Clinical Trial Protocol

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Implementation of the *Connect for Health* pediatric weight management program: study protocol and baseline characteristics

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We are implementing *Connect for Health*, a primary care-based intervention to improve family-centered outcomes for children, ages 2–12 years, in organizations that care for low-income children. We will use the 'Reach-Effectiveness-Adoption-Implementation-Maintenance' framework to guide our mixed-methods evaluation to examine the effectiveness of stakeholder-informed strategies in supporting program adoption and child outcomes. We also describe characteristics of children, ages 2–12 years with a BMI ≥85th percentile and obesity-related care practices. During the period prior to implementation, 26,161 children with a BMI ≥85th percentile were seen for a primary care visit and a majority lacked recommended diagnosis codes, referrals and laboratory evaluations. The findings suggest the need to augment current approaches to increase uptake of proven-effective weight management programs. **Clinical trial registration number:** NCT04042493 (Clinicaltrials.gov), Registered on 2 August 2019; https://clinicaltrials.gov/ct2/show/NCT04042493.

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Background & rationale

Childhood overweight and obesity place a substantial burden on morbidity and quality of life and represent a national health priority [1–3]. The prevalence of childhood overweight and obesity remain at historically high levels and socioeconomic disparities appear to be widening [4–7]. Many of the underlying causes of obesity are modifiable risk factors throughout the life course; these risk factors represent major causes of health inequalities [8]. Approaches for reduction of obesity include collaborative interventions that aim to engage and empower families in obesity management and work across primary care and community settings [9]; however, adoption of interventions in these settings are limited.

The primary care setting provides an opportunity to detect elevated BMI levels and provide interventions that can alter a child's risk for disease and poor health outcomes. The US Preventive Services Task Force (USPSTF) guidelines offer strong evidence for screening and evaluation, counseling for weight management, a balanced

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nutrition plan and physical activity, and behavioral management techniques for lifestyle changes [10,11]. Yet, the USPSTF recommendations are not routinely followed and children with obesity are seldom identified [12]. It is critical that programs address the socio-contextual factors that affect behaviors at multiple levels including the individual, family and environment to improve health outcomes [13–15].

The *Connect for Health* pediatric weight management program is a novel approach to care delivery that leverages clinical and community resources to improve family-centered outcomes for high-risk children with overweight or obesity. The *Connect for Health* trial examined the comparative effectiveness of two clinical-community interventions in improving child BMI z-scores and family-centered outcomes and enrolled 721 children, ages 2–12 years with BMI ≥85th percentile in MA [16,17]. Children were randomized to one of two arms: enhanced primary care, e.g., flagging of children with BMI ≥85th percentile, clinical decision support tools, parent educational materials, neighborhood resource guide and text messages; or enhanced primary care plus contextually tailored, individual health coaching. At the end of the one-year intervention, both intervention arms resulted in improved family-centered outcomes and child BMI; there were no significant differences in outcomes between the two intervention arms [16].

The purpose of this study is to examine the implementation of the *Connect for Health* program across four organizations that deliver care to low-income children in the USA who have disproportionately high prevalence of obesity. We describe the study design, the mixed-methods evaluation plan and baseline characteristics and clinical care of children with obesity receiving care across the organizations. We present the study protocol in conjunction with the baseline characteristics to provide a comprehensive overview of the implementation settings, provide a roadmap for other organizations with similar characteristics and patient demographics, and stress the need for programs such as *Connect for Health*.

Design

Overview of study design

We used the Consolidated Framework for Implementation Research to assess contextual determinants in preparation of implementation of the *Connect for Health* pediatric weight management program in four organizations that deliver primary care to low-income children in Boston, MA, Denver, CO and Greenville, SC [18]. The *Connect for Health* program includes: electronic health record (EHR)-based clinical decision support tools to guide clinicians in weight management; family educational materials; text messages for parents to support behavior change. We have previously described the pre-implementation phase in which we engaged clinician and parent stakeholders to assess needs and preferences of the program tools and implementation strategies; and to identify barriers and facilitators to adoption [19]. Following stakeholder engagement, we iteratively adapted the program components to suit the implementation contexts, as well as in consideration of sustainability and scalability. We used the 'Reach-Effectiveness-Adoption-Implementation-Maintenance' (RE-AIM) framework to guide the mixed-methods evaluation of the program's implementation [20]. Using a quasi-experimental design, we will examine the effectiveness of stakeholder-informed strategies in supporting program adoption and child outcomes. At baseline (i.e., 15-months prior to program implementation), we abstracted EHR data from the four organizations to describe characteristics of children, ages 2–12 years with a BMI ≥85th percentile. Figure 1 illustrates the conceptual model for the implementation of the *Connect for Health* program, which guided our implementation strategies and evaluation plan. The study was registered at Clinicaltrials.gov (NCT02124460) and the Partners Healthcare institutional review board approved this study. The standard protocol items: recommendations for interventional trials for clinical trial study protocols and the standards for reporting implementation studies reporting guidelines (Supplementary Files 1 & 2) were followed.

Setting, participants, & end-users of the program

The *Connect for Health* program is being implemented in 26 primary care practices of four geographically and demographically diverse healthcare organizations. The organizations include: Boston Medical Center and Massachusetts General Hospital in Boston, MA, Denver Health in Denver, CO and Prisma Health in Greenville, SC. We selected the organizations because they have pediatric or family-medicine practices that are hospital-based, federally qualified or community health centers that deliver care to racially-ethnically diverse, low-income population of children with high rates of obesity. All the healthcare organizations use the Epic EHR platform (Verona, WI) allowing for the rapid scaling of EHR tools. Boston Medical Center is an academic medical center and is the largest safety-net hospital in New England. Massachusetts General Hospital is an academic medical center in Boston,

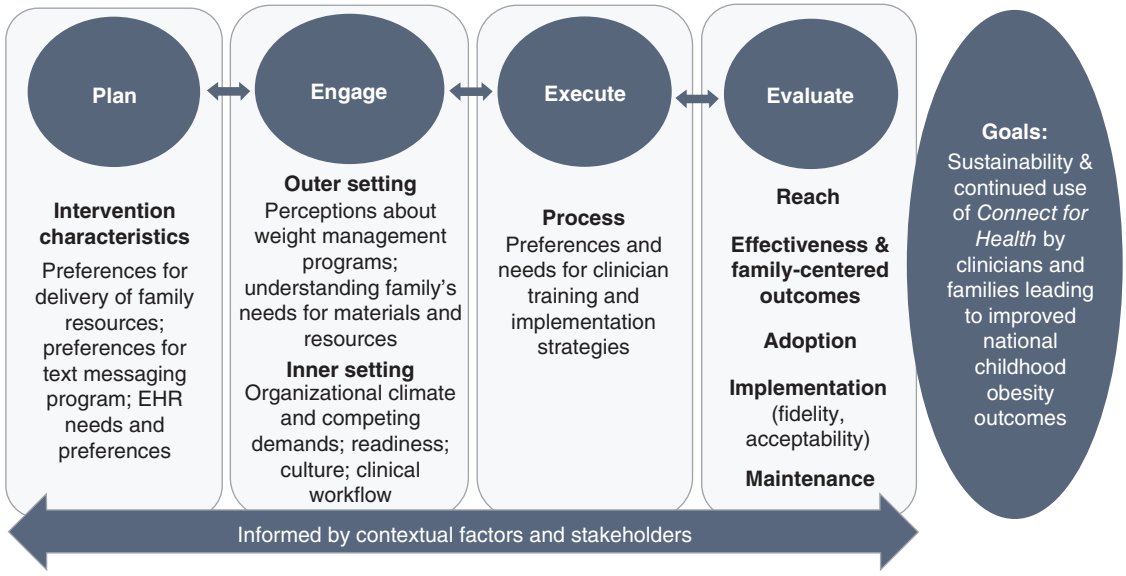

Figure 1. Implementation and Evaluation Approach for *Connect for Health* pediatric weight management program.
EHR: Electronic health record.

MA and has community health centers in surrounding cities. Denver Health is an academic health system, CO's primary safety-net institution, and the eighth largest federally qualified health center system in the US. Prisma Health is the largest multiregional health organization in SC.

The implementation of the *Connect for Health* program and its strategies are targeted toward pediatric or family-medicine primary care clinicians and is intended to be delivered during annual well-child visits or follow-up visits with the primary care team. Due to varying clinical workflows across the four healthcare organizations, physicians, physician assistants, nurse practitioners and medical assistants will use the program tools. Children, ages 2–12 years, with an elevated BMI and their families are the end-users of the program. During the preimplementation phase, each healthcare organization, based on their clinical population and needs, decided whether to make the program tools available for children with a BMI ≥85th or 95th percentile.

The Connect for Health program tools

Clinical-facing tools

The clinical decision support tools guide screening and management of childhood obesity. We created a Best Practice Alert (BPA), a flagging system that activates in the EHR for programmable patient specific characteristics that identify children with an elevated BMI at the time of a well-child visit. After a child's height and weight are taken and the data are entered into the EHR, a noninterruptive BPA appears to alert the clinician and/or staff to the elevated BMI. In addition to the BPA, we designed a SmartSet (an Epic visit template functionality) to assist clinicians in the best management practices for childhood obesity. The SmartSet prompts clinicians to document a diagnosis of overweight or obesity; discuss and document counseling on nutrition and physical activity; order laboratory evaluations as appropriate; make referrals to nutrition, weight management programs and other relevant services; place an order for the text-messaging program; provide educational materials and schedule a follow-up visit.

Family-facing tools

The family materials include a comprehensive set of printable patient educational handouts focusing on recommended behavioral changes that were adapted from the original trial based on stakeholder input [16,17,21,22]. The materials include an overview handout with the six behavioral messages and additional handouts focusing in-depth on each individual message. The messages include: healthy drink choices, screen-time, physical activity, following a balanced nutrition plans, sleep and social-emotional wellness. The tools also include an extensive library of social- and community-informed text messages to support behavior change. Clinicians and staff will enroll parents to receive the unidirectional, automated messages generally twice a week for 1 year. The community resource guides

Table 1. Characteristics of implementation strategies used to increase adoption of the *Connect for Health* program among pediatric primary care clinicians and staff.

Implementation strategy	Operationalizing the implementation strategies				Implementation outcome affected
	Actor	Action	Temporality	Dose	
1. Conduct ongoing training	Clinician champion; practice coach	Conduct trainings that focus on need for the program, evidence strength of the program and intervention components	Prior to program launch and ongoing throughout the implementation phase	Two trainings prior to program launch and then quarterly	Program uptake and fidelity
2. Provide local technical assistance and consultation	Clinician champion; practice coach; Epic analyst	Provide assistance in-person, over the phone and via email	Throughout the implementation phase	Ongoing as needed	Program uptake, feasibility and fidelity
3. Create a virtual learning community	Implementation support team	Provide education on the program and childhood obesity topics led by experts and offer continuing educational units	Will begin mid-way through the implementation period and last for 6–9 months	New module to be released monthly	Program uptake and fidelity
4. Alter incentive/allowance structures	Implementation support teams in conjunction with administrative leaders	Align program with healthcare organization's internal performance metrics and provide quality improvement bonuses	Throughout the implementation phase. Alignment with internal performance metrics that begins during the pre-implementation phase when adapting the program	Evaluated for qualification for bonus once during implementation phase	Program uptake, acceptability, and sustainability
5. Audit and provide feedback	Clinician champion; practice coach; implementation support team	Collect individual and practice-level metrics on utilization of the clinical decision support tools and deliver feedback reports to clinicians	Throughout the implementation phase	Feedback reports to be delivered quarterly	Program uptake
6. Facilitation	Clinician champion	Support and problem-solve with clinicians to encourage program adoption	Throughout the pre-implementation and implementation phase	As needed	Program uptake, acceptability and fidelity

assist families in identifying resources within their community that support behavior change. The community resource guides include sections on nutrition and food resources, physical activity and after-school programs, housing and utilities, and social services and healthcare. The family-facing materials have been translated into Spanish and Haitian Creole to ensure the program is accessible for the diverse communities that the four healthcare organizations serve. Besides materials being provided to families at their well-child visit, families can also obtain the patient educational materials and community resource guides from the *Connect for Health* website (www.c4hprogram.com).

Implementation strategies

The *Connect for Health* implementation strategies are designed to have an equity focus and support clinicians in the adoption of the program in primary care. During the implementation phase, each healthcare organization identified clinician champions, practice coaches and an implementation support team consisting of an Epic analyst and project manager. The implementation strategies are listed and operationalized according to the Expert Recommendations for Implementing Change [23,24] in Table 1. The strategies, such as conducting ongoing trainings and creating a virtual learning community, focus on educating clinicians about the program and best practices for screening and management of childhood obesity. Virtual learning communities have been widely used to increase knowledge and support practice change [25,26]. To support clinicians and staff, we will provide ongoing technical assistance to support their usage of the new EHR tools and other program components. Ongoing education and consultation are critical to provider adoption of clinical innovations and have been shown to be even more important than standalone training [23,27]. Clinician champions have been shown to facilitate change efforts by building organizational support [28] and by providing performance feedback that can support the adoption of evidence based practices [23,29–31]. To incentivize the uptake of the program, we aligned the program with each healthcare organization's internal performance metrics and when available, with quality improvement bonuses [32].

Outcome measures & evaluation

The RE-AIM framework has guided our evaluation and Table 2 shows our outcomes, measures and data sources.

Table 2. Study outcomes using the RE-AIM framework.

RE-AIM component	Measure	Data source
Reach	Child socio-demographic characteristics	EHR
	Rate of action taken on best practice alert among total number of best practice alerts fired	EHR
Effectiveness and family-centered outcomes	Change in BMI	EHR
	Family's experience with program	Parent survey administered within 8 weeks of well-child visit
Adoption	Setting-level characteristics (including number of practices, practice type)	Administrative data
	Staff-level characteristics (including clinicians and team members' role)	Administrative data
	Rate of Smart Set utilization and text messaging orders	EHR
Implementation		
Fidelity	Intervention & implementation fidelity checklist	Observation and interviews completed mid-implementation with clinicians, clinician champions and practice coaches
Acceptability	Acceptability of Intervention Measure	Survey administered mid-implementation to clinicians
Maintenance	Reach, effectiveness and adoption measures over time	EHR
	Clinical Sustainability Assessment Tool	Survey administered to unit chiefs, clinician champions and practice coaches

EHR: Electronic health record; RE-AIM: Reach-Effectiveness-Adoption-Implementation-Maintenance.

We will collect measures through EHR abstractions, surveys and informal interviews with leadership, clinician champions, practice coaches, clinicians and parents. To understand program reach, we will describe children's socio-demographic characteristics and will calculate the rate of action taken on the BPA among the total number of BPAs that were fired. We will measure adoption by describing setting- and staff-level characteristics and will report on SmartSet utilization and text messaging program orders. For implementation outcomes, we will assess fidelity to ensure the program is being delivered as intended with all core program components, and will measure program acceptability using the Acceptability of Intervention Measure [33]. We will evaluate reach, effectiveness and adoption measures over time to study maintenance, and will use the Clinical Sustainability Assessment Tool [34] to understand needs for program sustainment. We will calculate descriptive statistics for the reach, adoption, implementation and maintenance outcomes.

To understand effectiveness, we will examine changes in BMI z-score and family-centered outcomes over the course of program implementation. We will survey parents of eligible children eight weeks following their well-child visit to understand their experiences with the program. The survey, offered in English and Spanish, will include questions regarding how the program impacted behaviors and usefulness of the family-facing program tools. We will report on descriptive statistics of the survey.

We will use a quasi-experimental design to assess changes in BMI z-scores. We selected this design because we did not have enough sites for cluster randomization, randomizing within sites would have risked contamination, and the program has previously been shown to be effective and withholding the intervention would have not been ethical. Using only children who are eligible for the program, we will start with simple analyses that compare paired baseline and follow-up outcomes for each child. The baseline period will be 15 months prior to program implementation in which we will collect 2–3 measurements most proximal to the start of the program. We will also collect all BMI z-scores after the start of the program. A paired t-test will be used to compare the difference in the average pre-intervention and post-intervention BMI z-scores. While this approach assures the absence of confounders and excellent power, we have no control group. Any improvements that we observe could be present in other children, and therefore, not attributable to the intervention. Therefore, a regression discontinuity design will be used to assess program effectiveness by evaluating the reported changes in BMI z-scores. BMI z-scores will be collected pre-implementation and post-implementation for two groups of children: children who are eligible to receive the program (BMI $\geq$85th or 95th percentile) and 'quasi-control' children who are not eligible to receive the program (BMI between the 50th–85th percentile). From the observed pattern of changes in BMI z-scores in the quasi-control children, we can project what the BMI z-scores would be in children with an elevated BMI. We will then compare this projected pattern to the actual pattern in the children eligible to receive the program. A segmented regression model will be used to estimate the pattern in the control children, any acute change affecting

all children receiving the program equally, and any change in pattern that could affect the children with greater BMIs differentially.

Using an alternate design, we will evaluate changes in child BMI z-score by using a second control group of children with elevated BMIs at geographically and demographically matched community health centers. The inclusion of this secondary control group will allow us to match on BMI trajectories and will allow us to compare changes to BMI z-scores using a difference-in-differences design. We will collect data from community health centers through the Azara Healthcare Data Reporting and Visualization System (MA, USA). We will use multivariable linear regression models, adjusted for correlation due to repeated measures over time, to evaluate changes in BMI z-scores.

Baseline characteristics & obesity-related care metrics

To characterize our reach and target population, as well as understand current practices in obesity-related care at the healthcare organizations, we abstracted data from the EHR and collected the following information during the 15-month time period prior to program implementation: socio-demographics, BMI, BMI z-scores, BMI category (i.e., overweight, obesity and severe obesity), International Classification of Diseases, 10th Revision (ICD-10) codes for documentation of BMI, childhood obesity and nutrition and physical activity counseling, laboratory orders, referrals and the comorbid condition of asthma. The abstraction included children, ages 2–12 years with a BMI ≥85th percentile who were seen for a well-child visit at a practice implementing the program. The healthcare organizations implemented the program at different times, so the dates of the baseline periods differ. At primary care visits, we collected childhood obesity and nutrition and physical activity counseling ICD-10 codes. Laboratory orders included fasting glucose, hemoglobin A1c, ALT, AST and complete lipid panels. We searched laboratory orders completed at the time of well-child visits or during the visits 15-months prior. We included referrals to nutrition and weight management programs that were made at the time of well-child visits or during the visits 15-months prior. Referral data from Prisma Health were not available. We documented if a child had asthma as indicated by a prescription for albuterol, ICD-10 code, asthma referrals, historical registration of asthma or an asthma control test. For the laboratory orders, referrals and asthma documentation, when available, we also searched historical data as orders and referrals are not always recommended on a yearly basis. Historical data were limited due to availability in data warehouses. We calculated descriptive statistics for all the variables for each healthcare organization. Statistical analyses were completed using R Studio Software (version 3.5.1) and SAS (SAS Institute, NC, USA).

Results

During the 15-month period prior to implementation, 26,161 children with a BMI ≥85th percentile, ages 2–12 years were seen for a primary care visit. Estimated rates of childhood obesity across the organizations ranged from 35–50%. Across the four organizations, the mean (standard deviation [SD]) age of the children with a BMI ≥85th percentile was 7.8 (3.1) years and 49% of children were Hispanic, 22% were White and 18% were Black. Approximately 41% of families spoke a language other than English and 79% of children had public insurance. Table 3 shows the characteristics of children, ages 2–12 years with a BMI ≥85th percentile for the four healthcare organizations.

Table 4 shows the BMI, BMI z-score, BMI categories of children and obesity-related care metrics for children across the four healthcare organizations. Overall, approximately 48% of children had a BMI ≥95th percentile and 15% were in the severe obesity category defined as BMI ≥99th percentile. Between the organizations, the use of childhood obesity diagnosis codes and which family of codes was used (Z68 v. E66) varied, as well the usage between BMI categories. Most consistently, childhood obesity ICD-10 diagnosis codes were documented for children with severe obesity; the utilization for E66 codes was 60%. For children with obesity, the use was 44% and for children with overweight, the use was 17%. Counseling codes for nutrition and physical activity were not commonly used and usage was 7% for dietary counseling and 6% for physical activity. Orders placed for laboratory evaluations were more prevalent among children in higher BMI categories with the most orders being placed for the severe obesity category. For the overweight category, orders for all laboratory evaluations combined were 29%; for the obesity category 39% and for the severe obesity category 64%. Referrals placed for nutrition services and weight management programs increased between the BMI categories. Nutrition referrals were 4% for the overweight category, 7% for the obesity category and 16% for the severe obesity category. Weight management

Table 3. Characteristics of children, ages 2–12 years, with a BMI ≥85th percentile who were seen for a well-child visit during the 15-month period prior to program implementation (n = 26,161).

Child characteristics	Overall	Massachusetts General Hospital (September 2018–December 2019)	Boston Medical Center (July 2018–October 2019)	Denver Health (September 2018–December 2019)	Prisma Health (August 2018–November 2019)
	n = 26,161	n = 6752	n = 2494	n = 10,079	n = 6836
	n (%)	n (%)	n (%)	n (%)	n (%)
Age, mean (SD)	7.81 (3.14)	7.57 (3.25)	7.51 (3.27)	8.12 (3.04)	7.62 (3.08)
Sex					
Male	13,873 (53.03)	3583 (53.07)	1241 (49.76)	5453 (54.10)	3596 (52.60)
Female	12,288 (46.97)	3169 (46.93)	1253 (50.24)	4626 (45.90)	3240 (47.40)
Race/ethnicity					
Hispanic/Latino	12,923 (49.40)	3018 (44.70)	398 (15.96)	7579 (75.20)	1928 (28.20)
Non-Hispanic White	5786 (22.12)	1609 (23.83)	125 (5.01)	766 (7.60)	3286 (48.07)
Non-Hispanic Black	4585 (17.53)	664 (9.83)	1528 (61.27)	1206 (11.97)	1187 (17.36)
Non-Hispanic Asian	666 (2.55)	293 (4.34)	55 (2.21)	275 (2.73)	43 (0.63)
Non-Hispanic Other	675 (2.58)	479 (7.09)	40 (1.60)	136 (1.35)	20 (0.29)
Unknown	1526 (5.83)	689 (10.20)	348 (13.95)	117 (1.16)	372 (5.44)
Language	(n = 19,260)	(n = 6688)	(n = 2493)	(n = 10,079)	
English	11,337 (58.86)	4229 (63.23)	1629 (65.34)	5479 (54.36)	Not available
Spanish	6275 (32.58)	1998 (29.87)	152 (6.10)	4125 (40.93)	Not available
Other	1648 (8.56)	461 (6.89)	712 (28.56)	475 (4.71)	Not available
Insurance	(n = 20,085)	(n = 6731)	(n = 2451)		(n = 824)
Public insurance	15,945 (79.39)	4180 (62.10)	1961 (80.01)	9099 (90.28)	705 (85.56)
Private insurance	4140 (20.61)	2551 (37.90)	490 (19.99)	980 (9.72)	119 (14.44)

program referrals were 8% for the overweight category, 10% for the obesity category and 18% for the severe obesity category. Documentation of asthma ranged between 25 and 34% for the three BMI categories.

Conclusion

Pediatric primary care and community settings provide important opportunities to detect elevated BMIs, collaborate with families and deliver childhood obesity interventions. The *Connect for Health* pediatric weight management program is a scalable, proven-effective program that improves BMI and family-centered outcomes for children, ages 2–12 years. The program is being implemented in pediatric primary care practices of four healthcare organizations across the USA in which the majority of children are racially-ethnically diverse and low-income. We have described the study protocol for equity-focused implementation and evaluation and have described characteristics of children and obesity-related care metrics. During the 15-months prior to implementation, we found a low prevalence of guideline-adherent practices, including documentation of obesity and counseling codes, orders for laboratory evaluations and referrals for nutrition and weight management programs. The low uptake of these practices reinforces the importance of programs like *Connect for Health* being implemented in primary care.

The *Connect for Health* program was developed to follow the USPSTF guidelines and leverage clinical and community resources outcomes for children who are racially-ethnically diverse and from low-income communities given the persistent disparities in childhood obesity [5,11,16,17]. The results of the obesity-related care metrics demonstrated the opportunity to improve screening and interventions in the pediatric primary care setting. The USPSTF recommends screening for childhood obesity by calculating age- and sex-specific BMI [11]. Consistent with the literature, the use of childhood obesity diagnosis codes and exercise and counseling codes was low across the organizations resulting in missed opportunities to screen and document growth [35]. The documentation can also be reported to the Healthcare Effectiveness Data and Information Set allowing for accurate estimates of childhood obesity prevalence and trends. In their algorithm for childhood obesity assessment and management, the American Academy of Pediatrics recommends education, referrals to other healthcare providers and weight management programs and laboratory evaluations [36]. Despite these recommendations, uptake of screening, referrals and laboratory evaluations remain low as evidenced in our findings. Consistent with their algorithm, we found laboratory evaluations were ordered more often for children with obesity or severe obesity, as laboratory

Table 4. BMI and obesity-related care of children, ages 2–12 years, with a BMI ≥85th percentile who were seen for a well-child visit during the 15-month period prior to program implementation (n = 26,161).

	Overall	Massachusetts General Hospital (September 2018–December 2019)	Boston Medical Center (July 2018–October 2019)	Denver Health (September 2018–December 2019)	Prisma Health (August 2018–November 2019)
	n = 26,161	n = 6752	n = 2494	n = 10,079	n = 6836
	n (%)	n (%)	n (%)	n (%)	n (%)
BMI					
Mean (SD)	22.01 (4.43)	21.86 (4.27)	22.01 (4.60)	22.21 (4.38)	21.87 (4.57)
Z-score	1.77 (0.55)	1.76 (0.54)	1.78 (0.54)	1.76 (0.53)	1.78 (0.58)
BMI category					
– Overweight	12,484 (47.72)	3233 (47.88)	1163 (46.63)	4814 (47.76)	3274 (47.89)
– Obesity	9745 (37.25)	2566 (38.00)	952 (38.17)	3761 (37.32)	2466 (36.07)
– Severe obesity	3932 (15.03)	953 (14.11)	379 (15.20)	1504 (14.92)	1096 (16.03)
Childhood obesity diagnosis codes					
Overweight category					
– BMI 85th–95th percentile (Z68.53)	3030 (24.27)	190 (5.88)	5 (0.43)	1204 (25.01)	1631 (49.82)
– Diagnosis of overweight (E66.3)	2066 (16.55)	725 (22.42)	228 (19.60)	716 (14.87)	397 (12.13)
Obesity category					
– BMI ≥95th percentile (Z68.54)	4841 (49.68)	883 (34.41)	7 (0.74)	2183 (58.04)	1768 (71.70)
– Diagnosis of obesity (E66 codes)	4251 (43.62)	1415 (55.14)	655 (68.80)	1342 (35.68)	839 (34.02)
Severe obesity category					
– BMI ≥95th percentile (Z68.54)	2762 (70.24)	562 (58.97)	2 (0.53)	1219 (81.05)	979 (89.32)
– Diagnosis of obesity (E66 codes)	2363 (60.10)	782 (82.06)	339 (89.45)	587 (39.03)	655 (59.76)
Childhood obesity counseling codes					
Dietary counseling surveillance (Z71.3)	1824 (6.97)	155 (2.30)	4 (0.16)	207 (2.05)	1458 (21.33)
Exercise counseling (Z71.82)	1609 (6.15)	85 (1.26)	0 (0.00)	123 (1.22)	1401 (20.49)
Laboratory orders[†]					
Overweight category					
– Fasting glucose[‡]	865 (6.93)	0 (0.00)	0 (0.00)	1 (0.02)	864 (26.39)
– HgbA1c	1859 (14.89)	161 (4.98)	61 (5.25)	492 (10.22)	1145 (34.97)
– ALT	1934 (15.49)	709 (21.93)	17 (1.46)	598 (12.42)	610 (18.63)
– AST	662 (8.63)	33 (1.02)	18 (1.55)	Not available	611 (18.66)
– Lipid panel	1482 (11.87)	311 (9.62)	134 (11.52)	591 (12.28)	446 (13.62)
– Any lab order	3554 (28.47)	846 (26.17)	138 (11.87)	750 (15.58)	1820 (55.59)
Obesity category					
– Fasting glucose	894 (9.17)	2 (0.08)	6 (0.63)	4 (0.11)	882 (35.77)
– HgbA1c	2757 (28.29)	414 (16.13)	163 (17.12)	1106 (29.41)	1074 (43.55)
– ALT	2613 (26.81)	715 (27.86)	60 (6.30)	1168 (31.06)	670 (27.17)
– AST	830 (13.87)	101 (3.94)	58 (6.09)	Not available	671 (27.21)
– Lipid panel	2314 (23.75)	494 (19.25)	169 (17.75)	1106 (29.41)	545 (22.10)
– Any lab order	3755 (38.53)	834 (32.50)	194 (20.38)	1226 (32.60)	1501 (60.87)
Severe obesity category					
– Fasting glucose	561 (14.27)	2 (0.21)	9 (2.37)	7 (0.47)	543 (49.54)
– HgbA1c	2177 (55.37)	420 (44.07)	165 (43.54)	869 (57.78)	723 (65.97)
– ALT	1936 (49.24)	474 (49.74)	39 (10.29)	929 (61.77)	494 (45.07)
– AST	626 (25.78)	83 (8.71)	49 (12.93)	Not available	494 (45.07)
– Lipid panel	1953 (49.67)	440 (46.17)	163 (43.01)	883 (58.71)	467 (42.61)
– Any lab order	2505 (63.71)	552 (57.92)	185 (48.81)	954 (63.43)	814 (74.27)
Referrals[§]					
Overweight category	(n = 9210)				
– Weight management program	738 (8.01)	112 (3.46)	23 (1.98)	603 (12.53)	Not available
– Nutrition	395 (4.29)	298 (9.22)	16 (1.38)	81 (1.68)	Not available
Obesity category	(n = 7279)				
– Weight management program	747 (10.26)	147 (5.73)	105 (11.03)	495 (13.16)	Not available
– Nutrition	511 (7.02)	394 (15.35)	51 (5.36)	66 (1.75)	Not available

[†]Includes laboratory order placed at the time of well-child visit or prior to that visit. Historical data were available for MGH from June 2007 to December 2019, BMC from June 2018 to October 2019, Denver Health from January 2014 to December 2019 and Prisma Health from January 2011 to November 2019.
[‡]For Prisma Health, laboratory orders for serum glucose are shown.
[§]Includes referral order placed at the time of well-child visit or prior to that visit. Historical data were available for MGH from June 2015 to December 2019, BMC from June 2018 to October 2019 and Denver Health from April 2016 to January 2020.
[¶]Includes asthma documented at the time of well-child visit or prior to that visit. Documentation of asthma includes combination of albuterol prescriptions, ICD10 codes, asthma control test and historical registration of asthma. Historical data were available for MGH from August 2010 to December 2019, BMC from June 2018 to October 2019, Denver Health from December 2006 to December 2019 and Prisma Health from July 2009 to November 2019.
BMC: Boston Medical Center; HgbA1c: Hemoglobin A1c; MGH: Massachusetts General Hospital.

Table 4. BMI and obesity-related care of children, ages 2–12 years, with a BMI ≥85th percentile who were seen for a well-child visit during the 15-month period prior to program implementation (n = 26,161) (cont.).

	Overall	Massachusetts General Hospital (September 2018–December 2019)	Boston Medical Center (July 2018–October 2019)	Denver Health (September 2018–December 2019)	Prisma Health (August 2018–November 2019)
	n = 26,161	n = 6752	n = 2494	n = 10,079	n = 6836
	n (%)	n (%)	n (%)	n (%)	n (%)
Severe obesity category	(n = 2836)				
– Weight management program	498 (17.56)	170 (17.8)	104 (27.44)	224 (14.89)	Not available
– Nutrition	443 (15.62)	375 (39.35)	35 (9.23)	33 (2.19)	Not available
Asthma documentation¶					
– Overweight category	3177 (25.45)	946 (29.26)	297 (25.53)	1023 (21.25)	911 (27.83)
– Obesity category	2608 (26.76)	772 (30.09)	259 (27.21)	884 (23.50)	693 (28.10)
– Severe obesity category	1343 (34.16)	382 (40.08)	127 (33.51)	468 (31.12)	366 (33.39)

†Includes laboratory order placed at the time of well-child visit or prior to that visit. Historical data were available for MGH from June 2007 to December 2019, BMC from June 2018 to October 2019, Denver Health from January 2014 to December 2019 and Prisma Health from January 2011 to November 2019.
‡For Prisma Health, laboratory orders for serum glucose are shown.
§Includes referral order placed at the time of well-child visit or prior to that visit. Historical data were available for MGH from June 2015 to December 2019, BMC from June 2018 to October 2019 and Denver Health from April 2016 to January 2020.
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BMC: Boston Medical Center; HgbA1c: Hemoglobin A1c; MGH: Massachusetts General Hospital.

evaluations should only be ordered for children with overweight if they have risk factors present, and referrals should only be recommended after counseling with the primary care clinician. The *Connect for Health* program provides clinical decision support tools and clinician education, to screen, guide management practices and provide counseling in accordance with national guidelines to improve uptake of evidence-based practices.

The objective of this study is to increase adoption of the *Connect for Health* pediatric weight management program and evaluate the effectiveness of our implementation strategies. The study protocol we have presented is subject to potential challenges and limitations. As we implement the program, we will closely monitor program uptake and will take a practical approach by modifying our strategies and adapting as necessary. Throughout the implementation phase, we will document modifications to the program and implementation strategies using the framework for Reporting Adaptations and Modifications-Expanded [37,38]. We anticipate modifications to program delivery as three of the four healthcare organizations have shifted to telemedicine for well-child visits due to the COVID-19 pandemic. We selected pragmatic measurements for our evaluation plan; thereby we limited respondent surveys and selected outcomes that we could access through the EHR. Similarly, our baseline data pull was limited to variables within the EHR, as well as the availability of historical data (due to EHR vendor transitions) when searching for previously ordered laboratory evaluations, referrals and asthma documentation. For the current data abstraction, variables, including language, insurance and referral information were not consistently available resulting in missing data.

In conclusion, uptake of evidence-based practices for pediatric weight management fell well below expert recommendations across four organizations that deliver primary care to low-income children suggesting a substantial need for improving the delivery of high-quality care for children with obesity. Our findings emphasize the need to accelerate the adoption of proven-effective weight management programs particularly for children who are racially-ethnically diverse and from low-income households. The implementation of programs, such as *Connect for Health*, need to incorporate implementation strategies that address and advance child health equity.

Executive summary

- *Connect for Health* is a primary care-based intervention to improve family-centered outcomes for children, ages 2–12 years, in organizations that care for low-income children.
- The purpose of this study is to examine the implementation of the *Connect for Health* program across four organizations that deliver care to low-income children in the USA who have disproportionately high prevalence of obesity.
- This paper describes the study design, the mixed-methods evaluation plan and baseline characteristics and clinical care of children with obesity receiving care across the organizations, presenting the study protocol in conjunction

with the baseline characteristics to provide a comprehensive overview of the implementation settings, provide a roadmap for other organizations with similar characteristics and patient demographics, and stress the need for programs such as *Connect for Health*.

Author contributions

M Simione drafted the manuscript, conceptualized and designed the study, analyzed and interpreted the data, and drafted the initial manuscript. H Farrar-Muir, M Luo and ME Perkins analyzed and interpreted the data and critically reviewed the manuscript for important intellectual content. FN Mini, H Frost, EJ Orav, J Metlay, AH Zai, CJ Kistin, K Sease and SJ Hambidge assisted with interpretation of the data and critically reviewed the manuscript for important intellectual content. EM Taveras conceptualized and designed the study, interpreted the data and critically reviewed the manuscript for important intellectual content. The C4H Collaborative assisted with data collection and program implementation. All authors read and approved the final manuscript.

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No writing assistance was utilized in the production of this manuscript.

Ethical conduct of research

The study protocol was approved by the Partners Health Care institutional review board.

Data sharing statement

The datasets used during the current study are available from the corresponding author on reasonable request.

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