



Costs of Preparing to Implement a Family-Based Intervention to Prevent Pediatric Obesity in Primary Care: a Budget Impact Analysis

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Abstract

The costs associated with implementing evidence-based programs for pediatric obesity contribute to a lack of widespread adoption. This study examined the costs of preparing to implement the Family Check-Up 4 Health (FCU4Health), a family-centered behavioral program for the prevention of pediatric obesity and excess weight gain in primary care. Budget impact analysis was used to estimate the cost of preparing to implement FCU4Health (i.e., the activities to prepare for, but prior to, offering the service to families). Electronic cost capture methods were used to prospectively track personnel time associated with implementation preparation activities. We also estimated the cost of replicating these preparatory activities to inform future decisions to adopt the program and associated budgetary planning. The total cost of FCU4Health implementation preparation in three clinics and developing delivery materials and infrastructure was \$181,768, for an average of \$60,589 per clinic. Over two thirds of the total cost were personnel related, the largest of which was associated with the time spent developing automated fidelity coding for monitoring (20%), developing and tailoring clinical materials (16%), and training FCU4Health coordinators (15%). Due to these development costs associated with an initial implementation, that we anticipate would not be repeated in full, we estimated the cost to prepare FCU4Health for implementation in a future initiative will range from \$15,195 to \$17,912 per clinic. This study is a critical step towards equipping decision-makers with comprehensive short-term information about expected costs that are incurred immediately after choosing to adopt an evidence-based program.

Keywords Budget impact analysis · Family Check-Up 4 Health · Implementation cost · Health economics · Primary care

Introduction

One third of all 6- to 11-year-old children in the USA meet the criteria for overweight (body mass index [BMI] 85th to 94th percentile for age and gender) and 17.2% for obesity (BMI \geq 95th percentile) (Ogden et al. 2016). Prevention of obesity in childhood must focus first and foremost on maintaining a healthy weight and secondarily on preventing excess weight gain for children with an elevated BMI (August et al. 2008; Barlow 2007). The general economic benefits of preventing obesity are well established (Lehnert et al. 2012), but little cost information is available specifically for programs targeting obesity prevention in childhood (Lindsay et al. 2006).

Family-based behavioral interventions for the prevention of obesity in childhood are effective (e.g., Janicke et al. 2014; McGovern et al. 2008; Lehnert et al. 2012) and promoted as best practice by the Academy of Nutrition and Dietetics, the National Academy of Medicine, the American Academy of Pediatrics, the Endocrine Society, and the US Preventive Services Task Force (August et al. 2008; Barlow 2007; Hoelscher et al. 2013; National Research Council and

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Institute of Medicine 2011; Whitlock et al. 2010). However, even though a family-based prevention is highly appealing to healthcare providers and families (Kitzmann and Beech 2011; Rhee 2008), such practices are not yet well integrated within any healthcare delivery system in the USA (Leslie et al. 2016; Whitlock et al. 2010). We are currently testing the implementation of the Family Check-up 4 Health (FCU4Health), a pediatric obesity prevention program that is being implemented in three community settings in Phoenix as part of a randomized effectiveness-implementation hybrid trial for the prevention of excess weight gain.

As part of this effort, we are interested in characterizing the costs of preparing for the implementation of FCU4Health. Several barriers hinder implementation of family-based programs for obesity prevention in real-world healthcare systems (Leslie et al. 2016; National Research Council and Institute of Medicine 2011), and decision-makers often report that implementation costs—those prior to and during ongoing delivery—are a top reason for the lack of widespread adoption (Glasgow and Emmons 2007). Despite this, a review of the research found that less than 10% of published studies reported economic data concerning the implementation (Vale et al. 2007). Thus, we conducted a budget impact analysis (BIA) to assess the expected short-term changes in the expenditures for a healthcare organization or healthcare system after choosing to adopt a new EBP (Sullivan et al. 2014).

We use the term “implementation preparation” to refer to the resources and activities that are required to make the program available (i.e., to prepare a service delivery setting for delivery), prior to actually engaging any patients or families in the program—the second phase of the Exploration, Preparation, Implementation, and Sustainment (EPIS) framework (Aarons et al. 2011). This has also been referred to as the “installation” phase of the program implementation (Metz and Bartley 2012). The implementation process models define this unique period between when an organization chooses to adopt a new EBP and that EBP being available to clients in the organization as the “Preparation” phase (Aarons et al. 2011). Key activities of this phase focus on training staff, identifying communication channels and champions, adapting program materials, specifying staff roles for the delivery of intervention components, and establishing mechanisms for short- and long-term funding for the new EBP, which would include revenue generation for services rendered. Unlike many other prevention programs, obesity prevention services, such as those delivered through FCU4Health, are reimbursable under existing billing codes for behavioral intervention for obesity. As such, it is important for budget holders to understand the up-front costs of adopting the intervention, which are not reimbursable, prior to delivering services. For programs that provide services that are not reimbursable, it might not be necessary to separate up-front costs for installation but it is nonetheless informative to simply understand the amount of

time invested in the stage of implementation that happens before families can enroll—it is significant and can be a significant source of lost resources if implementation ultimately fails before families can be enrolled (Saldana et al. 2014).

Accordingly, the primary objective of this paper is to estimate, using BIA, the costs associated with the implementation preparation of the FCU4Health program in three agencies. First, we provide data concerning the specific costs of preparing to implement FCU4Health within this trial. Second, consistent with best practice in BIA of obtaining input from key stakeholders (Sullivan et al. 2014), we estimate a range of costs needed to replicate the implementation preparation, attempting to account for costs that were limited to this initial implementation of FCU4Health and those that would be required in a future adoption. This estimation analysis also includes site-specific estimates accounting for variation not captured in a total cost estimate for this multi-site trial. We also provide the reader with a range of expected expenditures for each major category of implementation preparation cost. This is an effort to further inform prospective budget planning that considers variability by specific line items. The results of this study provide a timely service to the field regarding a prospective, rigorous accounting of the costs to prepare to implement an EBP. These results are useful for the implementation support teams and for potential adopters as they are an accurate and realistic accounting of the investment needed to get an EBP such as FCU4Health ready for use by families that could benefit.

Method

Our analytic approach and reporting framework follow the guidelines set forth in the Principles of Good Practice for Budget Impact Analysis (Sullivan et al. 2014).

Participants

Participants in this study were individuals involved in preparing to implement the FCU4Health. Staffing of FCU4Health itself involves interviewers who conduct the family health routine assessments (varied in terms of education and job title) and coordinators who deliver the FCU4Health and follow-up support sessions focused on parenting and family management (education is typically a master’s level, independently licensed behavioral health provider). The implementation support team, housed within Arizona State University’s REACH Institute, included the program developers, expert trainers/supervisors, information technology support staff (multiple persons/roles), an implementation coordinator, and a research coordinator.

Additionally, as this trial is the first of the FCU4Health, a formal study aim was finalizing the adaptation of the program

for the new clinical target (i.e., obesity-related health behaviors) and for the integration with the primary care system. We convened a community advisory board specifically to guide adaptation in these areas (Berkel et al., [manuscript under review](#)). It should be noted that the majority of the adaptations to the FCU that led to the FCU4Health program occurred prior to the start of this trial (see Smith et al., [under review](#)). Adaptation in the context of this study focused on minor changes to ensure fit and feasibility in the specific clinics involved in this study.

Intervention Mix

FCU4Health is an adaptation of the Family Check-Up (FCU) program developed by Thomas Dishion (Dishion et al. 2008). The original FCU program demonstrated collateral benefits on obesity in two samples (Smith et al. 2015; Van Ryzin and Nowicka 2013). In early childhood, children at risk for obesity were less likely (Cohen's $d = .79$) to progress to being overweight or obese when they were in the FCU condition compared to services as usual (Smith et al. 2015). Smith et al. (2018) and Smith et al. ([under review](#)) provide descriptions of the FCU4Health program and the process involved in adapting the FCU for obesity prevention in pediatric primary care, most of which occurred prior to the start of the trial reported in this paper. This trial is comparing the delivery of FCU4Health compared to services as usual (Smith et al. 2018). We partnered with three urban primary care agencies serving high rates of low-income, ethnic minority families who are disproportionately affected by obesity. Two of the agencies are part of the nationwide network of Federally Qualified Health Centers, which uses the integrated care model that typifies the medical home (American Academy of Pediatrics 2002). We are leveraging this existing infrastructure to test an integrated/co-located service model within these two agencies. The third agency is using the strategy of referring patients identified in primary care to an external coordinator who delivers the program. In both models, the FCU4Health coordinators are responsible for delivering the program and coordinating care with other support services and resources.

Time Horizon

The implementation preparation phase of FCU4Health occurred over 28 weeks from October 1, 2016, through April 14, 2017, when enrollment of families into the trial began.

Perspective

The BIA perspective is that of the adopting primary care delivery site, also referred to as the budget holder. Specifically, we approached this prospective BIA with the goal of providing decision-makers with salient cost information that can

inform future implementation preparation efforts of FCU4Health in other settings.

Analytic Framework

We derived summary descriptive costs using a cost calculator approach, which has been noted to be the preferred computing framework when analyses are pertinent to the perspective of the budget holder (Sullivan et al. 2014). The cost calculator approach involves the specification of an interactive system capable of generating reports and analyses based on the time estimates and unit costs of various activities. The cost calculator used in this study was project specific and programmed in Microsoft Excel.

Input Data

Costs of Preparing to Implement FCU4Health Input data included labor and non-labor costs associated with installing the intervention (installation is defined as accomplishing the necessary tasks and ensuring that structural supports are in place before the first patient or family is served by the program; Metz and Bartley 2012); these data are reported in Table 1. All costs originated in and are presented in 2016 US dollars. Labor costs were based on time spent installing the intervention, which were accrued by the implementation support team, members of the agencies, and members of the community advisory board. Non-labor costs included equipment and supplies.

Estimated Costs Needed to Replicate Implementation Preparation Because this was the first time FCU4Health was installed, several activities required more time in this trial that would be anticipated for future efforts (e.g., tailoring clinical materials and developing an automated coding system). Thus, we estimated the proportion of time that would be needed to replicate the implementation preparation activities at new clinic sites, as shown in Table 2. Conducting this replication analysis was based on expert feedback from the community advisory board and staff from the delivery sites, from which estimates were derived via expert consensus from project leaders. From these values, we determined the total labor hours and costs associated with such a replication.

Data Sources

Costs associated with the implementation support team hours were generated based on actual 2016 annual salaries. Actual salaries of clinic site members were not directly obtained to reduce burden and maintain rapport with these individuals. Additionally, salary information is presented in aggregate to maintain deidentification. Annual salaries for these individuals were estimated using Arizona-specific salary averages from the Bureau of Labor Statistics' (2016) Occupational

Table 1 Budget impact analysis labor and non-labor input parameters

Variables	Input parameter	Reference
Average salaries		
Implementation support team ($n = 19$)	\$117,768	Actual salaries
Agency members ($n = 30$)	\$96,911	BLS 2016
Community advisory board ($n = 15$)	\$165,231	BLS 2016 & Actual salaries
Hardware		
iPads ($n = 20$) ¹	\$12,113	Purchasing order receipts
Microphones ($n = 20$)	\$2161	
Scales ($n = 10$) ¹	\$31,719	
Stadiometers ($n = 10$)	\$1228	
Software		
Portal	\$1755	
Software license	\$785	
Supplies		
Manuals	\$432	
Printing	\$641	
iPad cases ($n = 23$)	\$300	
Extension cables ($n = 20$)	\$180	
File folders	\$72	
Tripod mount ($n = 2$)	\$171	

¹ The cost of these items included an educational or bulk-order discount

Employment Statistics, based on each individual's position title and degree. Annual salaries for members of the community advisory board were based on actual 2016 annual salaries, if known, or 2016 salary cap levels as directed by the National Institutes of Health, if not known (National Institutes of Health 2015). Annual salaries plus fringe benefits at a standard rate of 28% were used to calculate a per-hour salary amount for each individual. These values were applied to each individual's time spent engaged in the implementation preparation activities, and then aggregated across these activities to derive estimates of the time spent and cost associated with completing each activity. Non-labor costs for equipment and supplies were based on actual amounts spent and were tracked from receipts and payment invoices.

Data Collection

During the implementation preparation phase of FCU4Health, members of the implementation support team documented the number of hours they each spent engaging in clinical, non-research activities related to implementation preparation. Each week during the duration of implementation preparation, the study staff completed an electronically administered survey (i.e., a cost capture template¹) developed for this study to document these efforts. Specifically, individuals reported on their time spent engaged in activities related to the clinical intervention,

¹ The cost capture template is available upon request from the corresponding author.

training to deliver the clinical intervention, preparing materials, preparing for delivery, as well as effort engaged in administrative duties and informatics. Time spent on the implementation preparation activities also were monitored among individuals at the clinic sites and members of the community advisory board who were not also members of the implementation support team. Specifically, the research team documented the number of hours individuals at the clinic sites spent participating in meetings and trainings related to the implementation preparation of FCU4Health.

Analyses

We used descriptive analyses to estimate the total number of labor hours and total labor and non-labor costs of implementation preparation. Additionally, exploratory descriptive analyses were conducted to estimate the cost of future efforts to replicate implementation preparation of FCU4Health. Given that these values are estimates and were not prospectively measured, we tested the sensitivity of the replication estimates by varying the values across a reasonable range for each activity. Both the estimates and the associated ranges for labor costs were based on the implementation plan to be used in future implementations and our experience in this study. The co-principal investigators of the study (the third and fourth authors) met and a consensus was reached on these estimated value and range for each item included in the budget impact analysis. For example, some activities would not need to be included in future efforts to the same extent as they were in this trial, such as developing materials, meetings

Table 2 Assumptions of estimates for replication input parameters for sensitivity testing

Labor costs	Estimate	Range
Developing or tailoring clinical materials	25%	15–30%
Meetings regarding clinical activities	50%	40–60%
Supervising delivery to pilot families	100%	100–200%
Developing or tailoring training materials	25%	20–35%
Meetings regarding training activities	25%	0–25%
Participating in training	90%	65–90%
Reviewing new or revised materials	25%	10–25%
Meetings to develop a delivery plan	50%	25–100%
Developing infrastructure to support delivery	30%	15–55%
Communicating by email	50%	40–60%
Hiring clinical staff	100%	95–105%
Automated coding development for fidelity ratings	0%	0–0%
Non-labor costs	Needed for replication?	
iPads (<i>n</i> = 20)	Required ¹	
Microphones (<i>n</i> = 20)	Optional ¹	
Scales (<i>n</i> = 10)	Required ¹	
Stadiometers (<i>n</i> = 10)	Required ¹	
Portal	Required	
Software license	Optional	
Manuals	Required	
Printing	Required	
iPad cases (<i>n</i> = 23)	Optional	
Extension cables (<i>n</i> = 20)	Optional	
File folders	Required	
Tripod mount (<i>n</i> = 2)	Optional	

¹ Could be substituted for alternative (i.e., less or more expensive) models

to plan the agenda and specific content of trainings, and developing infrastructure to support delivery. These activities are each estimated at 25% of the cost encumbered in the trial reported on in this study with relatively tight ranges (e.g., 15–35%), as they will still be tailored to the implementing site in the future, but will require far less time compared to the development that was completed in this initial implementation effort. Conversely, all FCU4Health coordinators will still need to be supervised early on after initial training. In this study, we provided what we consider to be the minimum amount; thus, the estimate is 100%, and the range is only allowed to go up (to 200%). Last, given that the costs were aggregated across three sites, we also separated the replication figures by the site to establish site-relevant estimates for future implementation preparation activities.

Results

Costs of Preparing to Implement FCU4Health

Sixty-four individuals participated in at least one implementation preparation activity: 19 (30%) were members of the

implementation support team, 15 (23%) were members of the community advisory board, and 30 (47%) were staff at the clinic sites (seven individuals among the clinic site staff also served on the community advisory board).

Total labor hours and costs associated with the implementation preparation across the three clinic sites are presented in Table 3. Total labor hours summed to 3011 h, and total labor costs summed to \$130,210 across the three clinics. The majority of labor hours were accrued by the members of the implementation support team (86%), followed by individuals at the clinic sites (13%) and the community advisory board (1%). Similarly, labor costs were primarily attributable to the implementation support team (87%), followed by individuals at the clinic sites (11%), and a community advisory board (2%). Developing and tailoring clinical materials was the most labor-intensive implementation preparation activity (22% of all hours), followed by time spent in FCU4Health training (17%), and time spent developing and tailoring training materials (13%). Automated coding development for fidelity monitoring of FCU4Health was the largest source of implementation preparation labor costs (\$25,750; 20%), followed by

developing and tailoring clinical materials (\$20,615; 16%), and time spent in FCU4Health training (\$19,193; 15%).

Non-labor costs are presented in Table 1 and summed to \$51,558. The vast majority of non-labor costs were associated with electronic scales used to weigh children to obtain BMI and body composition (\$31,719; 62%), followed by iPads used for the administration to families of the family health routines assessment, the first step of the FCU4Health program, and video recording of sessions (\$12,113; 23%). Thus, the total cost, aggregated across the three sites of the implementation preparation across three clinic sites was \$181,768. If divided equally, the average cost per site was \$60,589. However, as our estimates for replication in the next section indicate, there is some variability between sites that render an equal division artificial.

Estimated Costs Needed to Replicate Implementation Preparation

We estimated the proportion of effort that would be required to replicate FCU4Health implementation preparation at additional sites (see Table 2). Based on the estimated percentage of the costs accrued in this trial needed for replication, the total number of labor hours required in three new clinic sites would be 1231 h, with an associated labor cost of \$49,424 (Table 4) (and approximately \$16,475 per site if divided equally across sites). However, the cost per clinic will depend upon the number of sites due to the efficiencies associated with economies of scale.

Figure 1 provides a visual representation of the results of sensitivity testing for each labor activity replication estimate. As shown in the figure, the activity with the greatest variation for affecting implementation preparation costs is participating in meetings to establish a delivery plan, as the estimates range from increasing the actual costs observed by \$7544 to reducing them by \$3772 in a replication. Reducing the time spent participating in training could save the greatest amount (\$4798). Further, as shown in Table 4, replication estimates can vary for certain implementation preparation activities based on the type of primary care model in which the program will be implemented. For example, implementing the FCU4Health using a coordinated care model could require hiring clinical staff to meet increased demand for the service (i.e., 100% of the replication estimate attributed to this delivery model).² On the other hand, hiring clinical staff would not be necessary for the implementation using an integrated/co-located care approach because existing staff are typically

² In the current study, FCU4Health coordinators are employed by the ASU REACH Institute, who assumed the cost of hiring and training. In future replications, ASU could again assume these costs, but a different structure could also be implemented in which multiple adopting clinics contribute to the hiring of a FCU4Health team that serves a larger community in which the costs could be shared across sites.

trained to deliver the program. Given that the study sites delivered the program using these two different implementation strategies, the estimated replication amounts for a single site differ slightly with a range between \$15,195 and \$17,912.

We conducted a similar sensitivity analysis for non-labor costs. Table 2 indicates which equipment or supplies are required, are optional, or could be substituted for an alternative, less expensive version in a future implementation. For example, state-of-the-art medical-grade scales were purchased for this study, as accuracy and additional body composition measurements were needed as part of the research trial (in addition to supporting the clinical delivery of the program). However, for future implementation of FCU4Health in clinical practice, any scale that reliably measures weight would be sufficient, and most clinics could use their existing scales.

Discussion

Given that cost is often cited as the primary barrier to adoption and sustainability (Glasgow and Emmons 2007; Ritzwoller et al. 2009; Leslie et al. 2016; Raghavan 2017; Vale et al. 2007). We conducted a prospective BIA of the costs to prepare to implement the FCU4Health in primary care. Our study results indicate that the total cost of installing FCU4Health was \$181,768, or approximately \$60,000 per site for each of the three study sites. Nearly three quarters of the implementation preparation costs were labor costs, with training development and delivery, clinical material development, and automated coding development for fidelity monitoring of FCU4Health representing the largest labor costs. Most of the non-labor costs associated with the implementation preparation of FCU4Health were related to the electronic scales used to obtain BMI and body composition and iPads used to administer surveys and video record FCU4Health sessions. In exploratory analyses, we estimated that the cost of replicating FCU4Health in subsequent primary care settings would be between \$15,000 and \$18,000 per site or less than 1/3 of the costs incurred in the current study. Variation in the number of meetings about the FCU4Health delivery plan and the number of individuals participating in training would likely have the largest impact on the cost of replicating FCU4Health in other primary care settings. This reduced estimate is primarily due to the distinctness of this study being the first to implement FCU4Health, which requires more time for many activities than could be reasonably expected to occur in the future given that much of the development work was completed in this trial. Moreover, material costs were higher due to this trial being a funded research project that required precision measurement and high-quality audio and video-recording equipment

Although the costs of installing FCU4Health may appear high, it is important to point out that most behavioral

Table 3 Labor hours and costs for implementation preparation across three sites

	<i>N</i> ¹	Total hours	Proportion of total hours	Proportion of hours by implementation support team	Total costs	Proportion of costs by implementation support team
Clinical						
Developing or tailoring clinical materials	9	662	22%	100%	\$20,615	16%
Meetings regarding clinical activities	12	141	5%	92%	\$5694	4%
Supervising delivery to pilot families	1	2	< 0.1%	100%	\$106	< 0.1%
Training						
Developing or tailoring training materials	10	391	13%	90%	\$14,694	11%
Meetings regarding training activities	11	114	4%	91%	\$5142	4%
Participating in training	23	520	17%	48%	\$19,193	15%
Materials						
Reviewing new or revised materials	11	107	4%	100%	\$4065	3%
Intervention delivery						
Meetings to develop a delivery plan	49	281	9%	18%	\$15,088	12%
Developing infrastructure to support delivery	7	81	3%	100%	\$3538	3%
Administrative						
Communicating by email	15	328	11%	73%	\$13,726	11%
Hiring clinical staff	6	44	1%	100%	\$2599	2%
Informatics						
Automated coding development for fidelity ratings	6	340	11%	100%	\$25,750	20%
Total	64	3011	–	86% ²	\$130,210	87% ²

¹ Individuals can be counted in multiple categories

² Thirteen percent of hours and 11% of costs were accrued by the clinic sites, and 1% of hours and 2% of costs were accrued by the community advisory board

interventions have significant start-up costs (Saldana et al. 2014). Our study is the first of FCU4Health, which required the development, review, and tailoring of training and clinical materials for multiple sites as well as the development of infrastructure to support FCU4Health delivery. Because many of the training and clinical materials developed for this project can be reused by other primary care clinics that wish to implement FCU4Health, the costs of replicating FCU4Health in new delivery settings will be significantly lower (and presumably more attractive to decision-makers). Although these estimated costs for replication are not perfect, they are critically important for potential adopters as they more accurately reflect what will be incurred than the actual figures reported for this particular trial—the first of FCU4Health.

An advantage of the detailed, prospective, cost-capture-based approach of BIA when estimating implementation preparation costs is that information is associated with particular elements. For example, our analysis shows that the time spent by the implementation support team, individuals at the clinic sites, and the community advisory board communicating by email represented about 10% of all labor costs. Although we estimated that FCU4Health replication efforts will only require about half of those costs associated with email communication, future adopters of FCU4Health may want to consider

whether there are more cost-effective ways to use technology to exchange information about the implementation preparation (e.g., using SharePoint—software for helping collaborative teams stay organized and share information).

The overarching strength of this study is the prospective estimation of the costs to install a preventive intervention. Some readers may wonder how the estimates and totals resulting from this study differ from what could be ascertained from other sources, such as by contacting the FCU4Health purveyors to establish a contract for training and implementation support. In short, a prospective BIA provides a more accurate and comprehensive estimate of true costs incurred by capturing actual time and costs for staff time on specific activities. In a contract for implementation support, for example, these costs would be rolled into broader line items, such as “training” where a total cost to the adopter is provided but the individual costs within (time the trainer travels and conducts the training and the time spent on tailoring training materials) are not broken down. Our results also captured costs that may not be part of a contract for implementation, such as emails (time of implementation support team and clinic staff) and the cost of having clinic staff attend meetings and training sessions. Our results show that this is a non-ignorable amount of money and can vary quite widely depending on the readiness

of the site to implement. These costs should be considered as they are real costs incurred as a result of a decision to change practices within the service system.

Limitations

Despite the strengths, study limitations and some caveats should be acknowledged. First, because individuals at the clinic sites were not asked to complete the weekly cost-capture survey due to the perceived burden, we instead estimated their time on the project based on attendance at trainings and planning meetings using rosters captured on meeting log notes. As such, their salaries are estimated and some costs may not have been captured. For example, time spent communicating among the site staff and with the implementation support team about FCU4Health implementation and training could have been missed. However, the majority of labor costs were accrued by the implementation support team itself, whose salary estimates were known and whose time spent engaged in the implementation preparation activities was prospectively tracked. This adds to our confidence in the accuracy of the overall figures reported.

Second, cumulative (i.e., shared) versus site-specific costs make estimating replication costs more challenging. The

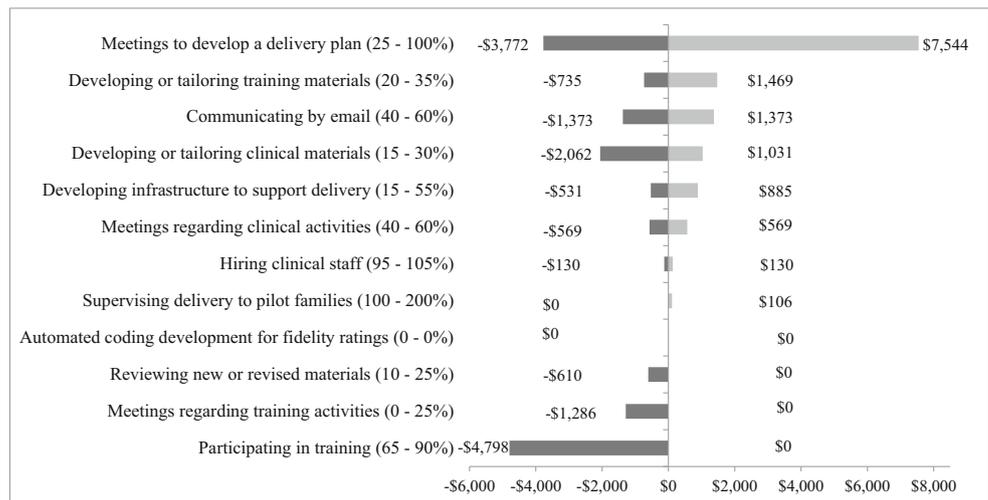
majority of the costs in this study were cumulative across three study sites, as several implementation preparation activities were relevant regardless of where the program was going to be implemented (e.g., tailoring clinical materials). Thus, it is difficult to assess with certainty the true cost per clinic site as these shared costs were simply divided equally among them. We did, however, attempt to estimate the site-specific costs based on our experience working with them. This information appears in Table 4. As can be seen in some line items, there is a variation among the sites. We included this estimation despite its imperfection to illustrate our experience of variation that occurred not only between the two implementation strategies being evaluated in the trial (coordinated care and integrated/co-located care models) but also between the two sites that were implementing the latter strategy. Although these sites share certain characteristics, we experienced significant variation between them in terms of operations, structures, and staffing that could be devoted the FCU4Health program, as well as the number of potential families that could be served due to differences in size. It is important to acknowledge this for future decision-makers as costs can vary widely as a result. Due to the imperfect estimation, we provide ranges for all totals. Validation of these estimates could occur by replicating these cost capture methods in subsequent FCU4Health implementation.

Table 4 Estimated replication costs of labor activities by individual sites

Labor activities	Total for three sites	Shared across sites (yes/no)	Coordinated care model		Integrated/co-located care model			
			Site A	%*	Site B	Site C	%*	%*
Clinical			\$	%*	\$	%*	\$	%*
Developing or tailoring clinical materials	\$5154	Yes	\$1718	33%	\$1718	33%	\$1718	33%
Meetings regarding clinical activities	\$2847	No	\$569	20%	\$1139	40%	\$1139	40%
Supervising delivery to pilot families	\$106	No	\$42	40%	\$27	25%	\$37	35%
Training								
Developing or tailoring training materials	\$3673	Yes	\$1224	33%	\$1224	33%	\$1224	33%
Meetings regarding training activities	\$1285	Yes	\$428	33%	\$428	33%	\$428	33%
Participating in training	\$17,274	No	\$4318	25%	\$6046	35%	\$6909	40%
Materials								
Reviewing new or revised clinical or training materials	\$1016	Yes	\$339	33%	\$339	33%	\$339	33%
Intervention delivery								
Meetings to develop a delivery plan	\$7544	No	\$1886	25%	\$2640	35%	\$3018	40%
Developing infrastructure to support delivery	\$1061	Yes	\$354	33%	\$354	33%	\$354	33%
Administrative								
Communicating by email	\$6863	No	\$1716	25%	\$2402	35%	\$2745	40%
Hiring clinical staff	\$2599	No	\$2599	100%	\$0	0%	\$0	0%
Informatics								
Automated coding development for fidelity monitoring	\$0	Yes	\$0	0%	\$0	0%	\$0	0%
Total replication costs	\$49,424	–		\$15,195		\$16,317		\$17,912

*Estimation of the percent of total costs attributable to each site

Fig. 1 Sensitivity testing around replication estimates for each FCU4H implementation preparation labor activity. Note: Each row shows the changes in cost, across the range of replication estimate values, from the total replication estimate.



Note. Each row shows the changes in cost, across the range of replication estimate values, from the total replication estimate.

A third limitation is that the estimate of the cost associated with hiring clinical staff for the coordinated care version does not include time or other costs (e.g., background checks) that would be incurred by the organization's human resources department. The estimate includes preparing and posting job announcements, reviewing applications, and interviewing candidates. Thus, the total cost to the organization to add staff specifically for FCU4Health will be higher when all costs are considered.

Conclusions

Our implementation preparation cost analysis is a critical step towards equipping decision-makers with comprehensive short-term information about the expected costs associated with adopting EBPs like FCU4Health. Due to the scarcity of such data in the literature, the generalizability of our findings and the applicability and accuracy of our methods for obtaining such data are difficult to assess. As noted by an expert panel of preventionists (Crowley et al. 2014), the field needs to conduct and publish prospective cost analyses across the entire implementation spectrum from preparation to implementation to sustainment. The relevance of these BIAs could be made even more informative if tied to an implementation framework such as EPIS, where specific implementation activities could be estimated within the phases. For preventive interventions in particular and EBPs in general, to be adopted and sustained, economic data needs to be available for budgetary planning across the implementation spectrum in addition to establishing a favorable cost-benefit ratio of the resulting effects of the program for children and families, as well as the implementing clinics.

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Compliance with Ethical Standards

Conflict of Interest JDS and CB co-developed the Family Check-Up 4 Health program with Thomas Dishion, the developer of the original Family Check-Up.

Ethical Approval This trial was designed in accordance with the basic ethical principles of autonomy, beneficence, justice, and non-maleficence and will be conducted in accordance with the rules of Good Clinical Practice outlined in the most recent Declaration of Helsinki. Data confidentiality and anonymity will be ensured. The project was approved by the Institutional Review Boards of Arizona State University (Protocol 00004530) and the Phoenix Children's Hospital (Protocol 17-001). All other institutions participating in this research provided signed reliance agreements ceding to the Institutional Review Board of Arizona State University. Any important protocol modification will be communicated to the Institutional Review Board of Arizona State University and updated in Clinicaltrials.gov.

Informed Consent Informed consent was not required for this aspect of the study as the data sources are administrative.

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