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GENERAL INFORMATION

Title of Dataset: Clinical factors in Aminoglycoside-Induced Ototoxicity in Neonates

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Dates of data collection:
Data collection started in August 2020 and ended in June 2023.

Geographic location of data collection:
Data was collected at neonatal intensive care units (NICUs), audiology clinics, and/or research laboratories at three sites:

- Oregon Health & Science University (OHSU), Portland, OR, USA
- University of Nebraska Medical Center: Children's Nebraska (UNMC), Omaha, NE, USA
- Vanderbilt University Medical Center (VUMC), Nashville, TN, USA

Information about funding sources that supported the collection of the data:
Data were collected for a study funded by the NIH National Institute on Deafness and Other Communication Disorders (R01DC016880). This research was also supported by National Center for Advancing Translational Sciences (NCATS), NIH, through Grant Award Number UL1TR002369. The funder had no role in study design, data collection, or analysis for the study. The content of the repository is solely the responsibility of the investigators and does not necessarily represent the official views of the funder/National Institutes of Health.

SHARING/ACCESS INFORMATION

Licenses/restrictions placed on the data:
Both publicly available and restricted datasets contained in this repository are available through a CC0 license. There are additional terms of use for the restricted data. Investigators wishing to use this dataset must request access by filling out the Application for Restricted Access Data form, providing requested items, and agreeing to the specified Terms of Use.

Links to publications that cite or use the data:
As of 2025-10-20, there are currently no peer-reviewed publications that cite or use these data.

Links to other publicly accessible locations of the data:
The Harvard Dataverse repository contains two versions of these datasets, and only one is publicly accessible:

- Unrestricted, public-available dataset
  URL: https://doi.org/10.7910/DVN/HOI7YM
- Restricted access dataset URL: https://doi.org/10.7910/DVN/JSVRC4

The restricted access dataset is also available on Harvard Dataverse cannot be accessed without first requesting access via submitting the Application for Restricted Access Data form and providing the information requested, undergoing review, and receiving permission from study personnel.

Links/relationships to ancillary data sets:
N/A

Was data derived from another source? No
If yes, list source(s): N/A

Recommended citation for public access datasets:
Garinis, Angela C.; Ramsey, Katrina L.; Baudier, Robin L.; Elman, Miriam R.; Putterman, Daniel B.; Tharpe, Anne Marie; Anderson-Berry, Ann; Steyger, Peter S., 2025, "Public access data for NICU Ototoxicity Repository", https://doi.org/10.7910/DVN/HOI7YM, Harvard Dataverse

Recommended citation for restricted access dataset:
Garinis, Angela C.; Ramsey, Katrina L.; Baudier, Robin L.; Elman, Miriam R.; Putterman, Daniel B.; Tharpe, Anne Marie; Anderson-Berry, Ann; Steyger, Peter S., 2025, "Restricted access data for NICU Ototoxicity Repository", https://doi.org/10.7910/DVN/JSVRC4, Harvard Dataverse

DATA & FILE OVERVIEW

File List:

- **Publicly available datasets** – These datasets include age and hearing result variables from the NICU Ototoxicity study available through the public release of the data. These datasets are available both as delimited files (.csv extension) and Stata-formatted datasets (.dta extension); the Stata files include variable and value labels and can be imported for use in R.
    - NICU_Ototox_Repo_cohort.csv – This dataset provides study identifiers for patients recruited by the study with indicators of which datasets they appear in.
    - NICU_Ototox_Repo_testages.csv - Age at testing for DPOAE, wideband, and tbABR
    - NICU_Ototox_Repo_scrnABR.csv - Low-level click ABR screening from visit 1 in NICU (35 dB nHL) (pass/refer)
    - NICU_Ototox_Repo_cABR.csv - Neurodiagnostic click ABR from visit 2 (70 dB nHL)
    - NICU_Ototox_Repo_tbABR.csv - Tone-burst ABR air conduction Wave V from visit 2, formatted long by ear/frequency (Hz)
    - NICU_Ototox_Repo_wideband.csv - Wideband absorbance from visits 1 and 2, formatted long by ear/frequency (Hz)
    - NICU_Ototox_Repo_DPOAE.csv - DPOAE from visits 1 and 2, formatted long by ear/frequency (Hz)
- **Restricted access dataset** (file name: NICU_Ototox_Repo_Restricted.csv; also, as a Stata-formatted .dta file) – This de-identified dataset includes additional demographic and clinical variables not available to be freely downloaded or accessed by the public. Access to these data is limited to users who have been approved after submitting the Application for Restricted Access Data form and required information. These restrictions help protect privacy, comply with ethical or legal standards, and ensure responsible data use.
- **README file** (file name: NICU_Ototoxicity_Repository_README.pdf) – This README file is included with the project to provide essential information for anyone wishing to understand, access, or use the data. It outlines the purpose of the dataset, its structure, access conditions, and any relevant usage guidelines. You are currently reading this file.
- **Data dictionary** (filename: NICU_Ototox_Repo_DataDictionary.pdf) – This document provides detailed information about the variables in all datasets available in this repository (including the restricted access dataset). It includes each variable's name, description, data type (e.g., integer, string, float), allowed values or ranges, and any relevant notes or definitions. The purpose of the data dictionary is to help users understand the structure, meaning, and proper use of the data, ensuring clarity and consistency in data analysis or interpretation.
- **R code used for analysis (**NICU_Ototox_Repo_Analytic_Code.R) – This is an R script file with the code used to analyze study data. The packages and corresponding versions used in analyses are documented as comments in the code.
- **Summary tables for incidence of maternal conditions** (NICU_Ototox_Repo_SummaryTables.pdf) – This document provides summary data on the incidence of maternal conditions for patient-level data cannot be shared due to sensitivity and privacy concerns. Any cell containing between 1 and 10 individuals is suppressed to protect patient confidentiality; a reported value of zero does not violate the minimum cell size policy. Suppressed values are indicated as “<11” In these tables.

Additional related data collected that was not included in the current data package:
Bone-conduction auditory brainstem response testing was conducted as a follow-up after certain abnormal results from Visit 2, but too few were indicted/collected to warrant inclusion (n<5).

Are there multiple versions of the dataset? N/A

METHODOLOGICAL INFORMATION

Description of methods used for collection/generation of data:

Table 1. List of abbreviations

Abbreviation	Full form
ABR	auditory brainstem response
C-ABR	click auditory brainstem response
AC-ABR	air conduction auditory brainstem response
BC-ABR	bone-conduction auditory brainstem response
TB-ABR	tone-burst auditory brainstem response
APGAR	appearance, pulse, grimace, activity, respiration
CC0	creative commons zero
CMV	cytomegalovirus
Co-I	co-investigator
CT	computed tomography
CUMC	Creighton University Medical Center
dBA	A-weighted decibels
dBC	C-weighted decibels
DPOAE	distortion product otoacoustic emissions
ECMO	extracorporeal membrane oxygenation
HIPAA	Health Insurance Portability and Accountability Act
HIV	human immunodeficiency virus
HSV	herpes simplex virus
MRI	magnetic resonance imaging
NICU	neonatal intensive care unit
OHSU	Oregon Health & Science University
PI	principal investigator
SD	standard deviation
SNR	signal to noise ratio
SPL	sound pressure level
TB	tone-burst
VUMC	Vanderbilt University Medical Center
VZV	varicella zoster virus
WB	wideband absorbance

Participant enrollment

Data for this research study was collected from eligible infants admitted to the NICU at OHSU, CUMC, and VUMC between August 2020 and June 2023. Research nurses screened infants for the following study eligibility within 7 days of admission to the NICU using electronic medical records. Infants were excluded if they met any of the following criteria:

1. Birth at <23 or >35 weeks gestational age
2. Infants receiving palliative care for end of life only
3. At the time of enrollment, a diagnosis of congenital hearing loss, or other known causes of hearing loss that includes: i)Hypoxia ii) Congenital iii) Hypothyroidism
4. Known congenital infections such as Herpes simplex, Rubella, Syphilis, Cytomegalovirus (CMV)
5. Patients with known craniofacial or otologic abnormalities such as midfacial hypoplasia, microtia, aural atresia, Down syndrome, extracorporeal membrane oxygenation (ECMO), exchange transfusions for hyperbilirubinemia, Bilateral grade 3-4 IVH with PVL or hydrocephalus

For infants meeting study criteria, research nurses approached parents or legal guardians to determine their interest in the study. Those that chose to have their infant participate in the study were asked to sign the informed consent form and any applicable site-specific HIPAA documents. Consent allowed for standard of care hearing tests; distortion product otoacoustic emissions (DPOAE), automated click auditory brainstem response (cABR) and middle ear assessment using wideband absorbance (WB) prior to discharge from the NICU. Parents/guardians of enrolled subjects were asked to return for follow-up diagnostic audiometry of their infant's hearing within 4-12 weeks after discharge from the NICU or the soonest time near this window.

Study procedures

Data on existing risk factors for hearing loss were collected for the study, including exposure to aminoglycosides, key exposures that may be associated with hearing loss (e.g., intubation), results of the routine newborn hearing screen performed during infants' NICU admission, results of subsequent follow-up hearing tests, and research hearing assessments. A more detailed description of the data collected for this study follows below. Once collected, all measures were entered and stored securely in a REDCap database hosted at VUMC and used by all sites. Audiologists collected and entered hearing data into REDCap and trained research nurses entered patient and family electronic medical record data into REDCap.

Newborn Screening and Initial Research Hearing Assessment (V1)

Subjects received usual newborn hearing screening (cABR, and/or DPOAE) prior to discharge, per standard hospital policy. Research study procedures were conducted separately from this clinical screening, prior to the infants' discharge. Infants who left without receiving the research hearing tests had up to 10 business days from discharge to return for testing. Those that did not return for testing within this timeframe were removed from the study. The research hearing assessment included:

- Otoscopy (external ear only to rule out obstruction)
- cABR (low level click, e.g. 35 dB nHL)
- DPOAEs recorded at 1/3 octaves (up to 10 kHz) at moderate levels (e.g., 65/55 dB SPL)
- Acoustic reflex varying from low-mid levels until threshold is determined (optional test to be completed when appropriate)

- WB absorbance measured using a moderate level stimulus

Infants may have been administered gentamicin, other aminoglycoside antibiotics, and/or any other study treatments as determined by their treating physician based on clinical indications, regardless of study participation.

Electronic health record information entered into REDCap

The following information from subjects' medical records were collected and entered into REDCap:

- At enrollment: gestational age at birth, birth age (age since birth), birth weight and length, race, gender, admission diagnosis including prematurity, known syndromes, APGAR (Appearance, Pulse, Grimace, Activity, Respiration) scores, and family history of hearing loss.
- Post-discharge: number days in NICU; imaging events such as CTs, MRIs and X-rays; procedure events such as lines, intubations, and operations; machine events including number of days of ventilation; problem list entries such as low birth weight, syndromes, poor feeding, hyperbilirubinemia, meningitis, and seizures; medication records such as vancomycin and loop diuretic use; clinical data to determine if there was suspected sepsis; lab results during NICU inpatient stay for evaluation of blood test results indicating sepsis; and medications administered during NICU inpatient stay which have side effects of hearing loss, or synergistic effect of hearing loss.
- Data external to the study sites: Hearing testing results from the subjects' medical records at sites not included in the study, and/or from relevant states' Department of Human Services where data could be obtained

Sampling of Ambient Sound Levels

Purpose and Rationale

Dosimeters were used to obtain sample recordings of the acoustic environment in open settings within each NICU. The goal of these measurements was to ensure fairly equivalent background noise levels at the most typical hearing screening location across study sites. This information would be helpful if needed to address significant differences in screening results across sites (e.g., different pass/fail rates). It is not the purpose of these noise measurements to provide data to demonstrate relationships between NICU background noise environments and hearing status in participants.

Dosimetry Sampling Guidelines

- Each site will select a typical hearing screening location (i.e., the most common screening location at that site) for quarterly dosimeter measurements (Y1). Measurements will be made annually in the same selected location after Y1 if noise estimates are consistent across sites. Dosimeter estimates of less typical testing locations will not be conducted for this purpose (e.g., private rooms, in an isolette).
- All dosimeters will be calibrated before and after the recording session following ANSI and manufacturer standards. Record calibration levels in spreadsheet (example dosimetry spreadsheet below).
- Dosimeters will be placed in an unoccupied pod/bed closest to a typical hearing screen location in an open setting.
- If a bed/pod is not available, please place the dosimeter on a shelf or cart near where you typically test the infants with a thin blanket under the dosimeter.

- Dosimetry microphones should be taped in the approximate location where the baby's head would be located for screening for the length of recording. o Length of dosimeter reading should be 8 hours.
- Location of dosimeter reading should mimic the approximate height of the head of the infant.
- All dosimeter recordings should include settings for L50, Leq, Lmax, and L10:
    a. A-weighted estimates (in dB SPL)
    b. fast response time
    c. 1s-s sample interval
    d. 30dB gain
    e. 3dB exchange rate

Maternal Health History
Information about mothers' health status during pregnancy was collected from their medical record when available, supplemented by a questionnaire inquiring about personal and family history of hearing loss, and entered into REDCap. Information collected from the maternal records included the following:

- Smoking and/or alcohol consumption during pregnancy
- Titer/culture results for HIV (human immunodeficiency virus)
- HSV
- VZV (varicella zoster virus)
- Rubella
- CMV
- Toxoplasmosis
- Syphilis
- Race/ethnicity of child

This information was not required for primary data analysis and considered optional if the mother wished to disclose it. See summary tables for incidence of maternal conditions (NICU_Ototoxicity_Repository_SummaryTables.pdf) for this information.

Follow-up Diagnostic Visit (V2)
Prior to discharge from the NICU, the research coordinator or audiologist scheduled a follow-up diagnostic audiometry visit with each infant's parents/ guardians to occur between 4-12 weeks following discharge. The team attempted to schedule a follow-up diagnostic visit with all participants regardless of screening audiological test results. Parents/guardians received a reminder phone call approximately one-week prior to the date of the infant's follow-up visit to review test procedures and discuss infant preparation. At this call, the research coordinator or audiologist answered questions and documented specific needs of the subject to alleviate any stress associated with the follow-up visit including transportation to the visit. To help facilitate follow-up appointment adherence if transportation was an issue, use of Uber Health services may have been utilized.

During the follow-up audiometry visit, the infant completed an otoscopy examination, acoustic reflex (optional test), the DPOAE, diagnostic automated auditory brainstem response (ABR; via air-conduction [AC-ABR] and bone-conduction [BC-ABR] as needed) and middle-ear WB testing. During DPOAE and WB testing, an ear-level probe microphone was placed in the infant's ear using a soft disposable tip, sounds played at comfortable volumes, and responses recorded. In the case where not all tests were obtained or the subject has evidence of middle ear dysfunction (e.g., absent DPOAEs,

abnormal WB based on reported norms and/or abnormal AC-ABR) at the first follow-up visit, the study was allowed up to two additional follow-up visits to obtain the specified hearing tests prior to the subject reaching 6 months old (corrected age). For subjects returning for follow-up visits with repeat testing, measurements from most complete visits (most measurement types and most usable ears) were used when available. However, some measurements could be from different V2 collection attempts, as indicated by the day of testing (daynum) variable.

For the diagnostic ABR test, electrode placement was dependent on the manufacturer's specifications for electrode montage and testing parameters. Correction factors were be applied per manufacturer or calibration of site-specific equipment used to obtain ABR (re: Vivosonic or Eclipse). Infants were nursed or comforted to sleep in a rocking chair or glider in a dimly lit audiometric sound booth to facilitate their transition to sleep.

Once the infant was quiet or asleep, they were tested in the following order:

i. Otoscopy (external ear only to rule out obstruction)
ii. Wideband Absorbance - if WB data are abnormal based on normative data provided by Hunter et al. (2016), the Audiologist should continue with the scheduled testing and schedule another follow-up only if the DPOAE and/or ABR results are also abnormal.
iii. DPOAE procedures performed as described above
iv. Diagnostic ABR (tone-burst (TB), air-conduction-two channel with single polarity (see below for tone-burst ABR [TB-ABR] testing order)
v. Click-evoked ABR at a moderate level (e.g., 70 dB nHL)
vi. BC-ABR using alternating polarity and low mastoid placement
vii. Acoustic reflex varying from low-mid levels until threshold is determined (optional test to be completed when appropriate)

TB-ABR testing using a single polarity was completed in the following order for quiet/sleeping infants:

i. TB 8 kHz (start at 30dB nHL to threshold)
ii. TB 4 kHz (start at 30dB nHL to threshold)
iii. Click ABR at a moderate level (e.g., 70 dB)
iv. B 2 kHz and TB 1 kHz (dBeHL)
    a. If responses are present at 30 dB nHL, then test levels were dropped to 10 dB nHL and 0 dB nHL until true threshold was determined.
    b. If responses are absent at 30 dB nHL, levels were increased using 20 dB nHL increments until threshold was determined.
    c. If hearing loss is noted at any frequency, we tested 500 Hz (to 20 dB eHL) to characterize the configuration of hearing loss across the frequency range, (e.g., flat, sloping, etc.).

We tracked all tones with abnormal responses to threshold. When a TB-ABR response was abnormal, we conducted a BC-ABR test using an alternating polarity with low mastoid placement (band or handheld). We began at the highest abnormal TB-ABR frequency, then progressed to lower frequencies as needed. Each site used the appropriate correction factors for their systems based on internal calibration and manufacturer specifications. These procedures were based on evidence-based research for pre- and full-term infants. Peak amplitude and latency estimates as a function of level

were considered for determining ABR thresholds. If hearing loss was observed during the follow-up testing of the infant, the study audiologist contacted the subject's doctor and/or managing clinical audiologist with the results. The subject's doctor/clinical audiologist conducted follow-up with the family to determine the infant's care moving forward. In some cases, the audiologist performed testing for both clinical and/or research purposes.

The following options were offered to facilitate a successful return visit and ensure retention of subjects:

- Infant care items for use during the follow-up visit include diapers, baby wipes, formula, blankets, toys, noise makers and a bassinette/crib. Non-disposable items will be sanitized prior to use by another infant.
- Subject compensation ($50 per follow-up visit) was offered to the parents or legal guardians as a means of compensation for their time for follow-up visits
- Parents/legal guardians were offered to pair their research visits with an existing clinic visit, and sibling care was provided upon request.
- The research coordinator or audiologist flexed their schedules to accommodate a joint clinic and research appointment.

Study population

The study initially planned to enroll 720 NICU babies across the three sites starting in 2019. After study delays due to the COVID-19 pandemic, recruitment was stopped early in 2023 after enrollment of 320 babies when the absence of clinical hearing loss was noted in the study population. Of the 320 babies enrolled in the study after study criteria were applied (see Participant Enrollment Section), two were disqualified from study participation and 24 withdrew prior to their first audiological visit. Of these, 294 babies completed their initial audiological visit and 249 completed their diagnostic visit, with usable data measured by ear varying for the diagnostic outcome measure.

Study analyses

Below are details of analyses that were performed as part of the original study using the collected data.

Outcomes used for analysis

In the absence of clinical hearing loss (i.e., because it was not observed in the study population), the primary hearing outcomes included:

- DPOAE signal-to-noise ratio (SNR) measured at high frequencies (>=4 kHz) at screening and diagnostic audiological visits (V1 and V2)
- DPOAE signal level measured at high frequencies (>=4 kHz) at screening (V1) and diagnostic (V2) audiological visits
- Tone burst (TB) ABR threshold at all frequencies measured at diagnostic visit (V2)
- TB-ABR Latency at all frequencies measured at diagnostic visit (V2)

Secondary hearing outcomes included:

- Automated click ABR measured at screening (pass/refer)
- Amplitude of TB-ABR at diagnostic visit

Exposure used for analysis

The primary exposure of interest is a four-level categorical variable of < or ≥3 continuous days of gentamicin dosing (i.e., in a single course) with or without suspected sepsis. Suspected sepsis is where

clinicians suspect sepsis regardless of whether sepsis is confirmed by culture. Secondary exposures investigated are cumulative days of gentamicin dosing (i.e., across courses) and maximum continuous days of gentamicin dosing regardless of sepsis status.

Methods for processing the data:
Data contained in each REDCap form were downloaded as separate data tables, cleaned, then merged by study ID. Data cleaning was comprised of the following activities:

- Screened but unqualified, withdrawn, and excluded participants were flagged
- Screenings for patients, individual ears, or specific measures with questionable or missing results were flagged
- Clean variables entered into REDCap
    - Assess the quality of variables and flag outliers, missingness, and other questionable values
    - Data audits performed on outliers/questionable values and study personnel asked about missing values
    - Corrections made to erroneous data and missing values updated where data were available
    - Simplify select categorical variables (e.g., race, ethnicity)
- Create/calculate study variables (e.g., exposure for suspected sepsis and ≥3 continuous days of gentamicin dosing use was created by categorizing days of gentamicin use into <3 and ≥3 days and suspected sepsis was similarly grouped into "Yes" and "No." A four level category was developed from the crosstab of these two variables; see the Data Dictionary for additional created/calculated variables)
- Tables with repeated measures were pivoted from wide to long

Parameters for audiological tests:

1. **Distortion-Product Otoacoustic Emissions (DPOAEs)**
    - **a.** *Frequency bands:* Data collected in 1/3 octaves (1, 1.5, 2, 3, 4, 6, 8, 10 kHz).
    - **b.** *Test time:* **60 seconds (Manual says 90s but the duration was reduced to save time)**
    - **c.** *L1 level:* **65 dB SPL**
    - **d.** *L2 level:* **55 dB SPL**
    - **e.** f2/f1 ratio: **1.22**
    - **f.** *Acceptable noise level:* **30 dB SPL**
    - **g.** *Test order:* **descending in frequency**
    - **h.** *Minimum DP Level:* ***-10 dB SPL***
    - **i.** *Minimum DP reliability:* **98%**
    - **j.** *Acceptable signal*-to-noise ratio criteria: **6 dB SNR**
    - **k.** *DP tolerance level:* **+/- 4 dB SPL**
    - **l.** Residual noise criteria: **-10 dB SPL**
2. **Wideband Absorbance (WB) Tympanometry**
    - a. Interacoustics Titan system
    - **b.** *Pressurized:* **+200 daPa to -200 daPa (downswept)**
    - **c.** *Pump speed:* **medium**
    - **d.** *Graph type:* **3D**
    - **e.** *Frequency range:* **1.0 to 8.0 kHz**
    - **f.** *Absorbance range:* **0 to 100%**
3. **Click-evoked auditory brainstem response (c-ABR)**
    - **a.** *Earphones:* **ER2s**

   b. *Insert foam tip size:* **ER3-14E or ER3-14B**

Screening automated click ABR (cABR)

   a. *Stimulus type*: **click**
   b. *Test level:* **35 dB nHL**
   c. *Polarity:* **alternating split**
   d. *Epoch:* **25ms**
   e. *Window display:* **25**
   f. *Filter:* **30-1,500 Hz**
   g. *Rate:* **37.7 seconds**

Diagnostic click ABR (c-ABR)

   i. *Stimulus type*: **click**
   b. *Test level:* **76 dB nHL**
   c. *Polarity:* **alternating split**
   d. *Epoch:* **25ms**
   e. *Window display:* **25**
   f. *Filter:* **30-1,500 Hz**
   g. *Rate:* **37.7 seconds**

4. **Tone-burst auditory brainstem response (TB-ABR)**
   a. *Test level:* **Threshold determined in dB nHL**
   b. *Test frequency:* **8, 4, 2, 1, 0.5 kHz)**
   c. *Polarity:* **rarefaction**
   d. *Epoch:* **25ms**
   e. *Window display:* **25**
   f. *Filter:* **30-1,500 Hz**
   g. *Rate:* **37.7 seconds**
5. **Bone-conduction auditory brainstem response (BC-ABR, data not included)**
   a. *Test level:* **Threshold determined in dB nHL**
   b. *Polarity:* **alternating (not split)**
   c. *Epoch:* **25ms**
   d. *Window display:* **25**
   e. *Filter:* **30-1,500 Hz**
   f. *Rate:* **37.7 seconds**

Standards and calibration information, if appropriate: N/A

Environmental/experimental conditions:
This was a prospective observational cohort study. As such, participants were not randomized or subjected to experimental conditions.

Describe any quality-assurance procedures performed on the data:
Item level data collection checks were performed for values of variables that were outside expected ranges and/or had logical inconsistencies.

People involved with sample collection, processing, analysis, and/or submission:

Table 2. People involved with the study by site and role

Site and Study role	Individual
OHSU	
Site PI, collected data	Angie Garinis
Site co-I, collected data	Angela Douglas
Pediatric audiologist, advised on study (but did not collect data)	Heather Durham
Collected data	Ilia Fong
Collected data	Julia Harris
Collected data	Daniel Putterman
Collected data	Jay Vachhani
Collected data	Kristin Milner
Collected data	Alec Martin
Supervised biostatistics team and analyses	Jodi Lapidus
Performed analyses	Robin Baudier
Performed analyses	Priya Srikanth
Prepared data and corresponding information for repository	Katrina Ramsey
Prepared data and corresponding information for repository	Miriam Elman
VUMC	
Site PI, collected data	Anne Marie Tharpe
Collected data	Brittany Day
Collected data	Hilary Davis
Collected data	Theresa Rodgers
Collected data	Bridget Smith
Site co-I, collected data	Hendrik Weitkamp
UNMC	
Site PI, collected data	Ann Anderson Berry
Collected data	Sara Jones
Collected data	Cindy Johnson
Collected data	Jessica Koraleski
Collected data	Emily Bosen
Collected data	Betty Oberle
Creighton University	
Lead PI, did not directly collect data	Peter Steyger*

*Lead PI moved from OHSU to Creighton; Creighton site not involved in data collection

RELATIONSHIPS BETWEEN DATASETS

Public datasets

Main participant table

Table	Unique id	Description	Cols.	N unique pid	N records
NICU_Ototox_Repo_cohort	pid	Public cohort table of all infants with usable audio results	43	309	309

Tables that link to the main participant table

These tables merge 1:m with NICU_Ototox_Repo_cohort on [pid]

Table	Unique id	Description	Cols.	N unique pid	N records
NICU_Ototox_Repo_testages	pid visit testname leftear	Age at testing for DPOAE, wideband, and tbABR	7	304	2223
NICU_Ototox_Repo_scrnABR	pid leftear	Low-level click ABR screening from visit 1 in NICU (35 dB nHL)	11	303	593
NICU_Ototox_Repo_cABR	pid leftear	Neurodiagnostic click ABR from visit 2 (70 dB nHL)	12	206	407

Tables that link to the tests-and-ages table

For all of these tables, the NICU_Ototox_Repo_testages table merges 1:m on the combination of [pid visit testname leftear]

Table	Unique id	Description	Cols.	N unique pid	N records
NICU_Ototox_Repo_tbABR	pid visit testname leftear	Tone-burst ABR air conduction Wave V visit 2, format long by ear/frequency (Hz)	11	210	1627
NICU_Ototox_Repo_wideband	pid visit testname leftear	Wideband absorbance from visits 1 and 2, formatted long by ear/frequency (Hz)	8	289	6952
NICU_Ototox_Repo_DPOAE	pid visit testname leftear	DPOAE from visits 1 and 2, formatted long by ear/frequency (Hz)	10	300	7496

Restricted access dataset

Table	Unique id	Description	Cols.	N unique pid	N records
NICU_Ototox_Repo_Restricted	pid	Restricted table with clinical and demographic variables	105	309	309

Variable List: refer to data dictionary

Missing data codes: refer to data dictionary

References

Garinis, A. C., Cross, C. P., Srikanth, P., et al. (2017). The cumulative effects of intravenous antibiotic treatments on hearing in patients with cystic fibrosis. *J Cyst Fibros, 16*, 401-409.

Hunter, L. L., Blankenship, C. M., Keefe, D. H., et al. (2018). Longitudinal Development of Distortion Product Otoacoustic Emissions in Infants With Normal Hearing. *Ear Hear, 39*, 863-873.