Evaluating the Efficacy of Different Electronic Medical Record Alerts to Increase Pediatric Lipid Screening Across a Large Integrated Health System

Version 1.2

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1 ABBREVIATIONS USED IN THE PROTOCOL

Abbreviation	Term
AAP	American Academy of Pediatrics
BPA	Best Practice Alert
EMR	Electronic Medical Record
HMT	Health Maintenance Tab
IRB	Institutional Review Board
NHLBI	National Heart Lung and Brain Institute

2 ABSTRACT

Cardiovascular disease is the leading cause of death in the United States, with greater than 600,000 people dying annually. The American Academy of Pediatrics began in 2008 with initial recommendations for lipid screening for all at-risk youth between 2-11 years of age. More aggressive guidelines have been recommended since 2011; however, little progress has been made in improving global screening for lipid disease in the pediatric population. This is a randomized controlled study examining provider and patient response to alerts in the electronic health record, to determine the most effective future alert structure to improve provider and patient compliance with evidence-based medicine practices. All pediatric patients between the ages of 9-11 that are seen in a primary care office, CareWorks, cardiology, nutrition, or during an endocrinology visit, their parents/legally authorized guardians, and their attending providers will be eligible for the study. Patients who were already screened or who previously received a diagnosis of familial hypercholesterolemia will be excluded. Patients will be randomized to a delayed-intervention control condition or one of three different alert types (health maintenance tab, best practice alert, or their combination) that their attending providers will receive. Outcomes will include lipid screening orders by providers (yes/no) and screening completions by patients (yes/no) within one week of the orders. The study timeframe will encompass six months of visits from study launch plus final delays in order completion. Analysis will assess which of the conditions results in the highest proportion of orders and completions for pediatric patients across the Geisinger Health System. After the end of the study timeframe, the most effective alert will be implemented for all eligible pediatric patients. We will also be looking exploratorily at 6-month pre-intervention data so we can run a pre-post analysis in addition to our comparison across study arms. This will allow us to assess and adjust for secular changes in screening over time, independent of the alerts.

3 BACKGROUND AND SIGNIFICANCE

Cardiovascular disease is the leading cause of death in the United States, with greater than 600,000 people dying annually. It is well known that there are both modifiable and non-modifiable risk factors, many of which begin in childhood. Early identification and intervention for those at risk is crucial. Pediatricians are perfectly positioned to prevent the development of cardiovascular disease and its consequences through implementation of universal screening processes. In 2008, the American Academy of Pediatrics (AAP) first recommended cholesterol screening for children between 2 and 10 years of age if they possessed certain risk factors: obesity, smoking, hypertension, diabetes, or a positive or unknown family history for dyslipidemia or cardiovascular disease. Recognizing that these guidelines missed up to 70% of affected children, the National Heart, Lung, and Blood institute (NHLBI) published updates in 2011 recommending all children between 9 and 11 years of age be screened for lipid disorders with a non-fasting lipid panel. The American Academy of Pediatrics (AAP) subsequently backed this recommendation and in 2016 published the Update on Preventative Pediatric Health Care, which reinforced the recommendation that all children of ages 9-11 should be screened for dyslipidemia, regardless of family history or presence of recognizable risk factors.

Since the updated recommendations for universal screening were released by the NHLBI in 2011, providers have been poorly informed of the AAP guidelines as well as the conflicting reports from national guidelines and treatment efficacy. The AAP reported that improved education may help change this thought process.

Over the last 12 months, 96,944 pediatric patients between the ages of 9-11 years were seen by a provider within the Geisinger system. Only 1,238 had a lipid screen drawn. Many providers are unaware of the current AAP guidelines, and ordering a lipid screen for this age range is not currently part of work flow.

4 HYPOTHESIS AND SPECIFIC AIMS

4.1 Hypothesis

Lipid screening in children ages 9 to 11 within our health system is low. We hypothesize that utilizing different electronic medical record alerts will result in a modest but significant increase in overall screening across the health system.

4.2 Specific Aim 1

To increase the overall number of children screened for lipid disorders per the AAP guidelines, utilizing electronic medical record alerts.

4.3 Specific Aim 2

To evaluate the effectiveness of electronic medical record alerts in completing a recommended health maintenance objective (lipid screening) for pediatric patients aged 9-11 per the AAP guidelines.

4.4 Specific Aim 3

To determine which EMR alert resulted in the highest number of ordered and completed lipid screens in order to inform best practice in our health system.

5 PRELIMINARY DATA

Over the last 12 months, 96,944 pediatric patients between the ages of 9-11 were seen by a provider within the Geisinger system. Only 1,238 (or 1.3%) had a lipid screen drawn. Many providers are unaware of the current AAP guidelines and ordering a lipid screen for this age range is not currently part of work flow.

6 STUDY DESIGN

6.1 Description

This study will be a randomized, prospective study in which patients of ages 9 to 11 who are seen within a primary care, CareWorks, cardiology, endocrinology, or nutrition clinic within our health system will be randomized 1:1 to one of four groups. Based on the group to which the patient is randomized, the provider seeing that patient will receive either no alert (control group, described below) or one of three electronic medical record alerts regarding the need for a non-fasting lipid panel for that patient:

- Best practice alert (BPA)
- Health maintenance tab (HMT)
- Both BPA and HMT

Providers of patients randomized to the control group will not receive a BPA or HMT, which reflects the current standard care process.

There will also be a 6-month pre-intervention data pull completed so we can run a pre-post analysis in addition to our comparison across study arms.

6.2 Study Population

6.2.1 Approximate Number of Subjects

We plan to enroll all eligible pediatric participants in this study (see inclusion and exclusion criteria, below). In a recent six-month period, according to Slicer Dicer, there were 7,906 established and new well child visit for 11-year-olds in the Geisinger system. Assuming similar population levels for 9- and 10-year-olds, we expect to enroll into our study approximately 24,000 pediatric participants as well as their parents/LARs and providers during our six-month enrollment period. However, we will enroll into the study all eligible participants who present at qualifying Geisinger sites during that period. Additionally, for exploratory analysis, we will enroll 21,000 pediatric participants from the six-month period just preceding the intervention, using the same inclusion criteria as below.

6.2.2 Inclusion Criteria

- Patients 9 to 11 years of age
- Seen within a Geisinger primary care, cardiology, endocrinology, CareWorks, or nutrition clinic within 6 months of study launch

6.2.3 Exclusion Criteria

- Patients with a completed lipid screen in the EMR
- Patients determined to have familial hypercholesterolemia based on prior screening (ICD E78.01 or Z83.42)

6.3 Enrollment

Patients will be automatically enrolled (via Epic) into the study and randomized to one of the four conditions when they are seen by a provider within the primary care visit, cardiology, endocrinology, CareWorks, or nutrition clinics. Their providers will be shown the appropriate prompt (based on patients' randomization) without the patient or family being aware of what group they are in. Some families will have a prompt in their MyGeisinger chart stating that a health maintenance is due (HMT and BPA + HMT arms).

6.4 Study Duration

6.4.1 Approximate Duration of Subject Participation

The study will run for approximately 12-18 months across all groups including the control group, which will receive no alert for the duration of the study (approximately 6 months), followed by 6 months of receiving the alert shown to be most effective in the initial study period.

6.4.2 Approximate Duration of Study

This study will be completed in approximately 12-18 months to allow for full collection of data on pediatric lipid screening for all 9-11 year old patients as well as the control group to have ample time to have a visit with a patient annually who may have been missed the first time around during the study.

6.5 Procedures

Patients who are eligible for this study will be randomized into one of four groups via an EPIC randomization algorithm run automatically at the time of the visit:

1. Control group (6-month delay before their providers will receive an alert)
2. Health maintenance tab
3. Best practice alert
4. Best practice alert and health maintenance tab

Geisinger Health System will introduce EPIC's Storyboard panel (a novel way of summarizing patient information) approximately one month into this study. The analysis plan will therefore attempt to test for the potential impact of this change.

The providers will be prompted to discuss and order screening lipid study that is non fasting at the time of the visit with the patient, based on the alerts above. Some families will have an alert in their MyGeisinger portal stating that a health maintenance test is due and to discuss with their provider.

The outcomes will be reviewed and classified as followed, for descriptive reporting purposes:

1. Lipid screening ordered
2. Lipid screening ordered and completed
3. Lipid screening ordered but not completed
4. Lipid screening declined with reason why
5. Alert not acted on at all

6.6 Primary Endpoints

The primary endpoint will include lipid screening orders by providers (yes/no) and screening completions by eligible patients (yes/no) within one week of the orders.

6.7 Secondary Endpoints

The secondary endpoint will include screening completions by eligible patients (yes/no) within six months of the orders.

6.8 Statistics

6.8.1 Statistical Analysis Plan

Analyses will test whether each of the active alert conditions have a significant impact on the outcomes, relative to the control group, as well as comparing across the BPA-only, HMT-only, and BPA+HMT groups. Interactions between Storyboard implementation in EPIC and the experimental conditions will be tested; if any are significant, further analyses will test whether and how results replicate in the different contexts before and after Storyboard introduction.

6.8.2 Statistical Power and Sample Size Considerations

As noted in Section 6.2.1, approximately 24,000 patients of age 9-11 are expected to come in for child wellness visits over the course of six months. Allowing for seasonal variations and patients who are ineligible according to study exclusion criteria, we still expect upwards of 18,000 patients over six months, but as noted above we will enroll all eligible participants throughout the study period. Randomly allocated at 4,500 patients per condition, this provides 95% power to detect very small (Cohen's d=0.076) mean effect size differences across any two conditions, using a threshold α=0.05 for a two-tailed test of statistical significance. Only more moderate effect size differences ($d \geq 0.20$) may be detectable in the time period prior to Storyboard implementation, where only around 650 patients are expected per condition.

Another way to conceive of this is if we assume a default screening rate of 1.3% (i.e., 1,238 patients, among 96,944, who had a lipid screen drawn). A sample size of 4,500 per condition allows us to detect a 1% increase in screenings (to 2.3%) with 95% power, using a binomial proportion z-test. A sample size of 650 per condition allows us to detect at least a 3.4% increase in screenings (to 4.7%) with 95% power.

6.9 Data Management

6.9.1 Data Collection and Storage

A Geisinger Data Broker will extract data from EPIC. This data set will be de-identified prior to being shared with the study team in an Excel spreadsheet. Data will be stored on a password protected computer on the secure Geisinger network.

De-identified data will be shared via ClinicalTrials.gov or the Open Science Foundation.

6.9.2 Records Retention

Data will be retained for at least 6 years, per Geisinger policy. The de-identified data set may be retained indefinitely for future research purposes.

7 SAFETY MONITORING

Not applicable.

8 SAMPLE COLLECTION AND RETENTION

Not applicable.

9 PROTECTION OF HUMAN SUBJECTS

9.1 Informed Consent

We are requesting a waiver of consent and HIPAA authorization for this study. This study imposes only minimal risks on pediatric patient-participants, their providers, and their parents/LARs (see section 9.2).

The purpose of this pragmatic trial is to inform implementation of a new EHR alert by learning how different alert formats (and the standard practice of no alerts at all) affect providers' behavior in ordering pediatric lipid panels and, subsequently, parents'/LARs' facilitation of blood draws for pediatric patients. It is well known that providers suffer from "alert fatigue" and Epic alerts are routinely ignored by providers. Similarly, the fact that a provider noticed an alert does not mean that he or she will act on it, nor does it mean that the patient or their parent/LAR will necessarily comply with the provider's alert-based recommendation. When implemented, alerts are intended to perform automatically, setting off a chain of provider and/or patient/parent behavior without any additional prompting from outside of the EHR system. For the study team to emphasize the presence or absence of a new alert via an informed consent process defeats the

purpose of the study, which is to understand how providers and parents/LARs behave in response to alerts *as they would be implemented universally at Geisinger*. Hence, this study could not practicably be carried out without the requested waivers of consent and HIPAA authorization.

Because the current status quo at Geisinger is no Epic alerts for pediatric lipid screening, temporary randomization to the no-alert condition does not adversely affect those participants' rights or welfare. Conversely, although it is currently the standard of care not to specially alert providers to the need for this test, universal screening is indeed considered best practice in pediatrics. Thus, patients randomized to have their provider alerted that they are eligible for this test, which might prompt a conversation with their parents/LARs about this test, also will not have their rights or welfare adversely affected by this study.

Finally, the alert format shown to have the greatest impact on uptake will quickly be implemented for all pediatric patients' providers.

9.2 Risks and Expected Benefits

There are no anticipated risks related to participation in this study. Per clinical guidelines, all participants in this study should be undergoing lipid screen as part of their standard care. Currently, providers are not alerted via Epic to the need to order this test. The purpose of this study is to determine the most effective way, within Epic, of alerting providers. All eligible pediatric patients, including those initially randomized to the standard of care/control arm, will eventually receive the alert condition determined to have the greatest effect on uptake of ordering by providers and, through them, blood draws facilitated by parents/LARs.

The primary benefit of this study is that we will learn which form of alert, if any, has the greatest impact on uptake of this recommended screening. Notably, Geisinger has committed to implementing whichever alert format turns out to have the greatest impact, thereby creating immediate benefit for all relevant Geisinger patients and their families. This benefit will extent to study participants who were initially randomized to other conditions and who are seen again at Geisinger prior to turning twelve.

The study team will only receive de-identified data to help minimize risk of loss of confidentiality.

9.3 Data Monitoring Plan

Not applicable.