



Children	800 maximum (20 medical records *10 practices at baseline, 10 medical records * 10 practices * 6 month action period)
Parents/caregivers	10
Telephone interviews with practice teams	10
Pediatric practice staff (nurses/non-pediatrician clinical staff members, front desk/administrative staff)	20-30
Telephone interviews with families/caregivers	5-10 maximum
Post-visit Family Surveys	700 (10 surveys at baseline *10 practices + 10 surveys * 10 practices *6 month action period)

## 11. ABSTRACT

**Briefly summarize the purpose and procedures of the proposed research (200 words or less).**

The *Family Engagement Quality Improvement Project (Family-Centered Care Quality Improvement Project: Round Two)* is a project of the National Center for Medical Home Implementation (NCMHI), a cooperative agreement between the American Academy of Pediatrics (AAP) and the Maternal and Child Health Bureau, Health Resources and Services Administration. The primary purpose of this quality improvement project is to improve family-centered care by increase participant knowledge and skills related to enhancing family engagement in clinical practice. The project will use a Model for Improvement approach through an intervention that consists of the following components: 1) formation of multidisciplinary practice teams that include a parent/caregiver partner; 2) collaborative/peer-based learning on topics related to the Model for Improvement and family engagement via two in-person learning sessions and monthly interactive conference calls/webinars; 3) using a list of recommended or evidence-based strategies and tools, teams test and implement changes designed to improve family engagement; 4) teams participate in individualized one-on-one coaching from a quality improvement advisor.

This project builds on lessons learned from the first iteration of the *Family-Centered Care Quality Improvement Project* facilitated by the NCMHI and approved on May 15, 2015. See Appendix A for study approval and details.

## 12. LITERATURE REVIEW

**Provide a brief review of the key literature, 2-3 paragraphs, with key references.**

A growing body of evidence supports family-centered care and its impact on health outcomes for children and families. The 2001 Institute of Medicine report, *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century* discusses the need to engage patients in their own health care decisions, inform patients of various treatment options, and improve access to information for patients and families.<sup>1</sup> These core components of family-centered care are also supported by the American Academy of Pediatrics (AAP). The American Academy of Pediatrics policy statement “Family-Centered Care

<sup>1</sup> Institute of Medicine, Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21<sup>st</sup> Century*. Washington, DC: The National Academies Press, 2001.

and the Pediatrician's Role", published in *Pediatrics*, indicates that family-centered care has been shown to improve patient and family outcomes, increase family and professional satisfaction, decrease health care costs, and improve effective use of health care resources.<sup>2</sup>

Despite research supporting implementation of family-centered care, only 67% of families indicated that their children received family-centered care over the last 12 months, as evidenced by data from the 2011/12 National Survey of Children's Health. In addition, only 54% of families indicated that their children receive coordinated, ongoing, comprehensive care within a medical home.<sup>3</sup> Since family-centered care is a key component of the patient-centered medical home, the standard of care for all children and youth, it is important to implement strategies and provide resources to enhance family-centeredness across pediatric practices.<sup>4</sup> This project aligns with AAP recommendations for provision of family-centered care in pediatric practice. Specifically, the project will provide tools and strategies to assist pediatricians and their teams to work with families in decision-making and information sharing across all practice settings, create opportunities for families to serve as advisors, and explore strategies to ensure the core concepts of family-centered care are incorporated into all aspects of professional pediatric practice.

The success of the project hinges on each practice team's ability to work effectively as a team and adapt to changes. Project staff and Expert Work Group members will further support the success of this project by providing evidence-based and evidence-informed tools, resources, and guidance to practice teams in order to improve quality of care provided to children and families.

### 13. PROTOCOL

Please answer ALL the questions below using as much space as necessary to provide a clear, detailed description of your research protocol.

a. **Describe the purpose, major research questions and hypotheses of the proposed study.**

This project builds on lessons learned from the first round of the *Family-Centered Care Quality Improvement Project* facilitated by the National Center for Medical Home Implementation (NCMHI) and approved on May 15, 2015. Given lessons learned from the first iteration of this project, the protocol for the second iteration has been changed to reflect the following:

- An increased amount of time for the action period (six months rather than three months) to allow sufficient time for testing of changes, sustainability, and spread of improvements at the practice level.
- A revised data collection plan, including review of medical records and post-visit family surveys, rather than utilization of the Family-Centered Care Assessment tool for Families (FCCA-F), which many practice reported was burdensome to distribute and difficult for families to understand in the first iteration of the project.
- Inclusion of multidisciplinary core improvement team members (rather than only pediatricians), including pediatricians, nursing and other non-pediatrician clinical professionals, front desk/administrative staff, and parent/caregiver partners.

#### **Purpose**

This quality improvement project will provide participating primary care pediatric practice teams with tools and strategies to improve family-centered care through enhanced family engagement in practice. A time-series design will be used. Repeated measurement of each team's processes involved in caring for patients using patient medical

<sup>2</sup> American Academy of Pediatrics, Committee on Hospital Care. Family-Centered Care and the Pediatrician's Role. *Pediatrics*. 2003;112(3):691 – 696

<sup>3</sup> National Survey of Children's Health. NSCH 2011/12. Data query from the Child and Adolescent Health Measurement Initiative, Data Resource Center for Child and Adolescent Health website. Retrieved 2/29/16 from [www.childhealthdata.org](http://www.childhealthdata.org)

<sup>4</sup> American Academy of Pediatrics, Medical Home Initiatives for Children with Special Needs Project Advisory Committee. The Medical Home. *Pediatrics*. 2002; 110(1): 184-186.

record reviews will be conducted at baseline and over the course of six months to track changes in practice related to family-centered care.

Specifically, members of the primary care practice teams will work individually and collaboratively to test, implement, disseminate, and plan to sustain strategies to improve family engagement in clinical practice through enhanced shared decision-making and connection of families to appropriate supports and services.

Using a convenience sample of 10 patient medical records reviewed each month, participating teams will make improvements so that by the final month the following will occur:

1. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that patient/family concerns were elicited at the most recent health supervision visit.
2. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that patient/family concerns were addressed at the most recent health supervision visit or a plan to address the concerns was made.
3. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that family strengths were identified and discussed at the most recent health supervision visit.
4. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that a post-visit medical summary or a comprehensive care plan was created or updated/maintained at a most recent health supervision visit.
5. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that a current copy of their post-visit medical summary or comprehensive care plan was reviewed through an active form of family engagement and offered to patients/families at a most recent health supervision visit.
6. 80% or more of patient medical records (ie, at least 8 of 10 medical records reviewed) have documentation that families received a follow-up discussion of age-appropriate screening results on the same day as the screening.

Using a convenience sample of 10 patient surveys per month, participating teams will make improvements so that by the final month the following will occur:

7. 80% of parents/families (ie, 8 of 10 parents surveyed) will indicate that their practice honored or respected parent/family values and beliefs.
8. 80% of parents/families (ie, 8 of 10 parents surveyed) will indicate that information about their child's health was explained in an easy to understand manner.
9. 80% of parents/families (ie, 8 of 10 parents surveyed) will indicate that individuals providing medical care to their child showed respect for the family.
10. 80% of parents/families (ie, 8 of 10 parents surveyed) will indicate that practice staff treated them with dignity and respect.
11. 80% parents/families (ie. 8 of 10 parents surveyed) will indicate that individuals providing medical care to their child involved families in decisions about their child health.

See Appendix B for details about the project aim and measures.

### **Hypothesis**

Providing pediatricians and their staff with tools, resources, and strategies to enhance family engagement in practice, along with support through a quality improvement learning collaborative, will improve care and systems in practice to enhance quality of health care delivery.

Over the course of the project period, core improvement team members (specifically, pediatricians, nursing and other non-pediatrician clinical staff, front desk/administrative staff) will:

- *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, application process is currently*

*underway). 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.*

- Devote necessary resources and time to testing and implementing changes in the practice over a specified 6-month action period and work to obtain buy-in from all members of the practice.
- Complete pre-work activities prior to Learning Session 1, including collection of baseline data (20 medical records of patients age 0-18 years seen for health supervision visits, per practice), completion of a pre-implementation survey, and participation in a 60-minute flipped classroom orientation call. Baseline medical record review will be completed using the Academy's Quality Improvement Data Aggregator (QIDA).
- Attend a 1.5-day improvement workshop (in-person Learning Session 1) at the beginning of the 6-month action period. Identify a parent/caregiver partner to attend this workshop as a member of the core improvement team (see below for more details on the role of the parent partner).
- Learn the *Model for Improvement* and implement Plan-Do-Study-Act (PDSA) cycles.
- Make appropriate changes in the structure of how care is monitored and delivered to patients and families.
- Regularly collect and transmit clinical measurements pertinent to the aims of the project.
- Review medical records of the first 10 patients age 0-18 years seen for a health supervision visit per month in the practice (total of 10 medical records per practice). Medical record review will be completed using QIDA. The data will be identified by practice name and available for all project participants and the expert work group to review during the course of the project through QIDA (password-protected). For participating practices with only one physician involved, the resulting data will be identified at the physician level (reported by the practice name).
- Share lessons learned and problem-solve with other participating practices through monthly conference calls and emails.
- Complete necessary pre-work for monthly conference calls/webinars (if applicable)
- Use the online password-protected Project Workspace (available through QIDA) and dedicated project listserv on a regular basis for ongoing support, information, and communication among practice teams.
- Complete a pre- and post- implementation survey during the project (one per team).
- Complete a Monthly Progress Report each month (one per team).
- Participate in at least two one-on-one quality improvement coaching calls with the project's quality improvement advisor.
- Collect up to 10 post-visit family/caregiver surveys, from families of patients age 0-18 years that were seen for health supervision visits, from the practice each month through the 6-month testing period.
- Attend a 1.5-day workshop (Learning Session 2) at the end of the 6-month testing period. The identified parent/caregiver partner at each practice will also attend this workshop as part of the core improvement team.
- Share results and progress about the project with other practice staff and physicians, including practice leadership.
- Participate in qualitative interviews with an evaluation consultant at the completion of the project (optional).
- If necessary, seek Institutional Review Board approval for participation prior to completion of pre-work.

Parent/caregiver core improvement team members may participate in some of the activities listed above. Additional information about parent/caregiver partner participation in the project, including a "job description" is provided below.

As a benefit of participation in this quality improvement project, if approved by the American Board of Pediatrics (ABP), pediatricians in the practice will be eligible for Part 4 (Performance in Practice) Maintenance of Certification (MOC) credits. This includes pediatricians represented on the core improvement team as well as other physicians in the project. The application for ABP Part 4 MOC is currently underway.

Practice teams will have the opportunity to learn and test strategies to improve family-centered care through family engagement, shared decision-making, and connection of families to appropriate supports and services. Participants will also have the opportunity to participate in collaborative learning and to share promising practices, challenges, successes,

and lessons learned. If improvements in care are achieved, the benefits to families/caregivers and children are likely to be significant.

**b. Describe the population, sample, and inclusion and exclusion criteria.**

Recruitment materials and an application will be used to select pediatric practice teams to participate in the project (see Appendix C, D, and E for the recruitment application, recruitment flyer, and recruitment email). Ten individual practice teams will be recruited nationwide to participate in the project. In order to be selected for the project, applicants must be from a primary care practice. Pediatric subspecialty practice teams will not be included in this project/study.

Applications will be reviewed by NCMHI staff, the quality improvement advisor, and the project Expert Work Group. Applications will identify practice team members who will serve as the “core improvement team members” from each primary care practice. These are the individuals who the project staff, consultants, and Expert Work Group members communicate with on a regular basis, are responsible for data collection/entry, and attend face-to-face meetings with other practice core improvement teams. They also relay information back to others in the practice so that system improvements can be made. The core improvement team members will be consented to participate by project staff and complete the duties outlined above. Core improvement teams will include 4 individual participants: a pediatrician, a nursing/non-pediatrician clinical team members (Registered Nurse, Medical Assistant, Physician Assistant), front desk/administrative staff, and a parent/caregiver partner (who is a parent/caregiver of a patient in the practice).

Once individual practice teams are selected to participate in the project, each team member will be required to sign a consent form for participation (Appendix F). Parents/caregivers will not have access to the QIDA workspace with practice team data or the project listserv and, as such, will not be asked to sign a consent form for participation in this project. Consent forms will be distributed via email by project staff and collected by project staff (expected primarily via email or fax with a few forms via postal mail if necessary) upon selection into the project with additional selection materials.

**c. Describe the different procedures planned for this study. What are the procedures you will use to collect data? How will you carry them out, and how will participants be involved? What measurements will be performed? Please include separate information for each different procedure that you plan to use.**

**Measures and Procedures**

The total time practice teams will be involved in the project is ten months: two months of baseline data collection and Learning Session 1, six months of testing/Action Period, and two months for Learning Session 2 and project evaluation. The project will consist of the following procedures:

- **Pre-work Period** (May - June 2016, 2 months)
  - Baseline medical record review (20 medical records per practice using QIDA)
  - Baseline post-visit family survey collection (10 post-visit family surveys per practice using QIDA)
  - Pre-implementation practice survey
  - “Flipped classroom” orientation call
- **Learning Session 1** (June 2016)
- **Action Periods** (July – December, 2016, 6 months)
  - Medical record review (10 medical records entered per practice using QIDA)
  - Monthly progress reports (1 report per practice, narrative)
  - Monthly conference call participation and any relevant pre-work associated with same
  - Monthly conference call evaluation survey
  - One-on-one quality improvement coaching calls (two calls per practice team)
  - Monthly post-visit family surveys (maximum of 10 surveys collected per practice per month)
- **Post-Action Period** (January – February 2017, 2 month)
  - Post-implementation survey

- **Learning Session 2** (January or February 2017, date to be determined, in-person meeting)
- **Additional Project Components**
  - Expert Work Group
  - Project work space and email group/listserv
  - Parent/caregiver partner
  - Qualitative interviews with practice teams (optional, including parent/caregiver partners)

### **Pre-work Period**

After recruitment of practice teams, an orientation call will be held for all core improvement team members. This call will utilize a “flipped classroom” structure, in which participants will be assigned homework (also known as pre-work) to complete prior to the call. The “flipped classroom” approach enhances engagement of participants and collaborative learning. The pre-work assignment will focus on quality improvement methodology. The call will be utilized to facilitate a discussion about quality improvement methodology, as well as roles and responsibilities of core improvement team members throughout the project. Practice teams will also learn how to utilize the QIDA software and how to complete baseline data collection and pre-implementation surveys. The medical record review tool, post-visit family survey data entry tool, and pre-implementation survey are included in this application as Appendices G, H, and I respectively.

### **Learning Session 1**

Core improvement team members will attend an improvement workshop (Learning Session 1) prior to beginning the 6-month action period. Parents/caregivers (additional information below) will also attend the learning session with their team to provide valuable perspective and insights regarding family-centered care and family engagement.

Parents/caregivers will also participate with the team in collaborative learning around family engagement. No data will be collected from the parents/caregivers. At the learning session, core team member participants will do the following:

- Review the aim, measures, and goals of the project
- Be oriented to the tools, measures, change package and data collection requirements
- Review results from baseline data collection
- Be trained in the use of the *Model for Improvement* for implementing process changes (Plan-Do-Study-Act cycles)
- Be educated on the content area (family engagement, shared decision-making, connecting families to appropriate supports and services)
- Discuss strategies for leadership buy-in, sustainability, and spread of improvements
- Discuss barriers to implementing changes and ways to overcome these barriers
- Hear from family advocates/leaders about strategies to enhance family-centered care
- Engage in individual and collaborative learning to plan at least one cycle of change to implement during the first month of the 6-month action period

Upon completion of Learning Session 1, attendees will be asked to complete an anonymous survey (Appendix J) to evaluate their experience throughout the learning session and provide suggestions for improvement.

### **Action Period**

The quality improvement advisor, project staff, and project Expert Work Group developed a change package with tools, resources, and specific examples of PDSA cycles that can be implemented to make improvements related to family-centered care through family engagement. During the 6-month action period, the practice teams will test changes and improvements in practice utilizing the tools, resources, and PDSA examples included in the change package. They will test the tools, use the data collection instruments, and track the measures in their settings in a sequential series of activities guided by the quality improvement advisor and designed to help the practice teams improve family-centered care through family engagement.

A simple time-series design will be used to determine the trend over time for clinical care process change among participating practice teams. Monthly medical record reviews will be conducted by core improvement team members for the first 10 patient medical records of patients age 0 – 18 years seen for a health supervision visit in practice. This data will guide improvement efforts. Practice teams will review run charts on a monthly basis, displaying data obtained from their medical record reviews as entered into QIDA. Run charts will help practice teams visualize their progress over time and also provide information to share with practice staff who are not part of the core improvement team in order to encourage buy-in, sustainability, and spread. Appendix G contains the QIDA medical record review tool that practice teams will use when entering data into QIDA. In addition to monthly medical record reviews, practice teams will provide feedback and information on their progress, successes, and challenges through monthly narrative progress reports (Appendix K). Each practice team will be required to complete one progress report each month. Results and feedback from the progress report will be shared with other practice teams on monthly conference calls (see below).

During each month of the 6-action period, practice teams will be required to collect up to 10 post-visit surveys (Appendix H) from families/caregivers in the practice. Surveys will be collected from families/caregivers who received a health supervision visit for their child age 0-18 years. These surveys are anonymous and do not contain any patient or family identifiers. Surveys will be entered into QIDA by a designated core improvement team member each month. Practice-level survey results will be shared with the practice teams during monthly educational conference calls. No patient identifiers or family identifiers will be presented, or known, through the surveys.

During the action period, each practice team will participate on two one-on-one quality improvement coaching calls with the quality improvement advisor. These calls are designed to provide technical assistance and support to each practice team related to planning, testing, and sustaining changes in practice. Since these calls are held with only one practice team at a time, each team will receive individualized support tailored to their particular practice setting and situation. Project staff will participate on these calls and provide further technical assistance if necessary. Successes and challenges shared with the quality improvement advisor by practice teams during these calls will be shared with other practice teams as promising practices.

The quality improvement advisor, with assistance from project staff and the project leader, will facilitate monthly conference calls/webinars with the practice teams. On these calls/webinars, core improvement team members will share results of their tests of change with the project staff, consultants, participants, and members of the Expert Work Group. Practice teams will have the opportunity to receive additional education regarding family-centered care, family engagement, shared decision-making, and connecting families to appropriate supports and services, among other topics. Aggregate medical record review data will be shared with all project participants (this data will not contain any pediatrician or patient identifiers) and strategies for making improvements based on aggregate data will be shared. In addition, participating pediatricians will share the results of their tests of change with the Project Leader, quality improvement advisor, Expert Work Group, staff, and other project participants. During the webinars, project participants will be able to share ideas, strategies, and learn from each other. An evaluation (Appendix L) will be sent to individual team members to complete after the conference calls/webinars. Evaluations will be anonymous and optional from each team member.

### **Post-Action Period**

At the conclusion of the 6-month action period, practice teams will be asked to again assess current existing practice-based systems for providing family-centered care through family engagement via a post-implementation survey (one survey per practice team, Appendix I).

### **Learning Session 2**

After the 6-month action period, a second 1.5-day workshop for practice teams will be conducted (Learning Session 2). Each practice team will be asked to attend the workshop along with their parent/caregiver partners, to share their



experience and provide valuable feedback on family-centered care and family engagement. No data will be collected from parents/caregivers. This learning session will provide participants an opportunity to do the following:

- Learn results of data collection (report on at the aggregate level, this data will not contain any patient names or identifiers)
- Hear from other teams about their experience, successes, and challenges
- Obtain additional information, tools, and resources related to family-centered care
- Discuss strategies for sustainability and spread of improvements
- Hear from parents/caregivers about their experiences with family-centered care, family engagement, and shared decision-making, among other topics

As with Learning Session 1, an anonymous evaluation survey (Appendix J) will be given to Learning Session 2 participants upon the completion of the learning session. The survey will evaluate participant satisfaction with the learning session and identify areas for improvement among future projects.

### **Additional Project Components**

- **Expert Work Group** -- The Expert Work Group has overseen the design of the project and will assist staff and consultants with implementation and evaluation. The Expert Work Group consists of AAP staff, experts in family-centered care and family engagement in pediatrics, a nationally recognized family leader with expertise in quality improvement, a quality improvement advisor, and an evaluation consultant. The Expert Work Group will be available to answer clinical and process-related questions and the quality improvement advisor will provide quality improvement coaching to teams, as needed. Expert Work Group members will participate in learning sessions, monthly educational conference calls/webinars, and one-on-one quality improvement coaching calls as necessary and appropriate. Expert Work Group members will also have access to the project work space and the email distribution list/listserv. Practice team members will be notified through the consent form that Expert Work Group members have access to data, resources, and information shared through the project work space. See Appendix M for the Expert Work Group roster.
- **Project Workspace and Listserv** – To assist in information sharing and provision of educational materials, a number of technology tools will be used throughout the project. The Academy’s QIDA will be used for data collection and will also serve as the password-protected project workspace. It will provide resources and tools related to the project, and include practice-level and project-level data (an aggregate of all participating practices’ data). This will allow a point of comparison for practice teams over the course of the project and has been helpful in previous quality improvement projects. The project listserv will include all core improvement team members. (Note: In some cases, practice teams may request to extend their core improvement team with additional members. In this case, any additional members will be asked to sign a consent form and will be treated as a member of the core improvement team.) The list will provide a forum for communication among practice team members, as well as serve as the main method of communication from the Expert Work Group and staff to the practices regarding project information (tool updates, data collection information and tools, monthly call reminders, etc). The Project Workspace and the project listserv will be available to the Expert Work Group members, but will not be accessible to parent/caregiver partners (additional information in following section).
- **Parent/Caregiver Partners** – All practice teams will be required to select and recruit a parent/caregiver partner for the project. No data will be collected from the parent/caregiver partners, with the exception of feedback provided by the parent/caregiver partner during the project’s qualitative interview process (upon the completion of the project). Recruitment materials include guidance on how to identify and select a willing and capable parent/caregiver partner. A “flipped classroom” orientation call held for the practice teams at the beginning of the project will outline roles, responsibilities, and expectations for the parent/caregiver partner as well as other team members. The selection of a parent/caregiver partner is in no way related to the medical record reviews. The project recruitment materials and application requests general (name and contact) information about the selected parent/caregiver partner, and ideally the parent/caregiver partner will commit to serving in this role (if the practice is selected for participation) by the time the application is submitted. All parent/caregiver partners must be committed and confirmed for each practice team before Learning Session 1.

Parents/caregivers have a unique and invaluable perspective on family-centered care and family engagement, and will help to guide and assist the practice team with their improvements related to these important topics. The exact roles and responsibilities of the parent/caregiver partner will be outlined in the project’s “flipped classroom” orientation call. A sample “job description” for parent/caregiver partners (Appendix N) will be provided to the parent/caregiver partners and practice teams to guide them in determining appropriate roles and responsibilities for their involvement with the practice’s quality improvement efforts. Parent/caregiver partners will attend the learning sessions and will be invited to participate on the monthly conference calls. As such, they will be present during the presentation of aggregate data (without practice or pediatrician identifiers), educational sessions, and other conversations among participants related to the project. However, the parent/caregiver partners will not have access to the password-protected Project Workspace. Core improvement team members will be notified in recruitment and application materials and in the consent form that parent/caregiver partners will have access to this data via the learning session and conference calls/webinars.

Parents/caregivers will be asked to participate in qualitative interviews upon the completion of the project, view Appendix O for the qualitative interview questions. Participation in the qualitative interviews is optional. Parent/caregivers will be given a consent form for participation in this portion of the project prior to the interview date (see Appendix P for a copy of the consent form specifically for parent/caregivers to participate in qualitative interviews). Parent/caregiver partners will have the option to participate on the qualitative interview with the rest of the practice team, or individually, based on comfort level of each parent/caregiver. Further information, including benefits for parent/caregiver participation in the project, is provided further in this application.

- **Qualitative Interviews with Practice Teams (Optional)** – Additionally, practice teams (including parents/caregivers) will have the option to participate in qualitative interviews via telephone with the project’s evaluation consultant. A paper telephone interview script (Appendix O) and data collection form will be used to conduct these interviews. The purpose of the interviews is to collect in-depth, qualitative information related to practice team and parent/caregiver experience in the project. Specifically, the interviews will focus on gathering data related to team experience with quality improvement methodology as well as implementing changes in family-centered care through family engagement. Interviews will be conducted by the project’s evaluation consultant. No project staff or Expert Work Group members will be on the calls. Results from the interviews will be presented in aggregate form with no practice or individual team member identifiers. Parents/caregivers will be invited to participate in these interviews; parents/caregivers can choose to participate in individual interviews, or with other members of the practice team. Participation in qualitative interviews is completely optional for all core improvement team members.

## Measurement

Measurement is an important part of any quality improvement effort. For this project, the Quality Improvement Data Aggregator (QIDA) system will be used for data collection. See Appendix B for a brief summary of the project measures, and Appendix G for a copy of the medical record review form. In addition to the medical record review measures, practice teams will collect post-visit surveys (Appendix H) from families/caregiver in practice each month. Practices will complete pre- and post- implementation surveys (Appendix I) during baseline and at month six of the project. Practices will complete monthly narrative progress reports (Appendix K) throughout each month of the 6-month action period. These surveys will collect additional data from practice teams and allow practice teams the opportunity to determine other, more systems-level improvements that can be made in practice. Qualitative interviews (Appendix O) will be conducted at the end of the project to gather feedback from core improvement team members on their satisfaction with participation in the project (interviews are optional for all project participants). Project staff will document changes suggested by practice teams during the learning session, monthly calls, monthly reports, and e-mail communications. Results from qualitative interviews will be analyzed for core themes and patterns. All results of the project will be documented to help inform future similar endeavors. Additionally, data collected from the participating practice teams will be analyzed by the quality improvement advisor to determine which changes practices prioritized and whether or not

a particular sequence of changes facilitates improvement. This analysis will inform dissemination efforts following the project.

- d. **What data will you collect? Please describe data collection for each phase, research strategy, tool, involved population etc. that you plan to use.** *Please include copies of all questionnaires, surveys, interview questions, etc. as appendices, and label each clearly so the IRB knows which questions, tool, etc. go with which research activity. If a draft of one of these documents is provided, it should be clearly labeled as such and a final version must be submitted before data collection begins.*

### **Medical Record Reviews (QIDA)**

The Academy's QIDA system will be used for data collection and reporting for this quality improvement project. A module specific to this project will be set up within the QIDA system. The module will include content on quality improvement methods and on improving family-centered care through family engagement. Participating practice teams will make small tests of change to test practice improvements related to these topics and will submit monthly practice medical record review data through this module as a means of tracking progress toward improvement. This project will collect data using medical record reviews and provide feedback on project measures using run charts created through QIDA. The project's evaluation consultant will conduct additional data analysis to determine incremental improvement over baseline for each practice. Each practice team will assign one person as the "practice administrator" for QIDA. This person will be designated to enter data for their team. The other three team members will not have rights in the system to enter data, but will be able to review and analyze data. Data will be entered on a monthly basis using a medical record review tool (Appendix G).

As with all QIDA modules, this module will be web-based and allow practice teams to enter their improvement data securely, view real-time data reports and provide access to a practice administrator to help facilitate practice wide implementation. The system allows for the production of various reports and clinician dashboards.

Data entered into the QIDA is without patient identifiers (see below) and will be entered by a designated member of the core improvement team through the use of the online data collection tool (Appendix G for Medical Record Review tool). These data will be transmitted electronically to the AAP via QIDA and will not contain any patient identifiers. For this reason, no parent/caregiver informed consent for data collection will be sought.

Every month for six months (and once at baseline), practice teams will take a total sample of 10 patients (20 at baseline) age 0-18 years seen for health supervision visits and transcribe the following de-identified data elements (in a dichotomous format) into QIDA:

- Patient and/or family concerns elicited at recent visit
- All patient/family expressed concerns addressed or plans made to address them
- Patient and/or family strengths were identified and discussed at the visit
- Post-visit medical summary or comprehensive care plans created and/or updated/maintained at the visit
- Current copy of the post-visit medical summary/comprehensive care plan reviewed with the family, through an active form of family engagement, and offered to the patient/family at this visit
- Patients and families received a follow-up discussion of age-appropriate screening results on the same day as the visit

To assist with medical record review and data entry, a medical record tip sheet has been created by project staff with guidance from the Expert Work Group and quality improvement advisor (Appendix G). The tip sheet clarifies what can and cannot be included as documentation for each of the aforementioned data elements.

Practice teams will have access to performance data for quality improvement purposes. The de-identified data elements from the online data collection tool, aggregated by practice, will be presented on each measure on a monthly basis to participating practice teams. Data is collected by practice, not by individual pediatrician, so no individual pediatrician data

will be identified or known to others involved in the project. Data will be reported by practice name and practice teams will be able to see the aggregate of other practice team data, as well as an aggregate of the entire 10 practices' data.

In addition to aggregate data describing performance on each measure based on the target goal, the project's evaluation consultant will conduct individual analysis of data to determine incremental improvements over baseline for each individual practice. This will be conducted by downloading/exporting data entered into QIDA. Project staff will download this data and share it with the project evaluation consultant over email. The downloaded data will have practice names but not individual pediatrician identifiers or patient identifiers. Run charts will be created to demonstrate incremental improvements over baseline for each individual practice team and will include practice names. This individual practice-level data will only be shared with individual practice teams. See Appendix Q for a sample run chart, displaying how data will be available for practice teams to view.

### **Pre- and Post- Implementation Surveys**

In addition to the medical record review described above, members of the core improvement team will be asked to complete a brief online pre- and post- implementation survey. Only one survey will be completed from each practice team (one before project implementation, and one after project implementation). This survey will be conducted using Survey Monkey.

The pre- and post- implementation survey(s) collect qualitative information related to practice characteristics, patient population, and family engagement knowledge and implementation. Practice teams will be asked to include the name of their practice on the pre- and post-implementation survey, as a way for staff to track survey submissions by practice teams. See Appendix I for a copy of the pre- and post- implementation surveys.

### **Learning Session Evaluation Surveys**

After participation in the project's two in-person learning sessions, practice team members will be asked to complete evaluation surveys (Appendix J). Surveys will be anonymous and will gather feedback from learning session participants about the quality of education provided throughout the learning sessions. Feedback from learning session evaluation surveys will be used by project staff, evaluation consultant, quality improvement advisor, and the Expert Work Group to improve the quality of further learning sessions.

### **Monthly Progress Reports**

At the end of each month throughout the 6-month action period, practice teams will be required to complete a monthly progress report. This report was developed by project staff, quality improvement advisor, evaluation consultant, and Expert Work Group members. The report will be available electronically through Survey Monkey. Only one report will be completed from each team. The report will include the name of each practice but will not include pediatrician names. Data from monthly progress reports will help the quality improvement advisor facilitate discussions during the monthly conference calls with practice teams and identify learning gaps, successes, and challenges practice teams may be facing. See Appendix K for a copy of the monthly progress report.

### **Monthly Educational Conference Call/Webinar Evaluations**

After each monthly educational conference call/webinar, practice team members will be asked to complete an evaluation survey. The survey will assess participant reactions, learning, and attitudes related to each educational call/webinar. Individual practice team members can complete individual surveys (more than one survey can be submitted per practice team) to provide individual feedback. The survey will be administered via Survey Monkey. Following each conference call/webinar, participants will be emailed a link to the electronic survey. The surveys will be anonymous. Results from these evaluations will be shared with the project staff, evaluation consultant, quality improvement advisor, and Expert Work Group members in order to improve the quality of educational conference calls throughout the duration of the project and in future endeavors. See Appendix L for a copy of the conference call/webinar evaluation form.

### **Post-Visit Family Surveys**

Each month, practice teams will collect up to 10 post-visit family surveys (Appendix H) from families/caregivers seen in the practice. These surveys are designed to obtain feedback from families/caregivers related to the care they receive within the practice. Practice teams will be asked to collect these surveys in an anonymous manner so that families cannot be identified. Practice teams will be given suggestions on how to collect surveys anonymously. For example, practice teams may leave a box in the waiting room to return the survey in an anonymous manner. The first 10 surveys that are received each month will be entered into the QIDA (see details below). Another methods practice team can use to collect post-visit family surveys is to have front desk staff collect surveys from the first 10 families that are seen in the practice each month for health supervision visits. All surveys collected by the practice teams will be entered at the end of each month and do not include family names, no patient or family identifiers will be known. Survey data will be entered into QIDA by a core improvement team member and will be anonymous, without any patient or family identifiers. Survey results will be presented during monthly conference calls in aggregate form, without patient or family identifiers. Survey data will be used to assess quality of family-centered care and family engagement provided by each practice. Practice teams will share their strategies/methods for collecting post-visit family surveys with

#### **Post-Implementation Telephone Interview Script and Data Collection Form (optional)**

Practice teams (including parents/caregivers) will participate in qualitative interviews via telephone with the project's evaluation consultant. A paper telephone interview script (Appendix O) will be used by the evaluation consultant to conduct these interviews. The purpose of the interviews is to collect in-depth, qualitative information related to practice team and parent/caregiver experience in the project. Specifically, the interviews will focus on gathering data related to team experience with quality improvement methodology as well as implementing changes in in practice. The project's evaluation consultant will take notes during the interviews in an effort to record responses directly on the hard copy interview script/form. The interviews will also be recorded using a digital voice recorder. The notes and digital voice recording files will be used by the project's evaluation consultant to create a transcript of the interview responses. Participants will agree to participate in the phone interviews when they consent to participate in the project, with the exception of the parent/caregiver partner. A consent form specific to participation in the qualitative interviews will be given to parents/caregivers prior to the qualitative interview (See Appendix R, S, and P for the invitation for parent/caregiver partners to participate in the interview, information about completing the consent form, and the consent form respectively. In addition, immediately before the interview begins, participants will be verbally informed that they do not have to answer any questions they do not wish to, and can stop the interview at any time. They will also be informed that the interview is being recorded. Parent/caregiver partners will be given the option to participate in qualitative interviews individually or with the rest of their core improvement team. All interview results will be presented in aggregate format through a final report submitted by the evaluation consultant at the end of the project. No participant identifiers or practice names will be included in the interview final reports.

#### **e. Describe other important information related to your protocol, if any.**

There is no other important information related to the protocol of this project.

### **14. PARTICIPANT IDENTIFICATION, RECRUITMENT, & SELECTION**

#### **a. Describe how potential participants will be identified (e.g., advertising, individuals known to investigator, record review, etc.). Explain how investigator(s) will gain access to this population, as applicable.**

Potential participants will be identified utilizing the following communication outlets:

- National Center for Medical Home Implementation Web site (announcement, recruitment flyer)
- National Center for Medical Home Implementation listserv
- Outreach to AAP chapter leadership (executive directors, presidents, and vice-presidents)
- AAP membership (through various email distribution lists to members such as SmartBrief and OnCall)
- National Center for Medical Home Implementation partners and stakeholders outside of the AAP (distribution lists), including but not limited to Family Voices, Association of Maternal and Child Health Programs, The

Catalyst Center, the National Coordinating Center for Regional Genetics Collaboratives, Patient-Centered Primary Care Collaborative, among others.

See Appendix T for a full list of recruitment outlets.

- b. **Describe the recruitment process, including the setting in which recruitment will take place and who will conduct recruitment.** *Provide copies of proposed recruitment materials (e.g., ads, flyers, website postings, recruitment letters/emails, and oral/written scripts).*

Ten primary care pediatric practice teams will be recruited nationally using the methods described below. The goal is to obtain a diverse sample of practices in terms of practice geographic location, practice setting (urban, rural, suburban), practice size, and practice type (eg, private practice, large academic center, Federally Qualified Health Center).

To be selected for participation in the project, practices must provide primary care services and see at least 10 patients age 0–18 years for health supervision visits per month. A recruitment flyer and invitation email (Appendix D and E) which contains information about the project and requirements for participation will be used to conduct recruitment. The flyer will be posted on the NCMHI Web site and distributed through the NCMHI listserv, as well as other communication outlets internal and external to the AAP. Project staff will conduct outreach with guidance from the Project Leader and Expert Work Group.

The recruitment flyer will include a link to the project application, available through Survey Monkey. All applicant information will be downloaded by project staff, imported into an Excel spreadsheet, and shared with the Project Leader, quality improvement consultant, and Expert Work Group, who will make recommendations about selecting practice teams for participation in the project. See Appendix C for a copy of the project application, which asks for the name, address, and additional contact information of all practice team members, including parent/caregiver partners.

A recruitment call will be held for any individuals who wish to learn more about the project, specifically the timeline, expectations, requirements for participation, project aim and measures. The quality improvement advisor and project staff will facilitate this call.

Upon selection into the project, practice teams will receive additional information about project participation in an acceptance letter (Appendix U). Practice teams who were not selected will receive a notification of non-selection letter (Appendix V) Practice teams will also be sent a consent form, to be completed by all members of the team, except for parent/caregiver partners who will not have access to data (Appendix F). Parent/caregiver partners will be given a separate consent form to complete for participation in qualitative interviews (Appendix P).

In addition to these materials, specific expectations for participation in the project will be presented on a “flipped classroom” orientation call, which will take place approximately one week after practice teams are selected into the project. The call will specifically outline the roles and responsibilities of the pediatrician team leader and the parent/caregiver, as well as other core members of the improvement team. The call will also provide an overview/introduction to quality improvement methodology. The call will be facilitated by the quality improvement advisor and project staff. Signed consent forms will be collected by staff following this call via email, fax or through ground mail.

**15. INFORMED CONSENT PROCESS**

- a. **Indicate the consent process(es) and document(s) to be used in the study. Check all that apply.** *Please provide copies of documents and/or complete relevant forms, as needed. For more information, see [OHRP Tips on Informed Consent](#); [OHRP Informed Consent Checklist](#); and, [OHRP Informed Consent FAQs](#).*

<input checked="" type="checkbox"/>	Informed Consent – Form → <b>Attach Consent Form</b> which includes all federally required elements of informed consent, Appendix F for practice teams, Appendix P for parent/caregiver partners to participate in qualitative interviews.	<input type="checkbox"/>	Assent – Verbal Script → <b>Attach Script</b> OR Assent – Form → <b>Attach Form</b>
<input type="checkbox"/>	Informed Consent – Verbal Script → <b>Complete and attach Waiver or Alteration of Informed Consent Request Form</b>	<input checked="" type="checkbox"/>	Waiver or Alteration of Informed Consent or Assent → <b>Complete and attach Waiver or Alteration of Informed Consent Request Form, Appendix W</b>
<input type="checkbox"/>	Other, explain:		

- b. **Who will obtain consent from participants or their legally authorized representatives?** *Check here if not applicable:*  *N/A*

Project (AAP) staff will obtain consent from individuals participating on the core improvement teams, which includes three people per team: pediatrician, nursing or non-pediatrician clinical team members, and front desk/administrative staff. Project staff will also obtain separate consent from parents/caregivers to participate in qualitative interviews prior to each qualitative interview.

- c. **Who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian)?** *Check here if not applicable:*  *N/A*

Core improvement team members will provide consent for participation in the project. These members include the pediatrician, nursing or non-pediatrician clinical team members staff, and front desk/administrative staff. Parent/caregivers will provide consent for participation in the qualitative interviews.

- d. **Describe the consent process, including how the federally required information will be presented to subjects (consent form, orally, information sheet, etc.). Include when and where consent will be obtained and how subjects and/or their legally authorized representatives will be provided sufficient opportunity to consider participation.** *Check here if not applicable:*  *N/A*

Upon selection into the project, participants will receive an email from AAP project staff containing additional materials about project participation, including the consent form, that are attached to their acceptance letter/e-mail. Specific expectations related to participation will be presented on a flipped classroom orientation conference call, which will also provide information about quality improvement methodology, taking place approximately one week after the practice teams are notified of their selection into the project. The purpose of this call is to describe roles, responsibilities, expectations, an overview of aims/measures, quality improvement methodology, project activities, and next steps related to the project. The call will be facilitated by the quality improvement advisor and project staff. The call will be held before any data is submitted for the project. Consent

forms will be collected by project staff following this call, primarily through email or fax, with some forms potentially submitted through postal mail. See Appendix F for a copy of the consent form.

- e. **Explain how the possibility of coercion or undue influence will be minimized in the consent process.** *Check here if not applicable:*  *N/A*

Upon selection into the project, practice teams will receive additional information about project participation, including a consent form, via email. This email will be sent to each practice team member's (except the parent/caregiver) email address on the team (contact information for each individual on the team will be required in the application). Ample time (approximately one week) will be provided for individual team members to review these materials. During the "flipped classroom" orientation conference call, practice teams will be provided an open forum to have all their questions and concerns related to participation in the project addressed by the quality improvement advisor and project staff. Staff contact information will be provided during this call and it will be announced to all individual participants that they may contact staff privately with any concerns or hesitations about their involvement.

- f. **How will it be determined that the subjects or the subjects' authorized representatives understand the information presented?** *Check here if not applicable:*  *N/A*

During the orientation conference call, practice teams will be provided an open forum to have all their questions and concerns related to participation in the project addressed by the quality improvement advisor and project staff. Staff contact information will be provided during this call and it will be announced to all individual participants that they may contact staff privately with any concerns or hesitations regarding their involvement. Consent forms will be submitted from individuals directly (on their own accord) rather than submitted in compiled format from the entire practice teams.

- g. **Describe additional information regarding the consent process, if applicable.**

No additional information.

## 16. CONFIDENTIALITY OF DATA

**Explain how information is retained, including storage, security measures (as necessary), and who will have access to the information. Describe for both electronic and hard copy records.** *If there are different sources of data and different levels of access, please attach a table to clearly outline who has access to what data.*

- a. **Who will have access to the data?**

The quality improvement advisor and AAP project staff will assist each practice team in tracking progress toward a pre-set target for each measure through a monthly data report (run charts). Monthly reports containing run charts for each practice will be generated by the QIDA and posted to the password-protected secure online project workspace, through the QIDA, by project staff. All patient data will be aggregated in the monthly reports for each practice with no individual patient or pediatrician data reported/specified. In the case that a participating practice has only one pediatrician, practice-level data will dually serve as pediatrician level data. This risk will be discussed on a one-on-one basis with the affected pediatrician(s) and the core improvement team members by the Expert Work Group, project staff, and quality improvement advisor during the orientation process.

Incremental improvements from baseline for each individual practice will be calculated by the evaluation consultant using exported data from the QIDA. This data will be exported by AAP staff and shared with the



evaluation consultant over email. No patient identifiers or pediatrician-level data will be included in this analysis, with the exception of those practices that only have one pediatrician, as discussed above. Aggregate and individual practice-level improvements over baseline will be shared with other practice teams. No patient or pediatrician-level data/identifiers will be included or known. See Appendix X for the QIDA Privacy Statement.

Practice teams will be able to view each other's reports through the Project Workspace (in QIDA) and these reports will be discussed during monthly educational calls. Experience in quality improvement work has shown that when practice teams are able to identify which practices experienced improvements, they are better able to discuss successful change strategies and implement these strategies to improve quality of care for patients and families.

In addition to project participants, AAP staff, the quality improvement advisor, the evaluation consultant, and Expert Work Group members will have access to the password-protected, secure online Project Workspace to view reports. Data will be analyzed monthly and at the conclusion of the project by the evaluation consultant and the quality improvement advisor.

Parents/caregivers who are part of the practice team will be present for the learning sessions and may be present on monthly educational conference calls and, as such, will have access to aggregate data presented during these times (eg, run charts, no patient identifiers). Parents/caregivers will not have access to the Project Workspace.

Faculty who participate on monthly educational conference calls and at learning sessions will have access to aggregate data presented at these times. Any sharing of additional data is at the discretion of the practice teams. Faculty will not have access to the Project Workspace.

**b. What are the methods to be used to ensure the confidentiality of data obtained (e.g., use of study codes, password protection, encryption, limited access, secure storage in locked locations).**

Comprehensive measures will be implemented to maintain subject confidentiality as appropriate (details provided below). The core improvement team will be provided with a username and password to access the secure online Project Workspace/QIDA. Each practice team will have a unique username/password that will not be shared with any other practice teams, project staff, consultants, or Expert Work Group members. Additional provisions for maintaining confidentiality for each specific type of data collection tool are described in the sections below.

**Pre- and Post- Implementation Surveys: Appendix I**

Each team will submit one survey before beginning the 6-month action period and one survey upon completing the 6-month action period. The practice team will be asked to complete the survey together. Data from the survey will be collected directly through Survey Monkey and stored on the Survey Monkey server under the password protected account of the AAP Division of Children with Special Needs. The data will be downloaded by project staff via Survey Monkey, which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. Data will be shared with the project's evaluation consultant, Pamela Kelley, PhD, via email for analysis. Any reports resulting from the pre- and post-implementation surveys will be in aggregate format without any participant or practice names. Practice teams will be provided with their individual pre- and post- implementation survey results at the second in-person learning session upon the completion of the project. These individual practice-level results will not be shared with other practice teams.

**Learning Session Evaluation Surveys: Appendix J**

At the end of Learning Session 1 and Learning Session 2, attendees (practice team members) will be asked to complete optional anonymous evaluation surveys. These paper-based surveys will be utilized to gather feedback from learning session attendees about their experience participating in the learning sessions. Feedback received

from the surveys will be collected by project staff, entered into an Excel spreadsheet, and shared with the project evaluation consultant, Pamela Kelley, PhD, over email for analysis. Anonymous results from the learning session evaluation surveys will be analyzed by the project evaluation consultant and shared with project staff, Expert Work Group, and quality improvement advisor.

#### **Medical Record Review Data: Appendix G**

Data entered into the QIDA system is without patient identifiers and will be entered by a designated member of the core improvement team through the use of the online data collection tool. One designated team member will have access to enter data into the QIDA system. These data will be transmitted electronically and securely to the AAP without any patient identifiers. For this reason, no parental informed consent for data collection will be sought, and parents/caregivers will not have access to the QIDA Project Workspace or data entry tool. Data will be due on the 30<sup>th</sup> of every month. Project staff will pull reports from QIDA using the practice names as identifiers.

Practice teams will have access to performance data for quality improvement purposes. The de-identified data elements from the online data collection tool, aggregated by practice, will be presented by measure on a monthly basis to participating practice teams. Data is collated by practice and not by individual pediatrician, so no individual pediatrician data will be identified or known to others involved in the project. Data that is specific to incremental improvements over baseline will also be presented, by measure, on a monthly basis to participating practice teams. Data will be presented by practice, therefore no patient or pediatrician-level identifiers will be shared. (Note: in the case that a participating practice has only one pediatrician, practice-level data will dually serve as pediatrician-level data. This risk will be discussed on a one-on-one basis with the affected pediatrician(s) and the core improvement team members by the Expert Work Group, quality improvement consultant, and project staff.) Data will be reported by practice name, and practice teams will be able to see the aggregate of other practices' data, as well as an aggregate of the entire 10 practices' data through the password protected QIDA module.

Core improvement team members designated to enter information into QIDA using the medical record review tool may encounter subjects who have not received recommended health services. If this occurs, project staff and leadership will ask practice teams to follow their usual procedures when noting patients who have not received needed services.

#### **Post-Visit Family Surveys: Appendix H**

Post-visit family surveys will be anonymous and contain no patient, family, or pediatrician level identifiers. Post-visit surveys will be distributed in paper/hard copy format to families with the practice name as the only identifier. Post-visit surveys will be entered into the QIDA system by a designated core improvement team member using a post-visit survey data entry tool (Appendix H). Hard copies of post-visit family surveys will be destroyed (shredded) as after they are entered into the QIDA system. No patient, family, or pediatrician-level identifiers will be known or available through the post-visit family surveys.

#### **Monthly Progress Reports: Appendix K**

During the 6-month action period, each practice team will submit a Monthly Progress Report which describes tests of change, assesses team progress, describes barriers encountered, strategies used, and other qualitative measures. Each team will submit their monthly progress report through Survey Monkey. The practice name will be collected on this report. Data from the report will be collected and stored through Survey Monkey under the password protected account of the AAP Division of Children with Special Needs. Project staff will download each report via Survey Monkey, which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. The report (identified by practice name only) will be shared with the quality improvement advisor, evaluation consultant, and Expert Work Group member via email. These reports will also be posted on the Project Workspace/QIDA, so that practice teams can learn from each other's experiences.

**Monthly Educational Conference Call/Webinar Evaluations: Appendix L**

During the 6-month action period six monthly educational conference calls/webinars will take place. Participants on the calls/webinars will be asked to complete evaluation surveys to assess the effectiveness of each call/webinar. These surveys are optional, and will be collected using Survey Monkey. Individual practice team members have the option to submit individual surveys. The surveys will be completely anonymous. Data from the survey will be collected directly through Survey Monkey and stored on the Survey Monkey server under the password protected account of the AAP Division of Children with Special Needs. The data will be downloaded by project staff via Survey Monkey which uses SSL (Secure Sockets Layer) encryption, which allows for secure transmission of data over the internet for data downloads and transfers. Data will be shared with the project's evaluation consultant, Pamela Kelley, PhD, via email for analysis. Aggregate reports of survey results (anonymous, no identifiers), will be shared with project staff, quality improvement advisor, and Expert Work Group.

**Qualitative Interviews (Optional): Appendix O**

At the end of the project's 6-month action period, the evaluation consultant, Pamela Kelley, PhD, will conduct telephone interviews with each practice team, including parents/caregivers. Parents/caregivers will have the option to participate on the call with the rest of the core improvement team or individually. No project staff or Expert Work Group members will participate in the interviews. Interviews will be recorded and Dr Kelley will take notes to record responses directly on the hard copy interview script/form. Notes and digital voice recording files will be used by Dr Kelley to create a transcript of the interview responses. Participants will agree to participate on the phone interviews when they consent to participate in the project. Parent/caregivers will agree to participate in the phone interviews by completing a consent form prior to each scheduled interview (Appendix O). Immediately before the interview begins, participants will be verbally informed that they do not have to answer any questions they do not wish to, and can stop the interview at any time. They will also be informed that the interview is being recorded.

Data from the paper telephone interview script/data collection form will be entered into an electronic Microsoft Excel spreadsheet by Dr Kelley. Each interview participant will be given a unique identification number and this number will be entered for each response. No names or identifying information will be entered into the spreadsheet. Dr Kelley will use the digital voice recordings to create a transcript of the interviews in the Excel spreadsheet. Data will be analyzed by Dr Kelley directly in Microsoft Excel to code for themes. Only Dr Kelley will have access to these data. The electronic spreadsheet data will be stored on a single, password-protected computer at the office of Kelley Analytics that is not part of a network and is protected by a firewall system. The paper telephone interview script/data collection forms will be stored in a locked file drawer located in the Kelley Analytics office in Princeton, NJ, to which only Dr Kelley has access. In accordance with the guidelines set forth by the US Department of Health and Human Services, paper telephone interview scripts/data collection forms will be stored for three years after the project is completed and then shredded. After transcripts have been created, Dr Kelley will destroy digital audio files in accordance with guidelines for recorded data set forth by the US Department of Health and Human Services.

For research and publications that may result from this work, all data will be reported in aggregate, and individual and practice data will not be identifiable. If practice data is presented, each practice will receive a unique identification number in the report. Potential publications may include a conceptual model of key barriers and potentially useful strategies that emerged from the project. No patient or practice staff will be identified in any report, publication, or presentation about this study. Practice names will only be used in the acknowledgement section of any potential publication. Practice teams will be given an option to not be acknowledged by name in any research and publications that may result from this work. If practice teams agree to be acknowledged in any potential publication, they will only be acknowledged by practice name and not by pediatrician name, therefore no pediatrician-level identifiers will be available.

- c. **Will you record any direct identifiers, names, social security numbers, addresses, telephone numbers, etc.? If yes, explain why it is necessary to record findings using these identifiers. Describe the method you will use to protect against disclosure of these identifiers.**

No identifiable Protected Health Information will be collected on patients and practices in this study; therefore, no HIPAA-specific measures are employed within the protocol. Practices and project participants will have access to performance data for quality improvement purposes, and data will be reported by practice name only. Identifiers will be included in this portion of the project only. Experience in quality improvement work has shown that when clinical teams are able to identify which practices have experienced improvements, they will be better able to discuss successful change strategies on monthly conference calls and better implement successful changes that lead to improved patient and family care.

Names and contact information (email, address, telephone numbers) will be requested on the application for all core improvement members. This information will only be available to AAP staff, Expert Work Group members and the quality improvement advisor.

- d. **What are the plans for data storage? Where, how long, and in what format (e.g., paper, electronic) will data be kept?**

Any electronic data will be maintained on secure networks or as files on password protected desktops for at least three years following completion of the study, analysis, and reporting of data. This includes digital files from qualitative interviews, which will be destroyed after three years. Raw data will be available on AAP computers/networks as well as the computer of Pamela Kelley, PhD, the project's evaluation consultant. These data will be secured via individual staff member's and Dr Kelley's password protected access to the computers and data storage areas.

All other project data, information, and resources accessed outside the AAP server and Dr Kelley's server will only be access through the secure, password-protected project workspace. It is expected that hard copy materials (paper consent forms submitted through postal mail) and data will be minimal, however they will be kept in a locked file cabinet by project staff and shredded after three years.

Post-visit family surveys collected at each practice will be destroyed (shredded) as soon as they are entered into the QIDA system. These surveys will be completely anonymous and have no patient, family, or physician identifiers.

- e. **What are the plans for the final disposition or destruction of the data?**

Electronic data will be destroyed with guidance and assistance from the AAP Department of Information Technology. Paper documents will be shredded.

## 17. HIPAA RESEARCH AUTHORIZATION

**Will you or any member of your research team collect or have access to any protected health information – PHI (individually identifiable health information that a covered entity creates or receives)?** *For information on HIPAA, see “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.”*

The following are considered identifiers:

- Names
- All geographic subdivisions smaller than a state (street address, city, county, precinct, zip code)
- Telephone numbers and fax numbers
- E-mail addresses
- All elements of dates (except year) including date of birth, admission, discharge, and death
- Social security numbers
- Medical record numbers
- Health plan numbers
- Account numbers
- Certificate / license numbers
- Vehicle ID numbers
- Device identifiers and serial numbers
- Web URLs
- IP address numbers
- Biometric identifiers (finger and voice prints)
- Facial photos / images
- Other unique identifying numbers

NO → Skip to 18.

YES

Which method will you use that allows PHI to be used by researchers according to the HIPAA regulations?

<input type="checkbox"/>	<u>All data are de-identified.</u> <b>Please explain in this section how the data will be de-identified</b> (e.g., all 18 elements described in HIPAA will be removed; or a person with appropriate expertise has determined, justified, and documented that the risk is very small that the information could be used alone or in combination with other available information - attach documentation).  Explanation:
<input type="checkbox"/>	<u>Limited Data Set.</u> <b>Please complete and attach, “HIPAA Limited Data Set for Research Request Form”</b> (Form can be obtained from the IRB administrator or can be found on the AAP intranet).
<input type="checkbox"/>	<u>Patient Authorization.</u> <b>Please attach a consent form that includes the required elements for a valid authorization or a separate stand-alone authorization form.</b>
<input type="checkbox"/>	<u>Waiver of Authorization.</u> <b>Please complete and attach, “HIPAA Waiver for Research Request Form”</b> (Form can be obtained from the IRB administrator or can be found on the AAP intranet).
<input type="checkbox"/>	<u>Other.</u> Please describe here.

**18. DATA ANALYSIS**

**Identify primary research questions and provide a brief overview of the analyses (data sources and variables to be used). Detailed statistical plans are NOT needed.**

This improvement project aims to identify whether providing pediatricians and their staff with the tools and resources necessary to enhance family engagement in practice, using quality improvement methods, will improve care and systems in practice to help practices improve family-centered care.

Improvements in care processes will be assessed by the proportion of medical records that contain data/information to reflect whether improvements have been made. The project's Expert Work Group will monitor the extent of improvements in care processes. This will enable the group to better understand the steps that clinical teams take to improve family engagement/family-centered care for families and children, the sequence in which they do so, and the tools and resources they find helpful.

The core improvement team members will be provided with monthly feedback reports consisting of run charts of data collected. Run charts, commonly used in quality improvement projects, are line charts in which measures are plotted graphically on a vertical axis and time is plotted on the horizontal axis. Appendix Q contains an example of a run chart. This method of graphical display enables team member participants to track their own progress and share their progress with practice leadership to enhance sustainability and spread of project activities.

Each core improvement team member will also be able to review the reports of other participating practices. This is done in order to facilitate sharing among practice teams as well as identify potential promising practices in family-centered care and family engagement. Practice teams will be identified by name for quality improvement purposes. Data will be reported in aggregate for each practice team and will include information on the measures tested. These reports will be posted to a secure, username and password protected Project Workspace (only practice team members, project staff, and the Expert Work Group overseeing this project have access to this site). In addition to the reports, practice teams will receive written and verbal feedback on the changes they are implementing on a regular basis through email and conference call interactions, particularly with the quality improvement advisor.

Process evaluation activities will enable project monitoring to determine if the project is implemented as planned and enable mid-project corrections. Impact evaluation will enable the research question to be answered. The evaluation plan includes the following activities:

- Attendance and evaluation from two in-person 1.5-day learning sessions
- Real time review and analysis of data from a pre- and post- implementation survey
- Analysis of baseline and monthly medical record reviews and report data
- Analysis of post-visit family survey responses
- Analysis of transcripts and notes from monthly conference calls, listserv communications, one-on-one quality improvement calls, and qualitative interviews

Frequency distributions and cross-tabulations of data will be conducted. Qualitative data will be analyzed to identify major themes.

**19. BENEFITS & INCENTIVES**

**Describe the benefits to the individual. State if there are no direct benefits to individual participants. If subjects will receive compensation or other incentives to participate, describe the incentive, including the amount and timing of all payments.**

Practice teams will have the opportunity to enhance quality of care provided in their practice, work with colleagues from across the country, learn from national experts, and access practical tools and effective strategies for implementation of family-centered care. If improvements in care are achieved, the benefits to families and children are likely to be significant.

Pediatrician participants may have the opportunity to receive Maintenance of Certification (MOC) Part 4 credit. Parents/caregivers may receive moderate stipends in the form of gift cards for their participation in the project. Nurses and other clinical staff, as well as front desk/administrative staff, will receive Certificates of Participation (Appendix Y) for participation in the project that will be shared with clinic leadership.

Practice teams will have the opportunity to network with national experts in family-centered care, receive technical assistance and support from the federally funded National Center for Medical Home Implementation, and showcase their improvements to practice leadership throughout the project.

## **20. RISKS**

**Describe the potential risks to the subject and precautions that will be taken to minimize them. Consider the range of risks, including physical, psychological, social, legal, and economic.**

Members of the practice team will collect patient data through medical record reviews. Only the Expert Work Group, project staff, and consultants will see unidentified data from the medical record reviews.

During the course of the project, core improvement team member participants will have access to view each practice teams aggregate data and may choose to share opportunities for improvement during the learning sessions and monthly calls, potentially introducing some psychological discomfort. Since the project will not report on individual clinician data, rather aggregate-level practice data, the risk of embarrassment to individuals will be minimal. In the case that a participating practice has only one pediatrician, practice-level data will dually serve as pediatrician-level data. This may cause a greater level of discomfort, and as such, will be discussed on a one-on-one basis with the affected pediatricians(s) and the core improvement team members by the Expert Work Group and staff during the orientation process.

Parents/caregivers will be present at Learning Sessions and may be present during monthly calls, which may make some team members uncomfortable in sharing information about their practice. Parents/caregivers will be given the option to participate on qualitative interviews individual with the evaluation consultant or with the core improvement team. This may also cause some psychological discomfort, particularly if parents/caregivers are sharing information about their experience in the child's clinical practice.

## **21. ALTERNATIVE TO THE RESEARCH**

**Describe any alternatives available to the subjects.**

Participation in this project is completely voluntary. Practice team members may refuse to participate or may stop participating at any time and for any reason without any penalty. If a pediatrician withdraws early, before meeting the minimum duration established for them to be eligible for MOC Part 4 points (if approved by the American Board of Pediatrics), they may no longer qualify for those points.

## **22. RESEARCH RELATED COSTS**

**Describe any costs that will be incurred as a result of the research procedures that are over and above what would be incurred by standard treatment (e.g., additional diagnostic tests, additional patient visits, drugs, etc.), and indicate who will be responsible for payment for them.**

Practice team member time to participate in the project.