

# Newborn hearing loss in the south of China: a cross-sectional study

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Yuanming Wang, Chen Cheng and  
Chuling Li 

## Abstract

**Objective:** Newborn hearing screening can identify congenital deafness and hearing loss. The current status of newborn hearing screening in the south of China is unclear. We aimed to assess the hearing loss of newborns in Dongguan, China.

**Methods:** A total of 62,545 newborns were enrolled in this retrospective, cross-sectional study between September 2015 and August 2020. The screening procedure was carried out using a two-step hearing screening. The trends were examined by the Cochran–Armitage trend test.

**Results:** From 2015 to 2020, the total initial newborn hearing screening rate was 98.16%, and it significantly increased over time ( $Z = 2.488$ ). The initial screening pass rate of newborns was 90.08%, and no significant difference was observed in the initial screening pass rate between different years ( $Z = 0.845$ ). After two-step hearing screening, the overall hearing screening pass rate of newborns was 94.65%. The overall hearing screening pass rate in normal newborns was higher than that in high-risk newborns (95.70% vs. 93.59%).

**Conclusion:** The initial newborn hearing screening rate increased yearly in the study period, but there was still an approximately 10% referral rate. The initial screening pass rate in China needs to be further improved.

## Keywords

Newborn hearing, hearing loss, screening rate, diagnostic brainstem response, distortion product otoacoustic emission, behavioral audiometry

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Department of Otolaryngology Head and Neck Surgery, Affiliated Dongguan Maternal and Child Healthcare Hospital, Southern Medical University, Dongguan, Guangdong, P.R. China

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## Corresponding author:

Chuling Li, Department of Otolaryngology Head and Neck Surgery, Affiliated Dongguan Maternal and Child Healthcare Hospital, Southern Medical University, No. 99 Zhenxing Road, Dongcheng District, Dongguan, Guangdong 523120, P.R. China.  
Email: [chulingld@outlook.com](mailto:chulingld@outlook.com)



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## Introduction

Hearing loss is the most common birth defect.<sup>1</sup> The reported prevalence of moderate and severe hearing impairment is 0.1% to 0.3% in healthy newborns,<sup>2,3</sup> and 2% to 4% in the intensive care population.<sup>4,5</sup> Children with undiagnosed hearing loss may experience severe delays in speech development and this causes psychological and behavioral issues, which may affect their social and learning skills.<sup>6,7</sup> Early detection of impaired infant hearing and timely intervention can enable these infants to achieve the same development as normal infants.<sup>6,8</sup>

Newborn hearing screening is a program that can identify congenital deafness and hearing loss, and it has been adopted in many countries. Early identification of hearing impairment leads to less adverse effects on infant development.<sup>9,10</sup> Children who are diagnosed early with hearing loss have more opportunity to develop language skills compared with children who are diagnosed later.<sup>6,11</sup> The age at which hearing loss is detected has been greatly reduced because of the popularity of hearing screening programs.<sup>12</sup> In the United States, the coverage of newborn hearing screening in 2016 was approximately 98% of all live births.<sup>13</sup> Furthermore, newborn hearing screening has been applied in China since 2000.<sup>14</sup> The national newborn hearing screening coverage in China was 86.5% in 2016, and hearing screening coverage in eastern provinces was higher than that in western provinces (93.1% vs. 79.4%).<sup>15</sup> In this study, we aimed to determine the current status of universal newborn hearing screening in Dongguan (China) using the latest data. Furthermore, the status of hearing screening in normal newborns and high-risk newborns was analyzed.

## Methods

### *Study design and population*

This retrospective, cross-sectional study was conducted in the Dongguan Maternal and Child Healthcare Hospital. A total of 63,717 newborns were born in this hospital from 1 September 2015 to 31 August 2020. After excluding 1172 newborns who did not receive universal newborn hearing screening, 62,545 newborns were included in this study. The written informed consent of each newborn was obtained from their parents, and the detailed information of all newborns has been deidentified. The study protocol was reviewed and received an exemption from ethics board approval by the Institutional Review Board of the Dongguan Maternal and Child Healthcare Hospital because of its retrospective, cross-sectional study design. The study conforms to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting observational studies.<sup>16</sup>

### *Screening process*

Newborn hearing screening procedures and the definition of high-risk newborns were applied in accordance with the Technical Regulation for the Neonatal Disease Screening (2010 edition) of the Ministry of Health of the People's Republic of China.<sup>17</sup> Screening was performed by screening personnel who had received specific training in neonatal screening techniques. The procedures were as follows. (1) Two-step screening with distortion product otoacoustic emission (DPOE) (Madsen Capella; GN Otometrics, Taastrup, Denmark) was applied to newborns with a normal birth. Initial universal hearing screening was

completed 48 hours after the birth of the neonates and before discharge. Those who did not pass the initial screening and those who missed the screening were screened before 42 days after birth (rescreening). Any neonates who failed the rescreening were diagnosed by diagnosticians within 3 months. (2) The automated auditory brainstem response (AABR) was used in newborns in the intensive care unit before discharge, and newborns who did not pass the screening were diagnosed by diagnosticians.

### *Assessment criteria*

Diagnostic tests included acoustic immittance (226 HZ and 1000 HZ probe sound), DPOAE, the diagnostic brainstem response (ABR), and behavioral audiometry. Behavioral audiometry was performed after the infant was 3 to 6 months old. The criteria for passing the initial screening and rescreening were based on the results of DPOAE or AABR, namely binaural pass, which meant that the newborn's hearing screening had passed, and the failure of any ear meant that the hearing screening had failed. The average hearing thresholds of 500, 1000, 2000, and 4000 Hz were used to classify neonatal hearing loss and hearing impairment as follows: mild (26–30 dB HL), moderate (31–60 dB HL), severe (61–80 dB HL), and very severe ( $\geq 81$  dB HL).

### *Statistical analysis*

Categorical variables are expressed as numbers and percentages. Comparison of the initial screening pass rate, rescreening rate, and rescreening pass rate of the newborn hearing screening was made by using the chi-square test or Fisher's test. The trends from 2015 to 2020 were examined by the

Cochran–Armitage trend test. All statistical analyses were two-sided, and  $P < 0.05$  was considered as statistically significant. SAS (version 9.4; SAS Institute Inc., Cary, NC, USA) software was used for statistical analysis.

## **Results**

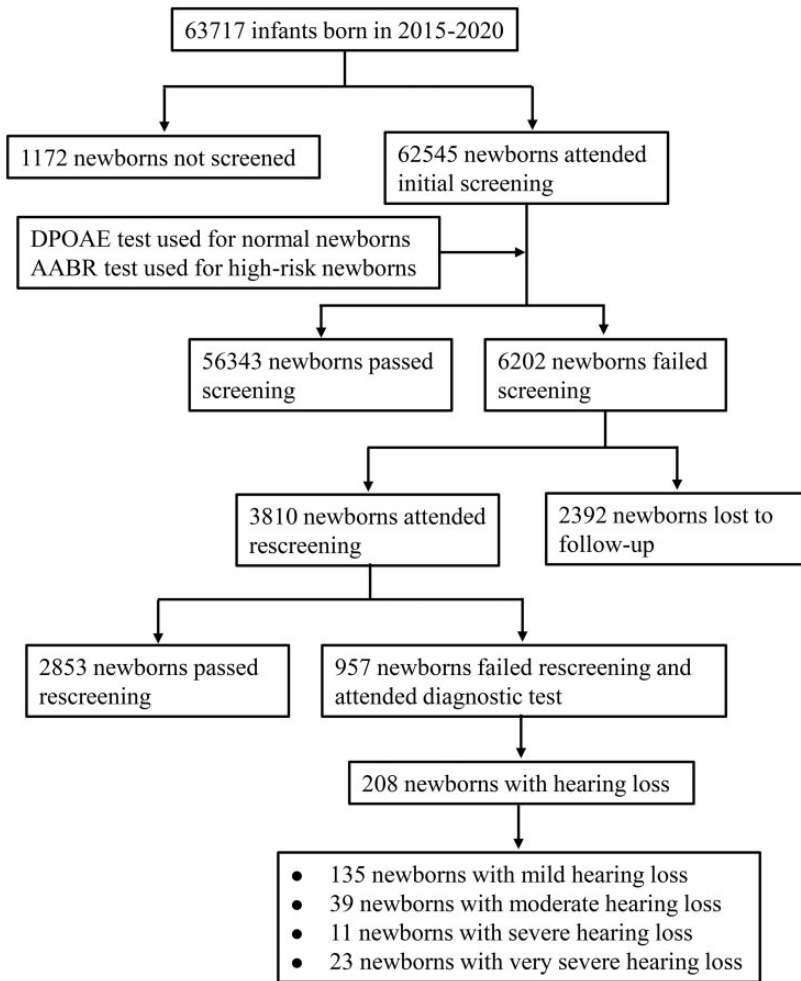
### *Newborns' initial hearing screening*

A total of 63,717 neonates were born in the Dongguan Maternal and Child Healthcare Hospital from September 2015 to August 2020 (Figure 1). Of these newborns, 62,545 (98.16%) received hearing screening, 56,343 (90.08%) passed the initial hearing screening, and 6202 (9.92%) failed the initial hearing screening.

The results of the initial hearing screening are shown in Table 1 and Figure 2. From September 2015 to December 2015, 3399 newborns were born, 3235 (95.18%) completed the initial hearing screening, and 2866 (88.59%) passed the initial hearing screening. The initial newborn hearing screening rate increased from 2015 to 2020, and the trend was statistically significant ( $Z = 2.488$ ,  $P = 0.013$ ). However, the initial hearing screening pass rate was not significantly different over time ( $Z = 0.845$ ,  $P = 0.398$ ) (Figure 2).

### *Newborns' hearing rescreening*

After the initial hearing screening, 6202 newborns who did not pass the initial hearing screening were rescreened. However, only 3810 (61.43%) newborns received rescreening and 2392 (38.57%) newborns were lost to follow-up. Of these newborns with rescreening, 2853 (74.88%) passed the rescreening and 957 (25.12%) failed the rescreening (Figure 1). After two-step



**Figure 1.** Flow diagram of the participants.

DPOAE, distortion product otoacoustic emission; AABR, automated auditory brainstem response.

hearing screening, 59,196 (94.65%) newborns passed the hearing screening, 957 (1.53%) failed the hearing screening, and 2392 (3.82%) were lost to follow-up.

The results of two-step newborns hearing screening are shown in Table 2. The trend of the hearing screening pass rate was not significant from 2015 to 2020 ( $Z=0.506$ ,  $P=0.613$ ).

### Diagnostic results of newborn hearing

A total of 957 newborns who failed the rescreening were diagnosed by diagnosticians, and 208 newborns were diagnosed with a hearing defect, accounting for 0.326% of all newborns. Of these newborns with a hearing defect, 135 (64.90%) had a mild hearing defect, 39 (18.75%) had

**Table 1.** Results of initial hearing screening from 2015 to 2020.

	2015	2016	2017	2018	2019	2020	Total
Number of alive newborns, n	3399	12,528	13,569	13,078	13,049	8094	63,717
Initial hearing screening, n (%)	3235 (95.18)	12,035 (96.06)	13,415 (98.87)	12,880 (98.49)	12,929 (99.08)	8051 (99.47)	62,545 (98.16)
Pass rate, n (%)	2866 (88.59)	10,654 (88.53)	12,071 (89.98)	11,743 (91.17)	11,618 (89.86)	7391 (91.80)	56,343 (90.08)
Failure rate, n (%)	369 (11.41)	1381 (11.47)	1344 (10.02)	1137 (8.83)	1311 (10.14)	660 (8.20)	6202 (9.92)

Initial hearing screening rate = (number of newborns who participated in the initial screening/number of alive newborns) × 100; pass rate of initial hearing screening = (number of newborns who passed screening/number of newborns who participated in screening) × 100.  
2015 includes September 2015 to December 2015 and 2020 includes January 2020 to August 2020.

a moderate hearing defect, 11 (5.29%) had a severe hearing defect, and 23 (11.06%) had a very severe hearing defect (Table 3).

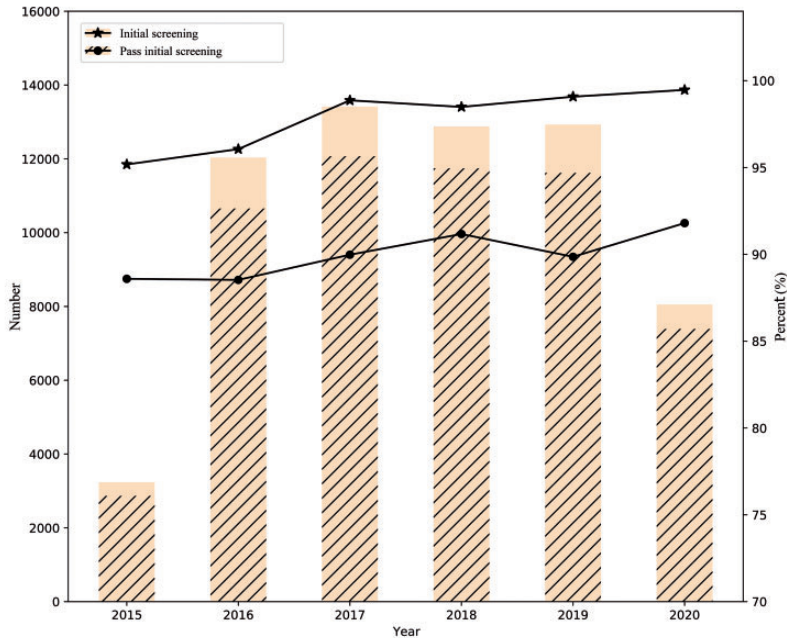
The diagnostic results of newborn hearing from 2015 to 2020 are shown in Table 3 and Figure 3. From 2015 to 2020, the trend of the diagnostic rate of a hearing defect in newborns was not significant ( $Z = -0.225$ ,  $P = 0.822$ ).

### Comparison of hearing screening results between normal newborns and high-risk newborns

From September 2015 to August 2020, 62,545 newborns participated in the initial hearing screening. Of these, 51,653 (82.59%) were normal newborns, 10,883 (17.40%) were high-risk newborns, and 9 (0.01%) newborns were not recorded. The initial hearing screening pass rate in normal newborns was significantly higher than that in high-risk newborns ( $P < 0.001$ ). The overall hearing screening pass rate in normal newborns was significantly higher than that in high-risk newborns ( $P < 0.001$ ). The diagnostic rate of a hearing defect in normal newborns was significantly lower than that in high-risk newborns ( $P < 0.001$ ) (Table 4). In the initial hearing screening, the referral rates of normal newborns and high-risk newborns were 9.43% and 12.21%, respectively.

## Discussion

This study examined the status of a large-scale newborn hearing screening in Dongguan, China. Newborn hearing screening was conducted by a two-step protocol using DPOAE and AABR. We found that the initial newborn hearing screening rate increased from 2015 to 2020, and the total initial screening rate was 98.16%. After two-step hearing screening, the overall hearing screening pass rate of newborns was 94.65%. The overall hearing screening



**Figure 2.** The number of newborns who received initial hearing screening and the passing rate of initial screening. “Number” indicates the number of newborns who participated in the screening and passed the screening (bar chart); “percent” indicates the percentage of the newborn hearing screening rate and the screening pass rate (line chart); “2015” includes September 2015 to December 2015; “2020” includes January 2020 to August 2020.

pass rates in normal newborns and high-risk newborns were 95.70% and 93.59%, respectively.

Newborn hearing screening is adopted in many countries because early identification of hearing impairment leads to less adverse effects on children’s development.<sup>9,10</sup> In China, hearing screening of newborns has been applied nationwide in accordance with the Maternal and Infant Health Care Act of 2000.<sup>14</sup> A previous study reported that the hearing screening coverage in China increased from 29.9% in 2008 to 86.5% in 2016.<sup>15</sup> Universal newborn hearing screening coverage reaches nearly 100% in some provinces of China, which is similar to the high coverage reported in the United States (98.0%),<sup>13</sup> the United Kingdom (97.5%),<sup>18</sup> and Poland (96.0%).<sup>19</sup> This study showed

that, from September 2015 to August 2020, 62,545 newborns participated in the hearing screening in Dongguan, and the initial hearing screening rate of newborns was 98.16%. The initial screening pass rate and overall hearing screening pass rate in newborns were 90.08% and 94.65%, respectively. The overall hearing screening pass rate in normal newborns was higher than that in high-risk newborns.

The referral rate and diagnostic confirmation incidence are also important for newborn hearing screening. High referral rates place a burden on patients and medical institutions. In our study in the initial hearing screening, the referral rates of normal newborns and high-risk newborns were 9.43% and 12.21%, respectively. Previous studies also reported that the

**Table 2.** Total results of newborn hearing screening.

	2015	2016	2017	2018	2019	2020	Total
Number of newborns at the initial hearing screening, n	3235	12,035	13,415	12,880	12,929	8051	62,545
Pass rate of screening, n (%)	2983 (92.21)	11,270 (93.64)	12,733 (94.92)	12,274 (95.30)	12,279 (94.97)	7657 (95.11)	59,196 (94.65)
Failure rate of screening, n (%)	34 (1.05)	185 (1.54)	211 (1.57)	235 (1.82)	213 (1.65)	79 (0.98)	957 (1.53)
Lost to follow-up, n (%)	218 (6.74)	580 (4.82)	471 (3.51)	371 (2.88)	437 (3.38)	315 (3.91)	2392 (3.82)

Total pass rate of screening = (number of newborns who passed the initial screening or rescreening/number of newborns who participated in the initial screening) × 100. "2015" includes September 2015 to December 2015 and "2020" includes January 2020 to August 2020.

initial screening referral rate of the two-step protocol was between 7% and 28%, and the final referral rate after the outpatient review was between 1% and 6%.<sup>20–24</sup> Some methods that have been reported to reduce the referral rate of newborn hearing screening are worthy of attention. Shang *et al.* showed that adding AABR tests for newborns who failed the otoacoustic emission test at the initial screening significantly reduced the referral rate without increasing misdiagnosis rates.<sup>23</sup> Although the addition of AABR testing may increase medical costs, it has obvious advantages in reducing the referral rate. Chung *et al.* showed that adjusting the timing of newborn hearing screening reduced the screening referral rate.<sup>25</sup> They recommend that hearing screening should be performed between 2 and 20 days after birth for normal newborns, and between 5 and 31 days for high-risk newborns.

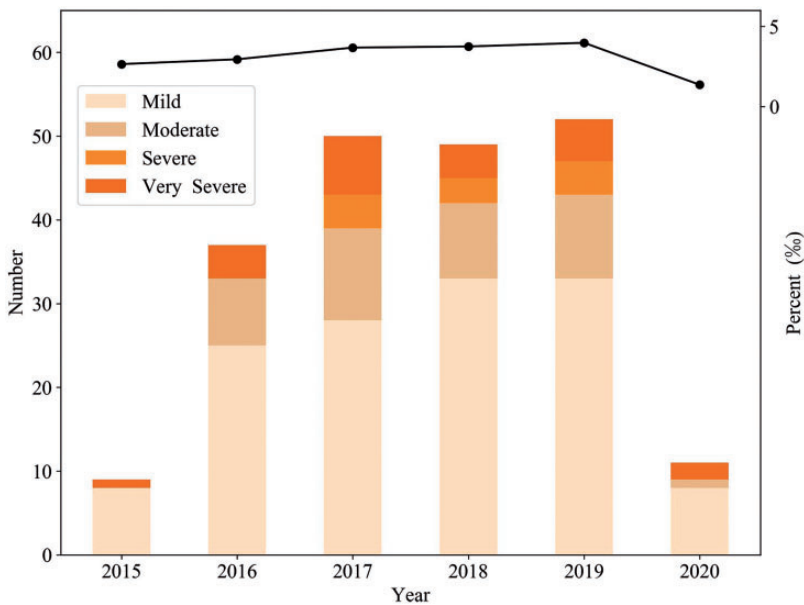
Early hearing screening plays an important role in the future development of children. Infants with mild to moderate bilateral or unilateral hearing loss can be identified by newborn hearing screening. In the past, these children were usually identified later in childhood when they experienced verbal or educational delays.<sup>12</sup> Additionally, children who are identified with hearing loss early have more opportunity to develop language skills compared with children who are diagnosed later.<sup>6,11,26</sup> Only children who are identified as being hearing impaired in the early stage and have hearing enhancement before 6 months of age have a better chance of developing like their peers.<sup>8,27,28</sup> A study by Pimperton *et al.* showed the beneficial effects of early recognition of hearing loss on relative expression language acquisition from childhood to adolescence.<sup>29</sup> Furthermore, early identification can provide a basis for early intervention. Early intervention can improve language effects, thereby providing support for simplifying

**Table 3.** Diagnostic results of newborn hearing defects from 2015 to 2020.

	2015	2016	2017	2018	2019	2020	Total
Hearing defect, n (%)	9 (2.65)	37 (2.95)	50 (3.68)	49 (3.75)	52 (3.98)	11 (1.36)	208 (3.26)
Mild, n (%)	8 (88.89)	25 (67.57)	28 (56.00)	33 (67.35)	33 (63.46)	8 (72.73)	135 (64.90)
Moderate, n (%)	0 (0)	8 (21.62)	11 (22.00)	9 (18.37)	10 (19.23)	1 (9.09)	39 (18.75)
Severe, n (%)	0 (0)	0 (0)	4 (8.00)	3 (6.12)	4 (7.69)	0 (0)	11 (5.29)
Very severe, n (%)	1 (11.11)	4 (10.81)	7 (14.00)	4 (8.16)	5 (9.62)	2 (18.18)	23 (11.06)

Rate of hearing defect = (number of newborns diagnosed with a hearing defect/number of alive newborns) × 1000;  
 proportion of mid/moderate/severe/very severe hearing defect = (number of newborns with a mid/moderate/severe/very severe hearing defect/number of newborns with a hearing defect) × 100.

“2015” includes September 2015 to December 2015 and “2020” includes January 2020 to August 2020.

**Figure 3.** Results of hearing defects in newborns from 2015 to 2020.

“Number” indicates the number of newborns with hearing defects (bar chart); “percent” indicates the percentage of newborns with hearing defects (line chart); “2015” includes September 2015 to December 2015; “2020” includes January 2020 to August 2020.

clinical pathways to ensure early expansion and cochlear implantation after diagnosis.<sup>30</sup>

Newborn hearing screening is closely related to social benefits and reducing the burden of related diseases. Early diagnosis of hearing impairment can effectively save the cost of intensive speech and language intervention and special education services in the future.<sup>31–33</sup> Semenov *et al.* found that

early (<18 months) cochlear implantation intervention was associated with better and longer quality of life improvement and direct implant costs in patients with an early diagnosis.<sup>34</sup> Keren *et al.* showed that newborn hearing screening detected and led to intervention in hearing impairment at an early stage, which improved the language ability, reduced education costs,



**Table 4.** Comparison of hearing screening results between normal newborns and high-risk newborns.

	Normal newborns	High-risk newborns	Chi-square statistic	P
Initial hearing screening, n	51,653	10,833	–	–
Pass rate of initial hearing screening, n (%)	46,780 (90.57)	9,554 (87.79)	77.627	<0.001
Pass rate of total hearing screening, n (%)	49,048 (95.70)	10,139 (93.59)	88.950	<0.001
Hearing defect, n (‰)	148 (2.87)	60 (26.79)	19.291	<0.001
Severity of hearing defect, n (%)	–	–	1.615	0.108
Mild	100 (67.57)	35 (58.33)	–	–
Moderate	28 (18.92)	11 (18.33)	–	–
Severe	9 (6.08)	2 (3.33)	–	–
Very severe	11 (7.43)	12 (20.00)	–	–

and increased life-long productivity compared with no screening.<sup>35</sup> Therefore, newborn hearing screening is significantly related to the healthy development of children and reducing the burden of related-diseases. However, there are differences in the hearing screening rates in different regions of China. The eastern region of China has higher hearing screening rates than those in the western region.<sup>15</sup> Improving the rate of newborn screening has important clinical and social value.

In this study, we used the most recent data to analyze the current status of newborn hearing screening in China. However, this study has some limitations as follows. First, the data of this study were extracted from Dongguan, and the results only reflected the current status of newborn hearing screening in Dongguan. The current status of newborn hearing screening in China should be derived from a comprehensive analysis of data from more regions. Second, 38.57% of newborns who failed in the initial hearing screening were lost to follow-up, which may have affected the rescreening pass rate. The reason for the loss to follow-up may be that newborns did not pass the initial hearing screening, which worried their parents, and the parents went to a better hospital for identification.

This study was based on recent data to analyze the current status of newborn hearing screening in Dongguan, China. The initial newborn hearing screening rate increased from 2015 to 2020. The overall hearing screening pass rate of normal newborns is higher than that in high-risk newborns.


#### Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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#### ORCID iD

Chuling Li  <https://orcid.org/0000-0002-1597-6626>

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