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Implementation of the NHLBI Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents: Rationale and Study Design for *Young Hearts, Strong Starts*, a Cluster-Randomized Trial Targeting Body Mass Index, Blood Pressure, and Tobacco

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Abstract

Background—Cardiovascular disease (CVD) and the underlying atherosclerosis begin in childhood, and their presence and intensity are related to known cardiovascular disease risk factors. Attention to risk factor control in childhood has the potential to reduce subsequent risk of CVD.

Objective—The Young Hearts Strong Starts Study was designed to test strategies facilitating adoption of the National, Heart, Lung and Blood Institute supported Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents. This study compares guideline-based quality measures for body mass index, blood pressure, and tobacco using two strategies: a multifaceted, practice-directed intervention versus standard dissemination.

Study Design—Two primary care research networks recruited practices and provided support for the intervention and outcome evaluations. Individual practices were randomly assigned to the

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intervention or control groups using a cluster randomized design based on network affiliation, number of clinicians per practice, urban versus nonurban location, and practice type. The units of observation are individual children because measure adherence is abstracted from individual patient's medical records. The units of randomization are physician practices. This results in a multilevel design in which patients are nested within practices. The intervention practices received toolkits and supported guideline implementation including academic detailing, an ongoing e-learning group. This project is aligned with the American Board of Pediatrics Maintenance of Certification requirements including monthly physician self-abstraction, webinars, and other elements of the trial.

Significance—This trial will provide an opportunity to demonstrate tools and strategies to enhance CV prevention in children by guideline-based interventions.

Keywords

guideline implementation; quality improvement; cardiovascular disease; prevention; cluster randomized trial; children

INTRODUCTION

Cardiovascular disease (CVD) and the underlying atherosclerosis begin in childhood,¹ and their presence and intensity are related to known cardiovascular disease risk factors and are correlated with the presence of atherosclerosis in adulthood.^{2,3} Central obesity, smoking, and hyperglycemia in adolescents impact quality of life, productivity and increase the risk of dying before age 55.⁴ Because CVD risk evolves over time, adopting healthy habits in childhood and maintaining healthy habits through adulthood may be pivotal for elevating the level of success of CVD risk reduction in adults.¹ A recent study lends credence to the benefits of reduced long-term risks; substantially reduced coronary artery disease risk was reported among individuals having low exposure to low-density lipoprotein (LDL)-cholesterol beginning early in life related to their favorable genetic variants.⁵

Pediatric preventive care visits are an opportunity to monitor health and provide anticipatory guidance to promote healthy habits and move individuals toward adoption of healthier behaviors. The current childhood obesity epidemic elevates the importance of addressing related risks at young ages. To guide implementation of CVD risk reduction efforts for children, the National Institutes of Health, National Heart Lung and Blood Institute (NHLBI) supported guideline: Reports of the Expert Panel on Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents,³ was published in 2011. The guideline includes comprehensive recommendations on care related to, nutrition and diet, physical activity, tobacco exposures, blood pressure (BP), lipids and lipoproteins, and overweight and obesity, the impact of family history on their management. The Guideline has been harmonized with the recommendations of Healthy People 2010⁶ and the prevention goals of the Affordable Care Act. While the guideline addresses secondary causes of risk factors which include other diseases (i.e. hypothyroidism, renal disease), medication-induced, and genetic risks this trial only addresses lifestyle related risk factors. Despite the complexity of the guidelines, their comprehensive nature potentially increases their impact, if fully implemented.

The *Young Hearts, Strong Starts* cluster-randomized controlled trial is designed to test strategies and tools for accelerating the adoption of these guidelines by pediatric and family medicine practices. This study focuses on changing care for select aspects of the guidelines that are addressed at most every health supervision visits for children ages 3 to 11 years. The objectives of this study are to determine the extent to which a multifaceted quality

improvement intervention used in *Young Hearts Strong Starts* increases the adoption of the newly published guideline recommendations for body mass index (BMI), blood pressure, and tobacco exposure among children seen in pediatric and family practices. This article describes the rationale and cluster randomized study design to facilitate implementation of guideline-driven care in these areas.

METHODS

Study Design

In this cluster-randomized trial, the units of observation were individual children (with outcomes abstracted from medical records for individual patients), and the units of randomization were practices. Randomization was done at the practice level because the intervention and primary outcomes focused on modifying practice systems. A summary of the study and intervention design and timeline is shown in Figure 1.

Study Sites

Sites for this study were 32 practices, 16 in each of two primary care research networks. The Pediatric Practice Research Group (PPRG) is a network of 52 pediatric and multispecialty practices in the Chicago metropolitan area led by researchers at the Ann & Robert H. Lurie Children's Hospital of Chicago Research Center and Northwestern University's Feinberg School of Medicine, Chicago, IL. Participating PPRG practices established Federal Wide Assurances and Inter-institutional Agreements with the Lurie Children's Institutional Review Board (IRB) and completed Business Associate Agreements with Lurie Children's, which allowed Lurie staff members to conduct record reviews at practice sites for project outcome evaluations. The other network, East Carolina University Network (E-CARE), includes pediatric and family medicine practices located throughout eastern North Carolina (NC). E-CARE is led by researchers at the Brody School of Medicine, East Carolina University, Greenville, NC. For purposes of this project, the IRB approved the study by expedited review as a research study, each practice signed a Memorandum of Understanding and Data Use Agreement, but the East Carolina University, and informed consent was not required from physicians or patients/families by either IRB.

Practice Recruitment

We recruited practices based on practice clinician interest in the topic of CV health and risk reduction. Also, we applied three strategies to further encourage practices to join this study. First, there was no charge to participate; in fact, each practice site received \$1,000 to offset time for research participation. Second, to foster individual clinician participation, we obtained approval through the American Board of Pediatrics for clinicians completing a defined protocol to earn 25 points toward Part 4, Maintenance of Certification (MOC). Third, we encouraged participation of practices randomized to the standard dissemination comparison group (control) by offering MOC participation in the 9 months following the study year. Thus, by easing the burden of research to the practice through the practice access fee, incentivizing clinicians needing MOC, and ensuring fairness by offering delayed MOC participation to clinicians at practices randomized to the control group, we were able to recruit the total of 32 practice sites.

Development of the Practice Intervention

Intervention design was partially guided by formative research with primary care clinicians who provide services to children. Focus groups information from a mix of physicians, nurse practitioners, and nutritionists, totaling 44 professionals, was used to better understand current practice and identify needs to address the recommendations contained in the

guideline. Most focus group participants indicated that they were especially interested in understanding how to better improve care practices regarding management of weight. It was also clear that the calculation of percentiles for BP and BMI were difficult in busy practices, and physicians, in particular felt uncertain about how to best assist patients and families to adopt more healthy diets and increase their physical activity. The focus group participants also expressed concerns about the implementation of the recommendations for universal lipid screening at age 10. A commonly mentioned concern was the difficulty in obtaining fasting samples and discomfort associated with the blood draw. We also convened a physician expert panel to provide guideline content expertise for developing the intervention toolkit.

The final intervention components, described below, included designated strategies to support practice change and a toolkit to support guideline implementation. We designed a 1-year intervention that includes known effective strategies that influence knowledge, attitudes, and assist in the process of changing provider care delivery⁶ by supporting practice system changes and adopting recently developed tools for clinical care.

Support For Practice Change

To support the implementation of the intervention we employed the practice change model for quality improvement in primary care practice, which has four components: motivation of key stakeholders, resources for change, external motivators, and opportunities for change.⁷⁶ These components were selected to address the common barriers to the adoption of clinical guidelines by physicians.⁶ A key contact was identified at each recruited practice to facilitate communication with the site. Generally this person had a high level of enthusiasm for the project. Clinicians choosing to work toward gaining Part 4 MOC points had mandatory participation in webinars and monthly self-abstraction of outcome measure performance, which was done on an individual provider basis and separately from the baseline and post intervention medical record abstraction completed for the research study.

Project communication strategies included a study Web site and study listserv. The Web site was the repository for information about the guidelines, copies of study resources, and a data collection module. This module was to facilitate identification of data entry error and range checks for medical record review by study staff for the project evaluation and for self-abstraction by clinicians for MOC. Clinicians could view graphs of their personal monthly progress on the Web site. All clinicians in intervention practices were automatically enrolled into a project listserv and provided with passwords to the study Web site, which also was the repository for past postings to the listserv.

To introduce the study we employed academic detailing visits⁸ by local network project leaders to each intervention practice and electronic postings/e-mail. Academic detailing sessions were scheduled at the convenience of practices, typically during the lunch hour with lunch provided. Sessions lasted about 45 minutes and included a slide presentation with an overview of the study purpose, the guidelines, and details of study participation, and sharing of the report of baseline medical record review findings at that practice. Electronic postings included an electronic version of the concise 73-page guideline summary, guideline slide sets, and a practice support toolkit... The project Web site also provided a vehicle for practices to share materials developed or identified by participating clinicians to support guideline adoption.

In addition, monthly collaborative webinars were held and recorded (posted to the Web site for later viewing if needed). Webinar content included a focus on quality improvement techniques, five topic-focused sessions led by known experts in the content area (motivational interviewing, hypertension identification and management, tobacco exposures,

BMI assessment and treatment, nutrition counseling) and sessions providing a forum for practices to share examples of successful practice change strategies. Study staff members followed practice and clinician progress to help coach, identify best practices, and offer technical assistance when needed. Study staff with expertise in CV risk-related care provided answers to specific questions posed by practice clinicians, as necessary.

Toolkit to Support Guideline Implementation—We developed and applied focused tools and strategies to aid clinicians in identifying and implementing strategies to improve guideline compliance around the three areas of focus: BMI, obesity identification, BP, and tobacco use and exposure. This toolkit included (1) guideline summary materials with an integrated set of guideline-based recommendations, (2) a clinical decision support tool (CDS, described below) for calculation of BMI and BP percentiles and input of relevant patient and family history to determine guideline-specific recommendations, and (3) a patient and family workbook to support lifestyle change.

The CDS tool. This tool was created for both mobile and desktop devices, facilitates adoption and use of the guideline by integrating assessment and treatment of CV risk factors with routine pediatric care. This mobile CDS tool includes (1) an integrated screener for risk factor assessment, (2) BP and BMI calculators (because interpretation of both depends on sex, age, and specific measures at the visit), and (3) tools to provide specific follow-up recommendations for BP management. The integrated screener was developed to collect data element inputs across several categories: social, behavioral, demographic, physical measurement, patient medical history, and family history. These data elements trigger guideline recommendation in seven risk factor domains: Family History, Lipids, Overweight and Obesity, Nutrition and Diet, BP, Physical Activity, and Tobacco Exposure. Stand-alone calculators enable users to rapidly determine percentiles and thresholds for a child's BMI and BP. Support for follow-up visits focused on BMI, lipid screening, and BP management are provided by additional modules within the CDS, including referral and treatment recommendations.

A Parent and Child Workbook for Giving Young Hearts, Strong Starts was developed by RTI and printed for the intervention practices. The workbook is 29 pages long, and uses simple language and colorful presentation to specifically address the lifestyle changes needed to reduce risk and improve CV health. Supplied to practices throughout the intervention, these books were prepared in sections as downloadable PDFs and made available on the study Web site.

This is a multifaceted intervention which includes interactions among the intervention practices and between the practices and the study personnel or guest speakers for the webinars that are a part of the intervention. We think there may well be changes in the patterns of office visits as BP, BMI or tobacco issues are identified that will require additional visits for management.

Cluster Randomized Design

Practices have many unique characteristics, including practice management type, number of providers, style of providing and documenting care, and differing patient characteristics. Regional differences, such as insurer processes and practice siting, add to between-practice variability.

Practices were randomized to either the intervention or control groups after the collection of baseline data from well child visits occurring prior to guideline publication. We used a matched pairs group randomized design (GRD) (also known as a cluster randomized trial) for this assignment. We first determined that each network would have 8 intervention and 8

control practices. We initially sorted practices into one of 8 strata formed by cross-classifying three factors: practice size (1–4 physicians vs. 5 physicians), practice type (pediatric vs. family, multispecialty practice), and practice location (located in a census-defined Metropolitan Statistical Area vs. nonmetropolitan area). The individual strata contained different numbers of practices. For every set of pairs of practices within a stratum, we randomly assigned one member of the pair to the intervention group and the other member to the comparison group. For practice type, all participating practices were pediatric except for one family practice and one multispecialty practice. Thus, this variable was not included in the group assignment. (Table 1) Control and intervention practices are insulated from each other. There are no regular meetings that they might attend. The practice networks do not maintain regular communication between practices outside of the structure of a specific project and there was no overlap between this trial and other quality improvement participation in either North Carolina or Illinois.

The control practices were sent electronic reports of baseline performance data for their practice and a link to the published guideline materials.

Selection of Outcome Measures to Assess Quality of Care Delivered

The full NHLBI CV Risk Reduction guideline is a comprehensive, complex document of 405 pages, supported by an extensive systematic literature review. The *Clinical Guideline Summary Report* developed for the project by RTI, a more concise 73 pages, has brief descriptions and extensive tables and algorithms on each of the eight areas in the guideline. Of these, some are more suitable to assessment of changes to care delivery strategies and documentation over a 1-year period than others.

We selected the BMI documentation and interpretation and management of obese and overweight children; BP documentation, interpretation, and management; and tobacco use and exposures and preventive counseling areas (Table 2) over others for several reasons. Some guideline aspects would require an extensive medical record review process to ascertain change. For example, practices use a wide array of strategies to obtain family history, including pre-visit surveys or online collection options, but these generally focus on specific types of visits (e.g., initial visit to the practice), and may not be repeated. Thus, focusing on changes to family history may be difficult to ascertain through medical record review, given that in any one month relatively few children have their first visit to the practice. Similarly, lipids and lipoprotein screening has varying recommendations by child age. Lipids screening is uniformly recommended at age 10 ± 1 year, making measurement of adherence not possible in the study's 1-year time frame. We also decided not to separately focus our evaluation on physical activity or diet and nutrition but instead to incorporate these lifestyle factors in the assessment and recommendations for BMI and BP.

To assess changes in care for each of the selected areas and the project overall, we constructed composites of the measures for each of the three areas and an overall study composite. Each composite represents the number of opportunities for the practice to adhere to guideline recommendations in each area. Thus the BMI composite is the sum of the number of patients having BMI measured and documented, BMI interpreted, and for those with elevated BMI, appropriate recommendations made, divided by the sum of the number of patients in the denominator of each individual measure in the composite.⁹

Our study's focus was to improve care related to the identification and delivery of CVD risk reduction. Thus, the key question is can we demonstrate changes in office visit processes and documentation resulting in enhanced delivery of CVD risk reduction guideline recommendations? To demonstrate this, we elected to conduct pre- and post-intervention medical record reviews. Records reviewed were visits in a selected time period without

regard to individual provider. We chose this strategy to best represent a practice-wide evaluation and obviate the need to follow individual children over time. Including child-level outcomes would require evaluation of many other child, family, and community factors. Further, our intervention period was 12 months—a relatively short time to assess patient-level changes through medical record documentation (e.g., for school-aged children, care provided at health maintenance visits would usually occur only once in that period). We decided to focus the record review on children ages 3–11 years using the following rationale:

- To conduct an efficient record review for outcomes evaluation, we desired to use records that maximized the number of applicable items in every record reviewed.
- We focused on children age 3–11 years for three main reasons: (1) most practices are not yet using the World Health Organization (WHO) infant growth curves to interpret BMI in children aged < 2 years, (2) recommendations for routine application of BP assessment begins at age 3 years, and (3) the timing of health maintenance for adolescents ages 12 and older may be infrequent and seasonal, making data review problematic for visits occurring in the fall/winter.

Data Collection

To maintain inter-practice consistency and lessen study burden on practices, outcome data were collected by study staff at the beginning and end of intervention period. The window selected for medical record review was the three months before the start of the intervention, with most recent visits a priority. Elements captured by review included

1. Patient demographics: eligibility (no terminal illness), age (years), race/ethnicity, insurance type, and sex;
2. Measurements: weight, height, BMI, BP;
3. Documentations of BMI percentile, BMI percentile interpretation, change in BMI trajectory, counseling for children categorized as overweight or obese, step up in care intensity for those not improving weight status, follow-up if overweight or obese;
4. Documentation of BP interpretation (recording of BP percentile), management if noted to be elevated;
5. Tobacco: secondary exposure or use (depending on patient age), and preventive counseling provided.

Statistical Power Calculation

Baseline medical record review included 30 subjects at each of the 32 participating practices, with follow-up record review of 40 subjects per practice. The numbers of practices and medical record abstractions that can be accommodated in the study are limited by time, cost, and logistical constraints. It was important, therefore, to carefully consider optimal sample sizes for the evaluation. This analysis is complicated by the multilevel nature of the design. Children clustered within a particular practice tend to be more similar to one another than they are to those in other practices. This introduces an additional source of variance that makes a GRD less efficient than conventional experimental randomization of individuals. The samples sizes presented below are therefore larger than they would be for a completely randomized design.

Optimal sample sizes were determined by conducting a statistical power analysis. We used PASS[®] software (PASS 2008; 08.0.12) to perform these calculations, using a test for two proportions as the analysis prototype, given available data for key assumptions.

For this evaluation, we calculated sample size using the following parameters: (1) $\alpha = 0.01$ (to account for the multiple outcome measures to be tested), (2) power = 0.80, (3) one-sided tests, and (4) an effect size of 15 percentage points based on a 65% guideline compliance rate in the intervention group vs. 50% in the comparison group. The one sided test was chosen because the change of interest in this trial is the improvement in delivery of the guideline derived measures of adherence in the intervention group compared to the control group. We do not have a basis to expect reduction in measure performance which would require two-sided tests.

The effect size is designed to capture absolute group differences of 15% or more for binary process of care outcomes. Somewhat smaller differences can be detected for comparison group rates that are closer to 0% or to 100%. A GRD involves a design effect (DE) defined as follows:

$$DE = 1 + (m-1)*ICC$$

Where

m = the average number of children per practice, and

ICC = the intraclass correlation for an outcome.

The ICC is the additional variance attributable to differences between practices.

We were unable to locate any studies in pediatric populations that provide ICC estimates for any of the process or physiologic outcomes of interest in this evaluation. In primary care clinical studies in adult populations, $ICCs$ for the same outcome varied widely from one study to the next. There is evidence that the variance is greater for quality of care measures than for patient characteristics or laboratory values. This is understandable in that practices are likely to have a greater influence on the type of care they provide than they do on the composition of the patients they serve.

On the basis of literature on adult quality measures, we believe that an $ICC = .05$ is a reasonable estimate (given the further assumption noted below related to the planned analysis) of the variance for process outcomes. We assumed that 32 practices would participate in the study. Under these assumptions of a one-tailed significance test, 40 patients are needed per practice (cluster) for the evaluation, for a total of $32 * 40 = 1,280$ patients. The change of interest in this trial is the improvement in the delivery of guideline derived measures of adherence. We are specifically interested in the improvement of measures in the intervention group compared to the control group and do not have a basis to expect a reduction in measure performance which would require two-sided tests.

These sample-size estimates may have been liberal in that our analysis models, described below, include covariate adjustments under the actual analyses to be implemented: multilevel models. A recent simulation suggests that covariate adjustments can often offset much of the loss in power inherent in GRDs as long as the covariates are related to study outcomes¹⁰

Data Analysis Strategy

Practices were randomly assigned to treatment and control. Because of the randomization, we will conduct our initial analysis to determine if there are no baseline differences between the two groups. If there are no differences, we will conduct an analysis of the follow-up data only, testing for an unadjusted intervention effect. If there is a difference in baseline values between the intervention and control groups, we will assess the baseline to follow-up differences for the control and intervention practices and will then assess the difference of

these differences for our analysis. These tests will be done for both individual measures and composite measures. The outcomes for individual measures will be binary measures, indicating for each medical record whether that particular individual activity had taken place. As medical record abstractions within offices are expected to be correlated, this analysis will be done using general estimating equation (GEE) methods to account for the correlated data—a violation of assumptions for ordinary logistic regression analysis—in variance estimation. These analyses will be conducted with SAS software, using the Genmod procedure, which is designed to model a wide variety of outcome distributions (including binary), and will be programmed to use the GEE method for variance estimation. The composite outcomes will be percentages defined at the office level. No correlated data existed at the level of offices so ordinary least squares assumptions held. These will be modeled using the Genmod procedure as well, assuming normally distributed error terms.

DISCUSSION

This project proposes to enhance certain aspects of practice care delivery with the intention to positively impact child health. The project establishes and tests systems to “fast-track” implementation of the NHLBI CV risk prevention guideline in pediatric primary care. Although the more typical time frame for research findings to become usual practice is 17 years,¹¹ we designed this multifaceted approach to facilitate more rapid implementation. Successful practice- and provider-level implementation of guideline-driven changes in primary care is usually the result of application of a multi-faceted approach.^{13, 14} Strategies for changing care include examining current systems to identify areas for improvement, followed by application of quality improvement processes; including a practice facilitator has been found to be particularly effective.¹¹⁵⁴ It has also been demonstrated that physician participation in quality improvement linked to MOC is an effective motivating strategy for improving care.¹¹⁶ Although the large number of preventative areas to address during health supervision visits¹¹⁷ may leave limited time to address CV risk factors at primary care preventative visits,¹⁸ the tools designed for this study are meant to help providers prioritize areas most important to an individual patient to reduce CV risk.

This proposed study design has several limitations. First, we will be working with practices that are interested in research and many of which have participated in past research projects. Practice leaders and clinicians at participating sites may be “early adopters” of change, so more readily amenable to the intervention than practices without research experience.¹⁹ Second, although the evaluation is at the practice level, MOC participation is at the individual level. If MOC participation determines clinician levels of participation in the intervention, care patterns within a practice may vary and we would be unable to detect this. Third, we limited our focus to specific aspects of the guideline. Additional study is needed to better understand implementation of guideline directives on lipid screening and other areas.

CONCLUSIONS

Young Hearts Strong Starts is a cluster randomized pediatric practice-based quality improvement and guideline adoption intervention that will assess the effectiveness of a multifaceted approach to changing care systems to support the use of the NHLBI Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents in 32 practices.

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Intervention Group

Control Group

^xIntervention:

Baseline external record review data for measures performance

Intervention tool kit with clinical decision support tool

Academic detailing

Monthly webinars for best practice sharing and QI skills building

*ABP Maintenance of Certification

Figure 1.
Implementation Timeline

Table 1

Practice Recruitment and Randomization

	ECU Practices contacted= 31 Practices declined = 14 Practice excluded = 1 (insufficient patient volume) Total participating = 16		PPRG Practices contacted = 22 Practices declined = 5 Practices excluded = 1 (insufficient patient volume) Total participating = 16	
Variable	Practices Randomized to Intervention	Practices Randomized to Comparison	Practices Randomized to Intervention	Practices Randomized to Comparison
Total #	N=8	N=8	N=8	N=8
Small	n = 4	n = 4	n = 5	n = 4
Large	n = 4	n = 4	n = 3	n = 4
Urban	n = 3	n = 5	n = 8	n = 8
Nonurban	n = 5	n = 3	n = 8	n = 8
Pediatric	n = 8	n = 6	n = 8	n = 8
Other ¹	n = 0	n = 2	n = 8	n = 8

¹ Multispecialty or Family practice

Table 2**Quality Measures**

Measures	Numerator	Denominator
1. BMI Measures		
a. BMI Recorded	BMI recorded in the medical record for each well visit	All patients age 3–11 at the most recent well child visit
b. BMI Interpreted	BMI recorded by percentile in the medical record or, if < 85th percentile, noted as normal	All patients age 3–11 at the most recent well child visit with BMI documented at the visit
c. BMI Recommendations	Action plan for BMI > 85th percentile is documented in the medical record	All patients with BMI > 85th percentile documented at the most recent well child visit
d. BMI Composite	Number of specified actions taken for BMI (numerator 1a + 1b + 1c)	Number of opportunities to address BMI (denominator 1a + 1b + 1c)
2. Blood Pressure (BP) Measures		
a. BP Recorded	All patients included in the denominator that have BP recorded in the medical record for the well child visit	All patients age 3–11 at the most recent well child visit
b. BP Interpreted	Systolic blood pressure (SBP) and diastolic blood pressure (DBP) recorded by percentile based on sex, height, and weight	All patients age 3–11 at the most recent well child visit with BP recorded
c. BP Recommendations	Action plan to address BP percentile (based on hypertension stage) is documented in the medical record	All patients with SBP and/or DBP meeting Fourth Task Force levels for prehypertension, Stage 1 hypertension, or Stage 2 hypertension ²
d. BP Composite (percentage of all opportunities realized to address BP)	Number of specific actions taken for BP (numerator 2a + 2b + 2c)	Number of opportunities to address BP (denominator 1a + 1b + 1c)
3. Tobacco Measures		
a. Tobacco exposures (age 3–4):	Tobacco exposure assessed for each child	All patients ages 3–4 years at the most recent well child visit
b. Use identification (ages 5–11 years)	Tobacco exposure and use assessed for each child	All patients ages 5–11 years at the most recent well child visit
c. Preventative and cessation	Prevent counseling and cessation	All patients ages 5–11 years at the most recent well child visits
d. Tobacco Composite	Number of specific actions taken for tobacco (Numerator 3a + 3b + 3c)	Number of opportunities to address tobacco (Denominator 3a + 3b + 3C)
4. Project composite	Number of specific actions taken in any area (Numerator 1d + 2d + 3d)	Number of opportunities to address any area (Denominator 1d + 2d + 3d)