PROTOCOL TITLE:

Understanding Disparities in Preventive Care Utilization, Hospitalization and Emergency Department visit Among Children of Deaf and Hard of Hearing Mothers: A Mixed-Methods Approach

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REVISION HISTORY

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1.0 Study Summary

Study Title	Understanding Disparities in Preventive Care Utilization, Hospitalization and Emergency Department visit Among Children of Deaf and Hard of Hearing Mothers: A Mixed-Methods Approach
Study Design	Observational study using the following linked datasets: 1) All Payer Claims Database (APCD) or state Medicaid data, 2) infant birth records from Vital Statistics Program, and 3) Pregnancy Risk Assessment Monitoring System (PRAMS) from Centers for Disease Control and Prevention (CDC)
Primary Objective	The objective of this study is to evaluate the differences in preventive care utilization, hospitalization, and ED visits between children of deaf adults (CODA) and non-CODAs, as well as to assess healthcare utilization of deaf mothers.
Secondary Objective(s)	
Study Population	The target population of this proposed study is children of deaf adults.
Sample Size	13,579,339
Study Specific Abbreviations/ Definitions	APCD - All Payer Claims Database CDC - Centers for Disease Control and Prevention CODA – Children of deaf adults ED – Emergency department DHH - Deaf and hard of hearing ICD-10-CM - Classification of Diseases, Tenth Revision, Clinical Modification STROBE - Strengthening and Reporting of Observational Studies in Epidemiology PRAMS - Pregnancy Risk Assessment Monitoring System DUA - Data use agreement LRT – Likelihood ratio test VIF – Variance inflation factor

2.0 Objectives*

2.1 Describe the purpose, specific aims, or objectives.

Objective: Evaluate the differences in preventive care utilization, hospitalization, and ED visits between children of deaf adults (CODA) and non-CODAs, as well as to assess healthcare utilization of deaf mothers.

State the hypotheses to be tested.

We hypothesize CODA will have higher rates of preventive care utilization, hospitalization, and ED visits than non-CODA.

3.0 Background*

3.1 Describe the relevant prior experience and gaps in current knowledge.

3.2 Existing research has demonstrated that deaf or hard of hearing (DHH) mothers are more susceptible to pregnancy complications and also experience higher rates of postpartum readmissions that their hearing counterparts. These findings suggest that CODA might also be vulnerable to long-term adverse health outcomes. However, there is no study evaluating CODAs' health outcomes beyond birth.

3.3 Describe any relevant preliminary data.

3.4 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.

Approximately 6% of reproductive-aged adults in the United States identify as DHH. DHH women exhibit pregnancy rates comparable to those without disabilities, but DHH individuals often face unique barriers to accessing healthcare information due to communication challenges. Healthcare providers' lack of training in accommodating hearing loss and utilizing alternative communication methods further hampers healthcare communication. This communication gap can lead to detrimental health outcomes, including delayed or insufficient perinatal care. Several studies have been conducted assessing the pregnancy experiences, maternal and birth outcomes, and associated healthcare costs of DHH mothers. However, there exists a notable dearth of information and research concerning healthcare and outcomes among CODA.

4.0 Study Endpoints*

4.1 Describe the primary and secondary study endpoints.

5.0 Procedures Involved*

5.1 Describe and explain the study design.

This is an observational cohort study using study using the following linked datasets: 1) All Payer Claims Database (APCD) or state Medicaid data, 2) infant birth records from Vital Statistics Program, and 3) Pregnancy Risk Assessment

Monitoring System (PRAMS), a surveillance project of the Centers for Disease Control and Prevention (CDC) from 29 states/jurisdictions (AR, AZ, CA, CO, DC, GA, KS, LA, MA, MD, ME, MI, MO, MS, MT, ND, NE, NH, NM, NY, OR, RI, SD, TN, VA, VT, WA, WI, and WV). Some states' PRAMS may not carry the necessary disability variables and thus will be excluded. This study follows the Strengthening and Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline for cross-sectional studies.

Where possible we will utilize linked datasets that are in our possession. Prior to using these datasets, we will ensure the states are notified of this new intended use and execute new data use agreements as necessary. For this study, we have received the fully linked dataset from AZ, and partially linked datasets from CO and MI. CO has provided linked APCD, birth records, and PRAMS data without the disability indicators (new variables can be easily requested). MI has provided linked Medicaid claims data and infant birth records so far. Our current DUA with CO allows for the re-use of the linked dataset for this new analysis. A new DUA will be established for the re-use of the AZ data.

6.0 Data and Specimen Banking*

There will be no banking of the data for future unrelated research.

7.0 Sharing of Results with Subjects*

No results will be shared with subjects. Aggregate data will be published.

8.0 Study Timelines*

This study is observational and utilizes data that already exists. We estimate that we will complete this study (primary analyses) by July 2027.

9.0 Inclusion and Exclusion Criteria*

9.1 Describe how individuals will be screened for eligibility.

Identification of Patients:
The target population is children of DHH mothers (CODA). From the mothers' Medicaid records, DHH status will be identified using International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes (H90xx or H91xx). Infants of these mothers will be classified as CODA and infants of mothers without these codes will be classified as non-CODA. Using the birth records, we will identify infants born between January 2016 and December 2022. Using the linked data, we will examine their APCD records for one year. Thus, the dates for this longitudinal study will be January 2016 through December 2023.

10.0 Vulnerable Populations*

10.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

11.0 Local Number of Subjects

The study population will be inclusive of all individuals meeting the study criteria (described above).

12.0 Recruitment Methods

No recruitment is necessary.

13.0 Withdrawal of Subjects*

Not Applicable

14.0 Risks to Subjects*

The linked datasets may contain month/year and zip codes related to the individual. However, the datasets will be from 29 states, and we will not be able to readily ascertain the identity of the individuals. There are no interventions or interactions with the subjects. All data sought already exists. We will abide by the terms of the DUA and make no attempt to identify the individuals whose information is included in the dataset. The main risk is that of a breach of confidentiality. This may occur should the state agencies or third party linking the datasets fail to remove all identifiers from the datasets. Should this occur, we will immediately notify the agencies of the breach. This study will abide by all applicable law, regulations, and standard operating governing the protection of human subjects, student information and protected health information.

15.0 Potential Benefits to Subjects*

There is no benefit to the subjects.

16.0 Data Management* and Confidentiality

16.1 Describe the data analysis plan, including any statistical procedures or power analysis.

Measurements: The primary exposure variable is mother's hearing status, which will be identified with a diagnosis of DHH using DHH-related ICD-10-CM codes H90xx and or H91xx. The inclusion of the code suffix "x" encompasses all potential codes associated with the specified code prefix. This method to identify DHH patients has been used in the several prior publications. Sensitivity analyses will use the CDC's PRAMS survey to identify non-DHH mothers and also mothers with no disabilities.

The primary outcomes of interest are whether the infants follow the recommended vaccination schedule, and whether the infants follow the recommended well-baby visit schedule for the first 12 months of life. The secondary outcomes of interest are binary variables indicating hospitalization, emergency department visits, and hospitalizations for the

first 12 months of life. Adjustment variables are sex, race, ethnicity, zip code level median income quartile, education level, marital status, plurality, birth order, preterm birth, low birth weight, and the Pediatric Medical Complexity Algorithm (PMCA). Sensitivity analyses will evaluate the outcomes for 24 months of life to ensure the robustness and validity of our findings. Extending the analysis to 24 months allows for a broader examination of well-baby visits and vaccination patterns and potential deviations from the recommended schedule over an extended period. It will also demonstrate the long-term outcomes (i.e., hospitalization and ED visits) beyond infancy.

Multivariable logistic regression models with state and year fixed effects will be used to assess the association of mother's hearing status with infants' compliance to well-baby visit and vaccination schedule. All regression models will be adjusted for the four adjustment variables with a year fixed effect. Variance inflation factors (VIF) will be used to assess multicollinearity between adjustment variables, and values of 10 or higher were considered concerning. After accounting for adjustment variable associations, we will examine whether mother's hearing status is associated with differences in infants' compliance to well-baby visit and vaccination schedule. To do this, we will perform likelihood ratio tests (LRTs) to compare five models.

Given the racial and ethnic disparities within DHH populations, as well as disparities in the outcomes evaluated in this proposed project, we will conduct a stratified analysis based on mothers' race and ethnicity.

A two-sided p value < .05 was considered statistically significant. We chose not to apply multiple testing adjustment. Implementing stringent adjustments increases the risk of Type II errors, which could cause us to erroneously overlook genuine relationships crucial for understanding the complex dynamics within this vulnerable population. Additionally, given the exploratory nature of our research, we prioritized capturing a comprehensive picture of these associations, acknowledging that future confirmatory studies could delve deeper into specific findings identified in this broad exploration. SAS V.9.4. (SAS Institute, Cary, NC, USA) was used for the analyses, with the exception of estimating the adjusted rate, for which STATA (StataCorp, College Station, TX, USA) was used. Figures were created using Excel (Microsoft, Redmond, WA, USA).

Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.

We will adhere to the data use agreement (DUA) required by the agencies. This DUA prohibits sharing or re-release of individual-level data to protect confidentiality. Results of this research project will be reported in aggregate without identification of individual patients, providers, or facilities.

16.2 Describe any procedures that will be used for quality control of collected data.

16.3 Describe how data or specimens will be handled study-wide:

- *What information will be included in that data?*

The datasets will likely constitute a Limited Dataset in that some states may provide month/year and we will be requesting zip codes if possible and permissible by the state agency. APCD or Medicaid, birth records, and PRAMS data (if available) will be requested from the state's agencies. We will request that the state agencies that govern the different datasets link the datasets together. We will then receive a limited dataset. In the instance that the state agencies are unable to perform the linkage on their ends, we will propose two methods. 1) Each agency will use an algorithm to create a study ID based on identifiers. The state agencies will then send us the individual datasets with the study ID and void of any direct identifiers (except month/year and zip codes). We will then link all datasets through the created study ID. 2) We will use a third-party to facilitate the linkages. Each agency will download the third-party software and create a study ID/token. The third party will then remove all identifiers from the data (except month/year and zip codes) and transmit the linked limited dataset to us.

- *Where and how data will be stored?*

Data will be stored on a folder on the Lundquist Department of Pediatrics' private server within the Lundquist network. All data will be kept in the same folder and will not be moved to keep track the data. The PI and her research team must login to Lundquist VPN to access the server and the stored data. All researchers have also completed all relevant CITI training and will review IRB protocol and be kept informed of all modifications. The Lundquist network is using Next-Generation firewall of Palo Alto with latest and up to date software and capabilities. All devices on the network are deploying XDR Sophos End point security and all network traffic is encrypted and secured using TLS 1.2. The Lundquist IT Team is using vulnerability scanning to discover and remediate any critical findings. After analysis is completed, the Eraser software program will be used to destroy the appended dataset containing all data, using the DoD three-pass option.

- *How long the data or specimens will be stored?*

Data will be stored until research is completed. Datasets will be destroyed or returned based on the terms of each executed data use agreement.

- *Who will have access to the data or specimens?*

Only individuals listed on this study and those specified on the agency's DUA.

- *Who is responsible for receipt or transmission of the data or specimens?*

Only individuals listed on this study and those specified on the agency's DUA.

- *How data or specimens will be transported?*

The agency will transmit the database in accordance with the agency's DUA.

17.0 Provisions to Monitor the Data to Ensure the Safety of Subjects*

This section is required when research involves more than Minimal Risk to subjects.

The research poses no more than minimal risk. There are no safety concerns.

18.0 Provisions to Protect the Privacy Interests of Subjects

18.1 Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.

18.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

18.3 Indicate how the research team is permitted to access any sources of information about the subjects.

The research involves analysis of linked datasets that are not fully void of identifiers. The datasets may contain month/year and zip codes related to the individual. However, the datasets will be from 29 states, and we will not be able to readily ascertain the identity of the individuals. There are no interventions or interactions with the subjects. All data sought already exists. We will abide by the terms of the DUA and make no attempt to identify the individuals whose information is included in the dataset.

19.0 Compensation for Research-Related Injury

19.1 If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

The study does not involve interaction/intervention. It is observational and presents no more than minimal risk.

20.0 Economic Burden to Subjects

20.1 Describe any costs that subjects may be responsible for because of participation in the research.

Not Applicable

21.0 Consent Process

21.1 Indicate whether you will you be obtaining consent

We seek a waiver of consent and authorization for use of health information. This research could not be practically carried out without these waivers. This study has an extremely low probability of causing harm.

22.0 Setting

22.1 Describe the sites or locations where your research team will conduct the research.

The research involves analysis of linked datasets that are not fully void of identifiers. The datasets may contain month/year and zip codes related to the individual. However, the datasets will be from 29 states, and we will not be able to readily ascertain the identity of the individuals. There are no interventions or interactions with the subjects. All data sought already exists.

23.0 Resources Available

23.1 Describe the resources available to conduct the research: For example, as appropriate:

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*

Not applicable. The research involves analysis of a large dataset. All data sought already exists.

- *Describe the time that you will devote to conducting and completing the research.*

3 years

- *Describe your facilities.*

This study involves analysis of information from existing national and state level databases, so recruitment will not take place. Research will be conducted in an office assigned to the researcher located in Building N25 at Lundquist.

- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of the human research.*

Not applicable

- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

All persons assisting with the research will read the investigator protocol and all study materials before starting the study. The PI meets regularly with her research staff to discuss the progress of the research and will make sure that each staff member understands their duties.