NEWBORN SCREENING IN NEBRASKA

ANNUAL REPORT TO THE LEGISLATURE

BLOODSPOT SCREENING FOR CONGENITAL INHERITED DISORDERS AND EARLY HEARING DETECTION & INTERVENTION

2021

NEBRASKA
Good Life. Great Mission.
DEPT. OF HEALTH AND HUMAN SERVICES

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ONE FAMILY'S STORY

In May 2022, our last little one was born, just like any other birth, for the most part. Miss Olivia made her entrance, and after going to the bathroom all over me twice, everything seemed to go normal. The birth, the stay, the feedings. Everything was just like my other two children.

Olivia wasn't even a week old when we got the call from our pediatrician, saying Olivia needed to come in to get a few tests done. We were told that one of the things they tested for with the newborn screening at birth came back very elevated.

Of course, we go right in. Get tests to confirm. Our pediatrician gave us a quick rundown of what was elevated and what we could expect.

We were told that it is very rare and that without treatment, results could be deadly.

We got a call from Children's Hospital in Omaha, saying we needed to come down for further testing right away. So we load up and head from Grand Island to Omaha. We got the testing, then left with some sliver of hope that maybe the tests were wrong.

That night, right after we got back home, we got the call that we needed to come back right away and go to UNMC. We leave the next morning, packed for a few days. Little did we know we would be staying for almost two weeks.

Olivia was admitted for observation of her liver, just one of the many side effects of Tyrosinemia Type 1. Tyrosinemia Type 1 can affect the heart, liver, and brain. She was born with basically two broken genes that help her process protein.

Olivia Prinzing
Courtesy of the Prinzing Family

I never realized processing protein was such a major life-threatening issue. She will forever be on a very strict vegan diet, always drinking formula and always taking a pill.

She has to do blood spot tests to keep an eye on her protein levels (among many other things). If they get too high or even too low, she may end up back in the hospital. There is no cure; the only thing that would help is a liver transplant. But that is a last resort.

We came to find out Olivia is the only one in Nebraska to be diagnosed with this. If it wasn't for that newborn screening at birth, the results for Olivia could have been deadly. We couldn't have been more thankful for that test and all the doctors and her dietitian she has to help keep her healthy.

Shayla and Matthew Prinzing

SCREENING

Nebraska's statute governing newborn screening (Neb. Rev. Stat. §§71-519 through 71-524) requires every baby born in Nebraska to receive the screening.

If not detected and treated in time, the effects can include brain and nerve cell damage, resulting in severe intellectual disability and damage to the infant or child's heart, kidney, liver, spleen, eyes, and hearing, physical growth problems, stroke, overwhelming infection, and infant death.

Newborn screening is a system coordinated by the Nebraska Department of Health and Human Services (NDHHS) Newborn Screening Program.

The system requires collaboration with hospitals, laboratories, healthcare professionals, and families and involves many elements, including:

- Proper and timely collection of quality specimens.
- Appropriate and timely transport of samples to the newborn screening laboratory.
- Rapid quality testing methods.
- Timely notification of the infant's physician.
- Appropriate referral of family to specialists for diagnosis, treatment, and counseling.
- Ensure access to needed specialized services and treatment for diagnosed infants.
- Evaluation and Quality Assurance/ Improvement efforts.

The goal of newborn bloodspot screening is to identify otherwise well-appearing newborns with life-threatening and debilitating conditions that would likely not be detected until damage has occurred.

SYSTEM OVERVIEW

The Department of Health and Human Services administers the program. The program partners with pediatric sub-specialists who see infants with positive screens to establish diagnosis and treatment.

An advisory committee meets quarterly to discuss technical and policy issues, monitor quality, and update professional and parent education. The advisory committee's membership consists of pediatric sub-specialists, pathologists, chemists, pediatricians, neonatologists, family practitioners, and representatives from the Nebraska Hospital Association, the Nebraska Medical Association, and families of affected children.

The follow-up staff at the Department of Health and Human Services ensures that the healthcare provider for every newborn who requires additional testing receives the necessary education to act accordingly and continues to follow up with calls, faxed letters, and education until the diagnosis is made or ruled out. The program conducts ongoing evaluation and quality assurance activities throughout the year.

METABOLIC FOODS AND FORMULA

The statute governing newborn screening in Nebraska also requires the Department to provide metabolic formula and foods to eligible patients (Neb. Rev. Stat. §71-520). Patients can be reimbursed up to $2000 per year for qualifying foods, and those meeting financial hardship criteria may be able to have the foods ordered for them by the Department.

The dieticians at Children's hospital work closely with the program to advise what foods are available that comply with statutory requirements as pharmaceutically manufactured foods that aid individuals in keeping the best control of their metabolic disorders for which this food is prescribed.

The program administers a contract for the ordering and distributing metabolic formula, in addition to a reimbursement system for metabolic foods, which ensures access to treatment for eligible individuals with inborn errors of metabolism.

The Nebraska Newborn Screening Program screens for 33 diseases with the healstick blood test that would likely not be detected until the infant becomes symptomatic. Better results are seen when infants are treated when they are asymptomatic, including the ability to save the infant's life or keep them from a lifetime of disability.

In 2021, this resulted in identifying and treating 61 newborns in time to prevent or reduce problems associated with specified conditions.

NEWBORN SCREENING BY THE NUMBERS

57,456
Total samples in 2021

24,799
Number of Births 2021

CONFIRMED POSITIVE FOR DISEASE
61
Diagnosis listed above is provided by baby's physician or specialist

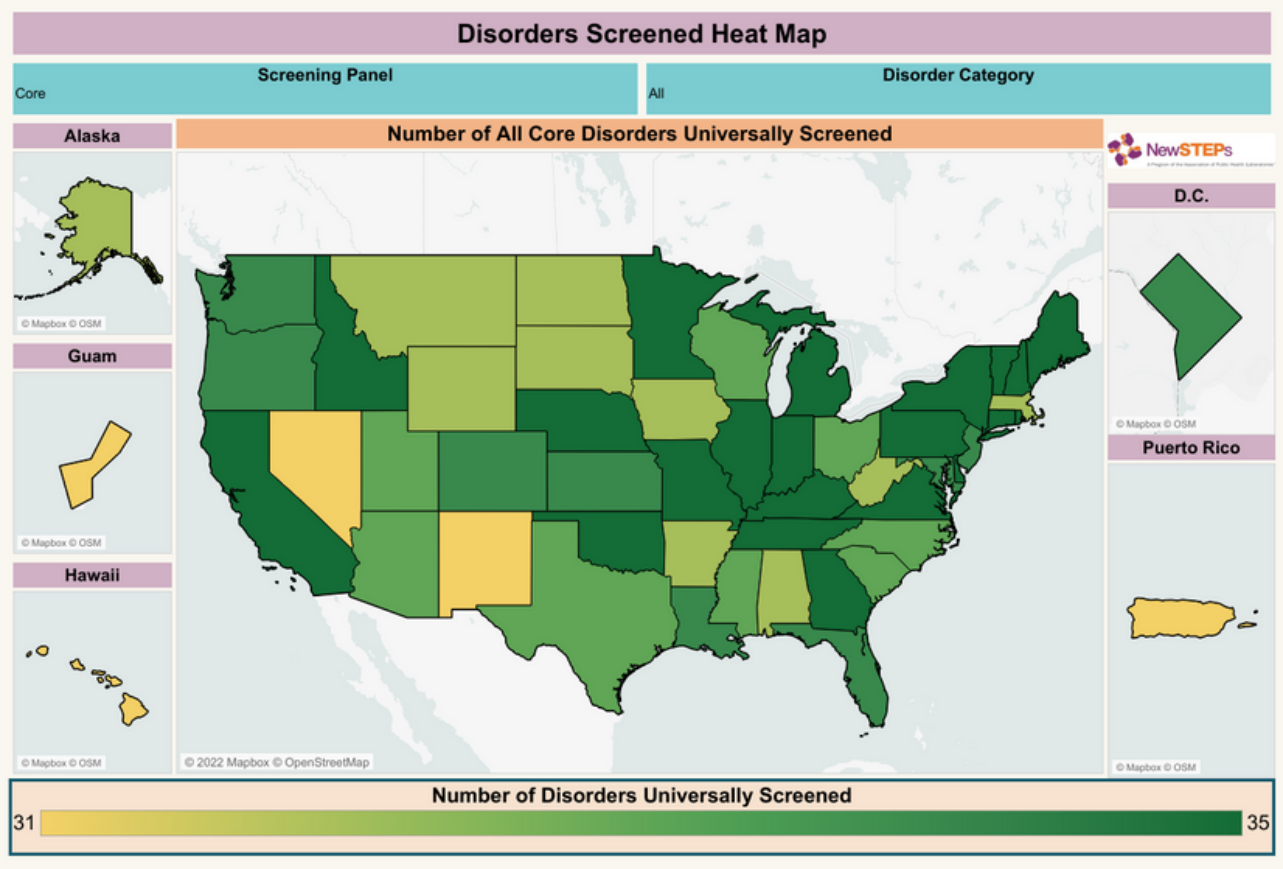
NUMBER OF HEMOGLOBINOPATHIES
453
Cases of hemoglobinopathies-Sickle Cell Disease, Thalessemia+Traits

2021 Confirmed Positives by Disease Type

Partial Biotinidase Deficiency	8
Mild Non-Classical CAH	1
Hypothyroidism (Congenital, Transient and Primary	18
Elevated TSH Due to Maternal Thyroid Antibodies	1
Other Specified Disorders of Thyroid	1
Cystic Fibrosis	9
CFTR-Related Metabolic Syndrome (CRMS)	1
Hemoglobin Disorders inlcuding Sickle Cell Disease	7
Arginase Deficiency (Argininemia)	1
Argininosuccinic Aciduria (ASA)	1
Glutaric Acidemia Type 1	1
Multiple acyl-CoA dehydrogenation deficiency (MADD Disease) (GA Type II) 1	1
Cobalamin (Vitamin B12) Metabolic Defect	1
Transient Tyrosinemia	3
Hyperphenylalaninemia (not treated)	1
Mucopolysaccharidoses type 1(MPS-1)	0
Pompe Disease (Later On-Set)	1
X-ALD (male)	2
X-ALD heterozygote (female)	1
Spinal Muscular Atrophy (SMA)	3

NEBRASKA NEWBORN BLOODSPOT SCREENING VS. OTHER STATES AND TERRITORIES

Nebraska is one of only 16 States Screening for ALL disorders recommended by the Recommended Universal Screening Panel, including Spinal Muscular Atrophy, which was added following legislation on November 14, 2020.



Heat Map by Number of Disorders Screened
Chart Courtesy Association of Public Health Laboratories (APHL)

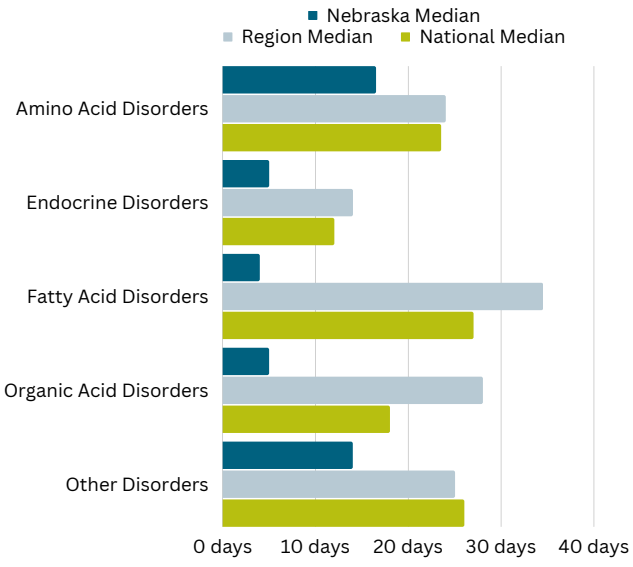
Spinal Muscular Atrophy is the leading genetic cause of death in young children. Nebraska had been prepared for years to add this disease to its panel due to the ability of its contract laboratory, PerkinElmer, to run advanced genetic testing. Much larger states have only recently begun screening for this disorder due to the complexity of the screening and often do not provide as much genetic information as Nebraska's laboratory. State public health laboratories in the region have not yet begun to screen for this devastating illness due to these technical restraints. Hence, infants born in Nebraska benefit from the State's commitment to Newborn Screening.

NEBRASKA TIME TO TREATMENT

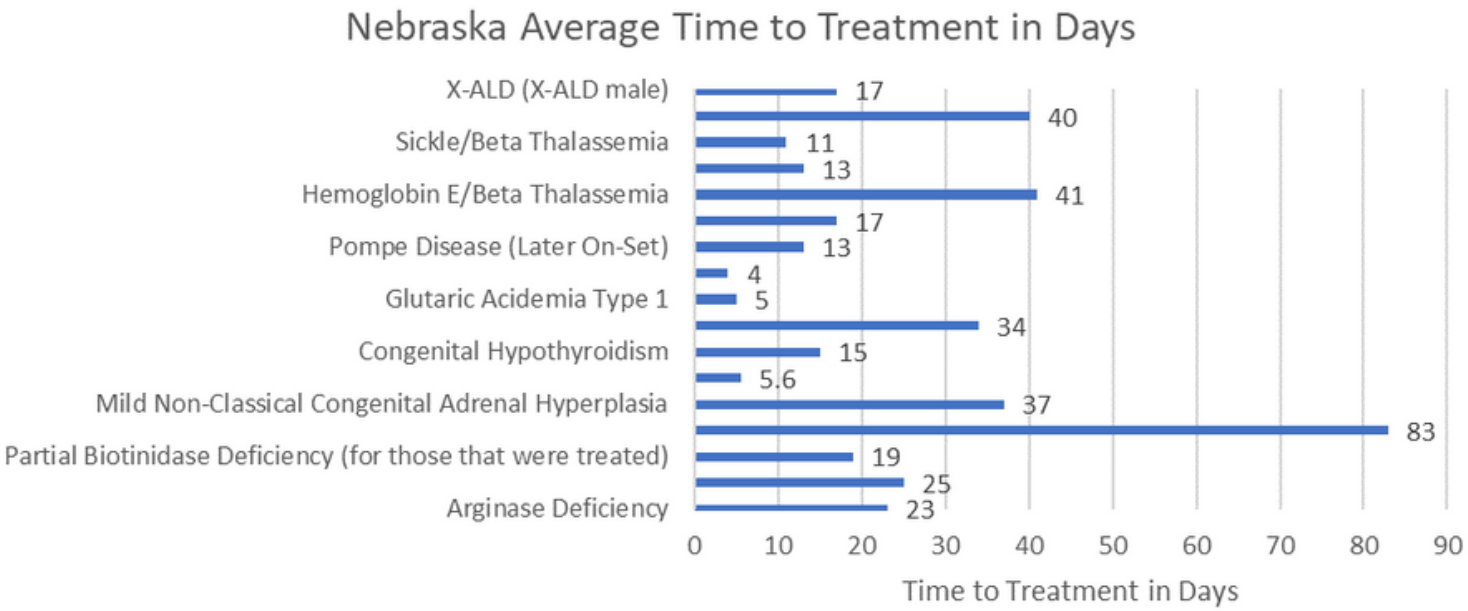
"It's second-to-none, especially in this part of the United States. I became involved with the program the first year I was here. It's a satisfying thing, it's good for everybody in the state, and you get to work with a big team of people, public and private."-

Dr. Richard Lutz, MD, retired Clinical Geneticist and Pediatric Endocrinologist member of the Nebraska Newborn Screening Advisory Committee.

Nebraska Time to Treatment Median vs. Regional and National Medians by Disorder Category in Days



Data Courtesy Association of Public Health Laboratories (APHL)



Data Courtesy Nebraska Newborn Screening Program

ADVISORY COMMITTEE

The Committee monitors national recommendations, trends, and reports and advises the program on recommended next steps, methods, or strategies. Nebraska's success can be directly tied to the Committee's recommendations and guidance. Nebraska's newborn population, families, and the program all benefit from the advisors who provide technical expertise and policy guidance to the Nebraska Newborn Screening Program.

Special thanks to Dr. Zoe González-García, MD (Children's), for chairing the Committee and to Dr. Jill Skrabal, Ph.D. (Children's), who served as Vice-Chair in 2021.

2021 Newborn Screening Advisory Committee

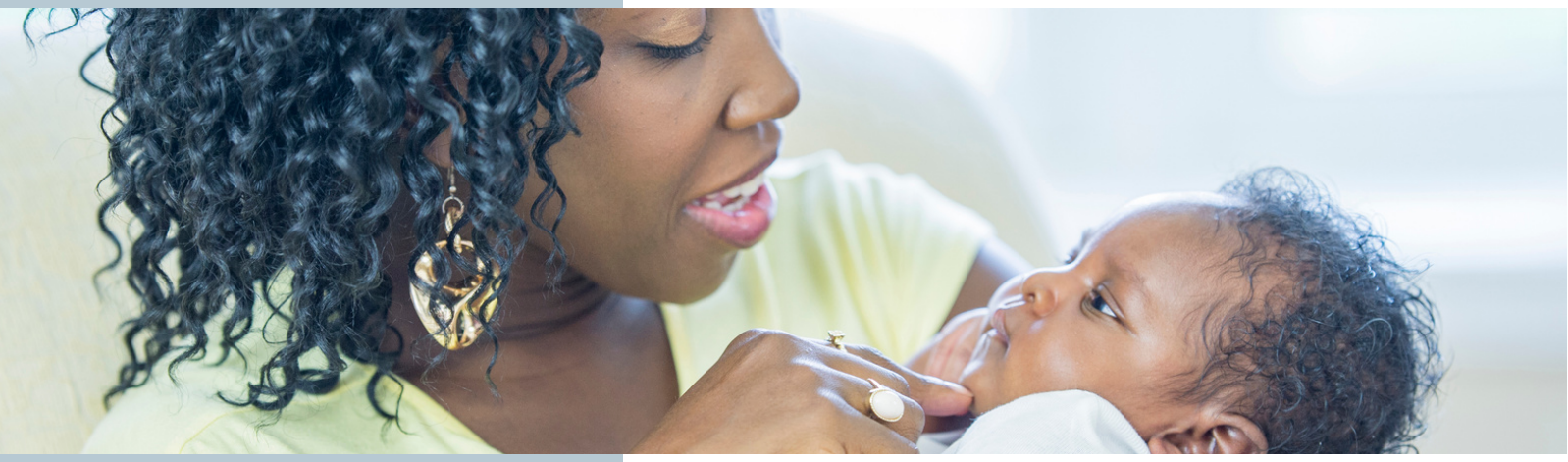
Jill Allen, RN	Nebraska Hospital Association
Khalid Awad, MD	Neonatology
Craig Baker, MD	Pediatric Genetics
Lawrence Bausch, MD	Neonatology
Angela Brennan, MD	Family Practice
Catherine Brooks, DO	Neonatology
Alyssa Cady, MS, CGC	Genetic Counseling
Jeanne Egger	Parent /Advocate
Zoe González-García, MD (CHAIR)	Pediatric Endocrinology
Jessica Hansen, MSN, FNP-C	Pediatric Genetics
James Harper, MD	Pediatric Hematology
Kathryn Heldt, RD	Metabolic Nutrition
Mary Kisicki, RN	Parent / Advocate
Richard Lutz, MD	Pediatric Endocrine, Metabolism, Genetics
Tiffany Moore, PhD, RN	Parent / Advocate
Hana Niebur, MD	Pediatric Immunology
Deborah Perry, MD	Pediatric Pathology
Samuel Pirruccello, MD	Pathology
Geetanjali Rathore, MD	Pediatric Neurology
Robert Rauner	ALD Foundation Advocate / Parent / Advocate
William Rizzo, MD	Pediatric Metabolism, Genetics
Kathy Rossiter, EJD, MSN, APRN	Medical Ethics Advisor
Jill Skrabal, Ph.D., RD (VICE CHAIR)	Metabolic Nutrition
Heather Thomas, MD	Cystic Fibrosis Clinic
Jamise Williams, MS	Parent / Advocate

NEBRASKA EARLY HEARING DETECTION AND INTERVENTION ANNUAL REPORT

The Nebraska Early Hearing Detection and Intervention Program develops, promotes, and supports systems to ensure all newborns in Nebraska receive hearing screenings, family-centered evaluations, and early intervention as appropriate.

Approximately one to three in 1,000 babies are born with permanent hearing loss, making hearing loss one of the most common birth defects in America.

Early detection and intervention provides the opportunity to engage in early intervention to reduce delays in language acquisition, academic achievement, and social and emotional development.



NEBRASKA INFANT HEARING ACT

The act also requires birthing facilities to educate parents about newborn hearing screening and any necessary follow-up care. The education includes information about the hearing screening test, the likelihood of the newborn having a hearing loss, follow-up procedures, and community resources, including referral for early intervention and a description of the normal auditory, speech, and language developmental process in children.

In addition, the act requires that regulations be promulgated to mandate newborn hearing screening if less than 95% of newborns in the state receive a hearing screening.

The Infant Hearing Act became a state law in Nebraska in 2000 and required the hearing screening of newborns in birthing facilities in Nebraska as a standard of care. Also in 2000, the Nebraska Department of Health and Human Services (DHHS) started the Nebraska Newborn Hearing Screening Program. Today the program is known as the Nebraska Early Hearing Detection and Intervention (NE-EHDI) Program and is funded through federal grants. This program strives to fulfill the following four main purposes of the Infant Hearing Act (Neb. Rev. Stat. §71-4735):

- **To provide early detection of hearing loss in newborns at the birthing facility, or as soon after birth as possible for those children born outside of a birthing facility.**
- **To enable these children, their families, and other caregivers to obtain needed multidisciplinary evaluation, treatment, and intervention services at the earliest opportunity.**
- **To prevent or mitigate the developmental delays and academic failures associated with late detection of hearing loss.**
- **To provide the state with the information necessary to effectively plan, establish, and evaluate a comprehensive system for the identification of newborns and infants who have hearing loss.**

BIRTHING FACILITY SCREENING PROGRAMS

Since 2003, 100% of the birthing facilities in Nebraska have been conducting hearing screenings, consistent with the Neb. Rev. Stat. §71-4742 requirement that a hearing screening test be included as part of the standard of care for newborns. In 2021, there were 51 birthing facilities conducting hearing screenings.

The COVID-19 Pandemic continues to impact aspects of NE-EHDI's work. "EHDI Process during COVID-19 Pandemic" was the first topic of information on the NE-EHDI website http://dhhs.ne.gov/EHDI in 2021. This provided information and resources to the public and healthcare providers on various topics related to hearing screenings. The EHDI follow-up team continues to see early discharges of newborns and hesitancy from parents in scheduling additional appointments, causing other follow-up work to ensure each infant is appropriately screened for differences in hearing.

PARENT EDUCATION

Recommending a hearing screening has been operationally defined as educating parents about newborn hearing screening, hearing loss, and normal communication development as required by Neb. Rev. Stat. §71-4740. The NE-EHDI Program provides free print and video educational materials to hospitals to help fulfill this requirement. Print materials are available in 14 languages.

Birthing facilities reported educating over 99% of parents about newborn hearing screening, hearing loss, and normal speech and language development in 2021. The statute also requires the Nebraska Department of Health and Human Services to educate parents of newborns not born in a birthing facility about the importance of newborn hearing screening and to provide information to assist them in having the screening performed within one month after the child's birth. This is accomplished through letters, phone calls, and printed materials to parents.

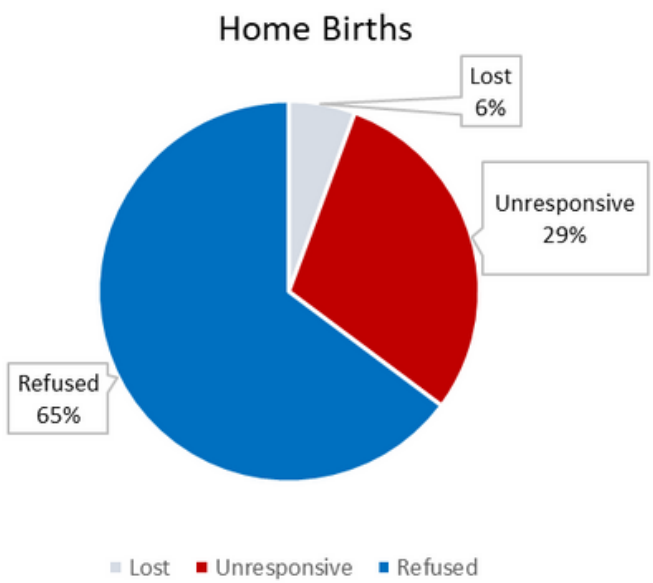
When an infant is identified as deaf or hard of hearing, parent(s) receive the Parent Resource Guide (PRG) from the audiologist, and a notification letter is sent to the primary health care provider. Hands & Voices (H&V)/Guide By Your Side (GBYS) Parent Guides also discuss the PRG with families to provide support and stress the importance of starting early intervention as soon as possible. The PRG was developed by NE-EHDI with the collaboration of many partners and is available in print or online at http://dhhs.ne.gov/EHDI-PRG.

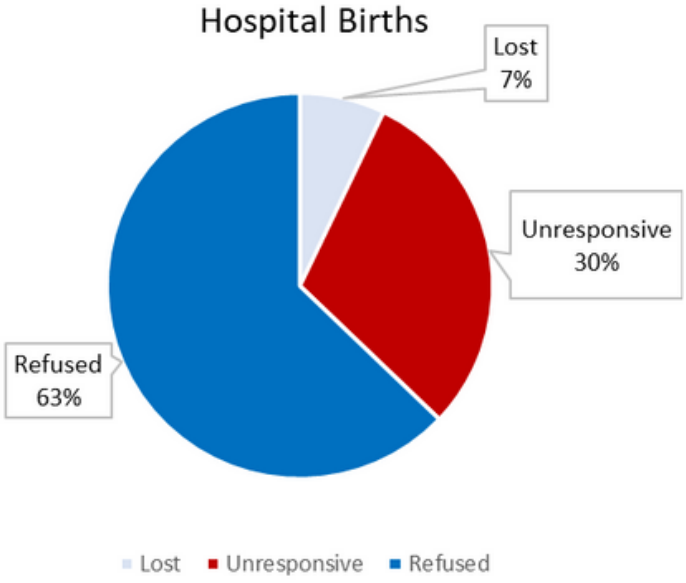
The NE-EHDI Program funding is received from the Health Resources and Services Administration/Maternal and Child Health Bureau (HRSA/MCHB), the Centers for Disease Control and Prevention (CDC), and the Maternal and Child Health (MCH) Title V Block Grant. The HRSA/MCHB grant funds the basic operations of the NE-EHDI Program. The CDC cooperative agreement primarily funds the development, implementation, and maintenance of the integrated electronic data reporting and tracking system. The MCH Title V Block Grant supplements funding for a small amount of the necessary operations costs for the NE-EHDI Program.

HEARING SCREENING AND FOLLOW-UP RESULTS

In 2021, 23,146 (94.3%) of those who received an inpatient hearing screening in Nebraska passed. An outpatient hearing screening or audiology evaluation is recommended for infants who do not pass the inpatient screening or who do not receive the inpatient screening.

Passed the screening or diagnostic testing	**24,471**
Expired inpatient or outpatient	**91**
Pending final screening or diagnostic testing	**23**
Diagnosed deaf or hard of hearing	**61**
Parents refused screening and/or diagnostic testing	**67**
Unresponsive (Parents did not complete protocol after communication with NE-EHDI program)	**65**
Lost (no respose to NE-EHDI letters and phone calls)	**9**
Moved out of Nebraska	**8**
Late onset deaf or hard of hearing (passed initial screening)	**4**
Total births tracked by the NE-EHDI program	**24,799**





TIMELINESS OF FOLLOW-UP PROCESS

The Joint Committee on Infant Hearing (JCIH) established guidelines suggesting that a hearing screening be completed by 1 month of age, an audiologic diagnostic evaluation be completed by 3 months, and, if needed, enrollment in early intervention be completed by 6 months. Over 96% of infants completed the inpatient/outpatient screening within one month of age. For the newborns who were recommended for an audiologic diagnosis, nearly 68% received the evaluation by 3 months of age in Nebraska (as of August 2022). This percentage is preliminary and will likely decrease due to the number of infants having an initial diagnostic evaluation and needing a confirmatory evaluation.

Records for the Early Development Network (EDN), Nebraska's Part C Early Intervention
The program indicates that 86% of infants residing in Nebraska that was diagnosed as deaf or hard of hearing were enrolled in EDN services by 6 months of age for families accepting Part-C services (as of August 2022).

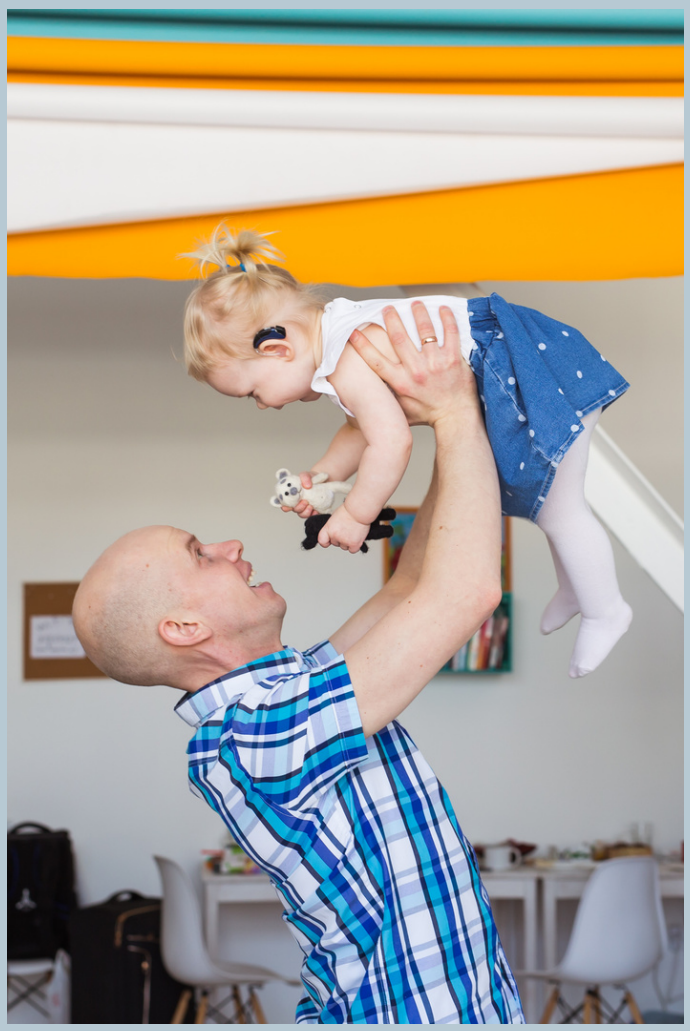
The purpose of the Infant Hearing Act (Neb. Rev. Stat. §71-4735) is to "... obtain needed multidisciplinary evaluation, treatment, and intervention services at the earliest opportunity and to prevent or mitigate the developmental delays and academic failures associated with late detection of hearing loss."

NEBRASKA EHDI ADVISORY COMMITTEE

The purpose of the NE-EHDI Advisory Committee is to provide direction and guidance to the NE-EHDI program regarding the newborn hearing screening system. Specific Advisory Committee activities include discussing and advising on goals for the NE-EHDI program, advising on the improvement of reporting and follow up protocols, assisting with increasing the program's responsiveness to the expanding cultural and linguistic communities, and guiding the long term planning and evaluation of the NE-EHDI system in the state.

Jessica Anthony	Early Development Network
Lisa Hobza	PTI Nebraska
Colleen Richart	Parent/Hard of Hearing Advocate/Advisor
Jonathan Arteaga	Nebraska Association of the Deaf
Jessica Hoss	Nebraska Hands & Voices/Guide By Your Side Parent Guide
Karen Rolf, Ph.D	Retired- Public Health Experience/Parent
Laura Beschaler, Au. D., CCC-A	Millard Public Schools
Shelli Janning	Nebraska Hands & Voices/Guide By Your Side Program Coordinator/Parent
Merry Spratford, Au. D., CCC-A	Boys Town National Research Hospital
Katie R. Brennan, MS, CCC-SLP (Vice Chair)	Barkley Center for Communications, UNL
Jayden Jensen	Deaf & Hard of Hearing Advocate/Advisor
Anne E. Thomas, Ph.D	University of Nebraska-Lincoln Dept. of SPED & Communication Disorders
Amy Bunnell	Early Development Network
Kim Texel	Head Start State Collaboration Office
Cole Johnson	Special Education Office, Nebraska Department of Education
Kristin Jolkowski, Au.D., CCC-A	Educational Audiologist, Lincoln Public Schools
Carlena Conard	York General Hospital- OB Director
Kristin Jolkowski, AuD., CCC-A	Lincoln Public Schools
Joanna Webster, Au.D, CCC-A	Children's Hospital & Medical Center
Brad Czaplewski	Deaf Educator, Educational Service Unit # 10
Ashley Kaufman, Au.D, CCC-A	Boys Town National Research Hospital
Stacie Ray, Au.D., CCC-A (Chair)	University of Nebraska-Lincoln Dept. of SPED & Communication Disorders/Nebraska Hearing Aid Banks Director/Parent
Susan Whitaker	Nebraska Commission for the Deaf & Hard of Hearing
Sue Czaplewski	Nebraska Department of Education- ESU #9
Sara Peterson	Teacher of the Deaf, ESU #13
Jana Wiblishouser	Parent/Advocate Advisor
Linsay Darnell, Jr	Deaf Advocate/Advisor
Kelly Rausch	Parent/Advocate Advisor
Pam Zegers, M.D.	Pediatrician, Complete Children's Health
Heather Gomes, MD (Chapter Champion)	Boys Town Otolaryngologist

NEBRASKA EHDI PROJECTS



Hands & Voices/Guide By Your Side

NE-EHDI collaborates with Nebraska Hands and Voices/Guide By Your Side (GBYS) by providing funds through a subaward to assist with family support to families with children that have been identified as Deaf or Hard of Hearing. The Hands and Voices Coordinator also assists with EHDI follow-up and educates families about the hearing screening process. This allows families to relate with a parent who has also experienced a child having varying degrees of hearing. There were 15 trained Parent Guides available to respond to the needs of families in Nebraska through this program, and they are actively serving 185 families.

Hands & Voices also hosts events throughout the year to provide networking opportunities for their families, including:

- Moms Night Inn in Scottsbluff & Lincoln
- Family Gatherings at PE 101 in Omaha, Kearney Children's Museum in Kearney, Rock-N-Joes in Lincoln
- Annual GBYS meeting in Lincoln
- Easter Egg Hunt in La Vista

HearU

The NE-EHDI Program continued to provide funds for the administration of HearU Nebraska and to help purchase loaner hearing aids in 2021. In 2021 there were 54 hearing aids provided and fitted for 29 children (age range of 1 month to 18 years) with “free” hearing aids provided by HearU Nebraska. Since 2008, HearU has provided 875 hearing aids were fitted to 533 children.

Parent Scholarships to the EHDI National Conference

NE-EHDI provided scholarships to two families who have children identified as deaf or hard of hearing to virtually attend the EHDI Annual National Meeting per our HRSA funding requirement. These parents could share their experiences with other NE-EHDI stakeholders at the Advisory Committee meeting and the Nebraska Stakeholder meeting, which was held after the virtual EHDI conference.

Program Staff

The staff of the **Nebraska Newborn Screening (Blood-spot) Program** is available to help with your questions at the numbers listed below. General areas of responsibility are listed:

Jillian Chance, Newborn Screening/Genetics Program Manager (402) 471-6733
Program planning, evaluation, and management, professional and patient education, metabolic formula
Krystal Baumert, Inherited Diseases Clinical Specialist (402) 471-0374
Metabolic, Congenital Primary Hypothyroidism, SCID, X-ALD, transfusions, and lysosomal storage conditions.
Sarah Ward, Inherited Diseases Clinical Specialist (402) 471-6558
Hemoglobinopathies, cystic fibrosis, Congenital Adrenal Hyperplasia
Michaela Howard, Inherited Diseases Quality Assurance/Improvement Specialist (402) 471-9731
Drawn early and unsatisfactory specimens, hospital QA monitoring, metabolic foods program, and homebirths

Website: http://dhhs.ne.gov/Pages/Newborn-Screening.aspx
E-mail contact: dhhs.newbornscreening@nebraska.gov
E-FAX: (402) 742-2332

Nebraska Newborn Screening Program
Department of Health and Human Services
P.O. Box 95026
Lincoln, NE 68509-5026

PerkinElmer Genetics Screening Laboratory Director Joseph Quashnock, Ph.D. 412-220-2300 (Pennsylvania)
PerkinElmer Genetics Screening, General Manager, PJ Borandi, 412-220-2300
****

The staff of the **Nebraska Early Hearing Detection & Intervention Program** is available to help with your questions at the numbers listed below. General areas of responsibility are listed:

Amanda Adams, Program Manager (402) 471-6770
Program planning, evaluation, and management, professional education, systems development
Jim Beavers, Business Analyst, (402) 471-1526 (Contract, part-time)
Data system planning and testing, development of reports, system security, training, and technical assistance
Angel Sumpter, Community Health Educator Senior, (402) 471-3579
Follow-up coordinator, the medical community and parent education, data management
Brittany Biere, Community Health Educator, (402) 471-6746 (SOS, part-time)
Follow-up, complex diagnostics, community outreach, special projects
Shelli Janning, Community Outreach Coordinator, (402) 237-9007 (contractor, part-time)
Follow-up, community outreach, education, family support

Website: http://dhhs.ne.gov/EHDI
E-mail: DHHS.NEEHDI@nebraska.gov
E-Fax: (402) 742-2395

Nebraska Early Hearing Detection & Intervention Program
Lifespan Health Services, Division of Public Health, DHHS
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Disclosures

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Any reference to a specific commercial product in the Newborn Hearing Screening section does not constitute or imply an endorsement, recommendation, or favoring by the Nebraska Early Hearing Detection & Intervention Program.

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