

Official Title of the study: **Effect of Varied Outreach Methods on Appointment Scheduling, Appointment Completion, and Receipt of MMR Vaccination**

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Redesigning Outreach Post-COVID-19 in Academic Pediatric Primary Care

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1. Objective

Our objective is to determine the effectiveness of varied outreach methods (e.g. automated reminder calls/text messages with or without personalized calls/texts, MyChart messaging) to children age 12-14 months, 4 years old, or 6-17 years old who are due for a WCC visit and don't have one scheduled in the next 45 days on the outcomes of appointment scheduling, appointment completion, and receipt of the MMR vaccination.

Background

The Cincinnati Children's Hospital Medical Center Primary Care offices serve as the medical home for over 33,000 children. The Pediatric Primary Care Center (PPCC), Hopple Street Health Center (HPC) and Fairfield Primary Care (FPC) serves an underserved population. Annually, these practices provide over 60,000 visits. Traditional outreach efforts in these offices have included reminder phone calls and/or texts when patients were overdue for well child care (WCC). These efforts were time and resource intensive, as they required personnel to manually complete and document attempts. Additionally, due to high resource needs to accomplish such efforts, there has been no outreach to those 6 years and older.

Numerous studies exist speaking to the efficacy of automated reminder (i.e. notifying parents of needed immunizations) and recall (i.e. notifying parents of overdue immunizations) systems, including text messaging systems.^{1,2,3} Other studies show that the combination of texting and calls proves even more successful in reaching patients.³ These systems are more cost effective and efficient. Differences in the timing of reminders to schedule, as well as the message itself, has been shown to make a difference in the outcomes of reaching patients or scheduling appointments.⁴ However, there remains a need for research that identifies the degree to which combinations of patient reminder systems improve outcomes, especially the outcome of on-time immunization, and how these approaches differ by age of child.¹

Following the COVID-19 pandemic shut-down in which thousands of well child appointments were cancelled or delayed, the importance of a systematic outreach process became more critical. The traditional process is non-standardized and the efficacy of the work is both unknown and expensive. Our objective is to determine the effectiveness of varied outreach methods (e.g. automated reminder calls/text messages with or without personalized calls/texts, MyChart messaging) to children age 12-14 months, 4 years old, or 6-17 years old who are due for a WCC visit and don't have one scheduled in the next 45 days on the outcomes of appointment scheduling, appointment completion, and receipt of the MMR vaccination.

2. Design/Method

To achieve our objective, we will conduct a 2×2 factorial randomized controlled trial. Randomization is justified because 1) it is a rigorous approach to answer our question and 2) we do not have the resources or appointment availability to personally contact every patient who is eligible and have them schedule immediately.

Patient Population:

Patients are eligible for inclusion in this study if they are in one of four eligible groups:

12-14 months AND	4 years AND
<ul style="list-style-type: none">• doesn't have a well visit scheduled in the next 45 days• have not yet received 12-month immunizations• have English and/or Spanish as preferred language	<ul style="list-style-type: none">• doesn't have a well visit scheduled in the next 45 days• has not had a well child visit in 365 days• have English and/or Spanish as preferred language

6-11 years AND	12-17 years AND
<ul style="list-style-type: none">• doesn't have a well visit scheduled in the next 45 days• has not had a well child visit > 365 days	<ul style="list-style-type: none">• doesn't have a well visit scheduled in the next 45 days• has not had a well child visit in 365 days

• have English and/or Spanish as preferred language	• have English and/or Spanish as preferred language
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Factors under study (levels):

Personal Contacts (12-14 month & 4-year-olds) Trial:

Number of automated messages sent prior to any personal contact attempts (1 vs. 2)

Number of personal contact attempts made by medical assistant (0 vs. 1)

	1 automated message sent	2 automated messages sent
0 personal contact attempt		
1 personal contact attempt		

MyChart Trial:

Families enrolled in MyChart will be selected and randomized into the following groups:

	no message	1 MyChart message sent	2 MyChart messages (e.g. Mon and Thurs)
Low Tailored Message			
High Tailored Message			

Number of messages (0 vs. 1 vs. 2); Type of messages (low tailored message with name only vs. high tailored message with date of last WCC and age included)

Televox (age 6-11yo) Trial:

Patients will be randomized into the following three groups. Patients with MyChart are excluded:

no message	Low Tailored Message 2 automated standard messages sent (e.g. Thu, Fri)	High Tailored Message 2 automated tailored messages sent (e.g. Thu, Fri)
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Televox (age 12-17yo) Trial:

Patients will be randomized into the following three groups:

no message	Low Tailored Message 2 automated tailored messages sent (e.g. Thu, Fri)	COVID Tailored Message 2 automated messages sent (e.g. Thu, Fri)
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Automated Message: Parents indicate their preferred mode of reminder (e.g. call or text message) when they schedule appointments. Cincinnati Children's uses a HIPAA compliant platform called TeleVox to send automated calls and text reminders to parents according to their preferences which are recorded in the Electronic Health Record (EHR).

Here is the script for **low tailored automated messages** that will be sent via call or text:

Clinic	Message 1*	Message 2*
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HPC	Hi! Hopple misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-517-2000, option 1 to schedule a visit as soon as possible.	Hi! If you haven't already, please call 513-517-2000, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at Hopple.
FPC	Hi! Fairfield misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-636-8259, option 1 to schedule a visit as soon as possible.	Hi! If you haven't already, please call 513-636-8259, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at Fairfield.
PPC	Hi! PPC misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-636-7722, option 1 to schedule a visit or walk in today.	Hi! If you haven't already, please call 513-636-7722, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at PPC or walk in today.

*Message Scripts have been translated into Spanish by Interpreter Services

This is the script for **high tailored automated messages** that will be sent via call or text:

Clinic	Message 1*	Message 2*
HPC	(INSERT FIRST NAME) was seen for a checkup at Hopple on XX/XX/XXXX & is due for a (INSERT CURRENT AGE) checkup. Please call 513-517-2000 opt 1.	If you haven't, please call 513-517-2000 opt 1 to schedule (INSERT FIRST NAME)'s (INSERT CURRENT AGE) checkup at Hopple. Stay up to date!
FPC	(INSERT FIRST NAME) was seen for a checkup at Fairfield on XX/XX/XXXX & is due for a (INSERT CURRENT AGE) checkup. Please call 513-636-8259 opt 1.	If you haven't, please call 513-636-8259 opt 1 to schedule (INSERT FIRST NAME)'s (INSERT CURRENT AGE) checkup at Fairfield. Stay up to date!
PPC	(INSERT FIRST NAME) was seen for a checkup at PPC on XX/XX/XXXX & is due for a (INSERT CURRENT AGE) checkup. Please call 513-636-7722 opt 1 to schedule or walk in today.	If you haven't, please call 513-636-7722 opt 1 to schedule (INSERT FIRST NAME)'s (INSERT CURRENT AGE) checkup at PPC or walk in today. Stay up to date!

This is the script for **COVID tailored automated messages** that will be sent via call or text:

Clinic	Message 1*	Message 2*
HPC	Hi! Hopple misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-517-2000, option 1 to schedule a visit as soon as possible. COVID vaccine is available if interested.	Hi! If you haven't already, please call 513-517-2000, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at Hopple. COVID vaccine is available if interested.
FPC	Hi! Fairfield misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-636-8259, option 1 to schedule a visit as soon as possible. COVID vaccine is available if interested.	Hi! If you haven't already, please call 513-636-8259, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at Fairfield. COVID vaccine is available if interested.
PPC	Hi! PPC misses you! (INSERT FIRST NAME) is due for a checkup. Please call 513-636-7722, option 1 to schedule a visit or walk in today. COVID vaccine is available if interested.	Hi! If you haven't already, please call 513-636-7722, option 1 to schedule (INSERT FIRST NAME)'s upcoming visit at PPC or walk in today. COVID vaccine is available if interested.

*Message Scripts have been translated into Spanish by Interpreter Services

Personal Contact Attempts: Medical assistant(s) will use the following message/script to personally contact families via text message and then phone call.

Clinic	Text Message*	Call Script*
HPC	Hi, this is [Staff First Name] from Hopple St. Health Center. [Pt first name] is due for a check up. I'll call in a day or two to help	Hi, this is [Staff First Name] from Hopple St. Health Center. I noticed that [Child's First

	<p>schedule that appointment or you can call 513-517-2000, option 1 to schedule.</p>	<p>Name] is due for a check up. Can I schedule that for you right now?</p> <p><u>Alternate script for leaving a voice message:</u> Hi, this is [Staff First Name] from Hopple St. Health Center. I noticed that [Child's First Name] is due for a check up. Sorry I missed you. Please call 513-517-2000, option 1 to schedule your appointment.</p>
FPC	<p>Hi, this is [Staff First Name] from Fairfield. [Pt first name] is due for a check up. I'll call in a day or two to help schedule that appointment or you can call 513-517-2000, option 1 to schedule.</p>	<p>Hi, this is [First Name] from Fairfield. I noticed that [Child's First Name] is due for a check up. Can I schedule that for your right now?</p> <p><u>Alternate script for leaving a voice message:</u> Hi, this is [First Name] from Fairfield. I noticed that [Child's First Name] is due for a check up. Sorry I missed you. Please call 513-636-8259, option 1 to schedule your appointment.</p>
PPC	<p>Hi, this is [Staff First Name] from PPC. [Pt first name] is due for a check up. I'll call in a day or two to help schedule that appointment or you can walk in today to have your child seen! You can also call 513-636-7722, option 1 to schedule.</p>	<p>Hi, this is [First Name] from PPC. I noticed that [Child's First Name] is due for a check up. Can I schedule that for your right now?</p> <p><u>Alternate script for leaving a voice message:</u> Hi, this is [First Name] from PPC. I noticed that [Child's First Name] is due for a check up. Sorry I missed you. Please call 513-636-7722, option 1 to schedule your appointment or walk in today to have your child seen.</p>

*Scripts have been translated into Spanish versions by Interpreter Services

Response variables (outcomes):

- Appointment **was scheduled** within 2 weeks of intervention (Y/N) (date of actual appointment may be greater than 2 weeks from intervention)
- Appointment **was completed** within 8 weeks of intervention (Y/N). Appointment completed within 8 weeks of randomization will be used for group who does not receive any intervention.
- (Primary Outcome) Receipt of MMR by 15 months of age or receipt of 2nd MMR dose by 3 months after randomization (Y/N)
- Receipt of 1st COVID vaccination (ages 12-17 years) within 8 weeks of first intervention (Y/N)
- Family member receipt of COVID vaccination in our health system within 8 weeks of first intervention

Blocking: (controlling for factors that might influence the outcome)

- Age (12-14 months, 4 years)
- Clinic location (PPC, HPC, FPC)

Personal Contacts (12-14 months & 4-year-olds) Trial:

Randomization: Eligible patient will be identified by running a report in the electronic health record (EHR). We will run this report, stratified by clinic location, and randomly assign patients into one of the four groups created by our 2 X 2 design. Groups will receive their assigned intervention in one of four successive weeks with the sequence randomly assigned (see table below).

Replication: We will conduct a total of 3 trials, repeating the randomization procedure every 4 weeks to identify children who become eligible: Weeks 1-4 = trial #1, weeks 5-8 = trial #2, weeks 9-12 = trial #3.

	1 automated message sent	2 automated messages sent
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0 personal contact attempt	Message sent on Thu (weeks 3, 5, 10)	Message sent on Thu & Fri (weeks 4, 6, 12)
1 personal contact attempt	Above plus attempt Mon – Fri of following week (weeks 2, 7, 11)	Above plus attempt Mon – Fri of following week (weeks 1, 8, 9)

MyChart and Televox Trials (6-17 years old):

Randomization: Eligible patients will be identified by running a report in the electronic health record (EHR). We will run this report, stratified by clinic location, and randomly assign patients into one of the study groups as described above. Groups will receive their assigned intervention in one of four successive weeks with the sequence randomly assigned (see table below).

We will randomize children who are eligible and implement interventions for each trial : Weeks 1-3 = Televox Trial 12-17yo, Weeks 4-7 = Televox Trial 6-11yo, Weeks 8-10 = MyChart Trial.

MyChart Trial:

	no message	1 MyChart message sent	2 MyChart messages (e.g. Mon and Thurs)
Standard Message	No intervention	Week A	Week B
Tailored Message		Week A	Week B

Televox (6-11yo) Trial:

no message	Low Tailored Message 2 automated standard messages sent (e.g. Thu, Fri) (weeks C, C)	High Tailored Message 2 automated tailored messages sent (e.g. Thu, Fri) (weeks D, D)
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Televox (12-17yo) Trial:

no message	Low Tailored Message 2 automated tailored messages sent (e.g. Thu, Fri) (week A)	COVID Tailored Message 2 automated messages sent (e.g. Thu, Fri) (week B)
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Of note, automated messages and/or personal contact attempts will not be completed if the parent schedules an appointment after being randomized but before receiving the intervention.

Covariates for logistic regression: (factors that might influence the outcome if not be balanced across groups)

1. Child age at the time of randomization (rationale: visits are less frequent for children age 4 years)
2. Parent preference for call vs. text mode of contact (rationale: calls may be more likely to get blocked than texts)
3. Parent with activated MyChart account (Y/N) (rationale: not dependent on calling scheduling center to make appointment)
4. Access to appointment: Number of days to 3rd next available appointment at patient's clinic at time their first automated message is sent
5. Patient receipt of any past immunizations (Y/N) (rationale: vaccine refusing parents will be unlikely to change even if they return for well child check)

6. School-age vs. adolescent patient age (rationale: adolescents less likely to get yearly check-ups)
7. Historical no-show rate
8. Community rates of COVID based on 7 day moving average.

Power/Sample Size

Personal Contacts (12-14 month & 4-year-olds) Trial:

We based our hypotheses (see table, below) on a systematic review's pooled estimates of effect size for automated messages and personalized calls finding 37% and 40% of children, respectively, completed immunizations.¹ Because of the significant cost involved in making personal contacts, the minimal difference in outcome that would make it worth the effort is high.

Hypotheses	% of children who receive MMR by 15 months of age	
	1 automated message sent	2 automated messages sent
0 personal attempts	20% ^C	35% ^B
1 personal attempt	50% ^A	65% ^{AB}

We calculated sample size needed per group to detect a difference for each of the contrasts below with alpha of 0.05 and power of 80%.

Contrast	Sample Size per Group
A vs C	36
B vs C	136
A vs. B	167
A vs. AB	167
B vs. AB	40
C vs. AB	16

To fully power the 2 X 2 factorial trial, we estimate needing 167 per group X 4 groups = 668 total subjects. There are currently 712 children eligible for the study. More will become eligible every month so we expect to far exceed the required sample size after 3 replications. If needed, we could increase the number of replications of the trial to reach the targeted sample size. We acknowledge that we are not powered to precisely estimate any interactions between interventions.

MyChart Trial:

In hypothesis testing for 0 message vs. 1 message vs. 2 messages, we will do the testing in a fixed sequence - test 2 messages vs. 0 message first, only if it is significant then test 2 messages vs. 1 message, thus the type I error rate of 0.05 is retained. Since the hypothesis testing of 2 messages vs. 0 message would be considered easier to achieve than the hypothesis testing of 2 messages vs. 1 message, the power analysis for this trial should be based on the design of (standard message vs. tailored message) by (1 message vs. 2 messages). We based our hypotheses (see table, below) on previous work indicating approximately 20% WCC appointment completion on automated text reminders. We anticipate that a tailored message increases the WCC appointment completion rate by another 10%.

Hypotheses		% of children complete WCC within 8 weeks	
		1 automated message sent	2 automated messages sent
Standard Message	2%	10% ^C	20% ^B
Tailored Message		20% ^A	30% ^{AB}

We calculated sample size needed per group to detect a difference for each of the contrasts below with alpha of 0.05 and power of 80%.

Contrast	Sample Size per Group
A vs C	199
B vs C	199
A vs. AB	293
B vs. AB	293
C vs. AB	62

We assume no difference between A vs. B and thus not consider powering the comparison between these two groups, but we will explore non-inferiority analysis for this comparison in data analysis. To fully power the above contrasts, we estimate needing 293 per group X 4 groups = 1172 subjects. Adding 293 in the zero message group, we would need a total of 1465 subjects. There are currently 1000 children eligible for the study. More will become eligible every month so we expect to exceed the required sample size after 2 replications. If needed, we could increase the number of replications of this trial to reach the targeted sample size. We acknowledge that we are not powered to precisely estimate any interactions between interventions.

Televox (6-11yo) Trial:

We calculated sample size based on the following hypotheses:

% of children complete WCC within 8 weeks		
no message	2 Low Tailored Messages	2 High Tailored Messages
2%	20%	30%

With alpha of 0.05 and power of 80%, to fully power the contrasts between the above groups, we need 293 per group X 3 groups=879 subjects. Currently there are 2500 kids eligible, so we expect to reach the targeted sample size.

Televox (12-17yo) Trial:

We calculated sample size based on the following hypotheses:

% of children complete WCC within 8 weeks		
no message	2 Low Tailored Messages	2 COVID Tailored Messages
2%	30%	40%

With alpha of 0.05 and power of 80%, to fully power the contrasts between the above groups, we need 356 per group X 3 groups=1068 subjects. Currently there are 1100 kids eligible, so we expect to reach the targeted sample size.

Analysis

We will conduct descriptive analyses to characterize the participants in terms of demographics and other potential covariates in consideration (child age group, parent's preference for call vs. text mode of contact, whether parent had activated MyChart account, access to appointment, whether patient receipt of any past immunizations, historic no show rate, and community rates of COVID). We will use chi square tests to examine whether participants in the 4 groups are similar in these characteristics.

For the Personal Contact (12-14 mo & 4 years old) trials, we will conduct intent-to-treat analyses using logistic regression models (without adjusting for covariates) for each of our three binary outcomes: completed appointment

within 2 weeks, completed appointment within 8 weeks, receipt of MMR by 15 months of age or receipt of 2nd MMR by 3 months after randomization. We will do pair-wise comparison among the 4 groups and adjust p value of each comparison for multiplicity. If participants in the 4 groups differ on potential covariates, we will conduct additional analyses adjusted for these variables.

For the MyChart and Televox Trials (6-17 years old), we will conduct intent-to-treat analyses using logistic regression models (without adjusting for covariates) for each of the binary outcomes: scheduled appointment within 2 weeks, completed appointment within 8 weeks, receipt of 1st dose of COVID vaccination (age 12-17 years) within 8 weeks, family member receipt of COVID vaccination within 8 weeks. We will do pair-wise comparison among the treatment groups and adjust p value of each comparison for multiplicity. If participants differ in potential covariates across treatment groups, we will conduct additional analyses adjusted for these variables. We will explore non-inferiority analysis for comparison the two groups that are expected to have similar appointment scheduled and completion rate in the MyChart trial.

We will also conduct per-protocol analyses according to the interventions actually received by the participants, recognizing that actual intervention received could be different from initial randomized intervention. For example, a parent allocated to group A might schedule an appointment after receiving the automated message and therefore would not receive a personalized contact attempt. In addition, we may explore potential interaction between the two interventions as a secondary analysis. All analysis will be conducted using SAS version 9.4.

Duration

The study will begin upon IRB approval and continue through December 31, 2022. During this time, we will discuss the significance of data, potential future projects and dissemination of results.

Process of Obtaining Consent

For this study, we request a waiver of consent due to the minimal risk to participants involved. Given the population we are attempting to contact using the various outreach methods has missed appointments, it would not be possible to obtain prospective consent. That said, we will honor parent preferences for how they receive automated messages. Collected data about appointment attendance and MMR vaccination status is already being documented in the EHR, and the collection of data will not affect the rights and welfare of subjects.

We request waiver of consent such that there is (1) potential, minimal, risks to the participant (see below), (2) de-identification of PHI, and (3) participation in the study will not affect current/future care received through CCHMC.

All identifying information will be removed once data collection is complete. Data will be kept securely on a CCHMC computer that is password protected. Any hard copies of data will be locked in a private office.

Facilities and Performance Sites

Data analysis will be done on the Main Campus of CCHMC and at the CCHMC primary care offices (PPCC, HPC, FPC, and SBHCs).

Potential Benefits

The results of this study will aid CCHMC pediatric primary care centers in improving and redesigning an outreach system to children behind on necessary preventative services who have gaps in needed primary care. It will identify the most effective ways to reach, engage, and schedule patients for care when appropriate. This will enable the primary care offices to allocate the appropriate amount of resource to outreach efforts moving forward, ensuring high risk children receive reminders for care.

Potential risks, discomforts, inconveniences, and precautions

The only significant risks are breach of confidentiality and potential discomfort/inconvenience associated with receiving texts or phone calls indicating that care gaps exist for a child. As noted above, personal health information (PHI) will be obtained via the electronic medical record. After obtaining this information, patients will be de-identified in the created database and securely stored.

Risk/Benefit analysis

While immediate benefit to any given individual or family is unknown, this study involves minimal risk.

Outreach Methods Study Protocol

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Cost of Participation

There is no cost for participation.

Payment for Participation

There is no reimbursement for participation.

Request for HIPAA Waiver

The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on the presence of the following elements:

- We plan to protect health information identifiers from improper use and disclosure by secure storage.
- We have an adequate plan to destroy identifiers at the earliest opportunity consistent with conduct of the research.
- We ensure the PHI will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.
- This research could not practicably be conducted without the waiver or alteration.
- This research could not practicably be conducted without access to and use of the PHI.

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