Financial Incentives for Completion of Fecal Occult Blood Tests Among Veterans
A 2-Stage, Pragmatic, Cluster, Randomized, Controlled Trial
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Background: Rates of patient completion of fecal occult blood tests (FOBTs) are often low.

Objective: To examine whether financial incentives increase rates of FOBT completion.

Design: A 2-stage, parallel-design, pragmatic, cluster, randomized, controlled trial with clustering by clinic day (ClinicalTrials.gov: NCT01516489).

Setting: Primary care clinic of the Philadelphia Veterans Affairs Medical Center.

Patients: 1549 patients who were prescribed an FOBT (unique samples of 713 patients for stage 1 and 836 patients for stage 2).

Intervention: In stage 1, patients were assigned to usual care or receipt of $5, $10, or $20 for FOBT completion. In stage 2, different patients were assigned to usual care or receipt of $5, a 1 in 10 chance of $50, or entry into a $500 raffle for FOBT completion.

Measurements: Primary outcome was FOBT completion within 30 days. Preplanned subgroup analyses examined 30-day FOBT completion. In stage 2, a 1 in 10 chance of $50 increased FOBT completion. In stage 2, a 1 in 10 chance of $50 increased FOBT completion compared with usual care (between-group difference, 19.6% [95% CI, 10.7% to 28.6%]; P < 0.001) but a $5 fixed payment and entry into a raffle for $500 did not. None of the incentives were more effective among patients who had previously been nonadherent to an FOBT than among patients who had previously completed an FOBT.

Results: In stage 1, none of the incentives increased rates of FOBT completion. In stage 2, a 1 in 10 chance of $50 increased FOBT completion compared with usual care (between-group difference, 19.6% [95% CI, 10.7% to 28.6%]; P < 0.001) but a $5 fixed payment and entry into a raffle for $500 did not. None of the incentives were more effective among patients who had previously been nonadherent to an FOBT than among patients who had previously completed an FOBT.

Limitations: Single Veterans Affairs medical center setting, short follow-up, use of 3-sample rather than 1-sample immunochemical FOBTs, limited power to detect small effects of incentives, inability to evaluate cost-effectiveness.

Conclusion: A 1 in 10 chance of receiving $50 was effective at increasing rates of FOBT completion, but 5 other tested incentives were not.

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Methods

A promising tool for improving rates of FOBT completion is financial incentives (12, 13), which capitalize on insights from behavioral economics that suggest patients overweight near-term costs and benefits (14). When prescribed FOBTs, patients may forgo completion because the tests confer a certain and immediate disutility in return for the uncertain and distant benefit of early detection of CRC for a few patients who screen positive and no tangible benefit for most patients who screen negative. This overweighting of tangible, short-term costs and benefits might be leveraged to promote FOBT completion by providing an immediate financial reward for this behavior, yet this approach remains untested.

The goal of this pilot study was to identify the dose and design of modest financial incentives that could increase rates of initial completion of prescribed FOBTs among VHA primary care patients. We used cluster randomization for practical reasons and to minimize contamination across patients, and we used a pragmatic design (15) to test incentives in a real-world clinical setting.

Methods

Design Overview

We conducted a 2-stage parallel-design, pragmatic cluster randomized, controlled trial in the primary care clinic of the Philadelphia Veterans Affairs Medical Center (PVAMC) between 14 February 2012 and 9 October 2012. The clusters were clinic calendar days. In stage 1, 40 clusters of all 713 patients who were prescribed an FOBT (Figure 1) were assigned to usual care or to receipt of $5, $10, or $20 incentives for completing their FOBT within

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30 days. In stage 2, 48 clusters of all 836 patients who were prescribed an FOBT (Figure 2) were assigned to usual care or receipt of incentives of $5, a 1 in 10 chance of $50, or entry into a $500 raffle for completing their FOBT within 30 days. Both stages included a usual care control group to account for temporal variation in FOBT completion. All incentives were disbursed as mailed paper vouchers that could be exchanged for cash at the PVAMC. The institutional review boards of the PVAMC and VA Ann Arbor Healthcare System approved the study. Need for patient consent was waived because the research involved no more than minimal risk and could not have been practically carried out without the waiver.

**Setting and Participants**

The clinic calendar day clusters were eligible for randomization if they occurred during each study period. Because of the waiver of consent, all patients in each cluster who had a new FOBT order were included in the study. After each clinic day we recorded how many FOBT kits were distributed and stopped each stage once we reached our target sample size for each group.

**Randomization and Interventions**

The unit of randomization was the clinic calendar day. All patients in a given day were assigned to the same condition to minimize contamination. In each stage the allocation sequence was based on a permuted blocked randomization schedule with a fixed block size of 8 that was generated by a study investigator who had no contact with patients or access to patient data.

Before each clinic day, the research coordinator inserted a brightly colored index card with the group assignment into all clinic FOBT kits. For patients randomly assigned to an incentive group, the card described the incentive they would receive if they completed and returned their FOBT within 30 days. For patients randomly assigned to the usual care control group, the card asked patients to complete and return their FOBT within 30 days.

All investigators and analysts were blinded to group assignment until all data were collected. The research coordinator could not be blinded to group assignment because she stocked the clinic with study FOBTs before each clinic day and distributed financial incentives after FOBT completion. However, she had no contact with study participants before FOBT completion. Clinic staff and patients could not be blinded because the interventions were integrated into usual care, which entailed clinic staff briefly counseling patients about how to complete their FOBT.

In stage 1, clusters of patients were randomly assigned to usual care or to receipt of $5, $10, or $20 for FOBT completion within 30 days. We chose these modest financial incentive amounts because, if found to be effective, they might be more likely to be adopted than a larger incentive. Further, many VHA patients have lower socio-
Focus was measuring the initial effects of incentives. How-ever, this precluded examination of the longer-term effects of incentives (19) and comparisons with alternative strategies tested in trials with longer follow-up (7, 20–24). We considered patients to have completed their FOBT within 30 days if they had an FOBT result in the Veterans Integrated Service Network 4 Data Warehouse within 45 days of an FOBT order. This definition reflected 2 logistic challenges inherent to this pragmatic trial. First, we could not determine the date of FOBT specimen collection and thus had to rely on the FOBT processing date in the Veterans Integrated Service Network 4 Data Warehouse. Second, there could be a lag of up to approximately 15 days between patient completion of an FOBT and processing (personal communication with PVAMC laboratory staff), so we added 15 days to the 30-day outcome window. In each stage we hypothesized that each incentive would increase the rate of 30-day FOBT completion relative to the control group.

In each stage, our protocol included a preplanned subgroup analysis in which we examined 30-day FOBT completion by nonadherence to (that is, failure to complete) a prescribed FOBT in the year before the study. We hypothesized that each incentive would be more effective among previously nonadherent patients relative to patients who had been adherent to (that is, completed) a prescribed FOBT in the previous year. We also conducted exploratory
Table 1. Characteristics of the Study Sample

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Stage 1 (n = 713)</th>
<th>Stage 2 (n = 836)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 167)</td>
<td>$5 (n = 158)</td>
</tr>
<tr>
<td>Men, n (%)</td>
<td>167 (100)</td>
<td>157 (99)</td>
</tr>
<tr>
<td>Mean age (SD), y</td>
<td>61.9 (7.6)</td>
<td>62.7 (7.2)</td>
</tr>
<tr>
<td>Race/ethnicity, n (%)*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>4 (2)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
<td>118 (72)</td>
<td>115 (74)</td>
</tr>
<tr>
<td>Black, non-Hispanic</td>
<td>40 (25)</td>
<td>39 (25)</td>
</tr>
<tr>
<td>Median household income, $†</td>
<td>40 869</td>
<td>43 346</td>
</tr>
<tr>
<td>Median with high school degree, %‡</td>
<td>81</td>
<td>82</td>
</tr>
<tr>
<td>Married, n (%)</td>
<td>42 (25)</td>
<td>49 (31)</td>
</tr>
<tr>
<td>Service connection, n (%)§</td>
<td>72 (43)</td>
<td>64 (41)</td>
</tr>
<tr>
<td>FOBT order in past year, n (%)¶</td>
<td>116 (69)</td>
<td>99 (63)</td>
</tr>
<tr>
<td>None</td>
<td>9 (5)</td>
<td>10 (6)</td>
</tr>
<tr>
<td>Adherent¶</td>
<td>42 (25)</td>
<td>49 (31)</td>
</tr>
</tbody>
</table>

FOBT = fecal occult blood test.
* Race/ethnicity data were obtained from the Veterans Integrated Service Network 4 Data Warehouse. For patients with more than 1 value in the race/ethnicity field, we took the first value according to the following hierarchy: Hispanic, white non-Hispanic, black. There were 9 missing values in stage 1 and 6 missing values in stage 2.
† Median household income for ZIP code of residence, obtained from the U.S. Census Bureau. There were 16 missing values in stage 1 and 8 missing values in stage 2.
‡ Median percentage of residents in ZIP code of residence with at least a high school education, obtained from U.S. Census Bureau. There were 16 missing values in stage 1 and 8 missing values in stage 2.
§ Veterans with a disease or injury that was incurred during or aggravated by service in the armed forces.
¶ FOBT order in the previous 12 mo that was followed by an FOBT result.
†‡ FOBT order in the previous 12 mo that was not followed by an FOBT result.

analyses of 30-day FOBT completion among patients who had no FOBT order in the previous year.

Statistical Analysis
We conducted separate analyses for each stage. All participants who were prescribed an FOBT were included in the analyses testing for differences between groups. SAS software, version 9.3 (SAS Institute), was used to analyze the data.

In all analyses we used PROC GENMOD to fit marginal models based on generalized estimating equations with a logit link and exchangeable correlation structure to produce parameter estimates and robust SEs. The clustering unit was the clinic calendar day. In the primary outcome models we adjusted for patient age, race and ethnicity, marital status, median household income in ZIP code of residence, percentage of residents with a high school education in ZIP code of residence, VA service connection, and FOBT nonadherence in the previous year. Data on patient characteristics were obtained from the Veterans Integrated Service Network 4 Data Warehouse except for median household income and percentage of residents with a high school education in ZIP code of residence, which were obtained from the U.S. Census Bureau.

For subgroup analyses, we fit separate models to data from 3 subgroups: 1) FOBT nonadherence (an FOBT order not followed by a result) in the previous year, 2) FOBT adherence (an FOBT order followed by a result) in the previous year, and 3) no FOBT order in the previous year. In these models we adjusted for the aforementioned patient characteristics except FOBT nonadherence in the previous year. Among patients with an FOBT order in the previous year, we fit models in which FOBT nonadherence interacted with each incentive group (25, 26).

Data were missing for a few baseline covariates. In stage 1, data on race and ethnicity were missing for 1.3% of patients; data on both median household income and percentage of residents with a high school education in ZIP code of residence were missing for 2.2% of patients. In

Table 2. 30-Day Completion of FOBTs Among All Patients

<table>
<thead>
<tr>
<th>Measure</th>
<th>Control (n = 167)</th>
<th>$5 (n = 158)</th>
<th>$10 (n = 185)</th>
<th>$20 (n = 203)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30-day FOBT completion (95% CI), %*</td>
<td>38.3 (31.9 to 44.6)</td>
<td>39.3 (28.1 to 50.4)</td>
<td>44.9 (38.2 to 51.6)</td>
<td>46.4 (40.2 to 52.5)</td>
</tr>
<tr>
<td>Comparison with control (CI), %</td>
<td>1.0 (−9.6 to 11.6)</td>
<td>6.6 (−3.7 to 16.9)</td>
<td>8.1 (−2.0 to 18.2)</td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td>0.85</td>
<td>0.21</td>
<td>0.118</td>
<td></td>
</tr>
</tbody>
</table>

FOBT = fecal occult blood test.
* Adjusted by using both observed and imputed data for age, race/ethnicity, median household income for ZIP code of residence, percentage of residents in ZIP code of residence with at least a high school education, marital status, service connection, and FOBT nonadherence in the past year.
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### RESULTS

Most patients were white men in their seventh decade of life. Nearly half had a VA service connection (that is, a disease or injury incurred during or aggravated by military service). In the year before the study, most patients had not been prescribed an FOBT and approximately one third had been nonadherent to a prescribed FOBT (Table 1).

In stage 1, none of the fixed payments led to a statistically significant increase in rates of 30-day FOBT completion compared with usual care (Table 2). The results were nearly identical when we used only observed data for baseline covariates (Table 3). In the subgroup analysis, there were no statistically significant interactions between previous FOBT nonadherence and any fixed payment incentives (Table 4). The intracluster correlation coefficient in stage 1 was 0.0067.

In stage 2, a 1 in 10 chance of $50 increased 30-day FOBT completion compared with usual care (between-group difference, 19.6% [95% CI, 10.7% to 28.6%]; \(P < 0.001\)). However, a $5 fixed payment and raffle for $500 did not lead to statistically significant increases in rates of 30-day FOBT completion (Table 2). The results were again nearly identical when we used only observed data for baseline covariates (Table 3). In the subgroup analysis, there were no statistically significant interactions between previous FOBT nonadherence and any of the incentives (Table 4). The stage 2 intracluster correlation coefficient was 0.029.

### DISCUSSION

In this 2-stage pragmatic cluster randomized, controlled trial, we found that fixed payments of $5, $10, and $20 did not increase rates of VHA patient completion of prescribed FOBTs. When we tested 3 different financial incentive designs that shared a common allocation of $5 per patient, we found that a 1 in 10 chance of $50 was effective at increasing rates of FOBT completion. None of the incentives were more effective among patients previously nonadherent to an FOBT than among patients previously adherent to an FOBT.

We searched the PubMed database using the terms financial incentives and fecal occult blood test to identify all...
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Table 3. 30-Day FOBT Completion Among All Patients by Using Only Observed Data for Covariates

<table>
<thead>
<tr>
<th>Measure*</th>
<th>Stage 1 (n = 713)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 167)</td>
</tr>
<tr>
<td>30-day FOBT completion (95% CI), %*</td>
<td>38.0 (30.4 to 46.2)</td>
</tr>
<tr>
<td>Comparison with control (CI), %</td>
<td>0.9 (–9.7 to 11.5)</td>
</tr>
<tr>
<td>P value</td>
<td>0.86</td>
</tr>
</tbody>
</table>

FOBT = fecal occult blood test.
* Adjusted by using only observed data for age, race/ethnicity, median household income for ZIP code of residence, percentage of residents in ZIP code of residence with at least a high school education, marital status, service connection, and FOBT nonadherence in the past year.

Table 4. 30-Day FOBT Completion Stratified by FOBT Order and Adherence in Past Year

<table>
<thead>
<tr>
<th>Measure*</th>
<th>Stage 1 (n = 713)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Control (n = 167)</td>
</tr>
<tr>
<td>No FOBT order (95% CI), %†‡</td>
<td>46.0 (39.0–53.1)</td>
</tr>
<tr>
<td>Previous adherence (CI), %‡§</td>
<td>63.0 (22.7–90.8)</td>
</tr>
<tr>
<td>Previous nonadherence (CI), %‡¶</td>
<td>18.0 (9.2–26.8)</td>
</tr>
<tr>
<td>P value for interaction*</td>
<td>0.89</td>
</tr>
</tbody>
</table>

FOBT = fecal occult blood test.
* 30-day FOBT completion rates derived from separate model fits to data from each subgroup.
† Patients who had no FOBT order in the 12 mo before the study.
‡ Adjusted by using both observed and imputed data for age, race/ethnicity, median household income for ZIP code of residence, percentage of residents in ZIP code of residence with at least a high school education, marital status, service connection, and FOBT nonadherence in the past year.
§ Patients with an FOBT order in the 12 mo before the study that was followed by an FOBT result.
¶ Patients with an FOBT order in the 12 mo before the study that was not followed by an FOBT result.
* From test of interaction between each financial incentive and previous FOBT nonadherence among patients who had an FOBT order in the 12 mo before the study.

trials published between 1 January 1980 and 30 August 2013 that evaluated the effects of financial incentives on patient FOBT completion. We found no such studies. Similarly, we found no relevant studies when we searched PubMed using the terms financial incentives and colon cancer and screening. Thus, our study appears to be the only randomized trial to have studied the effects of financial incentive dose and design on patient FOBT completion.

FOBT could be an ideal target for a patient financial incentive. The costs of the behavior are tangible and immediate, while the benefits are uncertain and distant. In contrast to obesity (29–31) and cardiovascular disease (32), which have been targeted with financial incentives, FOBT is an annual test for many patients and would require only 1 annual incentive per patient. This approach could be more scalable than strategies to increase FOBT completion that require one-on-one staff contact with patients (7, 23, 33).

Despite the appeal of incentives for FOBT completion, no fixed payments in stage 1 led to a statistically significant increase in FOBT completion rates. It is possible the fixed payments were too small to overcome many patients’ barriers to FOBT completion (34, 35), some of which may be impervious to financial incentives (36). In addition, many patients may have never been offered incentives for healthy behaviors; because the interventions were integrated into usual care, patients did not have formal opportunities to ask questions about the incentives and may have been reluctant to pursue them. Alternatively, we may have lacked sufficient power to detect smaller effects of incentives and moderators of their effects. The sample sizes in this pilot study provided sufficient power only to detect relatively large effects of incentives, and future research should test incentives with larger samples that would permit detection of smaller yet still clinically meaningful increases in rates of FOBT completion (27).

In stage 2 we allocated $5 per patient as a fixed payment, lottery incentive, or raffle incentive and found that only the lottery incentive increased the rate of FOBT completion. Such approaches leverage decision biases, such as overoptimism (37) and overweighting of small probabilities (38), and have promoted short-term behavior change across multiple health behaviors (29, 30, 32). Given the promise of lottery-based strategies, more data are needed to understand factors that contribute to their effectiveness. Interestingly, a raffle with a prize of $500, which should leverage the same decision biases, was not effective in increasing the rate of FOBT completion, perhaps because the perceived chance of winning the prize was too small. As with stage 1, larger sample sizes should be used in future research to reduce the chance that some of our null findings may have represented type II errors.

Although the stage 2 control group had an adjusted rate of 30-day FOBT completion that was less than the
adjusted rate of 30-day FOBT completion in the stage 1 control group, no changes in clinical processes during the study occurred that could have led to different patient responses to usual care. This finding suggests that this difference between the stage 1 and stage 2 control groups may have been due to seasonal variation or differences in unobserved patient characteristics, underscoring the importance of contemporaneous control groups in such a multistage pragmatic trial.

Our study has limitations. We tested incentives in one tertiary care, academically affiliated VAMC, and thus results may not be generalizable to all settings. The clinic staff, patients, and research coordinator could not be blinded, although data assessors were blinded until all data were collected. During our study, the PVAMC used an immunochemical FOBT that required 3 stool specimens, in contrast to other immunochemical FOBTs that require only 1 stool specimen and may lead to higher baseline completion rates (39). As single-specimen immunochemical FOBTs become more commonly used, tests of incentives in these settings would likely be of broad interest and relevance. The interventions were delivered within usual primary care, so it is possible they occasionally did not reach the patient; however, efforts were made to assure consistent delivery of the interventions. Our samples may have included some patients for whom an FOBT was ordered for diagnostic purposes; we cannot identify this subgroup but presume it is small and distributed equally across groups. Our follow-up data are limited to the 30 days following an FOBT order, which prohibited examination of important questions about the longer-term effects of incentives, such as whether incentives adversely affect rates of completion of subsequent nonincentivized FOBTs (19), and comparison of our results to the effects of alternative interventions that have been evaluated through longer patient follow-up (7, 20–24). Both the longer-term effects of incentives and their effectiveness compared with other strategies would be fruitful areas for future investigation. Our sample sizes provided insufficient power to detect smaller yet still clinically meaningful effects. We could not estimate the cost-effectiveness of the interventions, which would be an important area for future research. Finally, the Bonferroni correction may have been overly conservative and thus could have led to type II errors.

In summary, a small dollar amount delivered as a lottery incentive and integrated into usual care increased rates of patient completion of FOBTs. Our finding serves as an example of a low-cost, scalable innovation that can improve health care quality (40) by promoting patient adherence to a high-value clinical preventive service (41), and it adds to the growing evidence base supporting the effectiveness of financial incentives in improving health behaviors (for example, smoking cessation and weight loss) among VHA patients (29, 30, 42). Further, our study illustrates how pragmatic trials (15) can be used to efficiently test multiple financial incentive designs in real-world settings. More such efforts are needed to identify how, when, and where patient financial incentives can enhance prevention of chronic disease and improve the value of health care delivery.
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Disclaimer: The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs or the U.S. government.

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Appendix: Methods for Multiple Imputation of Covariates

All analyses were conducted by using SAS software, version 9.3. In stage 1, 3.5% of participants had missing data for 1 or more covariates. In stage 2, 1.7% of participants had missing data for 1 or more covariates. Missing data were primarily due to ZIP code match failures for U.S. Census Bureau data on median household income and percentage of residents with a high school education in ZIP code of residence. There were fewer missing data for patient race/ethnicity. Although we assume these data were missing completely at random (43), we performed our primary analyses in 2 ways to assess the sensitivity of the analyses to this assumption. First, we used multiple imputation to create 5 complete data sets by imputing values for missing covariates with the Markov Chain Monte Carlo method as implemented in PROC MI. The imputation model included all variables in the analysis model. We analyzed each imputed complete data set and then applied Rubin’s rules (44) as implemented in PROC MIANALYZE to combine the results and produce a single estimate with adjusted SEs. We confirmed that 5 imputations were adequate by checking the relative efficiency of our imputation procedure (44), which was 0.98 or greater for all imputed variables (43). Second, we compared these results with results obtained by using only participants with complete covariate data. Results were essentially identical. Therefore, we present all results based on the entire sample using multiple imputation for missing covariate values.

References

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