Automated Messaging to Improve Compliance With Diabetes Test Monitoring

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Objectives: To evaluate the use of automated systems to prompt patients with diabetes mellitus to obtain overdue laboratory tests for its effectiveness in promoting test compliance and to compare letters, telephone messages, and combinations.

Study Design: Randomized controlled trial.

Methods: All subjects (N = 13,057) were adult members of Southern California Kaiser Permanente with diabetes and with no record of glycosylated hemoglobin, low-density lipoprotein cholesterol, and urinary microalbumin tests in more than 1 year. The effectiveness of automated telephone calls and letters was compared versus a no-contact control group using the following 5 intervention groups: letter, call, letter that is followed by a call 4 weeks later, call that is followed by a letter 4 weeks later, and letter-call-letter combination. Messages were in English and in Spanish. Adherence to all testing was compared at 8 weeks and 12 weeks after initial contact using χ^2 test and logistic regression analysis.

Results: The proportions of each study group compliant with all tests were 18% to 19% among controls, 21% for a letter or a call, 25% for a letter-call or call-letter, and 26% for a letter-call-letter; letter-call and call-letter were significantly different versus controls (P <.001), and letter-call-letter was not significantly different versus letter-call. Older age was associated with compliance (P <.001).

Conclusions: The pairing of automated letters and telephone calls in any order was more effective than any single intervention in promoting compliance with diabetes monitoring tests. The relative cost of the letter-call and call-letter approaches to outreach should be considered to determine which is preferred in any given situation.

(Am J Manag Care. 2009;15(7):425-431)

For author information and disclosures, see end of text.

About one-third of all persons in the United States older than 65 years have 3 or more chronic conditions,[1] and 23% of persons older than 60 years have diabetes mellitus.[2] Chronic disease care involves periodic monitoring of disease status and risk factors. In diabetes care, periodic (usually semiannual) measurement of blood glucose level control, lipid levels, and urinary protein excretion is used to adjust therapy and to change healthcare behavior to reduce morbidity and mortality.[3] The National Committee for Quality Assurance and other agencies often include annual disease-monitoring tests among measures of quality and performance.[4]

Compliance with disease-monitoring tests traditionally requires periodic patient visits. Outreach to noncompliant patients can be time-consuming if healthcare providers must maintain a list of patients with chronic disease, track those who are noncompliant, and attempt contact themselves. Automated outreach to patients can alleviate some of the burden on providers and bypass the need for an office visit. Although automated systems admittedly are less personal, they can be reliable and may be more cost-effective overall in reaching a portion of noncompliant patients.

The most common forms of outreach are by mail and telephone, and these are often effective in certain settings such as childhood immunizations.[5] There is less information available on the combination of mail and telephone outreach, especially in chronic disease. The combined use of mail and telephone outreach is promising because these interventions can complement one another through different means of communication. We evaluated the effectiveness of an automated outreach system to prompt patients with diabetes to have recommended monitoring tests. Response rates to mailed letters and telephone messages used singly and in combination were compared to determine the most effective method of outreach.

METHODS

This randomized controlled trial evaluated 5 automated messaging strategies to prompt compliance with diabetes laboratory monitoring tests. The study was staggered over 2 consecutive 3-month periods, referred to as study phases, to coincide with quarterly outreach efforts and to maximize sample size. Compliance rates were compared between

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Take-Away Points

Chronic disease care often requires periodic monitoring of disease status. Noncompliance with monitoring can lead to less optimal control of risk factors.

- A randomized trial was conducted to compare the use of automated telephone calls and mailed letters versus a no-contact control group among 13,057 patients with diabetes mellitus who had not had routine diabetes monitoring tests in more than 1 year.
- The combination of a letter and a telephone call in either order increased compliance with laboratory testing by 6% to 7%, a 50% increase over controls.
- Automated telephone calls and letters can be effective in changing the behavior of noncompliant patients with diabetes.

intervention groups and the no-contact control group. The Southern California Kaiser Permanente Institutional Review Board approved the study. Informed consent was waived. All analyses were performed using SAS 9.1 (SAS Institute, Cary, NC) and STATA 9.2 (StataCorp LP, College Station, TX).

Participants

Study subjects were all members of Southern California Kaiser Permanente (referred to as the health plan), an integrated healthcare system that provides comprehensive care to 3.1 million members at 12 medical centers and at hundreds of satellite clinics throughout southern California. All members have similar coverage benefits and copayments for healthcare services, including office visits and laboratory tests. About 93% of members have a pharmacy benefit.

All adult members of the health plan with diabetes were potentially eligible for the study. Members with diabetes were identified by a diabetes case identification database that has been used by the health plan since 1999 for individual patient care and for population outreach. Cases were identified by a combination of the following: (1) *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis codes (250.x, 357.2, 362.0, 366.41, or 648.0), (2) glycosylated hemoglobin (A1C) laboratory test result exceeding 7.5%, or (3) dispensation of oral hypoglycemics or insulin. Women with gestational diabetes were excluded. Data on lipid levels, urinary microalbumin levels, A1C levels, and other test results were updated daily. Health plan enrollment and death data were updated monthly and weekly, respectively, to remove nonactive members. Similar case identification criteria were evaluated in 1997 by comparison with a diabetes clinic electronic record developed at a health plan medical center: the sensitivity was 93%, and the positive predictive value was 95%.[6]

Health plan members with diabetes were passively enrolled if they met the following criteria: (1) age older than 18 years; (2) no A1C, low-density lipoprotein cholesterol (LDL-C), and urinary microalbumin tests in more than 365 days; and (3) a birthday within the next 3 months. Members are routinely targeted for preventive medicine outreach close to their birthday, as the experience of the health plan suggests improved response near birthdays, and annual outreach efforts can be organized around these dates.

Intervention

The goal of the intervention was to increase diabetes laboratory monitoring in a resistant population. Outreach could occur by telephone or by mail using a fully automated system already in use. Components of the outreach system included frequently updated administrative databases containing members' contact information, the diabetes case identification database, the laboratory test result database, an algorithm to determine when a member needed laboratory tests, a telephone messaging and mail generating system, and a team to prepare and deliver the outreach.

Telephone calls began with a standard greeting saying that the message to follow was from Kaiser Permanente. The message was in English and informed the recipient to call a toll-free number to receive a message from his or her health plan. Members who called in used an interactive menu to select English or Spanish and retrieved the message by inputting their medical record number. The message was just over 100 words and about 40 seconds in length. The member was informed that he or she may have diabetes and was due for laboratory tests that had already been ordered. The tests were named, and the member was directed to go to his or her local health plan laboratory for the tests. A busy signal resulted in up to 2 more attempts to make telephone contact on subsequent days. Telephone calls were made between the hours of 10 AM and 8 PM. Ninety-five percent of all health plan members have a telephone number on record. The message scripts may be viewed in **eAppendix 1** and **eAppendix 2** available at **www.ajmc.com**.

Mailed letters on Kaiser Permanente letterhead were personally addressed, informed the member that health plan records indicated that he or she may have diabetes, provided a number to call if that was in error, stated the importance of monitoring tests, and directed the addressee to obtain these tests at his or her local health plan laboratory. The text of the letter occupied the top half of the page, and a "laboratory slip" for the needed tests was placed at the bottom of the page. One side of the letter was in English, and the other side was in Spanish. Locations and hours of local laboratories were provided, and the letter was electronically signed by the nurse lead of the local medical center diabetes care management program. Almost 100% of all health plan members had

an address on record. A copy of the letter may be viewed in eAppendix 3 (available at **www.ajmc.com**).

Telephone calls and mailed letters were used alone and in combination among the following 5 intervention groups: (1) letter once only (letter), (2) telephone call once only (call), (3) letter that is followed by a telephone call at 4 weeks for nonresponse (letter-call), (4) telephone call that is followed by a letter at 4 weeks for nonresponse (call-letter), and (5) letter that is followed by a telephone call at 4 weeks for nonresponse, followed by a second letter at 8 weeks for continued nonresponse (letter-call-letter). The letter-call-letter combination was chosen as the most extensive outreach in the belief that the response would be best among all possible triplet combinations. The control group received no contact. Standard outreach at the time was by letter, but because the effectiveness was unknown, permission was obtained to delay standard contact for 4 months in the control group. Subjects who remained noncompliant after the first phase of the study were not entered into the second phase. Laboratory test orders were placed automatically into a regionwide ordering system; each order was active for 90 days. All control group and study group subjects had orders placed at the beginning of the outreach effort; control group subjects had no information that an order had been placed for them.

Outcomes

The primary outcome, termed compliance, was completion of all 3 laboratory tests (A1C, LDL-C, and urinary microalbumin) by 12 weeks after the date of the first attempt at subject contact. The 12-week mark was chosen because it was 4 weeks after the last letter in the letter-call-letter intervention, allowing for comparison across all intervention arms. Additional outcomes included compliance at 8 weeks for all but the letter-call-letter group. All test results and dates were available electronically from a centralized laboratory reporting system. If a subject died or disenrolled before the end of follow-up, the subject was maintained in his or her group.

Randomization

Just under 2 weeks before the intervention start date, which corresponded with the health plan's quarterly-batch outreach effort, eligible health plan members were randomized into the study groups. The results of randomization were communicated back to the health plan's outreach team to alter the usual automated outreach process, which already used telephone calls and letters for other programs. Randomization into study arms in the proportions described herein was computer generated.

Sample Size

In phase 1, interventions starting with a mailed letter (letter, letter-call, letter-call-letter) were compared with controls, and in phase 2, interventions starting with a telephone call (call, call-letter) were compared with controls. Preliminary data suggested a laboratory test compliance rate of 40% for a letter that is followed by a call. We sought to have sufficient power to detect a difference to 35% (letter group) and to 45% (letter-call-letter group). Using a significance level of $P > .05$ and 80% power, a 2-sided test of proportions and equal-sized groups required 1574 subjects per group. The control group response rate was estimated to be 20%. The control group was set at approximately one-fifth of the anticipated intervention group size (n = 325). When the time came for the phase 1 population outreach, there were more eligible patients than anticipated, and these were randomly divided into the intervention arms until power was close to 90%. In phase 2, we aimed for 90% power to detect a difference between 35% (call group) and 40% (call-letter group), which required 2008 subjects per group. In phase 2, the control group was set at 70% of the intervention group size to detect a 5% difference in compliance, from 30% to 35%. The control group was increased in size for phase 2 in response to a smaller-than-expected difference between the control and letter groups in phase 1.

Statistical Analysis

Study arms and the effects of randomization were assessed using χ^2 test and Wilcoxon rank sum test. All subjects' data were analyzed according to initial randomization whether the subject was successfully contacted or was lost to follow-up. Compliance was compared between intervention groups and the corresponding phase 1 or phase 2 control group using χ^2 test. To examine compliance by subject characteristics and to compare phase 1 and phase 2 interventions, all subjects were included in a multivariable logistic regression analysis. Adjustment was made for the study phase, and each intervention group was compared with the combined phase 1 and phase 2 controls. After laboratory test results were available, we detected subjects who received 1 or more laboratory tests between randomization and the start of the intervention; there were 982 such subjects. We performed a secondary analysis with these subjects excluded: odds ratios (ORs) were less than 5% different and are not shown.

RESULTS

There were 13,057 subjects in the study (7108 in phase 1 and 5949 in phase 2). Characteristics of the subjects are listed in Table 1. The mean age of subjects was 51 years. Most subjects (54%) were male. Administrative records indicated that 10% of subjects preferred communicating with their healthcare provider in Spanish. The median (SD)

Table 1. Characteristics of Study Subjects

Characteristic	All Subjects (N = 13,057)	Controls (n = 1875)[a]	Letter (n = 2916)	Letter-Call (n = 1934)	Letter-Call-Letter (n = 1933)	Call (n = 2199)	Call-Letter (n = 2200)
Age, mean (SD), y	50.9 (11.9)	50.9 (12.2)	50.7 (12.0)	51.4 (11.8)	51.3 (11.7)	51.0 (11.9)	50.5 (12.1)
Sex, %							
Male	54.1	55.2	52.3	52.9	54.5	55.6	54.7
Female	45.9	44.8	47.7	47.1	45.5	44.4	45.3
Race/ethnicity, No. (%)[b]							
White	2976 (22.8)	419 (22.3)	642 (22.0)	481 (24.9)	464 (24.0)	492 (22.4)	478 (21.7)
Hispanic	1847 (14.1)	265 (14.1)	444 (15.2)	273 (14.1)	283 (14.6)	284 (12.9)	298 (13.5)
Black	1340 (10.3)	176 (9.4)	294 (10.1)	200 (10.3)	185 (9.6)	239 (10.9)	246 (11.2)
Asian	666 (5.1)	100 (5.3)	145 (5.0)	124 (6.4)	110 (5.7)	109 (5.0)	78 (3.5)
Other	398 (3.0)	58 (3.1)	86 (2.9)	60 (3.1)	63 (3.3)	57 (2.6)	74 (3.4)
Unknown	5830 (44.7)	857 (45.7)	1305 (44.8)	796 (41.2)	828 (42.8)	1018 (46.3)	1026 (46.6)
Language, No. (%)							
English	9276 (71.0)	1318 (70.3)	2089 (71.6)	1343 (69.4)	1334 (69.0)	1611 (73.3)	1581 (71.9)
Spanish	1340 (10.3)	204 (10.9)	315 (10.8)	196 (10.1)	193 (10.0)	205 (9.3)	227 (10.3)
Other	122 (0.9)	26 (1.4)	25 (0.9)	21 (1.1)	23 (1.2)	10 (0.5)	17 (0.8)
Unknown	2319 (17.8)	327 (17.4)	487 (16.7)	374 (19.3)	383 (19.8)	373 (17.0)	375 (17.0)

[a]The control group had 325 subjects in phase 1 and 1550 subjects in phase 2.
[b]Randomization resulted in small but statistically significant ($P = .002$) differences in the distribution of race/ethnicity across study arms. There were no significant ($P < .05$) differences in the distribution of other subject characteristics across study arms.

Table 2. Compliance With All 3 Laboratory Tests at 8 Weeks and at 12 Weeks

Weeks	Controls (n = 325 for Phase 1 and n = 1550 for Phase 2)	No. (%) Compliant With Testing				
		Letter (n = 2916)	Letter-Call (n = 1934)	Letter-Call-Letter (n = 1933)	Call (n = 2199)	Call-Letter (n = 2200)
Phase 1						
8	39 (12.0)	466 (16.0)	402 (20.8)[a,b]	413 (21.4)[a,b]	—	—
12	57 (17.5)	598 (20.5)	491 (25.4)[b,c]	503 (26.0)[a,b]	—	—
Phase 2						
8	198 (12.8)	—	—	—	311 (14.1)	410 (18.6)[a,d]
12	298 (19.2)	—	—	—	453 (20.6)	558 (25.4)[a,d]

[a]$P < .001$ vs controls.
[b]$P < .001$ vs letter.
[c]$P < .01$ vs controls.
[d]$P < .001$ vs call.

household income based on address of residence and US census block was $57,700 ($25,900). Phase 1 occurred in the third quarter of 2005, and phase 2 occurred in the first quarter of 2006.

Response (ie, compliance) was best in the interventions using both mail and letter outreach. The results of each intervention at 8 weeks and 12 weeks are given in Table 2. Compliance in the phase 1 and phase 2 control groups was 12% to 13% at 8 weeks and 18% to 19% at 12 weeks. A letter alone and a call alone were not significantly different versus controls ($P = .06$ [letter] and $P = .23$ [call] at 8 weeks and $P = .21$ [letter] and $P = .31$ [call] at 12 weeks). Compliance with laboratory testing was significantly greater ($P < .01$) when outreach involved 2 or more attempts at contact (letter-call,

call-letter, and letter-call-letter) than when either no contact was made (controls) or only 1 attempt at contact was made (letter or call). The letter-call group compliance was 21% at 8 weeks and 25% at 12 weeks; corresponding compliance for the call-letter group was 19% and 25%, respectively. The letter-call-letter group compliance (21% at 8 weeks and 26% at 12 weeks) was not significantly different from that of the letter-call group at 12 weeks (P = .65). Using logistic regression analysis to control for study phase, age, sex, and race/ethnicity, there was no significant difference between the letter and call groups at 8 weeks and at 12 weeks (P = .28 and P = .48, respectively) or between the letter-call and call-letter groups at 12 weeks (P = .66). The multivariable-adjusted ORs of compliance in each intervention group versus controls were 1.23 (95% confidence interval [CI], 0.91-1.66) for letter, 1.58 (95% CI, 1.16-2.15) for letter-call, 1.67 (95% CI, 1.23-2.27) for letter-call-letter, 1.09 (95% CI, 0.92-1.28) for call, and 1.46 (95% CI, 1.25-1.72) for call-letter.

Table 3. Logistic Regression Analysis of Patient Characteristics and the Odds of Compliance With All 3 Laboratory Tests at 12 Weeks Among 12,998 Subjects[a]

Characteristic	Odds Ratio (95% Confidence Interval)	*P*
Age, y		
40-49	1.50 (1.30-1.72)	<.001
50-59	1.86 (1.63-2.12)	<.001
60-69	2.25 (1.95-2.59)	<.001
≥70	2.45 (1.99-3.01)	<.001
Female sex	1.00 (0.92-1.09)	.91
Race/ethnicity		
Asian	1.29 (1.05-1.57)	.02
Black	1.06 (0.90-1.24)	.48
Hispanic	1.02 (0.88-1.18)	.83
Other	1.13 (0.88-1.45)	.34
Unknown	1.02 (0.92-1.14)	.66
Language		
Spanish	1.18 (1.02-1.36)	.03
Other	1.07 (0.70-1.63)	.75
Unknown	0.99 (0.89-1.11)	.87
Household income	1.02 (1.00-1.03)	.07

[a]The number of subjects for the logistic regression analysis was reduced by 59 because of invalid or unmatched home addresses for imputing the median household from US census data. Reference groups were 18 to 39 years for age, white non-Hispanic for race/ethnicity, and English for language. Control variables included study phase and group (interventions and control).

Some demographic groups had greater compliance following the interventions (Table 3). Characteristics associated with an increased odds of compliance across all study groups included older age (by decades from 40 to ≥70 years, P <.001 across all ages), Asian race/ethnicity (OR, 1.29 vs whites; P = .02), and Spanish-language preference (OR, 1.18 vs English; P = .03). The compliance of men and women did not differ (P = .91), and household income was not clearly associated with compliance (P = .07).

DISCUSSION

Our main finding is the success of the paired combination of automated letter and telephone messaging compared with either intervention alone. Both a letter followed in 4 weeks by a call and a call followed in 4 weeks by a letter produced a 12-week compliance rate of 25%, which was 6% to 7% higher in absolute response rate versus the no-contact control group (about a 50% increase in odds). These findings help clarify which outreach options may be most effective to promote disease monitoring by laboratory tests among large, diverse populations with diabetes.

The modest increase in compliance observed in our study is not unexpected given that the target population had not had diabetes monitoring tests in more than 1 year, despite full insurance coverage. Response rates for immunization outreach range from a 1% to 20% absolute increase,[5] and the increase in the odds of a response ranges from 1.5 to 2.5 for immunizations and breast cancer screening.[5,7] Response rates may have been reduced somewhat by requiring compliance with all 3 tests, which involves not only a blood draw but also a urine sample.

The success of the intervention pair in relation to the alternatives studied seems understandable. The combination of the 2 outreach methods may help overcome some of the disadvantages of either method. For example, a mail message may reach those without a telephone or who are hard of hearing, while a call may reach those with difficulty reading or who discard mail. A second contact may communicate to patients that their health plan or provider is giving needed advice. Perhaps by the third contact in the letter-call-letter group, those individuals susceptible to the outreach had al-

ready responded, suggesting little need for continuing the same effort.[8] Rather than abandoning those who remain noncompliant, they can be referred to diabetes or chronic disease case managers who attempt in-person calls; alternatively, medical records of noncompliant patients can be flagged to help prioritize testing on their next visit.

To our knowledge, previous studies have not examined combinations of automated outreach for chronic disease monitoring; however, there is an extensive and reviewed literature on interventions to improve preventive services such as immunizations and breast cancer screening.[5,7] A few studies compared combinations of telephone calls and mailed letters or postcards to encourage compliance with tests or treatments. In a study[9] similar to ours that compared letters and automated telephone messages for increasing immunization rates among children (n = 648), the combination of a letter followed by a call 1 week later was more effective than either a call or a letter alone. In that immunization study, the letter-call combination was not significantly better than the call-letter combination but was preferred on the basis of cost-effectiveness. A letter followed by a telephone call has also been noted to improve breast cancer screening versus a no-intervention control group or a letter alone.[10-12] The setting and target populations may have an effect on study results. In a study[13] aimed to increase childhood immunization rates among an inner-city population, an automated call was no less effective than a combination of an automated call that was followed by a live call versus a mailed reminder; however, the call was only slightly better than no intervention.

Some demographic characteristics were associated with compliance in the present study. Although the reasons are not apparent from our study, there was an increasing response across all intervention groups with increasing age. Among racial/ethnic groups, Asians appeared to have a slightly greater response rate than whites. Although Hispanics (as a racial/ethnic group) did not respond more than non-Hispanic whites, those whose preferred language was Spanish were slightly more likely to respond across all intervention groups than English speakers. A similar finding of an increased response rate among Spanish speakers was found using reminder or order cards for immunization rates among children.[14] Although sufficient evidence has not yet accumulated, there may be a greater potential to reach patients with chronic disease who face a language barrier and are not yet aware of recommended care than there is among English speakers, who may have other reasons for noncompliance.

In this study and in the most similar published study,[9] the letter-call and call-letter interventions were similarly effective. These paired interventions had an advantage over the letter-call-letter approach in that they required only 2 attempts at contact, had the same response rate, and were more cost-effective. In any given setting, the choice between letter-call and call-letter is perhaps best made on a cost basis. If these 2 approaches are deemed equivalent, then whichever intervention is more expensive could be used second, targeting nonresponders; however, this calculation is complicated somewhat by differential response to the first contact.

This study is potentially limited in a general sense by the fact that there are many possible variations in outreach details that may affect patient compliance. For example, such details include an electronic signature from the patient's primary care provider or a telephone message in the voice of the provider. Other combinations of interventions were possible (such as call-letter-call, letter-letter-call, etc) but for practical reasons were not tested. It is possible that some providers initiated contact with noncompliant patients themselves, but any such efforts would be randomly distributed and would not bias comparisons. The study results may not be generalizable to other populations and to other outreach needs such as medication adherence. For example, diabetes-related testing may be easier or harder to do than testing for other chronic conditions based on ease of testing, patient knowledge, or the perceived value of the test. The population of the health plan studied herein is diverse and of middle household income, and results may not generalize well to populations of very low socioeconomic status or to health systems that are not integrated and capable of electronically identifying and monitoring chronic disease status.

When paired, automated mail and telephone outreach can effectively increase compliance with diabetes laboratory test monitoring. At least in the case of a third attempt at contact using a letter, there was nothing gained by the additional effort. Patients who remain noncompliant will likely require a change in outreach method to achieve recommended disease monitoring (such as live contact by a case manager). These findings may help streamline similar outreach efforts in chronic diseases and perhaps in other clinical scenarios (such as cancer prevention) that require periodic compliance with test monitoring.

Acknowledgments

This research was supported by Merck Health Management Services, West Point, PA. We thank Richard Contreras for preparing data on median household income, Jiaxiao Shi for assistance with statistical tests, the entire Southern California Kaiser Permanente outreach team, and Julie Frame and Kelly Green for their support in the implementation of this study.

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Author Disclosure: The authors (SFD, RKN, FHZ) report no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

Funding Source: This research was supported by Merck & Co Health Management Services.

Authorship Information: Concept and design (SFD, RKN, FHZ); acquisition of data (SFD, RKN); analysis and interpretation of data (SFD, FHZ); drafting of the manuscript (SFD, FHZ); critical revision of the manuscript for important intellectual content (SFD, RKN, FHZ); statistical analysis (SFD); provision of study materials or patients (FHZ); obtaining funding (SFD, FHZ); and supervision (SFD, FHZ).

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