Early Hearing Detection and Intervention Quality Improvement Project
Consent to Participate Form

The Early Hearing Detection and Intervention Quality Improvement Project (EHDI QI) is being conducted by the National Center for Medical Home Implementation in the American Academy of Pediatrics. The EHDI program is funded by a cooperative agreement with the Maternal and Child Health Bureau of the Health Resources and Services Administration.

PURPOSE OF THE PROJECT

Participating practice teams will have a unique opportunity to assess and work to improve their practice when it comes to identifying and tracking infants who do not pass newborn hearing screens, referring these infants to the appropriate follow-up, and having meaningful discussions with family members regarding hearing screening results.

The quality improvement project makes use of the Institute for Healthcare Improvement (IHI) Learning Collaborative and Web&ACTION models, where teams will come together at the start of the project for an in-person Learning Session and will subsequently report virtually and collaborate each month on the results of the two-month long action periods, or Plan-Do-Study-Act (PDSA) cycles.

HOW WE SELECTED YOU

You were selected because the application you submitted met the criteria for participation. A total of 5 pediatric practices will participate in this quality improvement project.

WHAT WE WILL ASK YOU TO DO

Over the 8-month project period, each practice team will:

- Devote necessary resources and time to testing and implementing changes in the practice over the specified quality improvement period and working to obtain buy-in from additional members of the practice.
- Test and implement appropriate changes in the structure of how newborn hearing screening results are accessed and utilized to identify infants who do not pass their initial screening and need diagnostic follow up, using QI methodology.
- Review records of all infants ages 6 weeks and 4 months who do not pass the newborn hearing screen (about 4 records per practice) as well as the records of 20 infants ages 6 weeks and 4 months who do pass the newborn hearing screen per practice (up to 44 medical records total), seen in the practice during the review month of the Action Period. Record review and data collection of clinical measurements pertinent to the aims of the project will be completed using the AAP Quality Improvement Data Aggregator (QIDA).
- During project pre-work/baseline, review records from the past three months of all infants ages 6 weeks to 4 months who did not pass the newborn hearing screen as well as the records of 20 infants ages 6 weeks and 4 months who did pass the newborn hearing screen per practice (up to 55 medical records total). Record review and data collection of clinical measurements pertinent to the aims of the project will be completed using the AAP Quality Improvement Data Aggregator (QIDA).
- As part of project pre-work, hold a brief interview/discussion using the provided interview/discussion guide with a family from your practice who has a child diagnosed with hearing loss or who has a child who failed the initial hearing screen to assess gaps in patient care and to develop change strategies based on these gaps. Please note the following: the qualitative data/information from family interviews will not be submitted as part of the project.
- Attend a one-day improvement workshop (in-person Learning Session) at the beginning of the action period on February 12, 2017. Identify a parent/caregiver partner to attend this workshop as a member of the practice quality improvement team.
- Complete monthly progress reports due at the end of each month from February 2017-July 2017.
- Test innovations in care delivery to improve newborn hearing screening follow up in the medical home.
- Share lessons learned and problem-solve with other participating practices during the monthly webinars/conference calls.
- Use the online password-protected Project Workspace in QIDA and dedicated project email group on a regular basis for ongoing support, information, and communication among practice teams.
- Complete a pre- and post- implementation survey(s).
- Decide how to best share learnings with other physicians and staff in the practice using the newborn hearing screening follow up tools and QI resources provided.
- Participate in one (1) one-on-one coaching call with the Quality Improvement Advisor during the project period.
- Participate in a post-project feedback call with the quality improvement advisor and other practice teams at the end of the project (optional).
- If necessary, seek local Institutional Review Board approval for participation prior to Expert Group selection as a practice team participant in the QI project.
- Pediatrician leader only: serve as Local Leader in the attestation process required by the American Board of Pediatrics for Part 4 Maintenance of Certification (MOC) (if approved). Duties include providing each pediatrician in the practice interested in participating for MOC credit a document describing the requirements of their participation, monitoring pediatrician participation and attesting that eligible pediatrician completed the project’s completion criteria.

**PROJECT DURATION**

The project will be implemented over the course of eight months, from January 2017 through August 2017.

**RISKS OF PARTICIPATION**

This project is considered to be minimal risk. This means the risks and discomfort associated with participating in this project are no greater than those ordinarily encountered in day-to-day life or during the performance of routine physical or psychological examinations or tests.

Potential loss of confidentiality

Any time information is collected, there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential, however this cannot be guaranteed (see confidentiality section below).

Publications on the findings of this project will report data at the aggregate level only. No individual-level participant or parent/caregiver data will be reported.

**BENEFITS OF PARTICIPATION**

Practice teams (and individual team members) will have the opportunity to enhance the care they provide for patients in regards to EHDI, and will do so while ensuring appropriate follow-up care, diagnostic testing, and ongoing communication of results with the family. They will also have the opportunity to work with colleagues from across the United States, learn from national experts, access practical tools and effective strategies for how to deliver better care, and receive ongoing support for improvement. If improvements in care are achieved, the benefits to patients and families are also likely to be significant.
Pediatrician participants may have the opportunity to receive MOC Part 4 credit—the application process is currently underway.

COMPENSATION
Participants will not be paid or compensated in any way for participating in this project.

CONFIDENTIALITY
Data collected will not include Protected Health Information. For any research publications resulting from this work, practices (or individuals) will not be linked with the data and only practice level data (aggregate) will be reported. No patients or practice staff will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, the AAP will take all steps allowable by law to protect the privacy of personal information.

For quality improvement purposes, data will be aggregated by practice. In addition, practices will be identified by name in communication for quality improvement purposes with project staff working on the project. You will be able to use a secure online module to view reports of your practice’s aggregate data, as well as aggregate data from other practices. Similarly, other participating practices will be able to view your practice’s aggregate data via the secure online module. Data will be stored on a secure network with password protection. For research purposes, all data will be reported in aggregate, and individual practice data will not be identifiable. Potential publications may include a conceptual model of key barriers and potentially useful strategies that emerged from this project. Practice names will only be used in the acknowledgement section of any potential publications.

VOLUNTARINESS
Your participation in the project is completely voluntary. You may refuse to participate or you may stop participating at any time and for any reason without any penalty or impact. If a pediatrician withdraws early, before meeting the minimum requirements established for them to be eligible for ABP Part 4 MOC credit, he/she may no longer qualify for credit.

The investigators also have the right to stop your participation at any time. This could be because you have failed to follow the commitments described above or because the entire study has been altered or stopped.

WHOM TO CONTACT
This study was approved by the AAP Institutional Review Board. If you have any questions about the project, please contact Christina Boothby (contact information below). If you have any questions or concerns about your rights as a research subject, please contact Erin Kelly, AAP Institutional Review Board Administrator, at 847/434-4075.
CONSENT TO PARTICIPATE

I have read this statement, and I understand what it says. I agree to participate in this study under the conditions outlined above.

Please check ONE box to indicate your consent:

☐ I will participate in the full study, including the post-project feedback call.

☐ I will participate in the study but not the post-project feedback call.

Signature Date _______________________________________

Printed Name _______________________________________

If you choose to participate in this project, please check the appropriate box, sign, scan and e-mail to:

Christina Boothby, MPA
Manager, Division of Children with Special Needs
American Academy of Pediatrics
Email: cboothby@aap.org
Phone: 847/434-4311

You may also send a fax to:

Beth Evans
Division Coordinator
Division of Children with Special Needs
American Academy of Pediatrics
Fax: 847/228-5034

Consent forms must be received no later than January 5, 2017.

Please keep one copy for your files.

If you would like further information about this project, contact:

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Phone: 847/434-4311