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

NCT number: **NCT04567342**

Document name: **Statistical Analysis Plan**

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The results of the Outreach Methods study will be assessed as described in this document. This statistical analysis plan begins with an overview of the key components of the study, including its design, objectives, and outcomes measures. This is followed by a detailed description of the statistical analyses that will be utilized to address study hypotheses.

1. Overview of study: This study used a 2x2 factorial randomized control trial to test the impact of automated text/telephone messages and personal contact attempts on well child care (WCC) scheduling and completion and receipt of MMR vaccine. We randomized eligible patients to 1 of 4 groups: 1 automated message (Group 1), 2 automated messages (Group 2), 1 automated message plus personal contact attempts (Group 3), or 2 automated messages plus personal contact attempts (Group 4). We generated random allocation sequence stratified by clinic location using block randomization (with a block size of 4). Based on sample size calculations, we planned to enroll a minimum of 668 subjects overall aged 12-14 months old and 4 years old that met eligibility criteria based on data obtained from the electronic health record (EHR) from three academic pediatric primary care practices.

1.1 Study Objective: Test the effectiveness of text/telephone outreach messages and personal contact attempts on well child care (WCC) scheduling and completion and receipt of MMR vaccine.

Working hypothesis: Twenty percent of patients in Group 1, 35% of patients in Group 2, and 50% of those in Group 3, and 65% of those in Group 4 would receive the MMR vaccine by 15 months of age (for children who were 12-14 months old) or receipt of the second MMR dose by 3 months after first intervention (for children 4 years old).

1.2 Outcome measures

Primary

- Receipt of MMR by 15 months of age (for children who were 12-14 months old) or receipt of the second MMR dose by 3 months after first intervention (for children 4 years old).
    - Receipt of MMR (yes or no) based on electronic health record documentation

Secondary

- Well-child visit scheduled within 2 weeks of receiving first intervention
    - Appointment scheduled (yes or no) based on electronic health record documentation
- Well-child visit completed within 8 weeks of receiving first intervention
    - Appointment completed (yes or no) based on electronic health record documentation

1.3 Time points of interest

- Receipt of MMR (by 15 months of age or by 3 months after first intervention for children 4 years old)
- Scheduled well-child visit (within 2 weeks of receiving first intervention)
- Completed well-child visit (within 8 weeks of receiving first intervention)

1.4 Data Management

CCHMC CRC will guide data management for this project as described in the study protocol.

1.5 Interim Safety Analyses

No interim analyses are planned for this study.

2. Statistical Reports

2.1 Report Generation

2.1.1 Software

All statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA) under Microsoft Windows operating system

2.2 Analysis Populations

2.2.1 Completion

Subjects will be considered to have completed the study on the study end date on 8/6/21.

2.2.2 Missing data

We will use data obtained from patient's electronic health record (EHR) to calculate our primary and secondary outcomes. Missing outcome data could occur for several reasons, such as errors of medical documentation or the patient no longer in the primary care registry.

2.3 Statistical Report Contents

The following section outlines the contents of the final statistical analysis. For all analyses, subjects who are enrolled in the study and are eligible will be analyzed in the groups to which they were allocated.

2.3.1 Description of study population

Sample size:
The total number of subjects who are enrolled will be given.

Demographics and Clinical Characteristics, Patient and Parent:
Demographic and clinical characteristics as measured at baseline will be summarized by trial arm. Variables to be summarized are: child age, child sex, child race, child ethnicity, insurance, parent communication preference absence of past patient receipt of tetanus and acellular pertussis (DTaP) vaccine as a proxy for childhood vaccine refusal, and patient lifetime historical institutional no-show rate. Variables will be summarized using descriptive statistics appropriate for each type of data item.

Baseline characteristics with large differences between groups will be included in analyses as covariates.

2.3.2 Primary outcome analysis

Primary outcome: Receipt of MMR by 15 months of age (for children who were 12-14 months old) or receipt of the second MMR dose by 3 months after first intervention (for children 4 years old).

- Receipt of MMR (yes or no) based on electronic health record documentation

For the primary outcome, we will use a modified Poisson regression models to estimate risk ratio (RRs) with statistical significance defined as 2-sided $p < .05$. If participants differ in potential covariates across treatment groups, we will conduct additional analyses adjusted for these variables.

2.3.3 Secondary outcome analyses

- Well-child visit scheduled within 2 weeks of first messages sent.

We will use a modified Poisson regression models to estimate risk ratio (RRs) to examine appointment scheduling within 2 weeks among the randomized groups. If participants differ in potential covariates across treatment groups, we will conduct additional analyses adjusted for these variables.

- Well-child visit completed within 8 weeks of first message sent.

We will use a modified Poisson regression models to estimate risk ratio (RRs) to examine appointment scheduling within 8 weeks among the randomized groups. If participants differ in potential covariates across treatment groups, we will conduct additional analyses adjusted for these variables.