Email-based Reminders Promoting Recommended Pediatric Preventative Visits
(NCT05317884)

Study Protocol with Statistical Analysis Plan

April 8, 2022

Study Protocol

Purpose

The purpose of this study is to assess, prospectively, the effect of email reminders for well-child check (WCC) visits on adherence to these visits among those who have not yet scheduled the visit. The investigators hypothesize that sending reminders will increase scheduling WCC visits, attending WCC visits, and being up to date for the child's required immunizations beyond what occurs in the absence of these reminders.

Background

Regular attendance at recommended WCC visits is associated with having up-to-date immunizations. Standard care involves scheduling a follow-up WCC visit at the end of the current visit. However, if the child's parents do not choose to schedule a follow-up visit at that time or miss a WCC visit, they may not be offered another easy opportunity to schedule one. That is, they would have to remember to schedule a visit and contact the clinic proactively.

In this study, 30 days before a child is due for their WCC visit, parents who have not yet scheduled a WCC visit for up to 30 days (for 5-month-olds) or 60 days (for all other ages) after their child is due for a visit will be randomly assigned to two groups with a random number generator. One group will receive an email reminder, while the other group will not receive any reminder.

The randomization of participants to different conditions will be in place until 800 participants have been identified and randomly assigned to one of the arms (estimated sample to detect at least a 10% absolute difference) or 180 days, whichever comes first. To account for delays in updating clinical databases, the final outcome data will be checked 90 days after the last eligible visit (for a maximum study period of 270 days).

Methods

Sample

The eligible participants will be parents (or the contact of record) of children aged 5, 8, 11, 14, or 17 months at the time of list generation. The child will need to have no WCC visits scheduled 30 days (for 5-month-olds) or 60 days (for all other ages) after their due date for a WCC (i.e., month 6, 9, 12, 15, or 18) and be currently seen at Pediatric clinics within Geisinger's umbrella (i.e., have at least one prior visit). In addition, the parent will need to have an email address and not have opted out of receiving any system emails.

Experimental conditions

A list of eligible participants will be generated each day, and a randomizing function in SQL will assign them to the treatment or control condition. Those in the treatment condition will be sent a reminder email, that tells the parent that their child will be due for a WCC in four weeks,

emphasize the importance of these visits, and provide contact information for them to schedule an appointment, as well as a convenient hyperlink for those with online patient portal access. Those in the control condition will not be sent a reminder email.

Outcome measures

The primary outcome measure will be a binary variable indicating whether a WCC visit was scheduled 30–60 days from the email, as determined by billing code; in the absence of a billing code, either a visit type or reason that mentions WCC will be included.

The secondary outcome measures will be a binary variable indicating whether a WCC visit was completed 30–60days from the email (as established by billing codes) and a binary variable indicating whether the child's immunization status is up to date 60 days from the email (as established by the absence of immunization care gaps in the record).

Additional data that will be collected will include email opens, scheduling follow-up WCC visits (i.e., 61–150 days after the email), having any General Pediatrics visit 30–60 days from the email, having any office visit 30–60 days from the email, and immunization status for Measles/Mumps/Rubella vaccine (MMR), Hepatitis A, Hepatitis B, and Varicella.

Statistical Analysis Plan

As of the writing and uploading of this plan, enrollment has not yet begun, and data have not yet been examined.

Primary Research Question: Do reminder emails increase scheduled WCC visits?

H1: Those who received reminder emails will have a higher percentage of WCC visits scheduled compared with those in the control group.

For all analyses, a logistic regression model will analyze the outcomes as a function of condition. The control condition will be the reference group. For all tests, two-tailed p-values < 0.05 will be used to determine statistical significance. Only the first WCC visits of patients within the study period will be analyzed.

Secondary Research Question: Do reminder emails increase completed WCC visits and immunization?

H2: Those who received reminder emails will have a higher percentage of WCC visits completed compared with those in the control group.

H3: Those who received reminder emails will have a higher percentage of eligible children with up-to-date immunizations compared with those in the control group.

Additional Analyses

For the primary and secondary analyses, we will conduct separate robustness checks adding immunization status at the day the email was sent as a control variable.

To examine engagement with the email, the percentage of people who opened emails will also be examined.

We will also examine the broader effects of the intervention on engagement with the health system, specifically, General Pediatrics visits and any office visits.

A more distal goal of the project is to get otherwise unengaged parents to continue scheduling WCC visits for their child. Thus, we will also look at the effect of the intervention on WCC visits for the child's next due date.

Finally, immunization for MMR, Hepatitis A, Hepatitis B, and Varicella are of particular interest for the research team, so we will also examine if the intervention individually affected each of those immunization rates.