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Development of a digitized Early Hearing Detection and Intervention – Information System (EHDI-IS) in Japan

日本における難聴早期発見・介入 デジタル情報管理システム（EHDI-IS）の開発

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学籍番号: 20S3063　　氏名: ホロウェル　ジェイソン

研究指導教員: 城間将江　教授

副研究指導教員: 富澤晃文　准教授

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ホロウェル　ジェイソン

要旨

難聴児の発達においては、生後 1 か月以内に難聴を発見して 3 か月までには精密検査を終え、6 か月までに適切な療育を開始することで（1-3-6 目標）、通常発達児と遜色ない言語発達も可能として、先進国では新生児聴覚スクリーニングの鉄則となっている。日本における新生児聴覚スクリーニングの現状に関する文献や公的報告書によると、スクリーニング検査の初回実施率は年々向上している。一方で、データ管理がアナログである故に、関連する施設や専門家間の情報共有も遅く、療育につながるまでの目標実現を阻害している可能性があり、データ管理のデジタル化が必要と考えられた。そこで、本研究では聴覚スクリーニング、フォローアップ検査・診断・介入のデータを管理するための EHDI-IS（難聴早期発見・介入のデジタル情報システム）を開発し、その有効性を評価することを目的とした。　研究 I では、日本全国 47 都道府県の保健福祉部局を対象に新生児聴覚スクリーニングに関するアンケートを実施し、33 都道府県から回答を得た。そのうち 11 県は半構造化面接による聞き取り調査にも協力してくれた。インタビューにおいても、人手不足を理由にスクリーニングの結果や精密検査のフォローアップおよび介入状況を正確に効率よく把握するのは困難であるとの回答を得、EHDI-IS の開発は意義あるものと判断された。研究 II では、新生児聴覚スクリーニング関連データの収集や管理のための EHDI-IS ウェブアプリを開発し、1 県で試験的に運用した。その結果、入力されたデータは、複数の施設や関係者間で即時に情報共有でき、スクリーニングでリファーとなった難聴児や家族に対して迅速かつ適切な支援を提供できることが示唆された。今後は全国的な展開方法を検討する予定である。

キーワード：聴覚障がい、新生児聴覚スクリーニング、EHDI-IS、デジタル化

Development of a digitized Early Hearing Detection and Intervention – Information System (EHDI-IS) in Japan

Jason Hollowell

Abstract

For children with hearing loss, it is considered a fundamental rule in developed nations throughout the world that if hearing loss is detected within the first month of life, a follow-up examination is completed by 3 months, and appropriate medical care is initiated by 6 months (the 1-3-6 goals), language development comparable to that of normally developing children is possible. According to the literature and published reports on the current status of newborn hearing screening in Japan, hearing screening test rates have been increasing year by year. However, as data is still managed in analog format in many municipalities, thus making information sharing among related facilities and specialists inefficient, the realization of the 1-3-6 goals is hindered. It was thus considered necessary to digitize the management of related data. The purpose of this study was therefore to develop and evaluate the effectiveness of an EHDI-IS (Early Hearing Detection and Intervention – Information System) for managing data from hearing screening, follow-up testing, diagnosis, and intervention. In Study I, a questionnaire regarding newborn hearing screening was sent to health and welfare departments in 47 prefectures throughout Japan with responses received from 33 prefectures. Eleven of these prefectures also participated in subsequently administered semi-structured interviews. The EHDI-IS development was deemed significant as the interviewees indicated that it is difficult to accurately and efficiently track screening results, follow-up examinations, and intervention status due to lack of manpower. In Study II, an EHDI-IS web application for collecting and managing newborn hearing screening-related data was developed and piloted in one prefecture. The results showed that the data entered could be used for immediate information sharing among multiple facilities and stakeholders, and could provide prompt and appropriate support to children with suspected and diagnosed hearing loss and their families.

keyword : Hearing impairment, NHS, EHDI-IS, Digitization

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I. General Introduction

Severe to profound congenital hearing loss in newborn infants occurs at a frequency ranging from less than 1 to as high as 5 per 1,000 births [1]. Hearing loss of this magnitude has a significant negative impact on language acquisition and cognitive development in these children and the degree of this impact is directly related to the age at detection of hearing loss and subsequent intervention [2–4]. Early detection of hearing loss, via newborn hearing screening (hereafter NHS) programs, enables early intervention specifically designed to significantly ameliorate the impact of hearing loss. The Longitudinal Outcomes of Children with Hearing Impairment (LOCHI) study conducted in Australia, has recorded the effect of early cochlear implantation or hearing aid fitting on children with hearing loss; documenting improved speech, language, cognitive ability, and general functional performance outcomes [5]. In addition to early detection and device fitting, intervention frequency and methodology have been shown to be equally important, if not even more influential, in maximizing spoken language outcomes for children with hearing loss [4].

Additional support for UNHS (universal newborn hearing screening) programs, from a public health and economic perspective in Japan, is provided via a 2018 study conducted by Kataoka et. al. [6] in which the cost of UNHS programs is demonstrated to have a positive cost-effectiveness value due to reduced expenditures for social welfare and mandatory education as early detection and intervention results in reduced needs for special education. Studies in Australia have also shown UNHS costs to be offset by reductions in subsequent support related expenditures [7] and reports published by the National Center for Hearing Assessment and Management in the U.S. state that identification of hearing loss at birth reduces special education costs by $400,000 per child by the time of high school graduation [8].

Screening programs are more accurately described as Early Hearing Detection and Intervention programs, or EHDI programs. The guideline and protocol specified by the Joint Committee on Infant Hearing (JCIH), often termed the 1-3-6 goals, are used for evaluation of EHDI programs [9]. Those are:

Guideline

1. All newborns receive newborn hearing screening by 1 month of age
2. All newborns referred for follow-up testing receive diagnostic evaluation by 3 months of age
3. All newborns diagnosed with hearing impairment receive early intervention services by 6 months of age

Protocol

1. 95% of all newborns screened for hearing impairment by one month of age
2. 4% or less of all screened newborns referred for follow-up
3. 90% of infants referred for follow-up receiving follow-up testing by 3 months of age
4. 95% of infants diagnosed with hearing impairment, and who's families have opted for the use of amplification, receive amplification within one month of hearing impairment confirmation
5. 90% of children identified with hearing impairment begin an early intervention program by 6 months of age
6. 90% of children identified with hearing impairment receive a standardized developmental assessment for language and nonverbal cognitive development by 12 months of age

1. Background

1) History of Newborn Hearing Screening

The recorded history of hearing screening, starting with school age children, dates back to 1876 when Clarence Blake published an article focusing on methods of identification and intervention for children with hearing impairment [11,12]. As a result of insufficient understanding about language acquisition and limitations in testing methodologies and their underlying technology, it was not until almost one hundred years later that testing of newborns for hearing impairment began in the form of small-scale pilot research projects. Janet Hardy reports, in 1959, on a study of 327 infants tested via a "distraction technique" for the identification of hearing impairment [13]. A few years later, in 1964, Marion Downs reported on the use of a more scientific method for identifying hearing impairment in newborns using a signal generator to replace the somewhat cruder implements used in the "distraction technique" [14]. Progress thereafter accelerated and in 1971, a few months after the first Conference on Newborn Hearing Screening was held, the JCIH issued its first statement on neonatal screening for hearing impairment [15,16]. In the years since then, as technology has advanced and knowledge about the efficacy of intervention for children with hearing impairment has increased, the JCIH has issued nine updated position statements with the latest, in 2019, calling for accelerated guideline goals of 1-2-3 for those programs that have successfully achieved the 1-3-6 goals [17].

2) Modern Newborn Hearing Screening Methods

Modern newborn hearing screening is widely conducted using electro-physiological tools that were developed in the mid to late 1970s. The two generally accepted methods of measurement are the OAE (otoacoustic emissions) test and the ABR (auditory brainstem response) test. Both tests involve noninvasive procedures; however, their measurement parameters differ.

The OAE, first reported upon in 1978 by Kemp, utilizes a technique which measures sounds, termed acoustic impulse responses, originating from the ear after it is stimulated by an external sound source [18]. The OAE test is performed by placing a small probe in the ear of the newborn. The probe consists of a speaker, which presents sound of specific characteristics, and a microphone which measures the sounds generated from within the ear in response to the sounds presented by the speaker. The OAE equipment is designed to reduce the potential of interference from background noise, however, administering the test in a quiet environment is recommended. Test results are recorded as either a "Pass" or "Refer" with no need for result interpretation by the test technician.

The ABR concept was first reported upon in the late 1960s and was shortly thereafter, in 1971, described in detail [19]. The ABR test measures electrical impulses in the brain, generated in response to sounds presented through the ears. These impulse signals are measured within a time window of approximately 10 milliseconds after the presentation of sound and present in the form of five waves termed Wave I through Wave V. For newborn hearing screening, the AABR (automated auditory brainstem response) test involves placing sensors on the baby's head and neck, and fitting headphone cups over or earbuds into the baby's ears. Like the OAE, when used for newborn hearing screening, the AABR result is reported as a simple "Pass" or "Refer" with no need for interpretation by the test technician.

Newborn hearing screening test methods must have suitable specificity, sensitivity, and positive predicative value levels. Specificity is determined by how accurately the test returns a negative result when no hearing impairment exists, which is a pass result in the case of newborn hearing screening. Sensitivity is measured by how accurately the test returns a positive result, a referral in the case of newborn hearing screening, when hearing impairment does exist. Positive predictive

value (PPV) is calculated by dividing the number of positive results, those with diagnosed hearing impairment, by the total number of referrals. Thus, if ten babies are referred and only two of those babies are diagnosed with hearing impairment, the PPV would be 2/10 or 20%. If, however, all ten of the referred babies are diagnosed with hearing impairment, the PPV would be 10/10 or 100%. A higher PPV ensures fewer babies are wrongly referred for follow-up testing thus reducing unnecessary stress for the parents. Screening programs are, for this reason, encouraged to strive for referral rates of 4% or lower [9].

Various research has shown AABR to be a more desirable methodology due to a significant reduction in referral rates equating to fewer false positive results and thus a higher PPV [20,21]. Modified methods for OAE administration, such as using higher frequency sounds and delaying the administration of the test to allow for clearing of mucus, fluid, and other obstructions in the newborn's ear, have been shown to yield reduced referral rates supporting the continued use of the technology [22]. As such, both methodologies, sometimes in combination, continue to be used for newborn hearing screening in programs throughout the world.

3) Newborn hearing screening in Japan

Although hearing loss is not included in the newborn mass screening program in Japan, which began in 1977 [23,24], in 2007, the year after government-funded pilot programs for newborn hearing screening had ceased, the Japanese government issued a statement requesting that all prefectures and metropolitan districts offer newborn hearing screening to all newborns [25]. The document explained that funding for these programs was provided by a substantially increased funding program for "addressing the declining birthrate". The document also included a note indicating its purpose as "technical advice" in accordance with a 1947 law on local autonomy indicating the lack of a legally binding force behind the communique [25]. Several

years later, in 2012, the Ministry of Health, Labour and Welfare (MHLW) encouraged all screening results be recorded in the mother and child health handbook, a book used by mothers to record various health-related information about their child, within four months of birth by adding information to the standard format of the book [26,27]. The MHLW's proactive stance on newborn hearing screening influenced a 2015 request from a group of related healthcare organizations, including the Japan Association of Obstetricians and Gynecologists and the Japanese Society of Otorhinolaryngology-Head and Neck Surgery, among sixteen others [28]. The signatory organizations requested funding from the federal government to implement newborn hearing screening for all infants. The MHLW issued an additional notice in March 2016 in response to this request, and also as a result of findings from a survey conducted in 2014, which revealed a very low rate of localities reimbursing for the cost of testing (109/1,741 or 6.26%) [29]. This additional notice reaffirmed that funding for newborn hearing screening was, in fact, provided as part of a significantly expanded national program to address the declining birthrate.

Subsequently, efforts have been made at the prefectural level to strengthen newborn hearing screening programs through collaboration between prefectural government agencies, hospitals and birthing clinics, and locality offices responsible for providing reimbursement funding to testing hospitals and clinics.

Results from various researchers and organizations, investigating the status of newborn hearing screening in Japan, provide evidence of a gradually evolving condition. In early research from 2004, Mishina [30] reported results from a 2002 survey in which he found the percentage of hearing impaired children attending special preschools, whose hearing impairment was identified via screening, to be 55%. The same statistic for children attending preschool at deaf schools was reported

as 33%. More recently, in 2018, the Japan Association of Obstetricians and Gynecologists (JAOG) reported on a survey conducted in 2017 based upon screening data for 2016 [31]. Their survey, administered to 2,369 medical birthing facilities, cited a screening rate of 87.6% for the year 2016. This calculation is based upon valid response data rather than upon the total births for that year. While not generalizable to the entirety of births for that year, the figure represents a significant advancement in terms of the number of newborns receiving hearing screening in Japan.

Amid this backdrop, the Japanese Ministry of Health, Labour and Welfare has published five annual reports on the status of newborn hearing screening in Japan. These reports were made publicly available, via the Ministry's website, for the years from 2014 to 2019 with no report provided for 2015. Analysis of the data provided in the five reports shows gradual advancement in terms of overall screening rates. Similar to the above mentioned JAOG survey, consideration of the data from the perspective of total annual births in the country, reveals screening rates somewhat lower than those cited, with a known-screening rate of 80.7% in 2019 versus the 90.8% rate cited as a result of the number of newborns accounted for in the report [32]. A graphic representation of the progress achieved over the course of the five annual reports is reproduced in figure 1 with permission from Hollowell and Takagi [32].

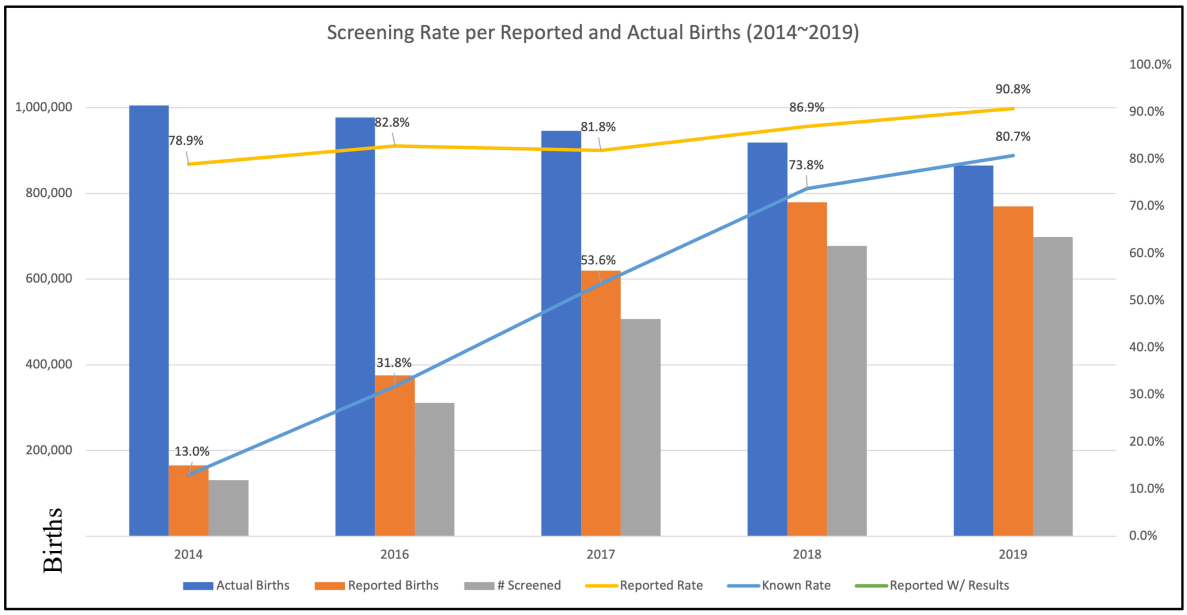

Figure 1 – Screening Rate per Reported and Actual Births (2014~2019)

The annual reports, produced by the MHLW, were compiled based upon questionnaires sent to all localities (cities, towns, and villages) in Japan. Localities were surveyed about their knowledge of screening test results. 1,133 of 1,741 localities reported knowledge of screening test results in the first report for 2014. The percentage of newborns screened over the course of the six-year term covered by the five reports has increased rapidly as the discrepancy between reported newborns and annual recorded newborns has decreased significantly. At the same time, however, the ability of these programs to respond efficiently, when a newborn hearing screening test results in a referral, remains underdeveloped. The reasons for this state of underdevelopment are manifold.

Funding, to offset the cost of newborn hearing screening, is one factor that is proposed to be crucial to ensuring all newborns receive screening. A study conducted in 2018, using a hypothetical cohort in Okayama, Japan, found a cost-effectiveness ratio, for funded newborn hearing screening programs, of 1 to 1.015 [6]. In the most recently available 2019 report from the MHLW, however, public funding for newborn hearing screening was provided by only 52.5% of the 1,741 localities in

the country [33]. A lack of such funding to offset the cost of screening is problematized by the JAOG in the afore mentioned survey report documentation [31].

In addition to funding schemes, which play a significant role in ensuring the success of early detection and intervention programs (EHDI), the fact that multiple parties are required to participate in the EHDI program introduces logistical hurdles. Figure 2 depicts the flow associated with newborn hearing screening as outlined by the Oto-Rhino-Laryngological Society of Japan [34].

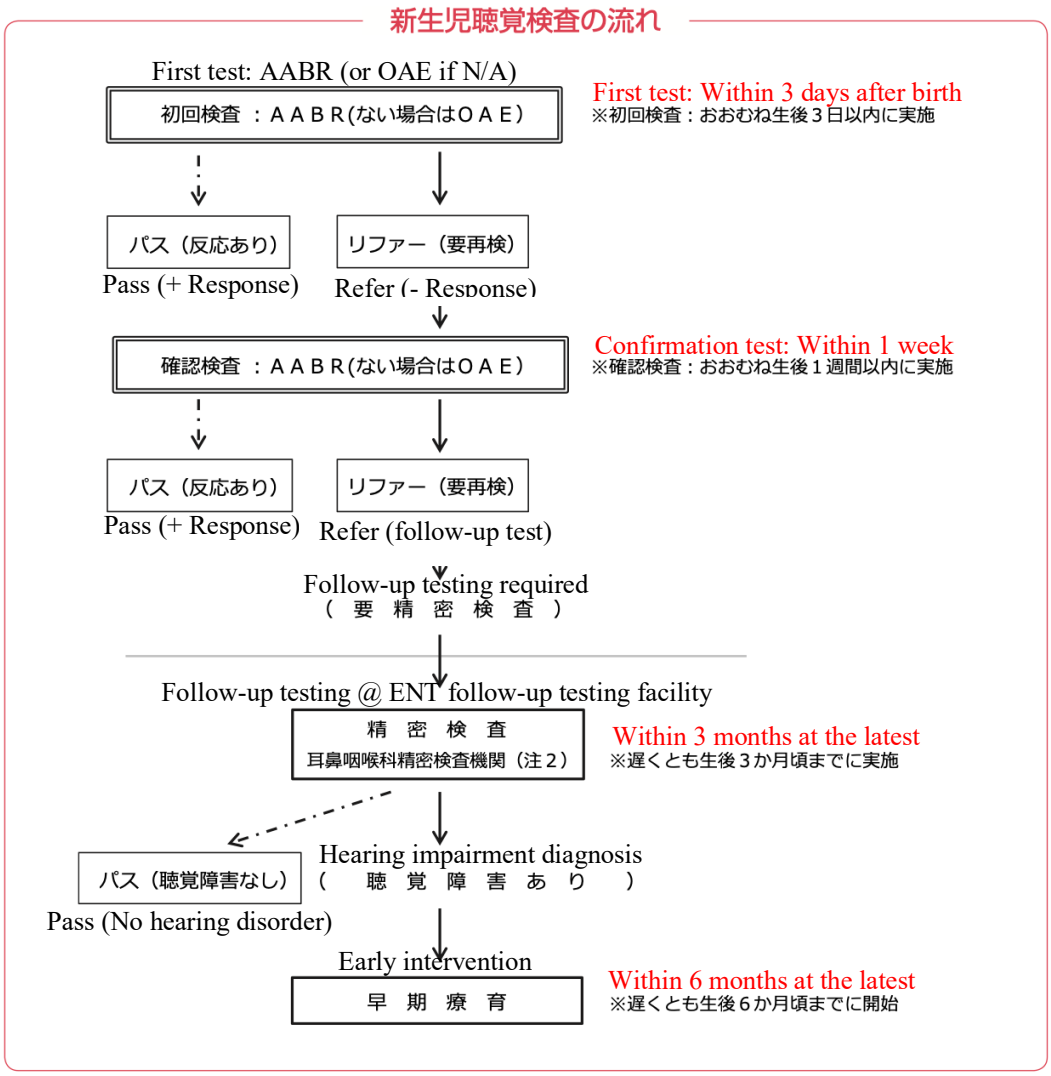

Figure 2 – Newborn hearing screening flow

The flow chart outlines the process via which newborns are to be screened minimally within one month and ideally within three days after birth, receive a confirmation test within one week after birth, receive follow-up testing for a referral

within three months, and begin intervention within six months of birth. The difficulty, however, in achieving these goals lies in the fact that multiple entities are involved in this 1-3-6 process. Each entity must receive necessary information in a timely manner in order to ensure that testing and intervention can occur within the specified timeline. These entities include, but are not limited to, the initial screening testing facility, the locality (city or town of residence of the child), the affiliated public health office, the follow-up testing facility, the prefectural child health and welfare division, and intervention service providers such as schools for the deaf, among others. The emergence of an efficient systematic EHDI program is thus hindered because information is often transmitted in analog formats and is relayed linearly rather than shared via a central source.

4) Necessity of an EHDI-IS

This situation suggests that the utilization of an Early Hearing Detection and Intervention – Information System (EHDI-IS) could greatly increase the efficiency of information flow and thus provide all entities involved with actionable data. It would additionally, allow prefectures to function as program monitoring and management entities via the ability to monitor EHDI program goals, such as the 1-3-6 goals, in real time thereby enabling more timely improvement efforts.

2. Goals of this research

The main goal of this research was to develop a digitized EHDI-IS for newborn hearing screening management and support. The proposed system is to be used at a level which encompasses all entities involved in an EHDI program. This means the system is most effective at a prefectural, or higher, level. In order to ensure that the system would effectively serve all entities involved, it was important to establish an understanding of the status of these prefectural EHDI programs and incorporate this understanding into the design of the EHDI-IS. The developed EHDI-IS will function to enable more accurate and efficient detection of hearing loss in newborns, as well as tracking and surveillance of those children with the goal of providing maximally effective intervention and support services. It will also enable the monitoring and maintenance of EHDI program standards of excellence.

3. Structure of this research

This research was divided into two studies:

1. Study I – Survey of the status of prefectural EHDI programs
    - Part 1 - Questionnaire administered to public health offices in the 47 prefectures of Japan
    - Part 2 – Semi-structured interviews
2. Study II - Development of an Early Hearing Detection and Intervention – Information System (EHDI-IS)

4. Ethical provisions

The studies undertaken for this thesis were conducted with the approval of the Ethics Committee of the International University of Health and Welfare (approval number – 21-Ig-187) as well as with the approval of the ethics committee of Shizuoka General Hospital (approval number – SGHIRB#2022005). An explanation of data handling procedures was given to prefectural officials replying to the questionnaire and a consent form was included in the online questionnaire. Participants in the semi-structured interviews were given informed consent explanation orally and consent was obtained orally as well as via e-mail communication. Data obtained via part one and two of study one was secured via password protection in addition to being anonymized to prevent prefectural or individual identification.

5. Terminology

AABR - Automatic Auditory Brainstem Response

ABR - Auditory Brainstem Response

CDC - Centers for Disease Control

EHDI – Early Hearing Detection and Intervention

EHDI-IS – Early Hearing Detection and Intervention - Information System

ERP - Enterprise Resource Planning

JAOG – Japan Association of Obstetricians and Gynecologists

MHLW - Ministry of Health, Labour and Welfare

MOODLE - Modular Object-Oriented Dynamic Learning Environment

NHS - Newborn Hearing Screening

OAE - Otoacoustic Emissions

PPV - Positive Predictive Value

UNHS - Universal Newborn Hearing Screening

II. Study 1 – Survey of the status of prefectural EHDI programs

1. Part I – Questionnaire administered to public health offices in the 47 prefectures of Japan

1) Introduction

In order to obtain new information about the status of newborn hearing screening from the prefectural perspective, a questionnaire partially modeled on the information provided in the annual reports published by the MHLW was created. The questionnaire included questions about the degree to which prefectures were aware of specific features of newborn hearing screening. Additional questions, not answered in the information reported by the MHLW, were also included. These questions focused either upon the timeliness of information exchange, the timeliness of follow up testing, diagnosis, and intervention, and upon the methods used for relaying, storing, and analyzing data. Other questions, at the end of the questionnaire, asked for participants to participate in semi-structured interviews to be conducted after the completion of the questionnaire. The entire questionnaire is included in appendix 1. An English translation is included in the appendix with the original which was administered in Japanese. In the second part of study I, a subset of the prefectures from part one were interviewed in order to gather additional detailed information, not easily obtained from a questionnaire, about each individual EHDI program.

2) Methods and Materials

i) Participants

To obtain information about the status of prefectural EHDI programs, a questionnaire was sent to child health and welfare offices in all 47 prefectures in Japan.

ii) Procedure

A questionnaire consisting of 16 scaled response questions was created. The first 11 questions used a 4-point scale designed to measure the degree to which each responding prefecture was aware of various aspects of the EHDI program operating within its borders. The goal was to determine not only the level of awareness of the number of children screened, referred, re-tested, and diagnosed, but to also determine the degree to which prefectures were aware of timeliness, accuracy, and intervention. The remaining 5 questions used slightly varying 5 option criteria designed to determine how EHDI related data was obtained, managed, and analyzed. The goal of these questions was to provide insight into data procurement and management efficiency and to determine how frequently prefectures were analyzing their EHDI program.

The questionnaire was prepared using the open source version of the web-based survey tool Limesurvey [35]. Request letters, including a URL, and a QR code with the link embedded, were sent to the child health and welfare office in each prefecture. In order to make questionnaire response as easy as possible, several days after sending letters via postal mail, an e-mail containing the same information was sent to each office. The online questionnaire was available for a period of 27 days.

iii) Analysis

Analysis of questionnaire response data was performed using three methods. The primary method was simple aggregation of response data. The number of responses to each option was aggregated and graphed using Microsoft Excel. The second method of analysis was a score comparison between two sets of responding prefectures. The median score was used for this comparison. The third method was the generation of a correlation matrix to identify relationships between questions. The correlation matrix was generated using "jamovi", an open source graphical user interface statistical analysis software built on the "R" statistical computing language and environment [36,37]. Prefectural GDP and annual births, for the year 2020, were included in this correlation matrix for additional relational consideration.

3) Results

Thirty-three of the total 47 prefectures responded to the survey resulting in a response rate of 70.21%. Aggregation charts for each of the thematic groupings in the questionnaire; screening information related, early intervention related, information procurement methods related, and data storage and reporting frequency related are presented below.

i) Response Aggregation

Screening Information Related Questions

Response to questions in this thematic group, displayed in figure 3, show that while most prefectures have an awareness level of 80% or higher for screening testing, referral, and follow-up testing numbers, questions 1(1) ~ 1(3), level of awareness drops for information related to timing of follow-up testing, question 1(4).

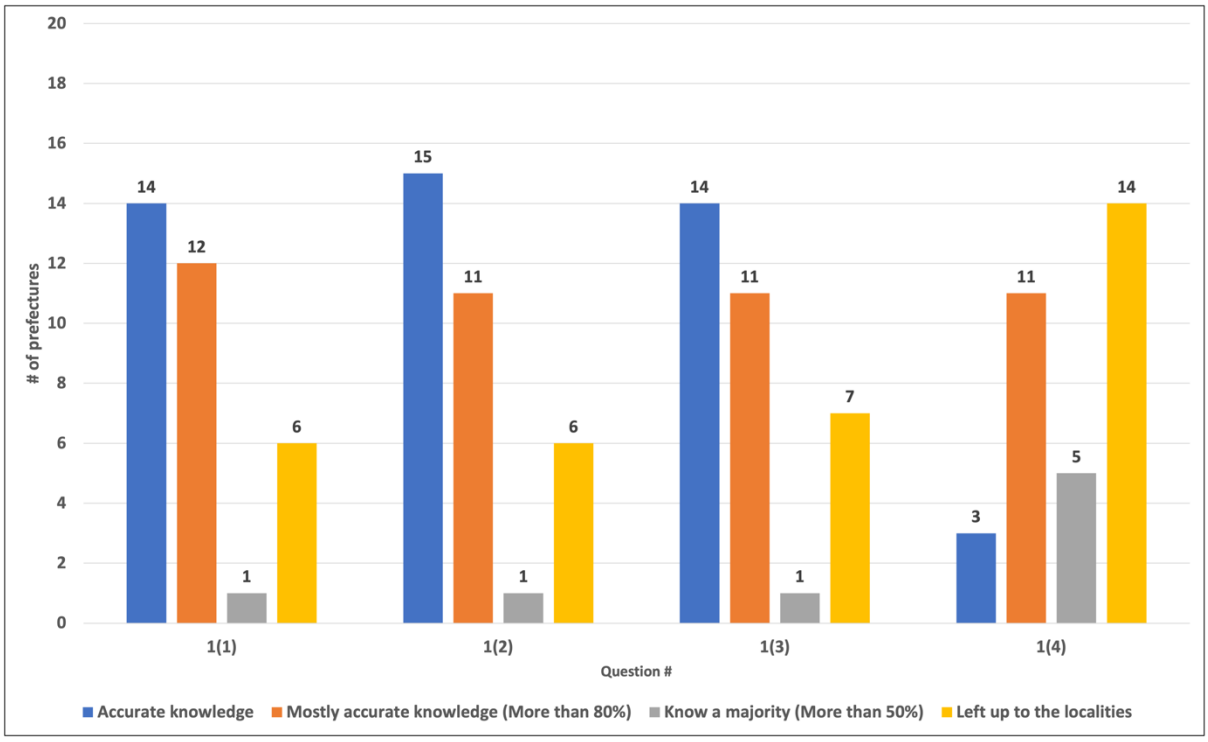

Figure 3: Screening Information Related Questions

Early Intervention Related Questions

Similar to the screening information related theme, as shown in figure 4, responses to questions in the early intervention related theme show that prefectures have the highest level of awareness for numbers of diagnoses, questions 2(2) ~ 2(4) but for questions related to timely information relay, question 2(1), or questions related to intervention after diagnosis, questions 2(5) ~ 2(7), level of awareness drops considerably.

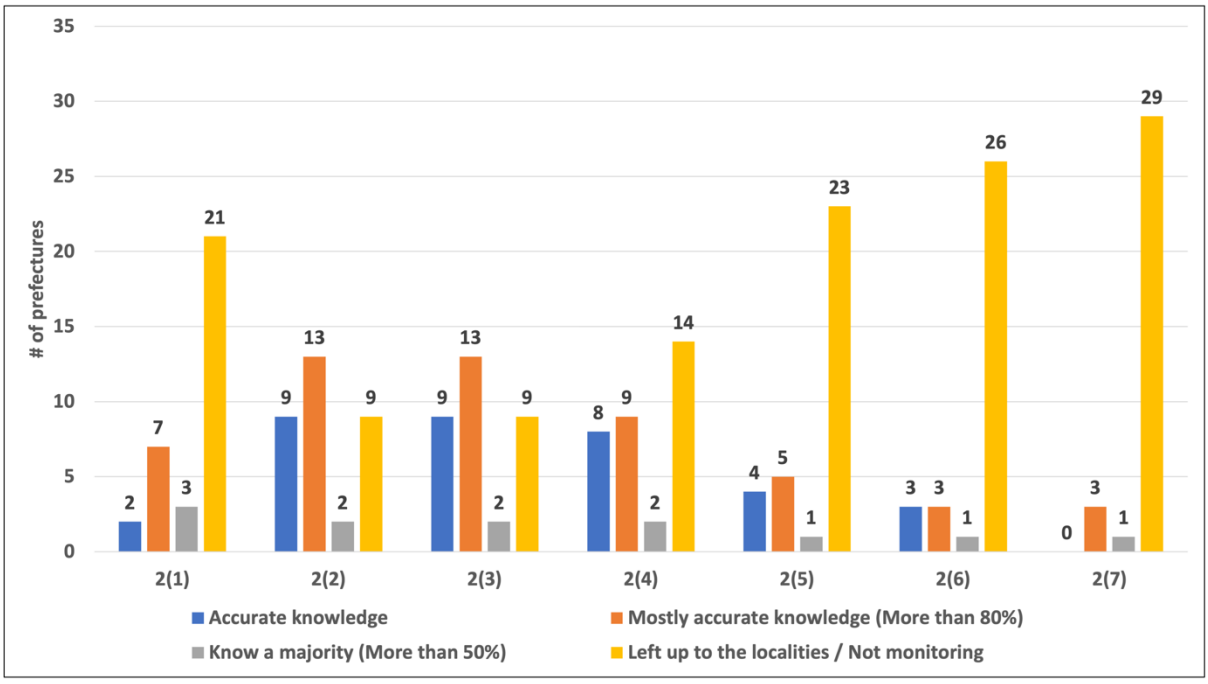

Figure 4: Early Intervention Related Questions

Information Procurement Method Related Questions

Responses to the information procurement method related questions, displayed in figure 5, show that, aside from one prefecture on question 3(2), none of the prefectures obtain information via a digital pathway. Note that none of the responses entered, when the "other" option was selected, could be interpreted as a digitized form of information procurement.

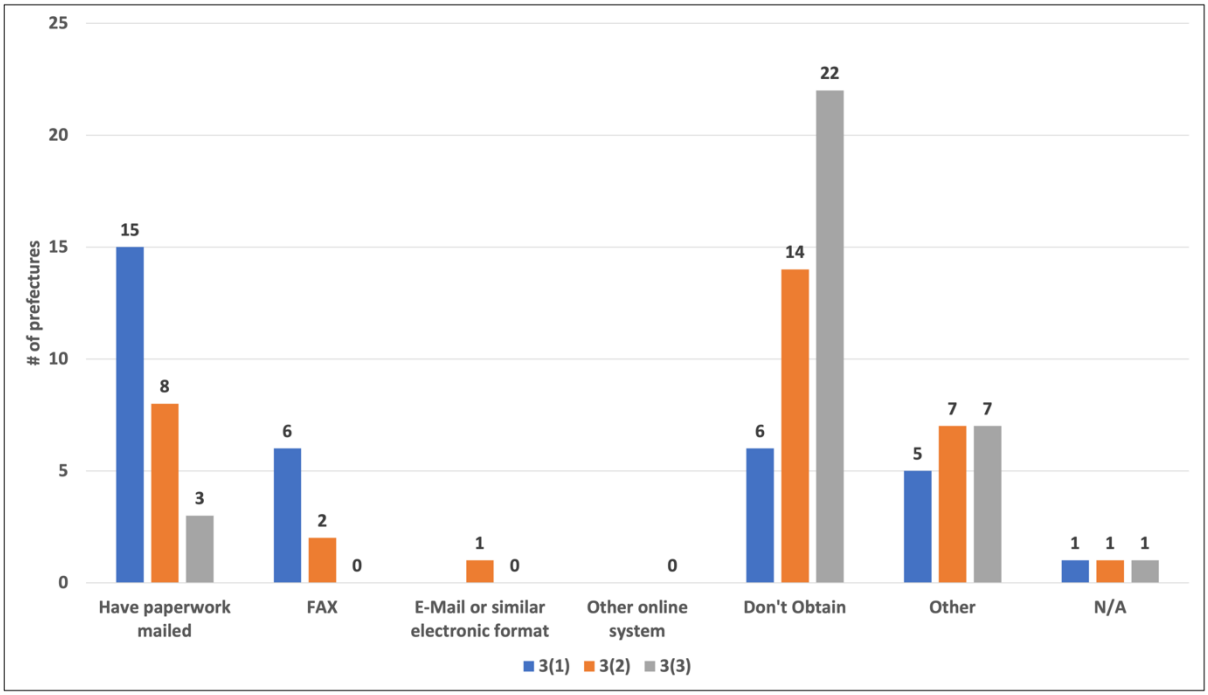

Figure 5: Information Procurement Questions

Data Storage and Reporting Frequency Related Questions

Responses to the question about data storage methods, question 4(1) displayed in figure 6, show that most prefectures store data in a digitized format. Note that no specifics were provided for the "other" response to this question.

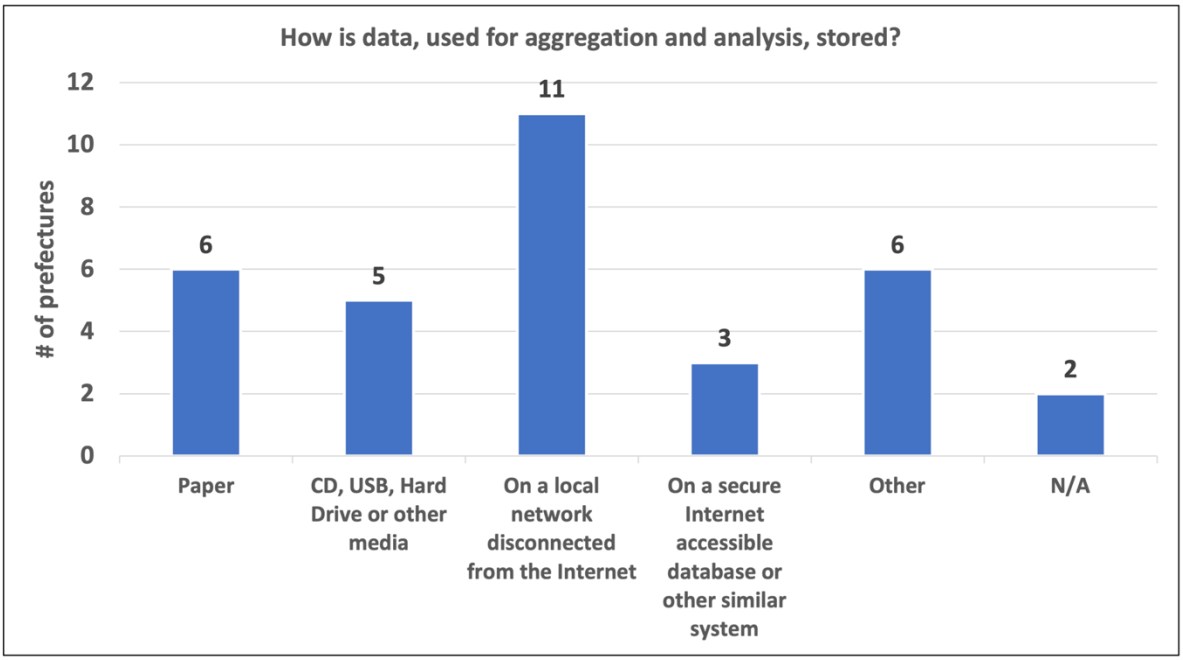

Figure 6: Data Storage Method Question 4(1)

Responses to the data aggregation frequency related question, displayed in figure 7, show that most prefectures aggregate and analyze data annually. Three prefectures responded that they aggregate and analyze data on a monthly basis.

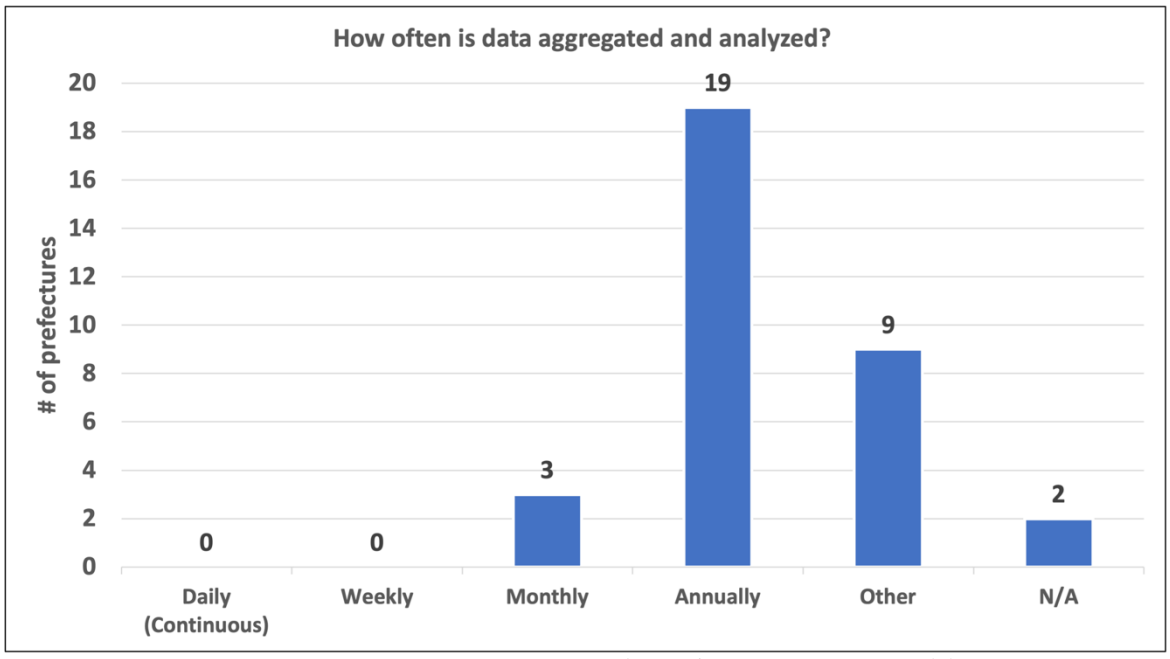

Figure 7: Data Aggregation and Analysis Frequency 4(2)

ii) Score Comparison

Scores were generated for each of the 4 point scaled questions 1(1) through 2(7). The median score for a group of three prefectures, which indicated data analysis frequency higher than annually, is compared with the remaining 30 prefectures, which indicated a frequency of annually or higher, is shown in table 1.

Table 1: Numeric Score Comparison on Frequency of Data Analysis

Median of numeric response comparison of prefectures who analyze data monthly with all other prefectures											
Group / Q	1(1)	1(2)	1(3)	1(4)	2(1)	2(2)	2(3)	2(4)	2(5)	2(6)	2(7)
3 Prefectures Analyzing Data Monthly	3	4	4	2	2	2	4	4	4	3	1
Remaining 30 Prefectures	3	3	3	2	1	3	3	2	1	1	1

iii) Correlation Between Questions

There are strong significant correlational relationships between items 1(1), 1(2), and 1(3). Strength decreases for relationships between these three and question 1(4). Of additional note is the moderate significant correlation between items 1(4) and 4(2) and 2(4) and 4(2). The correlation matrix, displaying statistical relationships between questions and the two additional factors, prefectural GDP and annual births, is shown in table 2 in landscape layout for easier viewability.

Table 2: Correlation Matrix
N = 33 for all items

Correlation Matrix

	Q1(1)	Q1(2)	Q1(3)	Q1(4)	Q2(1)	Q2(2)	Q2(3)	Q2(4)	Q2(5)	Q2(6)	Q2(7)	Q4(2)	Births	GDP
Q1(1)	—													
Q1(2)	0.96 ***	—												
Q1(3)	0.91 ***	0.95 ***	—											
Q1(4)	0.62 ***	0.64 ***	0.66 ***	—										
Q2(1)	0.34	0.34	0.28	0.15	—									
Q2(2)	0.58 ***	0.64 ***	0.67 ***	0.47 **	0.22	—								
Q2(3)	0.58 ***	0.64 ***	0.67 ***	0.47 **	0.22	1.00 ***	—							
Q2(4)	0.48 **	0.52 **	0.59 ***	0.54 **	0.08	0.80 ***	0.80 ***	—						
Q2(5)	0.14	0.09	0.14	0.39 *	0.14	0.36 *	0.36 *	0.43 *	—					
Q2(6)	0.06	0.02	0.06	0.39 *	−0.06	0.26	0.26	0.28	0.73 ***	—				
Q2(7)	0.13	0.10	0.13	0.32	0.13	0.09	0.09	0.06	0.56 ***	0.55 ***	—			
Q4(2)	0.25	0.30	0.26	0.51 **	0.21	0.28	0.28	0.45 **	0.33	0.11	0.02	—		
Births	−0.29	−0.32	−0.33	−0.36 *	−0.10	−0.14	−0.14	−0.08	−0.25	−0.25	−0.14	−0.26	—	
GDP	−0.30	−0.30	−0.32	−0.45 **	−0.14	−0.13	−0.13	−0.06	−0.35 *	−0.40 *	−0.22	−0.34	0.91 ***	—

Note. * p < .05, ** p < .01, *** p < .001

2. Part II – Semi-structured interviews

1) Methods and Materials

i) Participants

A question at the end of the questionnaire conducted in study 1, polled respondents about their willingness to take part in follow-up semi-structured interviews. 11 of the 33 prefectures that replied to the questionnaire volunteered to be interviewed and booked an interview via an online scheduling system.

ii) Procedure

When booking their interviews, volunteers specified a preference for the interview format with a choice between either an online session, using the Zoom online meeting system, or via telephone [38]. 6 respondents selected the Zoom option and 5 selected the telephone option. Interviews conducted via telephone were recorded using an inline recording device, manufactured by RadioShack, connected to a Zoom H6 audio recorder. Audio only was recorded for interviews conducted via Zoom using the screen capture software Camtasia 2020 from TechSmith [39]. An interview guide, based upon the themes from the online questionnaire, was created and the interviewer used this guide for each interview to govern the structure and flow of the interview. The interview guide, with English translation, is included as appendix 2, in the appendix section.

iii) Analysis

The qualitative data obtained from the semi-structured interviews was analyzed via a hybridized coding method using a deductive coding scheme followed by the identification of additional themes through a secondary inductive coding step. For this process, all interview data was transcribed into the ATLAS.ti qualitative data analysis software tool [40].

2) Results

Transcripts from the 11 interviews revealed a total of 667 dyads between the researcher and the interviewees. Interview conversations ranged in dyad length from 24 to 115 dyads with the average exchange length being 60.64 dyads.

A deductive coding template was generated based upon the thematic components of the interview. This template was expanded upon via an inductive coding process using the ATLAS.ti software tool. The final coding scheme, listed in hierarchical form is included in appendix 3. The scheme consists of 13 coding groups and a total of 49 codes. Many of the codes are organized within each group as scalar contrasts to elucidate a specific condition or characteristic. Other codes, such as "For MHLW" and "Proactive" were created via the inductive process. These specific codes were generated from multiple statements about reasons for aggregating and reporting on the state of newborn hearing screening. Codes were applied only to utterances made by the interviewees with a total of 393 code application instances being used when the coding process was completed.

All prefectures interviewed provided screening rates and these are listed in table 3, in order of annual prefectural births from low to high. The prefectures are divided into four annual birth groups ranging from less than 10,000 to more than 30,000 as indicated in the table. While questions about screening rates could have been included in the questionnaire administered in part I, they were intentionally left out. Semi-structured interviews were planned from the outset and asking for details about screening rates during the interview provided an opportunity for the creation of an atmosphere in which additional questions about NHS programs were contextualized and thus contributed to the promotion of cordial discourse. As such, early questions in the semi-structured interview, from which this data was obtained,

functioned as a pathway for subsequently obtaining rich details from each prefecture that could not have been obtained via a questionnaire.

Table 3: Prefectural Screening Rates

	Prefecture	Screening Rate
Less than 10,000 annual births	Pref-H	99.40%
	Pref-G	96.42%
	Pref-A	98.00%
	Pref-E	91.70%
10,000 to less than 20,000 annual births	Pref-B	97.60%
	Pref-D	98.10%
	Pref-C	98.30%
	Pref-I	99.00%
20,000 to less than 30,000 annual births	Pref-K	96.40%
More than 30,000 annual births	Pref-J	83.00%
	Pref-F	Upper 80s

Of the 11 prefectures that were interviewed, the two largest prefectures, from the perspective of annual births, are also the two with the lowest reported screening rates of 83.00% and upper 80s. During the interviews, these two prefectures, prefectures J and K, provided statements about the difficulty of gathering data from the various birthing clinics within their prefecture. When data was obtained, delays in procurement made the monitoring of time sensitive target goals extremely difficult. Both of these prefectures described EHDI programs that have made significant progress in recent years but that still struggle to procure data and manage the program within their prefecture.

On the other end of the spectrum, three of the prefectures that participated in the semi-structured interviews indicated that they analyze newborn hearing screening related data more frequently than annually. These were prefectures H, G, and I. Two

of these three, prefectures H and I, have the two highest stated screening rates, 99.40% and 99.00%.

3. Discussion

Much information was obtained from parts I and II of study one. The primary goal of study one was to obtain information that would inform the EHDI-IS system being developed in study two. As such, discussion of results obtained from study one is limited to factors which directly inform study two.

Results from part one indicate that 75% or more of the responding prefectures have 80% or higher awareness of the basic statistics for newborns screened, number of referrals, and follow-up tests, questions 1(1), 1(2), and 1(3). This percentage falls to 42.42%, however, for knowledge about the amount of time required for obtaining a follow-up test, question 1(4). This shift in level of awareness was also observed in questions focused on early intervention with the highest levels of awareness observed for numbers of concrete diagnoses, questions 2(2) and 2(3). Much lower levels of awareness are observed for items such as knowledge about whether the public health nurse receives NHS results prior to the one-month visit, question 2(1), details about monitor and follow-up, question 2(4), and questions about intervention services provided, questions 2(5) through 2(7). Responses to the questions about information procurement, questions 3(1) through 3(3), show that when information is obtained, virtually all prefectures receive the information in analog format with only one prefecture indicating that information was received via e-mail and only in one case, question 3(2). Although almost all prefectures receive data in analog format, many indicated that information was stored digitally, suggesting that information was converted from analog to digital format for analysis and storage. Finally, only three prefectures responded that they were analyzing data on a monthly basis with the majority, 19 prefectures, responding that they analyze data

annually. Comparison, using median scores, of these three prefectures, with the remaining thirty, on questions using the 4-point scale suggests that the more frequently aggregating prefectures have a somewhat higher level of awareness for most of the items with a lower median score for only question 2(2).

Further considering this subset of 3 prefectures, that analyze data monthly, the correlation matrix analysis reveals a significant correlation of modest value between questions 1(4) and 4(2) as well as between questions 2(4) and 4(2). This shows that prefectures that reported to analyze data monthly, also reported having a higher level of awareness for questions 1(4) and 2(4), questions about timing and ongoing monitoring respectively. This may support the hypothesis generated from the median score comparison. Additionally, the inclusion of GDP and annual birth numbers in the correlation matrix shows that both are correlated, to varying degrees, with level of awareness, especially for items related to timing or post-diagnosis details. As annual births increase, the level of awareness appears to decrease.

Analysis of interview data obtained from the semi-structured interview process focused upon this aspect of information handing and analysis in order to inform the ongoing development of the EHDI-IS. Information gleaned from the interviews with the three prefectures that aggregate and analyze data monthly, strongly suggests that these prefectures demonstrated the highest levels of operating EHDI programs among those interviewed. Each provided detail about organized programs with broad support from the various entities within the prefecture. Additionally, they all described programs that had at least one full-time coordinator tasked with monitoring the status of referrals and all subsequent data related to follow-up and diagnosis. Each of these three prefectures noted that, due to their low annual birth numbers, with some coordination and effort, it was possible to monitor some EHDI program targets such as screening rate and hearing loss occurrence frequency. They

commented, however, that monitoring of time related information was hindered due to the fact that information was relayed in analog format on case-by-case bases.

None of the 11 prefectures interviewed were currently using an EHDI-IS and many prefectures expressed concerns about the timeliness and quality of information exchanged within their program. Analog pathways for information relay and dissemination, even in the case of highly developed and efficient programs, were described as factors which limited the EHDI program and made overall program evaluation and identification of areas for additional improvement difficult and time consuming. These findings provided support for and informed the ongoing development of the EHDI-IS.

III. Study 2 – Development of an Early Hearing Detection and Intervention – Information System (EHDI-IS)

1. Development

1) Introduction

Results from parts I and II of study one indicate that as prefectures strive to better monitor and manage their EHDI programs, the process of information procurement, management, sharing, and analysis is difficult and inefficient. This was observed to be true for prefectures across the spectrum. To help empower newborn hearing screening programs to function as evolving EHDI programs, via an action research approach, a digitized system for recording and managing newborn hearing screening data was developed, piloted, trialed, and evaluated. This system was designed to serve the role of an EHDI-IS as defined by the CDC [10]. This definition consists of 8 goals, each including a set of "SHALL", "SHOULD", and "MAY" statements. The 8 goal statements are:

1. Document unduplicated individually identifiable data on the delivery of newborn hearing screening services for all infants born in the jurisdiction.
2. Support tracking and documentation of the delivery of follow-up services for every infant/child who did not receive, complete, or pass newborn hearing screening.
3. Document ALL cases of permanent hearing loss, including congenital, late-onset, progressive, and acquired cases for infants/children <3 years old.
4. Document the enrollment status, delivery, and outcome of EI services for infants and children with hearing loss <3 years old.
5. Maintain data quality (accurate, complete, timely data) of individual newborn hearing screening, follow-up screening and diagnosis, early intervention, and demographic information in the EHDI-IS.
6. Preserve the integrity, security, availability, and privacy of all personally-identifiable health and demographic data in the EHDI-IS.

7. Enable evaluation and data analysis activities.
8. Support dissemination of EHDI information to authorized stakeholders.

2) Methods and Materials

At the outset, the goal was to design a system that would significantly accelerate the storage and flow of information for the purpose of expedient communication and action. This would, for example, enable quick communication to multiple parties when a newborn hearing screening test resulted in a referral. It would also enable real time tracking of screening percentages, referral rates, and hearing impairment occurrence frequency, among others. Early-stage planning and development took place in advance of part 1 and 2 of study 1 with mid-stage system refinement directly informed by results obtained from both parts of study 1.

Early-stage planning involved numerous information gathering sessions with cooperation from the Shizuoka Prefectural Office for Child Services and Welfare, the Shizuoka City Office for Child Services and Welfare, the Infant Hearing Support Center housed in the Shizuoka General Hospital, and various private birthing clinics in the city of Shizuoka. The primary concern, voiced by multiple parties from the information gathering sessions, centered on the handling of information that could be used to identify a specific individual as outlined in Goal number 6. Bearing in mind both the individual conceptualizations of what constitutes personal information as well as the legal definition of personal information in Japan, a system utilizing an identification number, termed the "Hearing ID", was developed and agreed upon. Use of the Hearing ID would retain the ability to adhere to Goal 1 with some intentionally built-in limitations, explained in detail in the procedure section below.

In addition to clearly defining the principles of the EHDI-IS system, it was necessary to determine what technology would be utilized for delivering the system.

An extensive search of existing technologies was undertaken with initial short-term experimental trials of approximately five systems conducted. Guidelines established for system selection were:

1. The system must be economically scalable, meaning increasing the number of users of the system should not result in increased costs as doing so may threaten ongoing use of the system.
2. The system must be capable of granting access to different users with different levels of access permission. For example, a birthing clinic shall be able to view only records added by the clinic itself.
3. The system must be fortified and accessible to only users who possess legitimate login and access credentials.
4. The system must provide for easy external back up of data.
5. The system must be intuitive and easy for new users to learn to use.
6. The system must include a feature for reading QR codes.
7. The system must be customizable and designed for easy expansion of new feature sets as they become required or desired.
8. The system should in principle be designed such that its use provides some degree of convenience to those entering screening result data so as to not add undue additional workload and, when possible, should provide features that serve to minimize workload through increased efficiency.

The system decided upon was the enterprise resource planning (ERP) system ERPNext [41]. Enterprise resource planning systems are designed to manage the various activities involved in the business process. As such, they are, by design, positioned to administer a system which requires interaction from various entities within that system, all having different roles and levels of access associated with each role. As it is an open-source software package, economical scalability with ERPNext is easily achieved. Additionally, the extremely rich feature set, including a Healthcare Domain package, positioned the software to offer more than sufficient levels of expandability. In fact, the initial implementation of the EHDI-IS was deemed to use only a small fraction of the features included in the ERPNext system.

However, as unneeded features could be deactivated and thus did not pose risk in terms of either vulnerability or usability, it was deemed the ideal choice. A test instanced was installed by the researcher and demonstrated to various individuals participating in the information gathering sessions for feedback and general reaction. Specific requirements were documented in a Software Requirement Specification (SRS) and funding for system customization was secured from the Shizuoka Prefecture Office of Child Services and Welfare. A one-year support contract was entered into with Frappe, the business entity behind ERPNext, from March 31, 2022, for the purpose of customization and support. A copy of the SRS shared between the researcher and Frappe is included in appendix 4.

2. Trialing and evaluation

System Pilot

A pilot test of the system was conducted between July 13 and August 31, 2022. During this time, two birthing facilities entered test data, not affiliated with actual newborns, into the EHDI-IS for the purpose of identifying potential issues in the workflow required to log newborn hearing screening test results in the system. During this time, approximately 60 records were entered into the EHDI-IS without issue. During this period, information gathered from the semi-structured interviews was used for improvement modification and tuning of the system. For example, a notification feature was added in order that various offices in the prefecture would be notified immediately when a referral result was recorded in the system.

System Trial

Entry of actual newborn hearing screening test results, associated with newborns, began from September 1, 2022. Six birthing clinics in Shizuoka Prefecture began participating from the beginning of the trial phase and a manual accompanied by the following materials was distributed to each clinic. A copy of the manual is included in appendix 5.

1. Sets of QR code stickers, with unique Hearing IDs embedded, adequate for 6 months of births for each clinic calculated from the annual number of births per clinic.
2. Unique login username and password credentials for each clinic.
3. Instructions for logging into the EHDI-IS and recording newborn hearing screening results in the system.
4. Copies of the release form to be signed by a parent or guardian of the child acknowledging screening test approval and data retention.

The production of system usage manuals for other entities including follow-up testing hospitals, prefectural and regional public health offices, and intervention service providers is currently underway.

1) Procedure

EHDI-IS

The process of recording newborn hearing screening test results for birthing clinics is outlined below including methodological explanations and illustrations.

Step 1

A newborn hearing screening test is conducted on a newborn two to three days after birth. The results of the test are recorded in the EHDI-IS by a technician or administrator at the birthing clinic by first removing one of two paired QR codes and placing it in the mother and child health handbook. The remaining paired QR code is placed on the screening test fee reimbursement form which is sent to the locality where the baby resides. In the event of a return home birth, no reimbursement form exists and the second QR code sticker is placed on paperwork retained by the clinic in their medical records system. For clinics and hospitals who retain all records on in-house electronic systems, the QR code sticker is placed on the retained copy of the consent form and later scanned into the hospital record system. Photos depicting the QR code stickers in the mother and child health handbook and on the screening test fee reimbursement form are included in figures 8 and 9.

（様式１）

新生児聴覚スクリーニング検査受診票

下記の児の新生児聴覚スクリーニング検査を依頼します。

委託医療機関　様

○○市町長

（助成上限額）

自動ABR	円	ＯＡＥ	円

保護者の方へ

●この受診票は、出産後、最初の新生児聴覚スクリーニング検査時にお使いください。
●検査は出産後入院中に受けてください。里帰り出産等で入院中に受けられない場合は出産後１ヶ月までに受けてください。ただし、医師の指示がある場合を除きます。
●生後○ヶ月を超えると、助成は受けられませんので注意してください。
●この受診票は、市(町)内在住の方が委託医療機関で利用できます。ただし、市(町)外へ転居した場合は使用できませんので、転居先の市(町)にお問合せください。
●この受診票は、もの聴覚検査を実施した場合に、検査方法に応じて一定金額を上限として助成するものです。実際の検査費用が助成上限額を超えた場合は、自己負担額が発生しますので、ご了承ください。
●この受診票は委託医療機関から○○市(町)に提出されます。
●この受診票は、原則再発行はできません。
●新生児聴覚スクリーニング検査の内容は、静岡県乳幼児聴覚支援センターのホームページでご確認ください。URL　https://shizuoka-kikoesupport.jp/

交付番号	
交付日	
新生児氏名（生年月日）	（　・　・　）
保護者氏名	
住所	

（医療機関記載用）

新生児聴覚スクリーニング検査を実施したので報告します。

年　月　日

○○市町長　あて

所在地
委託機関名
医師名　　印

受診年月日	年　月　日（生後　か月　日）
出産施設	□ 自院出産　□ 他院出産
検査方法	実施した検査にチェックしてください □ 自動 ABR（自動聴性脳幹反応検査） □ OAE（耳音響放射検査）
検査結果	22639999
紹介先医療機関	検査結果が要再検だった場合、紹介先医療機関をチェックしてください □ 沼津市立病院　耳鼻咽喉科 □ 静岡県立総合病院　耳鼻咽喉科 □ 聖隷浜松病院　耳鼻咽喉科 □ 浜松医科大学　耳鼻咽喉科 □ その他（　）

※ 受診票のサイズは、基本的に妊婦健診票及び乳児健診票に準じる。
※ 受診票の色は、「黄緑色」を基本とし、妊婦健診票及び乳児健診票と混同しないよう配慮する。

Figure 8
NHS Test 'ticket' and reimbursement form.

（受診者用）

先天性代謝異常症等スクリーニング結果票

様 baby

本票は、母子健康手帳に添付して保存して下さい。

生年月日	採血年月日	初回・再検	報告年月日	検査番号
		初回		

フェニルケトン尿症	ホモシスチン尿症	メープルシロップ尿症	ガラクトース
正常	正常	正常	正常

クレチン症	先天性副腎過形成
正常	正常

検査機関　（財）静岡県予防医学協会

22639999

Figure 9
Mother and child health handbook

Step 2

After affixing the paired QR code stickers to the mother and child health handbook and the test fee reimbursement form, or alternative document, thereby allocating the newborn a Hearing ID, data is entered into the EHDI-IS by first scanning either of the paired QR codes into the Hearing ID field in the system. The field associated with the Hearing ID is preformatted to access the camera of the device being used to enter the data. A specialized QR code reader is only required if the facility entering data is not in possession of a device with a camera. In practice, using either a smart phone or tablet device, with a built-in camera, streamlines the data entry process. In addition to entering the Hearing ID, the data listed below is entered and thus associated with the unique Hearing ID.

Data entered into the system:

1. Hearing ID – Entered via QR code scan
2. Screening Yes/No – Default set to Yes
3. Sex – Drop down menu (Male / Female)
4. Date of Birth – Date selected via the use of a pop-up calendar
5. Locality of residence – Drop down list of all localities in Shizuoka
6. Date of hearing test – Default set to date of entry, editable via pop up calendar
7. Facility name – Auto populated based upon logged in user
8. Screening test method – Auto populated with AABR, OAE also selectable
9. Screening result – Auto populated with "Pass", "Refer" selectable
10. Number of test administrations – Pull down option 1 ~ 10

Conditional fields – These fields appear only when "Refer" is selected

11. Screening result right ear – Drop down menu - "Pass", "Refer"
12. Screening result left ear - Drop down menu - "Pass", "Refer"
13. Referral hospital – Name of designated follow-up testing hospital. Drop down menu of the four designated hospitals plus an "other" option. The "other" option triggers the appearance of an additional field for details about the referred facility.

14. Phone – Phone number of parent for follow-up contact, with parent's approval
15. Mother and child health handbook number – manual entry
16. E-mail – Manual entry with approval from parent

A screen capture of this data entry screen, with "Refer" selected, is included in figure 10. The small square shaped object in the far right of the Hearing ID field is the QR code reader activation button. Clicking on the square activates the reader and initiates use of an attached camera for smart phones, tablets, and computers that have a camera embedded or attached.

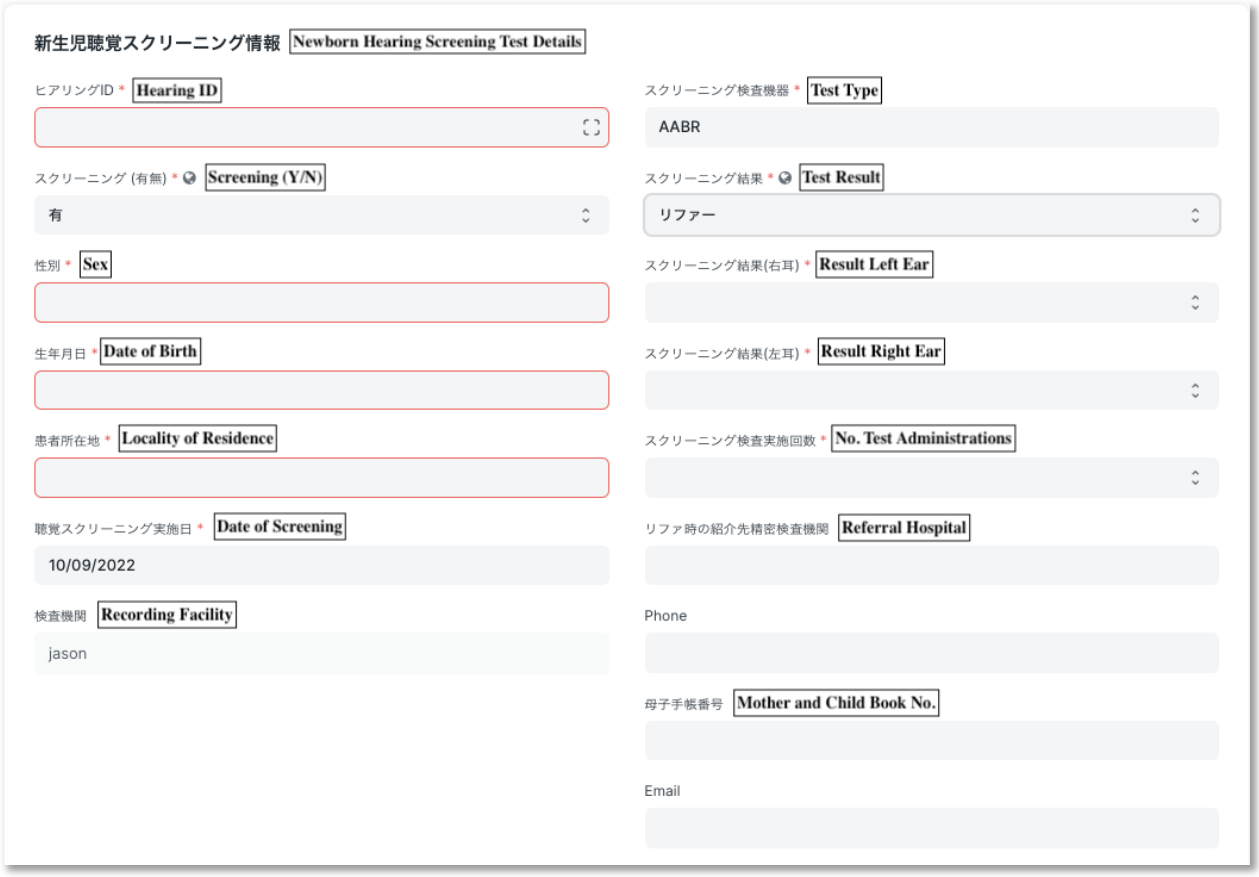

Figure 10: Screening Result Data Entry Screen

Explanation

The locality of residence field is used for multiple purposes including invoicing and notifications. At the end of each month, each clinic is required to package all test fee reimbursement slips for each individual locality and send them to the locality along with an invoice in order to be reimbursed, at a set rate, by the locality for the

tests administered. AABR tests are reimbursed at a rate of 4,700 yen per test and OAE tests at a rate of 2,100 yen per test. The reimbursement rates are standardized prefecture wide in Shizuoka. On the first of each month, the EHDI-IS automatically generates invoices per clinic for all localities associated with newborn hearing test records in the system. Clinics need to simply confirm the test count on the invoice and print the invoice to include it with the test fee reimbursement forms to be sent to each locality.

The locality field is also utilized when a newborn hearing test results in a referral. When a referral is recorded in the system, a preformatted e-mail message is automatically sent to the public health nurse office associated with that locality. The e-mail notifies the public health nurse office that a referral has occurred in their district and includes the Hearing ID associated with the referral. A representative from the public health nurse office, who has received login access to the system, is directed to log in to the EHDI-IS and search for the referral Hearing ID. The public health nurse office account is granted a role and access permissions in the system that allow the office to view only records associated with children who reside within their locality. After finding the appropriate Hearing ID, the representative can find the mother and child health handbook number associated with the record in the system. This number subsequently enables the public health nurse office official to access information about the child and family. The official is able to access associated personal information due to the fact that details connected to mother and child health handbook numbers are stored on a local system accessible to officials in the public health nurse office. The public health nurse office may also utilize the phone number, if one was entered in the system, for the purpose of confirming records and for subsequent communication. The timeliness of this communication enables the public health nurse office to begin preparation for and prioritize the one-month post-

birth visit even before the mother and child have been discharged from the clinic or hospital.

The referral hospital field, which appears only in the case of an NHS test referral result, is used in a similar fashion, as the EHDI-IS also generates an automated e-mail that is sent to a designated official at the referred hospital. While the hospital has no access to personal identification information at this stage, it can alert administrative staff to provide priority registration for follow-up testing for newborn hearing screening referrals. Additionally, in the event of a delay in the child appearing for a follow-up test, the hospital may contact the public health nurse office for assistance in encouraging the family to receive follow-up testing.

The ERPNext system, underlying the EHDI-IS, is designed such that notifications of this nature can be sent to various parties. Settings regarding what action in the system should trigger a notification, where the notification should be sent, and the details of the notification can be added when required thus positioning the EHDI-IS to be able to flexibly conform to needs as they arise.

An additional feature of the EHDI-IS system is a dashboard used to display a set of basic statistical data to the various end users. The dashboard displays the number of births, the number of hearing screening tests, and the number of referrals over time in graphic form with the ability to toggle the time frame from daily, weekly, monthly, or other customizable time frame. These simple data enable the real time display of statistics such as the referral rate. Additionally, the values displayed on the dashboard vary depending on the role of the logged in user. As such, a birthing clinic may view the dashboard from the perspective of their clinic to monitor screening and referral rates. Referral rates from the expanded context of the entire system can also be displayed thereby informing individual clinics of the macro level statistics for reference and comparison. A screenshot of the dashboard as of early

November of 2022 is included in figure 11. English translation for the chart types is included in red.

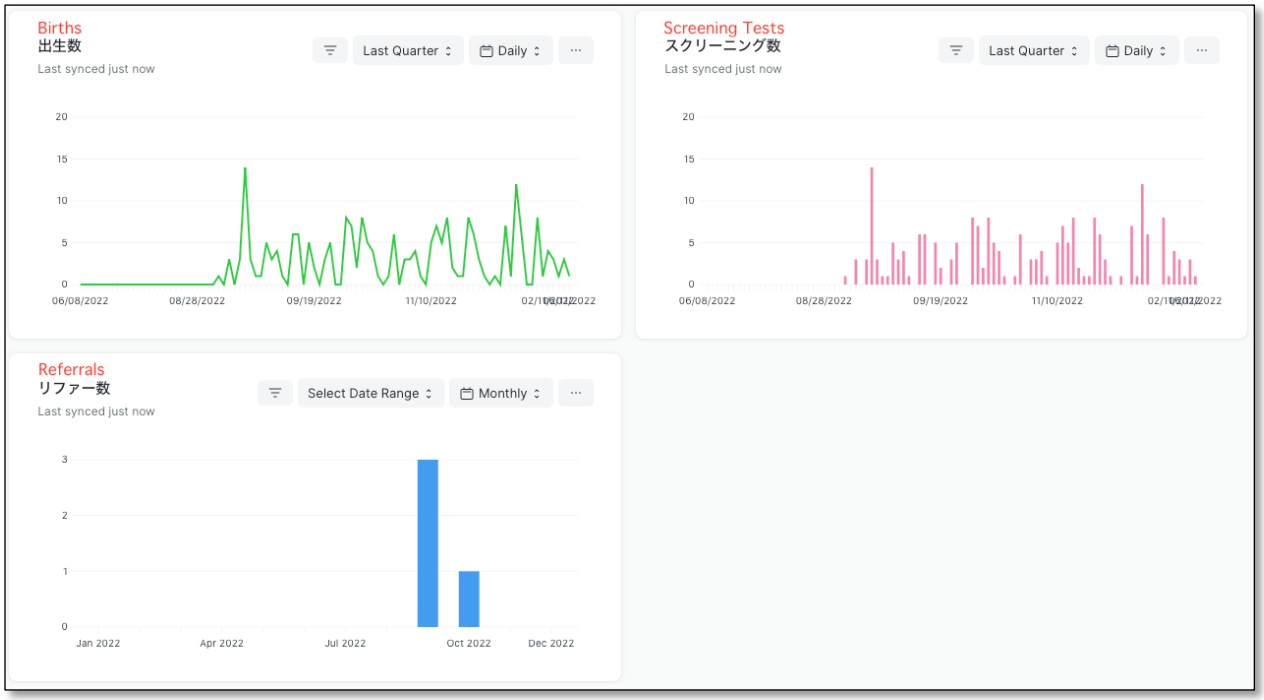

Figure 11: Screening Status Dashboard

A feature request from the Shizuoka Prefecture Office of Child Services and Welfare was to provide an avenue for informing the parents of children, who received a referral on the newborn hearing screening test, about the importance of follow-up testing. Although each birthing clinic distributes leaflets to the families of children who receive a referral, given the timing, when the mother and child are still in the clinic or hospital, and the overall emotional nature of the childbirth experience, concern existed about the level of uptake of the information contained in the leaflets. The phone number field in the EHDI-IS, which has information recorded only in the case of a referral, is used to send a text message to the telephone of the owner who is presumably the mother or father of the newborn. This text message contains a basic reminder about the importance of obtaining a follow-up test and a link to a support web site maintained by the Infant Hearing Support Center in the Shizuoka General Hospital. The site provides various information about congenital hearing impairment, follow-up testing, intervention services, as well as contact

information for parents who would like to consult with a speech therapist or other Center staff member.

Support System

The second phase of research project two was to redesign the existing static support site by converting it to a dynamic site capable of providing login access to various parties involved in the hearing impairment detection and intervention process. The site was converted to use the Moodle content and learning management system and was designed to provide custom individualized services to the families of children with hearing impairment [42].

As the flow of information was observed, throughout the studies conducted for this paper, to be often incapable of providing parties involved in the EHDI with timely and detailed actionable data, similar to the EHDI-IS, the goal for the support system was to enable it to expediently provide maximally useful information to each party accessing the site. The first basic example of how the updated site would be better positioned to provide timely information is to examine the method that was used for posting information about periodic intervention service-related events, for example, hosted by the Infant Hearing Support Center. With the previous static site, information would need to be first compiled, then relayed to the company that managed the site often via a face-to-face meeting, and subsequently added to the site by the company in charge. The nature of this communication chain meant that implementing changes to the site in terms of the information it provided, could take several weeks to a month for each update. The new site enables multiple users to be granted login accounts, each which can be associated with a role and permission set. The front page of the site includes an announcements forum feature to which staff in the Infant Hearing Support Center may post information, including links, attachments, media, etc. which are then instantaneously added to the site. While a

simple addition, this feature represents one step toward empowering the EHDI to be more proactive.

A detailed description of the Moodle feature set is beyond the scope of this paper; however, two customizations conducted specifically for this research are introduced below. The first is an automated account creation scheme which positions the EHDI-IS system to generate login accounts for accessing the Moodle system when a record for a child who receives a referral on the NHS test is recorded in the EHDI-IS. The second was the development of a psychometric test plugin for the Moodle platform. This plugin enables the use of developmental assessment measures within Moodle and thus empowers the families of children with hearing impairment by providing them access to objective measures designed to help them support their child as he or she develops.

The process for account creation via the EHDI-IS system was set up to be a two-step process. The first step utilizes a basic SQL command which writes specific information to a custom table within the database each time a row, with specific characteristics, is added to a designated table in the same database. Specifically, when a row is added to the designated table in the EHDI-IS which contains the "Refer" label for the NHS test result, a conditional ON UPDATE SQL trigger command duplicates a subset of the information added at that time to a different table in the database. The subset includes, the Hearing ID and the date of birth in month, day, year (mm,dd,yyyy) format. The second step in creating login accounts on the support site is to setup the external database authentication plugin feature of Moodle to use the table created in step one above for authenticating logins to the site. The external database plugin checks the table, which is continuously maintained via the ON UPDATE SQL trigger, and uses the Hearing ID as a login username and the date of birth as the first time login password. Users logging in to the site for the

first time are led through the process of associating a name, which can be a pseudonym, e-mail address, and other information with the account being authenticated. At the same time, users accessing the support site are prompted to acknowledge the information handling policy utilized by the site via a consent form. Once the user has authenticated, and thus created their account on the site, they can access various support information, customized communication channels, and intervention tools provided via the site.

The second of the two Moodle customizations was the development of a psychometric test plugin. The plugin was developed such that it may deliver any psychometric test that is administered by presenting a list of binary option questions or descriptors. In its developed form, the plugin presents text based binary option descriptors, however it can easily be modified to present other content such as images. When initially setting up the psychometric test plugin, the following settings must be assigned to control the characteristics of the assessment.

1. Stop after N "rarely" responses
2. Start subsequent test N items prior to first "rarely" from previous stop

These two settings are customized to the assessment tool that the plugin was specifically designed to deliver, the Japanese version of the Functional Listening Index – Pediatric (FLI-P) [43]. The FLI-P is a functional listening assessment tool that contains 64 descriptors which are each evaluated as either "Rarely" or "Mostly" depending on how often a child is observed to be able to do the functional listening task outlined in each descriptor. The assessment is designed to be administered to children ages 0 to 6 years with the goal of assessing the developmental status and trajectory of a child's functional listening ability. Localization of the English version of the FLI-P for use in the Japanese context began as a component of this research. The Japanese version is currently in the final steps of reverse translation

confirmation and will, upon completion, be certified by The Shepherd Centre in Australia as the official Japanese version of the FLI-P. An initial investigation using the draft version of the FLI-P(J) conducted via a cooperative research effort led by a researcher at NTT, obtained data via a questionnaire from 2,976 respondents. This data was obtained via the use of an online survey company and may serve to establish an initial rough baseline for normalizing the FLI-P(J) on normal hearing children in Japan. Future research will document the baseline evaluation of the FLI-P(J) after which broad use via the plugin developed for this study will be possible. A copy of the pre-final version of the FLI-P(J) is included in appendix 6.

The purpose of the Moodle plugin development was to enable the test to be administered by the parents of children with hearing impairment. After the parent has created an account on the site and setup their child within the psychometric test plugin, the parent can select a speech therapist from the list of therapists that appear in the system, allowing the therapist to administer the test as well as see results of administrations conducted by the parents. The developmental trajectory of each child is graphed within the plugin with separate lines for speech therapist evaluation and parental evaluation. Screen shots of the score graphing and test administration record are included figure 12 and figure 13.

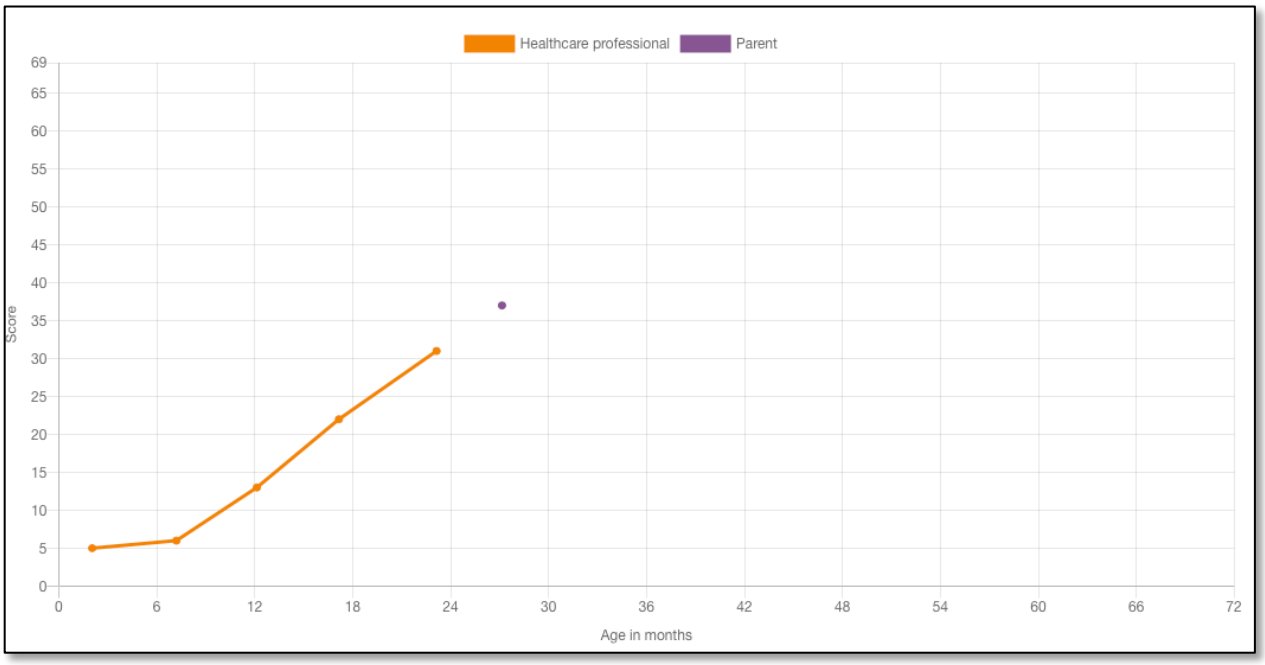

Figure 12: Graph of FLI-P Administrations - Speech Therapist = 5, Parental = 1

The orange line in the above graph depicts the developmental trajectory measured by a healthcare professional such as a speech therapist. The trajectory plotted by speech therapist evaluations is based upon 5 separate evaluations as shown by the small dots on the line. Only one parental evaluation has been completed thus the presence of a single purple dot. As parental evaluations are added, a line is drawn from each point plotted.

Age in days	Administered by	Score	Notes	Date
826	Test User	37	-	14 Oct 2022
704	Jason Hollowell	31	-	14 Jun 2022
522	Jason Hollowell	22	-	14 Dec 2021
369	Jason Hollowell	13	-	14 Jul 2021
219	Jason Hollowell	6	-	14 Feb 2021
62	Jason Hollowell	5		10 Sep 2020

Figure 13: FLI-P Administration Record
(Notes can also be added to each administration instance)

The five speech therapist evaluations, plotted in figure 12, are listed below the developmental graph as shown in figure 13. The "test user" administration shown was conducted by a system user designated as the parent for the child being evaluated.

2) Evaluation

EHDI-IS

Ongoing evaluation of the EHDI-IS is being undertaken via two pathways. The first, and long term ongoing evaluation format is a systematic evaluation utilizing a matrix constructed from the functional standards put forth by the CDC [44]. The matrix constructed from these standards and completed with evaluation coding as of the end of October, 2022, is included in table 4. Each of the goal statements is accompanied by a list of "**shall"**, "**should"**, and "**may"** descriptors. Shall is defined as a mandatory, should as recommended, and may as optional features and capabilities of the system. During the trial implementation of the system, evaluation is focused upon the "shall" statements, however, when applicable, current functionality from the perspective of "should" and "may" statements is also noted. In the matrix below, "shall" items are shaded in grey, "should" items are highlighted with a dotted pattern, and "may" items have been left unshaded. A circle, in the evaluation matrix below the descriptor number, indicates that the EHDI-IS designed for this research is performing or capable of performing the task, triangles indicate capability with some adjustment in either the EHDI-IS software system itself or in the procedure agreed upon by all parties using the EHDI-IS. Finally, an X indicates the system is not yet able to perform the task. A copy of the "shall", "should", and "may" descriptors, as published by the CDC, is provided in appendix 7.

Table 4: EHDI-IS Evaluation Matrix

	Goals	EHDI-IS Evaluation Matrix												
1	Document unduplicated, individually identifiable data on the delivery of newborn hearing screening services for all infants born in the jurisdiction.	1.1 O	1.2 O	1.3 O	1.4 O	1.6 O	1.7 ▲	1.8 O	1.5 ▲	1.9 O	---	---	---	
2	Support tracking and documentation of the delivery of follow-up services for every infant/child who did not receive, complete or pass the newborn hearing screening.	2.2 O	2.3 O	2.5 O	2.6 O	2.7 O	2.8 O	2.10 ▲	2.1 ▲	2.9 O	2.11 O	2.4 O	2.12 ▲	---
3	Document all cases of hearing loss, including congenital, late-onset, progressive, and acquired cases for infants/children <3 years old.	3.1 O	3.2 ▲	3.3 ▲	3.4 O	3.7 ▲	3.5 ▲	3.6 ▲	---	---	---	---	---	---
4	Document the enrollment status, delivery and outcome of early intervention services for infants and children <3 years old with hearing loss.	4.1 O	4.2 O	4.3 O	4.4 ▲	4.5 ▲	4.6 O	4.7 ▲	4.8 ▲	4.9 O	4.10 ▲	4.11 ▲	4.12 ▲	4.13 ▲
5	Maintain data quality (accurate, complete, timely data) of individual newborn hearing screening, follow-up screening and diagnosis, early intervention and demographic information in the EHDI-IS.	5.1 O	5.2 O	5.3 O	5.5 O	5.6 O	5.4 O	5.7 O	5.8 ▲	5.9 O	---	---	---	---
6	Preserve the integrity, security, availability and privacy of all personally-identifiable health and demographic data in the EHDI-IS.	6.1 O	6.2 ▲	6.3 O	6.4 O	---	---	---	---	---	---	---	---	---
7	Enable evaluation and data analysis activities.	7.1 O	7.2 O	7.3 O	---	---	---	---	---	---	---	---	---	---
8	Support dissemination of EHDI information to authorized stakeholders.	8.1 O	8.2 O	---	---	---	---	---	---	---	---	---	---	---

Regarding item 1.5, the system is capable of documenting risk factors but under the current implementation no agreement about recording such factors in the system has been made. As such, further work is required before the system can be used in this manner. Regarding item 1.7, documenting when a child does not receive a screening, which is rare, is possible and reasons for not screening the child can be recorded within the system, however, similar to item 1.7, no agreement about

obtaining and recording this information has been reached and it is thus currently not being recorded. Regarding item 2.1, documenting outside of the prefecture return home births is an ongoing issue in prefectures throughout Japan. Return home childbirth data is difficult to obtain, especially when a newborn hearing screening test is conducted, and the child receives a pass result. When a return home birth child receives a referral on the newborn hearing screening test, the family of that child may later enter the healthcare system for diagnostic and subsequent intervention services. However, the current system implementation relies upon the issuance of a Hearing ID at the time of birth instead of at the time of first contact. While the EHDI-IS is capable of recording and managing this data, procedures for issuing a Hearing ID to children who were screened outside of the prefecture must be put in place before this important item can be deemed to be cleared. In regards to item 2.10, the current system will provide information about children who have not received follow-up services and is capable of recording additional related information, however, without additional policy implementations, this information cannot be entered into the system. Regarding item 2.12, the current system is capable of generating and disseminating a standard-based hearing plan of care document when such standard-based plans are developed and entered into the system. Regarding item 3.2, the system is currently designed to enable data entry for children identified with hearing loss at some time after newborn hearing screening timing. As with item 2.1, policies for generating a Hearing ID and recording of associated data after newborn hearing screening timing must first be put into place before the EHDI-IS will be able to fulfill this requirement. Regarding item 3.3, the system currently uses standards for classifying hearing loss used throughout Japan. These are mild hearing impairment (25dB ~ less than 40dB), moderate hearing impairment (40dB ~ less than 70dB), severe hearing impairment (70db ~ less than

90dB), and profound hearing impairment (90dB and above) [45]. Regarding item 3.7, the system currently functions to provide lists of infants with presumed congenital hearing impairment but the ability to provide lists of late-onset, progressive, and acquired hearing loss first requires policy agreements about how such information is to be captured and recorded within the system. Similarly, regarding items 3.5 and 3.6, risk factors and information about later occurrence of hearing loss can be entered into the system if and when policies for obtaining and recording this information are established. Regarding the two "shall" items under goal 4, 4.4 and 4.5, these items refer to an intervention funding scheme not applicable in the Japanese context. However, information about intervention service can be recorded in the EHDI-IS after such practice is agreed upon and authorized. For this reason, these items have been evaluated with the triangle marking. The status of items 4.7, 4.8, 4.10, 4.11, 4.12, and 4.13 is also marked with a triangle indicating that the EHDI-IS system is capable of managing this information and that the limitation exists in terms of establishing agreement upon and policies for utilizing the system for this purpose. Regarding item 5.8, the EHDI-IS was designed to protect individual identity by utilizing the Hearing ID number, which is linked to each individual via documentation maintained outside of the EHDI-IS by each locality. For this reason, while the system is capable of housing notes and other documentation about interactions, doing so increases the likelihood that information stored within the system can be used, by itself, to identify an individual. As personal information storage and access policies are clarified and implemented within the system, plans to expand the amount and content of information stored within will be implemented. Regarding the final item marked with a triangle, item 6.2, the system is capable of linking with other systems for the purpose of data relay, however, it is currently not configured in such a

manner and thus policy statements governing the details of such a configuration have yet to be developed.

A scoring scheme, displayed in table 5, to evaluate progress against the CDC functional standards, was developed and used to evaluate the EHDI-IS system designed for this research. Points are allocated for each item descriptor with the "shall" and "should" statements carrying the most weight and the "may" statement being rated the same for either a "O" or "▲" evaluation. No differentiation was made for "may" scoring provided that the evaluation indicated systematic capability to perform the task. The differentiation in scoring for the "shall" and "should" statements reflects either that the task is currenting being performed, an "O" evaluation, or that the task is possible from a system perspective, evaluated with the "▲" mark, once its implementation has been agreed upon by the various parties involved in EHDI program implementation. As they are presented as rigid requirements, the "shall" statements are weighted more heavily than the required but not mandatory "should" statements. Additionally, inability to perform a task, regardless of the requirement level, is evaluated with a zero.

Table 5: EHDI-IS Scoring Scheme

	Rating based score		
	O	▲	X
Shall	3	2	0
Should	2	1	0
May	1	1	0

The scoring scheme was applied to the matrix and percentage ratings were derived for each goal and for the system overall. The EHDI-IS evaluation matrix, presented previously, is reproduced in table 6 with scoring information and rating scores displayed.

Table 6: EHDI-IS Evaluation Matrix with rating data

Goal	EHDI-IS Evaluation Matrix													Sub Score / Total Possible	Goal Rating
1	**1.1 O**	**1.2 O**	**1.3 O**	**1.4 O**	**1.6 O**	**1.7 ▲**	**1.8 O**	**1.5 ▲**	**1.9 O**	---	---	---		23	95.83%
	3	**3**	**3**	**3**	**3**	**2**	**3**	**2**	**1**					24	
2	**2.2 O**	**2.3 O**	**2.5 O**	**2.6 O**	**2.7 O**	**2.8 O**	**2.10 ▲**	**2.1 ▲**	**2.9 O**	**2.11 O**	**2.4 O**	**2.12 ▲**	---	27	93.10%
	3	**3**	**3**	**3**	**3**	**3**	**2**	**1**	**2**	**2**	**1**	**1**		29	
3	**3.1 O**	**3.2 ▲**	**3.3 ▲**	**3.4 O**	**3.7 ▲**	**3.5 ▲**	**3.6 ▲**	---	---	---	---	---	---	14	73.68%
	3	**2**	**2**	**3**	**2**	**1**	**1**							19	
4	**4.1 O**	**4.2 O**	**4.3 O**	**4.4 ▲**	**4.5 ▲**	**4.6 O**	**4.7 ▲**	**4.8 ▲**	**4.9 O**	**4.10 ▲**	**4.11 ▲**	**4.12 ▲**	**4.13 ▲**	23	79.31%
	3	**3**	**3**	**2**	**2**	**2**	**1**	**1**	**2**	**1**	**1**	**1**	**1**	29	
5	**5.1 O**	**5.2 O**	**5.3 O**	**5.5 O**	**5.6 O**	**5.4 O**	**5.7 O**	**5.8 ▲**	**5.9 O**	---	---	---	---	22	95.65%
	3	**3**	**3**	**3**	**3**	**2**	**2**	**1**	**2**					23	
6	**6.1 O**	**6.2 ▲**	**6.3 O**	**6.4 O**	---	---	---	---	---	---	---	---	---	11	91.67%
	3	**2**	**3**	**3**										12	
7	**7.1 O**	**7.2 O**	**7.3 O**	---	---	---	---	---	---	---	---	---	---	7	100%
	3	**2**	**2**											7	
8	**8.1 O**	**8.2 O**	---	---	---	---	---	---	---	---	---	---	---	5	100%
	3	2												5	

Total	132	89.19%
	148	

Goals one and two are evaluated highly with only one "shall" statement each requiring additional policy decision making to be fully implemented. Goals three and four, however, require significant additional policy construction and implementation with three of the five "shall" statements for goal three and two of the five for goal four as of yet not implemented within the system. Of the subsequent four goals, 5 ~ 8, only one "shall" statement, 6.2, is evaluated as currently not being

performed. Overall, the system is evaluated highly with no rating of complete incapability. Additionally, as explained, in all instances where tasks are evaluated to be less than fully implemented, the limitation is a result of non-existing policy agreements rather than in limitations of the information management system itself. As such, the system is prepared to accommodate future policy decisions and their implementation.

In addition to the long-term evaluation set out via the evaluation matrix, a short-term in-house evaluation was conducted by obtaining feedback from all parties using the system and via evaluation of the system's observed capabilities thus far. Feedback was obtained from parties utilizing the EHDI-IS in a Working Group formatted committee which met prior to and during the pilot and trial of the system. Feedback obtained in these sessions centered upon streamlining the data entry process with the purpose of minimizing the workload for the birthing clinics and clarifying the system login procedure for other entities such as for public health office workers. As a result of this feedback, the data entry process was modified as follows:

1. Default date of birth was set to two days prior to date of data entry. Because test data was observed to be most frequently entered two days after the child was born, this default slightly streamlines the data entry process for birthing clinics. When this default is incorrect, clinics adjust the date as required.
2. Information about the sex of the child is only required in the event of a referral result on the newborn hearing screening test. The sex of the child is not entered for tests resulting in a pass result.
3. The requirement to enter the number of times a test was administered, was removed.

Additionally, the process for affixing the QR code to the mother and child health handbook is scheduled to change from April of 2023. This change will entail affixing the QR code to the mother and child health handbook at the public health office

prior to issuing the book to mothers who appear at the office to report their pregnancy and forthcoming childbirth. There are two significant observed merits to this proposed change. First, affixing the QR code in the public health office enables the public health office to construct a database linking the Hearing ID, embedded in the QR code, to the individual to whom the mother and child health handbook is distributed by linking it with the mother and child health handbook number before the book is distributed. Without this database, under the current implementation method, the connection between the Hearing ID and the individual to whom it was distributed, is made when a birthing clinic enters the mother and child health handbook number, however, this process was deemed to be labor intensive and potential for error was a concern. With access to a preconstructed database, when the EHDI-IS sends notifications about a referral result to the public health office, public health nurses are able to immediately obtain information about the individual in question and prioritize their visit to support the family and ensure timely follow-up testing. The second benefit to affixing the QR code to the mother and child health handbook prior to its distribution is to significantly reduce the workload required by the birthing clinic as well as to reduce the possibility of mistakenly affixing the wrong QR code to a mother and child health handbook. Additionally, affixing the QR code to the mother and child health handbook in advance of its distribution removes the need for a second matching QR code on the NHS reimbursement form thus reducing workload and materials costs. This adjusted practice is forecasted to increase the number of birthing clinics that are willing to use the EHDI-IS and thus participate fully in the evolving EHDI program in Shizuoka.

3. Results

From September 1, 2022, until October 31, 2022, data associated with 202 newborns was successfully entered into the system. Each birthing clinic was able to login to the system and survey their own data, reviewing the number of screenings, referral rates, and generating invoices to be sent to the localities associated with children born in their clinic. During the trial, a total of 4 children were referred for follow-up testing as a result of their newborn hearing screening test, representing a referral rate of 1.98% thus far. In terms of NHS related statistics, of the four referrals that have been registered in this system thus far, two children were determined to have normal hearing, one child was lost to follow-up due to extenuating circumstances that resulted in the child moving to a different prefecture upon release from the hospital after birth. The remaining one child has received their first initial follow-up visit and is awaiting interpretation of follow-up testing at roughly one month after birth at the time of submission of this manuscript. In addition to the referral rate observed thus far, these preliminary data indicate a false positive rate of 50%. In terms of positive predictive value, excluding the lost to follow child, the rate will be 33.33% if the child awaiting follow-up test results is diagnosed with hearing impairment.

4. Discussion

The notification system was set, during the trial of the system, to notify only the Shizuoka Child Welfare and Health Services office in the event of a referral on a newborn hearing screening test. For children residing in other localities, notifications were set to be sent to the Infant Hearing Support Center housed within the Shizuoka General Hospital. As other localities in Shizuoka begin participating in the use of the EHDI-IS, the associated public health offices will be added so they may receive notifications for referred children who reside within their jurisdiction. Of the 4 children referred during the trial of the system, all were Shizuoka City residents. The first two referrals occurred several days after the start of the pilot trial and before the notification feature had been activated. Because the system was being monitored daily, when the referral appeared in the system, the researcher noted the details and relayed the information directly to parties assigned to provide support services. From the third referral onwards, the notification system was fully functional and automatically initiated e-mail communication to the Child Welfare and Health Services office in Shizuoka City. Officials in the office reported the degree of efficiency of communication to be high to the extent that it preempted notification of the birth itself. Owing to the existing ability to retrieve information about the newborn's mother via use of the mother and child health handbook number, the office was able to retrieve records and prioritize the preparation process for sending a public health nurse to visit the mother and newborn.

When used to track the amount of time required for follow-up testing, some improvement adjustments were made to the system to facilitate information access. When the child referred for follow-up testing appears at a hospital, the hearing ID can be referenced from the mother and child health handbook for recording basic details about the follow-up tests and diagnosis in the EHDI-IS. However, thereafter,

no connection between the hearing ID and records in the hospital patient information system exist, making subsequent information tracking difficult. To alleviate this issue and retain personal information safety within the EHDI-IS, a decision to add the hearing ID to the hospital patient information tracking system was made. This allows later reference and access to the data stored in the EHDI-IS in a fashion similar to that of the public health and welfare offices. For the two children that were diagnosed with no hearing impairment, the times required for diagnosis were thirteen days and one month and thirteen days with an average of 28 days.

Overall, the system has thus far proven effective at relaying actionable information in a timely manner as well as providing real time information which allows for ongoing evaluation of the various components of the EHDI.

1) Addendum

Result data, which was accurate at the date of initial submission of this manuscript on 11/7/2022, has been updated as new data have quickly accumulated during the revision process. As of 12/29/2022, when the revised version of this manuscript was submitted, data associated with 373 newborns had been entered into the system. A total of 6 children were referred for follow-up, representing a referral rate of 1.61%. One child was recorded as loss-to-follow because of relocation to a different prefecture. Three children were diagnosed to have normal hearing, one child was diagnosed with profound hearing loss, and one child currently awaits follow-up testing. Withholding the loss-to-follow child and the child currently awaiting follow-up from calculation, a PPV of 25% is calculated. Regarding the support system for the child identified with hearing loss, preparation of access details for the family is currently underway. These updated details are regarded as additional evidence of the ability of the EHDI-IS to monitor in real-time the data associated with the EHDI program in Shizuoka Prefecture.

IV. General Discussion

Results from the two studies conducted for this research indicate that EHDI programs in Japan exist at the prefectural level and that these programs vary in their level of development and implementation. Findings from the questionnaire conducted in part 1 of study 1, suggest that approximately 80% of the responding prefectures have some level of knowledge about basic details of the EHDI program within their jurisdiction. However, in respect to knowledge of more specific information, such as time required for testing, diagnosis, and intervention, or whether public health nurses are aware of newborn hearing screening results in planning for or executing their one-month post birth visit, the degree of knowledge was reported to be much lower. A higher level of knowledge of such details, however, was observed to exist for prefectures reporting higher levels of frequency for data aggregation and analysis suggesting the possibility of an elevated degree of ability on the part of these prefectures. Additionally, comparison against annual prefectural births and prefectural GDP suggests a potential relationship between the number of annual births and the degree to which the prefecture is aware of the status of the EHDI operating within its borders. This relationship may reveal a limitation in terms of manpower for prefectures with higher birth counts. This supposition is logical when considering the fact that a higher birth count also suggests an increased number of localities or birthing facilities or both.

Part 2 of study 1 further elucidated knowledge gleaned from part 1 and provided support for the hypothesis that aggregating and analyzing data more frequently appeared to be linked to a higher level of understanding of the status of the EHDI within the prefecture. In fact, only prefectures aggregating data more frequently than annually were observed to be monitoring statistics such as referral rate and positive predictive value. While not exclusively limited to the higher frequency data

aggregation and analysis group, a higher level of understanding about the timing required to administer follow-up testing and to commence intervention services was more commonly displayed by prefectures in this group. The semi-structured interviews revealed concerted efforts, on the part of all eleven prefectures interviewed, to minimally understand the status of the NHS in the prefecture and, for more developed programs, to be very actively and proactively working toward the development of a full-fledged EHDI program.

The action research conducted in study 2, informed directly by the results obtained from parts 1 and 2 of study 1, revealed that an improvement in information flow and sharing, via the use of an EHDI-IS, proved to instantaneously empower parties involved in the EHDI program through the timely relay of actionable data. Via the use of a unique "Hearing ID" it was possible to store records in the system that maintain unique identifier status without posing any newly introduced risk in terms of personal information storage and controlled sharing. In line with the EHDI-IS functional standards, proposed by the CDC, maintaining unique identification status enables the EHDI to both function to its maximum potential and to be monitored for ongoing improvement. The trial EHDI-IS system was able to monitor screening rates, positive predictive value, and time required for follow-up testing in addition to relaying information efficiently to parties involved with supporting the families of children identified with potential hearing impairment as well as establishing a framework for providing direct support to the families of children diagnosed with hearing impairment. As of the compilation of this research, no children recorded in the system have been diagnosed with hearing impairment. As such, the functionality of the direct support system has yet to be trialed with families seeking advice, guidance, and support. From a system capability perspective, however, the system is complete and has been tested on pseudo users and awaits authentic users seeking

guidance and support. Note the exception to this included in the addendum to the discussion section for study II.

Results from the studies conducted suggest that the key factor influencing the establishment and implementation of a successful EHDI program is a network of committed and dedicated professionals, including doctors, speech therapists, educators, and public servants who share a vision. A feature of the handful of highly developed EHDI programs identified from the questionnaire administered in part 1 of study 1, and subsequently interviewed in part 2, was that each of the programs were comprised of multiple dedicated parties all working synergistically, to differing degrees, toward a shared goal of quickly identifying potential hearing impairment in newborns, efficiently confirming and diagnosing this hearing impairment, and subsequently commencing effective intervention to ensure cognitive and linguistic development on par with hearing peers. While difficult to code in the semi-structured interviews, a balance of power in these programs was apparent from the level of confidence presented by the interviewees in addition to the thorough detail in the information provided.

V. Limitations and Future Plans of this Research

Although each of the studies conducted for this manuscript fielded valuable information and results, they are not without weaknesses. Efforts to obtain responses from more prefectures via an expanded communication campaign may have resulted in a higher response rate which would provide additional information about EHDI programs in Japan. Additionally, question refinement may have resulted in the ability to obtain additional information about each of the prefectures surveyed. The content of semi-structured interviews would benefit from an initial pilot of the interview process enabling refinement of questions and their ability to field informative details about each program.

The EHDI-IS developed and trialed in study 2 requires significant cooperative efforts on the part of all parties that will benefit from the information and data flow it enables. As such, it is crucial that all parties are included in the development process, first stage piloting, and ongoing refinement efforts after a trial phase is commenced. Additionally, due to the existence of non-resident and return home births, the EHDI-IS is most effective when used on a national scale or minimally setup such that prefectural EHDI-IS systems are integrated to allow for tracking such anomalous cases.

Concrete plans for the use of the EHDI-IS developed under this research include expansion from fiscal year 2023 to all birthing facilities and public health offices in Shizuoka City. Thereafter gradual expansion throughout the prefecture is planned. Plans to offer use of the system to other prefectures with the larger goal of nationwide adoption are currently being discussed and formulated.

VI. Summary and Conclusion

The research conducted for this paper differs from previous research on the status of newborn hearing screening in Japan in several ways. In the first study, rather than surveying individual localities, a questionnaire was administered to prefectural child health and welfare offices. This is because efforts to detect potential hearing impairment, conduct follow-up testing, make diagnoses, and commence intervention services, involve entities that exist across multiple localities. In the second part of the first study, interviews with a subset of the respondents from the surveyed group, provided additional rich information about the structure of EHDI implementation and management. In study two, a system for recording and managing newborn hearing screening, which enables instantaneous information sharing and exchange, was developed. The system developed and trialed was directly informed by results obtained from parts one and two of the first study. A system of this type enables data accumulation, analysis, and action which heretofore has not existed in Japan.

EHDI programs in prefectures throughout Japan exist in various forms and at different developmental stages. Based upon findings from the questionnaire administered in part 1 of study 1 and the subsequent semi-structured interviews conducted in part 2, it is apparent that of the prefectures which enjoyed the most fully developed EHDI programs, this development was observed to exist in parallel with a demonstrated high level of agreement and support from a broad range of related parties. Programs of this nature enjoyed support from a team comprised of birthing clinics, hospitals, public health offices, midwives, and locality and prefectural public servants. Programmatic robustness and stability garnered as a result of this "team effect" positioned each program to not only be able to provide crucial services to newborn children but to also grow and evolve. A strong entity,

whether external in the form of the MHLW annual survey or internal in the form of an influential leader, was observed to reactively motivate prefectures as they worked to periodically build an understanding of the NHS and EHDI program operating within their borders. A more diverse network of individuals from various fields working toward a shared goal, however, was witnessed to result in comparatively superior EHDI programs. These programs enjoyed a type of built-in redundancy as a result of the proportionately distributed EHDI program operational and management responsibilities. A sudden adjustment in personnel as a result of transfer, retirement, or for other reasons, does not threaten the stability of these sufficiently institutionalized programs.

Results from this research suggest that EHDI programs in prefectures throughout Japan would benefit from additional clarification and distribution of program related tasks with the goal of building a stabilized institution. To this end, the use of an EHDI-IS was observed, in one trial instance, to effectively provide emerging institutions, in varying stages of their establishment, with the information and data required to strengthen the EHDI program and inform it as it evolves. The existence of the mother and child health handbook in Japan presents a natural pathway for recording information related to newborn hearing screening and subsequent intervention efforts in the case of a hearing impairment diagnosis. As multiple parties from different institutions and agencies are involved in the hearing detection and intervention process, the EHDI-IS, linked to each individual child via an anonymized hearing ID added to the mother and child health handbook, enables the timely dissemination of crucial information which empowers the various entities comprising the EHDI to work synergistically together in maximizing the linguistic and cognitive development of each child served by the program. Additionally, the use of an EHDI-IS will empower EHDI programs to continuously monitor the

degree to which their program is meeting the 1-3-6 guideline and will provide valuable information for guiding successful programs as they strive to meet the newly accelerated 1-2-3 guideline set by the JCIH.

Dedication

This manuscript and the work it is constructed upon is dedicated to my family, Hitomi and Hana. Their support, understanding, and love enabled me to stay the course. To Hana, thank you for being my daughter and for enabling me to be the father I have become.

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Appendices

Appendix 1 – Questionnaire

新生児聴覚スクリーンニングに関するアンケート調査(オンライン)

Newborn Hearing Screening Online Questionnaire

アンケート調査にご協力いただきたくお願い申し上げます。

Your cooperation in replying to this questionnaire is requested.

I. 貴部署または関連部署における新生児聴覚スクリーニングや早期介入状況についてご教示ください。

Please answer from the perspective of your office and affiliated offices in respect to newborn hearing screening and early intervention services.

A. 新生児聴覚スクリーニング Newborn hearing screening related

1(1)。県の出生数に対する年間新生児聴覚スクリーニング数をどの程度把握していますか。

To what degree are you aware of the annual number of screenings per the annual recorded births in your prefecture?

a. 正確に把握している (Accurate knowledge)
b. ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)
c. ある程度（５割以上）は把握している (Know a majority - 50% or more)
d. 各自治体に任せている (Left up to localities)

1(2)。スクリーニングでリファーとなった児の数をどの程度把握していますか。

To what degree are you aware of the number of children who receive a referral on the newborn hearing screening test?

a. 正確に把握している(Accurate knowledge)
b. ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)
c. ある程度（５割以上）は把握している (Know a majority - 50% or more)
d. 各自治体に任せている (Left up to localities)

1(3)。スクリーニングでリファーとなった児のうち、精密聴力検査を受けた児の数を把握していますか。

To what degree are you aware of the number of referred children who received a follow-up hearing test?

a. 正確に把握している(Accurate knowledge)
b. ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)
c. ある程度（５割以上）は把握している (Know a majority - 50% or more)
d. 各自治体に任せている (Left up to localities)

1(4)。スクリーニングでリファーとなった児が精密聴力検査を受けるまでの期間を把握していますか。

To what degree are you aware of the time required for referred children to receive a follow-up test?

a. 正確に把握している (Accurate knowledge)
b. ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)
c. ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.各自治体に任せている (Left up to localities)

B.早期介入状況 Intervention related

2(1).保健師による１ヶ月訪問の際、新生児聴覚スクリーニング検査結果を把握していますか？

To what degree do you know whether the public health nurse is aware of the results of the newborn hearing screening test when she/he makes the “one month after birth” visit?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.各自治体に任せている (Left up to localities)

2(2).新生児聴覚スクリーニング検査でリファーとなった後の精密検査機関における検査結果を把握していますか？「難聴有り」と診断された児

To what degree are you aware of how many children who received a referral on their newborn hearing screening were diagnosed with hearing impairment as a result of follow-up testing?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

2(3).新生児聴覚スクリーニング検査でリファーとなった後の精密検査機関における検査結果を把握していますか？「難聴無し」と診断された児

To what degree are you aware of how many children who received a referral on their newborn hearing screening were diagnosed with normal hearing as a result of follow-up testing?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

2(4).新生児聴覚スクリーニング検査でリファーとなった後の精密検査機関における検査結果を把握していますか？「経過観察中の児」

To what degree are you aware of how many children who received a referral on their newborn hearing screening were specified as “monitor and follow-up” as a result of follow-up testing?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

2(5).早期介入プログラムやサービス（例：特別支援学校乳幼児相談、児童発達支援センター、県の支援機関等の療育機関）に相談した難聴児の数を把握していますか？

To what degree are you aware of how many children and their families, diagnosed with hearing impairment, have consulted with an early intervention service provider (e.g. special school for the deaf counselor, child

development support center, prefectural support, or other rehabilitation institution?)

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

2(6).難聴と診断された児の早期介入（補聴器装用等）開始年齢（月齢）を把握していますか？

To what degree are you aware of the age (months) of amplification onset (hearing aid use, etc.) for children diagnosed with hearing impairment?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

2(7).難聴と診断された児の就学時における言語や発達に関する情報を把握していますか？

For children diagnosed with hearing impairment, to what degree are you aware of the language and developmental assessment tools used for making decisions about entry to elementary school?

a.正確に把握している (Accurate knowledge)

b.ほぼ正確（８割以上）に把握している (Mostly accurate knowledge - 80% or more)

c.ある程度（５割以上）は把握している (Know a majority - 50% or more)

d.特に把握していない (Not monitoring)

II.データや情報の収集方法及び管理方法について、ご教示ください。Please answer the questions about data procurement, analysis, and storage methods.

C. 情報収集方法 Data Procurement Methods

3(1).聴覚スクリーニング検査機関（出産施設）からどのようにデータを入手していますか。

How is data obtained from the screening facilities (birthing clinics)?

a.書類を郵送してもらう (Sent via postal mail)

b.FAX

c.電子メールまたはその他の電子フォーマット (Sent via e-mail)

d.その他のシステムへのオンライン記録 (Via an online system)

e.その他 (Other)

3(2).精密聴力検査機関で精密検査を受けた際、その結果をどのようにして得ていますか。

For children who receive a follow-up test, how are the results of the follow-up test received from designated follow-up testing institutions?

a.書類を郵送してもらう (Send via postal mail)

b.FAX

c.電子メールまたはその他の電子フォーマット (Sent via e-mail)

d.その他のシステムへのオンライン記録 (Via an online system)

e.得ていません (Not obtaining)

3(3).上記２の指定機関以外で精密検査を受けた際、結果はどのように得ていますか。

Separate from #2 above, for children who receive a follow-up test, how are results of the follow-up test received from non-designated follow-up testing institutions?

a. 書類（紙媒体）を郵送してもらう (Sent via postal mail)
b. FAX
c. 電子メールまたはその他の電子フォーマット (Sent via e-mail)
d. その他のシステムへのオンライン記録 (Via an online system)
e. 得ていません (Not being obtained)
f. その他 (Other)

D. 情報管理方法 Data Storage

4(1). 集計や分析のために、データや情報はどのように管理されていますか
How is data, that is used for aggregation and analysis, maintained?

a. 紙媒体 (Paper form)
b. CD、USB、ハードドライブなどのメディア (CD, USB, hard disk or other media)
c. インターネットから隔離されたローカルネットワーク上 (Local network separated from the Internet)
d. セキュリティーのかかったインターネットデータベースまたはその他の類似したシステム上 (Stored on a secured Internet accessible network)
e. その他 (Other)

4(2). データの集計・分析はどのくらいの頻度で行っていますか
How often is data aggregated and analyzed?

a. 毎日（即時）(Daily / Continuously)
b. 毎週 (Weekly)
c. 毎月 (Monthly)
d. 毎年 (Annually)
e. その他 (Other)

E. 追加情報提供の可能性について Additional Information Request

1. このアンケートでご答え頂いた内容以外、個別の質問に対して貴県で対応をして頂けますか。可能であれば、電話、対面、オンラインなど面談方法を相談させていただきます。
Would you be willing to participate in an interview conducted for the purpose of obtaining information in addition to that provided here? Interviews will be conducted either face to face, by telephone, or online.
a. はい (Yes)
b. いいえ (No)
2. 上記１で「上記１で「はい」とお答えの場合、ご連絡先を教えてください。ご担当者様に再調査協力依頼書をお送りいたします。
For those who answered “Yes” to the above question, please provide the following.
担当部署： (Division / Office)　　担当者： (Name)
連絡先（電話、FAX、メールアドレスなど）：(Contact phone, fax, e-mail address)
3. 本アンケートに関するご意見 Additional comments/observations regarding this questionnaire.
「自由記載」Comment box

アンケート調査にご協力くださいましてありがとうございました。
Thank you for your cooperation in answering the questions on this questionnaire.

Appendix 2 – Interview Guide

半構造化インタビューガイド (Semi-Structured Interview Guide)

I. 所轄部署または関連部署における新生児聴覚スクリーニングや早期介入状況
Office and affiliated offices in respect to newborn hearing screening and early intervention services

A. 新生児聴覚スクリーニング Newborn hearing screening related

1. 県の出生数に対する年間新生児聴覚スクリーニング数
Number of annual screenings per births in the prefecture
a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. 県としてスクリーニング率に対する考え方：課題や達成点等 - Prefectural perspective of the screening rate, problem identification, evaluation, etc.

2. スクリーニングでリファーとなった児の数 - Number of referrals
a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. リファー数と率に対する考え方：課題や傾向等 - Prefectural perspective of the referral rate, problem identification, evaluation, etc.

3. スクリーニングでリファーとなった児のうち、精密聴力検査を受けた児の数 - Number of referred children who received follow-up testing
a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. 精密聴力検査を受けていない児の要因や背景 - Follow-up on children who did not receive screening and understanding of reasons

4. スクリーニングでリファーとなった児が精密聴力検査を受けるまでの期間 - Amount of time required to obtain follow-up testing for newborns who receive a referral
a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. 実施時期に影響していると考えられる要因 - Factors influencing the time required to receive follow-up testing

B. 早期介入状況 - Early intervention related

1. 保健師による１ヶ月訪問の際の新生児聴覚スクリーニング検査結果 - Does the public health nurse have screening results when making the 1 month visit?
a. 把握の場合の情報の活用方法 - If yes, how is information utilized?
b. 情報利用に関する課題 - Issues surrounding the use of this information?

2. 新生児聴覚スクリーニング検査でリファーとなった児の精密検査結果 - Results of follow-up testing
2a. 難聴と診断された児 - Number identified with hearing impairment
a. 把握している実数、およびその人数（率）に対する考え方（経過などに対しての評価等）- Issues identified with occurrence frequency?
2b. 難聴無し、と診断された児 - Number identified with no hearing impairment
a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. 結果に対する課題 - Issues with data as analyzed?
2c. 経過観察中の児 - Monitor and follow-up

a. 実数(可能な範囲でよい) - Actual numbers (when possible)
b. 経過観察のフォロー方法 - Method of follow-up

3. 早期介入プログラムやサービス（例：特別支援学校乳幼児相談、児童発達支援センター等の療育機関）に相談した難聴児数 Number of children receiving early intervention services (special school for the deaf counselor, child development support center, prefectural support, or other rehabilitation institution?)
   a. 実数(可能な範囲でよい) - Actual numbers (when possible)
   b. 一般的な相談内容 Content of intervention and support services
4. 難聴と診断された児の早期介入開始年齢（月齢）- Age in months of the child at the beginning of intervention services?
   a. 実数(可能な範囲でよい) - Number of children (when possible)
   b. 介入時の年齢 - Average age
5. 難聴と診断された児の就学時における言語や発達に関する情報 - Language and cognitive development assessment tools used for decision making when child enters school?
   a. 発達評価検査や項目－Developmental assessment categories?
   b. その現状に対する課題 - Issues identified with this process?

II. データや情報の収集方法及び管理方法 (Data procurement and storage)

C. 情報収集方法 (Data procurement)

1. 聴覚スクリーニング検査機関（出産施設）からどのデータ入手方法 - How is data obtained from the birthing clinics?
   a. その方法についての利点や課題。- Issues identified with this method?
   b. その方法を理由している経緯 - How did this method originate?
   c. データ入手方法の今後の計画や展望 - Plans for adjustment to this system?

2. 県で指定された精密聴力検査機関で精密検査を受けた際のデータの入手方法 - How is data obtained from the specified follow-up testing hosptials?
   a. その方法についての利点や課題。- Issues identified with this method?
   b. その方法を理由している経緯 - How did this method originate?
   c. データ入手方法の今後の計画や展望 - Plans for adjustment to this system?

3. 上記２の指定機関以外で精密検査を受けた際、データの入手方法 - How is data obtained from non-specified follow-up testing hospitals?
   a. その方法についての利点や課題。- Issues identified with this method?
   b. その方法を理由している経緯を調べる。- How did this method originate?
   c. データ入手方法の今後の計画や展望 - Plans for adjustment to this system?

D. 情報管理方法 (Data management)

1. 集計や分析のために、データや情報の管理について。- How is data used for aggregation and analysis managed and stored?

a. その方法についての利点や課題。- Issues identified with this method?
b. その方法を理由している経緯を調べる。- How did this method originate?
c. データ入手方法の今後の計画や展望 - Plans for adjustment to this system?

2. データの集計・分析頻度について。- How frequently is data aggregated and analyzed?
   a. その方法についての利点や課題。- Issues identified with this method?
   b. その方法を理由している経緯を調べる。- How did this method originate?
   c. データ入手方法の今後の計画や展望 - Plans for adjustment to this system?

Appendix 3 – Semi-Structured Interview Codes

Code Group	Code
Data Analysis	For MHLW
	NationalSurveyRef
	Proactive
	ProcureStore-Analog
	ProcureStore-Digital
	Personal Information
Diagnosis	Precise
	Unknown
	Vague
Follow-Up & Timing	FLW-Details
	FLW-Goal
	FLW-None
	FLW-Vague
	FLWTime-Details
	FLWTime-None
	FLWTime-Vague
Frequency of Data Analysis	AnalysisFreq-Annual
	AnalysisFreq-Biannual
	AnalysisFreq-Monthly
	AnalysisFreq-Quarterly
Funding Scheme	Fund-All
	Fund-Some
	Fund-None
Future Plans	Plans-No
	Plans-Yes
Intervention & Timing	InterventionInfoNo
	InterventionInfoYes
	InterventionTiming-Precise
	InterventionTiming-Unknown
	InterventionTiming-Vague
Non-Resident Births	NRB-Precise
	NRB-Vauge
Out of Prefecture Births	OOP-Precise
	OOP-Vague
Problem Identification	Problemident-No
	Problemident-Yes
Public Health Nurse Information	PHNVisit-Certain
	PHNVisit-Unknown
	PHNVisit-Vague
Questions	Q-ForImprovement
	Q-ForResearchOutput
	Q-Other
Screening	ReferRate-Precise
	ReferRate-Unknown
	ReferRate-Vague
	Screen-FalsePNo
	Screen-FalsePYes
	Screen-PPVYes
	Screen-Precise
	Screen-Vague

Appendix 4 – SRS

Software Requirements Specification

for

<ERPNext – Custom Newborn Hearing Screening (NHS) System Development>

Version 2.0

Prepared by <Jason Hollowell>

<Shizuoka General Hospital – Research Support Center, Hearing & Language Center>

<10/08/21>

Introduction

Purpose

The goal for customizing the ERPNext Healthcare domain is to position it as a central data center for all newborn hearing screening (NHS) related information. This will allow individual birthing clinics to accurately monitor the status of screening from their local perspective as well as to aggregate data for the generation of invoices sent to localities (cities and towns) for screening test reimbursement. Additionally, the system will be accessible by follow-up testing hospitals, public health offices, and the Hearing and Language Center with each having granularly controlled access to data a system functionality.

Document Conventions

No special conventions are used to designate priority levels for the desired features of this software development. When such priorities exist, they will be noted in the text proceeding the explanation of the feature.

Intended Audience and Reading Suggestions

This document is intended for software developers at ERPNext and Frappe, the project requester, and other research oversight committee members from the requesting institution Shizuoka General Hospital – Research Support Center and the Hearing and Language Center (for the purpose of progress reporting).

Project Scope

The system will function to record and manage hearing screening related information for newborns in Shizuoka Prefecture. Data will be entered into the system such that individual patient identity is unknown. Individual patient data will be linked to a "Hearing ID" which is to be coded into a QR code. As such, one component of the data entry will involve reading a QR code.

References

In conjunction with this project, a separate support system is being planned. The current plan is to configure that system to access one table in the ERPNext database (or to setup a 'mirrored' table via database triggers) that will function to create a login/authentication pathway for particular users (families of children who have received a "referral" as a result of the NHS).

Product Perspective

This system will be the first digitized online system for the data that will be input and managed. As such, it is not replacing an already existing system. Data to be entered into the system are as follows:

Initial Patient Creation (by birthing clinics where NHS is conducted)

1. **Hearing ID** (via QR code) – Pre-created and distributed to all facilities that conduct NHS
2. **Mother/Child Book ID** – This will be either manually entered or scanned via a barcode
3. **Hearing screening** – Yes / No – This will be used to track overall screening rates
4. **Sex** – The sex of the child (Male / Female) To track epidemiological data (hearing loss rate by sex).
5. **Date of birth** – The date of birth for the child
6. **Date of screening** – This will be used to monitor the number of days after birth that the screening test is conducted. It will additionally be used to track the amount of time between initial screening and follow-up screening in the event that the initial screening result is a referral (see #10, #11 below).
7. **Locality** – The city or town where the child lives. This will be used to aggregate data per each locality for the purpose of generating invoices. (Note – Each locality reimburses NHS testing clinics for the number and type of NHS tests they conduct each month.)
8. **Testing Clinic** – Ideally this will be automatically recorded by detecting the logged in user. This will be used for multiple purposes:
    a. To fill required information when generating invoices.
    b. To monitor referral rates from a higher up (Research Support Center) perspective. In the event that a particular clinic has a referral rate higher than 2%, technical support may be provided to ensure the quality of their testing procedure and/or equipment review may be initiated.
    c. To track epidemiological data (hearing loss rate, etc.) by geographic region.

9. **Screening test type/equipment** – Two possible tests are possible (AABR, OAE). Each test is reimbursed at a different rate (AABR = 4,700 Yen, OAE = 2,100 Yen). As such, the type of test is important from the perspective of the NHS testing clinic being able to generate invoices. Additionally, the test type will be used to track referral rates per test type. It is generally understood that the OAE test results in a higher referral rate than AABR. Data aggregation via this system will allow for objective data analysis of such trends.
10. **Screening Test Result** (Right ear) - The initial NHS test result is a binary (Pass or Refer)
11. **Screening Test Result** (Left ear) - The initial NHS test result is a binary (Pass or Refer)
12. **Number of times the test was conducted** – Practitioners are encouraged to run the test no more that roughly 3 times. Some practitioners conduct fewer or more in determining the result. This data will enable analysis that may provide insight into the most appropriate number of test trials. (Note – this does not include retests conducted during a different session (time/date).
13. **Confirmation test** – Yes / No – This signifies tests conducted in a different session (time/date).
14. **Number of times the confirmation test was conducted**
15. **Referral Hospital** – In the event of a referral on the NHS test, the family is referred to a hospital where a follow-up test is conducted. There are four official follow-up hospitals in the prefecture. However, some clinics do not refer patients to one of the four official follow-up institutions. As such, we require an "other" option that subsequently requires the name of the "other" institution to be entered.
16. **E-Mail address** – In the event of a referral result on the NHS test, the clinician (nurse, doctor, or admin staff) will ask the parent for an e-mail address. If the parent agrees to provide the address (signs a waiver), the address will be entered and subsequently used to disseminate information about hearing loss and the importance of getting a follow-up test as quickly as possible.

Follow-Up Test Data – When children who received a referral receive follow-up testing, the results of the follow-up test will be entered, as a lab test or clinical procedure, and linked to the patient via the Hearing ID (QR Code). Ideally, the follow-up testing institution will login to the ERPNext system, scan the QR code to find the patient and add the results. Data to be included in the follow-up test record are:

1. **Test date** – This will allow for accurate monitoring of how much time transpires between the referral and follow-up test.
2. **Test type** – This may be one of several different types of test (ABR, ASSR, CT-Scan, Genetic testing, etc.). For this additional record, the test type can be a lab test, within the ERPNext framework, that includes results. As such, results would be added within the test that is selected.
3. **Testing institution** – The desire is for this to be like #8 for the initial record above in that it can be populated automatically based upon the logged in user.

Product Features

The main purpose of the system is to manage newborn hearing screening data in an online digital system to streamline the process, make administrative work more efficient, and to enable monitoring of the status of various aspects of said program such as for the purpose of providing timely intervention services.

User Classes and Characteristics

Users of the system will be:

1. Birthing clinics (screening testing facilities) – Screening data entry, statistics monitoring, invoice generation
2. Public health offices (public health nurses) – Monitoring of referrals in their district
3. Follow-up testing hospitals – Adding follow-up test results to records created by the birthing clinics.
4. System administration and support (Hearing and Language Center) – Monitoring system use, conducting tutorial sessions to familiarize users with the system, creation and distribution of a manual and required documents (QR codes, etc.) to birthing clinics and follow-up testing hospitals.
5. Researchers (affiliated with the Hearing and Language Center) – Aggregate data, monitor referral rates, hearing impairment occurrence rates, intervention timing, etc.

Operating Environment

The system will be installed on a satisfactory server (16GB RAM, Ubuntu, Nginx, PHP, Maria DB) (self-hosted or rented from a vendor such as Amazon Web Services). As there is a requirement to have the data hosted within Japan, SSH access will be provided to ERPNext/Frappe during piloting and trailing of the system.

Design and Implementation Constraints

The only currently identified constraint is that there is a need to host the system on a server within Japan. Server hosting will be acquired by an employee of Shizuoka General Hospital and all required access information (SSH etc.) will be provided to ERPNext development staff.

User Documentation

Documentation will be created in Japanese for all users by the Hearing and Language Center.

Assumptions and Dependencies

An external system, Moodle, will be used to provide support to families of children who receive a referral on the newborn hearing screening. The current plan is to provide access to this system via an authentication method which uses an external database table. As such, we need to be able to allow the Moodle system to access a table in the ERPNext MariaDB where the HearingID and the Mother/Child Book ID is housed. The authentication process will involve Moodle checking for a "refer" test result in the DB table and subsequently providing authentication access (via use of the HearingID as username and Mother/Child Book ID as password). The authentication process will be a one-time event. After initial login to the Moodle system, all user data will be stored within the local Moodle DB.

System Features

The system will be used primarily by birthing clinics, follow-up testing hospitals, and researchers. The following feature sets will be detailed from the perspective of each user type.

Birthing Clinic

The following is an outline of the use of the NHS system from the birthing clinic perspective.

2.1.1 System login via clinic specific account

Each birthing clinic will be provided with an account used to access the system. Our plan is to provide each clinic with a QR code reader. For logging into the system, QR codes will be provided within a manual as follows: 1 QR code for site access (a URL), 1 QR code for username entry, 1 QR code for password entry. Although it may run contrary to current ERPNext design, the plan is to issue only one account per clinic as the entity from the perspective of the entire system is "clinic" rather than "individual user". If clinics with high birth rates require/request additional accounts, we hope to be able to meet this request by creating additional accounts. For this reason, it may be desirable to create the initial account with future flexibility in mind. For example, "Staff One" at "ABC Clinic" thus enabling future creation of "Staff Two) and "ABC Clinic"

2.1.2 New Patient Creation

As outlined in 1.6, birthing clinic staff will need to create a new patient account and enter data related to the newborn hearing screening. The data set is specified in 1.6 above.

2.1.3 Invoicing

At the end of each month, clinic staff are required to generate invoices to be sent to each locality (city, town, village) associated with the residence of their patients who received a screening test that month. There is thus a need for invoice generation as follows:

a. Clinic staff selects "Generate Invoice"

b. The staff member selects the time frame (e.g. 5/1/20 ~ 5/30/20)

c. The staff member selects the locality (e.g. Town A)

Given the filters applied via the above criteria selection process, the system will subsequently filter out all tests administered during the specified time frame, for the specified locality and generate an invoice to be sent to that locality for reimbursement. Note – There are two test types (as specified in 1.6 above). They are invoiced at different rates. Thus, the invoice should multiply the number of each test type by the rate and then add the two totals to calculate the total of the invoice.

2.1.4 Data analysis

Each birthing clinic should have access to a dashboard which provides some simple data analysis for their clinic. The data to be displayed is as follows:

a. Screening rate (number of screenings per births) (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom)
b. Referral rate (number of referrals per screenings conducted) (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom)
c. Hearing loss rate – this will only be available after a follow-up test is conducted and results are added to the system.
d. Referred patients that have / have not received follow-up testing (or follow-up test results have not been added to the system)

Follow-up Test Hospitals

The following is an outline of the use of the NHS system from the follow-up test hospital perspective.

2.2.1 System login via hospital specific account

Each follow-up test hospital will be provided with an account used to access the system. The plan is to provide each hospital with a QR code reader. For logging into the system, QR codes will be provided within a manual as follows: 1 QR code for site access (a URL), 1 QR code for username entry, 1 QR code for password entry. Although it may run contrary to current ERPNext design, the plan is to issue only one account per hospital as the entity from the perspective of the entire system is "hospital" rather than "individual user". If hospitals with high referral testing numbers require/request additional accounts, we hope to be able to meet this request by creating additional accounts. For this reason, it may be desirable to create the initial account with future flexibility in mind. For example, "Staff One" at "Hospital 1" thus enabling future creation of "Staff Two) and "Hospital 1"

2.2.2 Patient record update

The follow-up test will add data to the patient record using the following process:

a. Scan the QR code in the patient's Mother/Child Book after having logged into the system.
b. Once the record is retrieved, the clinical test results and diagnosis details will be added.

2.2.3 Data analysis

Each hospital should have access to a dashboard which provides some simple data analysis. The data to be displayed is as follows:

a. Referrals – Hospitals should be able to see how many referrals have been made to their institution for follow-up testing. (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom)
b. Hearing loss diagnosis rate per follow-up referrals (calculated by dividing hearing loss diagnosis by total number of follow-up tests conducted). (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom)

Research

The following is an outline of the use of the NHS system from the researcher perspective.

2.3.1 System login via researcher specific account

Each research entity will be provided with an account used to access the system. Our plan is to provide each entity with a QR code reader. For logging into the system, QR codes will be provided within a manual as follows: 1 QR code for site access (a URL), 1 QR code for username entry, 1 QR code for password entry. Although it may run contrary to current ERPNext design, the plan is to issue only one account per research entity as the entity from the perspective of the entire system is the research entity rather than "individual user". This will likely change in the future but as the initial plan is to have only one researcher account, this setup should be sufficient.

2.3.2 Data analysis

Researchers should be able to access the system from a more 'global' perspective in order to obtain aggregated data across birthing clinics and hospitals. Some types of data analysis that may be desired are:

a. Data analysis of overall screening rates. (number of screens / births) - (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom)
b. Data analysis of hearing loss occurrence frequency (occurrence per time period). (Ideally this can be filtered by time (e.g. weekly, monthly, yearly, custom) Additionally, it will be necessary to filter by locality to investigate possible anomalies (i.e. higher than normal hearing loss frequency in a particular region, etc.)
c. Referral rate per region and clinic over time. This may be used for follow-up training to improve abnormally and undesirably high referral rates.

Junior/Senior High School or Hearing Impaired Support Center

The following is a brief description of a future planned entity that may access the system. There is no need to include these details under the current development agreement, however, we do hope that the functionality can be designed such that addition of this role is possible in the future.

2.4.1 System login via 'school or support center' specific account

Each school or center entity will be provided with an account used to access the system. Our plan is to provide each entity with a QR code reader. For logging into the system, QR codes will be provided within a manual as follows: 1 QR code for site access (a URL), 1 QR code for username entry, 1 QR code for password entry. Although it may run contrary to current ERPNext design, the plan is to issue only one account per entity as the entity from the perspective of the entire system is the entity rather than "individual user". This will likely change in the future but as the initial plan is to have only one researcher account, this setup should be sufficient.

2.4.2 New Patient Creation

Somewhat different from the details listed in 1.6 above, we are currently considering using this system to also enter records of youths with hearing impairment. For these individuals a hearing ID can be issued. If they have details about their screening, those may be entered as well but if this information is unavailable, the data entry personnel will simply select "no" for #3 under 1.6 (Hearing Screening "Yes", "No"). A subset of desired data for these individuals is as follows:

a. Locality of residence (city, town, village name)
b. School name – this could be populated the same as #8 under 1.6 using the name of the institution logged into the system.
c. Name of staff who is entering the data record
d. Position of staff member listed in c above (administrator, teacher, counselor, etc.)
e. Status of student (patient) for the record being added (in lower percentile of class, simple announcement of status, inquiry from student) ← This information will be used for subsequent follow-up and support.
f. Initials or name of student (or other pseudonym)
g. Year in school
h. Details of hearing loss (via text entry box)
i. Use of hearing support (deaf school periodic visitation, language development support, other)
j. Any special treatment at your school for this student? (Either a pull-down list or text box – current plan is for a pull down with the final option being "other" which triggers a text entry window)
k. Special requests regarding this student (text box).

新生児聴覚スクリーニング検査結果集約アプリ

EHDI-IS

「新スクアプリ」
利用マニュアル（新スク実施施設用）

第 1 版

作　成　者	静岡県立総合病院乳幼児聴覚支援センター
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5　新スクアプリ入力マニュアル.....

- 各自治体への検査費用請求書作成について.....
- 検査データの集計について.....

1　新スクアプリ導入の目的について

近年の新生児聴覚スクリーニング後の世界的な流れとして、生後 2 か月までの診断、3 か月からの早期介入がその後の音声言語発達の点から望ましいとされるようになりました。

そのためには、早期の精密聴力検査機関受診、そして確実に療育、介入につなげる、難聴児とその保護者へのきめの細かい支援が必要となります。

つまり、新スク結果が早期に確実に関係者に共有されることが求められています。

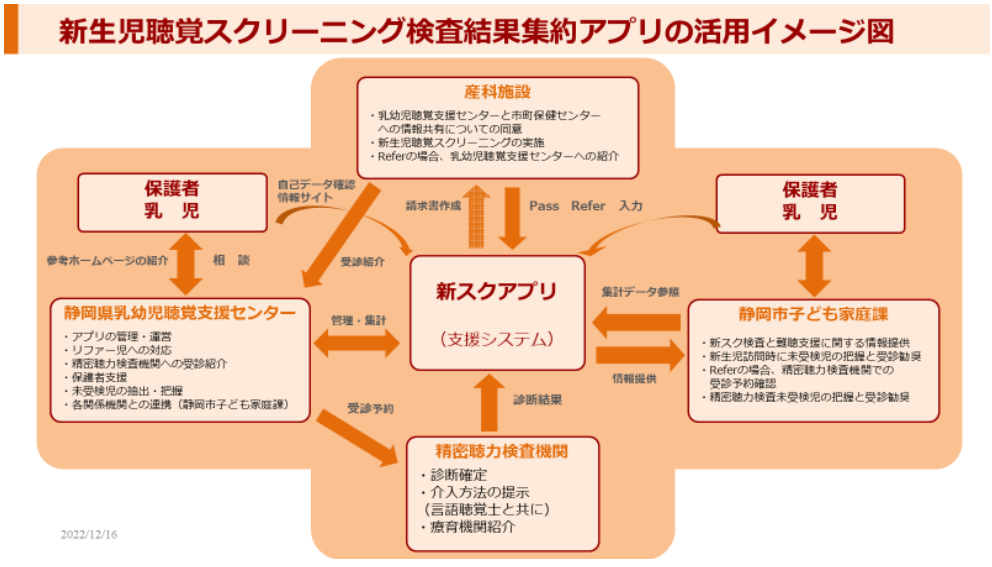
それを可能にするために、検査実施施設での電子入力を行い、ネットワークを利用して、新スクと refer 後の精密機関での診断結果が、遅延なく医療機関、行政（乳幼児聴覚支援センター）、保健師に共有されることが必須となります。

令和 3 年度、静岡県からの委託を受け、乳幼児聴覚支援センターでは、静岡県立総合病院きこえとことばのセンター特別研究員のホロェル・ジェイソン氏の主導で、この新スクアプリを開発いたしました。

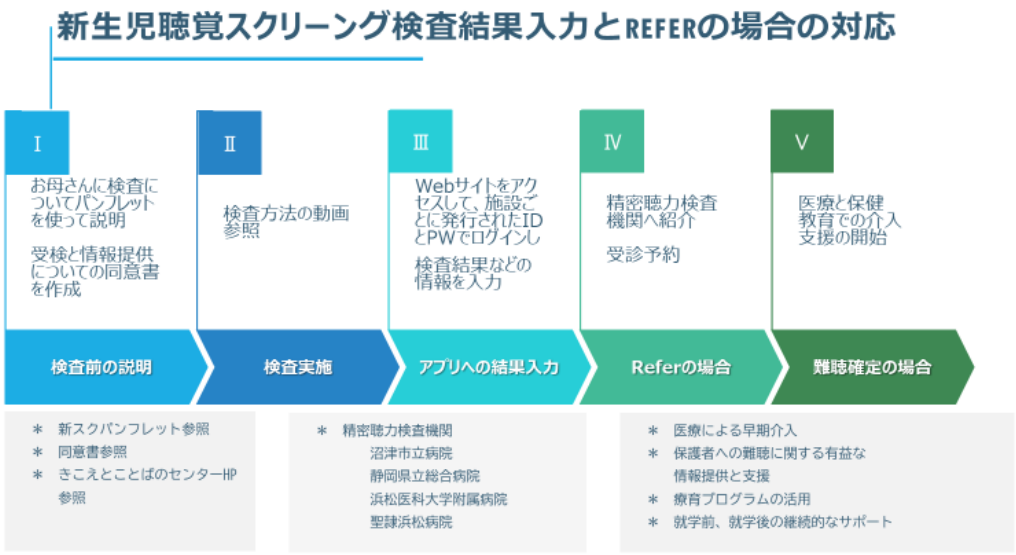
個人情報に充分配慮をしつつ、入力作業など、現場のご負担を極力減らして、なおかつ検査料の集計、請求処理の事務軽減を図るようデザインされております。

日頃みなさまにご協力いただいている、新生児聴覚スクリーニング検査の効果が、一層高まるものと考えております。 どうぞ、ご理解、ご協力をいただければ幸いです。

2　イメージ図参照



3　新生児聴覚スクリーニング検査からの流れ



＊リファーの場合、難聴の有無の確定のために、必ず精密聴力検査機関での受診をできるだけ早くするよう保護者の方に勧めていただき、できるだけ、退院前に受診予約を取ってください。

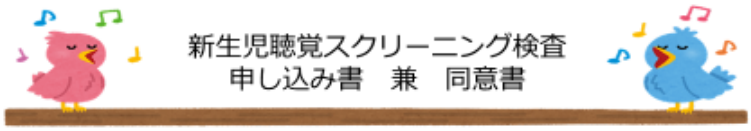
早期に精密聴力検査機関を受診すると、即日の簡便な検査で約 7 割の児が pass となり、保護者の安心につながります。

4　同意書の作成について

＊新スクパンフレットを利用して、お母さんにスクリーニング検査の必要性の説明を行ってください。

＊乳幼児聴覚支援センターでの相談を受けられること、詳しい情報提供があることを伝えてください。
（きこえとことばのセンターホームページをご参考ください）

様式2-3　（保護者　→　新スク実施機関）



新生児聴覚スクリーニング検査
申し込み書　兼　同意書

赤ちゃんは、周囲から語りかける言葉や色々な音などをきいて育っていきます。
しかし、1000人に1～2人の赤ちゃんに生まれつきのきこえにくさ（難聴）があると言われています。
新生児聴覚スクリーニング検査は、赤ちゃんの難聴を早く発見し、適切な援助を開始するための検査です。
詳しくは、「新生児聴覚スクリーニング検査について」のリーフレットや、乳幼児聴覚支援センターHP上で動画も紹介していますので、ご覧ください。

静岡県乳幼児聴覚支援センターでは、検査で「要再検査」となり不安を感じる保護者や、難聴が確定した児の保護者への相談事業などを行っています。
母子への切れ目ない支援のために、新生児聴覚スクリーニング結果の医療機関と静岡県乳幼児聴覚支援センター、行政（市町保健センター）との情報共有が欠かせません。
新生児聴覚スクリーニング検査の受検の同意とともに、その結果を公的機関が共有することの同意を頂ければと思います。

【保護者記入欄】　※［　］内の、いずれかに○をつけてください。

○私は新生児聴覚スクリーニング検査について、理解しました。　**［はい ・ いいえ］**

○私の子どもが新生児聴覚スクリーニング検査を受けることを希望します。　**［はい ・ いいえ］**

○新生児スクリーニング検査実施後、以下の内容について静岡県乳幼児聴覚支援センター、行政機関と情報を共有することに同意をいただけますか。

・保護者の方のご連絡先
・赤ちゃんの生年月日、性別
・新スク検査を受けた医療機関及び、検査結果
・精査機関受診の場合は、紹介先の精密検査機関及び精査結果

［同意します ・ 同意しません］

※個人情報に関する取扱いについては、裏面の事項をお読みください。

申し込み年月日	年　月　日
保護者のお名前	
保護者住所	携帯番号（　　）

※同意書兼申込書は各施設で保管してください。

1　利用目的について

収集した個人情報は、医療サービス提供やお子さんとご家族への早期支援のため以外には使用しません。

2　第三者への提供について

収集した個人情報については、乳幼児聴覚支援センター、お住まいの市町、精密聴力検査機関のみ情報提供いたします。ほかの第三者への情報提供はいたしません。

3　個人情報の開示・訂正・削除・利用停止請求について

保護者から個人情報の開示・訂正・削除・利用停止請求があれば、すぐに対応します。乳幼児聴覚支援センターへ御連絡ください。

＊里帰り分娩の場合、同意書に QR コードシールを貼って保管してください。

＊リファーの場合、同意書の保護者からの情報をアプリに入力してください。

5　新スクアプリ入力マニュアル

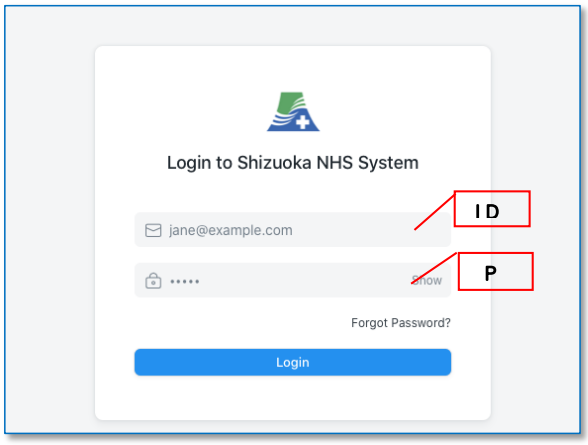
＊入力デバイスは、iPad、　iPhone、　PC＋QR コードリーダーのいずれでも可能

＊アプリには、母子手帳番号、出生日、保護者の住民票の住所の入力が必要

① Web サイトをアクセス　　https://www.screen.shizuoka-kikoesupport.jp

② **ログイン**をクリック

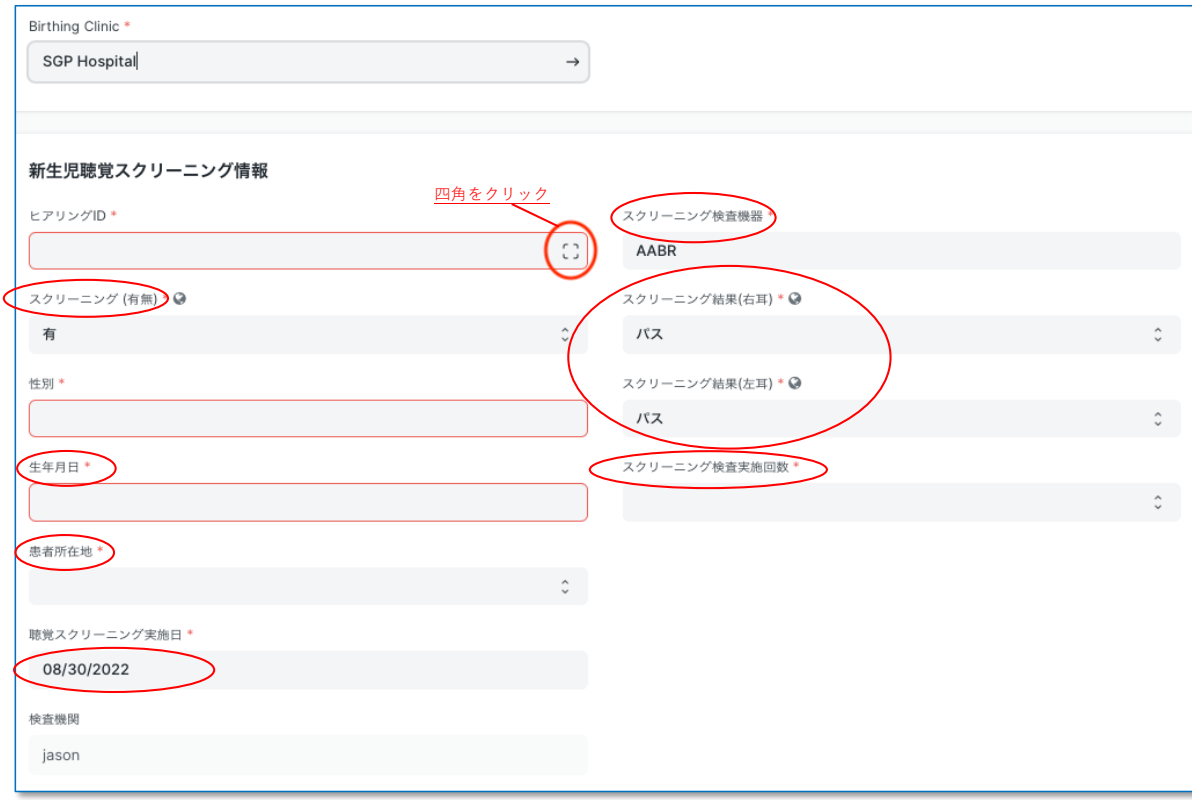
③ 施設ごとに付与されたアプリ専用の ID と PW を入力し、ログイン



④ ログイン後開いた画面で、ヘルスケアをクリック

⑤ 患者をクリックし、開いた画面で追加患者をクリック

⑥ 新しい患者と表示される画面、まずその患者のヒアリング ID を入力、ヒアリング ID セルの右に表示される四角をクリックして、入力デバイスのカメラ（もしくは QR コードリーダー）を使用して QR コードを読み取ると、その患者のヒアリング ID がセルに自動入力される



＊令和 5 年 4 月 1 日以降に静岡市で発行される「母子手帳」の検査記録のページに、その赤ちゃんのヒアリング ID（QR コードシール）が貼られていますので、それを読み取ってください。

それより前に発行された手帳には貼られていませんので、その場合は、施設ごとに配布された QR コードシールを読み取り、ヒアリング ID を入力してください。

（個人情報保護の観点から、このアプリ内で個人を識別するために、名前ではなくヒアリング ID を使用し、個人を特定できるのは、母子手帳を発行する行政担当者、保健師になります）

⑦　情報を入力

1　生年月日のデフォルトは、入力日の 2 日前（入力すると年齢が自動に入る）になっているので、必要な場合、変更する
2　患者所在地（検査日に住民票があるところ：検査費用の請求先自治体）
3　スクリーニング実施日のデフォルトは、入力日になっているので、必要な場合は、変更する
4　スクリーニング検査使用機器、 検査結果（パス・リファー）、実施回数を入力

⑧　リファーを入力すると、新たな画面が表示されるので、下記情報を入力する

1　性別を入力（パスの場合は非表示になっている）
2　二次検査受診の紹介先精密聴力検査機関
3　保護者の電話番号・・・メールアドレスより簡易に入力できる
4　母子手帳番号（母子手帳番号にすでに QR コードが貼ってある場合は不要）
5　Email アドレス・・・リファー後の保護者支援のための情報提供（入力努力項目）

⑨　情報を入力したら、画面右上の青い保存をクリックし、データを保存する

⑩　保存後、患者リストが表示される

＊リファーを入力すると、その患者さんの担当の母子保健担当セクションにリファーが出た通知メールがアプリから自動で送信されます。
それを受けた保健担当セクションで、母子手帳番号から個人を特定し、赤ちゃん訪問を早めに訪問する また、保護者の不安軽減につながる有益な情報提供ができるよう、担当の保健師などに配慮をいただきます。

＊確定診断や受診後の経過については、新スクアプリからの自動通知メール（kikoesupport の gmail）がリファーの結果を入力していただいた産科施設に送信されます。詳しい内容は、アプリ内で確認できる。内容を確認できますので活用ください。

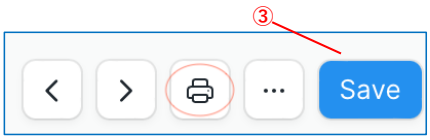
6　請求書発行

1　スクリーニング検査費用の助成を行っている各自治体（保護者の住民票所在地）への請求書が、自動的に発行されます。

請求書は、ヘルスケアの画面「カスタムドキュメント」の「Bulk Invoice 」をクリック

2　表示される画面に請求書の一覧（各自治体の請求書様式）が、表示される

3　リストを選択すると、患者情報の所在地の自治体の毎月ごとの各自治体への検査費用請求書が自動的に作成されるので、印刷して使用する



ダッシュボード（集計）

1　ヘルスケア画面から、スクリーニングステータスをクリック

2　入力したスクリーニング検査の情報から、随時データを集計した状態でモニタリングできる

現在表示されている情報

a. 出生数
b. スクリーニング数
c. リファー数

データをチェックすることで、検査機器の管理などに活用できる

＊きこえとことばのセンターホームページで、このマニュアルのダウンロードができます。
その他、新スク検査方法の説明動画をはじめ、難聴支援についての各種情報提供を掲載しておりますのでご利用ください。

http://shizuoka-kikoesupport.jp/

＜お問い合わせ先＞

静岡県立総合病院　きこえとことばのセンター
静岡県乳幼児聴覚支援センター　事務局

〒420-8527　静岡市葵区北安東 4-27-1

Tel:054(247)6111　Fax:0548247)6171

Mail: gh-nyuyoji-asc@i.shizuoka-pho.jp

Appendix 6 – FLI-P(J) Pre-Final Edition

FUNCTIONAL LISTENING INDEX – PAEDIATRIC (FLI-P)™

チェックシート

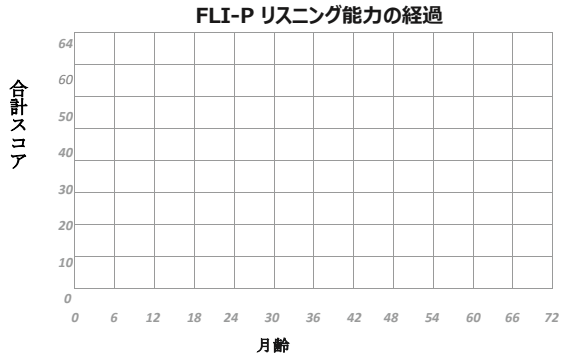
児童名: _____ **生年月日:** _____

このフォームの使用方法

FLI-P（Functional Listening Index）小児用には 6 つのステップがあります。ステップ 1 から始め、各項目の「時々」または「大抵」に☑マークをつけていきます。各ステップの「大抵」のスコアをすべて合わせ、「合計」に記録します。左下の表の「合計スコア」は全ステップの合計スコアです。左下の表にスコアの合計と子どもの月齢、さらに保護者か医療従事者どちらがスコアを付けたのかも記録します。FLI-P のチャートでチェックする際は、毎回、子どもの合計スコアと月齢の接点を右下のグラフに点で記入し、リスニング能力の経過を観察します。

ご利用の際は、ユーザーガイド、項目の詳細、および利用規約をご参照ください。

日付	合計スコア	子どもの月齢	保護者・医療従事者



	時々	大抵	合計
ステップ 1：音に対する反応			
1.1 大きな音にビクッと驚く			
1.2 歌うように話しかけると、こっちを見たり微笑んだりする			
1.3 動物の声や乗り物の音をまねると、少なくとも *3*、*4* つの音に耳をかたむける			
1.4 話し声や歌声、音楽を *20* 秒から *30* 秒間、目で追うものがなくてもしっかりと聞いている			/7
1.5 大き目に出したリング *6* 音全てが聞こえている			
1.6 音がでている方向がわかる			
1.7 ささやき声が聞き取れる			
ステップ 2：音と意味の関連づけ			
2.1 話しかけると、声で返す			
2.2 話しと歌の違いがわかる			
2.3 最低 *2* 人の家族の声がわかる			
2.4 テレビ、タブレット、電話から流れるお気に入りの歌や音楽がわかる			
2.5 童謡を *2*、*3* 曲続けて熱心に聞くことができる、又は大好きな本の読み聞かせに *2*～*3* 分集中できる			
2.6 身近な音が何の音か知っている			/11
2.7 複数人での会話で話している人の顔を見る			
2.8 よく歌っている童謡を聞くと、次にくるフレーズや振り付けがわかる			
2.9 顔が見えなくても、至近距離から普通の声で出すリング *6* 音を全て聞き取ることができる			
2.10 声を聞くだけで、喜んでいるのか怒っているのかわかる			
2.11 振り付けをせず、聞いただけで少なくとも *3* 曲の童謡を認知できる			

チェックシート

FUNCTIONAL LISTENING INDEX – PAEDIATRIC (FLI™-P)

	時々	大抵	合計
ステップ 3：簡単な会話の理解			
3.1 聞き慣れた 3 つの音の真似ができる			/12
3.2 動作や身振りなしで単語や短い文を理解できる			
3.3 鳴き声など *3*～*4* の音を真似た時に、何の音かわかる			
3.4 自分の名前を呼ばれると呼んだ人を見る			
3.5 指で差さなくても、頼んだ物を取ってくれる			
3.6 いくつかの言葉のまねをする			
3.7 リング *6* 音の「ア」「ウ」「イ」「ン」を明瞭に繰り返すことができる			
3.8 リング *6* 音の「ス*(ss)*」と「シ（*sh*)」の違いがわかる			
3.9 大好きな歌の中の言葉を口ずさむ			
3.10 短い文や単語を *10* 個理解できる			
3.11 身近な人やペットなど、名前を *3* つ知っている			
3.12 騒がしい場所でも自分の名前が呼ばれたことがわかる			
ステップ 4：様々な状況での言語理解			
4.1 唐突な、その場とは無関係な簡単な指示に従う			/11
4.2 歌で最初に出てくる振り付けのみでなく、それ以降の振り付けも知っている			
4.3 *2*～*3* 語の簡単なフレーズを繰り返す			
4.4 よく聞く歌の一節を歌うことができる			
4.5 頼んだ *2* つの物を持ってくることができる			
4.6 *1* つの文で *2* つの指示を出し、それに従うことができる			
4.7 リング *6* 音全てを正確に繰り返すことができる			
4.8 テレビやタブレット、スマホで聞いたことのある単語やフレーズの真似をする			
4.9 口に出す音をほとんど真似できる			
4.10 正確にリング *6* 音の全てを *3* メートル以上離れていても繰り返すことができる			
4.11 テレビやタブレット、電話からの質問や指示に従ったり、答えたりできる			
ステップ 5：会話や話を最後まで聞く			
5.1 電話で身近な人の声がわかる			/14
5.2 外で覚えた新しいフレーズを子どもが口にして驚いたことがある			
5.3 部屋の中のある「もの」の説明をすると、それが何なのかわかる			
5.4 大好きな本のあるページの説明をすると、そのページを指摘できる			
5.5 大好きな歌をだいたい歌うことができる			
5.6 大好きなおもちゃや遊びについての簡単な質問に答えることができる			
5.7 音の似ている単語を聞き分けることができ、意味が違うことも理解している			
5.8 頼んだ *3* つの物を持ってくることができる			
5.9 事前に何について話すかを伝えれば、短い会話ができる			
5.10 同じ文の中に *3* つの指示を入れても、それに従うことができる			
5.11 知っている物や動物について、ヒントを出せばそれが何なのか当てることができる			
5.12 知っている単語 *5*～*6* 個を使った文を正確に繰り返すことができる			
5.13 物の名前を *3* つか *4* つ言うと、その共通点がわかる			
5.14 頼んだ *4* つの物を持ってくることができる			
ステップ 6：様々な日常生活での聴き取りを向上する			
6.1 電話で身近な人と簡単な会話ができる			/9
6.2 ヒントを出すと、身近なものでなくてもそれが何か当てることができる			
6.3 一緒に本を読んだ後で、その本の中の出来事を正しい順序で覚えている			
6.4 新しい単語が *1* つか *2* つ入っていても、*8*～*10* 語の文を簡単に繰り返すことができる。			
6.5 言い方によって文の意味が変わることを理解している			
6.6 分節を *5* つ以上含む複雑な指示に従うことができる			
6.7 テレビやタブレット、電話で聞いた *8*～*10* 語の文を、新しい単語が少しあっても簡単に繰り返すことができる			
6.8 騒がしい場所でも、指示に従ったり、会話したり、話を聞いたり、質問に答えることができる			
6.9 騒がしい場所でも、電話で会話をしたり、デジタル機器からの音声を聞いたり、質問に答えたり、その内容について話すこともできる			

Appendix 7 – EHDI-IS Evaluation Descriptors

The Shall, Should, and May priorities are indicated at the beginning of each statement.

Goal 1 – Document unduplicated individually identifiable data on the delivery of newborn hearing screening services for all infants born in the jurisdiction.

1.1 (Shall) Provide unique patient record for each newborn child in the jurisdiction
1.2 (Shall) Receive and document information about patient's birth encounter and newborn admission information in a timely manner.
1.3 (Shall) Receive and document patient's maternal demographic information.
1.4 (Shall) Receive and document all individual newborn hearing screening procedures and results, in a timely manner.
1.5 (Should) Receive and document information about risk factors of infant hearing loss at the time of newborn hearing screening.
1.6 (Shall) Review incoming and existing patient records and document the most recent newborn hearing screening status and outcomes of the patient.
1.7 (Shall) Receive and document information on the reason why an infant hearing screening is not performed or completed.
1.8 (Shall) Provide the ability to capture and document information about an infant's NICU stay and transfer status.
1.9 (May) Receive submissions of newborn hearing screening information in accordance with interoperability standards endorsed by CDC for message content, format, and transport.

Goal 2 – Support tracking and documentation of the delivery of follow-up services for every infant/child who did not receive, complete, or pass newborn hearing screening.

2.1 (Should) Provide a unique patient record for each infant/child born out of the jurisdiction but currently reside within the jurisdiction and is in need of hearing screening or diagnostic follow-up.
2.2 (Shall) Provide the ability to generate and present a list of infants who did not pass newborn hearing screening and are in need of follow-up rescreening and/or diagnostic evaluation.
2.3 (Shall) Provide the ability to generate and present a list of infants who did not receive or complete newborn hearing screening and are in need of recommended screening and/or diagnostic evaluation.
2.4 (May) Provide the ability to make referrals for recommended follow-up services.
2.5 (Shall) Receive and document referrals made.
2.6 (Shall) Receive and document information on screening procedures and results in a timely manner. *
2.7 (Shall) Receive and document information on procedures and results of ALL follow-up audiological diagnostic evaluation services in a timely manner. *
2.8 (Shall) Receive and document information whenever there is a change in the patient's hearing status and/or an update on previously inconclusive/incomplete diagnostic result.

2.9 (Should) Receive and document information about referrals and/or recommendations made following an audiological diagnostic evaluation.
2.10 (Shall) Receive and document information on the reason why an infant did not receive recommended follow-up services.
2.11 (Should) Provide the ability to notify parents and healthcare providers of infants who are in need of follow-up services.
2.12 (May) Provide the ability to generate, present, and transmit a standard-based Hearing Plan of Care document to guide follow-up practices. *

Goal 3: Document ALL cases of permanent hearing loss, including congenital, late-onset, progressive, and acquired cases for infants/children <3 years old.

1.1 (Shall) Receive and document information on all confirmed hearing loss cases identified through the newborn hearing screening follow-up process and reported from audiological providers.
1.2 (Shall) Provide the ability to receive and document information on additional infants/children with hearing loss that are not identified through the newborn hearing screening follow-up process. *
1.3 (Shall) Use the ASHA standards for classifying degree of hearing loss.
1.4 (Shall) Provide the ability to generate and present the patient's complete screening and diagnostic service history including date, location, type, and results of tests performed and/or diagnosis made, for every documented permanent hearing loss case in the EHDI-IS.
1.5 (Should) Receive and document information on hearing loss risk factors.
1.6 (Should) Provide the ability to regularly evaluate incoming and existing hearing screening and diagnostic information to continually refine, modify, and efficiently identify late onset, progressive, and acquired hearing loss.
1.7 (Shall) Provide the ability to generate and present separate lists of infants/children with presumed congenital (referred on newborn hearing screening) and late-onset/progressive/acquired hearing loss.

Goal 4: Document the enrollment status, delivery, and outcome of early intervention (EI) services for infants and children with hearing loss <3 years old.

4.1 (Shall) Provide the ability to identify infants/children who need EI services.
4.2 (Shall) Receive and document information about referrals to Part C services.
4.3 (Shall) Receive and document information about eligibility to Part C services.
4.4 (Shall) Receive and document information on Part C early intervention services enrollment.
4.5 (Shall) Receive and document information on other not-Part C early intervention services enrollment. *
4.6 (Should) Receive and document recommended audiologic intervention method upon a hearing loss diagnosis from providers.
4.7 (Should) Provide the ability to receive and document data on early intervention outcomes.
4.8 (Should) Provide the ability to receive information from Part C on children who have a hearing loss that were identified in Part C but were not previously reported to EHDI.

4.9 (Should) Provide the ability to generate letters or other communication materials to notify or remind parents, healthcare and EI providers of infants' need for EI services.
4.10 (Should) Provide the ability to receive and document information about comorbidity – e.g., a child who is automatically in Part C for an established condition that is NOT hearing loss, but the child is later diagnosed with hearing loss.
4.11 (Should) Receive and document information about a child transitioning out of or leaving Part C EI services.
4.12 (May) Receive and document information what Part C EI services are planned for children who are diagnosed with hearing loss.
4.13 (May) Receive and document the referral disposition for children in the EHDI-IS who are eligible for Part B 619 services.

Goal 5: Maintain data quality (accurate, complete, timely data) of individual newborn hearing screening, follow-up and diagnosis, early intervention, and demographic information in the EHDI-IS.

5.1 (Shall) Provide the ability to regularly evaluate incoming and existing patient records to identify, prevent, and resolve duplicate and fragmented records.
5.2 (Shall) Store all EHDI-IS minimum Data Elements. (Completeness, Uniqueness, Timeliness, Validity, Accuracy, Consistency)
5.3 (Shall) Provide the ability to obtain other Core Data Elements.
5.4 (Should) Provide the ability to obtain Extended Data Elements.
5.5 (Shall) Provide the ability to analyze information with respect to data quality. *
5.6 (Shall) Retain all patient data in the system until the patient reaches at least 3 years old, except where prohibited by law, regulation, or policy.
5.7 (Should) Allow re-activation of a case when new information has arrived that illuminates the disposition of a case.
5.8 (Should) Provide the ability for staff to record notes on phone interactions with the public under each child's file.
5.9 (Should) Provide the users with easy access to metadata, system documentation and a user guide.

Goal 6: Preserve the integrity, security, availability and privacy of all personally-identifiable health and demographic data in the EHDI-IS.

6.1 (Shall) Have written confidentiality privacy practices and policies based on applicable law or regulation that protect all individuals whose data are contained in the system.
6.2 (Shall) Have written data sharing and confidentiality/privacy agreement with any other information systems which the system links to and/or shares data with.
6.3 (Shall) Have user access controls and logging, including distinct credentials for each user, least-privilege access, and routine maintenance of access privileges.
6.4 (Shall) Operated or hosted on secure hardware and software in accordance with industry standards for protected health information, including standards for security/encryption, uptime, and disaster recovery.

Goal 7: Enable evaluation and data analysis activities.

1.1 (Shall) Provide the ability for authorized users to extract and use data to assess program progress towards achieving national/jurisdictional benchmarks.
1.2 (Should) Provide the ability to generate performance measurement reports, as defined by the jurisdictional system evaluation plan.
1.3 (Should) Provide the ability for authorized users to export data to other data management and analytical software tools such as MS Excel, SAS, SPSS, etc.

Goal 8: Support dissemination of EHDI information to authorized stakeholders.
8.1 (Shall) Provide the ability to generate, present and transmit standard and/or custom-defined reports for authorized users without assistance from system vendor or IT personnel.
8.2 (Should) Provide the ability for authorized healthcare providers to electronically access newborn hearing screening and follow-up service information of their patients.

* (In accordance with scope of practice, organizational policy and jurisdictional law)