve indicating reduced mobility; type «B» curve associated with absence of mobility; and type «C» curve showing a shift toward negative middle ear pressure[17].

Additionally, tympanometry may be performed using the wideband technique, which offers advantages over conventional 226 Hz and 1000 Hz tympanometry commonly used in clinical practice. Wideband tympanometry covers a broader frequency range, allowing greater sensitivity in detecting subtle middle ear alterations. This test also applies absorbance measurements, using stimuli such as chirp to improve assessment accuracy[18,19].

The mentioned tests provide an evaluation of auditory function, from neural responses in the brainstem to the perception of auditory stimuli at different frequencies. ABR allows estimation of auditory thresholds and verification of auditory pathway integrity up to the brainstem, while ASSR measures auditory thresholds at multiple frequencies simultaneously, being extremely useful in newborns[2].

In this scenario, understanding the factors that influence the effectiveness and timeliness of the diagnostic process becomes essential to ensure achievement of the goals established by child hearing health programs. The Neonatal Hearing Screening Guide[20] emphasizes that screening success is not limited to its performance in the maternity ward but depends on effective coordination with diagnostic and intervention services to ensure completion of the process by 90 days of life, supported by well-structured protocols for diagnostic confirmation and intervention, ensuring that all stages — screening, referral, diagnosis, and rehabilitation — occur in an articulated, equitable, and timely manner. For this, it is essential that health systems are organized into effective care networks with well-defined flows, traceability of referrals, and longitudinal surveillance of cases, especially for those with risk indicators[2,9,10,11,24].

Method

The project was submitted to the Research Ethics Committee (CEP) of Pontifícia Universidade Católica de São Paulo and approved under the number CAAE: 86208224.9.0000.5482.

Study type

This study adopted an exploratory descriptive research design with a quantitative and qualitative approach.

Location

The research was conducted at *Centro Audição na Criança* (CeAC) – Hearing in Children Center, a service of *Divisão de Educação e Reabilitação dos Distúrbios da Comunicação* (DERDIC) - Division of Education and Rehabilitation of Communication Disorders, a reference center in hearing health for pediatric care, for evaluation, monitoring, and auditory intervention in children suspected of hearing loss, from the Pontifícia Universidade Católica de São Paulo in the municipality of São Paulo.

Subjects

Medical records of infants were selected via a convenience sample who attended the hearing health service from January to December 2025 for diagnostic evaluation after failing UNHS. Inclusion criteria were infants who failed UNHS and were part of follow-up referrals from health services or who did not undergo newborn hearing screening at hospital discharge. Records lacking essential information and records of children older than 1 year were excluded. Children were scheduled according to platforms provided by the Municipal Health Department of São Paulo or by the State Health Department, as coordinated by CeAC.

Data Collection Procedure

Weekly, on Mondays and Wednesdays, the professional reviewed medical records and checked the following variables: date of birth, date service commenced (commonly the consultation with the responsible physician), date audiological diagnosis

started, date audiological diagnosis was completed, number of appointments attended, total number of appointments needed to complete diagnosis, number of no-shows, referring center, distance from residence to the service, audiological diagnosis result, as well as presence/absence of risk indicators for hearing impairment. Data were stored in an Excel spreadsheet.

Statistical Analysis

Pearson correlation coefficient was calculated to measure the correlation between age at diagnosis completion and diagnosis duration (age at diagnosis completion minus age at diagnosis start) and quantitative variables: age at diagnosis start, number of no-shows, number of risk indicators for hearing loss (IRDA), number of appointments required, and distance from home.

The distributions of age at the completion of diagnosis and the duration of diagnosis in the groups with and without hearing loss were compared using the Kruskal-Wallis test (Fisher and van Belle, 1993). Children with any type and degree of hearing loss in at least one ear were considered as having hearing loss.

To evaluate the combined effect of the variables, the following were analyzed: age at the start of diagnosis, number of absences, number of IRDA, number of encounters needed, distance from residence, presence of hearing loss, and age at the end of diagnosis; multiple linear regression models were adjusted by the least squares method[21]. The adequacy of the models was assessed through residual analysis.

Results

The initial study sample consisted of 26 children referred to the service after failing Universal Newborn Hearing Screening. Of these, two were excluded from the analysis. One medical record was excluded due to lack of essential information for composing the study variables, which prevented its inclusion in descriptive and inferential analyses. The other was excluded because it corresponded to a child older than 1 year, thus not meeting the previously established age criteria. Therefore, the final sample consisted of 24 children.

Sample characterization

The sample definition derived from the total number of eligible medical records during the analyzed period, considering the adopted inclusion and exclusion criteria. Thus, the final composition with 24 children does not represent an arbitrary selection but the available cases adequate to the methodological scope of the research. For inferential analyses, only children who completed the diagnostic process were considered, totaling 19 cases, since the completion of diagnosis was a necessary condition for analyzing variables related to temporal outcomes.

Contextualization of the reduction in the number of service cases

Over recent years, CeAC has undergone changes in the organization of the care network, affecting the volume of children followed in the service. In this context, the reduction in the number of cases can be understood in light of the reorganization of referral flows and the decentralization of auditory care to other network points. This aspect is not an analytical variable of the present study but is relevant to contextualize the final sample size and the institutional setting in which the research was developed.

Table 1 shows the frequencies and percentages of children referred by different institutions. It is noted that Hospital Amparo Maternal was the entity that referred the highest percentage of children (41.7%). This can be explained by the fact that, analyzing the territory, CeAC is the closest reference for the hospital mentioned.

Table 1. Frequencies and percentages of children referred by hospitals, maternity wards, or CER

Hospital, maternity, or CER	N	%
CER Campo Limpo	1	4.2
CER IV MILTON ALDRED	2	8.3
Hospital Amparo Maternal	10	41.7
Hospital Geral do Grajaú	1	4.2
Municipal Hospital Dr. Ignacio Proença de Gouvêa	3	12.5
Municipal Hospital Dr. Mauro Pires da Rocha (Campo Limpo)	3	12.5
Municipal Hospital Dr. Moysés Deutsch (M'BOI MIRIM)	1	4.2
Municipal Hospital Maternity Professor Mario Degni	1	4.2
São Luiz Gonzaga Hospital (Santa Casa da Misericórdia)	1	4.2
Santa Catarina Maternity	1	4.2
Total	24	100

Summary measures for the distance from residence to the diagnostic service are found in Table 2, and individual and mean values are shown in Figure 1. Distances varied from 1 to 32 km.

Table 2. Summary measures for distance from residence to diagnostic service (km)

N	Mean	Standard deviation	Minimum	Median	Maximum
24	17.0	8.7	1	17	32

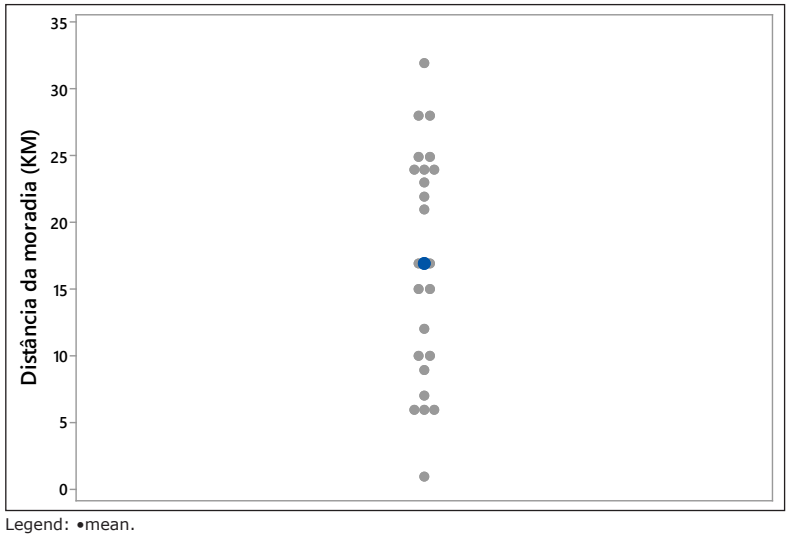

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Figure 1. Individual and mean values of the distance from residence to the diagnostic service

Table 3 presents summary measures for the age in days at which diagnosis was initiated. It is noted that 50% of children began diagnosis at 57 days or older. Six children (25%) began diagnosis at 90 days or older. Among the cases with later initiation, frequent presence of NICU stay, prematurity, and use of ototoxic drugs was observed, indicating that in these cases, the start of diagnosis is directly related to the child's clinical condition, since audiological examinations depend on clinical stability and hospital discharge possibility. Thus, length of hospitalization is a determinant factor for the beginning of the diagnostic process.

Table 3. Summary measures of age at the start of diagnosis (in days)

N	Mean	Standard deviation	Minimum	Median	Maximum
24	78	55.8	20	57	218

Based on the results in Table 4, 2 of the 24 children had no risk indicators for hearing loss. The number of indicators ranged from 1 to 6. The indicator with the highest prevalence (Table 5) was the use of ototoxic drugs. Qualitative analysis also revealed that among recorded congenital infections, cases of congenital cytomegalovirus and syphilis appeared, and among genetic syndromes, records corresponded to trisomy 21.

Table 4. Summary measures of the number of IRDA

Number of IRDAs	N	%
0	2	8.3
1	8	33.3
2	6	25
3	3	12.5
4	3	12.5
5	1	4.2
6	1	4.2
Total	24	100

Table 5. Frequencies and percentages of IRDA

IRDA	No		Yes		Total	
	N	%	N	%	N	%
Family History	16	72.7	6	27.3	22	100
Prematurity	15	68.2	7	31.8	22	100
Use of Ototoxic Agents	12	54.5	10	45.5	22	100
Mechanical Ventilation	19	86.4	3	13.6	22	100
Very low birth weight (less than 1500g)	18	81.8	4	18.2	22	100
Congenital Infections (*)	18	81.8	4	18.2	22	100
Craniofacial anomalies (**)	18	81.8	4	18.2	22	100
Genetic syndromes that express hearing loss (***)	19	86.4	3	13.6	22	100

(*) toxoplasmosis
(**) ear and temporal bone
(***) T21

Of the 24 children, 5 (20.8%) did not complete the diagnosis and 19 (79.2%) did. Table 6 presents summary measures of the number of absences among those who completed and those who did not complete the diagnosis. Qualitative analysis shows that non-completion was not exclusively related to absenteeism. There were children who did not complete the process even with no recorded absences, children with one or two absences, and one case classified as dropout.

Table 6. Summary measures of the number of absences

Completed	N	Mean	Standard deviation	Minimum	Median	Maximum
No	5	1	1	0	1	2
Yes	19	0.5	0.6	0	0	2
Total	24	0.6	0.7	0	0.5	2

The following results relate to children who completed the diagnosis.

The number of visits needed varied from 1 to 5 (Table 7). The median age, in days, at which diagnosis was completed was 126 days (Table 8). Thus, at least 50% of children completed diagnosis at an age older than recommended (90 days). Only 4 children (21.1%) completed diagnosis by 90 days of age. Figure 2 presents cumulative percentages of ages at diagnosis completion. The interpretation of this figure is as follows: to know the percentage of children who completed diagnosis by a particular age (x-axis), draw a vertical line from the age of interest and check the cumulative percentage at the intersection with the blue curve. The graph exemplifies how to obtain the percentage of children completing diagnosis at age less than or equal to 90 days.

Table 7. Summary measures of the number of required visits

N	Mean	Standard deviation	Minimum	Median	Maximum
19	3.2	1.2	1	3	5

Table 8. Summary measures of age at completion of diagnosis (in days)

N	Mean	Standard deviation	Minimum	Median	Maximum
19	138.9	49.3	64	126	239

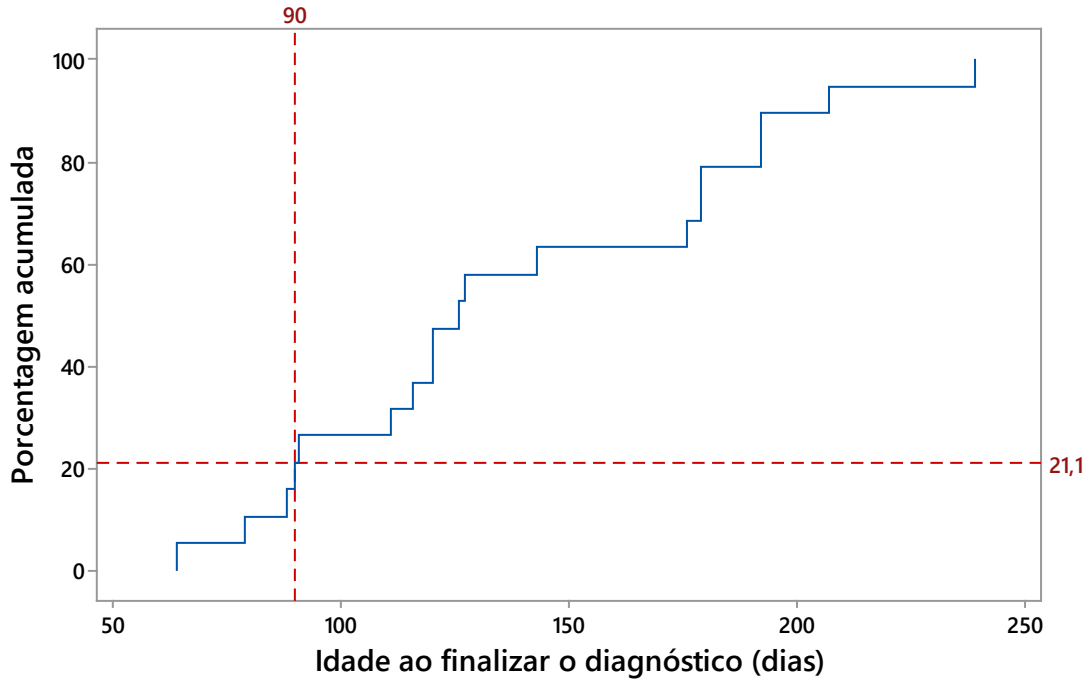

Figure 2. Cumulative percentage of age at diagnosis completion

Summary measures were also calculated for the duration of diagnosis, defined as: age at diagnosis completion minus age at diagnosis initiation, in days (Table 9). It is noted that some children initiated and completed diagnosis on the same day.

Table 9. Summary measures of the difference between age at completion and age at start of diagnosis (diagnostic duration, in days)

N	Mean	Standard deviation	Minimum	Median	Maximum
19	62.5	37.8	0	56	165

Table 10 presents the frequencies and percentages of children in each combination of hearing loss type and degree in the right ear. It is noted that 7 (36.8%) children have hearing considered normal, 8 (42.1%) have mild conductive hearing loss, 2 (10.5%) have moderate mixed hearing loss, 1 (5.3%) has mild sensorineural hearing loss, and 1 (5.3%) has moderate sensorineural hearing loss.

The results for the left ear are presented in Table 11 and can be interpreted similarly.

Table 10. Frequencies and percentages of hearing and type of hearing loss in the right ear

Right ear hearing	Degree of Hearing Loss	N	%
Conductive	Mild	8	42.1%
	Moderate	0	0.0%
	Total	8	42.1%
Mixed	Mild	0	0.0%
	Moderate	2	10.5%
	Total	2	10.5%
Sensorineural	Mild	1	5.3%
	Moderate	1	5.3%
	Total	2	10.5%
Normal		7	36.8%

Table 11. Frequencies and percentages of hearing and type of hearing loss in the left ear

Hearing RE	Degree of Loss	N	%
Conductive	Mild Degree	3	15.8%
	Moderate Degree	2	10.5%
	Total	5	26.3%
Mixed	Moderate Degree	3	15.8%
	Total	3	15.8%
Sensorineural	Mild Degree	1	5.3%
	Severe Degree	1	5.3%
	Total	2	10.5%
Normal		9	47.4%

Table 12 shows the joint frequency distributions and percentages of hearing in both ears. It is noted that of the 7 individuals with normal hearing in the right ear, 1 has conductive hearing loss in the left ear, and 1 has sensorineural hearing loss in the left ear.

Table 12. Combined frequencies and percentages of hearing loss in both ears

		Left Ear Hearing				
Right Ear Hearing		**Conductive**	**Mixed**	**Sensorineural**	**Normal**	**Total**
Conductive	N	4	1	0	3	8
	%	21.1%	5.3%	0.0%	15.8%	42.1%
Mixed	N	0	2	0	0	2
	%	0.0%	10.5%	0.0%	0.0%	10.5%
Sensorineural	N	0	0	1	1	2
	%	0.0%	0.0%	5.3%	5.3%	10.5%
Normal	N	1	0	1	5	7
	%	5.3%	0.0%	5.3%	26.3%	36.8%
Total	N	5	3	2	9	19
	%	26.30%	15.80%	10.50%	47.40%	100.00%

Inferential analysis: This part of the analysis will verify the existence of associations of interest between study variables. Only children who completed the diagnosis will be included in the analysis.

Association between Residential Distance and Number of Absences

The Pearson correlation coefficient between the residential distance to the diagnostic service and the number of absences was 0.20 (p = 0.424). Therefore, there is no linear correlation between the two variables.

Association of Age at Diagnosis Completion with Age at Diagnosis Initiation, Absences, Number of Risk Indicators for Hearing Loss (RIHL), Number of Visits Required, Residential Distance, and Hearing Status

Table 13 presents the Pearson correlation coefficients between age at diagnosis completion and the quantitative variables considered in this part of the analysis. Scatterplots illustrating the joint behavior of age at diagnosis completion and the quantitative variables are presented in Figure 3. Each graph includes a regression line to better visualize possible linear trends in the data points. These results indicate that the age at diagnosis completion tends to increase with age at diagnosis initiation (p-value = 0.001) and with the number of RIHL (p-value = 0.086). In the latter case, the p-value is close to 0.05, and the lack of statistical power can be attributed to the small sample size. There is no correlation between age at diagnosis completion and the other quantitative variables.

Table 13. Pearson correlation coefficients of age at completion of diagnosis and age at start of diagnosis, number of absences, number of IRDA, number of required visits, and distance from residence

Variable	Correlation coefficient	p-value
Age at diagnosis onset	0.72	0.001
Number of absences	0.18	0.459
Distance from residence	0.29	0.224
Number of meetings	0.06	0.816
Number IRDA	0.40	0.086

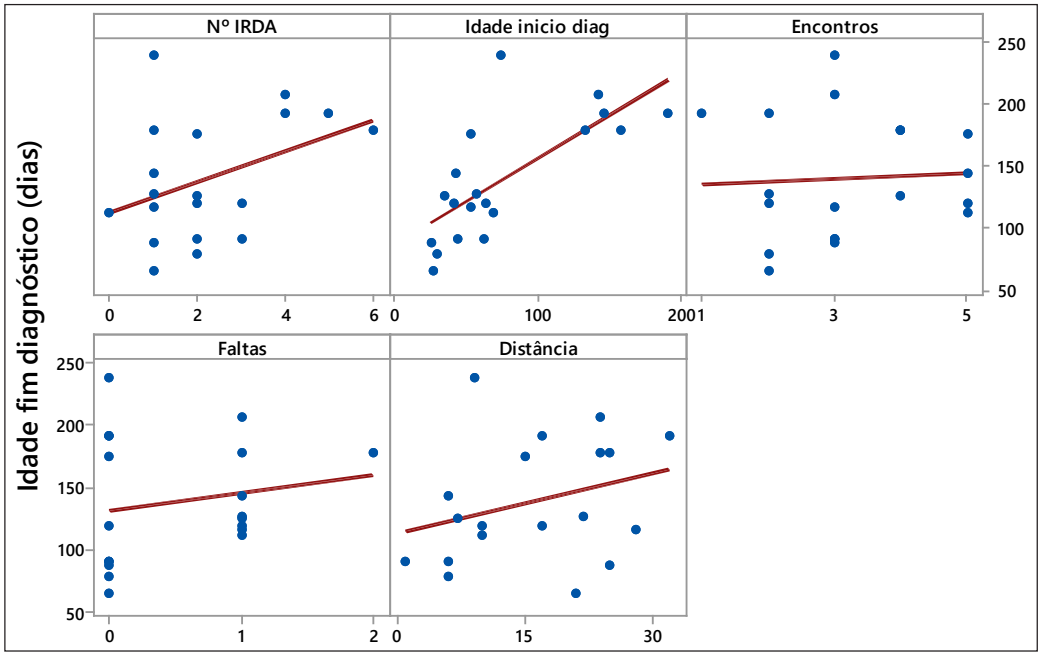

Figure 3. Scatter plots of age at diagnosis completion and age at diagnosis start, number of absences, number of IRDA, number of required appointments, and distance from residence

Table 14 presents summary measures of age at diagnosis completion according to the occurrence of hearing loss in at least one ear. The means and medians of age observed in the group with hearing loss are lower than those in the group without hearing loss. However, there is no significant difference between the age distributions in the two groups (Kruskal-Wallis test statistic = 2.34, 1 degree of freedom, p-value = 0.126).

Table 14. Summary measures for age at completion of diagnosis according to the occurrence of hearing loss in at least one ear

Loss	N	Mean	Standard deviation	Minimum	Median	Maximum
No	5	166.8	58.3	64	192	207
Yes	14	128.9	43.7	79	120	239
Total	19	138.9	49.3	64	126	239

To evaluate the joint effect of the variables age at diagnosis initiation, number of absences, number of RIHL, number of visits required, residential distance, and hearing loss in at least one ear — that is, the effect of each variable in the presence of the others — on age at diagnosis completion, a multiple regression model was fitted. The response variable was age at diagnosis completion, and the explanatory variables were age at diagnosis initiation, number of absences, number of RIHL, number of visits required, residential distance, and hearing loss in at least one ear. The model fitting process used a backward elimination variable selection procedure. At the end of this process, the only variable selected to compose the model was age at diagnosis initiation. The obtained estimates are summarized in Table 15.

Table 15. Summary of results obtained from model adjustment where age at completion of diagnosis was the response variable and explanatory variables were age at start of diagnosis, number of absences, number of IRDA, number of required visits, distance from residence, and hearing loss in at least one ear

Term	Coefficient	Standard error	Test statistic	p-value
Constant	86	14.9	5.78	<0.001
Age at diagnosis onset	0.69	0.163	4.24	0.001

Thus, the regression equation relating age at diagnosis completion to age at diagnosis initiation is given by:

$$\textit{Age at diagnosis completion} = 86.0 + 0.69 \times \textit{Age at diagnosis initiation.}$$

Therefore, for every 10-day increase in age at diagnosis initiation, the age at diagnosis completion increases, on average, by approximately 7 days.

The other explanatory variables considered in the analysis did not contribute additionally to age at diagnosis initiation in explaining age at diagnosis completion: residential distance (p = 0.912), hearing loss (p = 0.618), absences (p = 0.333), number of RIHL (p = 0.506), and number of visits (p = 0.268). The R^2 value obtained was 51.4%. Model adequacy was evaluated through residual analysis.

Discussion

The present study analyzed the audiological diagnostic process of children who failed Universal Newborn Hearing Screening (UNHS), emphasizing characterization of the timing of initiation and completion, factors associated with duration, and identified audiological profiles. The results reveal relevant clinical and organizational findings that may contribute to the improvement of early detection and intervention practices for childhood hearing impairment, as advocated in the World Report on Hearing[5], which emphasizes that early detection and appropriate management of hearing loss are essential for optimal child development.

In the present sample, the mean age at diagnosis initiation was 78 days, with a median of 57 days and a range from 20 to 218 days. Among the 19 children who completed the process, the median age at diagnosis completion was 126 days, and only four children (21.1%) completed the diagnosis by 90 days of life. These results show a gap from the 1-2-3 goal proposed by the Joint Committee on Infant Hearing[4], according to which screening should occur by the first month, diagnosis by the second month, and intervention by the third month of life. However, interpretation of this finding requires caution. Later initiation of diagnosis should not be automatically understood as delayed access to the service, since in a significant portion of cases, especially among children with NICU stay, prematurity, ototoxic drug use, very low birth weight, and other significant neonatal conditions, deferral was related to the need for clinical stability to safely and reliably perform the tests. Thus, in the context of this sample, the observed delay was not exclusively organizational but also clinically conditioned.

This distinction between clinical and organizational factors is central for the proper interpretation of the results. Clinical delay refers to situations where the child, due to their neonatal condition, does not yet have sufficient physiological stability to complete the diagnostic process within the ideal timeframe. Organizational delay results from fragmentation along the path between screening, referral, and diagnostic confirmation, limited appointment availability, and difficulty coordinating between different network points. The study findings suggest the coexistence of these two dimensions. It was observed, on the one hand, that children with higher numbers of risk indicators for hearing loss (RIHL) and a history of neonatal hospitalization tended to begin the process at older ages. On the other hand, even among those who started diagnosis before 90 days, completion within the recommended timeframe was uncommon, demonstrating that earlier entry, although fundamental, was not sufficient alone to ensure timely completion. Thus, the problem is not restricted to initial access but also involves the health system's capacity to sustain an effective diagnostic process[23].

In the Brazilian context, the organizational factor is impacted by issues such as scarcity and uneven distribution of speech-language pathologists, limited equipment availability, and lack of unified protocols across states[22]. Moreover, socioeconomic variables — including family income, maternal education, and access to private health care — exert direct influence on the performance of neonatal tests, as demonstrated by Mallmann et al.[23]. These aspects reveal a reality in which access to early hearing loss detection remains restricted to certain social groups, configuring a scenario of selectivity and exclusion. Thus, adherence to the goals proposed by the JCIH is linked to an ideal organizational care network scenario, which contrasts with the reality of Brazil's Unified Health System (Sistema Único de Saúde [SUS]), where timely diagnosis is often unfeasible. Even in cases where diagnosis occurs within the timeframe, continuity of care is compromised by factors such as scarcity of hearing rehabilitation centers and the need for intermunicipal or interstate travel, limiting the effectiveness of early intervention. Therefore, rather than understanding guideline non-compliance as an isolated service failure, it should be recognized as a consequence of structural, cultural, and territorial limitations affecting the health system in Brazil and other international contexts.

The analysis of clinical and organizational factors is corroborated by the multiple regression model, in which the only variable remaining associated with age at diagnosis completion was age at diagnosis initiation. The estimated equation indicated that for every 10-day increase in age at diagnosis initiation, there was an average increase of approximately 7 days in age at completion, with a coefficient of determination of 51.4%. This is a statistically consistent and clinically relevant finding, as it demonstrates that the timing of entry into the process exerts decisive influence on the temporal outcome. However, the strength of this

association does not support a simplified interpretation. Age at initiation is not a neutral variable but simultaneously synthesizes the child's clinical conditions, hospital stay duration, referral flow, and service responsiveness. Thus, its statistical significance reflects the convergence between biological and institutional factors that structure the hearing care pathway[20].

In light of this scenario, updating public policies emerges as an essential strategy to overcome regional and structural inequalities that compromise the effectiveness of Neonatal Hearing Screening (NHS) in the country. To this end, the Ministry of Health launched, in 2025, the Guide for Conducting Neonatal Hearing Screening (NHS) and Care Follow-up[20], aiming to promote greater uniformity and qualification of actions at the national level. The document presents updated guidelines for organizing the neonatal auditory care network, proposing more integrated care pathways among levels of care—from screening to rehabilitation. Furthermore, it explicitly recognizes the need to adapt strategies to regional specificities, considering variables such as professional availability, local infrastructure, and diverse sociocultural contexts. By adopting equity as a guiding principle, the guide emphasizes that the universalization of screening and follow-up will only be possible through coordinated actions that respect the particularities of different regions of the country, offering technical support to managers and professionals in constructing viable, efficient, and culturally sensitive care pathways. The consolidation of these guidelines represents a significant advance for strengthening the auditory care network within the SUS and an important step toward realizing the rights of children with hearing impairment in Brazil.

The high prevalence of risk indicators for hearing loss (RIHL) underscores the clinical complexity of the sample. Of the 24 children studied, 22 presented at least one risk indicator, with ototoxic drug use being the most frequent. Additionally, Appendix 1 records the presence of congenital cytomegalovirus, congenital syphilis, trisomy 21, mechanical ventilation, prematurity, and NICU stay in various combinations. These findings characterize a clinically vulnerable group whose diagnostic pathway tends to be more demanding from both technical and care perspectives. Nevertheless, the presence of multiple RIHLs was not linearly associated with the final audiological outcome. There were children with four, five, and even six indicators who exhibited normal bilateral hearing, while hearing loss was also observed in a child without RIHL. This result aligns with the literature and reinforces that risk indicators should not be interpreted as direct determinants of hearing loss but rather as markers for enhanced surveillance[24]. Analytically, this complexity is also reflected in the fact that the number of RIHLs showed only a trend toward association with age at diagnostic completion, without remaining as an independent explanatory variable in the final model. This suggests that the impact of RIHLs may occur indirectly, through worsening clinical condition, the need for increased monitoring, and an expanded number of procedures required until diagnostic completion. In other words, RIHLs appear to contribute less as isolated statistical explanations and more as elements that intensify the clinical trajectory of children, rendering the process more sensitive to complications, repetitions, and reassessments.

In this context, the discussion about the number of visits becomes particularly relevant. Among children who completed the diagnosis, this number ranged from 1 to 5, with a mean of 3.2 visits. Contrary to an interpretation centered solely on adherence, the results indicate that a higher number of visits was mainly related to the complexity of the diagnostic pathway. There were children with conductive, mixed, and sensorineural hearing loss who required four or five appointments, as well as cases with prolonged duration even in the absence of absences. This aspect is especially important because it demonstrates that, in certain cases, it is expected that the process demands more visits, particularly when repetition of exams, evolutionary follow-up, and diagnostic refinement are necessary. Pediatric audiological diagnosis is not limited to a single procedure but involves the combination of otoacoustic emissions (OAE), auditory brainstem response (ABR), and when indicated, auditory steady-state response (ASSR), in addition to integrated interpretation of clinical, electrophysiological, and behavioral data. In specific situations, the use of masking, the need to repeat recordings, and the pursuit of greater reliability of responses make the process necessarily more complex[6].

This discussion is particularly important in cases of conductive hearing loss. In the right ear, there was a predominance of mild conductive hearing loss (42.1%), followed by normal hearing,

whereas in the left ear normal hearing was most frequent, although conductive, mixed, and sensorineural losses were also present. The analysis of individual trajectories described (Appendix 1) shows that some of the most prolonged pathways occurred precisely among children with conductive hearing loss. This finding is significant because it dispels the notion that conductive hearing loss would, by definition, be a simple or quickly resolved case. In young children, especially in the post-neonatal screening context, conductive alterations may be associated with middle ear instability, episodes of otitis media with effusion, and fluctuations in auditory responses, which impose caution in diagnostic confirmation. In these cases, specific protocols and increased follow-up may be necessary to differentiate transient changes from persistent conditions, avoiding both overdiagnosis and underdiagnosis. This interpretation is supported by the recommendations of the British Society of Audiology[6] and the Infant Hearing Program[9], which emphasize the need for rigorous protocols and careful reassessments in diagnostic confirmation.

At the care level, another important aspect concerns adherence to follow-up. Although the number of absences was slightly higher among non-completed cases, there was no correlation between home distance and attendance at the service. This result supports a crucial conceptual review: distance does not equate to access. Actual access to the service depends on concrete conditions of transportation, availability of public or private transport, financial cost, time spent, urban logistics, weather conditions, and the possibility of reorganizing family routines. From this perspective, the absence of association between mileage and absences suggests that measuring geographic distance is insufficient to capture the complexity of access to care. This interpretation aligns with the World Report on Hearing[5], which emphasizes the role of organizational and relational factors, such as welcoming, effective communication, and care coordination, in adherence of families to follow-up.

The duration of the diagnostic process, considered as the difference between the age at onset and at completion, averaged 62.5 days. Although this interval is acceptable from a technical standpoint, it does not compensate for the initial delay. In other words, even when the diagnosis was carried out efficiently, starting late compromised meeting the 90-day goal. This finding was statistically supported: for every 10-day delay in the beginning of diagnosis, the final age increased by approximately 7 days. This finding gains relevance in light of studies by Sininger et al.[25], which demonstrated that children diagnosed and intervened early perform significantly better in receptive and expressive language compared to those identified later, regardless of the degree of hearing loss. Thus, data from the present study reinforce that early diagnosis is not only an organizational or chronological issue but constitutes a determining factor for communicative and cognitive outcomes, evidencing that delays in initiating the process can reduce opportunities for adequate language development even when the diagnostic duration, once started, is relatively short.

Evidence in the literature indicates that the timing of entry into the diagnostic process directly impacts its duration and outcome. In a multicenter study conducted by Deng et al.[26] involving data from nine U.S. states, it was observed that infants who began diagnosis earlier had a higher likelihood of completing the process within recommended deadlines, reinforcing the importance of timely entry into the auditory health system. In the present study, a negative correlation was identified between age at onset and duration of the diagnostic process, i.e., children who arrived older at the specialized service completed the evaluation within a shorter time frame. This tendency can be understood by several factors. First, greater neurological and auditory maturity in older age groups reduces the influence of transient variables common in the neonatal period—such as presence of vernix caseosa, residual amniotic fluid, or middle ear instability—favoring greater stability in responses to objective tests and decreasing the need for test repetition[7].

Associated with this, family guidance occupies a strategic position. Although this aspect was not directly measured, the study's findings allow the inference that preparation of the child for examinations—especially regarding sleep, feeding, and routine organization on the day of the appointment—may affect the quality of the recorded data and, consequently, the number of visits required. In procedures such as ABR, inadequate preparation conditions can compromise obtaining reliable responses and generate the need for rescheduling or repetition. Thus, adherence should not be interpreted merely as the family's responsibility but as a product of the quality of guidance provided by the

service, clarity in communication, and the empathy offered from the initial referral[9].

Finally, the R^2 value of the predictive model for age at diagnostic completion was 51.4%, indicating that age at process onset is a highly explanatory variable. The lack of significant contribution from other variables—number of RIHLs, absences, home distance, and presence of hearing loss—demonstrates that, in the context of this sample, early entry into the system is the principal determinant for diagnostic process success. This finding is strongly aligned with the JCIH 1-2-3 goal[4] and international guidelines advocating the implementation of neonatal auditory screening and diagnostic systems based on active surveillance, accessibility, traceability, and continuity of auditory care.

Conclusion

The findings of the present study allow us to conclude that the audiological diagnostic process for children who failed Universal Newborn Hearing Screening (UNHS) is multifactorial, clinically conditioned, and organizationally influenced. In this context, the main barrier to completing the diagnosis within the recommended timeframe, up to 90 days of life, was shown to be related to the timing of the child's entry into the specialized service, rather than the execution or duration of the diagnostic process itself. The age at the start of diagnosis was the primary predictor of the age at completion, evidencing its direct impact on the possibility of meeting the established milestones for early diagnosis of hearing impairment.

Although most children presented multiple risk indicators for hearing loss (RIHL), and some required a greater number of visits, these factors alone were not determinants of the total duration of the process. Similarly, variables such as distance from residence, number of absences, and quantity of RIHL did not constitute significant barriers to follow-up adherence. These results indicate that the effectiveness of care depends not only on objective conditions of access but also on elements such as welcoming, proper guidance to families, and qualified communication among different levels of the care network.

Regarding the audiological findings, the predominance of mild conductive losses and the substantial number of normal hearing diagnoses, even after failure in UNHS, reinforce the importance of diagnostic confirmation through rigorous and well-defined protocols. These results highlight the need for continuous monitoring of the quality of hearing screening and referral criteria to avoid both false positives and unnecessary overload of specialized services. Although not statistically significant, the presence of hearing loss showed a tendency to be associated with longer diagnostic completion times, which is clinically plausible given the greater complexity of these cases.

The results also indicate the need to strengthen the care pathway following failure in UNHS, through greater clarity in coordination between screening, referral, diagnostic confirmation, and follow-up. In this process, integration among maternity wards, primary care, pediatrics, and specialized services is fundamental. Notably, in this context, the pediatrician's role during the first year of life is emphasized, both in surveillance of children with risk indicators and in maintaining the connection with the auditory care pathway. Timely pediatric follow-ups can facilitate recognition of the need for follow-up, reduce referral losses, and enhance the continuity of care.

From a management perspective, the findings of this study suggest concrete measures to improve the care pathway flow, such as offering appointments within the same week for newly referred cases, allowing more than one sequential consultation when clinically feasible, reserving time slots for children with higher complexity, and making scheduling more flexible according to the needs of the service and families. Such strategies do not eliminate clinically conditioned delays but may reduce organizational delays and increase the resolution capacity for cases suitable for investigation. In this regard, a significant contribution of this study lies in demonstrating that improving the diagnostic process depends not only on increased productivity but also on the ability to distinguish, within the care pathway, cases whose delay results from clinical condition from those whose delay stems from system weaknesses.

Finally, the results reinforce the relevance of early detection and intervention of hearing loss for better language and communicative development outcomes. Thus, the importance of enhancing coordination mechanisms between neonatal hearing screening and diagnostic services is reaffirmed, to ensure timely referral and enrollment of children. Only through effective integration among differ-

ent points of the network will it be possible to consolidate more effective child auditory health actions, guarantee early diagnosis, and promote the full communicative development of children with hearing loss.

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