REGULATORY AND COMPLIANCE APPROVALS: NIH HUMAN SUBJECTS SECTIONS

INCLUSION OF WOMEN AND MINORITIES

Distribution of Subjects.
The proposed research will involve the use of existing datasets that were previously approved by human subjects' committees and funded by federal grants at the Waisman Center of the University of Wisconsin-Madison. Families were recruited to participate through the Waisman Center clinics and regional birth-to-three programs in Madison, Wisconsin, as well as social media outlets and word of mouth.

- Women: All caregivers who participated in the laboratory recordings were female. One father participated as a triad with the mother and child. Our study includes 23 infants at risk for CP between 11-14 months of age. This sample includes 11 females and 12 males. No infants were excluded from participating based on sex.

- Minorities: The participant ethnicity demographics were consistent with those of the Madison, Wisconsin areas (15 white, 5 more than one race, 3 not reported). No infants or families were excluded on the basis of racial/ethnic group membership.

Rationale for Selection.
All efforts were made to originally enroll an equal number of male and female infants and those from diverse racial/ethnic groups across the various recruitment methods.

Proposed Outreach Programs.
No proposed outreach programs are included in this project, as it draws from existing datasets.

Included and Excluded Groups.
There were no race or ethnicity exclusions for the study.

- Inclusion criteria: The inclusion criteria for the larger longitudinal study required that infants: 1) have motor delay or a medical diagnosis related to birth complications associated with CP, 2) have hearing within normal limits per parent report, and 3) be from a monolingual English-speaking home.

- Exclusion criteria: Infants who did not have motor delay or a diagnosis related to CP were excluded. Children with a medically diagnosed hearing loss were also excluded as a known confound in the study of vocal development.

INCLUSION OF CHILDREN AND INDIVIDUALS ACROSS THE LIFESPAN

Existing Datasets or Resources.
The proposed project includes existing data previously collected from 23 infants at risk for cerebral palsy (CP) between 11-14 months of age and their caregivers. This child age range was selected because previous research has suggested that prelinguistic vocal development is likely to occur in typical infants between 0-12 months, prior to the onset of first words. Infants at risk for developmental disabilities are likely to show delays in the emergence of prelinguistic vocal stages; thus, we seek to understand prelinguistic vocal performance at the latest possible age of typical infant development. The analysis of vocal behaviors during recordings of parent-infant interactions is critical to mimic the kinds of naturalistic interactions during which infants are likely to produce their most speech-like vocalizations.

Existing speech outcome data collected around 36 months of age is also available for analysis from all 23 infants. Speech outcome data collected in toddlerhood is critical to frame our prelinguistic vocal behavioral findings against developmental outcomes at an older time point. The approximate 36-month time point was selected as an approximate age when typical children are likely to be combining intelligible phrases of speech. This age is also the latest possible time point at which we have available data for inclusion in this study. Caregiver ages will vary.

RECRUITMENT AND RETENTION

The study uses data from an existing cohort; therefore, no recruitment and retention plans are required.

PROTECTION OF HUMAN SUBJECTS

1. RISKS TO HUMAN SUBJECTS

a) Human Subjects Involvement, Characteristics, and Design

Overall study design: The data to be used in the proposed project is a secondary dataset collected as part of a larger, longitudinal study on communication development in cerebral palsy (CP). All recording data is housed in a secure server at the Waisman Center. Audio recordings of parent-infant interactions (mean: ~12 minutes) collected during laboratory visits will be used for analysis. Perceptual vocal coding and instrumental acoustic data extraction and analysis will be conducted using these recordings. Speech outcome data will be derived from ~36-month data of all 23 infants. Analyses will be conducted by the PI, student coder, and the mentorship team, all of whom have active HIPAA and CITI certification training.

Subject population: The study will include data from 23 infants between 11-14 months of age (~12 months) previously recruited for a risk of CP based on birth history.

Collaborating sites: All data was collected at the Waisman Center at the University of Wisconsin-Madison in Madison, WI. No collaborating sites participated in this longitudinal study.

b) Study Procedures, Materials, and Potential Risks

Planned research procedures: During prior participation, parents brought their infants to the laboratory to the Waisman Center for approximately 1-to-1.5-hour visits for data collection. Digital audio/video recordings were collected during these sessions. Audio of previously collected parent-infant interactions of the 23 infants will be analyzed using perceptual and acoustic methods. Speech outcomes will be identified using the most recent laboratory visits using clinical judgment by a certified speech-language pathologist.

Previously collected data sources: Data previously collected from an ongoing NIH-funded project (R01 DC01653; PI: Hustad) will be used in this project. Included research material has already been obtained from infants at risk for CP, including recording audio of parent-infant interactions at the ~12 month and outcome time points. Identification numbers are already assigned to each infant which will be used to link infant data at all times of coding and analysis. Only the PI and laboratory research team members who have an explicit need to know the linkages between names and code numbers have access to this information.

Potential risks to subjects: There are no foreseeable risks associated with previous participation in this study. There are no known reports from families regarding damaging effects to their physical or emotional state because of their participation in this longitudinal study.

Alternative treatments and procedures: There are no alternative treatments or procedures involved in the present study because these data have already been collected.

2. ADEQUACY OF PROTECTION AGAINST RISKS

a) Informed Consent and Assent

Process for obtaining informed consent: Data from the included sample of infants has already been collected. During previous participation, all caregivers were given a thorough, verbal description of the goals of the longitudinal study, participation involvement, and tasks to be completed at laboratory visits. Caregivers provided written consent and ongoing assent for their infant to participate.

Waivers: No waivers of informed consent were used to collect data from participants.

b) Protections Against Risk

Planned strategies for protecting against risks: Risks to subject confidentiality are minimized by adopting suitable data storage procedures. All audio files and coded data are labeled with the infant identification numbers so that no identifying information is available during coding or analysis. The linkage between these numbers and identifying information for all infants is kept in a secure online database and in a locked file cabinet within a locked room in a different location from audio files. Digital audio recordings are maintained in a secure laboratory server. Access to all online media is password protected using duo-authentication methods and restricted to only those individuals working on the research project. No identifying information regarding the identity of speakers will accompany any data reported from this project. Using these procedures, all reasonable precautions are taken to minimize linking any PHI to the research data.

Plans for ensuring intervention in the event of adverse effects: Because our project draws on existing databases of recordings, no adverse effects are anticipated.

Plans for handling incidental findings: Because our project draws on existing databases of recordings, no incidental findings are anticipated. Laboratory assistants and managers were present for the laboratory visit to discuss and manage incidental findings as they occurred in real time (e.g., suggesting referrals to appropriate medical providers).

c) Vulnerable Populations

Rationale for the involvement of infants: The proposed project involves vulnerable populations, specifically infants at risk for a developmental disability (CP). During their participation, all guidelines were followed to meet HHS regulatory requirements for parental permission and child assent (45 CFR 46.408) as described above and hereafter. IRB approval was received with annual review conducted throughout the duration of human subject participation. Parental informed consent was obtained by caregivers or legal guardians. Although infants were too young to formally obtain assent, infants' demeanor and activity levels were monitored during laboratory sessions to ensure comfort for continued participation. Breaks were provided as needed per parental request or infant discomfort.

3. POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO PARTICIPANTS AND OTHERS

Potential benefits of the research: Families received summary statements after each laboratory visit that provided information about their infant's performance in the laboratory tasks and speech and language development. Data and information collected from participants is used to conduct research studies and disseminate knowledge to improve our understanding of speech, language, and communication development and CP in children.

Reasonable risks to participant benefits: The risks to participants are negligible in relation to the anticipated benefits because data have already been collected, and risks during the time of participation were minimal. The potential benefits to families are outweighed by the minimal risks involved.

4. IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Importance of knowledge gained from the proposed research: This project is expected to make significant contributions to our understanding of vocal biomarkers for speech impairment in CP. The inclusion of infants at risk for CP can lay foundations for more precise differential diagnosis of later speech impairment. The proposed project is expected to add to the existing literature on how infants with neurological damage gain control of the capacity to vocalize and develop speech. We expect that knowledge and dissemination of research completed under this proposal will inform our understanding of early identification for communication disorders.

Reasonable risks to knowledge importance: The potential benefits to the contributions to scientific research in developmental disabilities are outweighed by the minimal risks involved.