Mammogram Mail- and Phone-based Interventions

(NCT 05853848)

Study Protocol with Statistical Analysis Plan

May 12, 2023

Study Protocol

Background

Mammogram screening for women, starting at age 50, can significantly reduce the risk of complications due to breast cancer. The Geisinger Health Plan (GHP) has conducted prior outreach intended to promote and increase annual mammogram screening by mailing different versions of postcards to women on the month of their 50th or 64th birthdays. The study team is working with GHP to test whether postcards or other modalities can improve upon a lack of outreach and whether live calls can improve upon other modalities, in part by making the outreach more salient and difficult to ignore, and in part by making it easier for women to schedule.

Objectives

The study will involve randomized assignment to different versions of outreach, including a current standard postcard encouraging patients to schedule their mammograms, a formal letter, an auto-dialer voice message with option to respond, and a live call from a GHP care gaps coordinator. The primary aims of this study are to evaluate, prospectively, whether live calls improve upon other outreach modalities, in terms of mammogram completion, as well as assess whether any of the outreach modalities improve upon an absence of outreach. The analyses will thus also compare each modality against (delayed) control groups consisting of contemporaneous patients randomized to intervention arms who have not yet received any outreach.

Design

This study is a randomized controlled trial with 4 study arms. The total number of initially identified eligible patients who can be contacted via both mail and phone will be divided by 7 to estimate the number of unique patients contacted across 7 sequential waves of outreach occurring from May through November 2023. At each wave, a random subset of $1/7^{th}$ of the total will be randomized to arms, with slightly larger or smaller subsets selected over time if needed, to compensate for patients becoming newly eligible or ineligible over time (e.g., due to records of completed mammograms prior to the outreach date). Furthermore, a maximum of 300 live calls can be fielded per month, so randomization to the live call arm will be restricted to 300 whenever there are more than 1,200 patients to randomize in a given wave. Auto-dialer messages and live calls will be rolled out across each month, whereas postcards and letters will both be sent in two rounds per month, two weeks apart.

Methods

Female GHP members ages 51 through 74 who are overdue for an annual mammogram will be included in the study. Inclusion and exclusion criteria are largely determined by Healthcare Effectiveness Data and Information Set (HEDIS) guidelines developed by the National Committee for Quality Assurance (NCQA) to assess breast

cancer screening. Included in the intervention are women between the ages of 52 and 74, as of December 31, 2023. Excluded are women who have had a mammogram (screening, diagnostic, film, digital, or digital breast tomosynthesis) claim between October 1, 2021 and the monthly data pull preceding each monthly wave of outreach, as well as women who have not been continuously enrolled with GHP during that timeframe—i.e., they have had a gap in enrollment of greater than 45 days (or 1 month, for Medicaid beneficiaries) in a given calendar year, or any gap in enrollment between October 1 and the data pull for outreach. Also excluded are GHP members in hospice, using hospice services, or receiving palliative care in 2023. Excluded are Medicare members 66 years of age or above as of the date of the data pull for outreach who are either: (1) enrolled in an Institutional SNP any time during 2023, (2) living long-term in an institution during 2023, or (3) 66 years of age or above as of December 31, 2023 with both frailty and advanced illness (as defined by 1+ claim/encounter for frailty in 2023 and any of the following during 2022 or 2023: 2+ visits with a diagnosis of advanced illness, 1+ acute inpatient encounter with a diagnosis of advanced illness, 1+ acute inpatient discharge with advanced illness diagnosis, or a dispensed dementia medication). Finally, excluded are patients who had a bilateral mastectomy at any time before the data pull for outreach: bilateral mastectomy, unilateral mastectomy with a bilateral modifier, history of bilateral mastectomy, or any combination of codes indicating mastectomy on both left and right side. Mammogram screening evidence comes from GHP claims data, as well as Geisinger electronic health record data and St. Luke's University Health Network, WellSpan Health, PrimeMed Medical Group, Family Practice Center, and Equipt Health data, with GHP claims data trumping other sources except where claims are not on file. The intervention began on May 10, 2023.

At each wave, a random subset (as described above) of currently eligible patients will be randomized to all four of the following study arms:

1. Current **standard postcard** encouraging patients to schedule their mammograms and to contact Geisinger for help doing so.
2. **Formal letter** telling patients that they are overdue and including contact information as above
3. **Auto-dialer** voice message allowing patients to respond to schedule
4. **Live call** from a GHP care gaps coordinator helping patients schedule while speaking with them.

The remaining patients will serve as contemporaneous controls for patients in the other arms, during the span of time prior to which they are included in an active outreach arm. The controls will include patients eligible for outreach at the time the comparison patients are randomized to the corresponding active arms; they will exclude patients who become eligible at a later date. For example, controls for patients in wave 2 will consist primarily of patients assigned to wave 6, excluding those wave 6 patients who will not have been eligible for outreach at the time of the wave 2 rollout. Additionally, to account for patients who are eligible initially but become ineligible over time, those patients will be randomized to control groups as available. In the example above, a random subset of patients who become ineligible prior to the rollout of other waves will be added to the wave 2 control group.

Finally, for analysis, given that control patients do not have an intervention send date, the starting date will be randomly chosen for each to match one of the treatment arms' send dates.

Power Analysis

With 17,640 patients, we would have 80% power to detect a 2.5% absolute increase in mammograms with two-tailed alpha of .05, between each among standard postcard, letter, and auto-dialer arms, and live calls, assuming a 13.1% baseline incidence of mammograms completed within 180 days. The detectable increase becomes 1.8% when comparing across no-outreach controls and each among standard postcard, letter, and auto-dialer arms, or 3.0% across controls and live calls, assuming an 8.9% mammogram incidence within 120 days. The outcome duration varies according to the availability of appropriate comparator samples. The target effect size and number of patients are informed by practical considerations regarding the anticipated number of eligible women in 2023, the acceptable duration of the intervention (approximately 7 months), the acceptable delay between intervention and outcome being recorded, and effects that seem achievable and useful if achieved.

Project Status

Outreach has begun, as of May 10, 2023 (IVR and live calls) and May 12, 2023 (postcards and letters). No outcome data have been accessed as of the time this file was posted.

Statistical Analysis Plan

Planned Analyses

Primary Outcome: *Mammogram completed*

The outcome is determined according to HEDIS criteria and based on a combination of GHP claims data and other sources. The time frames vary according to the availability of appropriate comparator samples. Time frames are specified for each of the analyses below.

Question 1: Does calling people increase mammogram completions relative to other modalities of outreach?

We will test the hypothesis that live calls increase the probability of mammogram completions within 180 days of outreach, relative to other modalities.
Analysis 1 (Confirmatory): Time Frame: In the 180 days following the outreach
We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = live call, 1 = standard postcard, 2 = formal letter, 3 = auto-dialer). This analysis will include all enrolled patients.

Question 2: Do different modalities of outreach increase mammogram completions relative to no outreach?

We will test the hypothesis that each of the individual modalities increases the probability of mammogram completions within 120 days of outreach, relative to passive control groups.

Analysis 2.1 (Confirmatory): Time Frame: In the 120 days following the outreach
We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = passive control, 1 = standard postcard, 2 = formal letter, 3 = auto-dialer, 4 = live call). This analysis will include patients in the first 3 waves of active outreach, along with a passive control group consisting of the contemporaneous 120 days of the last 3 waves of outreach, during which outreach will not yet have occurred for those patients.

Other Pre-specified Outcomes

We will run the analyses described above on the following additional outcomes:

1. Mammogram completed – namely, do different modalities of outreach increase mammogram completions relative to each other? We will test whether individual modalities are differentially effective in increasing the probability of mammogram completions within 180 days of outreach, relative to each other (for those modalities not already compared by the analyses above).
   [Time Frame: In the 180 days following the outreach]

We will run an OLS regression including a categorical predictor variable coding for experimental arm (0 = standard postcard, 1 = formal letter, 2 = auto-dialer), as well as a separate OLS regression (0 = formal letter, 1 = auto-dialer). This analysis will include patients in all 7 waves of outreach.

2. Breast malignancy risk detected
   High risk of malignancy, among patients visiting Geisinger clinics and, as available, outside Geisinger (yes/no)
   [Time Frame: In the 210 days following the outreach]

3. Mammogram appointment scheduled
   Appointment scheduled for mammogram, among patients visiting Geisinger clinics (yes/no)
   [Time Frame: In the 30 days following the outreach]

Covariates

An interim call to action—calling or speaking with GHP for help with scheduling—may not be as helpful for patients typically seeking care at non-Geisinger clinics as those going to Geisinger health system clinics. Also, we may not get data on mammogram completions as reliably from outside the Geisinger system. Therefore, all the regressions described above will also explore including as a covariate and interaction term whether or not the patient has an attributed Geisinger PCP.

Analysis Notes

Recent work suggests that OLS regressions are appropriate in randomized experiments with binary outcome variables such as ours (Gomila, 2021).