Supplemental Information

APPENDIX

In this appendix, we profile a typology of 3 types of practices characterized by their level of need for help in making practice improvement changes. We provide examples of each type of practice and describe the course of its practice change facilitation.

LOW-NEED PRACTICES

One third of the practices in the CHEC-UPPP program ($n = 10$) were identified as Low Need. The facilitator was able to visit 90% of these practices every other week rather than every week because their run charts showed steady, consistent improvements. Most of these practices (80%) had a small or medium burden of change, meaning that not many changes in processes were needed to reach the outcome measures. Most (80%) were small or medium in size, and most (70%) were not high volume. Most (60%) had a strong physician leader, and some (40%) had a champion, or a staff member who regularly interfaced with the facilitator and helped to promote change within the practice. All had an effective decision-making process with either a strong leader (ie, a clinician who was extremely involved in leading the entire practice team and making most of the decisions for the entire practice) or a democratic process (ie, members worked as a group with no singular leader, making decisions as 1 cohesive team). These practices also tended to be independent, engaged, and organized. Once a plan for change was made, the practices fitting this profile implemented changes and did not experience many barriers. Their weekly chart audits showed improvement fairly quickly, and new processes seemed to work well and to be sustainable.

For these practices, the facilitator's role may have been to keep practices engaged by giving reminders, run charts, and other feedback (but less frequently) and to be a resource for the practice if needs arose (eg, patient handouts, supplies). Based on the characteristics of practices fitting this profile, the facilitator could expect to be able to manage communications with the practice easily, having confidence that there would be minimal confusion among practice members and that members would understand and convey 1 clear message to one another. Additionally, the facilitator could expect practices to adopt changes quickly and trust practices in this profile to make changes on their own, to make good judgments about changes, and to implement them with little assistance. Therefore, the facilitator was able to step back and allow practices in this profile to act more independently.

The Low-Need practice described in the next section, is not typical of this profile in that it is large (more than 4 clinicians) and serves a high volume of patients. However, this atypia on these 2 factors illustrates that combinations of key characteristics and consideration of a practice's counterbalancing strengths are important in determining the intensity of the approach that the facilitator must take.

LOW NEEDS CASE EXAMPLE 1

This is a large, busy practice with 1 full-time physician (the owner of the practice), 1 part-time physician, and 1 nurse practitioner, as well as other staff (eg, nurses, office manager). The lead physician is the key decision maker in the practice but respects the opinions of the other providers and staff (eg, office manager). Therefore, the facilitator worked mainly with the lead physician with main goals and with the other physician to troubleshoot issues that came up. The practice is busy and a bit chaotic, but it is also functional owing to good working relationships among staff members and effective group problem solving. The facilitator witnessed other people making key decisions or taking on leadership roles. For example, despite transitioning to an EMR at the beginning of their intervention phase, the practice was able to achieve most of the program goals fairly quickly, as the part-time physician stepped up to take the lead on changing their EMR templates to include easy ways to document the program's targeted services. The 1 area that this practice did not quickly improve on was lead screening. The facilitator worked with them and educated them on the guidelines, and the practice was able to work through the issues by using the facilitator as a support person, especially when they became busy and overwhelmed with other things (eg, issues that arose related to implementing a new EMR).

LOW-NEEDS CASE EXAMPLE 2

Another large, busy practice that fit into the Low-Needs profile was a large practice with several physicians, a nurse practitioner, and many nurses (including a lead nurse) and medical assistants, as well as a variety of support staff (eg, receptionists and billing staff).

This practice has a lead physician, the owner of the practice, who is very motivated, determined, and focused. Her leadership style is autocratic and effective. However, the practice experienced high staff turnover during the course of the study. The practice has a history of being very involved in the community and is very high-achieving (eg, they take pride in having excellent immunization rates). The lead physician was very enthusiastic about the project and began strategizing and implementing changes immediately on start of the intervention.

The practice made quick changes that were sustained throughout the intervention and follow-up phases of the study. The internal characteristics of the practice, along with the guidance of the facilitator, were responsible for the practice's high success rates. The leadership style and motivation of the key provider were important factors. Also contributing to the practice's success was the engagement of the practice staff, as substantiated by the practice's excellent meeting attendance and willingness to communicate with the facilitator throughout their time in the study. The practice staff members were good problem solvers, using the EMR to their advantage (eg, they were proactive in changing their EMR templates to promote compliance with the study outcome measures).

The facilitator quickly assumed a support role. The practice called on the facilitator for additional supplies and to help troubleshoot fluoride varnish billing issues. The practice was relatively self-sufficient and able to maintain high levels of screening rates with the facilitator operating at a minimal level in the practice (ie, the facilitator was able to scale back audit and feedback from once a week to every other week starting at week 14). The practice members were engaged throughout, and they took advantage of the feedback given by the facilitator (eg, they hung up run charts in the break room).

INTERMEDIATE-NEEDS PROFILE

The CHEC-UPPP team placed practices that received a moderate amount of tailoring to reach CHEC-UPPP goals into the Intermediate-Needs profile. Roughly one-third (9/30) of the practices were placed into this profile. The facilitator eventually went to an every-other-week intervention visit schedule with one-third, and the facilitator took on a support role with only 1 of these practices (11%). Most (67%) had medium-large or large burden of change. Most (89%) were small or medium in size, and most (78%) were not high volume. Only 4 (44%) had a strong physician leader, but most (67%) had a champion. Some (56%) had neither a democratic process nor a strong leader, suggesting that slightly more than half of these practices did not have a clear decision-making process. Like those in profile A, these practices tended to be independent, engaged, and organized. Once a plan for change was made, the facilitator often had to give more frequent reminders, additional tools, or alternative suggestions for how to implement changes. Based on the characteristics of practices fitting this profile, the facilitator could expect to be able to manage communications with the practice fairly easily, having confidence that there would be little confusion among practice members and that members would usually understand and deliver 1 clear message to one another. Education of staff may have been required, and providers may not have been as enthusiastic or aligned with some of the program goals as those in the Low-Needs profile, or they may have experienced some other barriers. Therefore, the facilitator may have had to nudge practices toward a decision while helping them to prioritize changes.

INTERMEDIATE-NEEDS PROFILE CASE EXAMPLE

An example of a practice that fit into Intermediate-Needs profile was a medium-size, moderately busy practice with 1 full-time and 2 part-time physicians, 3 medical assistants, a receptionist, and an office manager. Each physician makes most decisions individually, but some decisions are made as a group or are influenced by the office manager. The practice is very motivated and community-oriented. Providers have close bonds with patients and know their families well. Providers are especially interested in childhood obesity and asked for many resources on the subject throughout their time in the study. This site required quite a bit of education and persuasion, as there were a couple of misunderstandings and disagreements with the recommendations behind the study goals. For example, one of the providers questioned the validity of using BMI to estimate a patient's adiposity. In response to this, the facilitator requested for the project principal investigator, a pediatric endocrinologist, to contact this provider to talk through this issue and answer specific questions. The providers also had some concerns about the safety of fluoride varnish at the beginning of the program, which the study team addressed by providing an ingredient list of fluoride varnish and by obtaining a statement about the safety and efficacy of the product from the study's pediatric dentist.

After addressing the practice's concerns regarding BMI and fluoride varnish, the practice quickly achieved program goals related to obesity detection and management and dental decay prevention. The facilitator was able to assume a support role with this practice with the exception of the targeted service of lead screening. The practice physicians were not in agreement with the lead screening recommendations, specifically that some children are required to be screened because they reside in a high-risk zip code. The practice physicians felt that a great number of their patients who reside in

high-risk zip codes are not actually at high risk for lead exposure because the live in newer neighborhoods within the zip codes. The facilitator took great care to convey a message of understanding to the physicians (ie, letting them know that she trusted their clinical judgments and that she trusted that they knew their patients best), while attempting to motivate them to comply with the recommendations (which were also a state law) to achieve success in the study. After several weeks of intervention, 2 of 3 practice physicians agreed to comply with this recommendation as a way to achieve success with the study. The office manager was an ally to the facilitator in providing extra encouragement and reminders to the physicians. Eventually, the office manager was able to convince the third physician to comply with the recommendation by explaining that lead screening was going to be part of meaningful use in the near future, so this is something that they will continue to be evaluated on. By listening and understanding the concerns of the providers, providing education, and becoming an ally with the office manager, the facilitator was able to guide this practice to success.

HIGH-NEEDS PROFILE

The CHEC-UPPP team placed practices requiring a high intensity of tailoring to reach CHEC-UPPP goals into the High-Needs profile. Roughly one-third (11/30) of the practices were placed into this profile. The facilitator maintained the weekly intervention schedule with the exception of 1 (9%) practice and took on more than just a support role with all of the practices. Most (64%) had a medium-large or large burden of change, most (64%) were medium-large or large, and most (73%) were high volume. None of these practices had a strong physician leader, and most (73%) also did not have a democratic process, suggesting that most did not have a clear, effective decision-making process. However, most (73%) did have a champion, which made it possible for the facilitator to communicate with and disseminate information (eg, feedback) to the practice.

Once a plan for change was made, the facilitator often had to give more frequent reminders or give alternative suggestions for how to implement changes. While their dedication to providing excellent health care for their patients was always apparent, practices in this group may have faced internal practice organizational challenges or experienced significant barriers that made change difficult. Providers may not have been as enthusiastic or in alignment with some of the program goals or may have felt that the program goals were not a priority, and education of staff and/or providers and giving continual reminders in combination with negotiation or persuasion may have been needed. Additional feedback (eg, provider-specific feedback or feedback anonymously comparing their practice site with others in the study) may have been given to increase motivation to change. Therefore, as with practices in the Intermediate-Needs profile, the facilitator may have had to nudge practices toward a decision while helping them to prioritize changes.

Because of the size and other practice characteristics, the facilitator could expect there to be less clear communication among practice staff. Therefore, communications with these practices tended to be more difficult for the facilitator to manage, and the facilitator took steps to minimize any potential confusion. Those without an effective decision-making process or a champion created the need for an even more intense tailoring process because time and effort was needed to partner with each provider in the practice to effectively assist them in making changes for their practice to meet goals as a whole. This meant the facilitator had to be aware of each provider's schedule, patiently wait to catch each one between examination visits without being burdensome, or communicate with each in alternative ways (eg, by leaving a note for them before leaving their office or by sending them an e-mail message with important communications on her return to the office). The facilitator made it clear that she respected their time by giving short, concise messages and by suggesting changes that would help to streamline their processes, save time, and make documentation quick and easy. The facilitator carefully balanced the practice's needs with the study's needs by giving these practices leeway in making changes at their own pace while keeping study administrators informed of their progress and advocating for accepting slower rates of change.

In general, practices meeting the High-Needs profile tended to be less independent, engaged, and organized than practices in the other profiles, and therefore required the greatest facilitation intensity. Because disengagement did not necessarily indicate disinterest in the project as a whole and because these practices tended to be less independent and organized (eg, may have taken more time to initiate and maintain changes, may have lacked a protocol for ordering, replacing, and storing tools), many of the practices fitting into this profile tended to be more opportunistic, using study tools to the utmost and taking advantage of everything the study and the research team had to offer. For the facilitator, this sometimes meant going above and beyond study protocol for distribution of resources and tools and being patient while the practice completed an extensive trail-and-error process.

HIGH-NEEDS PROFILE CASE EXAMPLE

An example of a practice that was placed into the High-Needs profile was a large, busy practice with roughly 10

physicians, an office manager, several medical assistants and other support staff (eg, receptionists and other administrative staff). This practice is very organized and businesslike. Although this practice has a lead physician, it also has a democratic decision-making process. The physicians meet 1 time per month at an off-site meeting location. The physicians and office staff at this practice were among the most welcoming and engaged of the sites in our program. They were very open to feedback and suggestions, and the physicians were approachable. They were very interested in the tools (eg, patient handouts, BMI wheels) that the facilitator gave them, and they used a lot of them. They also requested tools for their second site, which did not participate in CHEC-UPPP because it did not meet the inclusion criteria for the study. The process of keeping both sites supplied with many tools was very time-intensive for the study staff, but the practice was very appreciative and this helped to keep the enrolled practice engaged.

Because of their enthusiasm for the project, it came as a surprise to the CHEC-UPPP team when the practice did not make improvements in the first month, despite weekly intervention visits by the facilitator. Their shared decision-making process, although effective, caused a slowdown in the change process. Another unforeseen barrier was that the practice was anticipating a switch from using paper records to using a new EMR at the beginning of their intervention. The facilitator, knowing that sometimes EMR implementation can be delayed, suggested that the practice allow the CHEC-UPPP team to make revisions to the practice's paper well-visit templates to speed up the practice's progress with meeting the program goals. The practice was hesitant to have the team do this and stated that they preferred to write in their documentation for targeted services delivered for each well-child visit even though most providers were not complying with doing this.

After weeks of encouragement by the facilitator and a meeting between one of the study physicians and the lead practice physician, which included giving the practice peer-comparison feedback, the practice admitted that they were purposely delaying change and that they planned on implementing the program goals once the new EMR was put in place. As a result of this meeting, the lead physician agreed that the practice would immediately begin to work on the program goals, and shortly after this meeting, the practice learned that the EMR implementation was being delayed. This led to the practice finally agreeing to allow the facilitator to change their well-visit forms to provide spaces for documentation of the program's targeted services. The CHEC-UPPP team retyped the office's well-visit forms, as no electronic versions existed, for each age-specific form (13 templates total). In addition, to lower the burden on the practice and to ensure compliance, the team kept the enrolled practice and their noneligible second site stocked by printing out ample copies of each template, which the facilitator delivered to them throughout their remaining time in the intervention and follow-up phase. This added to the intensity of efforts undertaken with this practice by the study team.

Shortly after these changes were made, the practice's rates improved dramatically and remained high throughout the remainder of the study. This is an example of a practice in which intensive tailoring and persistence, using a variety of methods, led to the practice's eventual success in the program. The CHEC-UPPP team spent a great deal of time with the practice (eg, giving reminders and audit and feedback approaches) as well as working on fulfilling requests for the practice behind the scenes. Because of the practice's openness to feedback and the approachability of the physicians, the facilitator was able to discuss their slower rates of improvement, to uncover the reason for their delay (ie, anticipation of their new EMR), and make a plan for change that the practice was comfortable with.

TABLE A1 Data Sources Used for Comparative Case Study Data Analysis

Source	Recorded During	Item
Facilitator	Preintervention baseline visits	Observations including communication styles among staff; emotional climate of office
		Staff interactions with patients
		Atmosphere of waiting room, break room, work areas
		Availability of patient educational handouts
		General practice work flow
		Interview of key practice staff members to learn practice set-up
		Staff composition and roles
		Appointment schedules
		Procedures followed preintervention for delivery of the targeted services
	Intervention visits	Tools given to practice
Intervention team		Barriers identified
		Suggested process changes
		Evaluation of goals met each week (run charts)
		Interactions experienced one-on-one with providers and staff
Study coordinator	Meetings with practice	Notes from interactions
	Phone calls/e-mails	Communication logs
Intervention team	Weekly study meetings	Minutes that included suggestions for tailoring made by the study administrators
Study data managers	Chart review	Progress notes from 2 d spent bimonthly in practice completing chart reviews
All practice staff	Pre- and postintervention	Attitude and knowledge questionnaires
Providers	Postintervention	Satisfaction survey
Quantitative data	Preintervention/baseline and intervention phases	Weekly run-charts and outcome measures from bimonthly chart reviews

TABLE A2 Delivery of Targeted Services During Intervention: Adjusted Results Comparing Practices With Different Needs for Facilitation Intensity

% Performance (95% CI)	Baseline	2 mo	4 mo	6 mo	Sustainability, 2 mo
Obesity screening and counseling					
Low-intensity practices	8.5	81.5	91.9	93.5	93.3
Medium-intensity practices	5.5	63.6	85.0	87.4	86.4
High-intensity practices	2.5	54.9	75.3	79.5	79.1
Lead screening					
Low-intensity practices	81.1	89.9	93.6	95.0	96.0
Medium-intensity practices	78.1	85.1	91.1	94.2	96.0
High-intensity practices	47.8	65.7	75.8	80.0	82.9
Fluoride varnish application					
Low-intensity practices	1.5	76.6	94.0	88.2	91.4
Medium-intensity practices	1.0	64.1	88.5	79.7	82.3
High-intensity practices	<1.0	48.0	81.8	67.6	75.0

Print Form

CONSORT CHECKLIST

Table. CONSORT 2010 Checklist of Information to Include When Reporting a Randomized Trial[a]

Section and Topic	Item No.	Checklist Item	Reported on Page No.
Title and abstract			
	1a	Identification as a randomized trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	5-6
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A
Participants	4a	Eligibility criteria for participants	6, 9-10
	4b	Settings and locations where the data were collected	6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	9-10,
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	10-11
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomization Sequence generation	8a	Method used to generate the random allocation sequence	7
	8b	Type of randomization; details of any restriction (such as blocking and block size)	7
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	7
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	7
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/A
	11b	If relevant, description of the similarity of interventions	N/A
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	13,14
	13b	For each group, losses and exclusions after randomization, together with reasons	13,14
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6,7,10
	14b	Why the trial ended or was stopped	N/A
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13-14, T
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13-18, T
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	13-18, T
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Apper
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A
Comment			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21-22
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	21-22
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18-22
Other information			
Registration	23	Registration number and name of trial registry	1
Protocol	24	Where the full trial protocol can be accessed, if available	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	1

[a]We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomized trials, noninferiority and equivalence trials, nonpharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see http://www.consort-statement.org.