Reducing Diagnostic Errors in Primary Care Pediatrics (Project RedDE!)

Few studies rigorously investigate diagnostic error reduction efforts and even fewer focus on children.[1] A recent review led by a co-investigator of this proposal suggests a need for empirical studies to test interventions to reduce diagnostic errors, and that most existing studies focus on adults, lack rigorous process and outcome measures, suffer from non-experimental or quasi experimental designs, and/or were limited to a single institution.[10] Evidence for reducing pediatric diagnostic errors is rare and often not current: the implementation of a pediatric trauma team reduced delayed and missed diagnoses of major injuries from 4.3% to 0.46%.[2] Computer aided differential diagnoses reduced mean time to diagnosis of all pediatric inpatients from 2.8 days to 1.9 days in 1975.[3] Research on interventions to prevent pediatric diagnostic errors is needed.

Project RedDE! will focus on 3 specific, high-risk, pediatric ambulatory diagnostic errors each representing a unique dimension of diagnostic assessment: evaluation of symptoms, evaluation of signs and follow-up of diagnostic tests. Adolescent depression (i.e. symptoms) affects nearly 10% of teenagers,[4-7] is misdiagnosed in almost 75% of adolescents[8] and causes significant morbidity.[9] Signs of pediatric elevated blood pressure are misdiagnosed in 74-87% of patients,[10,11] often due to inaccurate application of blood pressure parameters that change based on age, gender and height. Actionable pediatric laboratory values (diagnostic tests) are potentially delayed up to 26% of the time in preliminary investigations and 7-65% in adults,[12,13] leading to harm and malpractice claims.[14-16]

The Expert Group has organized Project RedDE! as a multisite, prospective, stepped wedge cluster randomized trial testing a quality improvement collaborative (QIC) intervention within the American Academy of Pediatrics' Quality Improvement Innovation Networks (QuIIN) to reduce the incidence of pediatric primary care diagnostic errors. Through this project, the following resources and components will be available to participating practices during the designated intervention period:

- A project coach/mentor with expertise in the measure areas
- Monthly webinars with peer participating practices, expert group members and specialists
- Extensive interactive virtual learning sessions (3 during the 21 month period)
- Access to a project listserv to exchange ideas, strategies and learn from each others' failures.

Project RedDE! will focus on improving the appropriate identification and long term outcomes of children and youth with conditions and diagnoses that may be identifiable via diagnostic tests and labs. This project also focuses on improvements in systems that track children and youth with identifiable conditions and diagnoses in order for appropriate follow up, communication, and care coordination take place. This project is being funded through a grant between the Agency for Healthcare Research and Quality and Albert Einstein College of Medicine (AECOM) (1R01HS023608), to which the AAP is a subcontractor.

Project Aims

Fifteen primary care practices will be included in the second wave community of learners and will collaborate over up to 21 months to make improvements in practice. The specific aims of the project include:

Specific Aim: **To determine whether a quality improvement collaborative consisting of evidence-based best-practice methodologies, mini-root cause analyses, data sharing, and behavior change techniques, is associated with a reduction in 3 specific diagnostic error rates in a national group of pediatric primary care practices.**

The goal of this proposal is to reduce diagnostic errors by tracking diagnostic errors rates (outcomes measures) and reliably performing best practices for diagnosing adolescent depression, pediatric elevated blood pressure and actionable laboratory results (process measures). This two phase and three cohort intervention will consist of implementing QIC methodology in all of the practices to assist teams in reliably performing the processes that will reduce the diagnostic error outcomes via evidence-based tools. Each of the three cohorts will serve as an intervention site for one diagnostic error and a control site for another diagnostic error in the first phase. For 8 months, each of the three practice cohorts will test and implement improvements in this specific, randomly assigned initial diagnostic error. At the end of the project, Wave 2 practices will have the option to receive resources and materials to intervene on the third and final error. Practices will intervene on one diagnostic error for 16 months and one for 8 months.

Hypothesis 1: Implementation of a quality improvement collaborative will lead to a 40% reduction in missed diagnosis of adolescent depression.
Hypothesis 2: Implementation of a quality improvement collaborative will lead to a 30% reduction in missed diagnosis of pediatric elevated blood pressure.
Hypothesis 3: Implementation of a quality improvement collaborative will lead to a 45% reduction in delayed diagnosis of actionable laboratory results.

Three Secondary Aims/Hypotheses

- To determine if participation in a QIC effect changes for phase 1 versus phase 2 participants, who serve as the control group in the first or second 8 months of the collaborative.
- To further investigate the epidemiology of three ambulatory pediatric diagnostic errors: missed diagnosis of adolescent depression, missed diagnosis of pediatric elevated blood pressure, and delayed diagnosis of actionable laboratory results.
- To evaluate patient outcomes related to these diagnoses including outcomes after positive depression screening, missed elevated blood pressure screening and delayed diagnosis of actionable laboratory values.
- To determine if practice enrolled in Wave 2 of the collaborative reduce diagnostic errors faster than Wave 1 practices.

Diagnostic errors in ambulatory pediatrics cause significant morbidity and optimal prevention strategies are unknown. Based on adult literature, a multifaceted QIC strategy is needed to successfully address these errors. QICs are ready to serve as the system for testing the best practice methods of reducing preventable harm. Furthermore, this proposal will gain additional insights regarding the epidemiology of these diagnostic errors via baseline data collection. The outcomes of this project will serve as a foundation for future projects aimed at global reductions of pediatric diagnostic errors across settings and diagnoses.

Participating Practices

Applicants are expected to identify a core multidisciplinary improvement team of 3-5 members to lead the effort (these are considered the project participants). This team should be comprised of a lead physician, and include two additional persons, such as a manager, nurse, and/or administrative or office support staff. All applications received will be reviewed by the project's Expert Group. Once practices are selected to participate in the project, each physician and staff member on the core improvement team will be asked to sign a consent form. In addition, any lead physicians who are AAP member pediatricians will be asked to join the QuIIN.

As part of quality improvement work, it is important for a practice to identify the core improvement team to lead the improvement efforts in the practice. Core improvement team members are considered quality improvement project participants as they are individuals who the QuIIN Expert Group communicate with on a regular basis, are responsible for the data collection/entry, and attend live webinar learning sessions and monthly conference calls with other practice core improvement teams. They also relay information back to others in the practice so that improvements to the system can be made. These team members will be consented to participate and complete the duties outlined below.

Practice Selection

All applications received will be reviewed by the project's Expert Group, which is comprised of primary care provider leaders, pediatric geneticists, and quality improvement experts. Up to fifteen primary care clinical teams will be selected, representing a diversity of geographical locations, practice settings (urban, rural, suburban), practice size, and type of organization (eg, private practice, FQHC, hospital outpatient departments). Practices will also be selected based on (1) having 30 well-visit encounters per month for age 3 and above, (2) having 30 well-visit encounters per month for age 11 and above, and (3) ability to pull patient records by age, labs performed and potentially by blood pressure.

It is advised that each practice as a whole have at least 30 encounters with unique patients aged 11 and above monthly and about 30 encounters with unique patients aged 3 and above monthly. No practices will be excluded based on size as even the smallest practices have sufficient patient panels to collect the data required over a 21 month period.

Applicants are expected to have identified a team and documented in the application the commitment of the senior leadership to support this project over an up to 21 month involvement period.

If selected, all core improvement team members will be asked to sign a consent form and the physician leader will be asked to join the Quality Improvement Innovation Networks (QuIIN), a program of the American Academy of Pediatrics. Joining QuIIN is free and easy and requires completion of a simple membership application available at http://quiin.aap.org.

Benefits of Participation

Participation in this nationally recognized project would provide many benefits to involved teams:

- Test strategies for improving care that will become a national model
- Work with colleagues from around the country
- Learn from national experts and receive ongoing support for improvement
- Receive American Board of Pediatrics Part 4 Maintenance of Certification credit (approved!)
- Reduce the likelihood of patient harm by identifying and decreasing diagnostic errors systemically

Timeline for Participating Practices and Team Members for Project RedDE!

Application Process:	**Pre-work:**		**Phase #2:**		**Phase #3:**	**Wrap-up phase:**
• Form core improvement team and determine roles of each member • Determine if local IRB will be necessary • Complete project application • Investigate capabilities in pulling eligible charts via EHR or billing records/paper charts at your practice	• Practice selection and random assignment to 1 of three groups • Submit consent form, practice inventory & baseline data collection for the first set of diagnostic error measures • Participate in orientation webinar • Participate in Learning Session 2	**8 month Phase #2**	• Participate in 1-2 monthly video conferences • Collect monthly data (chart review, process measures, and mini-root cause analysis) and intervene on one set of diagnostic error measures (for which the practice collected baseline data for in the Pre-Work phase • Collecting outcome data only on a second set of diagnostic error measures to serve as baseline for the second error. • Test changes using PDSA cycles • Provide feedback on tools • Work with assigned coach/expert	**8 month Phase #3**	• Participate in Learning Session 3 • Submit practice inventory survey • Participate in 1-2 monthly video conferences • Collect monthly data (chart review, process measures, and mini-root cause analysis) and intervene on two sets of diagnostic error measures • Collect monthly data for the third diagnostic error • Test changes using PDSA cycles • Provide feedback on tools • Work with assigned coach/expert	• Submit practice inventory • Participate in Learning Session 4
December-February 2016	**March-June 2016**		**June 2016 – January 2017**		**February-September 2017**	**Oct 2017-November 2017**

Specific Expectations

Wave 2 Participation Practices –

Each participant on the core improvement team will:

- Be engaged in the project for an estimate of 21 months (including pre work and evaluation). For the first 3 months you will be asked to collect baseline data on one of the diagnostic errors. During the next 8 months you will be asked to intervene and continue collecting data on that diagnostic error, and collect baseline data on a second diagnostic error. During the 8 months following that, you will be asked to intervene and continue collecting data on both these first two diagnostic errors, and collect baseline data on the third diagnostic error. Finally, for the last 2 months you will be asked to engage in wrap-up activities which will involves participation in a Learning Session videoconference, practice inventory completion and ensuring data collection is complete. Agreeable to a random assignment to one of three groups. Wave 2 practices will only intervene on two of the three diagnostic errors, but will be asked to collect data on all three errors over the course of your participation (see schedule in bullet point above). As a member of a selected practice team, you will be part of a collaborative group that will intervene on one of the following combinations of 2 diagnostic error topics: 1) missed opportunity to diagnose adolescent depression and delayed actionable labs, 2) delayed actionable labs and missed elevated blood pressure, or 3) missed elevated blood pressure and missed opportunity to diagnose adolescent depression. While Wave 2 practices will only intervene on two diagnostic errors, Wave 2 practices will have the option to access all resources from the collaborative to intervene on that third error. Please see the timeline for a visual description of the groups, phases and data collection expectations.
- Devote necessary resources and time to testing and implementing changes in practice over a specified action period (16 months), while collecting data from patient charts each month, and working to obtain buy-in from all members in this practice.
- Before the 16-month action period, complete about 3 months of pre-work activities including the collection and entry of baseline chart data (50 charts for one of the diagnostic errors – the one the practice will intervene on first), identifying referring partners, and participate in a 60 minute live and recorded orientation webinar.
- If necessary, seek Institutional Review Board approval for participation prior to completion of pre-work.
- All selected core improvement teams will submit up to 16 months of data that will consist of monthly evaluation of 17 eleven year-old or older patient charts; 10 three year-old and older patient charts with elevated blood pressure; and 10 patient charts with applicable actionable abnormal labs. The data will be identified by practice name and available for all project participants and leadership to view during the course of the project through the AAP QIDA. Note: Chart review will be completed using the QIDA system.

    - Included in this data collection plan above, each practice will collect two sets of 8-month diagnostic error data without specific interventions tied to the measure. This period of data collection will serve as a dataset to compare against the data collected during that practice's intervention phase and serve like a baseline for those two measures. Unlike the baseline of 50 charts collected during the pre-work period, these datasets will represent 10-17 charts monthly for 8 months.
- Regularly collect and transmit clinical measurements pertinent to the aims of the project.
- Learn the Model for Improvement and other quality improvement strategies.
- Make appropriate changes in the structure of how care is monitored and delivered to patients.
- Participate in 3 two-day live video conference learning sessions (learning sessions will be 6-12 business hours in length) on two consecutive days) to be held June 6, 2016 (8-hours), February 2017 and October 2017. Learning sessions will not require any travel and will be conducted every 8-10 months during the project.
- Participate in 1-2 monthly webinars aimed at sharing best practices, reviewing collaborative data and using quality improvement resources.
- *During the intervention phases of data collection for two of the diagnostic errors,* Collect two screening-related process measures for up to 14 months (no baseline data points required) for:
    - Number of patients aged 11 and older who have a recorded depression screen in their chart for the last month (up to 14 data points)
    - Number of patients aged 3 and older with blood pressure checked and documented at triage for the last month (up to 14 data points)
    - Number of instances where unread/unacknowledged labs were in providers' Inboxes for more than 72 hours (up to 14 data points)
    - Note: The process measure will be aligned with the diagnostic error/s for which the practice is intervening.
- Completion of up to three mini-root cause analysis as a core improvement team per month for a diagnostic error. Each mini-root cause analysis will involve recording 15 standardized patient and systems factors that could have led to the error.
    - Four questions from the full mini-root cause analysis will be collected via SurveyMonkey.
- Completion of practice inventory to gather practice demographics, trends and behaviors three times via SurveyMonkey (estimated March 2016, March 2017 and March 2018)
- Test innovations in care delivery, tracking the provision of appropriate care, and in the improvement of care to pediatric patients per the measurement plan.
- Participate in monthly coaching sessions or office hours with a QI coach.
- Share lessons learned and problem-solve with other participating practices through monthly conference calls and listserv e-mail.
- Use e-mail and the Internet on a regular basis for ongoing support, information, and communication among practice teams.
- Have a wired Internet connection, computer and USB-supported webcam to connect to monthly video conferences, learning sessions and coaching session provided via the Zoom technology ***(***http://zoom.us/)
- *Physician leader only: serve as Local Leader in the attestation process required by the American Board of Pediatrics (ABP) for Part 4 Maintenance of Certification (if approved). Includes providing each physician in practice interested in participating for MOC credit a document describing the requirements of their participation, monitoring physician participation, and attesting that they met the project's completion criteria.*

All clinicians in the practice are encouraged to participate in this project by using the tools and strategies identified and providing charts for review. Physicians who would like to claim credit (including those not identified on the core improvement team), must meet the criteria established by the AAP and the minimum standards set by the ABP for all QI projects outlined below.

AAP-Established Minimum Criteria for Participation

Physicians are eligible for MOC Part 4 credit if they meet the following criteria:

- ☑ The project requires physician participation for pre-determined two 8 month Phases. Physicians must:
- ☑ Lead the implementation for the Practice Improvement Network (PIN) Reducing Diagnostic Errors in Primary Care Pediatrics QI Project (Project RedDE!) project core changes for 8 months.
- ☑ Provide direct or consultative care to patients as part of the project
- ☑ ***Physician Leader:*** Attend 4 meetings that can be learning session webinars or conference calls/webinars where collaborative data are reviewed or plans for new improvement activities are made.
  Other participating physicians: Attend at least 4 meetings at which collaborative data are reviewed and plans for improvement activities are made (can be local team meetings, conference calls/webinars, or learning sessions)
- ☑ Collect and submit data on a subset of patients as defined by the project
- ☑ Review periodic (monthly) run charts and use data to guide future improvements
- ☑ Implement change package ideas/tools designed to improve diagnosis errors

ABP Minimum Standards for Participation for All QI Projects

- Provide direct or consultative patient care in the improvement project
- Complete 1 or more tests of change to improve care
- Collect, submit and review data in keeping with the project's measurement plan
- Collaborate actively by attending at least 4 project meetings
- Maintain active in the project for the minimum duration required by the project (minimum criteria established by AAP)
- Complete participation under current ABP certificate or MOC cycle

Data Sharing and Reporting

As part of the quality improvement project, participants will share data with project participants and leadership. This will allow practices to learn from one another and share strategies and barriers. In addition, it will allow the project leadership to continually identify needs and offer ongoing support and assistance to the participants.

QuIIN Expert Group members (consisting of AAP staff, QI Advisor, and expert leaders) will have access to the identifiable (by practice) data from the chart reviews, root cause analysis, annual practice demographic surveys and anecdotes and stories shared via the listserv and in learning sessions, allowing them to identify areas of need and provide ongoing assistance throughout the project.

For quality improvement purposes, data will be aggregated by practice. In addition, practices will be identified by name in communication for quality improvement purposes. Each participating team will be able to use the secure password protected QIDA system to view reports of their practice's aggregate data, as well as aggregate data from other practices. Data collected will not include protected health information. Data will be stored on a secure network with password protection. Project data will be stored indefinitely in the QIDA system, but once a project closes, only AAP QIDA staff will have access to the data.

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 an ID number in the report. Potential publications may include a conceptual model of key barriers and potentially useful strategies that emerged from this project. No patients or practice staff will be identified in any report or publication about this study. Practice names will only be used in the acknowledgement section of any potential publication.

Institutional Review Board (IRB)

Project RedDE! has received approval from the AAP Institutional Review Board. No identifiable protected health information is being collected for this project; therefore, HIPAA authorization will not be needed from patients in order for your practice to participate. Note: your hospital or healthcare system may also require IRB approval. Often, the information supplied in the AAP IRB Application will be applicable to your own local or hospital IRB application as well and may be sufficient. If not, the AAP IRB application will be provided so that it can be adapted to meet your needs; a copy of the AAP IRB will be made available upon your request.

Application Checklist

- ❑ Please review the following documents:
  - Project Overview and Requirements Sheet
  - Electronic Application
- ❑ After reviewing the above materials, please submit the electronic application (due **February 22, 2016** for full consideration)
- ❑ If you are interested in obtaining a letter of support from the Project RedDE! leadership that can be shared with the leadership at your organization, please contact Liz Rice-Conboy, with this request.
- ❑ Upon our receipt of your application materials, the application will be reviewed by the Expert Group. Once project teams have been selected, we will contact you to welcome your team to the project.
- ❑ Please do not hesitate to contact Liz Rice-Conboy, MS, QuIIN: ericeconboy@aap.org or 847/434-7103

We look forward to the opportunity of working with you and your team!

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