Study Title: The INFLUENTIAL Trial- Inpatient FLU Vaccination Program Effectiveness: National Trial Implementing Best Practices And Learning Collaboratives

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You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

This study plans to learn more about whether a stakeholder-informed, standardized inpatient vaccination program will increase influenza vaccination rates of hospitalized children across US pediatric health systems. The first part of the study is to form a multidisciplinary team of stakeholders, including parents, providers, nurses, pharmacists, informaticists, data analysts and communication experts across three sites in synthesizing a best practice implementation guide for an inpatient influenza vaccination program. This work will then help inform development of an influenza vaccination program, which will be rolled out as a randomized controlled trial across 12 health systems in the US.

Other people in this study:

Up to 60 people from Children's Hospital Colorado, Seattle Children's Hospital and Lurie Children's Hospital will participate in the study.

What happens if I join this study?

If you join the study, you will be asked to a) participate up to 5 workshops, b) meet monthly over a 6 month period to review and finalize a best practice implementation guide, c) participate in a post-intervention interview, and/or d) complete up to 2 brief surveys, which will take less than 20 minutes to complete. The content of each workshop will be as follows:

Workshop 1-Introduction and Objectives: Review current practices, share facilitators of and barriers to influenza vaccination at each site, and review the latest evidence regarding pediatric inpatient influenza vaccination programs. Outline the core elements of our best practice implementation guide.
Workshop 2-Informatics Strategies: We will discuss tools in the electronic health record (EHR) and discuss the use of data analytic tools to routinely collect, review, and disseminate standardized influenza vaccination metrics for specific patient groups and hospital settings.
Workshop 3-Education and Communication: We will discuss what education is required (e.g., information regarding common concerns and misconceptions, effective communication strategies) and how this information can be best delivered to parents, staff, and providers.
Workshop 4-Process Mapping and Workflow: We will identify key questions for each hospital to consider as they implement the influenza vaccination program. Topics may include vaccine supply, distribution, and workflow considerations.
Workshop 5-Team Engagement and Other Considerations: We will discuss other core components, including hospital leadership support, establishing a multidisciplinary leadership team, identifying flu champions, and fostering end-user engagement through incentives like maintenance of certification (MOC) credit.

During these activities, you need to be willing to share your ideas. You will be encouraged to provide feedback about influenza vaccine screening, communication, and administration based upon your knowledge, opinions, and experiences related to influenza vaccination of hospitalized children.

The sessions may be video recorded so that the research team can focus on leading the discussions and review details at later time points. Only the research team will have access to these recordings.

After completion of all activities by the second year, you will be finished with the study.

What are the possible discomforts or risks?

There are no known medical risks at this time to participation in this study. The main risks of this study are that you may feel uncomfortable participating in the group discussions. However, you may skip any questions you do not want to answer.

There is a potential risk that people outside of the research team will see your responses to the information collected for the study. We will do all that we can to protect your information, but it cannot be guaranteed.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about how to develop a standardized influenza vaccination program to minimize the impact of the influenza virus and its impact in children's lives.

This study is not designed to treat any illness or to improve your health.

Who is paying for this study?

This research is being funded by the Agency for Healthcare Research and Quality (AHRQ).

Will I be paid for being in the study?

You will be paid to be in the study as follows:
Workshops: $40 gift card will be offered to each workshop participant for help developing program guidelines

Meeting attendance: A $20 gift card will be offered for attendance at each meeting. Surveys: A $5 gift card will be provided for each of the two surveys completed Interviews: A $35 gift card will be provided for participation in interviews.

We will be using a gift card platform for this study. The Internal Revenue Service (IRS) requires that we report as income when we pay you. A research team member will ask you to complete an IRS W9 form to meet these IRS requirements. Without this number, we can't pay you for being in this study.

Will I have to pay for anything?

It will not cost you anything to be in the study.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study investigators may decide to stop your participation for study related reasons. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Given that the risks of being involved in the study are minimal, and that this study involves healthy volunteers, we do not anticipate any research-related injury to occur. The term "research-related injury" means physical injury caused by drugs or procedures required by the study which are different from the medical treatment you would have received if you had not participated in the study.

Who do I call if I have questions?

The researcher carrying out this study is Dr. Suchitra Rao. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Rao at 720 777 2823. You will be given a copy of this form to keep. You can also call the responsible Institutional Review Board (COMIRB) at 303-724-1055.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.
The institutions involved in this study include

- University of Colorado Denver
- Children's Hospital Colorado (CHCO)
- Seattle Children's Hospital
- Lurie Children's Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to keep your information a secret. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Suchitra Rao, MBBS, MSCS
Children's Hospital Colorado 13123 E. 16th Ave., B055
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

The investigator (or staff acting on behalf of the investigator) will use your information for the research outlined in this consent form. They will also make some of the following research data collected in this study available to AHRQ, but this will be in the form of summary data, without any personal information.

Information about you that will be seen, collected, used, and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Role (if staff)

What happens to Data that are collected in this study?

Researchers at the University of Colorado, Children's Hospital Colorado and the hospitals involved in this study work to find the most effective vaccination program.

- The data given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study the data collected.
- If data are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

I give my permission for the study doctor (or someone he or she chooses) to contact me in the future to ask me to take part in more research.

☐ Yes ☐ No _____Initials

Agreement to be in this study and use my data
I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my

information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____ Date:_____

Print Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____

*Witness Signature:_____Date_____

*Witness Print Name: _____

*Witness of Signature
*Witness of consent process
*Only required if person signing consent is blind, illiterate, or when using a short form.