



# Epidemiological Profile of Neonates in Hearing Screening at a Maternity of a Tertiary Hospital in the state of Santa Catarina, Brazil

Juan Diego Gimenes Lopes<sup>1</sup> Carolina Disconzi Dallegrave<sup>1</sup> Nadine Hellmann Delfino<sup>1</sup>  
Rúbia Lauxen<sup>1</sup> Taise Marcelino<sup>1</sup> Carlos Eduardo Monteiro Zappelini<sup>1</sup>

<sup>1</sup> Universidade do Sul de Santa Catarina (UNISUL), Tubarão, SC, Brazil.

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Address for correspondence Juan Diego Gimenes Lopes, Medical School Student. Rua Antônio Hulse, 53, apto. 102, Bairro Dehon – Tubarão, Santa Catarina, SC, Brasil (e-mail: juangimeneslopes@gmail.com).

## Abstract

**Introduction** The newborn hearing screening (NHS) test aims the early diagnostic of hearing deficits that may also harm the full development of communication and learning of the affected child.

**Objective** Trace the clinical and epidemiological profile of children born between July 2016 and July 2019; in addition to the outcome of the NHSs and factors related to failure in the hearing tests at a maternity of a tertiary hospital in Santa Catarina, Brazil.

**Methods** The present is a cross-sectional study. A census of those born in the period defined for study was performed and a script was developed for the review of medical records, based on the literature.

**Results** The sample can be considered homogeneous in relation to gender and age. The pregnant women had an average of 30.9 years. There were 30 neonates (1.9%) that did not undergo NHS. New evaluations were required in 288 patients (18.2%). Finally, 24 (1.5% of the population) remained with insufficient results in the retest. The following variables achieved statistical relevance with higher failure rates in tests and/or retests: natural delivery ( $p = 0.007$ ), arterial hypertension present ( $p = 0.002$ ), use of hydralazine ( $p = 0.038$ ), and use of dipyron in the test ( $p = 0.041$ ) and retest ( $p = 0.003$ ). Younger mothers had higher levels of normality in the test ( $p = 0.003$ ) and retest ( $p = 0.161$ ). The correlations between the other variables and the outcomes were not statistically significant.

**Conclusion** False positives (62.8%) in the first test showed a value higher than the ideal goal; those who did not undergo the NHS (1.9%) and who needed evaluation by a specialist, due to failure in the retest (1.5%), are within the quality goals defined by the Joint Committee on Infant Hearing (JCIH) in 2007.

## Keywords

- ▶ neonatal screening
- ▶ otoacoustic emissions
- ▶ hearing loss

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## Introduction

The ability to identify sounds is decisive for the language evolution process to be adequate. Hearing development starts in the fetal phase and is followed by multiple steps: before language and speech, the child needs to detect, locate, differentiate, memorize, identify, and interpret sound stimuli; all steps are essential for the process to be completed and its interruption would hinder full development.<sup>1</sup>

For every thousand births, 1 to 6 newborns will have hearing loss. Among those who require intensive care, this incidence rises from 10 to 40 affected.<sup>2</sup> There are several risk factors for hearing loss, such as: family history of permanent hearing loss in childhood, neonatal intensive care, mechanical ventilation, exposure to ototoxic drugs, intrauterine infections (cytomegalovirus, herpes, rubella, syphilis, zika virus and toxoplasmosis), postnatal infections, craniofacial anomalies, neurodegenerative disorders, Apgar from 0 to 4 in the first minute, or 0 to 6 in the fifth, and low birth weight, among others.<sup>2-4</sup>

Measures must be taken early for the difficulties resulting from sensory deprivation to be mitigated.<sup>1</sup> The Newborn Hearing Screening (NHS), also known as the little ear test, tracks hearing impairment in the maternity ward; the use of sound amplification and rehabilitation should begin until the six months old, if hearing loss is confirmed.<sup>2</sup> In 2010, Law Number 12,303/10 was created, making screening mandatory in hospitals and maternity hospitals; two years after that, the Brazilian Ministry of Health published the Guidelines for Attention to NHS, to guide the professionals involved.<sup>5</sup>

Otoacoustic emissions (OAEs) in neonatal screening are advantageous because they are easy to perform. The integrity of the outer hair cells, located in the cochlea and responsible for the amplification of sound, are analyzed with OAEs.<sup>6</sup> When newborns reach the parameters of normality, they have “passed” the hearing screening; otherwise, they have “failed” the test.<sup>6</sup> If the newborn does not receive approval in the first procedure, it must be the retested in a maximum period of thirty days.<sup>2</sup> Afterwards, if the failure persists, a complementary audiologic and otorhinolaryngological analysis is recommended.<sup>2</sup>

The main obstacle in registering OAE is environmental noise, since not all places have the ideal acoustic pattern.<sup>7</sup> Other factors that might also interfere with test results are: sneezing, movement, the evaluator’s experience with the equipment used, the number of neonates previously evaluated by the professional, among others.<sup>7,8</sup> Thus, both the activity state and the physiological processes can cause a weak response level of otoacoustic emissions.<sup>7</sup> As recommended by the American Academy of Pediatrics, the quality model for NHS programs states that the percentage of false positives in screening should not exceed 3%.<sup>9</sup> However, this amount is still not reached, affecting the quality of the programs, in addition to medical and transportation expenses, and causing suffering to the parents— due to the worry and uncertainty regarding the health of their child.<sup>10</sup>

This study’s hypothesis is that the existence of changeable factors (prenatal care and elements inherent to the otoacoustic emissions test) can cause a low-quality NHS results, and the identification of these factors can contribute to a significant improvement in the screening quality.

Given the relevance of early detection of hearing loss and the factors commonly associated with its occurrence, the present study, which was conducted in a tertiary hospital, aimed to assess the clinical and epidemiological profiles of patients born between July 1st, 2016, and July 1st, 2019, as well as the result of the NHS and the variables related to test and retest alterations. We analyzed the rate of newborns who had altered testing (if the alteration is within the limits considered acceptable in the literature, or if there is failure to perform the screening and newborns are being discharged without undergoing it) and highlighted the topic. Additionally, we aimed to identify the factors associated with screening failure so that medical professionals and service providers could implement changes to improve the first test’s results and avoid the need for retesting and the consequences arising from a patient with a suspected congenital hearing loss. Finally, we assessed the quality of testing by using the number of false positives (which are identified when patients pass the retest) and possible associations.

## Methods

This was an observational study with a cross-sectional design. All live births occurring between July 2016 and July 2019 at a private hospital in the city of Tubarão, state of Santa Catarina, southern Brazil were included, and those with insufficient data were excluded.

According to a report provided to researchers by the Hospital’s Information Technology, there were 1583 newborns in the period proposed for study. However, the records of the respective mothers were also reviewed, thus, the number of records evaluated was approximately 3166. As it is a census, it was not necessary to calculate the minimum sample.

In the previously mentioned report, the newborn’s and mother’s numbers of attendance were included, allowing access to the electronic medical records of both, stored in the Tasy Philips (Koninklijke Philips N.V., Amsterdam, Netherlands) software, since the medical chart review script proposed the search for information about the prenatal period, which is commonly available only in the maternal medical record.

For data collection, a standardized questionnaire was developed by the researchers based on the literature, consisting of data from the newborn (gender, birth weight, height at birth, Apgar score in the first minute after birth, Apgar in the fifth minute after birth, head circumference (CP), first ear test, ear retest, route of birth delivery, and gestational age) and maternal data (origin, age, comorbidities, use of medications during pregnancy, and complications during pregnancy). After collection, some variables were grouped for better analysis and comparison with the literature, among them: weight at birth,

in grams, divided into low (< 2,500 g), eutrophic (2,500–3,999 g), and high ( $\geq 4,000$  g)<sup>11</sup>; Apgar was divided between: normal (5–10 in the 1<sup>st</sup> minute and 7–10 in the 5<sup>th</sup> minute) and changed (0–4 in the 1<sup>st</sup> minute, 0–6 in the 5<sup>th</sup> minute)<sup>12</sup>; finally, gestational age was divided in: preterm (<37 complete weeks), term (37 to less than 42 complete weeks) and post-term (42 weeks or more).<sup>11</sup>

The collected data were stored in the Excel (Microsoft Corp., Redmond, WA, United States) software and the analysis was performed using the Statistical Package for the Social Sciences (IBM SPSS Statistics for Windows IBM Corp., Armonk, NY, United States), version 20.0. The descriptive analysis was performed through absolute numbers and proportions, the measures of central tendencies were described in the mean and standard deviation (SD) or median forms and intervals.

To test the existence of a statistically significant difference between the groups of categorical variables, the Chi-square and Fisher exact test were used, as appropriate, in addition to the Student *t*-test and its non-parametric equivalents to test differences in means, also according to the adequacy of the data. To compare the outcomes of interest and the characteristics of the newborns and their mothers, the prevalence ratio (PR) was calculated. A statistically significant difference was considered for *p*-values  $\leq 0.05$ .

As the present study is a survey of medical records, the waiver of the informed consent form was requested. Data collection only started after approval by the Ethics in Research Committee of Universidade do Sul de Santa Catarina (under number 3.618.248), and the study followed the regulatory guidelines and standards proposed by tResolution 466/2012 of the Brazilian National Health Council.

## Results

In the evaluated period, 1,583 individuals were born in the study's institution. Of these, 30 (1.9%) did not undergo hearing screening. Most of the studied population consisted of boys (839; 53.0%), born at term (1,197; 75.6%), with an average birth weight of 3,202.9 g (SD  $\pm$  573.9), and average birth height of 47.9 cm (SD  $\pm$  2.8). As for the route of birth delivery, there were 1,378 births (87.0%) through cesarean section. More information about newborns is available in **Table 1**.

Maternal age ranged from 19 to 45 years, with an average of 30.9 years (SD  $\pm$  5.1). Separating the age groups, 22 (1.4%) mothers were aged  $\leq 19$  years, 1,247 (78.8%), between 20 and 35 years, and 308 (19.5%) were aged  $\geq 36$  years; there was no data on age for the 6 (0.4%) remaining mothers.

Among the newborns who underwent screening, the majority ( $n = 1,265$ ; 79.9%) had NHS results within normal standards; 84 (5.3%) showed no response in the initial test with otoacoustic emissions in the right ear, 99 (6.3%) in the left ear, and 105 (6.6%) in both. Thus, a total of 288 (18.2%) newborns presented alterations in the first NHS and, therefore, would need a retest.

Of the 288 who failed the NHS, 181 (11.4% of the studied population) were retested and obtained normal results,

**Table 1** Distribution of newborn characteristics in a tertiary hospital maternity

VARIABLES		N	%	
Gender				
	Male	839	53.0	
	Female	733	46.3	
	U <sup>a</sup>	11	0.7	
Weight (g)				
	Low	140	8.8	
	Eutrophic	1,355	85.6	
	High	65	4.1	
	U <sup>a</sup>	23	1.5	
Height (cm)				
	30–40	36	2.2	
	41–50	1,261	79.7	
	> 50	226	14.3	
	U <sup>a</sup>	60	3.8	
Apgar score				
	1 minute	Changed	18	1.1
		Normal	1,514	95.6
		U <sup>a</sup>	51	3.3
	5 minutes	Changed	05	0.3
		Normal	1,528	96.5
U <sup>a</sup>		50	3.2	
Type of delivery				
	Preterm	198	12.5	
	Term	1,197	75.6	
	Postterm	02	0.1	
	U <sup>a</sup>	186	11.7	
Cephalic perimeter (cm)				
	$\leq 32$	184	11.6	
	$\geq 33$	1331	84.1	
	U <sup>a</sup>	68	4.3	

Abbreviation: Apgar, appearance, pulse, grimace, activity, and respiration.

Note: <sup>a</sup>Uninformed.

which represented a rate of 62.8% of false positives in the first test. Among those retested, there were no emissions in the right ear of 8 (2.8% of 288) neonates; 7 on the left (2.4% of 288) and 9 on both (3.1% of 288), totaling 24 newborns (8.3% of 288 and 1.5% of the total sample of 1,583) who remained with inadequate results on the OAE test. There is no record of retest for 83 patients (28.8% of 288). **Fig. 1** shows the distribution of the findings in both tests.

As for gender, 77.7% ( $n = 651$ ) of the boys passed the test, while 20.3% ( $n = 170$ ) failed. Among the girls, the findings were 82.4% ( $n = 604$ ) and 15.8% (116), respectively. It is worth noting that, although there is not statistically

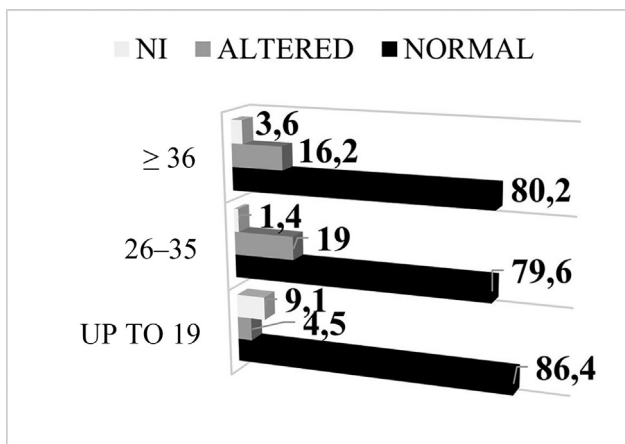
1583 NEONATES (100%)		
TEST		
30 NOT SCREENED (1,9%)	1265 NORMAL (79,9%)	288 ALTERED (18,2%)
RETEST		
83 MISSING (5,2%)	181 NORMAL (11,4%)	24 ALTERED (1,5%)

**Fig. 1** Distribution of the results of NHS. The figure shows the distribution of test and retest results in newborns between July 2016 and July 2019, in a tertiary maternity hospital in Tubarão, SC, Brazil.

significance ( $p=0.064$ ), gender was positively associated with the first “failed” test in boys (PR = 1.18; 95% CI) and negatively in girls (PR = 0.87; 95% CI). In the retest, 1.7% of the male patients had the same results, which is similar to the 1.6% noted in the female patients ( $p=0.053$ ).

The route of birth delivery was statistically relevant when cross-analyzed with the first test ( $p=0.007$ ), with a correlation between the vaginal route and more “failure” test results being observed. In the second evaluation, there was no relationship between the route of birth delivery and higher failure rates ( $p=0.125$ ); 1.6% of the patients who were born vaginally and 1.7% of those born by cesarean section failed.

Additionally, maternal age was statistically significant ( $p=0.003$ ) in the first test, with less changes in the younger group: in the group of mothers up to 19-years-old, 86.4% ( $n=19$ ), the newborns exhibited normal test results; mothers with 20 to 35 years of age, 79.6% ( $n=992$ ) newborns obtained normal test results, while for the parents aged 36 years or older, 80.2% ( $n=247$ ) of the patients passes the test during screening. More details in ► **Fig. 2**.



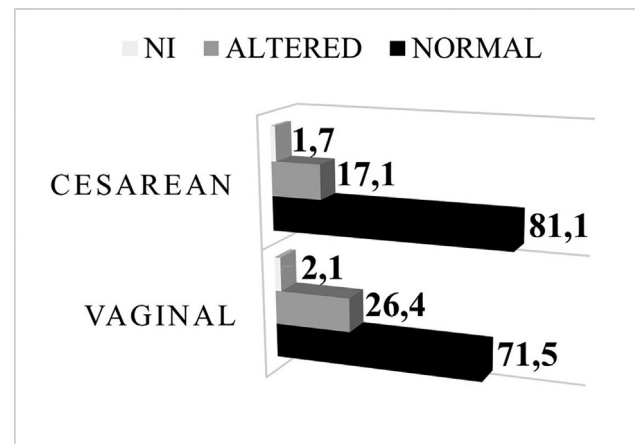
**Fig. 2** Correlation between maternal age and the first hearing screening. The figure shows the highest proportion of normal tests among newborns of younger mothers. Percentage values. Abbreviation: NI = Not informed.

In the group of older puerperal women (36 years of age or older), we identified a higher rate of altered retests; however, there was no statistical significance ( $p=0.161$ ). In the group of younger mothers ( $\leq 19$  years), 95.5% ( $n=21$ ) of the newborns were non-retested patients, 4.5% ( $n=1$ ) of retests with normal results, and there were none ( $n=0$ ) with altered results. In the intermediate maternal age group (20–35 years), 86.5% of the neonates did not undergo retest, 12.1% ( $n=150$ ) of the patients were retested with normal results, and 1.4% ( $n=17$ ) had altered results for the second time. Finally, in the group of mothers with higher age (36 years or more), 86.5% ( $n=1,077$ ) of the newborns did not undergo retest, 9.2% ( $n=28$ ) presented normal retest results, and 2.9% ( $n=9$ ) presented altered tests.

It is important to note that lack of retest considered here is due to both the fact that the newborn passed the first screening test and the absence of information of some who needed to undergo a second test.

Maternal comorbidity was detected in 213 (13.5%) pregnant women. Only the presence of arterial hypertension, gestational or not, was related to higher rates of NHS ( $p=0.062$ ) and retest ( $p=0.002$ ) with “failure” results. In the first test, 61.5% ( $n=16$ ) of the infants of hypertensive women had normal results and 34.6% ( $n=09$ ) altered; in one case (3.8%), the information was not present. The infants of normotensive women had 80.2% ( $n=1,248$ ) of normality, 17.9% ( $n=279$ ) of abnormality, and 1.9% ( $n=29$ ) were not informed. The values found in the retest are available in ► **Fig. 3**.

Medication use was identified in 47.6% ( $n=754$ ) of the mothers. When analyzing each active principle reported in medical records, only hydralazine and dipyron showed statistical relevance with failure in NHS. In the group that used hydralazine ( $n=7$ ) at some time during pregnancy, 28.6% ( $n=02$ ) of abnormal tests ( $p=0.038$ ) were identified. When we analyzed the number of abnormal tests in the group of mothers who did not use the drug ( $n=1,574$ ), the number of abnormal tests was lower: 18.6% ( $n=286$ ). Retest results did not show significant correlations with the use of



**Fig. 3** Relationship between the route of delivery birth and the first hearing screening. The figure shows the highest proportion of abnormal tests among those born by natural birth. Percentage values. Abbreviation: NI = Not informed.

**Table 2** Result of the first Neonatal Hearing Screening related to characteristics of the newborn, route of delivery and maternal age

VARIABLES			TEST				
			NORMAL		ALTERED		
			N	%	N	%	p
Gender		Male	651	51.9	170	59.4	0.064
		Female	604	48.1	116	40.6	
Height (cm)		30–40	26	2.2	06	2.2	0.065
		41–50	1,012	85.0	228	85.1	
		> 50	152	12.8	34	12.7	
Weight (g)		Low	119	9.5	17	6.1	0.320
		Eutrophic	1,078	86.3	252	90.0	
		High	52	4.2	11	3.9	
Apgar score							
	1 minute	Altered	14	1.1	04	1.4	0.438
		Normal	1,208	98.9	275	98.6	
	5 minutes	Altered	03	0.2	02	0.7	0.769
		Normal	1,220	99.8	277	99.3	
Cephalic perimeter (cm)							
		≤ 32	152	12.5	27	9.9	0.358
		≥ 33	1,060	87.5	246	90.1	
Parturition							
		Caesarean	1,117	89.0	236	82.2	0.007*
		Vaginal	138	11.0	51	17.8	
Type of birth							
		Preterm	160	14.5	33	12.5	0.817
		Term	942	85.3	231	87.5	
		Postterm	2	0.2	0	0.0	
Maternal age (years)							
		≤ 19	19	1.5	1	0.3	0.003*
		20–35	992	78.9	237	82.3	
		> 35	247	19.6	50	17.4	

Abbreviation: Apgar, appearance, pulse, grimace, activity, and respiration. Notes: \*Statistically significant ( $p < 0.05$ ). For a better demonstration, the cases in which the variables were not informed were omitted; therefore, the sum of the cases reported in the table does not total 1,583.

hydralazine ( $p = 0.361$ ). Dipyron was related to changes in test ( $p = 0.041$ ) and retest ( $p = 0.003$ ).

The relationships between the other variables with altered test and retest showed no statistical significance. ► **Table 2** shows the rates found for approval or not in the first hearing screening test, according to the characteristics of the newborn, route of birth delivery, and maternal age. ► **Table 3** contains the same variables referring to the NHS retest.

## Discussion

This study aimed to evaluate the clinicoepidemiological profile of children born in a private tertiary hospital in the

city of Tubarão, southern Brazil, regarding the NHS results of these newborns and the factors associated with failure in the test and retest.

The world prevalence of hearing loss is high, when compared with other pathologies also assessed in neonatal screening.<sup>2</sup> In Brazil, 1.3% of children aged 0 to 14 years have hearing loss, as shown in the 2010 census.<sup>13</sup> However, assistance in hearing health services has been gradually expanded each year, as well as concessions for hearing aids.<sup>14</sup> ► **Fig. 4** illustrates the ideal flowchart to be performed on the NHS.

The majority (98.1%) of the 1,583 children born between July, 2016, and July, 2019, at the studied institution was

**Table 3** Result of the second Neonatal Hearing Screening related to characteristics of the newborn, route of delivery, and maternal age

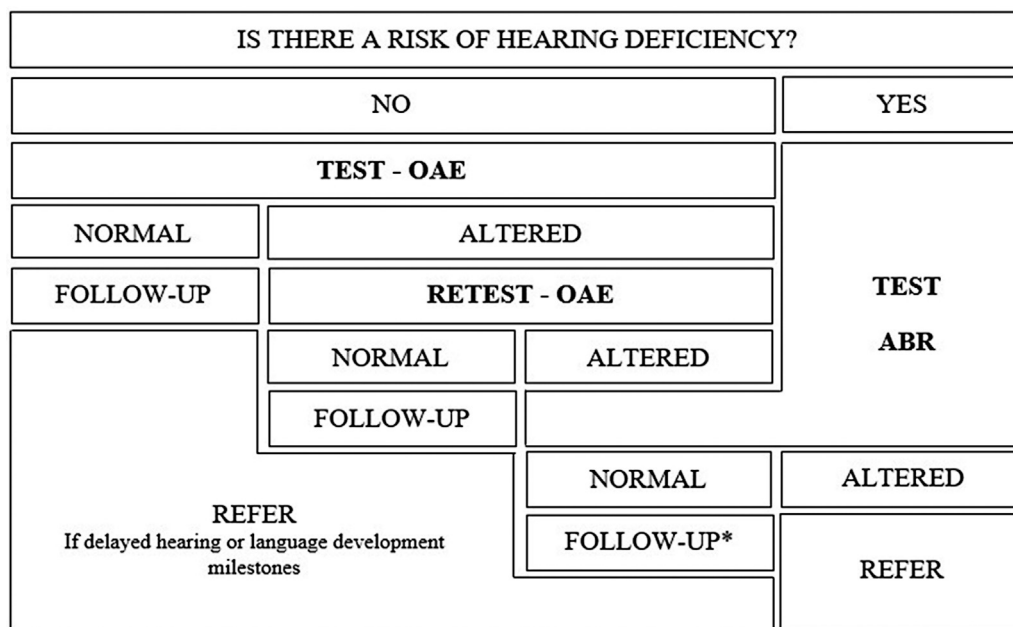
VARIABLES				RETEST						p-value
				NORMAL		ALTERED		NOT PERFORMED		
				N	%	n	%	n	%	
<b>Gender</b>										
			Male	111	62.0	14	53,8	172	52.2	0.053*
			Female	68	37.9	12	46,2	651	47,8	
<b>height (cm)</b>										
			30–40	03	1.7	1	4.2	31	2.4	0.900
			41–50	148	85.1	21	87.5	1,093	84.8	
			> 50	23	13.2	2	8.3	165	12.8	
<b>Weight (g)</b>										
			Low	10	5.6	2	8.0	128	9.4	0.379
			Eutrophic	165	91.7	22	88.0	1,168	86.2	
			High	5	2.8	1	4.0	59	4.4	
<b>Apgar score</b>										
		1° min	Altered	1	0.6	0	0.0	17	1.3	0.599
			Normal	178	99.4	26	100.0	1,310	98.7	
		5° min	Altered	0	0.0	0	0.0	5	0.4	0.679
			Normal	179	100	26	100.0	1,323	99.6	
<b>Cephalic perimeter (cm)</b>										
			≤ 32	14	7.9	3	12.5	167	12.7	0.178
			≥ 33	164	92.1	21	87.5	1,147	87.3	
<b>Parturition</b>										
			Caesarean	149	83.2	23	88.5	1,203	88.3	0.125
			Vaginal	30	16.8	3	11.5	159	11.7	
<b>Type of birth</b>										
			Preterm	19	11	4	16.0	175	14.6	0.728
			Term	154	89	21	84.0	1,022	85.2	
			Postterm	0	0.0	0	0.0	2	0.2	
<b>Maternal age (years)</b>										
			< 19	1	0.5	0	0.0	21	1.5	0.161
			20–35	150	83.9	17	65.4	1,077	78.8	
			> 35	28	15.6	9	34.6	269	19.7	

**Abbreviation:** Apgar, appearance, pulse, grimace, activity, and respiration.

**Notes:** \*Statistically significant ( $p < 0.05$ ). For a better demonstration, the cases in which the variables were not informed were omitted; therefore, the sum of the cases reported in the table does not total 1,583 individuals. The “not performed” column refers to those who did not retest due to lack of need (normal result on the first test) or because they failed the retest.

submitted to the NHS, and the missing (1.9%) can be attributed to the absence of qualified professionals during the weekend, in addition to parents not bringing their infant back to undergo testing. In public hospitals in the capitals of São Paulo and Rio de Janeiro, a screening coverage incidence of 39.3% and 19.8%<sup>6,8</sup> was found, respectively (disparity that may occur due to the institutions' lower investment capacity), considering the contemplation of 95% of the newborns as ideal.<sup>15</sup>

In the present study, 79.9% of those evaluated were classified as having OAE within the normal range. The remaining 18.2% needed a new assessment. A compilation of the literature has failure rates in the first test ranging from 8.0 to 25.3%.<sup>4,8,16,17</sup> Among those in need of a new test, 28.8% did not attend. In a similar study, only 4.9% abstained; however, that study was performed at the only institution responsible for hearing screening in the entire studied region.<sup>18</sup> Thus, it is worth highlighting the bias in the number



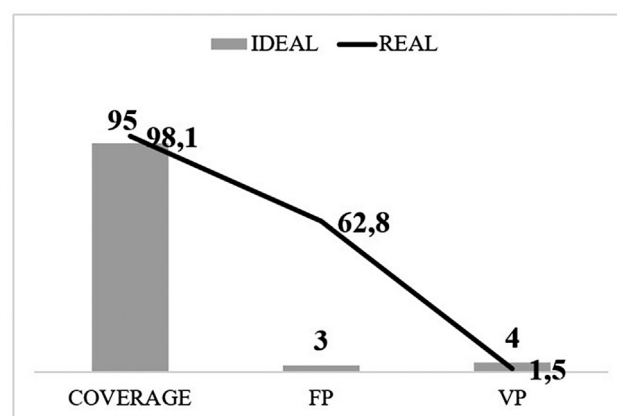
**Fig. 4** (Adapted) Flowchart of the NHS according to the Brazilian Ministry of Health, showing the order of priority of the NHS. Note: \*The monitoring of newborns with risk factors must be performed in specialized hearing health services.

of missing persons in the present study, since the neonates may have undergone the procedure at an institution closer to their home or, even, parents may have opted to continue treatment through the Brazilian Unified Health System (Sistema Único de Saúde, SUS, in Portuguese), without additional cost. Additionally, the lack of guidance on the NHS during prenatal consultations may reduce retest attendance. A study performed in Rio Grande do Sul warned medical professionals of the parents' lack of knowledge about NHS, since only 34.4% reported having received guidance on the topic during pregnancy.<sup>19</sup>

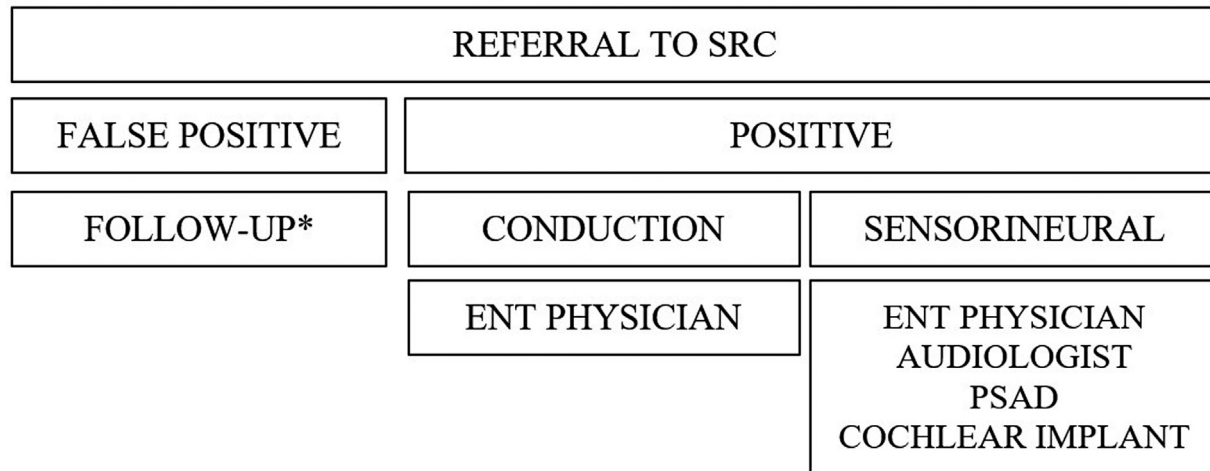
Among those who attended the retest, there were 181 (62.8%) false positives in the first test, which is higher than ideal value of 3.0%.<sup>15</sup> Once again, 24 (1.5% of the population studied) showed altered results. In the literature, failure rates in the second test varied from 1.3% to 6.6%, with the ideal index—used to determine the quality of service—being up to 4.0%.<sup>4,8,15-17</sup>

Regarding the goals cited here (95% of coverage, 3% of false positives, and 4% of failed retests), **Fig. 5** compares them with those found in the present research. It should be mentioned that the Joint Committee on Infant Hearing (JCIH) revised their definition of service quality in 2019. Numerical goals were abolished and strategies for better organization of the centers were adopted.<sup>20</sup> In our institution, for example, few patients did not undergo hearing screening. However, after the second test, it was identified that 62.8% of those initially screened were false positives, representing a high number of retests, which resulted in additional costs to parents, as well as anxiety and fear for the newborn's health. Medical professionals should also be aware of the number of retested patients with alterations that require adequate diagnosis and follow-up in a short period of time. If not, hearing screening is of little value.

The follow-up in cases of retest with “failure” results is referral to an otorhinolaryngologist, with the aim of examining and confirming the diagnosis with more advanced tests, defining therapy options, and establishing the follow-up of the affected patient.<sup>2</sup> This flowchart is best illustrated in **Fig. 6**. When confirming permanent hearing loss, for example, it is expected that the intervention, when instituted before six months of life, will enable better language development.<sup>2</sup> A study which monitored a cohort of neonates who failed to screen due to secretory otitis, and



**Fig. 5** Comparison between ideal and real rates found in the present study. The figure demonstrates the rates found in this study (“real”) and compares them with the ideal numerical rates (“ideal”) according to the 2007 JCIH. The first goal (“coverage”) is testing 95% or more of newborns. The second goal (FP) refers to the false positive threshold in the test, up to 3%. And the third goal (TP) is the maximum expected from altered retests, up to 4% of those tested. Therefore, 2 of the 3 goals were achieved. **Abbreviations:** FP, false positive, that is, those who failed the test but passed the retest; TP, true positive, that is, those who failed the test and retest.



**Fig. 6** (Adapted) Flowchart of the NHS, according to the Brazilian Ministry of Health, showing the the outcomes of the newborns after referral to specialized rehabilitation centers (SRCs). **Note:** \*The monitoring of newborns with risk factors must be performed in specialized hearing health services. **Abbreviations:** ENT, Otorhinolaryngologist; PSAD, personal sound amplification device.

results pointed out a higher risk of pathology recurrence, especially in the first year of life.<sup>21</sup> Thus, the limitation in auditory processing—and in the learning of those affected—could still occur after birth.

The sample of the present study is considered homogeneous in terms of gender and age of the newborns. As for weight, the extremes may be related to changes in sound perception. In larger newborns, the auditory canal will be larger and there will be more space for accumulation of vernix, increasing “failure” rates in the first test.<sup>10</sup> In this study, no significant correlation was found between weight and test ( $p = 0.320$ ) or retest results ( $p = 0.379$ ); similarly, height did not obtain a significant correlation ( $p = 0.065$  and  $0.900$ , respectively).

Age at the time of testing is one of the factors most often related to the need for a new test.<sup>10</sup> Those with less than 12 hours of life present an accumulation of vernix in the auditory canal up to six times greater than those with 24 hours of birth.<sup>10</sup> This factor was not evaluated in the present study, but it could justify the non-association between the children’s height and the result of the little ear test, if the evaluation took place mostly after 12 hours of life.

Among babies with low weight, the need for intensive care, use of ototoxic drugs, mechanical ventilation, and other potentially harmful interventions to capture sound stimuli is frequent, as numerous studies have already shown.<sup>3,8,22</sup> In a study performed in the Northern region of Brazil, it was found that “failure” results were significant for those with less than 1,500 g.<sup>3</sup> In the present study, even considering only those with up to 1,500 g, no statistical significance was found for altered results during screening. Such divergence can be attributed to the Brainstem Auditory Evoked Potential Test in Automatic Equipment (BAEP-A), which is part of the hearing screening protocol in the hospital of the mentioned study in neonates at high risk for developing hearing problems. This examination is not available at our institution.

In this study, the average maternal age was of 30.9 years, with a minimum of 19 and a maximum of 45 years, a

variation similar to that of another survey conducted in the Southern region of Brazil, with an average of 26 years.<sup>19</sup> Pregnancies at the extremities of the female reproduction cycle present a higher risk of complications during pregnancy, childbirth and the puerperium; consequently, they add predisposing factors for hearing impairment, leading to the need for periodic hearing assessments up to at least two-years-old.<sup>19</sup> Early pregnancy is related to a higher incidence of low birth weight and restricted intrauterine growth, while late pregnancy presents not only a higher number of low birth weight, but also preterm and impaired growth for gestational age, as well as a prevalent association with hypertensive disease, premature rupture of ovular membranes, and diabetes.<sup>23</sup> In this study, greater normality for the first test was found in the newborns of younger mothers and, although not statistically significant, a higher rate of altered retests in those of older mothers.

A cesarean rate between 10% and 15% has been considered ideal for more than three decades, since higher cesarean rates are not correlated with lower maternal or neonatal mortality.<sup>24</sup> Even so, in Brazil the rate is usually much higher than recommended, especially in private institutions.<sup>11</sup> A survey from Santa Catarina indicated that up to 88.0% of births were by cesarean sections in a predominantly private health care model.<sup>25</sup> In this study, the route of birth of 87.0% of the participants was by cesarean section. Vaginal delivery was associated with more failures in the first hearing test; as already discussed, the time of birth can be decisive for the approval or not of the newborn;<sup>10</sup> thus, the correlation between natural childbirth and a greater need for retesting can be justified by the faster recovery of postpartum women without surgery, resulting in shorter hospital stays and favoring testing within a few hours of life.

Regarding comorbidities, only systemic arterial hypertension demonstrated a statistically significant correlation with the altered screening test results. Maternal systolic blood pressure (SBP) above 160 mmHg is related to adverse outcomes for both women (stroke, pulmonary edema) and



children (prematurity, low birth weight, and congenital malformations, including those that compromise the auditory system).<sup>26–28</sup> Elevated blood pressure during pregnancy with a significant risk for congenital hearing loss had cutoff points determined in Asian studies: one of them determined a SBP of 156 mmHg associated with a diastolic blood pressure (DBP) of 103.7 mmHg, while another indicated only a DBP of 106 mmHg.<sup>22,29</sup>

As for the registered medications, only hydralazine and dipyron showed statistical relevance when correlated with failing assessments. In the first test, the vasodilator presented an abnormality index equal to 28.6%, versus 18.2% among the group that did not use it. Despite being an option in the treatment of hypertensive crises in pregnant women, in comparison with other antihypertensive drugs also recommended its use is associated with greater adverse outcomes for mother and child, such as maternal hypotension, persistent hypertension, placental abruption, fetal bradycardia, and need for cesarean section.<sup>26,30</sup> Therefore, this medication should not be chosen as the first treatment option.<sup>30</sup> Hearing loss at birth and in the initial months of life are added to the complications related to this medication.

Dipyron was related to changes in both tests. Despite being classified by the Food and Drug Administration (FDA) as category D, that is, evidence of fetal risk”, its use during pregnancy has been repeatedly verified.<sup>31</sup> A case report of G6PD deficiency relates the consumption of dipyron with hearing loss in patients with this erythrocyte enzyme disease—the most frequent in the population. Because it is oxidizing, the drug promotes intense hemoglobin denaturation, erythrocyte breakdown, hemolysis, and increased serum bilirubin, leading to encephalopathy due to hyperbilirubinemia, a severe neurological condition, which can result in death or permanent deficiencies, such as mental retardation, motor deficit, and deafness.<sup>32</sup>

Still regarding medications, we should note that the use of ondansetron was related to alterations in the first test’s results, but not in the retest. Nevertheless, there was no statistical significance ( $p = 0.552$ ). Recent studies have pointed out a higher risk of cranio-orofacial malformations associated with the use of this medication; both changes could impair the newborn’s hearing development.<sup>33,34</sup> In a note, the Brazilian Federation of Gynecology and Obstetrics Associations (Federação Brasileira das Associações de Ginecologia e Obstetrícia, FEBRASGO, in Portuguese) considered such studies controversial and, therefore, did not exclude antiemetics as a therapeutic option in pregnant women, although FEBRASGO recommends that it should no longer be used routinely as the first option.<sup>35</sup>

The association between altered tests during the screening and the number of risk factors presented by the newborn can be of great influence on the development of hearing, since the presence of a single risk indicator already predisposes a 2.4 higher rate of failure in the screening, according to a retrospective cohort that evaluated almost seven thousand individuals.<sup>14,16</sup> Moreover, there are findings indicating lower failure rates in children with only one risk factor, when compared with those with two or more.<sup>8</sup>

Neonatal screening allows for the early diagnosis of several pathologies, including hearing loss. Many of the conditions responsible for partial or total hearing loss can be prevented with prenatal monitoring, since some of the main objectives of this follow-up are the detection of potentially harmful pathologies for the mother and fetus, in addition to the early diagnosis of conditions that initially silent evolutions or are oligosymptomatic, and to providing guidance on habits that can affect adequate embryonic development, such as the use of specific drugs.<sup>36</sup>

This study is limited by the range of data (from a single private institution), in addition to not making BAEP-A available to those at high risk for hearing loss. There is also no data on the diagnosis of those who failed the retest or their follow-up.

The daily presence of professionals trained to carry out the tests is essential to expand the screening and test all children born in the institution. Furthermore, this study’s results highlight the need to better inform the parents about NHS and its importance, through guidance during the perinatal period. So, the performance of public authorities and the private sector is decisive in the creation of information campaigns and protocols that aim to improve screening rates, added to the monitoring of patients who need it, including those who have not failed any test, but who can develop hearing loss over time from the initial months of life, as well as other conditions that interfere with hearing, leading to learning and socialization difficulties.

Therefore, a cohort involving other local institutions is suggested, including the assessment of age at the time of screening, the result of BAEP-A, and risk factors acquired in the postnatal period, such as admission to a neonatal intensive care unit, mechanical ventilation, and infections.

When compared with the literature, the present study differs in that it evaluated a private institution of regional reference in NHS. Furthermore, the focus of this research on modifiable prenatal factors presents evidence that suggests a path for the prevention of congenital hearing loss.

## Conclusion

The present analysis involving institutions responsible for conducting NHS identified the existence of characteristics and protocols related to test and retest results that can be improved, collaborating to increase the qualification and resolution of care, and avoid excessive referrals.

The service evaluated in this study did not test 1.9% of those born during the proposed collection period; among those tested, 18.2% required a new assessment, the result of which referred 1.5% of the children to investigate the causes of the identified hearing deficits. Thus, the false-positive rate (62.8%) was higher than the index recommended by the scientific community, while the number of children who were screened and the percentage of them who needed referral after retest are within the expected rates of quality indicators.

The following variables were correlated with changes in test and/or retest: vaginal delivery route, arterial

hypertension present, hydralazine use, and dipyron use. The maternal age variable had a statistically significant value for less altered tests among the younger mothers.

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#### Conflict of Interests

The authors have no conflicts of interest to declare.

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