Encouraging Blood Donation in Patients With a Blood Type in Short Supply

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Statistical Analysis Plan

Brief summary

As of November 2021, partly due to the COVID-19 pandemic, there has been a months-long national shortage of several types of blood in the U.S. (O-Pos, O-Neg, A-Neg, B-Neg, and AB-Neg), which has extended to a local blood shortage within the Geisinger footprint encompassing central and northeast Pennsylvania. The broad aim of this healthcare operations quality improvement project is to determine whether a message indicating that a patient's own blood type is in short supply increases the likelihood that they will donate, compared to a message that mentions a blood shortage without referencing the patient's blood type, or no message at all. Scientists in Geisinger's Behavioral Insights Team (BIT), part of Geisinger's Steele Institute for Health Innovation, will collaborate with Miller-Keystone, where Geisinger refers patients who wish to donate blood and from whom Geisinger receives blood for clinical purposes. Patients with one of the needed blood types will be randomized to receive 1) a message about a blood shortage that does not specify the blood types in short supply or their own blood type (no-blood-type message), 2) the same message modified slightly to specify the recipient's blood type, and to mention that their blood type is in short supply (blood-type message), or 3) no message beyond normal system messages (shortage control group). A second no-contact control group of patients without any of the needed blood types will also be observed (no-shortage control group). Both the blood-type and no-blood-type messages are informed by behavioral science, emphasizing supply needs in local hospitals and providing community-relevant examples of why someone might need blood (e.g., farming or industrial accidents). With respect to the blood-type message, informing the recipient that they have one of the needed blood types may additionally increase their perception that they are in a semi-unique position to help someone in need as compared to a more general message that may suffer from a diffusion of responsibility effect. The BIT will compare how many patients in each group choose to donate blood. They hypothesize that: 1) patients who receive either message will be more likely to donate than patients who receive no message; and 2) patients who receive the blood-type message will be more likely to donate than those who receive the no-blood-type message.

Project status

The team had originally planned to enroll 20,000 patients per arm, and 80,000 patients total. However, the study team decided to stop the study with just under 15,000 patients per arm due to logistical constraints.

Specifically, reaching the target sample size would have required us to enroll many patients who live far from existing Miller-Keystone donation sites and far from the Danville and Bloomsburg areas where Miller-Keystone often runs blood drives. Due to staffing shortages, it was not feasible to set up the additional blood drives that would have been required to enroll these patients and reach the original target sample size.

As of 4/25/2022, enrollment is complete with eligible patients that live near an existing Miller-Keystone donation site or near Danville or Bloomsburg, where Miller-Keystone ran blood drives for patients in the study. The final sample includes total of 59,093 patients.

The team has extracted primary-outcome data for the first group of participants enrolled. The data were extracted in order to set up a data pulling and sharing protocol with Miller-Keystone. However, these initial data have not yet been analyzed, and data for patients enrolled subsequently have not yet been extracted. Additionally, data collection for some participants is ongoing. We plan to extract the remaining primary outcome data all at once on or after 6/6/2022, 6 weeks following the final message send date (4/25/2022).

With the final sample size of at least 14,772 patients per arm, we will have 80% power to detect an increase in donation rates from 1% to 1.35% between any two study arms, a 35% difference, with a two-tailed alpha of .05. With our original planned sample size of 80,000 patients (~20,000 per arm), we would have had power to detect a smaller increase, from 1% to 1.3%.

Sample and randomization

The sample includes Geisinger patients who have a blood type recorded in their electronic health record, are age 18 or older, and do not have a low hemoglobin test result (<12.5) recorded in the 3 months before the patient list was extracted.

For logistical purposes, we are running this study in several phases. We have already begun the study in patients living within 20 miles of Miller-Keystone's Pittston Donor Center based on their home ZIP code recorded in their electronic health record. In collaboration with Miller-Keystone, we will create a plan for expanding the study to other geographic areas within Geisinger's service area.

For each geographic location where we run the study, we will first identify all patients from our list who meet our inclusion criteria above. Then, patients who have a blood type in need (A-, B-, AB-, O-, O+) will be randomized into the **3 shortage blood-type groups.**

A randomly-selected group of patients without a needed blood type will be selected from the patient list within that geographic area for a fourth **No-shortage control** group of the same size as each of the shortage groups listed above.

In order to encourage donation in as many patients with needed blood types as possible, we plan to send messages to those in the shortage control group at a delay (after the primary outcome time frame has passed). The patients in this group will also be randomized to receive either the no-blood-type or the blood-type message.

Planned analyses

Primary outcome

Number of Participants Who Attended a Donation Appointment

> Attended a donation appointment within 6 weeks of their message send date, regardless of whether they donated. This outcome includes patients who were unable to donate for any reason (e.g., low hemoglobin) or patients who showed up to the appointment but decided to leave before donating.
>
> [Time Frame: Within 6 weeks of the final message send date]

Question 1: Are patients who receive either message more likely to donate compared with patients who do not receive a message?

Analysis 1: We will test the hypothesis that patients who receive a message donate at higher rates than patients who do not receive a message by running an OLS regression with a binary predictor variable indicating whether or not patients were sent a message.

Question 2: Is blood donation higher in patients who receive a message that includes their blood type and mentions that their blood type is in need compared with a message that does not mention their blood type?

Analysis 2: We will test the hypothesis that patients who receive the blood-type message will be more likely to donate than those who receive the no-blood-type message by running an OLS regression with a binary predictor variable indicating whether patients were sent the blood-type message or the no-blood-type message.

Notes about timeframes and analysis

Messages sent to patients within a geographic location will be divided into separate message dates so as not to overwhelm appointment scheduling at Miller-Keystone. Timeframes listed above refer to the amount of time elapsed from the send date for a given patient. For instance, the primary outcome timeframe is 6 weeks; thus, for the purposes of this study, a patient will be counted as having donated if they donated blood within 6 weeks of their message send date.

Patients in both control groups will be divided into separate message dates, each assigned to one of the message-date groups for the experimental arms. Each control group will be monitored for appointments and donations during a date range that is aligned with the date range for its corresponding experimental group.

All analyses will exclude patients who scheduled their appointment prior to their message send date.

Sensitivity analyses and robustness checks
The analyses above will be run using a time frame of 6 weeks from the message send date. However, as a robustness check, we will rerun *Analysis 2* on the subset of patients who open the messages, using a time frame of 6 weeks from the date each individual patient opened their message.

We will run an additional robustness check including only patients who scheduled an appointment within the 2 weeks following their message send date.

As another robustness check, we will remove all patients who live within 20 miles of Danville, PA, as these patients are likely to be health care workers. They are therefore more likely to already know their blood type and/or to know their blood type is in short supply.

Recent work suggests that OLS regressions are appropriate in randomized experiments with binary outcome variables such as ours (Gomilla, 2021). However, as a robustness check, we will also run the regressions described above as logistic regressions instead of OLS regressions.

Secondary outcomes

We will use the approaches described in *Analyses 1* and *2* above to evaluate the impact of the intervention on the secondary outcome measures listed in the pre-registration:

1. Number of Participants Who Successfully Donated Blood

   Attended a donation appointment within 6 weeks of their message send date and successfully donated, excluding patients who were turned away from or left their appointment without donating.

   [Time Frame: Within 6 weeks of the final message send date]

2. Number of Participants Who Scheduled a Blood Donation Appointment

   Scheduled an appointment within 2 weeks of their message send date.

   [Time Frame: Within 2 weeks of the final message send date]

3. Number of Participants Who Scheduled a Blood Donation Appointment

   Scheduled an appointment within 6 weeks of their message send date.

   [Time Frame: Within 6 weeks of the final message send date]

Additional exploratory analyses

1. Household members

   Patients who donate after receiving messages may also encourage members of their household to donate. We will run a negative binomial regression to test whether the number of donors residing at the same address as each target patient varies as a function of experimental group, whether the target patient donated or not, and the interaction between these variables.

2. First time donors vs. repeat donors

   We will evaluate whether message effectiveness differs based on whether the patient has previously donated blood at Miller-Keystone. To this end, we will run an OLS regression model, testing whether donations vary as a function of experimental group, a bivariate indicator for whether or not the patient has previously donated blood, and the interaction between these variables.

3. Geographic location

   Patients in certain geographic regions may be more receptive to our messages than others. We will test for differential effectiveness as a function of geographic region by running an OLS regression including a dummy coded predictor variable coding for geographic region (as defined by our separate outreach campaigns). We will test for an interaction between region and experimental group on donation behavior. If the interaction is significant, we will run post-hoc comparisons to probe for differences in the efficacy of our interventions separately by geographic region. If the interaction is not significant but the main effect of region is, we will run post-hoc tests on this main effect to understand how donation behavior differs by region.

   Importantly, our messages are being sent on different dates in geographic regions (with some overlap), and blood donation patterns vary across the year. To control for variation in blood donation, we will attempt to determine standard donation rates across time, and to include this variable as a covariate in our analysis.

4. Time to donation

   We will run regression models to test whether either intervention message influenced the timing (time elapsed since the message was sent) of donations.

5. Type of donation

   We will test whether there are differences in donation type (particularly whole blood and

red blood cell donations) as a function of experimental group.

6. Demographics

   We will run regression models to test for main effects of several demographic factors on donation behavior, along with interactions between these factors and message group. These demographic factors include binned age (18-24, 25-34, 35-44,45-54, 65+), sex, race, ethnicity, line of insurance (as a proxy for socioeconomic status), and Charlson Comorbidity.