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Opt-out Enrollment Increases Participation in a Remote Monitoring Intervention for Myocardial Infarction Patients

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Introduction

Many research studies are limited by low participation rates, threatening the generalizability of findings because participants likely differ greatly from non-participants.[1] Low participation rates could be a function of the opt-in approach to enrollment in which the default is to not participate. Behavioral economics research has shown that an opt-out approach can increase participation in retirement savings and organ donation while maintaining informed choice.[2,3]

We evaluated whether an opt-out approach will increase participation in a remote monitoring intervention among heart attack patients.

Methods

This is a prospective cohort study comparing enrollment rates using an opt-in to an opt-out approach. The intervention offered remote monitoring of medication adherence for patients recently discharged with heart attacks, as in a larger trial with opt-in enrollment. Those in the opt-in cohort were patients in a larger study with fee-for-service (FFS) Medicare coverage discharged from the University of Pennsylvania Health System (Penn) with a principal diagnosis of myocardial infarction. Participants were recruited in the 60 days after discharge by sending a recruitment letter to introduce the study, followed by up to five phone calls by research staff who obtained verbal consent to participate. Patients who agreed were

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sent remote monitoring medication bottles in a system configured with reminders, financial incentives, and social support to promote adherence. Those in the opt-out cohort were similar patients discharged from Penn with myocardial infarction but with insurance types making them ineligible for the larger study. To create an opt-out frame, these patients received the remote monitoring pill bottles with the initial mailing to simulate participation as the default, but otherwise received the same recruitment processes and the same intervention if they agreed to participate.

The primary outcome was the proportion of patients mailed recruitment material who agreed to participate in the clinical study. We used a chi-square test to compare the intervention and control groups, with p-value of <.05 considered statistically significant. We also compared the daily medication bottle opening rates for both groups in the three months after device set-up. Demographics and race/ethnicity data were obtained from the electronic health record. We received approval from the Institutional Review Board of the University of Pennsylvania and registered the protocol on ClinicalTrials.gov (NCT02139202).

Results

We approached 235 patients in the opt-in cohort and 52 in the opt-out cohort. The opt-in group included only FFS Medicare patients who were older, while the opt-out group had a broader mix of insurance types. Sixteen percent (95% CI, 11% to 20%) agreed to participate in the opt-in group, compared to thirty-eight percent (95% CI, 25% to 52%) in the opt-out group ($p < 0.001$). Medication bottle opening rates among participants were similar between the opt-in and opt-out groups during the three months after device set-up (86.9% vs. 89.8%; p-value=0.67).

Discussion

This study suggests that an opt-out approach to enrollment can significantly increase participation in trials of health system interventions. Importantly, medication bottle adherence post-enrollment was similarly high in the opt-out group, reflecting similar engagement among the additional participants. Opt-out procedures may increase participation by shifting the perceived default to participation, because the immediate provision of the wireless pill bottles creates an endowment effect, or by implying that the social norm is to enroll.[4] However, there was a greater loss of equipment in the opt-out approach and the effects may be limited to interventions with tangible devices, so larger studies are needed to confirm findings in other populations and conditions. For low-risk interventions, opt-out approaches can improve the efficiency of recruitment, expand the intervention to those who are otherwise less likely to participate, and increase generalizability of clinical trials to a broader population.

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Dr. Mehta had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Dr. Troxel serves on the Scientific Advisory Board of VAL Health. Drs. Asch and Volpp are principals and owners of VAL Health. Dr. Volpp has served as a consultant for CVS Caremark and received grants from CVS Caremark, Humana, Merck, Weight Watchers, and Discovery (South Africa).

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Table 1.

Eligible participants in opt-in and opt-out cohorts

	Opt-In (n = 235)	**Opt-Out (n = 52)**
Male [a]	140 (60)	36 (69)
65 and older [b]	192 (82)	12 (23)
Mean Income [c]	$55,916	$46,732
Race		
White	143 (61)	25 (48)
Black	54 (23)	17 (33)
Other	12 (5)	4 (7)
Unknown	26 (11)	6 (12)
Mailed		
Unreachable	69 (29)	15 (29)
Declined	96 (41)	13 (25)
Ineligible	22 (14)	4 (8)
Enrolled	**37 (16)**	**20 (38)**

[a] Values are reported as No. (%) unless otherwise indicated

[b] Age at date of discharge

[c] Household income data taken from Census Bureau 2007–2011 release