NCT03599557- The STOP-HPV Trial 1: Communication Intervention

Clinician Consent form

Date: 7/9/2018 (UCLA IRB #17-001772)

Practitioner Consent for Participation
Study Title: Improving HPV Vaccination Delivery in Pediatric Primary Care: The STOP-HPV Trial
Principal Investigators: Dr. Peter Szilagyi and Dr. Alexander Fiks

Introduction:
This consent form describes this research study and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask questions before making your decision about whether or not to participate.

This study is being conducted by Dr. Peter Szilagyi from the University of California – Los Angeles (UCLA) and Dr. Alexander Fiks from the Children's Hospital of Philadelphia (CHOP), with statistical support provided by the University of Pennsylvania (PENN). It has been approved by the Institutional Review Boards (IRBs) at UCLA, CHOP, and the American Academy of Pediatrics (AAP).

We are asking up to 50 practices to complete this study.

Purpose of Study

The overall goal of this study is to assess the impact of practitioner:

- Training on how to communicate about the HPV vaccine
- Performance feedback on the prevalence of missed opportunities for HPV vaccination among 11-17 year-olds
- Use of HPV vaccine prompts

Eligible practices will be asked to:

- Be in the study for approximately 28 months

Study Group	Participation
Intervention	Active participation for 28 months
Comparison	Active participation for the last 7 months

- Participate in the study procedures (see below)
- Allow your EHR vendor / health system or a designated administrator to securely share a HIPAA-limited dataset from your practice medical records with the Children's Hospital of Philadelphia, for the purposes of this study.

Study Procedures
If you decide to participate in this study, you will be asked to do the following:

1. Complete and return PROS Intake forms - practice and individual practitioner characteristics will be shared with the research team for study analysis and indefinitely retained in the PROS member database
2. Agree to not participate in any other HPV-related studies or projects for the duration of the study
3. Participate in a study training call/webinar (PROS will provide details)
4. Decide whether to receive Maintenance of Certification (MOC) Part IV credits for participation in study activities

5. You may be designated to complete monthly online surveys (~5-15 minutes each). One of these surveys will be approximately ~10-30 minutes long. Only one person per practice will be asked to complete these surveys.

If your practice is randomized to the Intervention group, practitioners and staff will also be asked to phase in the following over time (total time commitment will be ~6-7 hrs over 28 months):

- Participate in online activities on how to communicate about the HPV vaccine. Your clinical staff will also be asked to participate
- Review periodic performance feedback reports with online training and explanatory videos (sent by text or email
    - Performance feedback reports will list:
        1) Your HPV vaccination rates
        2) Your practice's overall vaccination rates
        3) Your study group's overall vaccination rates
    - You will be the only one who can see your own vaccination rates in these reports. If you are in a small study practice, it might be possible for others to back-calculate your rates based on their rates and the rates of the overall practice.
- Participate in one online activity on prompts to vaccinate. Your clinical staff will also be asked to participate

Online activities will be provided virtually and asynchronously, with links delivered via text message or email.

- Receive quick tips from the study team via text message approximately once weekly – you will be asked to provide your cell phone number to receive these text messages
- Complete 4 surveys throughout the study (~5-15 minutes each)

If your practice is randomized to the Comparison group, during the final seven months of the study practitioners and staff will also be asked to phase in the following over time (total time commitment will be ~ 3.5-5 hrs over 7 months):

- Participate in online activities on how to communicate about the HPV vaccine. Your clinical staff will also be asked to participate
- Review periodic performance feedback reports with online training and explanatory videos (sent by text or email)
    - Performance feedback reports will list:
        1) Your HPV vaccination rates
        2) Your practice's overall vaccination rates
        3) Your study group's overall vaccination rates
    - You will be the only one who can see your own vaccination rates in these reports. If you are in a small study practice, it might be possible for others to back-calculate your rates based on their rates and the rates of the overall practice.
- Participate in one online activity on prompts to vaccinate. Your clinical staff will also be asked to participate

Online activities will be provided virtually and asynchronously, with links delivered via text message or email.

- Receive quick tips from the study team via text message approximately once weekly – you will be asked to provide your cell phone number to receive these text messages
- Complete 4 surveys throughout the study (~5-15 minutes each)

For further information, please refer to the Practitioner Information Sheet.

Risks of Participation

This is a minimal risk study. Participation in this study will require some time to communicate with study staff, complete online activities, review feedback reports and complete surveys. Additionally, there is a minimal risk of loss of confidentiality, including potential disclosure of a patient's personal health information (PHI). We will implement numerous safeguards to avoid any potential breach of information. Finally, if your practice is small, it is possible that another participating practitioner could use their feedback report to calculate your vaccination rates based on their individual rates and the overall rates of your practice. However, other practitioners will never be given your individual rates. *Neither you nor your patients will be individually identified in these feedback reports.*

Benefits of Participation

As a participating study practitioner, you will be helping researchers identify potentially successful strategies to reduce missed opportunities for HPV vaccination. You will also be taught state-of-the-art techniques to optimize your HPV vaccination rates. Additionally, the results of the study may be shared with you after the study, which could benefit your practice by increasing awareness regarding which strategies may improve the timeliness of immunization delivery to improve HPV vaccination rates among adolescents. *If this study is successful, your patients may benefit from improved vaccination rates.*

If you are randomized to the Intervention group, you will be eligible to receive MOC Part IV credit (25 credits) for the performance feedback period. We are also seeking approval for separate MOC Part IV credit for the Prompts to Vaccinate period. If you are randomized to the Comparison group, we are also seeking approval for MOC Part IV credit as well.

Additional Costs

Standard text and data costs from your mobile plan may apply.

Compensation

As an acknowledgement of your time spent on this study, participating study practices will receive the following amounts, based on the number of participating practitioners. Both the Intervention and Comparison groups will be compensated as below.

Number of Practitioners Participating in the Study	Compensation Amount
One	$500
Two to Four	$750
Five to Nine	$1000
Ten or More	$2000

Please note that in addition to the amount above, we will also award a $100 bonus if all practitioners participate.

Please see the table below for a schedule of approximate payments:

Time of Compensation	Percent of Compensation Awarded
Intervention Group	
End of Period 1 (Months 1-7)	First 20%
End of Period 2 (Months 8-14)	Second 20%
End of Period 3 (Months 15-21)	Third 20%
End of Period 4 (Months 22-28)	Final 40%
Comparison Group	
End of Period 1 (Months 1-7)	First 25%
End of Period 4 (Months 22-28)	Final 75%

Sponsor Support

This study is sponsored by the National Cancer Institute of the National Institutes of Health under Award Number R01CA202261.

Confidentiality of Records

While we make every effort to maintain confidentiality, it cannot be absolutely guaranteed. Records which identify you, your practice and your patients, and the consent form signed by you, may be inspected by members of the

research team (AAP, CHOP and UCLA) and/or a regulatory agency. Study team members at PENN will have access to all electronic data. The results of this research study may be presented in aggregate form at meetings or in publications. We may ask for permission to use your practice/name in acknowledgements, to recognize your participation in PROS and in this study. However, your name will not appear in any such documents without your permission.

All practice-related study materials will be kept in secured locations in the care of PROS (surveys, consent forms, and other hard copy/electronic study materials), CHOP (survey data and other hard copy/electronic study materials) and UCLA (survey data and other hard copy/electronic study materials) for 10 years after the study ends.
Patient-related study materials containing Protected Health Information (obtained through your EHR system) will be kept in secure locations at CHOP (EHR data) for 10 years after the study ends. All patients will be assigned a unique study identifier.

10 years after the study ends, all data will be de-identified and stored in a permanent analytic dataset(s) with documentation at CHOP, UCLA the AAP, and PENN.

Text Messaging: When you use text messaging or telephone voice services, you are using commercial providers, which can lead to some risks to the privacy of your data if someone were to access your phone or the data from your phone (e.g., if someone breaks into the cell phone company's data network).These data could include your cell phone number and the messages or replies sent during the study and information from feedback reports.

We will protect your privacy to the fullest extent possible. One way to protect your privacy when you are using the text messaging technology is to set a password on your phone.

Additionally, a description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This site will not include information that can identify you. At most, the site will include a summary of the results. You can search this site at any time.

Information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks. The Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them. There are limits to this protection. The Certificate does not protect your information when you or your family voluntarily release information about yourselves; you consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care); or when a federal agency audits or evaluates research that it funds.

Voluntary Participation

Participation in this study is voluntary. You are free to not participate or to withdraw at any time, for whatever reason. If you withdraw, researchers will continue to use the information you have already provided as permitted by this informed consent form.

Contact Persons

If you do have any additional questions or concerns about the study, you may contact the director of this research, Peter Szilagyi, MD, MPH, at 301-206-6328. An Institutional Review Board, or IRB, is a committee organized to protect the rights and welfare of human subjects involved in research. If at any time you have questions about your rights as a research subject or the protection of human subjects, you may contact Erin Kelly, PhD, IRB Administrator at the American Academy of Pediatrics at 630-626-6075, or UCLA IRB at 310-825-7122.

Participant Consent

I have read the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have kept a copy of this form for my records and future reference.

Study Participant (Print Name): _____

Study Participant (Signature): _____ Date: _____

Study Participant Cell Phone Number: _____

If you would like to participate, please return a **signed** copy of this form to PROS via fax (847-434-8910) or email (to Margaret Wright at mwright@aap.org and cc to prosops@aap.org) if you want to participate in the study. **Please keep a signed copy for your files.**