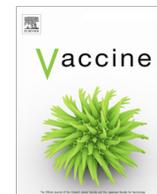


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Large-scale influenza vaccination promotion on a mobile app platform: A randomized controlled trial

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ABSTRACT

While health-care providers have used incentives in an attempt to motivate patients to obtain vaccinations, their effect on vaccination rates has not been systematically evaluated on a large scale. In this study, we examined whether mobile applications may improve population vaccination rates through enhanced communication and incentives education. Our study is the first randomized controlled trial assessing the effect of large-scale messaging combined with individualized incentives on influenza-vaccination rates. In this trial, we delivered messages regarding influenza vaccinations to 50,286 adults, aged 18 through 65, then compared the subsequent vaccination rate, the effectiveness of the message content and the timing. Multiple rounds of messaging occurred over a seven-week period during the 2016 flu season, after which vaccination rates were observed for one week. Participants were randomly assigned to one of three messaging approaches: conspicuous (highlighting the amount of rewards to be received for obtaining a flu shot); generic (promoting vaccinations with no mention of rewards); or no-message. Evidence of vaccination obtainment was indicated by medical and pharmacy claims, augmented by patients self-reporting through the mobile wellness app during the study period. Of the people assigned to receive messaging, 23.2% obtained influenza vaccination, compared to 22.0% of people who obtained vaccination in the no-messaging control arm. This difference was statistically significant ($p < 0.01$). The research revealed that messaging effectiveness decreased after each successive batch sent, suggesting that most participants responsive to messaging would become activated immediately after receiving one alert. Interestingly, in this large-scale study, there were no significant differences between conspicuous incentives and generic messaging, suggesting an important area for future research.

Trial Registration: clinicaltrials.gov identifier: NCT02908893.

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1. Introduction

Annual influenza vaccinations are recommended for all adults [1]. Although their effectiveness may vary yearly and per individual, vaccinations confer an optimal benefit when administered to a substantial portion of the populace, reducing the infectious burden of the virus and enhancing crowd immunity [2]. The benefits of widespread vaccinations among adults include reductions in hos-

pitalizations, co-infection with bacterial pneumonia, and lost work productivity [3]. Adults who obtain vaccinations are also less likely to pass influenza to close contacts and family members, which may include people with a higher risk of morbidity from infection, including the very young or very old. Influenza vaccinations are widely recognized as the “primary method for preventing influenza and its complications” [4].

Despite these advantages, influenza-vaccination rates remain low in the United States. Estimates from national surveys such as the Behavioral Risk Factor and Surveillance Study (BRFSS) and National Health Information Survey (NHIS) report rates of 40%, with wide variability depending on the specific population in terms of race, ethnicity, or age group [5,6]. Younger adults in particular have low vaccination rates, reported at only 36.7% for

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patients aged 18 through 49 years old and 43.7% for those aged 50 through 65 [7]. These rates lag well behind stated public health goals of 70% for the general population [8].

Approaches for improving vaccination rates could be categorized into three strategies: education; increased opportunity or access to vaccinations; and incentives. The first uses educational media, such as pamphlets, posters, or newsletters, to disseminate information on the value of vaccinations to as wide an audience as possible [9,10]. The second attempts to increase access and opportunities for patients to receive vaccination, such as nudging health-care providers to vaccinate patients or expanding vaccination locations to include workplaces or pharmacies [11]. The third uses consumer-based incentives, such as reduced-fee or free vaccination services, employer-based wellness credits, and even the threat of punitive actions – such as the suspension of work privileges – to encourage vaccination behaviors in the population [12,13].

While incentives, financial or otherwise, have been used to motivate actual vaccination behavior, their effect on vaccination rates has not been systematically evaluated on a large scale. Our study is the first randomized controlled trial assessing the effect of large-scale messaging, combined with individualized incentives, on influenza-vaccination rates.

Further, previous research has found that in scenarios involving treatments other than vaccinations, the effectiveness of incentive programs does not simply depend on the presence or size of potential rewards; rather, the conspicuousness of incentives – that is, transparency and visibility – is sometimes more crucial. Recently developed economic models propose that providers' failure to make incentives conspicuous to patients may be a common phenomenon with important consequences [14,15].

These aforementioned approaches can be employed synergistically. In particular, the advent of consumer mobile technology as a vehicle for digital communication and marketing has enabled the tight coupling of information delivery with individualized incentives. In non-health-related industries, this hybrid approach is already known to influence consumer behaviors [16]. Such approaches may prove particularly effective in driving health behaviors such as obtaining vaccinations: The combination of education, incentives, and increased access may collectively address misconceptions concerning risks, lower barriers, and remind people of the benefits of and opportunities for vaccinations.

In this study, we report the results of a randomized controlled trial conducted within the context of a health plan's wellness app. The study tests an inexpensive approach for delivering flu-vaccination message reminders to participating patients via smartphones. This approach allows for messaging that can directly address barriers to vaccinations across all dimensions. This study adds to the existing literature by testing the uses of different types of targeted messages (such as enhancing the visibility of incentive programs) and timing of messages (aligned with projected pharmacy visits) to improve flu-vaccination rates in a real-world setting with the intervention received alongside other features of the app. The trial is population-based using all eligible users. These features are the key components of pragmatic trials, an approach that has been advocated for the evaluation of mobile health technologies and apps [17]. The embedded randomization allows for the direct measure of the intervention's impact. The approach could be easily integrated into existing health apps.

Several recent randomized controlled trials examined the use of SMS messaging to improve influenza-vaccination rates in varying contexts. Stockwell et al. showed a modest improvement in vaccination rates among children and teenagers using SMS messages [18], while Herret et al. demonstrated the utility of SMS messaging for improving vaccination rates among adults in a primary-care setting [19]. Regan et al. found similar modest improvements in

a cohort of high-risk patients in Australia [20]. Yudin et al. found no effect of SMS reminders on vaccination in a cohort of pregnant women in the United States [21].

Current mobile applications offer a platform for health improvement through the delivery of content, services, and messaging, as well as the use of gamification to improve engagement. A recent observational study suggests that such approaches are feasible and potentially effective [13]. To our knowledge, no studies have utilized an experimental design to evaluate the effectiveness of mobile general wellness applications in impacting health-outcome behaviors, such as vaccination obtainment; furthermore, no other study has tested whether increasing incentive-program transparency results in improved vaccination rates.

2. Material and methods

2.1. Study design

The study is a three-arm (conspicuous message, general message, control/no message) randomized controlled trial conducted over a nearly 7-week period, from September 13, 2016 through November 4, 2016. An overview of the study design as well as the randomization process is shown in Fig. 1. Because the organization conducting the study does not have an internal IRB, this work was reviewed by Solutions IRB (<http://www.solution-sirb.com>) and exempted as benign behavioral research. The study is registered on clinicaltrials.gov (ClinicalTrials.gov Identifier: NCT02908893).

2.2. Participants

The initial study population included 77,946 participants from Humana, a large national health plan based in Louisville KY. To be eligible, participants had to be 18 to 65 years in age, continuously enrolled in a qualifying Humana health plan from January 1, 2015 through June 1, 2016, active users of the Humana wellness mobile app, and opted into receiving push notifications through the app. The app runs on any Apple iOS or Google Android mobile device.

Of the 77,946 participants who had downloaded the app onto a compatible mobile device, 27,660 were excluded because they were unable to receive push notifications from the app. A small proportion of the participants (<1%) opted out of receiving notifications from the app during the study period. The remaining sample consisted of 50,286 individuals with commercial coverage.

2.3. Interventions

As members of the Humana health plan, all participants were eligible to receive a flu vaccination at no cost. As part of its wellness program, Humana offers a mobile app, which encourages and rewards wellness activities (via points that can be exchanged to purchase items). All messaging interventions were delivered through the mobile app. Users who obtained and recorded an influenza vaccination with the mobile app earned points, regardless of their assigned intervention arms.

Hypothesis 1. Testing Message Type

As shown in Fig. 1, two messaging approaches were evaluated. The first approach, referred to throughout the paper as “conspicuous” [22], used the mobile app to message users that they could earn wellness points for obtaining the influenza vaccine². Recipients of these conspicuous messages are referred to as Group 1 in this paper. The second approach, referred to throughout as “generic,”

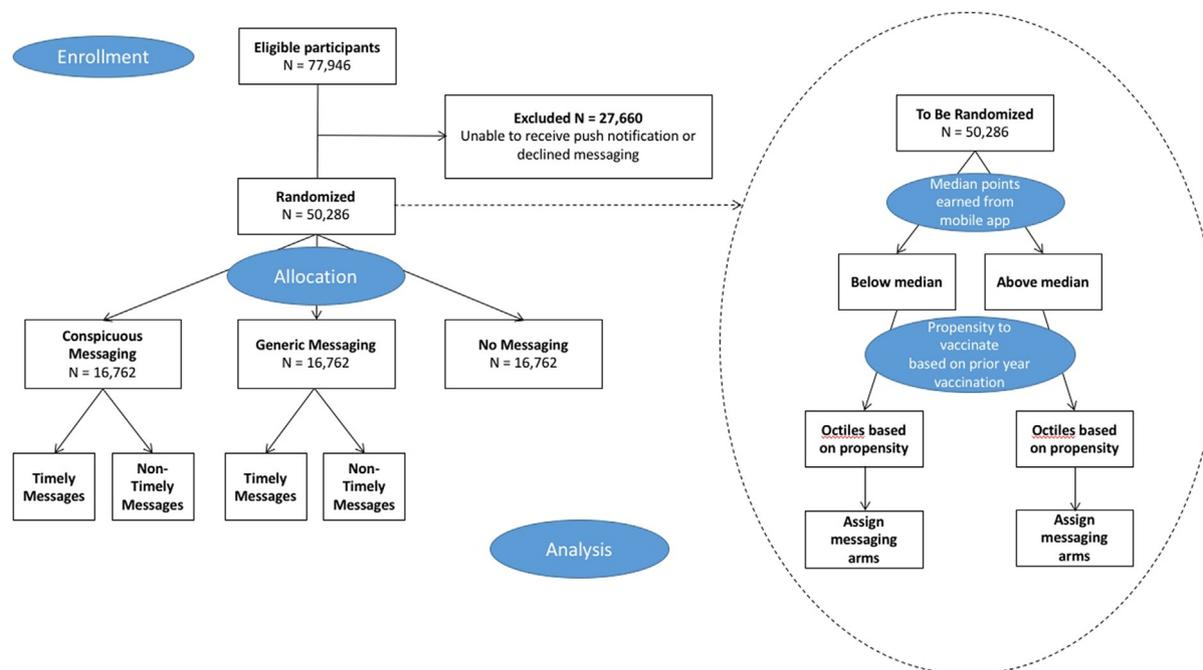


Fig. 1. CONSORT diagram for participant flow. Inset shows a diagram for how participants were randomized.

informed users via SMS that influenza vaccinations were recommended but made no mention of rewards or points. Recipients of the generic messages are referred to here as Group 2. Fig. 2 shows the wording of each of the messaging approaches within the mobile application. A third group, the no-messaging group or Group 3, did not receive any in-app messages about influenza vaccinations. Participants were randomized (discussed later) into equal groups of 16,762 for the conspicuous, generic, and no-messaging arms of the study. Messages were sent to participants in three batches over the study period. Each message batch was distributed over approximate two-week periods in 2016: The first was sent between September 13 through September 30, the second between October 3 through October 14, and the third batch from October 17 through October 28.

Hypothesis 2. Testing Message Timing

We evaluated whether timing the message to be received when a participant was likely to refill a medication would improve vaccination rates, as most pharmacies now offer vaccinations. Within each messaging arm, we assigned participants to have timely messages or non-timely messages. Pharmacy claims were used to predict the day that participants assigned timely messages were most likely to pick up prescriptions. These participants were then randomly paired with an individual in the non-timely arm. The in-app message was delivered to both individuals within two days of the expected prescription pickup by the person from the timely-message group. If a prediction for prescription pickup could not be made for a person assigned timely messages, we chose a random delivery date for the message within the batch-window period for both individuals in the pair.

2.4. Outcomes

The primary outcome was influenza vaccinations as documented via medical and pharmacy claims submitted to the health plan or when participants submitted proof of vaccination through the mobile app for reward points. To establish the effect of messag-

ing on vaccination obtainment, we attributed vaccination records with message batches up to one week after the messages were sent. The claims-data pull from the health plan was performed in late January 2017 to allow time for claims to be adjudicated. Influenza vaccinations were measured cumulatively from the beginning of the season (June 1, 2016) until the end of the trial period (November 4, 2016).

3. Randomization

Fig. 1 (inset) shows the randomization method for this study. We performed a block randomization based on participant engagement with the mobile app and wellness program to minimize behavioral confounders in the study. Participants were first divided into two groups based on the median earned incentive points from the mobile app for the study population. We then created a vaccination-propensity score by using medical-claims data from the prior year (June 1, 2015 through June 1, 2016) to train a regularized logistic regression model of an individual receiving a flu vaccination from 2015 through 2016 as documented in claims and pharmacy data. The two groups that were split on median earned points were further divided into octiles of propensity to vaccinate. The octiles became the final blocks, which were randomized into the intervention arms of conspicuous, generic and no-messaging.

3.1. Statistical methods

Comparison of vaccination rates among the different arms of the study was done with intention to treat analysis. Student's *t*-test for continuous variable comparisons and chi-square test for categorical comparisons were used when appropriate for secondary analyses. Relative risks were calculated directly and confidence intervals were calculated using the standard log transformation. Subgroup analyses by age group, income level, and estimated propensity to vaccinate followed the general analysis. All *p*-values are reported with 0.05 level significance with correction for multiple testing where appropriate [23,24].

Conspicuous Messages Arm

Push Notification

Headline

Body 1

Body 2

Flu Shot=200 Points

Get a flu shot

next time you visit a pharmacy

In-App:

Headline

Body 1

Body 2

Body 3

Flu Shot=200 Points

Get a flu shot at a pharmacy

next time you refill a Rx

Tap Activities to submit proof

Generic Messages Arm

Push Notification

Headline

Body 1

Body 2

Flu Shot

Get a flu shot

next time you visit a pharmacy

In-App

Headline

Body 1

Body 2

Body 3

Flu Shot

Get a flu shot at a pharmacy

next time you refill a Rx

Fig. 2. Sample Push Notifications and In-app Notifications. Conspicuous messages mentioned the opportunity for reward points, while generic messages only reminded users to obtain a flu shot.

4. Results

4.1. Primary outcome analysis

Table 1 shows the baseline characteristics of the study participants. Study participants had a mean age of approximately 41 years across the different treatment arms. Participants were more likely to be women, and hypertension was the most prevalent morbid condition, affecting about 20% of the participants. Only a small proportion of the participants had been affected by a flu event in the previous year, based on claims data, and across all the treatment arms, the vaccination rates had been generally low.

Of all participants identified with verified flu vaccinations across all arms, 9.6% had mobile proof only, 25.9% had claims verification only, and 64.5% had both. Of the people assigned to receive any messaging (Group 1 + Group 2, total N = 33,524), 7764 (23.2%) obtained influenza vaccinations, compared to 3696 (22.0%) people who obtained vaccination in the no-messaging control arm (Group 3). This difference was statistically significant ($p < 0.01$). Looking at the effect of specific messaging approaches, we found that the relative risk of influenza vaccination for participants in the conspicuous messaging arm (Group 1) compared to that of the no-messaging arm (Group 3) was RR = 1.06 [95% CI, 1.02–1.11]. The absolute difference between the groups was 1.38%, Number Needed to Message = 72.5 persons to gain an additional vaccination. The relative risk of the non-conspicuous messaging to no-messaging was RR = 1.05 [95% CI, 1.0–1.08], with an absolute risk difference of 1.11%, Number Needed to Message = 90.1 persons. There was no significant difference comparing the conspicuous messaging (Group 1) to the non-conspicuous messaging arms (Group 2).

4.2. Secondary analysis

Fig. 3a shows the vaccination-rate responses with messaging approaches for both the conspicuous (Group 1) and the non-conspicuous (Group 2) arms compared with the non-messaging control (Group 3). Vaccination rates increased over time, with participants in the messaging arms (Group 1 + Group 2) showing higher rates of vaccination compared with controls from the same period. The difference between the messaging arms and non-messaging control was significant ($p < 0.05$) for the first and third batches sent. The rate ratio for successive message batches was 1.09, 1.04 and 1.05 for first, second and third message batches respectively. Messaging effectiveness appeared to decrease over each successive batch sent, suggesting that the majority of participants responsive to messaging would become activated immediately after receiving a message.

We examined the relationship between estimated propensity to vaccinate, based on information from the prior year, and the

Table 1

Baseline characteristics of participants.

| | Conspicuous incentives arm | Generic messaging arm | No messaging arm |
|---------------------------------------|----------------------------|-----------------------|--------------------------|
| N subjects | 16,762 | 16,762 | 16,762 |
| Mean age (s.d.) | 41.5 (10.9) | 41.4 (11.0) | 41.6 (10.9) |
| Percent female (%) | 10,357 (61.9) | 10,487 (62.7) | 10,400 (62.1) |
| Medical conditions (%) | | | |
| Hypertension (%) | 3069 (20.2) | 3060 (20.1) | 2989 (19.6) |
| Coronary artery disease (%) | 316 (2.1) | 336 (2.2) | 312 (2.1) |
| Diabetes (%) | 935 (6.1) | 982 (6.4) | 1021 (6.7) |
| Respiratory illness (%) | 1199 (7.9) | 1203 (7.9) | 1219 (8.0) |
| Influenza event in the prior year (%) | 218 (1.4) | 218 (1.4) | 203 (1.3) |
| N vaccinated (%) | 3927 (23.4) ¹ | 3837 (22.9) | 3696 (22.0) ² |

¹ $p < 0.005$ compared to the no-messaging arm.

² $p < 0.01$ for combined conspicuous and generic messaging (N = 7764 [23.2%]) compared to the no-messaging arm.

observed vaccination rate during the study period (**Fig. 3b**). Overall, there appeared to be a near-linear relationship between a group's average propensity to vaccinate and the group's observed influenza vaccination rate at the end of the study period, although there were no significant differences within propensity subgroups between messaging approaches and control.

We did not find message timeliness to have a statistically significant different effect on flu-vaccination rates (23.3% vs 23% for timely vs non-timely messaging respectively, p -val = 0.46). Participants with lower income and from older age groups were more likely to be vaccinated, but we did not observe a statistically significant effect of messaging (conspicuous, generic or both) on vaccination rates during the study period (**Fig. 4**).

5. Discussion

The Center for Disease Control and Prevention (CDC) estimates that even a modest 1% increase in influenza vaccination rates could avert 96,600 illnesses, 46,400 medical visits, and 1390 hospitalizations [25]. A mobile platform sending reminder messages can increase the influenza vaccination rates by more than 1%. Messaging effectiveness decreased with each successive batch sent, suggesting that while messaging is effective in increasing immunization, the majority of participants responsive to messaging would become activated immediately after receiving one.

Our large-scale study found no significant difference in vaccination rates between Group 1 participants, who received conspicuous messages providing increased transparency around incentives for

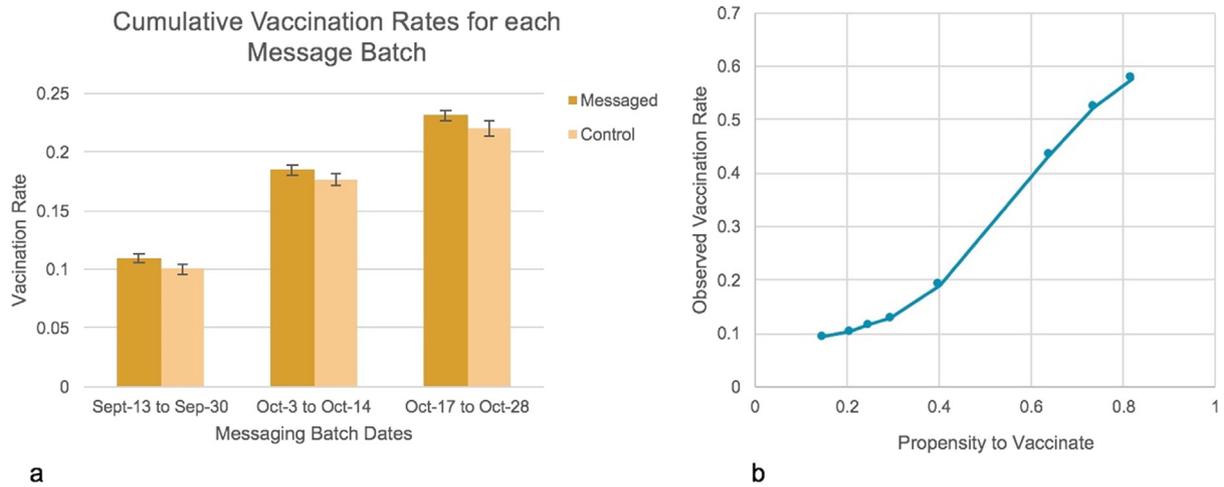


Fig. 3. Factors associated with influenza vaccination. (a) Cumulative vaccination rates based on fixed schedule of message batches. Vaccination rate was measured to one week after close of batch period. (b) Influenza vaccination rate vs octiles of propensity to vaccinate. Vaccination propensity is determined from medical claims data in the prior year (6/1/15 to 6/1/16).

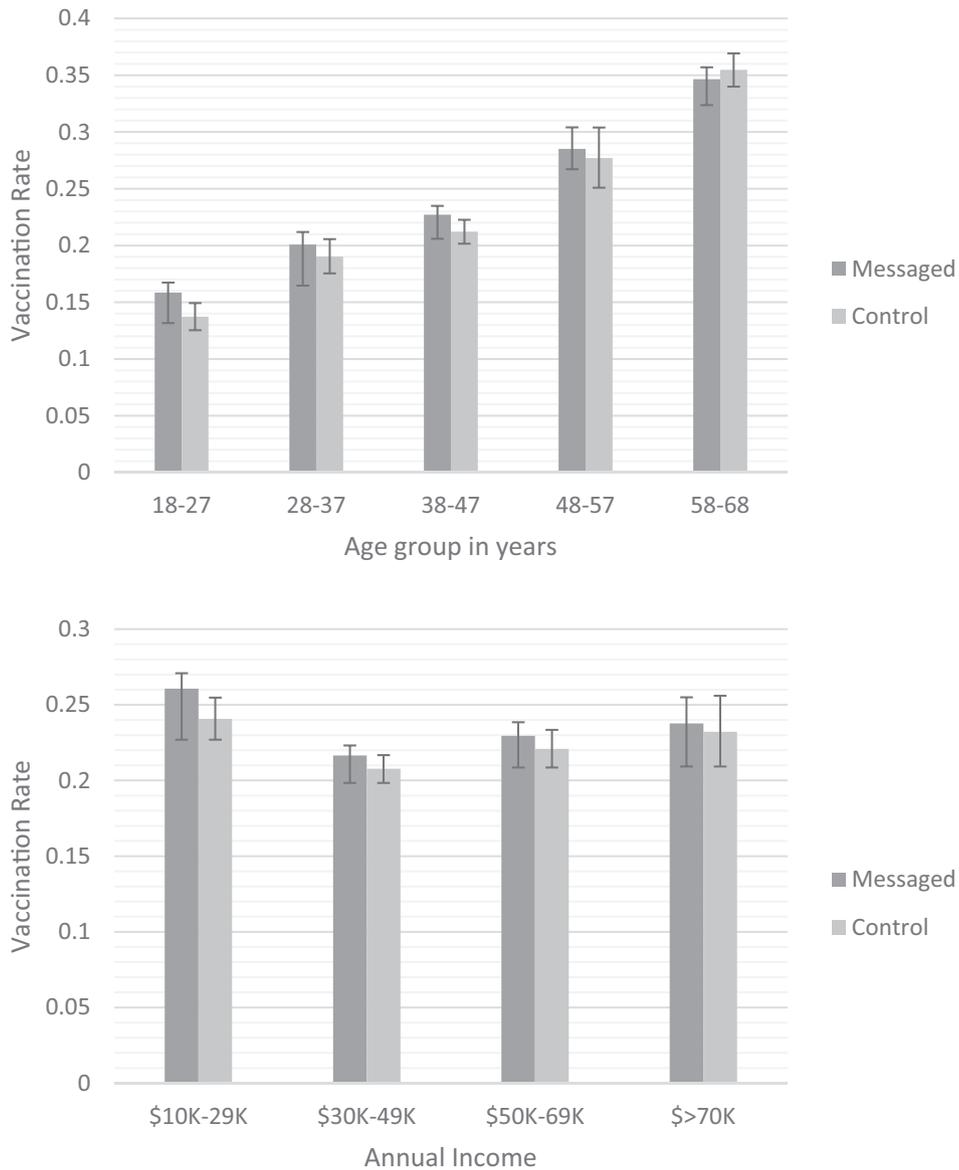


Fig. 4. Messaging effectiveness based on age and income.

obtaining vaccinations, and Group 2 participants, who only received simple vaccination reminders with no mention of incentives. It was hypothesized that increased transparency would enhance the incentive program's success; thus, the lack of statistical significance raises questions regarding vaccination incentives including their size, salience, and context in which they are communicated.

Although incentives, financial or otherwise, have been used to motivate actual vaccination behavior, their effect on vaccination rates has not been systematically evaluated on a large scale. Our study is the first randomized controlled trial assessing the effect of large-scale messaging combined with individualized incentives on influenza-vaccination rates. Our study is also unique in taking advantage of the emergence of cloud-based mobile applications in the health-care space. Further, our study was conducted within the context of a general-purpose wellness app, allowing for the assessment of impact in a real-world setting.

A recent study of the barriers to vaccination suggests five dimensions that impede uptake: access, affordability, awareness, acceptance, and activation [26], aligning with the more general health-behavior frameworks such as the Theory of Planned Behavior. Consumer mobile technology has the potential to remove these barriers by driving behavioral changes. Mobile technology may be particularly effective for the activation – or “ability to act” – dimension by moving beyond reminder messages and facilitating “nudging.” Still, traditional one-way SMS messaging has technological limitations compared to mobile health apps: Users are unable to interact with the messaging system, and the messages serve only as reminders to vaccinate.

Intention to vaccinate does not necessarily translate to actual vaccination behavior. A recent survey suggests that nearly half of all people who intend to obtain vaccinations do not [27]. Mobile health apps can directly address this. For example, Dale [13] utilized location services to inform users of their proximity to immunization-dispensing points and Milkman [28] prompted participants to establish an “implementation intention” by asking them to schedule a vaccination appointment. In addition to providing incentives, the present study delivered timely messages to a subgroup based on predicted refill times but found no significant differences as compared to the non-timely group; this may suggest the need to more fine-grained personalization strategies.

Our study has limitations. The participants all had access to mobile technology and appeared to reflect a younger cohort, the majority of whom were female. This may explain the relatively low vaccination rates that we observed in the study population. Because the incentives in the conspicuous messaging arm were given through the app, which has other competing rewards for healthy behavior, the content of the incentives may have been ignored by the participants. However, this would be expected to attenuate the measured effect size. Further, incentives were available to all study participants via the platform, regardless of their group, and may not have been sufficient to motivate people to obtain influenza vaccinations. The number of vaccinations, as assessed using medical and claims data, or even self-reported, may be incomplete, especially as vaccines may be provided at no cost through places of employment and other venues. Additionally, it should be noted that our method of estimating vaccination rate differs from that of the Centers for Medicare and Medicaid Services (CMS) Annual Flu Vaccine measure, which relies on the Consumer Assessment for Healthcare Providers and Systems (CAHPS) data. Nonetheless, our block-randomized research design provides a framework to efficiently test additional incentives structures within the context of a health plan's or health care provider's mobile platform. Finally, we note that our intervention and outcome assessment did not span the entire flu vaccination season,

which extends through March, though it spans beyond the flu-vaccination peak period, assumed to happen in mid-October.

As increasing transparency around vaccination incentives in this large-scale study was not statistically significant compared to simple reminder message, one must question the financial efficacy of incentive programs. Supplementary large-scale research should be conducted to assess the conditions under which incentive programs are cost effective.

6. Conclusion

We found a statistically significant benefit to using a mobile platform to nudge people to obtain vaccinations against influenza at a population level. Given that the development costs of the cloud-based mobile patient portals have already been justified by most insurance companies and healthcare systems, implementing an add-on messaging app and providing targeted reminders would be relatively inexpensive, and the downstream benefits of the increased vaccination rate would likely translate to substantial savings, both financially and in terms of individual co-morbidity. Given the trend among health-care providers and payers to use mobile technologies to engage and interact with patients, we believe that our findings may have important implications on how such technologies can be used to promote and effect healthy behaviors at population scale. This approach may have relevance to other population strategies for health behaviors.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: None.

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