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Process Evaluation of an Intervention to Increase Provision of Adolescent Vaccines at School Health Centers

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Abstract

Background. Vaccination programs in school health centers (SHCs) may improve adolescent vaccine coverage. We conducted a process evaluation of an intervention to increase SHC-located vaccination to better understand the feasibility and challenges of such interventions. *Method*. Four SHCs participated in an intervention to increase provision of recommended vaccines to 2,975 adolescents. We reviewed program materials and SHC staff reports, and interviewed parents to assess implementation fidelity and reactions to materials. *Results*. Ten percent of parents returned forms with consent to at least one vaccine. Of these, 79% checked the box consenting for "all recommended" vaccines, rather than indicating individual vaccines. SHCs sent supplemental mailings to some parents that clarified (a) vaccination costs or (b) human papillomavirus vaccine recommendation for boys and required parents to reconsent. This process resulted in loss of initial consent, primarily due to nonresponse. In interviews, parents who consented to vaccination indicated that intervention materials were clear and persuasive, but needed greater detail about costs and clinic processes. *Conclusions*. With limited additional investment, it appears feasible for SHCs to achieve a modest increase in the number of vaccinated adolescents. Providing a checkbox to indicate global consent for all recommended vaccinations, and close collaboration among individuals involved in intervention development, may facilitate vaccination efforts.

Keywords

adolescent health, evaluation, health promotion, health protective behavior, process evaluation, school-based, school-based health care

Vaccines recommended specifically for adolescents effectively prevent infections that lead to numerous diseases. United States guidelines suggest that 11- or 12-year-old adolescents should receive three vaccines: meningococcal conjugate vaccine (MCV4); tetanus, diphtheria, acellular pertussis (Tdap) vaccine; and human papillomavirus (HPV) vaccine, as well as annual seasonal influenza vaccines (Centers for Disease Control and Prevention [CDC], 2013a). Yet adolescent vaccination rates remain low. According to the 2012 National Immunization Survey–Teen, 85% of adolescents had received the Tdap vaccine, 74% had received MCV4, and 33% of females and 7% of males had received the recommended three doses of HPV vaccine (CDC, 2013b). Most of these vaccination rates are below the 80% coverage targets of *Healthy People 2020* (U.S. Department of Health and Human Services, 2011).

Several barriers hamper adolescent vaccination. Some of these, such as parents' concerns about immunization side effects, lack of transportation, and cost, are similar to barriers to vaccinating younger children (Kaplan, 2010). Others, such as infrequent contact with the health care system, lower rates of insurance coverage, decreased likelihood of having up-to-date immunization records, and limited awareness of new adolescent vaccines may be specific challenges for vaccinating older children (Ford, English, Davenport, & Stinnett, 2009; Irwin, Adams, Park, & Newacheck, 2009; Kaplan, 2010; Kennedy, Stokley, Curtis, & Gust, 2012; Rand et al., 2007).

Schools are a promising setting for adolescent vaccination because teens spend significant time there, and schools enforce immunization requirements (Moss et al., in press;

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Shah, Gilkey, Pepper, Gottlieb, & Brewer, 2014). School health centers (SHCs) provide health services to enrolled students at clinics located in schools, including vaccination. A recent systematic review found strong evidence that vaccination programs in schools can be effective in improving vaccine uptake among children (Guide to Community Preventive Services [GCPS], 2009). Moreover, many parents are receptive to school-located delivery of adolescent vaccinations, with even higher acceptability among families whose children have not recently seen a doctor (Allison et al., 2007; Clevenger et al., 2011; Kadis et al., 2011; McRee, Reiter, Pepper & Brewer, 2013; Reiter, McRee, Pepper, Chantala, & Brewer, 2012; Reiter, Stubbs, Panozzo, Whitesell, & Brewer, 2011).

SHCs face two key challenges to adolescent vaccine delivery: parental consent for immunization (Cooper-Robbins, Ward, & Skinner, 2011; Kaplan, 2010) and expanding vaccine programs with limited staff resources. In response to these challenges, we worked with SHC staff to develop and implement an intervention to provide parents with clear, motivational messages about vaccination, while streamlining clinic processes for obtaining parental vaccination consent.

This article reports on the process evaluation of this effort. Process evaluation investigates how a program is executed in order to assess and improve implementation. Documentation of implementation strategies is also important for intervention dissemination and translation from research to practice (Linnan & Steckler, 2002; Saunders, Evans, & Joshi, 2005).

Our process evaluation addresses four questions:

1. What aspects of the vaccination program did SHCs modify during implementation?
2. To what extent did parents find the vaccination program materials and communications to be clear, informative, relevant, and persuasive?
3. How much staff time and SHC resources did intervention implementation require?
4. On completion of the intervention and its modification, how many parents had consented to at least one adolescent vaccination?

Method

Participants

Researchers with Cervical Cancer-Free North Carolina (CCFNC), a statewide collaboration to foster cervical cancer prevention practices and research, partnered with an organization that managed SHCs in all four traditional high schools in one district in central North Carolina. The district student population was 63% White, 20% African American, 11% Hispanic, and 6% Other race/ethnicity, and 59% of students were eligible for free and reduced lunch (Rockingham County Schools, n.d.). Study participants were parents of 2,975 students enrolled in the four SHCs in September 2011.

Procedure

We created a vaccine information packet that included a cover letter signed by the SHC's director, a promotional flyer, a consent form, two vaccine information sheets, and a preaddressed, stamped return envelope. Materials were two-sided in color, with Spanish translations on the back. The cover letter emphasized the convenience of the SHC, the need for and safety of adolescent vaccines, and the importance of returning a completed consent form. The promotional flyer emphasized similar points but also added quotes and images of parents and teens. We designed the consent form to limit the amount of information parents needed to provide, removing requests for information already available in SHC files, and focusing on allergies and previous vaccination background. In the consent area, we included a check box allowing parents to globally consent to all recommended vaccines, or an option to check individual vaccinations. One information sheet explained Tdap, meningitis, HPV, and seasonal flu vaccines, and the second information sheet explained vaccines recommended earlier in childhood.

SHC staff implemented several procedures to encourage consent form return. Staff mailed the packets to parents to ensure they received it. Both before and after packet mailing, staff used the school's automated phone messaging system to call all parents with reminders about the consent forms. They sent undelivered packets to parents in students' backpacks. Students who returned forms by a specified date had a chance to win four movie tickets. The intervention as originally designed appears in the top half of Figure 1.

Instruments

Materials Tracking Report. SHC staff documented how many vaccine information packets they mailed, received back undelivered, and sent home in student backpacks. Each clinic also tracked how many consent forms came back by the end of January 2012, how many of the returned forms were signed, and the specific vaccines to which parents consented.

Parent Interviews. Between November 2011 and January 2012, we conducted telephone interviews with a subsample of parents who had indicated a willingness to be contacted on their returned consent form. Of 62 eligible parents, we completed phone interviews with 47 (76%). The interview contained closed-ended questions assessing the extent to which parents found the materials to be clear, informative, relevant, and persuasive. Interviewers also invited parents to elaborate on their responses, identify gaps in the materials, and provide suggestions for packet improvement through open-ended questions. Parents received $10 grocery store gift cards in appreciation.

Resource Reports. CCFNC and SHC staff tracked resources used in intervention implementation. Tracked expenses included mailing labels, postage, packets, incentives, and

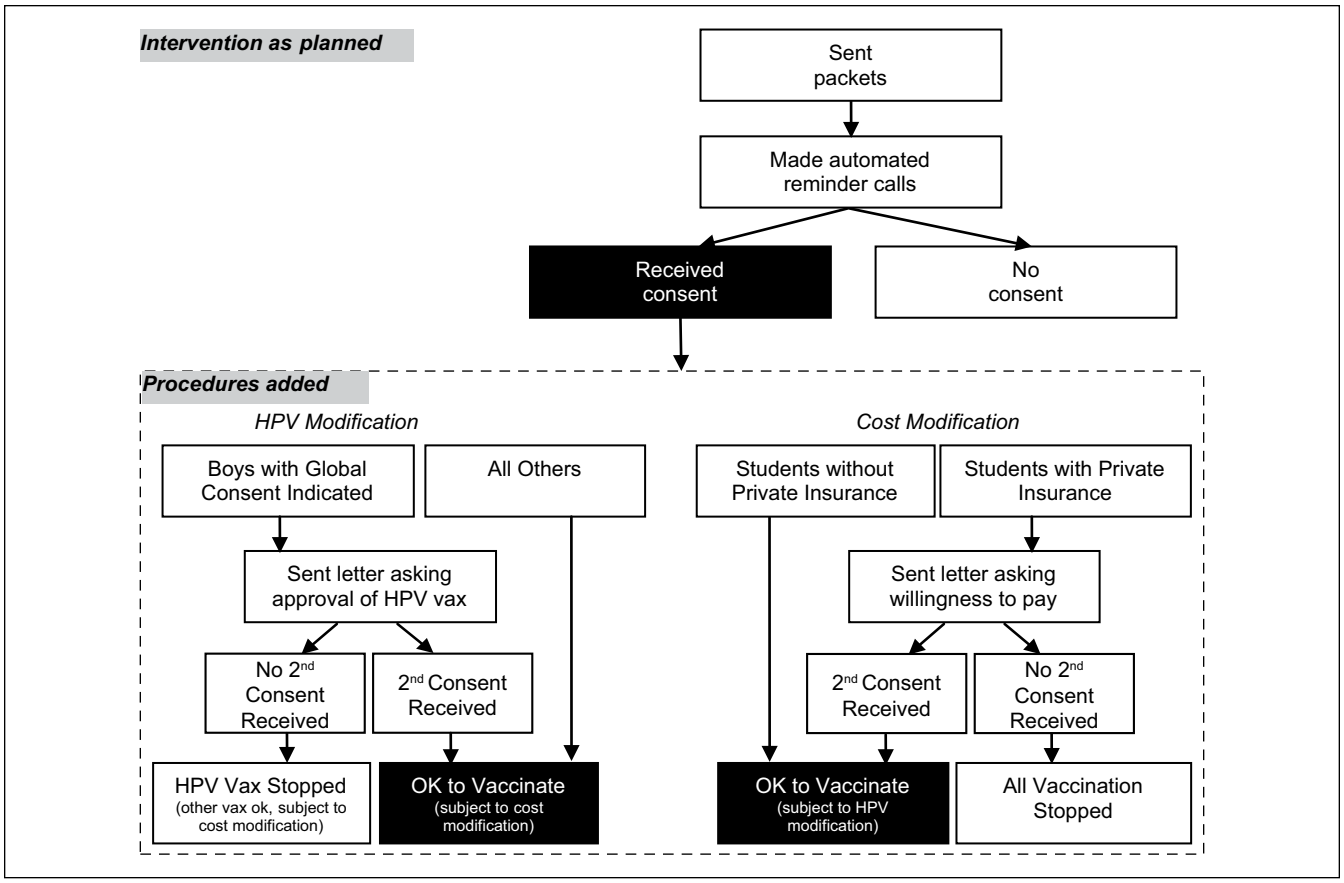

Figure 1. Intervention implementation as planned and modified.

other materials. Tracked time included person-hours required to prepare and send packets, remail packets, give undelivered packets to students, facilitate reminder calls, schedule vaccine visits, and complete additional intervention activities.

SHC Staff Communication. We communicated regularly with SHC staff through phone calls, e-mails, and site visits to document intervention implementation. We kept a communication log describing each discussion. After the intervention, we conducted a group debriefing to assess SHC staff perceptions of implementation barriers and facilitating factors.

Data Analysis

We analyzed quantitative data from the materials tracking report, the parent interviews, and the resource reports using SPSS Version 18 (IBM SPSS, Armonk, NY). Using qualitative data from parent interviews and staff communications, we identified themes related to our four process evaluation questions. For each data source, one CCFNC team member (SDG) first read through the open-ended material to identify topical codes and create a codebook. Two CCFNC team members (SDG, KEM) then independently used the codebook to identify themes that emerged from the data, resolving any discrepancies by consensus.

Results

Intervention Modifications

During implementation, we worked with SHC staff to make two modifications to the original intervention design. SHC staff had received questions from parents about the cost of needed vaccinations and whether consented male adolescents would receive the HPV vaccine. Both modifications consisted of additional communications with parents, as shown in the bottom half of Figure 1. The first modification was a letter and follow-up phone calls to 162 consenting parents of children with private health insurance that described the full price of each vaccine, and explained that parents would be responsible for paying any vaccine cost not covered by their insurance. The SHC was concerned that the increased demand for vaccine put them at risk for problems being reimbursed for vaccine costs and collecting administration fees. The second modification consisted of a letter and follow-up calls to the 79 parents who had consented to have their sons receive all recommended vaccinations (using the "check all" box), in order to confirm that parents knew

Table 1. Vaccination Consent Form Return and Consent.

School	Packets distributed (total)	Form unreturned	% of total	Form returned unsigned/without valid consent[a]	% of total	Form returned with consent for all vaccines	% of total	Form returned with consent for specific vaccines	% of total
1	660	541	82	46	7	51	8	22	3
2	739	641	87	25	3	59	8	14	2
3	840	704	84	51	6	66	8	19	2
4	736	609	83	47	6	70	10	10	1
Total	2,975	2,495	84	169	6	246	8	65	2

[a]Includes forms that came back unsigned, or came back without any indicated vaccines, or for which parents revoked vaccination consent following intervention modifications.

this global consent included HPV vaccine. These communications informed parents that the CDC recommends that boys receive HPV vaccine. For both modifications, SHC staff sought confirmation of the parent's original consent through parent signature or verbal authorization.

Parents' Perceptions of Intervention Materials

Nearly three quarters of the 47 parents interviewed remembered the mailed packet somewhat (51%) or very (23%) well, though less than half (43%) recalled receiving an automated phone call about the mailing. Almost all parents told interviewers they read the packet materials somewhat (43%) or very (49%) closely.

Parents generally found the intervention materials to be informative and persuasive. Most parents (70%) felt the materials increased their interest in vaccinating their children, though others noted the materials had no effect (28%), and one parent felt the materials lowered her vaccination interests (2%). Parents indicated that the intervention materials provided important details about which vaccines are recommended for adolescents, and several parents said they had previously been unaware of the HPV vaccination recommendation for boys. Parents also stated that the materials served as a reminder to determine whether their children were up to date on the vaccines and informed them that vaccines were available through the SHC.

Although most parents we interviewed found the materials clear and comprehensive, some parents recommended additions. Consistent with questions staff received, several parents indicated that vaccination materials could have better explained out-of-pocket costs, and how these compared with the amount they would pay for the same vaccines administered elsewhere. In addition, several parents wanted more information about the vaccination process at the SHC, including how staff would determine which vaccinations their children needed, when staff would give vaccines, and details about other SHC medical services.

Implementation Resources

Distributing the intervention materials, organizing and conducting automated and targeted telephone calls, facilitating communications associated with intervention modifications, fielding parent questions, and additional logistics consumed an average of 30 person-hours per SHC (range across SHCs: 18-52 person-hours). About half of this time (14 hours) was at the start of the intervention, as staff addressed and mailed packets. In addition, CCFNC research team members spent 78 hours assembling around 3,200 packets that we delivered to the SHC staff. Altogether, CCFNC and SHC staff spent an average of 4 minutes per packet. Presuming an hourly wage of $15 for packet assembly and $30 for other tasks, we estimate a total cost of $3.92 per prepared packet, comprising $2.45 for program materials (color printing, initial and return postage, and participation incentives) and $1.47 for labor.

Vaccination Consent

SHC staff mailed packets to 2,975 parents of students enrolled to receive care in their clinics (Table 1). Of these, 433 packets (15%) came back as undeliverable by mail, which SHC staff then sent home with students. Table 1 describes the final consent statuses, based on number of consent forms staff initially distributed and accounting for the consent confirmations the two intervention modifications required. About 10% (n = 311) of the consent forms came back with parent consent for at least one vaccine, and 84% (n = 2,495) were not returned. The remaining 6% (n = 169) of forms either came back without a valid consent (e.g., unsigned, no vaccines identified) or came with a consent that a parent later revoked. Of the parents who consented to vaccination, most (79%, 246/311) checked the box to consent for "all recommended" vaccines for teens, rather than indicating individual vaccines.

Each modification to the intervention resulted in the loss of initial consents, primarily because of lack of direct communication with targeted parents, rather than active refusal (Table 2). Of the 162 parents of privately insured children, 23% confirmed their consent after receiving the modification, 15% actively withdrew their consent, and 62% did not respond to the cost letter and were not reached by phone. Of the 76 parents of boys, 30% confirmed consent for HPV vaccine, 11% actively withdrew consent, and 59% did not respond to the letter and were not reached by phone. Success

Table 2. Intervention Modifications and Loss of Consent.

		Consent confirmed		Consent lost			
				Active refusal		Parent not reached	
	Consent form confirmation required[a]	*n*	%	*n*	%	*n*	%
Clarify vaccine costs (private insurance only)	163	37	23	24	15	102	62
HPV vaccine recommended for boys	76	23	30	8	11	45	59

Note. HPV = human papillomavirus.
[a]For cost clarification, the modification required confirmation of consent if parents had previously consented to any vaccination and were privately insured. For male HPV vaccination, the modification required consent confirmation if parents had originally consented to all necessary vaccines for a male student eligible for HPV vaccine.

contacting parents to confirm or revoke consent varied across sites, and only one reached the majority of targeted parents. SHC staff noted that time presented the biggest barrier to contacting parents.

Discussion

We implemented a low-resource intervention that successfully obtained consent for at least one vaccine from 10% of parents whose children were enrolled in a SHC. Previous research recommends childcare and school-based vaccination for younger children (Stubbs et al., 2014, GCPS, 2009), but evaluation of high school–located immunization programs is limited. A recent review of seasonal influenza vaccine specific programs documented high school coverage rates between 4% and 39% (Hull & Ambrose, 2011). Parents indicated the intervention materials were clear and persuasive and provided reminders about adolescent vaccination and information about the SHC vaccination program. Moreover, most parents who consented opted to provide global consent, using the "all recommended vaccine" checkbox, rather than identifying specific vaccines. Thus, it appears feasible for SHCs to deliver effective vaccination materials with relatively limited additional investment, once the materials have been developed. The process evaluation of this initiative, however, highlights several challenges for SHC vaccination programs that may limit program success if left unaddressed.

Information About Vaccination Cost and HPV for Boys

We identified two topics that likely require more explanation in vaccination program materials: vaccination cost and HPV vaccine for boys. Over one third of parents whom we successfully recontacted about vaccination cost, and one quarter of parents whom we successfully recontacted about male HPV vaccination, actively withdrew their consent, suggesting that parents needed more details about each to provide fully informed consent.

In contexts where vaccination costs depend on insurance status, providing cost information is important to both parents and SHCs. Previous research identifies cost as a key barrier for parent consent (Brewer et al., 2011; Brewer & Fazekas, 2007; Zimet et al., 2000), and difficulty navigating financial and insurance structures likely prevents some SHCs from offering comprehensive vaccination programs (Daley et al., 2009; Lindley, Shen, Orenstein, Rodewald, & Birkhead, 2009). According to parent interviews and staff feedback, parents want to understand the amount they will be required to pay out of pocket. However, communicating accurate cost information is difficult, as these amounts differ by vaccine and health insurance plan, with each insurance company offering hundreds of plans with different benefits. Even if materials listed the full price and covered amount of different vaccines for the most prevalent health insurance plans, parents' actual costs also depend on deductible levels and use. Unless recommendations to standardize vaccination costs and to expand the Vaccines for Children program (VFC) to cover administration fees for all eligible children and adolescents are implemented (Kaplan, 2010; National Vaccine Advisory Committee, 2009), SHCs will need to instruct parents to contact their insurance providers to determine out-of-pocket costs. Out-of-pocket costs should be less of an issue under the Patient Protection and Affordable Care Act (2010), as it requires private insurance policies to provide first-dollar coverage for vaccines.

SHC vaccination programs also need to disseminate clear information about HPV vaccine recommendations for boys. The Advisory Committee on Immunization Practices (ACIP) did not universally recommend HPV vaccine for boys until October 2011 (CDC, 2011). The vaccine materials we distributed in September 2011 used CDC language that described boys' HPV vaccination as an option rather than a recommendation. Parents may have had difficulty determining whether a global consent meant that boys would receive

HPV vaccine, and indeed staff fielded several calls from concerned parents. Previous studies found that only 20% of parents were aware that guidelines recommended the vaccine for boys (Reiter, McRee, Kadis, & Brewer, 2011), and a review of literature found widely varying rates of acceptability for HPV vaccine among mothers of sons (Liddon, Hood, Wynn, & Markowitz, 2010). Thus, even under the new ACIP guidelines, parents may need more education about this topic.

Partnerships Between SHCs and Researchers

Our process evaluation also provides insight on the utility of partnerships to enhance SHC vaccination processes. SHC staff and the CCFNC research team shared the ultimate goal of improving the health of adolescents through increased vaccination. Secondary priorities, however, likely differed between the two groups (Cooper-Robbins et al., 2011). The research team wanted to test intervention materials and processes, in part to determine the feasibility and value of disseminating the intervention to other SHCs. SHC staff needed to maintain the trust they had established with adolescents and parents, in order to ensure their ability to continue providing quality care. While these priorities usually aligned, they occasionally diverged, especially when intervention modifications in response to parent concerns compromised intervention fidelity. Modifications that required confirmation of previous parental consent taxed staff resources and resulted in significant loss of consent for vaccination.

In some cases, clear communication between partners about their priorities might avert implementation challenges. For example, during the materials development stage of our project, SHC staff had identified costs as a potential parental concern, and suggested including the list price of each vaccine in the mailed materials. The research team worried such information would be misleading, since list prices rarely reflect out-of-pocket costs, and opted to include a generic phrase about responsibility for noncovered costs. When parents contacted the SHC staff with questions about vaccination cost, however, the SHC staff felt they could not proceed with vaccination without providing the list price and confirming consent, fearing damage to their established relationship with parents.

Fortunately, when we needed to make modifications, SHC staff and the CCFNC research team worked together to quickly draft and distribute information. Our ability to do so was facilitated by the collaboration we had established during intervention planning. In retrospect, however, our planning process would have benefited from more communication. In an attempt to minimize SHC staff burden, the research team tried to limit the requests we placed on staff. Had we spent more time working with SHC staff in the planning stages to identify mutually satisfactory cost language, we may have avoided one intervention modification.

Of course, even the most thorough planning efforts will not prevent all intervention modifications. External events, such as new vaccination recommendations, can affect program processes or parent beliefs. Future SHC staff and research teams may want to establish a protocol to accommodate potential intervention modifications to minimize response time and program impact. Budgeting time to sufficiently implement unanticipated modifications will also be important.

Study Limitations

We did not track differences in adherence to implementation guidelines across clinics. As a result, we could not assess whether such differences existed and affected study outcomes. However, it is likely that SHCs will adapt any intervention to fit their workflow and staff capacity, and thus interventions must allow for some flexibility. The percentage of unreturned forms and overall consent rates were similar across the four sites, indicating that implementation variation did not result in substantial differences in participation.

More than one third of parents who returned consent forms did not sign them, identify which vaccinations their child should receive, or confirm consent following subsequent communications. In addition, most parents did not return the consent form. Prior vaccination is an important reason parents do not consent to school-located vaccination (Cooper-Robbins et al., 2011). This may be particularly relevant for the high school students in our study, as most of the vaccines on the form were recommended for younger adolescents. If parents of children who were or would be vaccinated elsewhere comprise the bulk of nonrespondents and refusals, our intervention may still have succeeded in reaching those parents who could most benefit from a school-located vaccination provider. Our methods did not allow us to determine the motivations of parents who did not return vaccination forms, primarily because patient privacy protections prevented us from contacting parents who did not return forms. In addition, our form allowed parents to mark consent for all recommended vaccines, or for specific vaccines, but did not include a third option that would allow parents to actively refuse consent. We were therefore unable to distinguish parent intent from parent error when blank forms were returned.

Implications for Practice

SHCs have emerged as a potentially important avenue for increasing vaccination rates among adolescents. Our process evaluation of a low-resource, multivaccine intervention illustrates the need for materials that contain information that is timely (e.g., HPV vaccination recommendations for boys) and relevant (e.g., out-of-pocket cost) in order to maximize consent. In addition, our results suggest two strategies for streamlining consent. First, providing a checkbox for parents to indicate global consent for all vaccinations for which their

teen is eligible is an option that proved popular among parents and may facilitate complete vaccination of teens. Second, a refusal check box, or a separate refusal form, as used in other programs (Boyer-Chuanroong, Woodruff, Unti, & Sumida, 1997) would allow staff to follow-up with parents who did not respond or who returned incomplete forms. Consent forms that let parents indicate reasons for refusal may inform future intervention efforts. In particular, if parents can indicate previous vaccination of their child, staff can target their outreach efforts efficiently. Finally, close collaboration among SHC staff and others involved in vaccination programs is critical for anticipating barriers and ensuring flexibility in implementation.

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Authors' Note

Ms. Turner was a graduate student in the Health Behavior Department at the time she worked on this project. The University of North Carolina Institutional Review Board approved the research.

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