

Development and Beta- Testing of the CONFIDENCE Intervention to Increase Pediatric COVID-19 Vaccination

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ABSTRACT

Introduction: Innovative strategies are needed to improve pediatric COVID-19 vaccination rates. We describe the process for developing a clinic-based intervention, CONFIDENCE, to improve

pediatric COVID-19 vaccine uptake and present results of our beta-test for feasibility and acceptability.

Method: CONFIDENCE included communication training with providers, a poster campaign, and parent-facing educational materials. We assessed feasibility and acceptability through interviews and

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measured preliminary vaccine intention outcomes with a pre-post parent survey. Interviews were analyzed using rapid qualitative methods. We generated descriptive statistics for variables on the parent survey and used Fisher's exact test to assess pre-post differences.

Results: Participating providers ($n = 4$) reported high levels of feasibility and acceptability. We observed positive trends in parents' ($n = 69$) reports of discussing vaccination with their provider and the parental decision to accept COVID-19 vaccination.

Discussion: Our next steps will be to use more rigorous methods to establish the efficacy and effectiveness of the CONFIDENCE intervention. *J Pediatr Health Care.* (2022) XX, 1–9

KEY WORDS

COVID-19 vaccination, pediatrics, intervention development, vaccine hesitancy

INTRODUCTION

Despite COVID-19 vaccines being available to adolescents aged 12–17 years since May 2021 and to children aged 5–11 years since November 2021, uptake of the vaccine series in this age group is suboptimal. As of early September, 31% of children aged 5–11 years and 61% of adolescents aged 12–17 years have completed the two-dose series, and only 14% of children aged 5–11 years and 29% of adolescents aged 12–17 years have received a booster ([Centers for Disease Control and Prevention, 2022](#)). Vaccine hesitancy among parents is a primary factor driving these low rates of uptake ([Alferi et al., 2021](#); [Rane et al., 2022](#); [Scherer et al., 2021](#)). Parents report safety concerns, fears about side effects, skepticism about the vaccine development and approval processes ([Szilagyi et al., 2021](#)), and the widespread perceptions that COVID-19 infection poses minimal risk to children and so the vaccine is unnecessary ([Ruggiero et al., 2021](#)). Although combating vaccine hesitancy will require collaboration across medical professionals, public health, and community organizations, research suggests that pediatricians will be the key messengers for parents. Parents have reported very high levels of trust in their child's pediatrician for information about the COVID-19 vaccine ([Alferi et al., 2021](#); [Purvis et al., 2021](#); [Scherer et al., 2021](#); [Szilagyi et al., 2021](#)), and many have reported a strong preference for their children to be vaccinated at their pediatrician's office ([Goulding et al., 2022](#); [Scherer et al., 2021](#)). Providers serving pediatric patients have echoed these sentiments, reporting that parents have expressed preferences for being able to bring their child to their primary care provider for the vaccine and wanting to hear from their pediatricians about vaccine information ([Ryan et al., 2022](#)).

As the pandemic continues, vaccinating children and adolescents remains a priority to enable them to safely return to social activities and to avoid potentially serious health complications related to COVID-19 infection ([Barrett et al., 2022](#); [Delahoy et al., 2021](#); [Molteni et al., 2021](#); [Zimmermann et al., 2022](#)). Given that vaccine hesitancy has been a growing problem ([He et al., 2022](#)), and we already have strategies to address this hesitancy ([Jarrett et al., 2015](#)), the

goal should be to draw from and adapt these strategies and evidence-based interventions that have been successful in addressing hesitancy around other vaccines ([Ryan et al., 2022](#)). Two emergent themes relevant to addressing COVID-19 vaccination are the critical role of the provider in parental communication ([Ellingson et al., 2022](#); [Gilkey et al., 2016](#)) and the success of multicomponent interventions ([Jarrett et al., 2015](#)). Thus, to increase parental CONFIDENCE in COVID-19 vaccination and increase pediatric vaccination rates, these strategies and interventions need to be adapted for relevance to the unique and urgent context that we are currently experiencing.

Informed by rapid qualitative research conducted by our team and adaptation of evidence-based strategies developed for other vaccines, our team developed and implemented a multicomponent practice-based intervention, CONFIDENCE: Clinicians for Effective COVID-19 Vaccine Conversations for Youth and Adolescents, to support health care providers in having conversations with vaccine-hesitant and resistant parents. The purpose of this paper is to describe the development process and results of the beta-test of the CONFIDENCE intervention.

METHODS

Intervention Development Process

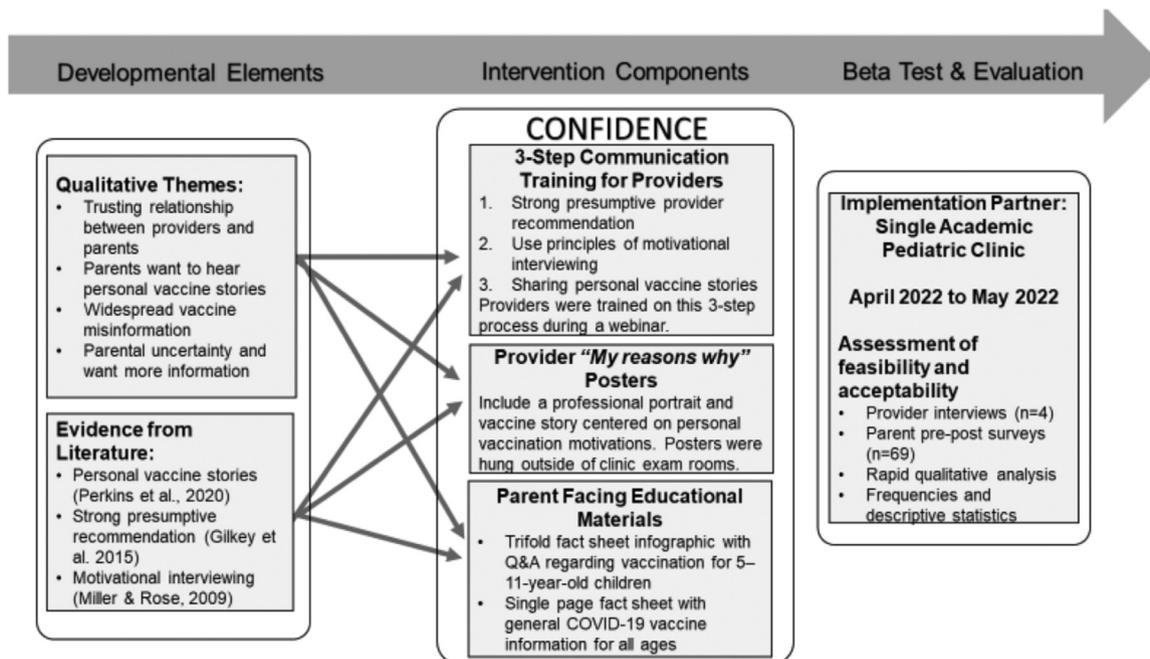
The CONFIDENCE intervention development drew from formative qualitative research with pediatricians and parents and review and adaptation of existing evidenced-based interventions in response to themes identified in the formative work.

Provider interviews and family focus groups

We conducted 16 semistructured interviews with pediatric and family medicine providers practicing in Central and Western Massachusetts ([Ryan et al., 2022](#)). The purpose of these interviews was to explore the perspectives of these providers and their efforts to vaccinate youth against COVID-19. We also held 10 focus groups with 78 parents from Worcester, MA ([Goulding et al., 2022](#)). Seven of these focus groups included parents/guardians of children aged 5–11 years and three included parents/guardians of adolescents aged 12–17 years. The focus group questions were designed to explore parents' perceptions of COVID-19 vaccination for their children. Topics covered included motivators and demotivators to vaccination, the perceived impact of COVID-19, and influences on vaccine decision-making. Trusted community partners were recruited for focus groups in English ($n = 6$) and Spanish ($n = 4$). We used rapid qualitative analysis to analyze interview and focus group data ([Vindrola-Padros & Johnson, 2020](#)). The resulting themes were translated into intervention components as outlined in the [Figure](#).

Identification and adoption of evidence-based interventions from other vaccines

We harnessed the expertise of our team in behavioral interventions and human papillomavirus vaccination to identify

FIGURE. CONFIDENCE intervention development and implementation process.

and adapt relevant evidence-based interventions for use with COVID-19 in response to themes identified in our formative qualitative work. Through literature review and team discussion, we designed an intervention that includes posters of selected personal vaccine stories (Perkins et al., 2020), a provider-delivered counseling algorithm that includes a strong presumptive recommendation (Gilkey et al., 2016) and motivational interviewing principles (Miller & Rose, 2009), and parent-facing materials as the key components of our intervention. We also designed a webinar to train providers in delivering the counseling component of the intervention.

CONFIDENCE Intervention

As shown in the Figure, the CONFIDENCE intervention consists of three key components, a three-step communication training for providers, a provider "my reasons why" poster campaign, and parent-facing educational materials.

Three-step communication training

We held a 1-hr online training in which we gave an overview of COVID-19 vaccine data, current vaccination rates, described the CONFIDENCE intervention, and demonstrated the provider counseling component via role-playing videos. The CONFIDENCE counseling algorithm involves a three step process. (1) a strong presumptive provider recommendation, such as

All of our providers are committed to keeping your child as safe as possible from COVID-19 infection, so we are strongly recommending that all our patients get the

vaccine as soon as possible. We can do that today at the end of your visit. (p. 2)

(2) Assess vaccine readiness and identify whether a parent is hesitant or resistant, deliver tailored assistance, and plan follow-up using motivational interviewing principles. (3) Sharing providers' personal vaccine stories. The approach is intended to encourage hesitant parents, be collaborative, and not alienate resistant parents. Six providers (50% of clinic providers) attended the training.

Provider "My reasons why" posters

For all interested providers, including nursing staff and residents, we held sessions with a professional photographer to take portraits, and a research team member worked with providers to develop their vaccine stories centered on their vaccination motivations. For example, one pediatrician shared the following:

I have 10-year-old twins that have asthma and a five-year-old. I got my children vaccinated to protect them and their grandparents. They all got their first dose at school and my 5-year-old got it on his birthday and proudly told everyone it was his first birthday present!

These photographs and personal vaccine stories were used to create custom posters supporting COVID-19 vaccination, which were displayed throughout the clinic.

Parent-facing educational materials

During the 1-hr online provider training, we also introduced providers to our parent-facing educational materials. These educational materials were developed to address common

questions and concerns raised by parents during the formative focus groups. Educational materials included a trifold fact sheet infographic with a question and answer session regarding COVID-19 vaccination for children aged 5–11 years and a single-page fact sheet with general COVID-19 vaccine information for all age groups. We supplied these educational materials in nine languages (English, Spanish, Portuguese, Vietnamese, Haitian Creole, Swahili, Pashto, Dari, and Farsi) and kept them stocked in the exam rooms of the clinic throughout the beta-testing period.

Beta-Test and Evaluation

We beta-tested the CONFIDENCE intervention in a pediatric primary care clinic associated with an academic medical center and the largest not-for-profit health care system in Central Massachusetts over 2 months. The clinic was recruited through professional connections within our institution. In this process, we identified a provider who served as the physician champion for this project and assisted with the dissemination of materials and implementation logistics. The clinic began administering COVID-19 vaccines in July 2021 and has administered an average of 176 COVID-19 vaccines per month between July 2021 and April 2022.

Study design

We used a mixed-methods approach to evaluate the CONFIDENCE intervention, employing provider interviews and pre-post parent surveys. Our Institutional Review Board determined that this project was not human subjects research.

Measures

Our primary measures were feasibility and acceptability for providers and parents. We conducted midpoint provider interviews at 4 weeks after the webinar training. Our team emailed all the providers ($n = 6$) who completed the webinar training to request their participation in short interviews via phone or video conferencing. We developed an interview guide to assess the following: participation in CONFIDENCE intervention components, acceptability, feasibility, as well as barriers and facilitators to implementation.

Acceptability was also assessed through parent surveys. These pre-post parent surveys (available in English, Spanish, and Portuguese) were completed by parents/guardians after well-child visits. In addition to acceptability, surveys also assessed: demographic information about the parent and child, the parent's COVID-19 vaccination status, the child's COVID-19 vaccination status, satisfaction with the conversation with the provider about COVID-19 vaccination, and future COVID-19 vaccine intentions for the child. Survey data collection began approximately 2 weeks before the webinar training (pretest), and continued for another 8 weeks after the training (posttest).

Analysis

To analyze interview data, we used rapid qualitative methods (Vindrola-Padros & Johnson, 2020). We developed a

summary template using the primary topics addressed in the interview guide, and two team members (Ryan et al., 2022) completed a summary for one interview and then met to discuss and resolve any discrepancies. Through this process, we added a domain to the template and then a single team member (GR) completed the remaining template summaries. These summaries were then organized into a matrix of domains and participants. For survey data, we generated frequencies and descriptive statistics. To account for small sample sizes, we used Fisher's exact test to explore pre-post differences.

RESULTS

Parent Surveys

In total, 106 parents completed the survey, of which 65.1% reported that their children were undervaccinated ($n = 69$), defined as 0 or 1 dose for children aged 5–11 and zero, one, or two doses for adolescents aged 12–17 years. Children aged < 12 years did not become eligible for a booster dose until May 19, 2022; therefore, to remain consistent with the recommendations at the start of the beta-test, we classified children aged 5–11 years with two doses of the vaccine series as being “up-to-date.” Demographic characteristics and vaccine status for the pre-post test sample are presented in Table 1. Only survey responses for parents of children classified as “undervaccinated” are reported. Parents in both the pre-posttest samples predominantly spoke English, identified as female, and had received two doses of the COVID-19 vaccine.

Parental responses regarding the questions about their interaction with the provider about the COVID-19 vaccine are presented in Table 2. Of note, parental reports of providers discussing COVID-19 vaccination, providers sharing personal vaccines story, and satisfaction with COVID-19 vaccine conversation were all higher in the posttest sample.

Provider Interviews

We completed interviews between late April and early May 2022 ($n = 4$) with providers who had participated in the webinar training. Results are organized below by the following themes, which emerged through the rapid qualitative analysis: participation in intervention components, feasibility, acceptability, and suggested adaptations.

Participation in intervention components

All providers reported participating in several intervention components; all attended the webinar, and three out of four shared their vaccine stories on a poster. The provider who did not participate in the poster campaign noted, “I have not had my photo taken yet, because the idea of seeing myself on that larger poster seems unappealing.”

Feasibility

Overall, providers reported that participating in the CONFIDENCE intervention was easy, straightforward, and did not require much time. One provider said that they appreciated that the training webinar was held during a regularly

TABLE 1. Comparisons of demographics and vaccine status for undervaccinated children preintervention and postintervention for the CONFIDENCE beta-test, Worcester, MA, 2022 (n = 69)

Response options	Preintervention, n (%)	Postintervention, n (%)
Language of survey ^a		
English	26 (83.3)	37 (94.9)
Spanish	5 (16.7)	2 (5.1)
Parents' gender		
Male	5 (16.7)	5 (20.5)
Female	25 (83.3)	26 (76.5)
Parents' race		
Black/African American	4 (13.3)	12 (30.1)
White ^b	20 (66.7)	10 (25.6)
Other	4 (13.3)	13 (33.3)
Hispanic/Latino	14 (50.0)	11 (31.5)
Parent vaccine doses received		
0 doses	8 (27.6)	6 (16.2)
1 dose	4 (13.8)	4 (10.8)
2 doses	9 (31.0)	19 (51.4)
3 doses	8 (27.6)	8 (21.6)
Did you see posters promoting COVID-19 vaccine in clinic?		
Yes	21 (77.8)	26 (78.8)
No	6 (22.2)	7 (21.2)
Child gender		
Male	17 (58.6)	19 (50.0)
Female	12 (41.4)	19 (50.0)
Child race		
Black/African American	4 (13.3)	10 (25.6)
White	16 (53.3)	11 (28.2)
Other	6 (20.0)	14 (35.9)
Child's ethnicity		
Hispanic/Latino	16 (59.3)	12 (36.4)
Child's age, years		
5–11	12 (40.0)	14 (35.9)
12–17	18 (60.0)	25 (64.1)

^aSurvey is also available in Portuguese, but we only received responses in English and Spanish.
^bIndicates statistically significant difference (p < .05).

scheduled meeting, so attending was not an additional burden. Barriers reported by providers were related to implementing the parent surveys and using the parent-facing educational materials. One provider noted that it was difficult to remember to give the survey to parents because providers are “so busy doing so many things.” In relation to the educational materials provided, another provider noted that “it’s always good to have. . . the more education the better” but also said they did not always remember the materials were in the exam rooms and available to distribute to parents. All the providers interviewed reported that they rarely used the educational materials and would need more reminders or easier access to them to integrate them into routine practice.

Acceptability

All providers interviewed reported high levels of acceptability with the intervention overall as well as the specific components. Generally, providers found the webinar training useful, though as one noted, “I do remember using it, at least with some patients that day, so I think it wasn’t necessarily new things, but it was stuff that’s definitely helpful to

have reinforced.” All those interviewed shared that it was “nice to have some, you know, external excitement about getting the messages out and things like that.”

Suggested adaptations

Finally, several participants commented on adaptations or improvements to the intervention and implementation on the basis of their experiences. These suggestions were primarily related to the parent-facing educational materials. Several participants noted that it has been difficult to stay up-to-date with the evolving recommendations and approvals for COVID-19 vaccination and that having regularly updated materials or talking points would be helpful. In response to the challenges in integrating materials into conversations with parents, one participant suggested that if the materials were available electronically, they could be integrated into patients’ after-visit summary reports, which may be a better means of dissemination.

DISCUSSION

The results of our beta-test of the CONFIDENCE intervention suggest that this approach promises to support

TABLE 2. Differences in experiences with provider and COVID-19 vaccine recommendation and vaccine intentions preintervention and postintervention for the CONFIDENCE beta-test, Worcester, MA, 2022 (n = 69)

Question	Response options	Preintervention, n (%)	Postintervention, n (%)	% change
Did the provider discuss COVID-19 vaccination today?	Yes	26 (86.7)	38 (97.4)	10.7
Did the provider share their own COVID-19 vaccine experience with you?	Yes	18 (60.0)	28 (71.8)	11.8
How satisfied were you with the conversation about COVID-19 vaccination for your child?	Very satisfied	19 (73.1)	32 (84.2)	11.1
	Somewhat satisfied	5 (19.2)	5 (13.2)	-6.0
	Not satisfied	2 (7.7)	1 (2.6)	-5.1
Did the provider give you any materials about COVID-19 vaccination today?	Yes	14 (48.3)	24 (61.5)	13.2
If yes, how satisfied were you with those materials? (n = 35)	Very satisfied	11 (84.6)	19 (86.4)	1.8
	Somewhat satisfied	2 (40.0)	3 (60.0)	20.0
	Not satisfied	0 (0.0)	0 (0.0)	-
Do you still have unanswered questions about COVID-19 vaccination?	Yes	2 (7.1)	2 (5.3)	-1.8
Did you decide to vaccinate your child today?	Yes	12 (44.4)	24 (61.5)	17.1
If you did not decide to vaccinate, how likely do you think you will vaccinate your child in the future? (n = 30) ^a	Very likely	6 (46.2)	2 (16.7)	-29.5
	Somewhat likely	2 (15.4)	9 (75.0)	59.6
	Not likely	5 (38.5)	1 (8.3)	-30.2

^aIndicates statistically significant difference (p < .05).

pediatric clinics in promoting COVID-19 vaccination. Specifically, intervention participants reported high feasibility and acceptability of participating in the intervention, and our survey data suggest positive trends in improving vaccine acceptance. However, we encountered several challenges related to implementing the CONFIDENCE intervention that need to be addressed before conducting a larger-scale intervention trial.

We found promising results in terms of feasibility and acceptability, as well as vaccine-related outcomes in the parent surveys. The principal component of the intervention was the three-step communication training outlining the provider-delivered counseling algorithm that aimed at empowering providers to improve communication with hesitant and resistant parents. The training outlined a process of giving a strong recommendation for the COVID-19 vaccine (Gilkey et al., 2016), followed by assessing vaccine readiness, exploring ambivalence, delivering tailored assistance, and planning follow-up using motivational interviewing principles (Miller & Rose, 2009), and sharing a personal vaccine experience, if possible, their own child's vaccination experience (Massey et al., 2021; Perkins et al., 2020).

Overall, providers reported high acceptability of this approach and ease of integrating it into their everyday practice. Increasingly, there is literature suggesting that the approaches used in our approach may be appropriate to reduce hesitancy around COVID-19 vaccination (Finney Rutten et al., 2021; Gabarda & Butterworth, 2021). However, to date, we have not found established evidence of the

effectiveness of combining these three approaches specifically for COVID-19 vaccine promotion in a pediatric population. In addition to our communication algorithm being acceptable to providers, there was also evidence of adoption of at least some of the other strategies in the results from the parent survey. Although our study was not powered to detect statistically significant pre-post differences, we saw more positive results in the posttest group on nearly all measures related to the conversation with the provider about vaccination. Importantly, we found that a higher percentage of parents in the posttest group reported that their pediatrician discussed COVID-19 vaccination at the visit, that the pediatrician shared their personal vaccine story, and that they had decided to vaccinate their child at the appointment. Together these findings suggest the successful integration of the training components into routine clinical practice.

Challenges to implementing the CONFIDENCE intervention as intended as well as to our data collection process were identified. Related to implementation, providers reported not using or distributing the educational materials to parents. The parent-facing educational materials (fact sheets and trifold brochures) were available in all examination rooms; however, as one provider noted, simply making them available was not sufficient. To ensure broader dissemination of these materials, one strategy, as suggested by one of the providers in our study, may be to integrate them into electronic health record platforms so that providers could attach them to patients' visit summaries. In terms of data collection, one logistical challenge we encountered was

related to the distribution of the surveys. The providers were responsible for distributing the survey to parents after their visit; however, as all the providers we interviewed noted, they did not always remember to do this. Moving forward, a more streamlined approach to data collection will be needed to ensure sufficient sample size to establish efficacy and, ultimately, the effectiveness of this intervention. To resolve both challenges, one potential solution could be workflow mapping (Ozkaynak et al., 2013) to identify alternative options for survey dissemination and integrating the parent-facing materials into visits. All clinics will likely have different processes for this; thus, implementation will need to be tailored to be appropriate for specific clinic workflows to ensure data collection is completed.

To date, most of the literature on pediatric COVID-19 vaccination has focused on understanding parental intentions (Scherer et al., 2021; Szilagyi et al., 2021) and factors affecting those intentions (Head et al., 2022; Rogers et al., 2021; Walker et al., 2021). Moreover, much of the literature on interventions to promote COVID-19 vaccination has explored either policy interventions (i.e., mandates [Mello et al., 2022; Sprengholz et al., 2022] and incentives [Thirumurthy et al., 2022]) or mass communication strategies (i.e., text messages, emails, social media; Freeman et al., 2021; Santos et al., 2021). However, few reports of clinic-based and provider-focused interventions focus on reducing parental hesitancy for COVID-19 vaccination. While a multilevel approach that includes policy and communication approaches will be needed to encourage hesitant and resistant parents to vaccinate their children, previous literature on pediatric vaccine interventions has identified that providers are critical to vaccination efforts (Frew & Lutz, 2017; Oh et al., 2021). As COVID-19 vaccination rates in the pediatric population remain low, identifying these best practices and building an evidence base around clinic-focused interventions should be a priority. Our future research will prioritize adapting and further testing the CONFIDENCE intervention to support pediatric practices in these efforts.

Strengths and Limitations

The primary strength of our approach to the CONFIDENCE intervention is that development and implementation were directly informed by our team's formative qualitative research (Goulding et al., 2022; Ryan et al., 2022) and existing evidence-based practices to promote vaccination (Ellingson et al., 2022; Gilkey et al., 2016). In addition, using rapid qualitative methods in our formative work and our evaluation of the beta-test allowed us to be responsive to the current context by moving from intervention development to implementation, evaluation, and dissemination in under a year (Vindrola-Padros & Johnson, 2020).

However, our results are subject to certain limitations. We completed the beta-test in a single pediatric clinic within an academic medical center setting, and thus we are unsure how this approach would translate in a community clinical setting. Moreover, because our goal was to establish feasibility and acceptability, we did not design this study to be

powered to detect significant pre-post test differences. Our ability to explore potential intervention effects was also limited by the challenges providers experienced in collecting survey data. Finally, it is important to note that parents' levels of hesitancy are dynamic, and although our intervention took place over a short period (10 weeks), the positive results we observed in vaccine acceptance could be due, in part, to changing public sentiments. Despite these limitations, we are encouraged by the positive results observed in this beta-test and believe that future randomized clinical trials are warranted to establish stronger evidence for the CONFIDENCE intervention.

CONCLUSIONS

In our beta-test of the CONFIDENCE intervention, we found high levels of feasibility and acceptability among participating providers and encouraging data from pre-post parent surveys. Despite the importance of clinic-based and provider-focused interventions for pediatric COVID-19 vaccination uptake, there have been few reports of efforts in this area. Moreover, COVID-19 vaccination will continue to be an important topic to address as rates of uptake for pediatric populations remain lower than any other age group (Centers for Disease Control and Prevention, 2022). As additional vaccines and boosters become available and recommended, supporting and empowering providers to counsel vaccine-hesitant and resistant parents will be crucial to protecting children and adolescents from the negative effects of the COVID-19 infection. The next steps will be to further test the CONFIDENCE intervention using more rigorous study designs and in community settings to establish efficacy for increasing parents' intentions to vaccinate their children.

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