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The Healthy, Immunized Communities Study: A pilot intervention to increase parents' intentions to get vaccines for their middle school children

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ABSTRACT

Pennsylvania shortened the provisional period for student vaccine compliance in 2018. We pilot tested a school-based health education intervention, *The Healthy, Immunized Communities Study,* to improve parents' intentions to get school-required (tetanus, diphtheria, acellular pertussis [Tdap]; and meningococcal conjugate [MCV]) and recommended (human papillomavirus [HPV]) vaccines for their children. In Phase 1, we partnered with the School District of Lancaster (SDL) to conduct four focus groups with stakeholders (local clinicians, school staff, school nurses, and parents) to inform the development of the intervention. In Phase 2, we randomized four middle schools in SDL to either the intervention (six email communications and school-community educational event) or control group. Seventy-eight parents took part in the intervention and 70 joined the control group. Vaccine intentions were compared within and between groups from baseline to 6-month follow-up with generalized estimating equations (GEE) models. Compared to the control, the intervention did not increase parents' vaccine intentions for Tdap (RR = 1.18; 95 % CI:0.98–1.41), MCV (RR = 1.10; 95 % CI:0.89–1.35), or HPV (RR = 0.96; 95 % CI:0.86–1.07). Among intervention participants, only 37 % opened $\geq$ 3 email communications and 23 % attended the event. Intervention participants reported high satisfaction with email communications (e.g., informative = 71 %) and felt that the school-community event met their educational objectives on key topics (e.g., immune system = 89 %). In conclusion, although we observed no intervention effect, our data suggest that this could be a result of the low uptake of intervention components. Further research is needed to understand how school-based vaccination-focused interventions can be successfully implemented with high fidelity among parents.

1. Introduction

Vaccines are one of the greatest successes in public health [1]. The U.S. Centers for Disease Control and Prevention (CDC) estimates that millions of lives have been spared and morbidity prevented as a result of vaccine development and uptake in the United States [2]. Despite vaccines' proven efficacy and safety, many parents delay or decline vaccination for their children, including vaccines required for school entry [3]. Geographic clusters of unvaccinated school-age children have resulted in an increase in recent vaccine-preventable outbreaks [4,5], posing a threat to the health of entire communities. As a result, increasing children and adolescent vaccination rates is a national priority as indicated through the Healthy People 2020 objectives [6] and new objectives set for 2030 [7].

Nationally, all states have laws requiring vaccinations for students, although exemptions vary between states: all states and DC grant exemptions for medical reasons, 45 states and DC grant religious exemptions, and 15 states allow philosophical exemptions [8]. Evidence indicates that school-entry requirements are effective at improving vaccination rates [9]; however, with parents' current ability to opt for exemptions in most states, a push towards enhancing vaccine uptake is warranted [10]. In Pennsylvania, state law requires all seventh-grade students to receive the tetanus,

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diphtheria, acellular pertussis (Tdap) vaccine and the meningococcal conjugate vaccine (MCV) upon the start of school, or risk exclusion from school until vaccinated or an exemption is submitted [11]. Philosophical and religious exemption rates are especially high (7.5 %) in Lancaster County, Pennsylvania, compared to the state average (2.9 %) [12]. Starting in the 2017/2018 academic year, Pennsylvania shortened the provisional period, a grace period that allows students to attend school without being vaccine compliant, from 8 months to 5 days from the start of school for multi-dose vaccines and 0 days for single-dose vaccines. This challenged schools to revise current immunization management practices [8]. This policy change served as the needed leverage in establishing a partnership between the School District of Lancaster (SDL) and our research team to address vaccine compliance barriers and improve vaccination rates.

A recent systematic review summarized evidence-based strategies for improving vaccination rates among children, and listed both school-entry requirements and school-based interventions as best practices [13]. Providing vaccine-oriented educational opportunities to parents and children is one of many promising approaches to implement in schools, especially with families who are less likely to attend regular well care visits and, therefore, do not receive provider recommendations [13]. However, limited research has tested the combined use of in-person and electronic communication and education to improve school vaccine compliance following the enactment of a new school-entry requirement policy. A study conducted in Indiana by Swallow and Roberts [14] showed that school-generated communication improves compliance with an existing school-entry requirement and suggests our approach is feasible.

The present work summarizes the partnership's two phases: 1) engagement activities conducted to inform the development of a novel school-based health education intervention, *The Healthy, Immunized Communities Study*, and 2) findings from the school-based pilot study (Fig. 1). The objective of the pilot study was to determine the initial efficacy of the school-based intervention to improve rates of parents' intentions to get required (Tdap, MCV) and recommended (human papillomavirus [HPV]) vaccines for their middle school-aged children. We hypothesized that parents who fully engage with the intervention would report higher levels of vaccine intentions than those in the control group at 6-month follow-up.

2. Methods

2.1. Phase 1: Engagement activities

2.1.1. Establishing the school-research partnership

In spring 2018 the study team – consisting of two project managers, one study coordinator, one marketing specialist, one physician-scientist, and one public health researcher – connected with SDL's administrators and head school nurse via phone and email to learn about district needs related to vaccine compliance and present potential project ideas. Through multiple conversations and data exchanges that were led by one project manager (AMH), they agreed on the shared goals to address vaccination compliance barriers and improve vaccination rates. To facilitate transparency and efficiency, SDL and the study team created a Memorandum of Understanding (MOU), which detailed the timeline and listed roles and responsibilities for both parties. The development of this school-research partnership took approximately-six months from the initiation of conversations to the completed MOU agreement.

2.1.2. Focus groups with stakeholders

After formalizing the partnership, the study team sought to understand how key school and community stakeholders responded to recent policy changes in the provisional period for school immunization compliance, their perspectives on school communication about vaccines, and feedback regarding future interventions to address barriers to vaccination compliance. We conducted one focus group with each of the following four stakeholder groups: local clinicians (n = 8), school nurses (n = 9), school staff (n = 7), and parents (n = 6). Eligibility criteria required participants fluently speak and read English; be 18 years of age or older; and depending on the stakeholder group, a SDL employee (nurse or staff), a parent whose child attends one of the targeted schools, or a licensed clinician serving the Lancaster community. If participants were interested and screened eligible through the online screener, the study team contacted them to arrange the focus group time and location (i.e., school, clinic). An electronic survey collected demographic data and informed consent before the focus group session. Participating clinicians were all non-Hispanic Whites and included women (n = 6) and men (n = 3). Four parents were non-Hispanic Whites and two were non-Hispanic Blacks, and all were women. School nurses were all women and reported themselves as non-Hispanic Whites (n = 5), non-Hispanic Blacks (n = 1), and Hispanics (n = 3). School staff were women (n = 5) and men (n = 1), and were comprised of three non-Hispanic Whites, one non-Hispanic Black, and two Hispanics. Roles included one administrator, one teacher, three social workers, and one administrative assistant.

Before starting group discussions, the facilitator reviewed the consent information and provided copies to all participants. Participants were asked to take turns speaking and to share their opinions openly. A study team member facilitated these sessions using a semi-structured guide that was developed to obtain information to inform the design and implementation of our pilot study. Questions were asked about challenges with recent policy changes regarding school immunization compliance, perspectives on school communication about vaccines, and feedback regarding potential health education interventions to address barriers to school vaccination compliance. Focus groups lasted one hour each, were audio recorded and transcribed. All focus groups occurred between July and October 2018. This qualitative study was approved by the Penn State College of Medicine's Institutional Review Board.

2.1.3. Qualitative analysis

The study team used a descriptive content analysis approach to analyze data from focus groups. This method enables the themes to flow from the data, which avoids using preconceived themes for coding [15]. Data analysis began with a first reading of all transcripts to obtain a sense of the text's whole meaning. Transcripts were then read word by word to derive organized themes based on how statements were related to each other. This analysis resulted in a codebook and a summary of the discussed themes. These data informed the development of a school-based health educational intervention aimed at increasing vaccine intentions and compliance among middle school parents.

2.2. Phase 2: Pilot study

2.2.1. School recruitment and randomization

The *Healthy, Immunized Communities Study* was a two-arm cluster randomized pilot study. In February 2019, all four middle schools serving sixth, seventh, and eighth grades, and enrolling a total of 2,082 students, from SDL were recruited and randomized to either the intervention or control groups. Two other schools were excluded because their primary populations were elementary and high school students, respectively, and the number of students

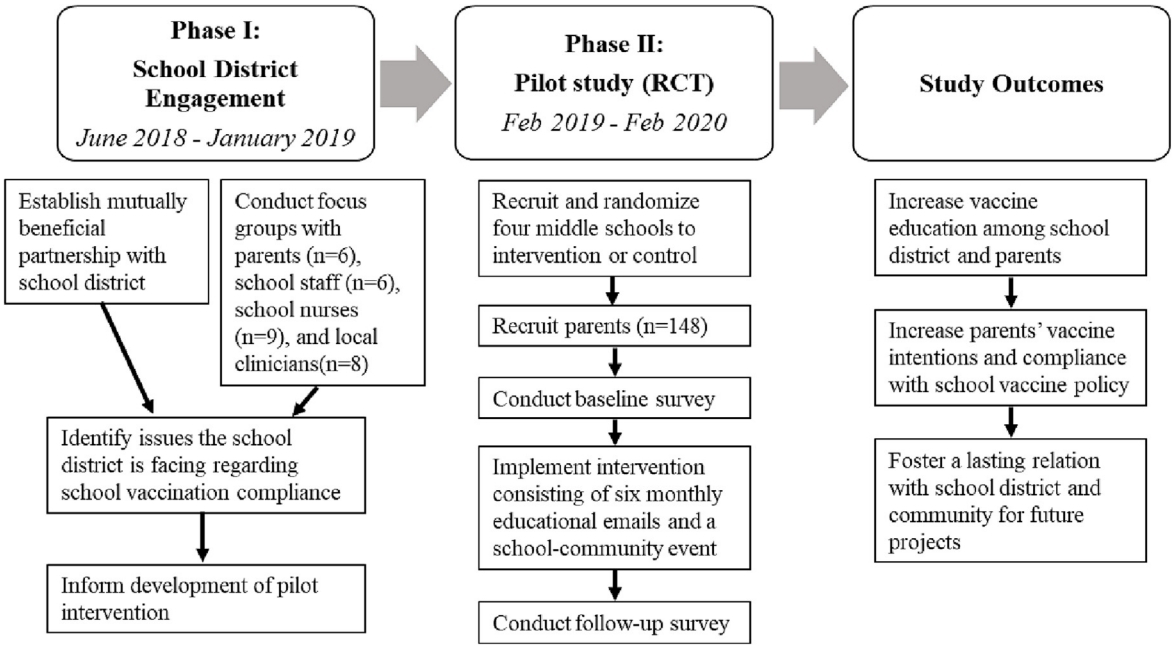

Fig. 1. Model for engagement and pilot study implementation in a school district partnership.

in middle school grades was small (296 students in total). Qualifying middle schools were randomized using a 1:1 ratio. The study principal investigator (JK) was blinded to the randomization assignments. The student populations were racially and ethnically diverse (60 % Hispanic, 18 % non-Hispanic Black, 12 % non-Hispanic White, 6 % Multi race/ethnic, and 4 % Asian) in each of the four middle schools, but very demographically similar across the schools (e.g., 100 % free lunch status, racial/ethnic distribution). Key social and economic characteristics of the population living in SDL include, 19.1 % people living below the poverty line, 61.2 % people are racial/ethnic minorities, 92.2 % of households have access to a computer, and only 24.4 % of adults ages 25 or older have a bachelor's degree or higher. The study was registered in clinicaltrials.gov (NCT03854734) and approved by the Penn State College of Medicine's Institutional Review Board.

2.2.2. Parent recruitment

To be eligible, parents had to be 18 years or older, have at least one child attending a participating SDL middle school, plan to live in the district through the next academic year, be fluent in English, and have a valid email address. Using a SDL mailing list, we sent a recruitment flyer to parents whose children attended any of the four targeted schools. The flyer was also shared on the schools' social media pages. The flyer included a QR (Quick Response) code to an online eligibility screener and a phone number for a telephone screener. The study team also attended school and community events (e.g., parent-teacher conferences, parent-teacher organizations' meetings, student chorus concerts, back-to-school orientation) to recruit participants. Parents were instructed that their decision to participate was voluntary and they could opt-out of the study at any time. At the beginning of the screener, parents were provided with consent information. Parents then gave their implied consent to participate by completing the screener.

Recruitment started in February 2019; however, we paused recruitment in March 2019 after identifying unusual responses in the online study screener (e.g., high rates of minority participants not present in our region, for example, Native Hawaiian or other Pacific Islander) and conflicting responses in the baseline survey. We excluded potentially fraudulent entries of individuals (n = 233) who did not respond by phone to confirm eligibility for the study. We resumed recruitment in April 2019 and enhanced enrollment procedures to require that all participants interact with a study team member (in-person at recruitment events or on a phone call after initial screener) to verify their identity. We extended recruitment into September 2019 to take advantage of school events at the beginning of the fall semester. Each parent recruited into the study represented a unique student and only one parent per family was eligible to participate.

2.2.3. Intervention components

The intervention condition was comprised of two components: email communications and a school-community educational event. Over the trial period, participants received a series of six email communications (every 3–4 weeks) that included evidence-based information on topics like the diseases prevented by recommended vaccines, the benefits of vaccination, where to get vaccines for their child, and common myth-busting responses to parents' concerns. The emails also provided specific information on vaccines required for school entry (e.g., compliance documentation, provisional period). The second component was a 2-hour, in-person, school-community educational event. The event provided participants with interactive learning activities and educational materials related to vaccination, overall wellness, and science. This school event took place in one of the two intervention schools and included parents (either enrolled or not in the study) from the intervention schools only. Participants in the control group received email communications on other topics of interest to SDL (e.g., mental health) but unlikely to affect study outcomes. To monitor intervention fidelity, we used a standardized procedure for recruitment, enrollment, and delivery schedule for email communications. We also tracked attendance to the school event and engagement with email communications.

2.2.4. Measurement

Participants completed two surveys, at baseline and 6-month follow-up. Parents' characteristics were assessed in the baseline survey and included age, gender, marital status, race/ethnicity, education, household income, relationship to the child, and their child's gender and school grade. The baseline survey also asked one item about parent engagement with school activities "During this school

year, how often have you participated in or volunteered for events with your child's school? For example: supervising lunch, chaperoning a field trip, school fundraising, etc." If parents had more than one child in a participating middle school, they were instructed to answer the surveys about their youngest middle school child (32 participants had $\geq$ 2 children in middle school). The primary outcome variable was parental intent to get school-required vaccines: Tdap and MCV. We also assessed intentions to get the HPV vaccine for their children. For each vaccine, baseline and post-intervention surveys asked parents to "indicate the status of these shots in your middle school student" with response options: "plan to get this shot before the first day of 7th grade," "up-to-date with this shot," "no plans to get this shot," or "have or plan to submit an exemption for this shot." For HPV vaccine we did not include the option "have or plan to submit an exemption for this shot" because the vaccine is not required for school entry.

The follow-up survey also asked parents in the intervention group to rate their satisfaction with email communications (e.g., informative, easy to understand, easy to read, helpful, accurate, interesting, and trustworthy) and information gained at the school-community event (e.g., needs for vaccines, HPV vaccine, vaccination resources in the community, school's communication efforts around vaccinations, herd immunity, disease outbreaks, and the body's immune system). These items used a 5-point response scale that ranged from "strongly disagree" to "strongly agree." Participants received $20 for completing the baseline survey and $25 for completing the follow-up survey ($45 total).

2.2.5. Analysis plan

Survey data were collected using REDCap, a secure web-based application for building and managing online surveys and databases [16]. The distribution of all variables were assessed prior to analysis using descriptive statistics. Continuous variables were checked for skewness using histograms, normal probability plots, box plots, and test for normality. Demographic variables were compared between the control and intervention groups at baseline using a Chi-square test or a two-sample *t*-test. The outcome variable, parental vaccine intention, was dichotomized for each vaccine asked in the survey as Intention to vaccinate/vaccinated ("plan to get this shot before the first day of 7th grade" or "up-to-date with this shot") or No intention to vaccinate ("no plans to get this shot" or "have or plan to submit an exemption for this shot"). The outcome variables of Tdap, MCV, and HPV vaccines were compared within and between treatment groups from baseline to post-intervention with a generalized estimating equations (GEE) model using the framework of a log-binomial logistic regression model. Risk ratios resulting from these models were used to quantify the magnitude and direction of any significant differences. Unfortunately, the study design and resultant sample size did not allow vaccination rate as the primary endpoint. Sample size calculation would require nearly 3,400 students per group (intervention and control) to find a conservative difference of 3 % as significant using a two-sided Chi-square test with a significance level of 0.05 and a power of 80 %. However, results from this pilot intervention will be used to inform the next larger study proposal for which vaccination rate will be the primary endpoint. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC) and a significance level of 0.05.

3. Results

3.1. Focus groups

Each focus group added both unique and complementary perspectives to school vaccination compliance and vaccine communication topics. Across all discussion groups, the following themes were consistent: challenges with school communication, stakeholder role in communication or vaccine compliance, practical recommendations for more efficient communication with families, and feedback on study intervention components. Specifically, local clinicians shared challenges with discussing vaccines with many parents, especially those hesitant to vaccinate, because of a growing skepticism of the medical community and the abundance of misinformation. They expressed many parents have negative opinions that, most of the time, were not based in science. One clinician said, *"I think someone that's skeptical in anything in healthcare. . .can go online and find 50,000 other people that feel the same way and build them up and empower them to say no and then trying to convince them otherwise, seems almost impossible*." Parent focus group discussions indicated frustration about timely and accurate vaccine communication from schools, especially about the provisional period for presenting student vaccine documentation and which vaccines were needed for their child. Parents shared, *"I've never really seen a paper come home until the last minute. . ."* and *"I think it would be nice to have an assembly or a night [where] you're actually told this is what you need*." School nurse and staff focus groups echoed similar concerns to the parents, indicating that there was no streamlined approach to vaccine communication in schools and it was an incredibly time-consuming task to reach out to parents. *"I'm in the district [for] almost 20 years and almost every year, it's a struggle regardless if they have eight months or five days [to get vaccinated],*" said one nurse. School staff also shared concerns about not having the knowledge or training background to understand the complexities of vaccine requirements when reaching out to remind parents. One staff-person said, *"I'm not a medical doctor so reading the chart to determine what is needed was really challenging.*" Both school nurses and staff agreed that one area of improvement would be to begin the communication to parents earlier in the school year to aid in more timely vaccine uptake and facilitate vaccine documentation at schools.

3.2. Pilot study

All families of a middle school student who attended one of the participating SDL schools were invited to enroll in the study (n = 2,082). The study enrolled 148 parents (Fig. 2). Participant characteristics by study groups are shown in Table 1. The intervention (n = 78) and control (n = 70) groups were equivalent in all demographic characteristics (p >.05). In the control group, we found statistically significant changes in vaccine intentions for Tdap (RR = 1.31, 95 % CI: 1.14, 1.52) and MCV (RR = 1.25, 95 % CI: 1.06, 1.52) from baseline to follow-up (Table 2). In the intervention group, there were no significant differences in intentions to vaccinate at follow-up (all vaccines $p > 0.05$). Comparing the intervention versus the control group, we found no statistically significant changes in intentions for any vaccine at 6-month follow-up (all p >.05).

Participants in the intervention group reported high satisfaction with the email communication component, with a majority strongly or somewhat agreeing that it was informative (71 %), easy to understand (70 %), easy to read (69 %), helpful (69 %), accurate (64 %), interesting (64 %), and trustworthy (59 %). Seventy-eight percent of participants in the intervention group accessed at least one email but only 37 % opened three or more of the communications based on data from the email distribution platform. The majority of participants who attended the school-community event reported that at that event, they learned about when their child needs to be vaccinated (78 %), the HPV vaccine (84 %), vaccination resources in the community (72 %), the school's communication efforts around vaccinations (83 %), herd immunity (72 %), the dangers of disease outbreaks (78 %), and the body's immune system (89 %). Only 23 % of intervention participants attended the event.

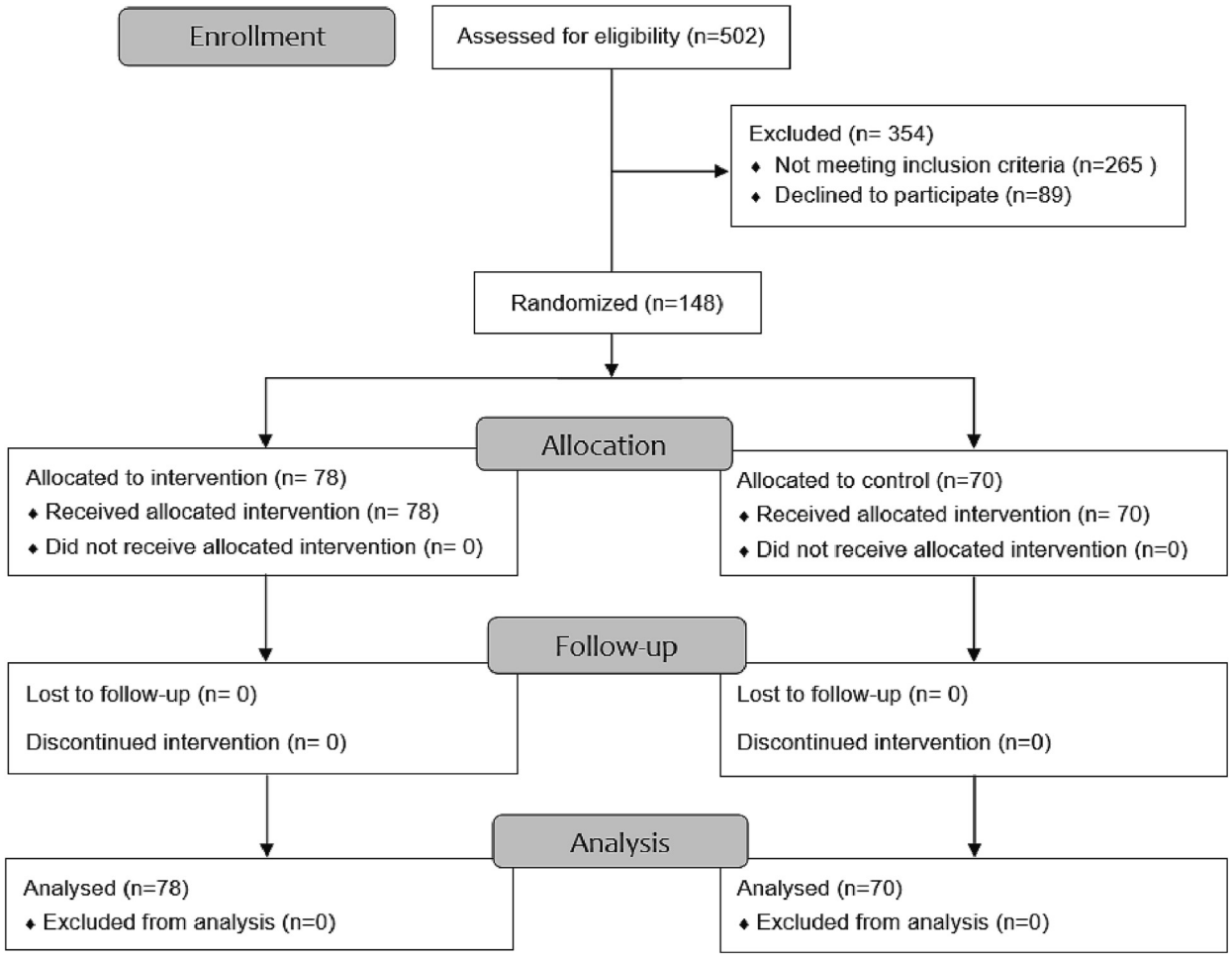

Fig. 2. CONSORT diagram showing the flow of participants through each stage of RCT.

4. Discussion

Public health practitioners call for the need to support schools in delivering evidence-based programming to combat the spread of anti-vaccination communication, restore parents' vaccine confidence, and improve student vaccination compliance [17–19]. In full partnership with a school district in Pennsylvania and after gathering feedback from key school and community stakeholders, we developed and implemented *The Healthy, Immunized Communities Study*. Our study did not find statistically significant increases in vaccine intentions among parents who participated in the school-based health education intervention versus those in the control group. The intervention's low performance might be related to our limited focus on vaccination education and promotion and the low uptake of intervention components by parents. On the other hand, participants rated the intervention highly in terms of satisfaction indicators and educational objectives.

Overall, the intervention did not increase parents' intentions to get Tdap, MCV, or HPV vaccines for their children at 6-month follow-up. Our intervention focused on vaccination education and promotion only, missing additional components needed to effectively connect students with vaccination services in the communities where they live. For instance, per the U.S. Community Preventive Services Task Force (CPSTF), to be effective, school vaccination programs should include at least two of the following four strategies: 1) vaccination education and promotion, 2) assessment and tracking of vaccination status, 3) referral of under-immunized students to vaccination providers, and 4) provision of vaccinations [20]. However, implementing many of these strategies is especially challenging in Pennsylvania schools. For example, vaccine dose reporting to the Pennsylvania Statewide Immunization Information System (PA-SIIS) is voluntary for most healthcare providers; as a result, a large number of them do not use the PA-SIIS [21]. This policy limits school nurses' and staff's ability to accurately assess and track students' vaccination status (CPSTF strategy 2) and make vaccine referrals when needed (CPSTF strategy 3) because PA-SIIS records are incomplete or do not exist for many students [22]. Also, only one of the four schools enrolled in the study participates in a school health clinic (SHC), where students receive primary care, including on-site vaccination (CPSTF strategy 4). Nationally, only 6 % of students from preschool through 12th grade receive care from the 2,300 SHCs that operate in the country. Although SHCs are more likely to operate in schools with high numbers of low-income, uninsured and minority students, many SHCs do not serve schools with adolescents. Acknowledging these systems barriers, we developed an intervention that local schools could implement within their existing capacities.

Our evaluation also showed low parent participation in intervention activities, with about one third (37 %) of intervention participants reading the majority of email communications and less than one fourth (23 %) attending the event. These low levels of intervention uptake may stem from many factors outside the domain of the study team and school leaders, including limited access to the internet to access email communications and com-

Table 1
Participant characteristics by intervention group (n = 148).

	Intervention (n = 78) n (%)	Control (n = 70) n (%)	*p* value
Age (years) Mean ± SD	40.46 ± 8.59	38.00 ± 9.79	0.11
Gender			0.22
Male	7 (9.3)	11 (16.2)	
Female	68 (90.7)	57 (83.8)	
Relationship status			0.83
Single, Separated, Divorced, Widowed	30 (39.5)	26 (37.7)	
Married, Living with Partner	46 (60.5)	43 (62.3)	
Race/Ethnicity			0.58
White	43 (55.8)	32 (45.7)	
Black/African American	7 (9.1)	6 (8.6)	
Hispanic or Latino	20 (26.0)	22 (31.4)	
Other	7 (9.1)	10 (14.3)	
Annual household income			0.17
≤$40,000	27 (36.0)	31 (44.9)	
$40,001 - $80,000	25 (33.3)	26 (37.7)	
>$80,000	23 (30.7)	12 (17.4)	
Education			0.06
High School or Less	29 (37.2)	35 (50.0)	
Some College	12 (15.4)	15 (21.4)	
College Graduate	37 (47.4)	20 (28.6)	
Relationship to child			0.76
Mother	66 (84.6)	56 (80.0)	
Father	8 (10.3)	9 (12.9)	
Guardian/Grandparent	4 (5.1)	5 (7.1)	
Grade of child			0.43
6th	33 (42.3)	37 (52.9)	
7th	29 (37.2)	22 (31.4)	
8th	16 (20.5)	11 (15.7)	
Gender of child			0.93
Male	44 (56.4)	40 (57.1)	
Female	34 (43.6)	30 (42.9)	
Parent participation in school events/year			0.06
≤1	37 (48)	41 (58)	
2–5	24 (31)	25 (36)	
≥6	16 (21)	4 (6)	

Note. SD = Standard deviation.

Table 2
Effects of the intervention on vaccine intentions.

	Vaccine intentions at baseline, %	Vaccine intentions at follow-up, %	Difference from baseline, Risk ratio (95 % CI)	Difference from control, Risk ratio (95 % CI)
Tdap				
Control	74.3	97.9	1.31 (1.14, 1.52)	Ref
Intervention	83.3	93.0	1.12 (1.00, 1.25)	1.18 (0.98, 1.41)
MCV				
Control	72.9	91.5	1.25 (1.06, 1.47)	Ref
Intervention	80.5	91.6	1.14 (1.00, 1.29)	1.10 (0.89, 1.35)
HPV				
Control	84.1	85.7	1.01 (0.94, 1.08)	Ref
Intervention	84.4	87.3	1.05 (0.96, 1.14)	0.96 (0.86, 1.07)

Note. Tdap = Tetanus, diphtheria, acellular pertussis; MCV = Meningococcal conjugate vaccine; HPV = Human papillomavirus; 95 % CI = 95 % Confidence Interval.

peting demands (e.g., multiple jobs, other family responsibilities) that prohibited parents from attending the school event as well as a lack of reliable transportation. A recent community health needs assessment identified these same individual-level factors and other social and community conditions as key contributors to health disparities in Lancaster County [23]. At the same time, our survey data showed that the majority of parents (53 %) have limited engagement in school activities. This suggests that low parent engagement in school-related initiatives is a larger issue in these schools and not exclusive to our intervention. Research shows that perceived social inclusion related to school is positively associated with intervention dose uptake in school-delivered interventions [24]. Future school-based vaccine-promoting interventions should develop strategies to facilitate parent engagement and promote social inclusion to maximize intervention uptake.

On the other hand, most intervention participants reported high satisfaction with the email communications (ranging from 59 % to 71 %), and most felt that the school-community event met their educational objectives on selected health topics presented at the event (ranging from 72 % to 89 %). Through a series of focus groups in the initial phase of the study, we sought to understand the needs and preferences for vaccination communication in SDL. An important strength of this study was the incorporation of that feedback into the pilot intervention, which seems to be reflected in the high levels of satisfaction with the two intervention components. Specifically, parent feedback on the format and content of communications led to the visual design of and information displayed in the emails. We also considered the recommendations of parents, school nurses, and school staff for the selection of educational activities and resources at the school-community event. Our eval-

uation data echoed those of the literature that there is greater satisfaction among community members when their voices and views are considered by researchers [25].

Another strength of the present study was the collaborative relationship we built with SDL and the schools' administrators, who actively supported many aspects of this research. For example, they approved the study team to recruit parents at school events and via mail communications using the district's mailing list. Utilizing these school resources helped recruit a diverse sample of participants from this low-income community while mitigating common suspicion among families and possibly improved participation and retention rates, as parents generally trust their child's school [26,27]. Consistent with the literature, school leadership buy-in and their ongoing involvement were key facilitators of implementing study activities in the school setting, including providing space and staff to successfully carry out the school-community event [28]. The study had several limitations including the small number of schools and that schools were located in the same school district, thus limiting generalizability. Although we interviewed key stakeholder groups in the formative phase of the study, we did not conduct interviews post-implementation to gather additional information about the study's successes and failures, which may have been helpful to better understand the low uptake of intervention components among parents. Another limitation of this study was the small number of participants who took part in the pilot intervention. Despite the limitation, our pilot work offered insights about the feasibility of our approach to be used in future studies involving school settings and parents of middle school children. The pilot intervention was implemented in a school district with high rates of vaccine exemption requests and limited school-clinical linkages to adolescent vaccination services. Future studies should work to identify the optimal intervention components to overcome the settings with similar challenges. Also, the improvements in parents' vaccine attitudes and beliefs observed in the control group might be caused by Hawthorne Effect bias or the result of competing vaccine promotion undetected by our study team. Additionally, we cannot rule out possible contamination between the intervention and control groups as families interact in community and social activities outside the school. Importantly, we verified the attendance list from the school event and all attendees corresponded to the intervention group. Finally, adolescents' vaccination status was self-reported by parents; this information was not confirmed with any vaccination records.

The new provisional policy for student vaccine compliance offers practical solutions that may better support schools in achieving higher rates of vaccination. First, all Pennsylvania school districts are eligible to apply to the School Immunization Catch-Up (SICU) Program, a federally-funded initiative that provides vaccines (including both MCV and Tdap) to schools to offer their students who meet Vaccines For Children eligibility (e.g., Medicaid patient, uninsured). Through the SICU program, and in combination with the delivery of vaccine education and promotion to families, schools can organize mass vaccination days before or during the first week of school to effectively improve their students' vaccination rates. Second, acknowledging the unique role of school nurses in communicating with students and parents about vaccine requirements, our team developed a toolkit to support their efforts [29]. The toolkit development was informed by feedback from twenty-one Pennsylvania school nurses [30]. To facilitate nurses' role in assisting families with vaccination policy adherence, the kit includes ready-to-use materials, such as a sample communication plan and timeline, notification letter templates for parents, and guidance on how to manage exemption requests.

4.1. Conclusion

School-based vaccine-promoting interventions seem a promising solution to increase student vaccine compliance because these interventions can be easily integrated within existing year-round school events [19,31]. However, our pilot intervention fell short of its intended effect; this result may stem from the low intervention uptake among parents and the lack of additional strategies connecting students to vaccination services. On the other hand, we found high levels of participant satisfaction that can be attributed to the deliberate incorporation of stakeholder feedback through the different phases of the study. Research is needed to develop strategies that promote parent engagement to maximize intervention uptake and the dissemination of existing resources to better support school nurses as they seek to improve vaccine communication with families.

Data availability

Data will be made available on request.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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