EVALUATING THE FEASIBILITY OF A MOBLIE COACHING INTERVENTION TO IMPROVE HPV VACCINE DELIVERY

Support Provided by: *The National Cancer Institute (*R21CA241518*); Lineberger Comprehensive Cancer Center; Cancer Control Education Program at the University of North Carolina Lineberger Comprehensive Cancer Center*.

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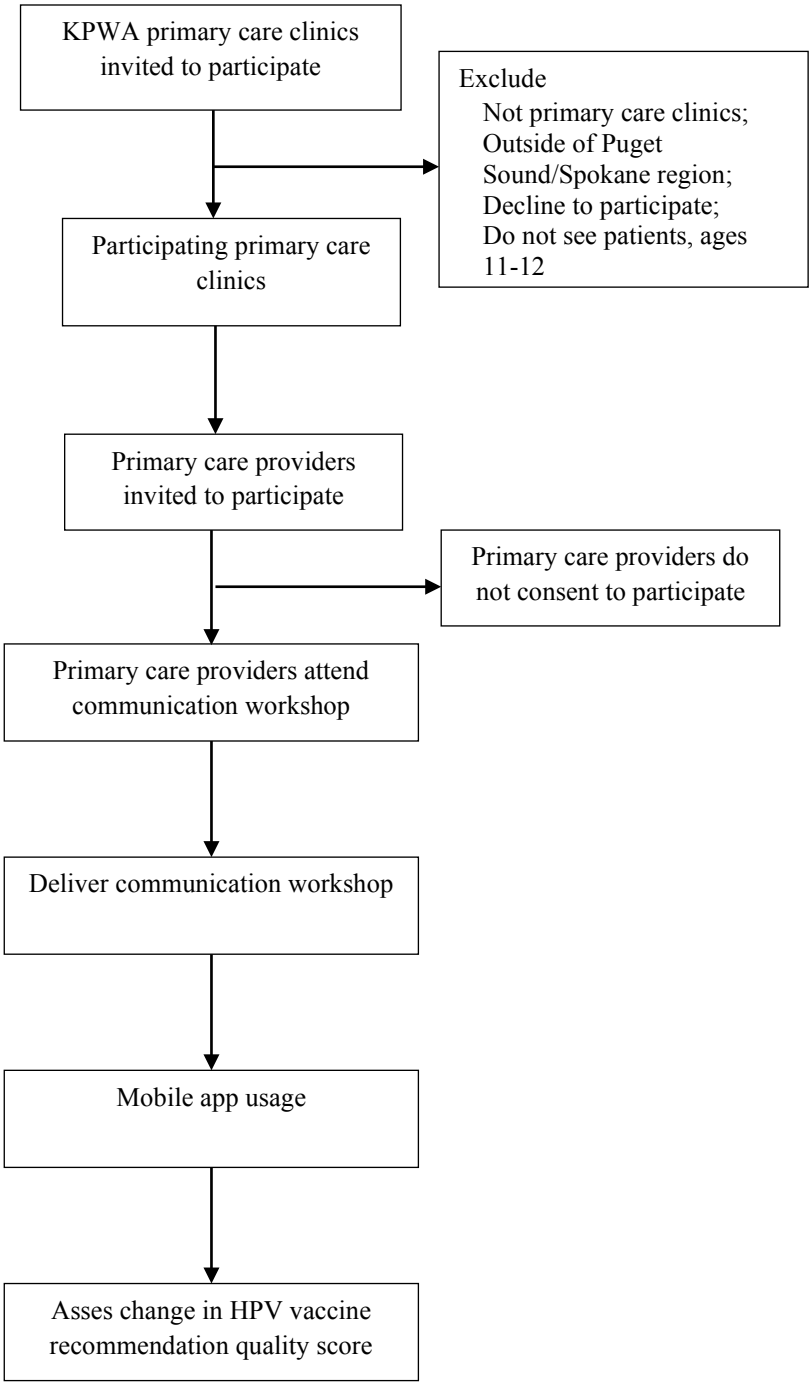
PROTOCOL SUMMARY

Title:	Evaluating the Feasibility of a Mobile Coaching Intervention to Improve HPV Vaccine Delivery
Summary:	The purpose of this study is to examine the feasibility of using Checkup Coach, a mobile coaching intervention, to improve the way that primary care providers recommend HPV vaccination to adolescent patients and their parents. To conduct this feasibility study, we will deliver the Checkup Coach intervention to Kaiser Permanente Washington primary care providers who routinely recommend HPV vaccine to adolescent patients. We will use a single-arm, pre-post design. Participating primary care providers will attend a 1-hour virtual communication workshop and then use a mobile phone app to receive additional coaching for 12 weeks. Providers will complete surveys at three time points: before the communication workshop, immediately after the workshop, and at 12-week follow-up. Surveys will assess changes in providers' self-reported HPV vaccine recommendation practices and beliefs about HPV vaccine, as well as the acceptability of the intervention. We hypothesize that providers' HPV vaccine communication will improve between baseline and 12-week follow-up.
Objectives:	To evaluate whether the Checkup Coach intervention improves providers' HPV vaccine recommendation quality. Primary outcome measure: The change in providers' composite score on a 5-item index of self-reported use of HPV vaccine communication practices from baseline to 12-weeks post-intervention.
Sample:	Primary care providers who treat 11-12 year old patients in participating Kaiser Permanente Washington pediatric and family medicine practices.
Phase:	Not applicable

Study Duration:	June 21, 2021 through January 14, 2022
Participation Duration:	Providers will attend a one-hour communication training workshop and use the Checkup Coach mobile phone app at their discretion for 12 weeks.
Description of Intervention:	The Checkup Coach intervention is a 1-hour virtual workshop on HPV vaccine communication, followed by 12 weeks of access to a mobile app that provides additional coaching.
Estimated Time to Complete Enrollment:	4 months

Schematic of Study Design:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

HPV is a highly prevalent sexually transmitted infection associated with over 34,000 cancers in the US each year. The annual cost of screening and treatment for HPV-related diseases totals $8 billion. Widespread HPV vaccination could prevent the infections that lead to most of these diseases, making the vaccine a powerful tool for cancer prevention.

National recommendations are for the completion of the 2-dose HPV vaccine series at ages 11-12. Timely completion is critical for protecting youth before HPV exposure and may enhance immune response. On-time vaccination, however, is not the norm in the US, with coverage at just 39% for 13-year-olds in 2017. This coverage is far below the Healthy People 2020 goal of 80% for ages 13-15, and suggests that interventions are urgently needed to improve uptake.

The present study seeks to improve healthcare providers' communication about HPV vaccine which is critical to increasing uptake. A provider's recommendation is among the strongest predictors of HPV vaccination. Adolescents who receive a high-quality recommendation versus none have over 9 times higher odds of series initiation. Additionally, interventions that include provider communication training improve HPV vaccination coverage.

Mobile apps are a promising way to extend provider training. Most providers use mobile devices professionally, and apps are an increasingly common vehicle for provider education. Whether app-based coaching could improve providers' HPV vaccine communication is unknown. However, the approach has been successfully piloted in other contexts (e.g., critical care), suggesting promise.

2.2 Rationale

Our study seeks to evaluate the feasibility of Checkup Coach, a quality improvement (QI) coaching intervention, including a mobile app, that we have developed to deliver HPV vaccine communication training. At the provider level, Checkup Coach is designed to improve HPV vaccine communication via ongoing assessment and tailored feedback.

At the clinic level, the app will provide quality improvement tools, including graphs of clinics' and providers' HPV vaccine coverage (i.e., % of patients vaccinated), for tracking shared goals for improvement. We will conduct this study to evaluate the feasibility of using the QI coaching intervention to improve HPV vaccine communication in primary care settings. If successful, this study will inform the future development of a randomized controlled trial to examine the impact of the Checkup Coach intervention on HPV vaccine uptake.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Potential short-term risks associated with participation include healthcare providers' loss of time and slight risk of embarrassment or discomfort in answering questions about their HPV vaccine recommendation practices. However, because the communication workshop is brief (<1 hour) and app use is discretionary, we expect loss of time to be minimal. Additionally, providers will have the option to refuse to answer any survey questions and can decline to use the mobile app. All answers to survey questions and data entered into the app will be kept confidential. Thus, the risk of embarrassment is anticipated to be very slight.

We do not anticipate immediate or long-range risks associated with participation.

2.3.2 Known Potential Benefits

By participating in this study there is a potential to increase provider knowledge and confidence for recommending HPV vaccination as a routine preventive service for adolescents. This study will also help inform a future larger randomized trial of the Checkup Coach intervention. The goal of that trail would be to develop a quality improvement tool that will help increase HPV vaccination coverage which could reduce the future incidence of HPV-related cancers.

3 OBJECTIVES

3.1 Study Objectives

The purpose of this study is to examine the feasibility of using Checkup Coach, a QI coaching intervention, to improve primary care providers' use of evidence-based communication practices to support routine HPV vaccination.

3.2 Study Outcome Measures

Outcome measures will be changes in providers' HPV vaccine recommendation practices and the feasibility of the Checkup Coach quality improvement intervention. Data will come from provider surveys at three time points and mobile app usage data.

3.2.1 Primary Outcome Measures

For each participating provider, we will assess the change in composite score on a 5-item index of self-reported HPV vaccine recommendation quality from baseline to 12-week post-intervention. Scores range from 5-25 (5 indicating the lowest quality score to 25 indicating the highest quality score).

3.2.2 Other Measures

We will assess the feasibility of the Checkup Coach intervention by evaluating:

- Use of the Checkup Coach mobile coaching app (measured as % of providers who use the Checkup Coach mobile app, assessed using app analytics; and measured as the mean number of times that app users access the app, assessed using app analytics).
- Intervention acceptability (measured as mean ratings for intervention convenience, organization, helpfulness, and whether participants would recommend it to a colleague, assessed using 5-point survey items).

4 STUDY DESIGN

This study will evaluate the Checkup Coach intervention using a single-arm, pre-post design with approximately 20 primary care providers at Kaiser Permanente Washington (KPWA). The intervention has two main components. In the first part of the intervention, participants attend a communication training workshop via a virtual conferencing platform. The workshop will be conducted by study staff and the KPWA Director of Preventive Care. The brief (<1 hour) workshop reviews evidence on HPV vaccination, models guideline-consistent recommendation practices, trains providers to address common parent concerns, and facilitates discussion of shared goals for improving. Workshop content is evidence-based and reflects communication practices supported by research evidence and recommended by the Centers for Disease Control and Prevention. At the end of the workshop, providers are asked to download and practice using the Checkup Coach mobile app.

In the second part of the intervention, which starts after the communication training, providers are invited to use the Checkup Coach mobile app for 12 weeks. The app is a QI tool designed to provide tips and tools for improving HPV vaccine communication. App functions include: (a) provider self-assessment of HPV vaccine recommendation practices; (b) feedback on their HPV recommendation quality in the form of a “recommendation goal score”; (c) research-tested messages for addressing parent concerns that are tailored to in-app self-assessments; and (d) a dashboard with graphs of provider- and clinic-level HPV vaccination coverage (i.e. % of 11-12 year old adolescents vaccinated).

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria

In order to be eligible to participate in this study, a provider must:

- Be a primary care provider in an invited KPWA pediatric or family medicine clinics in the Puget Sound/Spokane area
- Regularly treat adolescent patients, ages 11-12

5.2 Subject Exclusion Criteria

Providers not eligible to participate:

- Provide care in a clinic not invited to participate in the study
- Do not regularly treat adolescent patients, ages 11-12

5.3 Strategies for Recruitment and Retention

The KPWA Medical Director for Preventive Care will identify KPWA primary care clinics in the Puget Sound/Spokane area that administer HPV vaccine to adolescent patients, ages 11-12. He will invite clinics to participate in the study by contacting each site's clinical director. Once clinical directors agree to have their clinics participate, study staff will invite all primary care providers who regularly treat 11-12 year old patients in each clinic to participate.

5.4 Treatment Assignment Procedures

5.4.1 Randomization Procedures

None.

5.4.2 Masking Procedures

None.

5.4.3 Reasons for Withdrawal

Participants who request to withdraw will be given the option to discontinue participation in the intervention but continue participation in follow-up data collection activities. Participants who refuse this offer and request to completely withdraw from the study will no longer be contacted. There will be no investigator-initiated withdrawal.

5.4.4 Handling of Withdrawals

See above.

5.4.5 Termination of Study

Given the low-risk nature of this study, we do not anticipate grounds for premature termination.

6 STUDY INTERVENTION

6.1 Study Intervention Description

The Checkup Coach intervention offers two main components to primary care providers who care for adolescent patients: a webinar communication workshop and use of the Checkup Coach mobile app.

1. **Communication Workshop**. The Checkup Coach intervention begins with a brief (<1 hour), communication training workshop. Using a script and slides, the KPWA Director for Preventive Care and the study PI will meet with participating providers over a web-based meeting platform to: review evidence on HPV vaccination; model high-quality, guideline-consistent recommendations; train providers to address parent concerns; and facilitate discussion of shared goals for improving.

   At the end of the training, providers will be asked to download and begin using the Checkup Coach app. Downloading and using the app will be voluntary, and providers can consent to participate in the webinar training but decline all other study activities.

2. **Checkup Coach app**. Providers will be invited to use the Checkup coach mobile app at their discretion for the 12 week study period. If they have push notifications enabled, providers will be sent push notifications reminding them to use the app up to six times over the 12 week period. Providers will complete the in-app self-assessments and receive tailored feedback every time they use the app.

   A detailed description of the Checkup Coach self-assessment and tailored feedback is as follows:

   - Self-assessment of recommendation quality. Providers complete a very brief in-app self-assessment to determine how often in the last week they used 5 practices effective for recommending HPV vaccine according to national guidelines. Guidelines include delivering recommendations on time (i.e., ages 11-12), consistently to all eligible patients, and offering same-day vaccination services when possible. The app adds 5-point

response options to give an overall score and to identify areas for improvement.

- Recommendation Goal Score. The app displays a bar chart of providers' overall self-assessed recommendation quality score in reference to the goal of 5 (i.e., "almost always" using all 5 practices).
- Dashboard. The app presents line graphs of aggregate HPV vaccination coverage (i.e., % of patients vaccinated) over the study period for both the individual provider and their clinic.
- Tips for addressing HPV vaccine communication challenges. Providers complete an in-app 5-item self-assessment to identify parent concerns they "often" or "almost always" find difficult to ease. The app pulls from a library of 15 messages to suggest a research-tested response tailored to each concern (called "Tips for Talking to Parents" in the app). Those who indicate no concern receive randomly selected messages with encouragement to keep up their good work.

6.2 Dosage, Preparation and Administration of Study Intervention

Each primary care provider will attend one communication workshop which will last less than one hour. They will then be able to use the mobile app, at their discretion, for up to 12 weeks.

6.3 Modification of Study Intervention for a Subject

Not applicable.

6.4 Accountability Procedures for the Study Intervention

Not applicable.

6.5 Assessment of Subject Compliance with Study Intervention

Not applicable.

6.6 Concomitant Medications/Treatments

Not applicable.

7 STUDY SCHEDULE

7.1 Screening

Screening of eligible clinics and providers will be conducted by the KPWA Director of Preventive Care, using data from KPWA's internal records.

7.2 Enrollment/Baseline

Enrollment and pre-workshop data collection will occur simultaneously from July – September 2021. Communication workshops and post-workshop data collection will occur in the same period, from July – September 2021.

7.3 Follow-up

Mobile app use and data collection through the app will occur from July – December 2021. Twelve-week follow-up data collection will occur from October 2021 – January 2022.

7.4 Final Study Visit

Not applicable.

7.5 Early Termination Visit

Not applicable.

7.6 Unscheduled Visit

Not applicable.

8 STATISTICAL CONSIDERATIONS

8.1 Study Hypotheses

The Checkup Coach intervention will increase providers' HPV vaccine recommendation quality score.

8.2 Sample Size Considerations

We will test our hypothesis that Checkup Coach will increase providers' overall recommendation quality over the 12-week study period with approximately 20 providers. We acknowledge that our trial is underpowered to detect small differences or control for multiple testing. The purpose of a feasibility study is to estimate effect sizes for powering a large-scale RCT. By piloting our intervention in 5 or more different clinics, our study is designed to provide the data needed to lay this groundwork.

8.3 Planned Interim Analyses (if applicable)

Not applicable.

8.4 Final Analysis Plan

To assess change in providers' HPV vaccine recommendation behavior, we will compare providers' mean recommendation quality index scores between baseline and 12-week follow-up using Wilcoxon signed-rank tests. To assess changes in providers' cognitions and perceptions of their social environments, we will use Wilcoxon signed-rank tests to compare mean scores for each survey item and the knowledge index item (scores ranging from 1-5) between the baseline and post-workshop surveys and the baseline and 12-week follow-up surveys.

9 ETHICS/PROTECTION OF HUMAN SUBJECTS

9.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6; 62 Federal Regulations 25691 (1997).

9.2 Institutional Review Board

Study procedures have been approved by the Kaiser Permanente Washington Health Research Institute Human Subjects Review Office.

9.3 Informed Consent Process

Informed consent will be obtained from all participating providers, via Qualtrics online survey software, prior to participation in baseline data collection and the communication workshop.

9.4 Exclusion of Women, Minorities, and Children (Special Populations)

Not applicable.

9.5 Subject Confidentiality

Subject confidentiality is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. The study team will take precautions to ensure that subject confidentiality is maintained. All data will be stripped of patient-level identifiers and stored on a password-protected server accessible only to UNC study staff. Data will be reported in aggregate and will not identify participating clinics or providers by name.

9.6 Study Discontinuation

Not applicable.

9.7 Future Use of Stored Specimens

Not applicable.