

## C. PROPOSAL

### 1. Overall Goal and Objectives

This study aims to evaluate two communication trainings for family medicine physicians and pediatricians to improve their perceptions and provision of HPV vaccine. Coverage of HPV vaccination among US teens is low, far below Healthy People 2020 goals.<sup>1</sup> A central reason for low coverage is infrequent and inadequate healthcare provider recommendation of HPV vaccine.<sup>1,2</sup> We propose an intervention to train physicians to provide effective recommendations for the vaccine using participatory or efficient communication styles.

*Objective 1. Develop physician trainings on how to recommend HPV vaccine using participatory or efficient communication styles. Activities to reach this aim:*

- a. Survey a national sample of 375 primary care physicians to: assess perceptions of HPV vaccination; test training messages; and explore dissemination strategies.
- b. Integrate physician survey findings with findings from a survey of parents of adolescents (funded through a separate mechanism) and existing research literature to inform training development.
- c. Develop physician trainings for participatory or efficient communication with the aim of: educating physicians about HPV vaccination; increasing intentions to provide HPV vaccine; and imparting skills to effectively recommend HPV vaccine.
- d. Pilot test trainings in 2 clinics (not used in later aims). Refine the trainings based on formative research findings.

*Objective 2. Assess the impact of efficient and participatory trainings on physicians' perceptions of HPV vaccination and adolescents' vaccination status. Activities to reach this aim:*

- a. Conduct a 3-arm RCT comparing participatory physician training (10 clinics), efficient physician training (10 clinics), and no intervention control (10 clinics).
- b. Survey physicians regarding their vaccination perceptions before and after the training. Examine changes in vaccine perceptions among physicians in the intervention arms.
- c. Assess clinic-level HPV vaccination at 6-months post-intervention using clinical records obtained from the North Carolina Immunization Registry. Examine differences in adolescent vaccine coverage between intervention and control arms. The primary outcome is HPV vaccine series initiation at 6 months, and a secondary outcome is HPV vaccine series completion at 6 months.

*Objective 3. Assess the feasibility of providing training to physicians. Activities to reach this aim:*

- a. Assess the acceptability of communication training via a written survey of physicians.
- b. Assess costs of intervention delivery via staffing and expense tracking logs.

Trainings will focus on HPV vaccination, but will instruct physicians in how to make HPV vaccine recommendations as part of managing all vaccinations for their adolescent patients. This study will produce two sets of deliverables: 1) a package of evidence-based materials to support the national dissemination of the physician trainings; and 2) three manuscripts for publication in peer-reviewed journals.

## 2. Technical Approach

### 2a. Current Assessment of Need

**Widespread vaccination against HPV could dramatically reduce the incidence of cervical,<sup>3</sup> vulvar, vaginal, penile, anal, and possibly oropharyngeal cancers as well as genital warts.<sup>4</sup>** The Advisory Committee on Immunization Practice (ACIP) guidelines recommend routine vaccination for adolescents ages 11-12, with catch-up doses for females ages 13-26 and males ages 13-21.<sup>5,6</sup> ACIP adopted guidelines for routine vaccination in 2007 for girls<sup>5</sup> and 2011 for boys (although permissive recommendation for boys began in 2009).<sup>6</sup> Unfortunately, by 2011, the National Immunization Survey-Teen estimated that only slightly more than half of adolescent girls in the U.S. had received at least one dose of the three dose series.<sup>1</sup>

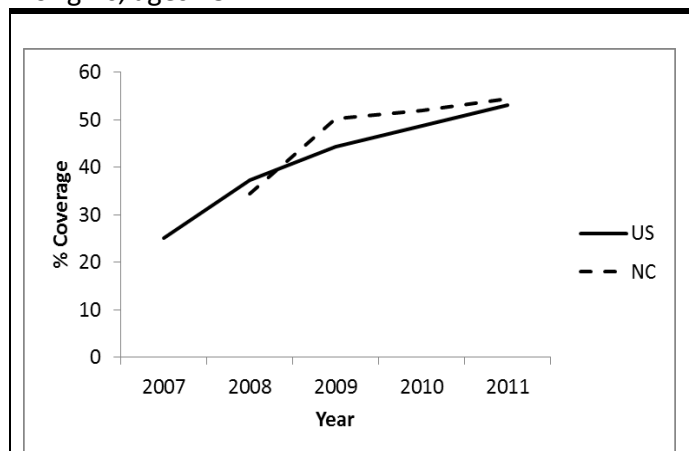
**State vaccination trends in North Carolina closely mirror national averages, making it an advantageous state in which to study HPV vaccination.** In North Carolina as in the nation, HPV vaccine uptake remains far lower among age-eligible adolescents than uptake of other recommended adolescent vaccines, including tetanus, diphtheria, and pertussis (Tdap) and meningococcal conjugate vaccine.<sup>1</sup> In North Carolina, Tdap vaccine coverage has markedly increased since its introduction in 2005 to 78% by 2011.<sup>1</sup> Meningococcal conjugate vaccine coverage has also increased steadily to 66%.<sup>1</sup> By contrast, HPV vaccine coverage has increased more slowly (Figure 1). Between 2010 and 2011, series initiation (i.e., receiving  $\geq 1$  dose) increased only modestly by 2 percentage points to reach 54% for girls with series completion reaching only 32%.<sup>1,7</sup> Our statewide surveys suggest that series initiation for adolescent boys in North Carolina is far lower at 14%.<sup>8</sup> A concerted effort will be needed to raise series completion for girls to the 80% goal set forth by Healthy People 2020.

**Physician's recommendation is a powerful motivator of HPV vaccination.**

In preparation for co-chairing a workshop for the President's Cancer Panel in fall 2012, Dr. Brewer systematically reviewed the literature on healthcare provider recommendation and HPV vaccine. The association between a doctor's recommendation and uptake was very large and highly robust across 7 studies of 18,955 patients (median odds ratio = 17.8).<sup>2,9-13</sup> For example, one recent study found a substantially higher HPV vaccine initiation rate among adolescent daughters of parents who had received a provider recommendation compared to those who had not (84% vs 20% initiation).<sup>13</sup> These findings demonstrate that physicians strongly influence parents' decisions about whether to get HPV vaccine for their adolescent children.

**Providers' hesitance to recommend HPV vaccine reflects both ambivalence about the vaccine and lack of skills and confidence for recommending it.** Though the majority of primary care physicians support routinely providing HPV vaccine to adolescents, their intentions to

**Figure 1.** Trends in HPV vaccine initiation ( $\geq 1$  dose) for girls, ages 13-17



recommend the vaccine per ACIP guidelines varies substantially due to beliefs and attitudes held about the vaccine and HPV in general,<sup>14</sup> as well as physician specialty.<sup>15</sup> Some providers are uncomfortable broaching topics related to sexual behaviors, including sexually-transmitted infections, with parents of young adolescents<sup>16</sup> which could explain the tendency for physicians to recommend the vaccine to older adolescents.<sup>16-18</sup> Many primary care physicians may also be employing a risk assessment strategy; they believe that the risk of contracting HPV among younger adolescents is lower than among older adolescents, and they expect to “catch” the adolescents before they become higher risk. For this reason, physicians may preferentially recommend the vaccine to those who are older and more likely to engage in sexual activity. Studies investigating physicians’ intent to vaccinate adolescents show a pattern that is consistent with this belief.<sup>19</sup> Additionally, providers are often unwilling or unable to engage with parents who are hesitant about having their teen vaccinated.<sup>20</sup> Physicians describe these conversations as time-consuming and detracting from job satisfaction.<sup>20</sup>

**Unfortunately, physicians often fail to provide effective recommendations for HPV vaccine.** Our CDC-funded CHIME Study in North Carolina interviewed 889 parents of adolescent girls in an area of the state with high rates of cervical cancer. The study found that only 27% of families had received a recommendation for HPV vaccine at baseline.<sup>2</sup> At follow-up, a little over a year later, only 38% of unvaccinated adolescents who had seen a doctor in the previous year had received a recommendation.<sup>2</sup> Another statewide survey of parents in North Carolina found that among adolescents who had not received HPV vaccine, 87% of males and 84% of females had a preventative care visit in which they could have received the vaccine but did not.<sup>8</sup> It is unsurprising then that one of the most common reasons parents give for not getting HPV vaccine is lack of a provider recommendation or clear provider-caregiver communication.<sup>1,2</sup>

**Providers need education and support in order to provide consistent and effective recommendations for HPV vaccine, but few evidence-based interventions are available.** At the time of HPV vaccine approval in the United States, a small literature of non-empirical papers provided recommendations to physicians and other health care providers on how to best communicate information and recommendations to have young women and adolescent girls vaccinated.<sup>21,22</sup> The papers proposed using a multi-modal approach to providing information about the vaccine and a collaborative decision-making process between providers, parents, and adolescent patients. More recently, research has investigated interventions to improve provider knowledge of HPV vaccine and provide better information to parents and adolescents.<sup>23</sup> “Educational tools” emerged as an important way to inform both providers and parents and facilitate vaccination.<sup>24</sup> However, these tools varied widely, and the evidence presented was qualitative in nature and did not clearly delineate best practices in regards to provider recommendations. The limited evidence-based data on what constitutes quality provider education points to the need to assess this area.

**Training providers to more effectively communicate about HPV vaccination is a promising approach.** Intervening directly with providers to improve their knowledge, attitudes, and communication skills is an “upstream” approach that stands to improve care for the many adolescents each provider sees each year. Communication training programs have been shown to have lasting effects<sup>25</sup> and to translate into improved consultation processes and patient health status.<sup>26</sup> Surprisingly, brief trainings seem to impact provider behavior as much as longer ones. Motivational interviewing, in which providers work with patients to explore their values

and goals, is a particularly well-studied communication approach; this strategy has been used effectively to change behaviors including smoking, nutrition, and medication adherence.<sup>27-30</sup>

**Research is needed to characterize what effective communication about HPV vaccination entails.** In addition to recommending HPV vaccine often, physicians must recommend the vaccine effectively. The success of patient-centered communication strategies suggests that techniques such as motivational interviewing will improve HPV vaccine uptake; indeed, some researchers have suggested this very approach as a way to explore patients' values thereby offering opportunities to build trust and tailor patient-provider communication.<sup>31,32</sup> At the same time, HPV vaccination is a health behavior quite different from smoking and other habitual, self-directed behaviors that typically constitute the focus of motivational interviewing. A more straightforward, "efficient" approach to recommending HPV vaccine may reduce ambiguity, and be more in keeping with the delivery of routine care.<sup>31</sup> In these ways, what constitutes quality communication with regard to HPV vaccination is not obvious, and medical educators have little evidence with which to guide their efforts in provider communication training.

**This study targets two primary audiences: primary care physicians and adolescent patients.** The proposed study aims to improve providers' perceptions and practices concerning HPV vaccination specifically and adolescent immunization more generally. In turn, this study aims to increase HPV vaccination rates among adolescents, thereby conferring protection from a range of diseases, including HPV-related cancers.

**The proposed research offers innovative solutions to the pressing public health challenge of low uptake of HPV vaccine.** This will be one of the first interventions that aims to improve provider perceptions of HPV vaccine, and one of few intervention trials aiming to increase HPV vaccine coverage. In addition, we will establish whether efficient or participatory approaches to communicating with patients yield higher HPV vaccine coverage. Many behavioral interventions are time and resource intensive, but clinical practice calls for approaches that clinicians can use quickly and effectively. For this reason, knowing whether a time-efficient approach increases HPV vaccination is of great relevance to clinical practice.

## *2b. Intervention Design and Methods*

Objective 1 centers on the development and pilot testing of communication training modules for physicians. Based on survey research findings and the expert opinion of a multidisciplinary advisory board, we will develop two theory-based training modules that will instruct physicians in recommending HPV vaccine using either an efficient or a participatory approach. We will pilot test the resulting trainings in 2 primary care clinics so as to identify "real world" barriers to implementation. In this way, we will use formative research to precisely tailor our intervention to match the needs of our target population.

### *2b.1. Survey a national sample of primary care physicians.*

**Participants and procedures.** We will contract with GfK Group, a large, multi-national research firm, to survey a national sample of 375 primary care physicians. Eligible physicians will be pediatric and family medicine physicians who provide routine primary care, including immunizations, to adolescents, ages 11-12. We will over-sample younger physicians, ages 35 or younger, who constitute a special focus of this study. Physicians will complete the brief (~10 minute) survey online and will receive GfK's standard incentives for participation.

*Measures.* The survey will consist of three parts. The first set of measures will assess physicians' perceptions of HPV vaccination, including knowledge of current practice guidelines; attitudes toward HPV vaccination in terms of safety, effectiveness, and parental acceptance; intentions to provide HPV vaccine to adolescents ages 11-12; confidence (or self-efficacy) to provide HPV vaccine recommendations; and key barriers to HPV vaccination. The second set of measures will test key training messages drafted by the study team. The third set of measures will explore physicians' preferences as to dissemination strategies for the training modules in terms of mode (e.g., in-person, online), venue (e.g., professional conferences, on-site CME training), and cost. We will use previously developed items, including those developed by our research group. If we need to develop new items, we will use our team's established methods of developing the items, vetting them with experts, cognitively testing them with the target population, and then pilot testing the instrument.

*Analysis.* We will use regression analyses to identify physician perceptions associated with HPV vaccination practices.

*2b.2. Integrate physician survey findings with parent survey findings and literature review.*

Prior to training development, we will integrate findings of the physician survey with two other sources of data to be collected by our study team in Fall 2013 via other funding mechanisms. First, we will review findings from a national survey of 1000 parents of adolescents, ages 11-18. This funded study will address perceived benefits and drawbacks of HPV vaccination as well as strategies for addressing identified challenges to having a child vaccinated. Second, we will also consider findings of a systematic review of healthcare providers' perceptions and provision of HPV vaccine. The goal of synthesizing survey findings and the existing literature is to provide a comprehensive and up-to-date review of barriers and facilitators to HPV vaccination that we will then use to prioritize training objectives.

*2b.3. Develop physician trainings for participatory or efficient recommendation of HPV vaccine.*

*Participants.* We will convene an advisory board to oversee the development of the physician communication training modules. The board will include pediatric and family practice physicians, parent advocates, and behavioral scientists with expertise in patient-provider communication, medical education, and evaluation.

*Materials and procedures.* Through an iterative process of design and feedback, the study team will work with the advisory board to create the efficient and participatory communication training modules. Each module will be designed to be taught in face-to-face meetings with providers. Training sessions are expected to last 40-50 minutes and will include three components:

**1. Didactic component to improve physicians' knowledge, attitudes, self-efficacy and intentions to vaccinate.** In the first part of the training session, an immunization educator (the study's project manager) will give physicians information on HPV vaccine, covering topics including effectiveness, safety, and the rationale for targeting adolescents ages 11-12, and low coverage rates compared to Tdap and meningococcal vaccine. Written materials, including a fact sheet, will underscore key messages. We will also provide a detailed clinical summary on HPV vaccine for providers who wish to learn more about the research evidence on vaccine efficacy and safety.

**2. Skills building component to improve communication practices.** In the second part of the training, the immunization educator will instruct physicians in how to deliver a recommendation for HPV vaccine using either the efficient or participatory approach. The form and content of recommendations, as described in greater detail below, will be captured in program materials including a written conversation guide as well as a reminder card consisting of key questions and phrases.

**3. Practice component to improve self-efficacy.** In the final portion of the training, physicians will practice making recommendations following the spirit of the “see one, do one, teach one” approach, thereby further improving their skills and confidence. The facilitator will offer feedback both during the training and in written comments delivered to physicians afterwards.

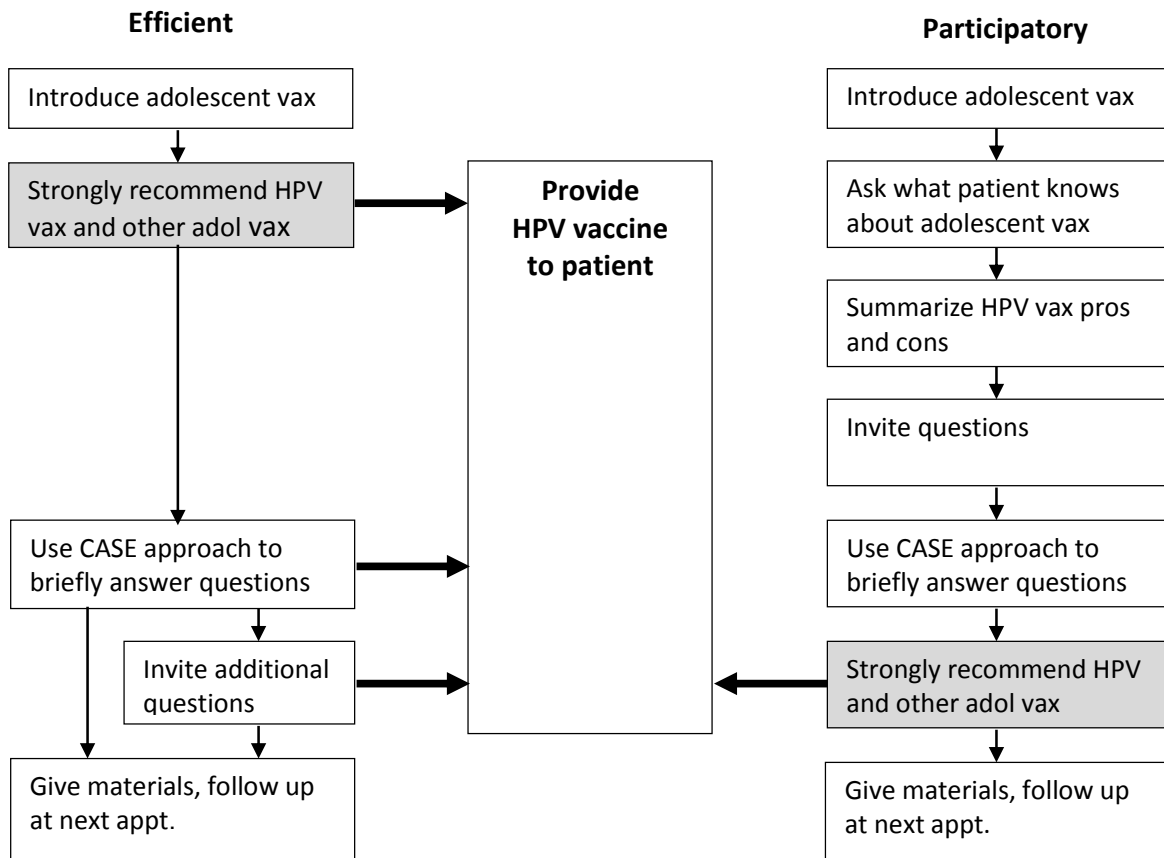
Participatory and efficient communication training modules will differ primarily in terms of the conversation guide that we will train physicians to use in recommending HPV vaccine (Figure 2). In the **efficient approach**, the physician will begin with a strong recommendation for adolescent vaccines, including HPV vaccine (e.g., “I strongly recommend these vaccines to all preteens in my practice. With your consent, we’ll get started.”) For parents/adolescents who give consent, the physician will administer scheduled vaccines without further discussion. For parents/adolescents who raise questions, the physician will then use messages and strategies learned in the training to address concerns. If parents/adolescents continue to express hesitancy, the provider will explore concerns in an open-ended fashion as time allows. The primary advantage of the efficient approach is that, for non-hesitant parents/adolescents, this strategy saves time. By foregrounding the provider’s recommendation and framing vaccination as an expected part of routine care, this approach may additionally inspire greater confidence in the recommendation. We anticipate that vaccine-related discussions using the efficient approach will last 1-2 minutes if parents/adolescents do not raise concerns and 5-7 minutes if parents/adolescents do raise concerns.

In the **participatory approach**, which is inspired by the tenets of motivational interviewing, the order of the discussion is reversed. The physician will begin by sharing information with the parent and then eliciting the parent’s/adolescent’s orientation toward vaccination with a question (e.g., “Before we get started, do you have any questions or concerns about these vaccines?”). The physician will next explore and address any concerns raised by the parent, in the same manner used in the participatory approach. The physician will close by giving his or her recommendation for HPV and other adolescent vaccines. The primary advantage of the participatory approach is that the physician actively elicits parents’/adolescents’ concerns in the beginning, thereby potentially engaging vaccine hesitant parents and building their trust. We anticipate that vaccine-related discussions using the participatory approach will last 4-5 minutes if parents/adolescents do not raise concerns and 7-9 minutes if they do raise concerns.

Participatory and efficient communication training modules will share certain features that support HPV vaccination. For example, both approaches will encourage physicians to give a strong recommendation for HPV vaccination alongside other adolescent vaccines; research suggests that this strategy of concomitant vaccination is more successful than singling out HPV vaccine as a special or different vaccine. Because Tdap is a school entry requirement for North Carolina sixth graders, concomitant HPV vaccination is an especially promising approach. Similarly, both communications trainings will focus on reducing missed opportunities by using

every office visit as an opportunity to vaccinate. In these ways, both training modules are designed to help physicians deliver a strong recommendation for HPV vaccine.

**Figure 2.** Two methods physicians can use to recommend HPV vaccine to patients.



We will develop brief scripts that address each element within the CASE approach (Table 1).<sup>33</sup> We will rely on our extensive experience with parent and adolescent attitudes toward HPV vaccine and other vaccines. Key perceptions generally follow the Health Belief Model: risks and benefits of vaccinating (e.g., safety), barriers to vaccinating (cost), and cues to action (doctor’s recommendation). HBM is a well-developed and widely-used model for understanding why people engage in health behaviors, and we have used the model to guide many of our studies about vaccination behavior.<sup>10,34,35</sup>

The role of the advisory board will be to assist the study team in further developing the training modules so as to make both the efficient and participatory approaches feasible in the context of the clinical encounter. The result of the development phase will be a package of materials to support implementation and dissemination of the training modules, including an intervention protocol, an evaluation guide, and related educational materials. The protocol will be a step-by-step guide designed to assist immunization educators in delivering the intervention with fidelity. Intervention materials will include a fact sheet and discussion guide to support physician communication.

*2b.4. Pilot test the participatory and efficient training modules.*

*Participants.* We will use the North Carolina Network Consortium to identify 2 primary care clinics to participate in pilot testing of the communication training modules. Within each clinic, we will assess HPV vaccine communication between 2 physicians and 3 of their adolescent patients, ages 11-12, and their parents (for a total of 4 physician and 12 encounters). Eligible clinics will be pediatric and family

practice clinics with 50 or more patients, ages 11-12, with active records in the registry. Eligible adolescents will be those who are accompanied by a parent and have not yet initiated HPV vaccine. We will offer incentives to clinics (\$1500), physicians (\$100), and families (\$30).

*Procedures.* We will obtain written informed consent from all physicians and parents participating in the study, as well as assent from adolescents. In each clinic, an immunization educator will deliver one training (participatory or efficient) to all physicians ( $n=4$  per clinic) in the clinic who recommend or administer vaccines. Training sessions will be brief (40-50 minutes). To evaluate the training modules from the perspective of participants, we will give a 25-item, self-administered questionnaire to physicians immediately following the training. We will additionally administer a 12-item follow-up survey to be completed and returned after the physician has practiced using the communication strategy with at least four patients.

To further evaluate physicians' ability to deliver recommendations with fidelity, we will audio-record medical encounters between 2 physicians and 6 adolescent-parent dyads per clinic (for a total of 4 physicians and 12 encounters). With each of the 4 physicians, we will also conduct 30-minute interviews which we will audio-record and transcribe.

*Measures.* The written survey of training participants will have items that assess physicians' satisfaction on the following dimensions: convenience, helpfulness, ease of understanding, length of session, instructor's effectiveness, and overall quality. The survey will also assess physicians' perceptions with regard to HPV-related knowledge and attitudes as well as intentions and self-efficacy related to recommending the vaccine to adolescents. Open-ended questions will elicit views on specific strengths and limitations of the training as well as suggestions for improvement. Follow-up surveys of physicians who have applied the approaches will assess the perceived acceptability and effectiveness, barriers to implementation, and intentions and self-efficacy to recommend HPV vaccine in the future.

We will assess audio-recordings of medical encounters to determine the fidelity with which physicians recommend HPV vaccine according to training guidelines. Measures will include:

**Table 1.** Example of CASE response to parent concern that HPV vaccination encourages sexual activity.

<b>Corroborate.</b>	It's true that there has been a lot of news coverage lately about the link between early sexual activity and HPV vaccine, so I can see why you might be concerned.
<b>About me.</b>	Vaccine safety is an issue I've followed closely for a long time. In fact, I attended a medical training about adolescent vaccination this year.
<b>Science.</b>	I can assure you that the safety of HPV vaccine has been thoroughly researched. The vaccine has not been linked to becoming sexually active. Although a small number of people do experience short-term side effects like soreness, the vaccine is very safe.
<b>Explain/advise.</b>	Delaying HPV vaccination will do nothing to prevent [NAME] from becoming sexually active, but delaying will put her at risk for getting HPV-related diseases like cervical cancer. I truly believe that getting HPV vaccine is the best thing for [NAME].



type of recommendation delivered (strong, optional, none), placement of recommendation (beginning, end), and use of questions to elicit concerns (yes, no). Interviews with physicians will focus on strengths and limitations of the approach as well as barriers to implementing.

*Analysis.* We will use descriptive statistics to analyze closed-ended survey data and content analysis to analyze open-ended data. We will use findings of these analyses to refine the communication training modules to address barriers and suggestions identified during the pilot.

## *2c. Evaluation Design*

The second phase of the study involves assessing the impact of the training modules on physicians' perceptions and adolescent vaccination coverage (Objective 2) as well as the intervention's feasibility (Objective 3). Using a 3-arm RCT with 30 primary care clinics as well as clinical records obtained from the North Carolina Immunization Registry, the study evaluation is designed to provide strong evidence of intervention effectiveness.

### *2c.1. Assess effect of physician trainings on adolescents' vaccination status.*

*Participants.* We will use data from the North Carolina Immunization Registry to identify pediatric and family practice clinics in the North Carolina Network Consortium with 50 or more patients, ages 11-12, with active records in the immunization registry. This study focuses on adolescents, ages 11-12, because this population constitutes the target age range for routine vaccination. Based on our prior work, we anticipate that 250 clinics will meet these criteria. All eligible clinics will be randomized to study condition, and the Consortium will then recruit the 20 intervention clinics based on condition assignment. Because control clinics will be passively assessed using the immunization registry, no recruitment is needed for these 10 clinics.

Within intervention clinics, providers eligible to attend the communication training will be physicians who recommend or administer vaccines. We estimate that on average 4 physicians from each clinic will attend a training, and we will aim for 80% participation. Given that younger physicians are less likely to hold perceptions that favor immunization, our recruitment team will extend special invitations to physicians with less than 10 years of practice experience since licensure. We will provide incentives to intervention clinics (\$1000) and physicians (\$100).

*Procedures.* After obtaining written consent from all training participants, we will deliver the intervention according to study arm: no intervention ( $k=10$  clinics); training on participatory communication ( $k=10$ ); or training on efficient communication ( $k=10$ ). The project manager will conduct training sessions. Trainings are expected to last 40-50 minutes and will be scheduled to occur during regularly scheduled clinic staff meetings when possible.

*Measures.* For all 30 study clinics, we will assess vaccine coverage levels among adolescents, ages 11-12. We will use immunization registry data to assess each clinic for coverage for HPV ( $\geq 1$  dose, 3 doses), meningococcal, and Tdap vaccines at two time-points: baseline and 6-months post-intervention. Our primary outcome measures will be HPV vaccine initiation among girls and boys, ages 11-12, at 6-months post-intervention.

*Analysis. Hypothesis 1.* *Both participatory and efficient communication training will improve HPV vaccine initiation, compared to no training.* To test this hypothesis in the full sample of 30 clinics, we will use logistic regression models to compare intervention clinics and control clinics on adolescents' HPV vaccination status ( $\geq 1$  dose) at 6-months-post-intervention. We will control for clinics' baseline level of HPV vaccine coverage and for clustering at the clinic level.

We expect to have 80% power to detect an 8% or larger absolute difference in HPV vaccine initiation between the control arm and the combined intervention arms (assuming alpha = .05). We anticipate that our intervention effect may be as large as 20%, based on the proportion of eligible patients (~40%) expected to visit clinics during the 6-month intervention period. To further assess intervention effectiveness, we will repeat this analysis for HPV vaccine series completion (3 doses) as well as receipt of meningococcal and Tdap vaccines.

**Hypothesis 2.** *Efficient communication training will be more effective than participatory training in increasing HPV vaccine initiation.* Using the same analytic approach, but only using data from the intervention conditions, we will compare the two intervention arms at 6-months-post-intervention in an exploratory analysis to determine which training module more successfully improves HPV vaccine initiation and completion.

### *2c.2. Survey physicians to assess effect of communication training on knowledge, attitudes, intentions, and self-efficacy related to HPV vaccination.*

*Participants.* Participants will be physicians ( $n=80$ ) in the two intervention arms.

*Procedures.* Before and after communications training, we will distribute 25-item, self-administered vaccine perception surveys to physicians. Surveys will take about 5 minutes to complete.

*Measures.* Closed-ended survey items will measure: 1) knowledge of HPV vaccination in terms of target age of administration, routine vaccination for boys, and Vaccine for Children (VFC) eligibility requirements; 2) attitudes toward HPV vaccination (safety, effectiveness, and acceptability to parents); 3) intentions to recommend HPV vaccine to adolescents ages 11-12; and 4) self-efficacy to provide HPV vaccine recommendations and address parents' vaccine-related concerns effectively. We will use previously developed items when possible. If we need to develop new items, we will use our team's established methods of developing the items, vetting them with experts, cognitively testing, and then pilot testing the instrument.

*Analysis. Hypothesis 3.* *Both efficient and participatory communication trainings will be effective in increasing physicians' knowledge, attitudes, intentions, and self-efficacy.* We expect both trainings to improve physicians' perceptions related to HPV vaccine recommendation. To test this hypothesis, we will analyze changes in pre-/post-survey scores by study arm with a meaningful increase for each item indicated by statistical significance and an average change of 0.5 points on a 5-point scale.

### *2c.3. Assess the acceptability of communication trainings to physicians.*

Concurrent with our assessment of trial outcomes, we will also examine the feasibility of our intervention in terms of: 1) its acceptability to physicians; and 2) the cost associated with the delivery of trainings. Acceptability measures constitute one important way to determine if the target audience (i.e., primary care physicians) was fully engaged in the intervention.

*Participants.* Participants will be physicians ( $n=80$ ) in the two intervention arms.

*Procedures.* We will assess acceptability of trainings via a 12-item evaluation survey that will be administered to physicians with the vaccine perceptions survey directly after the training.

*Measures.* As in the pilot project, a written survey of training participants will assess physicians' satisfaction using a 5-point response scale on the following dimensions: convenience, helpfulness, ease of understanding, length of session, instructor's effectiveness,

and overall quality. Additional open-ended questions will elicit comments on specific strengths and limitations of the training as well as suggestions for improvement.

*Analysis. **Hypothesis 4.** Efficient communication trainings will be more acceptable to physicians than participatory communication trainings.* Given the constraints of the clinical encounter, we anticipate that the efficient communication trainings will have more appeal to providers, leading to greater satisfaction with training. To test this hypothesis, we will analyze data derived from post-intervention surveys of physicians using *t*-tests of mean satisfaction scores. Regardless of differences between arms, we anticipate that both trainings will be highly acceptable, with mean satisfaction scores of at least 4.0 on a 5-point response scale.

*2c.4. Asses the acceptability of using efficient or participatory communication approaches to physicians.*

*Participants.* Participants will be physicians ( $n=80$ ) in the two intervention arms.

*Procedures.* To assess physicians' experience of actually using the recommended communication approach (participatory or efficient) with patients, we will survey them. During the training, we will ask physicians to practice using the communication approach with at least 4 of their adolescent patients. Physicians who agree to do so will write their "implementation intentions" on the face page of a 12-item written follow-up survey; the simple act of writing a plan in this way has been shown to be a powerful motivator of behavior. We will ask physicians to complete and return the survey after using the communication approach with 4 patients. Closed- and open-ended survey items will assess aspects of acceptability as outlined by Bowen and colleagues, including extent of use, satisfaction with the approach, self-efficacy, intent to continue to use, perceived positive or negative effects of use, and barriers to use.

*Analysis. **Hypothesis 5.** The efficient communication approach will be more acceptable to physicians than the participatory approach.* We anticipate that, by fitting better into clinic flow, the efficient communication approach will be more acceptable to physicians in terms of their satisfaction, self-efficacy, and intentions to continue use. To test this hypothesis, we will use *t*-tests to compare mean item scores between intervention arms.

*2c.5. Assess the cost of intervention delivery.*

*Participants, procedures, and measures.* To determine the cost of delivering the intervention, the project coordinator will keep an expense log to track the staff time that he/she and other study personnel devote to implementing the intervention. The coordinator will also log material- and travel-related costs.

*Analysis.* For the 20 intervention clinics, we will calculate the total cost of delivering the intervention by study arm. We will use these totals to calculate: 1) average cost per clinic; and 2) average cost associated with improving HPV vaccine initiation by 1 adolescent. We will use *t*-tests to compare these averages between intervention arms.

*2c.6. Disseminate project findings.*

This study is designed to produce two sets of deliverables for the dissemination of study findings. First, we will develop a package of evidence-based materials to support the national dissemination of the training module. At the beginning of Year 3, we will enlist the help of our advisory board to create a dissemination plan that will identify professional organizations and

funding opportunities to institutionalize communication training in healthcare settings. Materials developed during this study will include an intervention protocol and evaluation guide to support as well as a facilitator's guide to support the training.

We see two primary vehicles for disseminating our intervention: 1) AFIX consultations delivered by state health departments; and 2) Maintenance of Certification (MOC) board requirements. The AFIX program (or, Assessment, Feedback, Incentives, & eXchange) is a quality improvement program proven to raise immunization coverage via brief consultations with primary care providers; health departments in all 50 states currently implement the program. While the AFIX protocol does encourage providers to screen for vaccine eligibility at each clinical encounter,<sup>36</sup> it does not provide suggestions on how to talk with patients and their parents. The Feedback session, which includes time for provider education, is a prime opportunity for enhancing patient-provider communication skills. The provider training we propose to develop could be delivered in conjunction with AFIX visits.

Maintenance of Certification, a process by which primary care providers fulfill board requirements, is a second promising avenue for dissemination. Depending on our findings, we will seek to qualify one or both of our trainings to fulfill MOC requirements. In this way, we could provide a strong incentive for physician participation.

We will disseminate study findings more broadly via journal publications and conference presentations. We will draft three manuscripts for peer-reviewed publication to share the findings of formative, process, and outcome evaluations. We will also present this work at conferences, including the annual meetings of the Pediatric Academic Societies and the Society of Behavioral Medicine. Through these outlets, we will share evidence relevant to understanding the effectiveness of the training model as well as broader lessons learned about the impact of provider communication style on the provision of preventive care to adolescents.

### **3. Detailed Work Plan and Deliverables Schedule**

Year 1 will include administrative preparation, formative research, and intervention development. In Quarter 1 (Q1), we will hire a project coordinator, file an IRB application, draft the physician survey, and recruit 2 clinics to participate in pilot testing. In Q1-2, we will contract with GfK to pilot test and administer the physician survey. In Q2-3, we will convene the advisory board and develop the communication trainings. In Q4, we will pilot test and refine the trainings, while simultaneously recruiting clinics to participate in the RCT. In Q4, we will also draft 1 manuscript and 1 conference abstract based on the findings of the physician survey.

In Year 2 we will conduct the RCT. In Q1-2, we will deliver communication trainings to the 20 clinics in the intervention arms, and we will conduct survey research of physicians. We will use the North Carolina Immunization Registry to assess baseline immunization coverage levels at all 30 clinics. In Q3-4, we use the registry to determine 6-month-post-intervention immunization coverage levels. In Q4, we will conduct data cleaning and preliminary analyses.

Year 3 will consist of data analysis and dissemination. In Q1-2, we will complete the analysis of outcomes and process findings, resulting in two journal manuscripts and two conference abstracts. In Q2, we will reconvene the advisory board so as to present study findings, refine intervention materials, and assign dissemination tasks. In Q2-3, we will disseminate findings via the advisory board to CDC and seek MOC certification so as to foster institutionalization of trainings. We will also pursue additional funding for further testing and development.

**Table 2.** Deliverables schedule.

Deliverable	Description	Completion
Intervention materials (draft)	Training materials (fact sheets, clinical summaries, discussion guides); intervention protocol; evaluation guide; facilitator's guide	Year 1, Quarter 4
Physician survey findings	1 journal manuscript and 1 conference abstract	Year 1, Quarter 4
RCT study findings	2 journal manuscripts and 2 conference abstracts	Year 3, Quarter 2
Intervention materials (final)	Training materials (fact sheets, clinical summaries, discussion guides); intervention protocol; evaluation guide; facilitator's guide	Year 3, Quarter 2
Dissemination activities	Present findings to CDC; obtain MOC certification for trainings	Year 3, Quarter 3

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