Randomized controlled study of customized preventive medicine reminder letters in a community practice

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ABSTRACT

OBJECTIVE To test the effectiveness of customized, family-oriented reminder letters in activating patients to seek appropriate preventive services.

DESIGN Randomized clinical trial. One group received computer-generated, customized letters explaining recommended preventive procedures for each family member. A second group received a form letter listing recommendations for all preventive procedures for all age and sex groups. A third group (control group) received no letters.

SETTING A private medical centre, without university affiliation, in rural Quebec.

PARTICIPANTS From 8770 patients who met study criteria, 719 families were randomly selected. Data were available for 1971 of 1998 patients in these families.

MAIN OUTCOME MEASURES The Family Received Index is the proportion of all procedures for which a family was overdue that they received. The Family End-of-study Up-to-date Index is the proportion of procedures for which the family was eligible and for which they were up-to-date at the end of the study.

RESULTS The Family Received Index for families mailed customized letters was more than double the index for patients not mailed letters (Kruskal-Wallis P=.0139). Comparison of the Family End-of-study Up-to-date indices also demonstrated that families of patients sent customized letters were more likely to be up-to-date than families not sent letters (Kruskal-Wallis P=.0054). No statistically significant difference appeared between the number of preventive measures received by the control group and the form-letter group.

CONCLUSIONS This study demonstrates a clinically small but statistically significant value to customizing reminder letters.

RÉSUMÉ

OBJECTIF Évaluer l'efficacité des lettres de rappel personnalisées axées sur la famille pour inciter les patients à rechercher des services préventifs appropriés.

CONCEPTION Essai clinique randomisé. Un groupe a reçu des lettres personnalisées, générées par ordinateur, expliquant les interventions préventives recommandées pour chacun des membres de la famille. Un deuxième groupe a reçu une lettre circulaire énumérant les interventions préventives recommandées pour tous les groupes d'âge et de sexe. Un troisième (groupe témoin) n'a reçu aucune lettre.

CONTEXTE Une clinique médicale privée, sans affiliation universitaire, dans une région rurale du Québec.

PARTICIPANTS À partir de 8770 patients qui répondaient aux critères de l'étude, la randomisation a sélectionné 719 familles totalisant 1998 patients. On a pu obtenir des données sur 1971 de ces patients.

PRINCIPALES MESURES DES RÉSULTATS Le «Family Received Index» est le rapport entre le nombre total des interventions qu'une famille aurait dû recevoir et le nombre des interventions effectivement reçues. Le «Family Endof-Study Up-to-date Index» est le rapport entre le nombre d'interventions pour lesquelles une famille était admissible et le nombre d'interventions que les membres de la famille avaient effectivement reçues au terme de l'étude.

RÉSULTATS Dans le groupe des familles ayant reçu des lettres personnalisées, le «Family Received Index» s'est avéré plus du double de celui des patients n'ayant pas reçu de lettre (Kruskal-Wallis p=0,0139). La comparaison entre les groupes du «Family End-of-study Up-to-date Index» révèle également que les familles des patients ayant reçu une lettre personnalisée étaient plus susceptibles de recevoir l'intervention comparativement aux familles n'ayant pas reçu de lettre (Kruskal-Wallis p=0,0054). On n'a pas constaté de différence statistiquement significative entre le nombre des interventions préventives dispensées au groupe témoin et celles du groupe ayant reçu une lettre circulaire.

CONCLUSIONS Cette étude révèle que la personnalisation des lettres de rappel comporte un avantage clinique faible mais statistiquement significatif.

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ven in countries with modern health care systems, the proportion of patients who are not up-to-date with recommended preventive measures remains distressingly high.^{1.5} Improved compliance with effective preventive measures could lead to an important improvement in health.

Systems that remind or prompt physicians about patients' overdue preventive measures at the time of patient visits ("passive" reminder systems) have been shown to increase compliance with preventive procedures.⁶¹⁸ This approach is of little value for those who visit the office infrequently.¹⁹⁻²² An active outreach system is needed to remind these patients.^{11,12,17,23-27}

The only study that has investigated the combination of an active and passive system found that the combination was more effective than either one alone. This study, which was conducted in a family practice university-based teaching centre, used computer-generated reminders.¹² Ornstein et al¹² found a "dramatic" (approximately doubling) improvement in adherence to cholesterol screening, fecal occult blood testing, mammography screening, and tetanus immunization. Computer technology allows for customized reminder messages targeted to individual patients. Strecher et al²⁸ showed that customized or tailored preventive messages are more effective than generic preventive messages.

In our practice, a computerized physician reminder system had been in place since 1984, but many patients were not receiving preventive activities. We decided to test the additional value of two forms of outreach: the first a form letter appropriate for all patient's ages and both sexes and the second a customized letter based on a patient's previous preventive activity. This randomized trial was performed to assess the

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[†]Deceased. I thank Martin Bass for his contagious enthusiasm for research generally and his support for this project in particular. Martin was my Chief Advisor for the reporting of this research as a thesis and knew that Canadian Family Physician was interested in the paper before his death. value of a mailed customized letter with patient-specific preventive information versus a general form letter regarding prevention versus no outreach at all.

METHODS

Study design

The study used a randomized controlled trial design with two intervention groups and one control group. The study was not blinded in that physicians could be aware that a patient was a member of a family in the study if the patient mentioned that the family had received a letter. The study was pilot tested in a remote part of the practice catchment area, which was excluded from the main study to minimize contamination.

We oriented the mailings to the entire family because the family is central to the paradigm of family medicine.²⁹

Setting and computer system

This study involved the clinicians and patients of the Wakefield Family Medicine Center in western Quebec, 40 km north of Ottawa.³⁰ All medical costs, including preventive medical services, were paid from a publicly funded medicare system. The principal investigator was no longer a member of the practice during the study period and visited the practice to oversee the study for 1 day every 3 months. One other senior physician left the practice as the study began.

The medical centre had been computerized since 1984. No computers were placed in the examining rooms. Summary medical information was collected on an encounter form, and the billing clerk entered the data. Physicians had to complete the encounter form to be paid. Information in the computer database permitted identification of overdue preventive procedures for patients. The computer printed this and other clinical information on the encounter form³¹ for each patient. In this way, for several years before this study, physicians could determine at a glance any outstanding preventive procedures for any patient making an office visit.

Selection of study sample

Eligible patients had been registered for a minimum of 1 year and had made at least one visit to the office in the preceding 2 years. The random selection of the study sample was applied to individual patient registration numbers in the medical record software system. Once an individual was selected, his or her entire family was randomly assigned to one of the three arms of the study. Randomized controlled study of customized preventive medicine reminder letters in a community practice

Intervention

The computer-generated customized letters sent to the first study group reminded patients of outstanding preventive procedures using nonmedical language in a standardized format. The letter began with a covering page followed by one page for each family member. For each family member, a paragraph outlined each preventive procedure for which the patient was eligible as determined by age, sex, family history, and previous illness. The tone was positive and nonthreatening. Mumps, for example, was described as being able to "cause important complications for young men." Dates family members had last received the procedures were provided so they could determine whether they were overdue.

The second study group received a form letter, which outlined all the recommended preventive procedures for all ages and both sexes. The text explaining each preventive measure was identical to the text in the customized letter except the date the procedure was last done was not provided. The third study group received usual care with no outreach.

Letters were sent by regular mail at times convenient to the medical practice between September 1990 and March 1991. There were no stamped, addressed return envelopes.

Practitioners decided, on the basis of the information available to them in 1990, which procedures they would include in the letter and for which age, sex, and medical history they would recommend the procedures and at what interval.⁵ Practitioners agreed to follow the Canadian Immunization Guidelines in place at that time but were unable to reach consensus on cholesterol screening and decided, therefore, not to refer to cholesterol in the letter.

In keeping with the recommendations of the Task Force on the Periodic Health Examination, all individuals older than 65 and those with high-risk diseases, such as chronic obstructive lung disease and diabetes, were recommended to receive the influenza vaccine annually. We agreed Pap smears should be performed yearly from the onset of sexual activity to age 35, every 3 years from age 35 to 59, and every 5 years after age 60. Our recommendation for mammography screening differed from that generally recommended at the time in that the group decided to recommend that mammography be performed yearly between the ages of 40 and 50 and every other year between the ages of 50 and 74. The group's recommendation that measles, mumps, and rubella vaccine be repeated again at adolescence for male and female patients preceded the current recommendations by several years. We decided to recommend fecal occult blood testing in the stool yearly after age 45. The process by which these decisions were reached and the literature on which they were based is detailed elsewhere.⁵

RESEARCH

Outcomes

Two main outcome variables are reported in this project: Family Received Index and Family End-of-study Up-to-date Index. The Family Received Index is the proportion of all procedures for which a family was overdue that they received. The sum of the number of preventive procedures received by family members during the study period was divided by the sum of the number of preventive procedures for which the family was overdue at the time the letters were mailed to calculate the index.

Family End-of-study Up-to-date Index is the proportion of procedures for which the family was eligible and for which they were up-to-date at the end of the study. The number of procedures for which the family was up-to-date at the end of the study was divided by the number of the procedures for which the family was eligible at the time the letters were mailed. This second measure was included to give a sense of the magnitude of the outcome.

Patients were considered to have chronic illness if they had ever had colon cancer, depression, diabetes, hypertension, alcoholism, arthritis, anxiety, asthma, breast cancer, hyperventilation syndrome, hypoglycemia, any cardiac problem, insomnia, leukemia, lung cancer, lymphoma, metastatic cancer, or prostatic cancer. The degree of chronic illness in the family was the sum of the individual scores for family members.

Data collection and measurement techniques

We collected data at baseline and at 2, 4, and 6 months after the letters were mailed. We validated physician recording of preventive measures by comparing patients' charts with the encounter forms and measured the data input error rate. A procedure was considered done when it was ordered.

For study purposes, we assigned a mailing date to the control group to avoid a systematic error that could occur with delays. The date a batch of the customized and form letters were sent was considered the "sent date" for an equal number of families receiving no letters. Data were measured by abstracting information from the medical office record computer system and exporting data to flat ASCI II files, which were then organized in an SPSS systems file for analysis.

Data collection omissions or errors were discussed with the patient's physician. New physicians

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Table 1. Comparison of study groups

CHARACTERISTICS OF STUDY GROUPS	NO LETTER (SD)	FORM LETTER (SD)	CUSTOMIZED LETTER (SD)	TEST <i>P</i> VALUE
Families	263	252	204	
Individuals	682	676	613	
Mean family size	2.6	2.7	3.0	.02*†
Mean family age (years)	41.6 (18.9)	41.9 (19.8)	37.5 (18.69)	.03*‡
Mean baseline proportion of procedures up-to-date	.341 (.292)	.285 (.269)	.365 (.300)	.008*§
Most family members speak English (%)	47.9	46.4	52.0	.485†
Mean percentage of male family members (%)	47.7 (29.6)	47.7 (26.4)	50.1 (24.6)	.565 [‡]
Mean no. of chronic diseases in family unit	2.33 (2.35)	2.08 (1.94)	2.21 (1.95)	$.654^{\dagger}$
Mean baseline procedures overdue	4.02 (.292)	4.39 (.268)	4.13 (.301)	.249 [‡]
Families with members older than 65 (%)	20.5	24.6	17.6	.193†
Families with children younger than 5 (%)	12.9	14.7	18.6	$.226^{\dagger}$

*Significant difference among the three groups, P < 0.05.

[‡]Analysis of variance.

[§]Kruskal-Wallis test.

and locums were carefully instructed on data collection issues, and this instruction was repeated 2 months later. Data-input clerks were carefully trained, retrained, and monitored. For 100 randomly selected patients in the study, an audit was performed comparing the SPSS data set and patients' paper charts.

The accurate and up-to-date electronic family linkages^{30,32-34} required for this study were achieved using a module of the office medical record computer system, which generated demographic update sheets for all patients with appointments for the day.³¹

Analysis

The unit of random assignment was the family and the unit of analysis was the family. The intervention was a "family" intervention, being a letter mailed to an entire household. χ^2 , ANOVA, and Kruskal-Wallis one-way ANOVA by ranks analysis were the primary statistical techniques. An α level of .05 was taken as representing statistical significance.

Sample size calculations were performed using an α level of 0.05 and a power (1- β) of 0.8 and assuming a one-tailed test. We used the literature to approximate baseline preventive rates. Because the smallest increase to be detected in our study was for Pap smears, the sample size needed to detect a clinically significant difference for Pap smears would be

sufficient to detect all estimated changes. We used the age and sex distribution of the practice to determine how many women were needed in the study to detect a difference between the main experimental group and the control group, including an adjustment for patients who would leave the practice.

Ethics

Care was taken not to include sensitive information in the letters because all members of the family might read the letter. An ethics review board approved the project as described. The letter was approved by the provincial medical licensing authority.

RESULTS

Background

From the 8770 patients who met the criteria, 719 families were randomly selected. The families were then randomly assigned to one of the three study groups. We have data on 1971 of the 1998 (98.65%) individual patients in the 719 families.

There were no missing values for the postal code, family identification number, intervention group assignment, age, or sex. For language and marital status, 5.3% and 3% of values, respectively, were missing. For the doctor who most frequently saw the patient, 2.5% of values were missing.

 $^{^{\}dagger}\chi^{2}$ test.

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We compared preventive activity for 5% of individuals between the electronic data set used in the analysis and the paper charts at the Wakefield practice. We found four of 1971 patients or 3.73% of the electronic patient charts to be missing the recording of six preventive procedures (5.6%). In each case the preventive procedure had been done by the physician, evidenced by the recording of the procedure in the paper chart or the presence of a Pap smear or mammography report.

The three intervention groups showed no statistically significant differences in the doctor who most frequently saw the family members or in six other variables reported in **Table 1**.

The mean baseline proportion of procedures upto-date at the time of mailing of the letters, the number of members in the family, and mean family age did differ in the three groups. This difference was statistically significant (**Table 1**).

The proportion of eligible persons for each procedure who were up-to-date at the time of mailing for the total sample were as follows: Pap = 38.5%; mammogram = 23.6%; adult tetanus = 42.2%; fecal occult blood testing = 15.6%; measles, mumps, and rubella (MMR) vaccine = 59.4%; influenza vaccine = 54%; DPT TOPV vaccine = 43%; and MMR booster = 16.4%.

Preventive activity among study groups

We used two outcome variables to determine how important customizing the reminder letters was in activating patients to seek appropriate preventive health services and to test whether the combination of an active and a passive system is more effective than just a passive system. Both showed the customized letter group to be statistically significantly better than the form letter group or no letter group at increasing compliance with preventive procedures. The Family Received Index and the Family End-of-study Up-to-date Index are presented in **Table 2**.

Preventive activity for each procedure

The proportions of overdue procedures that were performed (the received index for each procedure) were calculated for each family for each study group and compared. Only Pap smears ($\chi^2 P = .04$) and MMR booster vaccines ($\chi^2 P = .04$) showed a statistically significant difference. **Table 3** shows a clear trend for the other procedures, in each case favouring the customized letter.

Potentially confounding variables

Statistical significance of the comparison among the intervention groups was retained after controlling for

the three variables that were not evenly distributed among the three groups. Correlation with the number of members in a family was not statistically significant for either outcome variable. For the received index the Pearson's r=.0478, and for the up-to-date index the Pearson's r=.0431. The *P* value was greater than 0.01 and accounts for less than 0.19% of the variance in each case.

The correlation between the received index and mean average age was Pearson's r=.0816 (P>.1) and was not statistically significant. The up-to-date index did have a significant correlation r=-.1422, P<.001 with average age. Because the group receiving customized letters had a lower average age, controlling for age would serve to increase the study group differences and hence the statistical significance in the analysis.

Table 2. Comparison among groups

OUTCOME VARIABLE	NO LETTER (N = 249)	FORM LETTER (N = 245)	CUSTOMIZED LETTER (N = 192)	P VALUE
Mean Received Family Index	.0350	.0411	.0718	.0139*
Mean End-of-study Up-to-date Family Index	.36	.31	.40	.0054*

The main outcome variable, the received index, did correlate, albeit weakly, with the baseline up-to-date variable in a statistically significant way (Pearson's r=.1416, P<.01). This degree of correlation signifies a slight relationship. The baseline up-to-date data for each procedure showed that the form letter group accounted for some of the differences among the groups. This means our previous reporting of differences among the groups that did not take this confounder into account underestimated the contribution of the form letter. Given the robustness of the ANOVA and for simplicity of analysis, we chose to control for this confounder with simple linear regression analysis.

To avoid multiple comparisons, the customized letter was compared with no letter. A comparison between the customized letter group and the no letter group adjusted for the baseline up-to-dateness confounder using analysis by linear regression retained the statistical significance of the comparison (β =.1073, *P*=.023). Comparing the form letter group with the no letter group and adjusting for confounding did not reach statistical significance (linear regression β =.029, *P*=.520).

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DISCUSSION

Those receiving the customized letter obtained more preventive procedures, but the form letter did not improve compliance with preventive procedures. Customization made a statistically significant difference, although the absolute effect size was small.

The Health Belief Model³⁵ suggests information alone is insufficient to change health behaviours. People often fail to assimilate information and lack the motivation or willpower to do what they know they ought to do.³⁶ People are unrealistically optimistic about their chances of avoiding problems. This model suggests that effective preventive efforts must go beyond merely providing information with reminder letters to affecting attitudes, values, and decision making.

On the other hand, the best comparison in the literature found a much larger effect size than we found. The study by Ornstein et al¹² took place in a family practice residency training centre; health services research conducted in urban tertiary care university centres does not always apply to community practice.³⁷ Another important difference is that our principal investigator visited the practice for only 1 day every 3 months during the study. Having a champion of preventive measures in the practice has been suggested as a determining factor of success or failure for the delivery of preventive services in primary care.³⁸ It is likely that, for

most of the research reported in the literature on the effectiveness of reminder systems, a champion is on site as the principal investigator of each study.

The small effect size found in our study can also be explained, in part, by the extremely positive wording of the letter. Response to a reminder letter depends on the wording of the letter.³⁹ Letters can be written to make it more difficult for patients to deny the importance or applicability of an issue. The letter could have been more directive as to when and how patients should act to protect themselves.

Orienting the mailing to the entire family is new. In some two-parent families, one parent takes the lead in organizing health care for the family. Mailing a single letter could help this person in his or her efforts to encourage family members to seek preventive care.

Representativeness of the sample

The representative sample of families used in this study was achieved in a way that introduced the potential bias of oversampling large families. Instead of using addresses, for ease of sampling, we in essence used last names. Once an individual was selected from the computerized database of active patients, his or her entire family was assigned to one of the three arms of the study by random assignment. Selecting the study sample in this way allows the possibility that the study sample will over-

OVERDUE INTERVENTION	NO LETTER N (%)	FORM LETTER N (%)	CUSTOMIZED LETTER N (%)	TEST <i>P</i> VALUE
Pap (all intervals)	5/120 (4.2)	5/124 (4.0)	12/88 (13.6)	.04*†
Mammogram (all intervals)	4/99 (4.0)	2/102 (2.0)	4/69 (5.8%)	.41†
Adult tetanus	3/316 (0.9)	6/340 (1.8)	8/262 (3.1)	.26 [‡]
Flu (over 65)	9/47 (19.1)	8/48 (16.7)	6/30 (20.0)	.11†
Flu (chronic disease)	3/20 (15.0)	1/11 (9.1)	3/17 (17.6)	.75†
Fecal occult blood test	5/238 (2.1)	4/236 (1.7)	9/183 (4.9)	.14‡
MMR vaccine	0/26	0/35	0/19	N/A
HIB vaccine	1/17 (5.9)	0/25 (0.0)	1/16 (6.3)	.39†
DPT TOPV (all)	1/32 (3.1)	1/49 (2.0)	3/36 (8.3)	.42†
MMR booster	0/141 (0.0)	2/134 (1.5)	5/128 (3.9)	.04*†
TOTAL	31/1056 (2.9)	29/1106 (2.6)	51/842 (6.1)	.013*‡

 Table 3. Proportion of those overdue for tests who received procedures

*Statistical significance P <.05.

 ${}^{\dagger}\chi^2$ (Fisher's exact test was used when only two or three individual procedures were received).

[†]Kruskal-Wallis analysis was corrected for ties (Kruskal-Wallis was used when more than three procedures were received).

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represent larger families because the more members there are in the family, the greater the chance any member will be selected. Because there was no relationship between the number of members in a family and either outcome variable, this bias has limited importance for the study.

Generalizability of the study

There are several threats to the external validity of this study. The Canadian health care system does not charge patients directly for any of the preventive services tracked in this project. Physicians in this study were paid fee for service and received no additional money for ordering or providing preventive procedures. There is a financial disincentive because preventive medicine "slows them down."⁴⁰ The rural nature of the practice, the relative poverty of the population, and the departure of the two most senior partners just before the study all affected the study but are not necessarily reproduced elsewhere.

Mailing customized letters in large numbers is feasible only in practices that are extensively computerized. The general applicability of any reminder program that requires a practice to have an accurate and continuously up-to-date family registration is limited because of the cost of implementing such a system.^{31,32}

Design weaknesses

A mild selection bias was introduced because physicians could refuse to allow any letter to be sent (15 families were affected). Increased awareness of prevention in the office because of the conduct of a study could have caused a contamination effect on the group not receiving letters. For some preventive procedures, the outcome measure in this study was ordering of tests rather than actual provision or delivery of the test.

Design strengths

The pilot test was conducted in a separate geographic area of the practice. Virtually all the information required for this study had been routinely collected

Key Point

Although a statistically significant increase in preventive services was found in patients who received customized reminder letters, the absolute change was small. in the practice for 4 years before the study was begun. The fact that the study was nearly invisible to the practising physicians helped the researchers gather complete data.

Conclusion

This study demonstrated a statistically significant increase in patients seeking appropriate preventive health services after they had received customized reminder letters. At the time of patients' visits, physicians were reminded of procedures overdue for patients and other members of their families. We showed that combining active and passive preventive medicine reminder systems is more effective than using a passive system alone.

The effect size was much greater in the published study that most closely resembles this project. Our effect size could be increased with a more strongly worded letter or with a champion present in the practice. The effect size in our study is too small to warrant the cost of preparing customized letters for most practices. Finally, this study has demonstrated that it is possible to conduct preventive services research in community-based practices.

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