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Clinical decision support tools to increase HPV vaccination in pharmacies Pilot Study

Aim 2 Pharmacy Staff Consent Form

Hello,

We are writing to invite you to participate in a research study that is looking at ways to improve the delivery of Human Papillomavirus (HPV) adolescent vaccines at your pharmacy. The study is called "**Clinical decision support tools to increase HPV vaccination in pharmacies (the CDS Tools Pilot) Study".** We plan to use the information we learn from the study to create processes that makes it more convenient for parents to get their child's vaccine at their local pharmacy rather than at their doctor's office. It is our hope that by making it easier to obtain the vaccines we will ultimately increase the adolescent HPV vaccination rate and reduce the incidence of cancer caused by HPV.

We are reaching out to you because you are a pharmacy staff member employed at a community pharmacy who has agreed to participate in this study.

Your decision to participate in this research study is voluntary. You do not have to participate if you do not wish to do so.

If you choose to participate in this study, you will be asked to:

- Read this Consent Form, ask questions if you have them, and then click on the "I Consent" button below to confirm your decision to participate.
- Complete a 10 to 15-minute, online, pre-intervention survey.
- Receive training on how to use the new or refined clinical decision support (CDS) tools.
- Use the CDS tools developed for this study to facilitate HPV vaccination. The CDS tools may include 1) clinic-level assessments and feedback, 2) proactive use of an immunization information system (IIS), 3) provider reminders, and 4) patient reminder and recall systems. Provide study information to potential parents obtaining an HPV vaccination for their adolescent children. Information will be provided through 1) printed and electronic flyers made available by the study team; 2) email communication (if applicable and feasible); and 3) face-to-face conversations. The information will provide an overview of the study, what parents can expect from participating in the online survey (length: 10-15 mins), and the $20.00 gift card incentive they will receive upon completion. The flyer will direct them to the study team for further information and consent.
- Complete a 10 to 15-minute, online post intervention survey.
- At least one member per pharmacy will be asked to participate in a post-implementation debrief focus group to solicit feedback on their experience with using the CDS tools tested for

this study.

- One staff member per pharmacy will be asked to provide audit data of pre intervention and post intervention vaccination rates for their pharmacy, once, at the end of the study. This deidentified pharmacy data will include the following variables for all patients ages 9 to 17 at participating pharmacies:
  - Birth year (to confirm age)
  - Sex/gender
  - Race and ethnicity (if captured)
  - Insurance type
  - Vaccination year
  - Vaccine type
  - Pharmacy where the patient was immunized (using a unique code assigned to each pharmacy)
  - Pharmacist or pharmacy technician who immunized the patient (using a unique code assigned to each staff member)

Your participation is voluntary. You can stop or withdraw from the study at any time or refuse to answer any questions.

All data will remain confidential. Your answers to the survey questions will remain private and be stored without identifying information to protect your confidentiality. Study results will be combined before being published. Some organizations may need to look at your research records for quality assurance or data analysis. These include:

- Researchers involved with this study.
- Institutional Review Boards (IRBs), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Office for Human Research Protections and other agencies as required.

Research is designed to benefit society by gaining new knowledge. You may not benefit personally from participating in the study. It is possible that commercial software may be developed, or a patent could result from this study. If that happens you will not benefit financially from that development. We anticipate few risks or discomforts involved from being in this quality improvement study. There is a remote chance of loss of confidentiality (we take many steps to make sure this does not happen). Some survey questions may make you feel uncomfortable. You can skip any questions that make you feel uncomfortable, and you are able to withdraw from the study at any time. Employment of pharmacy staff at the selected pharmacies will not be affected if staff either wish or do not wish to participate in this study.

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Some questions may be sensitive or cause embarrassment to participants.

We estimate that up to 50 parents and 70 pharmacy and software development staff will participate in this study. Participants will receive a $20 (cash or electronic gift card) when they complete their post intervention survey to thank them for their time. The digital gift card code will be emailed to you. Those who participate in the post-implementation debrief focus group will receive $100 for their time.

This study is being funded by Fred Hutchinson Cancer Center Philanthropy and has been approved by their Institutional Review Board (IRB).

If you have questions about this study, please contact Dr. Parth Shah. His contact information is below.

If you have questions about your rights as a research participant in general, you may contact the Director of the Fred Hutch Institutional Review Office at irodirector@fredhutch.org or 206-667-5900.

Please click on the "I Consent" button below if you agree to participate. Doing so will automatically take you to the 10-15-minute pre- intervention survey.

Thank you very much.

Sincerely,

Parth Shah, PharmD, PhD (Study Chair)
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and the CDS Tools Pilot Study Team

I Consent