Effect of Physician Notification Regarding Nonadherence to Colorectal Cancer Screening on Patient Participation in Fecal Immunochemical Test Cancer Screening: A Randomized Clinical Trial

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IMPORTANCE
Increasing participation in fecal screening tests is a major challenge in countries that have implemented colorectal cancer (CRC) screening programs.

OBJECTIVE
To determine whether providing general practitioners (GPs) a list of patients who are nonadherent to CRC screening enhances patient participation in fecal immunochemical testing (FIT).

DESIGN, SETTING, AND PARTICIPANTS
A 3-group, cluster-randomized study was conducted from July 14, 2015, to July 14, 2016, on the west coast of France, with GPs in 801 practices participating and involving adult patients (50-74 years) who were at average risk of CRC and not up-to-date with CRC screening. The final follow-up date was July 14, 2016.

INTERVENTIONS
General practitioners were randomly assigned to 1 of 3 groups: 496 received a list of patients who had not undergone CRC screening (patient-specific reminders group, 10 476 patients), 495 received a letter describing region-specific CRC screening adherence rates (generic reminders group, 10 606 patients), and 455 did not receive any reminders (usual care group, 10 147 patients).

MAIN OUTCOMES AND MEASURES
The primary end point was patient participation in CRC screening 1 year after the intervention.

RESULTS
Among 1482 randomized GPs (mean age, 53.4 years; 576 women [38.9%]), 1446 participated; of the 33 044 patients of these GPs (mean age, 59.7 years; 17 949 women [54.3%]), follow-up at 1 year was available for 31 229 (94.5%). At 1 year, 24.8% (95% CI, 23.4%-26.2%) of patients in the specific reminders group, 21.7% (95% CI, 20.5%-22.8%) in the generic reminders group, and 20.6% (95% CI, 19.3%-21.8%) in the usual care group participated in the FIT screening. The between-group differences were 3.1% (95% CI, 1.3%-5.0%) for the patient-specific reminders group vs the generic reminders group, 4.2% (95% CI, 2.3%-6.2%) for the patient-specific reminders group vs the usual care group, and 1.1% (95% CI, −0.6% to 2.8%) for generic reminders group vs the usual care group.

CONCLUSIONS AND RELEVANCE
Providing French GPs caring for adults at average risk of CRC with a list of their patients who were not up-to-date with their CRC screening resulted in a small but significant increase in patient participation in FIT screening at 1 year compared with patients who received usual care. Providing GPs with generic reminders about regional rates of CRC screening did not increase screening rates compared with usual care.

TRIAL REGISTRATION
clinicaltrials.gov Identifier: NCT02515344
Colorectal cancer (CRC) is the third most frequent cancer worldwide, accounting for 694,000 deaths in 2012 and was the second most lethal cancer after lung cancer. The five-year survival rate depends on the stage at diagnosis: the rates for the localized stage, local extension to the lymph nodes, and the metastatic stage in 2013 were 90.1%, 70.8%, and 13.1%, respectively. Screenings based on sigmoidoscopy or fecal tests are associated with a decreased 10-year mortality rate. Many countries have implemented CRC screening based on fecal immunochemical tests (FIT). In France, asymptomatic individuals aged 50 to 74 years receive a postal invitation to consult their GPs to obtain a FIT testing kit. The GP refers patients with a positive test result to a gastroenterologist for a colonoscopy. Colonoscopy screening is reserved for symptomatic or high-risk individuals on the basis of family history, and GPs serve as gatekeepers for access to colonoscopy.

Patient participation in CRC screening is a major challenge. National participation in CRC screening in France was only 29.8% from 2013 to 2014, far below European goals. In 2015, the French national health system switched from the fecal occult blood test to FIT because of its higher sensitivity and specificity. Prior work has examined patient-focused strategies to increase participation in CRC screening, such as postal mailing of screening kits, written or telephone reminders, and tailored navigation. However, research has not sufficiently explored whether reminders directed to GPs increases patient participation.

The objective of this study was to evaluate whether providing GPs with a list of their patients who were at average risk of CRC but had yet to undergo CRC screening would increase patient participation compared with either informing GPs generically about regional-level CRC screening rates or maintaining usual care.

Method

Study Design and Participants

The study was a cluster randomized clinical trial with 3 parallel groups conducted from July 14, 2015, to July 14, 2016, in 2 areas on the French west coast. General practitioners were clustered within practices to avoid contamination bias stemming from shared tracking mechanisms and communication among GPs within a practice. The study protocol was approved by the human subjects ethics committee of Rennes. A waiver of individual participant-level informed consent was provided by the ethics committee. The full protocol is included in the Supplement.

General practitioners in the Loire-Atlantique and Vendée areas with at least 100 patients older than 16 years on their patient list according to the national health care insurance system were eligible. In October 2014, information about the study was sent to 1501 GPs, who could opt out of participation by contacting the research team.

Since 2015, FIT rather than fecal occult blood test screening has been used in France. FIT screening every 2 years is recommended for patients at average risk of CRC, based on (1) being between the ages of 50 years and 74 years; (2) having neither a personal history of CRC or adenoma larger than 1 cm nor a family history of CRC; and (3) manifesting no symptoms of CRC. Colonoscopy screening is reserved for patients at elevated risk of CRC corresponding to approximately 15% of the population aged 50 years to 74 years.

In the French CRC screening program, local health associations invite patients to participate in the screening if they are eligible for and have yet to complete their FIT screening in the preceding 24 months. The invitation advises them to obtain a FIT kit during a physician’s visit because kits are not mailed directly to patients. Each patient is asked to mail the completed FIT kit with a stool sample in a prepaid envelope. Test results are sent to the patient, the GP, and the local public health association. Patient participation is tracked at 3 and 6 months after the invitation letters are mailed. Patients who have not returned a FIT screening within 3 months are defined as nonadherent. Nonadherent patients may receive as many as 2 written reminders: the first at 3 months and the second at 6 months after the first invitation. Patients with a positive test result are referred to gastroenterology for colonoscopy. Local health associations maintain a tracking system that integrates information from the national health insurance system, FIT laboratories, pathology laboratories, hospital information systems, gastroenterologists, GPs, and the cancer registry, in accordance with European guidelines. French GPs receive financial incentives based on the number of CRC screening tests their patients complete, which for the study period was €60 (US $70) for the first 10 completed FIT tests up to an annual maximum incentive of €1030 (US $1205) per year.

Our study focused on the subset of the GP’s average-risk patients who had not completed FIT testing within the 3 months of receiving the first CRC screening invitation. Patients were eligible to participate in our study if they (1) had not returned the FIT and were candidates for the 3-month reminder letter as of July 14, 2015, the start of our study, and (2) were listed as a primary patient of a participating GP. The 3-month reminder letter included a supplemental letter from the study investigators explaining the study. Patients could opt out of participation by contacting the research team. No data related to the study were collected for patients who had opted out.

Key Points

Question Does providing general practitioners in France with a list of nonadherent patients improve patient participation in fecal immunochemical test colorectal cancer screening?

Findings In this randomized clinical trial, providing general practitioners with a list of patients who had not undergone fecal immunochemical test screening resulted in a small but significant increase in patient participation compared with patients who received usual care. Generic reminders with general information did not increase patient participation.

Meaning Providing general practitioners in France with a list of their nonadherent patients resulted in a modest increase in patient participation in fecal immunochemical test screening.
Figure. Participant Flow for Enrollment and Allocation to the Study Groups

- 1501 GPs mailed information about the study
- 801 Medical practices assessed for eligibility in the study’s geographic area
- 19 GPs Excluded
  - 1 Refused to participate
  - 18 Practice cessation, no longer a GP, moved, deceased

10 476 Practices randomized

- 268 Practices randomized to patient-specific reminders (506 GPs; mean per practice, 1.89; median, 1 [range, 1-6])
- 267 Practices randomized to generic reminders (504 GPs; mean per practice, 1.89; median, 1 [range, 1-7])
- 266 Practices randomized to usual care (472 GPs; mean per practice, 1.77; median, 1 [range, 1-8])

- 640 Patients excluded
  - 413 Medical reasons
  - 227 Administrative reasons

- 615 Patients excluded
  - 384 Medical reasons
  - 231 Administrative reasons

- 560 Patients excluded
  - 362 Medical reasons
  - 198 Administrative reasons

Intervention and Control Procedures

In July 2015, General practitioners were randomly assigned to 1 of 3 groups (Figure). To avoid contamination bias, the unit of randomization was by medical practice rather than by GP. Randomization was computer generated and stratified over the 2 geographic areas.

The GPs in the patient-specific reminders group were mailed their first list of patients a few days after the study began (July 2015) and a second updated list was mailed in November 2015. They were informed that they could request another copy if they lost the original list. The GPs were advised of tips that could help them follow up with patients: integrate informatics reminders with each patient file, ensure that medical practice secretaries recontacted each patient on the list, or place the list on their desks. There was no specific requirement, and the GP had the freedom to decide how to use the information. General practitioners in the generic reminders group received CRC screening rates in the local administrative district. They received neither a list of their patients who were nonadherent nor specific instructions or suggestions on how to encourage patients to complete the screening. General practitioners in the usual care group received no information about CRC screening rates. Although the screening program offers a pay incentive to physicians whose patients complete the screening, this incentive was not part of...
the study, did not change over the study period, and did not differ across groups.

Study End Points
The primary end point was patient participation in FIT CRC screening 1 year after the 3-month reminder had been mailed. Participation was calculated as the proportion of patients who had completed FIT screening among all average-risk patients eligible for CRC screening, which was determined at the beginning of the study. The number of CRCs identified as a result of the FIT screening was also a primary end point. However, these data are not yet available from the national cancer registry.11,12

Secondary end points included screening participation rates in subgroups based on patient characteristics including sex, age, low socioeconomic status (defined as an annual income < €8593 [<US $10 054] for an individual or < €12 889 [US $15 080] for a couple), and presence of a severe chronic disease (defined using a list of 30 severe chronic diseases leading to high costs for patients).13 The economic costs related to each reminder strategy was a planned secondary end point, but these data are not yet available and are not reported in this article.

Post hoc outcomes analyzed whether patient participation to FIT screening was linked to characteristics of the GPs (sex, age, practice location, and activity).

Data Collection
Data regarding patient participation were stored by regional public health authorities, based on recommended procedures implemented for general care.6 As reported previously, local associations overseeing the screening program used a dedicated computerized database that allowed for the collection of data from all partners involved (national health insurance systems, the FIT laboratory, pathology laboratory, hospital information system, gastroenterologists, GPs, patients, the regional cancer registry). Patients who completed the FIT within a year of receiving their first reminder were classified as adherent, whereas other patients were classified as nonresponders. Based on this classification, no data were missing.

Patient and GPs’ characteristics were extracted from the national health care insurance database. This data extraction procedure allowed for complete collection of data related to patient and GPs’ characteristics.

Statistical Analysis
The objective of this analysis was to be as exhaustive as possible in the recruitment of GPs to avoid selection bias. We estimated that at least 1300 GPs would participate among all those eligible, corresponding to 433 in each group. Based on this recruitment, we assumed that participation in CRC screening would be at least 12% higher in the patient-specific reminders group than in the other groups (absolute mean difference, 67% vs 55%; estimated SD, 0.61; bilateral α risk, 5%; statistical power, 80%). Participation in the usual care group was estimated at 55% using the following data. During 2012 and 2013, participation in the fecal occult blood test screening was equal to 38.2% in Western France based on rates measured by the regional public health authority. Based on a literature review,9 we hypothesized that participation in CRC screening would be higher after introduction of the FIT (vs the fecal occult blood test). International studies concluded that using the FIT rather than the fecal occult blood test significantly increased participation from an odds ratio (OR) of 0.86 to 2.14 (median, 1.44).7,14-18 Thus, the study power was based on a projected participation rate of 55% (38.2% × 1.44).

The significance threshold was P < .05. Testing was 2-sided. The study design avoided having missing data. The modified intention-to-treat method was applied and included all randomized GPs. General practitioners who had changed their eligibility criteria (practice cessation, practice reorientation, address modification, or death), either before the randomization or during the study, were excluded from the analysis.

For the primary end point, the GP was the statistical unit of analysis. Each GP was characterized by the ratio of participation of their patients 1 year after participation invitations were sent. This ratio was defined as the number of patients who sent back their FIT screen to the number of patients who at the beginning of the study had not sent back their FIT screen (continuous variable). The results were confirmed with a mixed-model regression analysis adjusted for all GP characteristics as shown in Table 1. Medical practices were considered a between-unit random effect. The randomized group was considered a fixed effect. The random effect accounted for correlations among GPs in the same practice. A global analysis of variance test was performed to compare participation among all groups. If the null hypothesis was rejected, then comparisons between the usual care group with the others would be performed.

Patient factors associated with participation in CRC screening (prespecified analysis provided in the protocol) were assessed with a mixed-general linear model for which the Y was the status of each patient depending on whether he/she participated (logical variable). The patient was the statistical unit. In this model, the GP was considered a within-unit random factor, and the variables were patient characteristics. No selection procedure was performed.

In post hoc analyses, GP factors associated with patient participation in the FIT screening were assessed by a mixed-general linear model for which the Y predicted was the percentage of participation of each GP (continuous variable). General practitioners were the statistical unit. Additionally, medical practices were considered between-random effects, and the fixed variables were GP characteristics. No selection procedure was performed.

Analyses were performed using R 3.2.0 statistical software. The GLIMMIX and the Mixed Procedures of SAS version 9.4 (SAS Institute Inc) were used to estimate the models including the random effects.

Results
Participants
A written study description was mailed to 1501 GPs identified as eligible for the present study, located in 801 medical practices. One GP opted not to participate (Figure). Between mailing the study introductory letter in October 2014 and
randomization in July 2015, 18 GPs were excluded because of practice cessation, practice reorientation, address modification, or death. Another 36 GPs were excluded after the randomization for the same reasons. Among 1482 randomized GPs (mean age, 53.4 years; 576 women [38.9%]), 1446 completed the study and were included in the analysis, 496 of whom were randomized to the patient-specific reminders group; 495, to the generic reminders group; and 455 to the usual care group.

Table 1. Demographic Characteristics of the General Practitioners in Each Group

<table>
<thead>
<tr>
<th>No. (%) of Patients</th>
<th>Patient-Specific Reminders (n = 496)</th>
<th>Generic Reminders (n = 495)</th>
<th>Usual Care (n = 455)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>201 (40.5)</td>
<td>183 (37.0)</td>
<td>181 (39.8)</td>
</tr>
<tr>
<td>Men</td>
<td>295 (59.5)</td>
<td>312 (63.0)</td>
<td>274 (60.2)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>53.3 (52.4-54.1)</td>
<td>53.1 (52.2-53.9)</td>
<td>53.6 (52.7-54.5)</td>
</tr>
<tr>
<td>27-40</td>
<td>75 (15.1)</td>
<td>69 (13.9)</td>
<td>53 (11.6)</td>
</tr>
<tr>
<td>41-50</td>
<td>93 (18.8)</td>
<td>107 (21.6)</td>
<td>97 (21.3)</td>
</tr>
<tr>
<td>51-60</td>
<td>178 (35.9)</td>
<td>176 (35.6)</td>
<td>175 (38.5)</td>
</tr>
<tr>
<td>&gt;60</td>
<td>150 (30.2)</td>
<td>143 (28.9)</td>
<td>130 (28.6)</td>
</tr>
<tr>
<td>Practice location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>23 (4.6)</td>
<td>31 (6.3)</td>
<td>33 (7.3)</td>
</tr>
<tr>
<td>Semirural</td>
<td>231 (46.6)</td>
<td>233 (47.1)</td>
<td>192 (42.2)</td>
</tr>
<tr>
<td>Urban</td>
<td>242 (48.8)</td>
<td>231 (46.7)</td>
<td>230 (50.6)</td>
</tr>
<tr>
<td>Medical visits/y, mean (95% CI)</td>
<td>3589.8 (3449.7-3729.9)</td>
<td>3717.0 (3577.5-3856.5)</td>
<td>3636.2 (3487.6-3784.8)</td>
</tr>
</tbody>
</table>

Table 2. Demographic Characteristics of the Patients in Each Group

<table>
<thead>
<tr>
<th>No. (%) of Patients</th>
<th>Patient-Specific Reminders (n = 10 476)</th>
<th>Generic Reminders (n = 10 606)</th>
<th>Usual Care (n = 10 147)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>5719 (54.6)</td>
<td>5763 (54.3)</td>
<td>5497 (54.2)</td>
</tr>
<tr>
<td>Men</td>
<td>4757 (45.4)</td>
<td>4843 (45.7)</td>
<td>4650 (45.8)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (95% CI)</td>
<td>60.8 (60.6-60.9)</td>
<td>60.9 (60.8-61.1)</td>
<td>60.9 (60.8-61.1)</td>
</tr>
<tr>
<td>50-60</td>
<td>5408 (51.6)</td>
<td>5420 (51.1)</td>
<td>5087 (50.1)</td>
</tr>
<tr>
<td>61-70</td>
<td>3731 (35.6)</td>
<td>3701 (34.9)</td>
<td>3707 (36.5)</td>
</tr>
<tr>
<td>71-74</td>
<td>900 (8.6)</td>
<td>956 (9.0)</td>
<td>854 (8.4)</td>
</tr>
<tr>
<td>&gt;74</td>
<td>437 (4.2)</td>
<td>529 (5.0)</td>
<td>499 (4.9)</td>
</tr>
<tr>
<td>Presence of a chronic diseasea</td>
<td>2695 (25.7)</td>
<td>2703 (25.5)</td>
<td>2589 (25.5)</td>
</tr>
<tr>
<td>Low socioeconomic statusb</td>
<td>308 (2.9)</td>
<td>288 (2.7)</td>
<td>323 (3.2)</td>
</tr>
</tbody>
</table>

* Defined using a list of 30 severe chronic diseases leading to high costs for patients.13

* Defined as an annual income less than €8593 (<US$10 054) for an individual or less than €12 889 (<US$15 082) for a couple.

**Table 1 shows the sex distribution and demographic characteristics of the GPs in each group.

Of the 33 044 patients (mean age, 59.7 years; 17 949 women [54.3%]), 1815 were excluded for medical or administrative criteria, so that the follow-up at 1 year was available for 31 229 (94.5%) (mean age, 60.9 years; 16 919 women [54.4%]): 10 476 patients in the patient-specific reminders group, 10 606 patients in the generic reminders group, and 10 147 patients in the usual care group. Table 2 presents the demographic characteristics of the participants.

**Participation in FIT Screening (Primary End Point)**

At 1 year, the mean patient participation per GP was 24.8% (95% CI, 23.4%-26.2%) in the patient-specific reminders group, 21.7% (95% CI, 20.5%-22.8%) in the generic reminders group, and 20.6% (95% CI, 19.3%-21.8%) in the usual care group, with between-group differences of 3.1% (95% CI, 1.3%-5.0%) for patient-specific reminders vs generic reminders, 4.2% (95% CI, 2.3%-6.2%) for patient-specific reminders vs usual care, and 1.1% (95% CI, −0.6% to 2.8%) for generic reminders vs usual care (Table 3).

**Patient Factors Related to Participation (Secondary End Points)**

Patients with a low socioeconomic status and patients who had a chronic disease were less likely to complete the FIT screening (Table 4).

**GP Practice Characteristics Related to Participation (Post Hoc Analysis)**

The following GP practice characteristics were associated with greater participation in FIT screening of patients who were non-responders at the beginning of the study: younger physicians, GPs receiving a greater number of medical visits per year, and GPs who had fewer non-responders on their list at the beginning of the study (Table 5).
In this open, randomized 3-group study, providing GPs with a list of patients who were nonadherent to CRC screening was associated with a modest increase in FIT participation compared with providing GPs with generic reminders about regional CRC screening rates or providing no reminders. These results were consistent across statistical models considering either GPs or patients as the statistical unit after adjustments for GP or patient characteristics. The analysis demonstrated a significant absolute difference of 4.2% between the patient-specific reminders group and usual care group, even though the statistical plan was designed to detect an anticipated difference of more than 12%. The reason this difference could be detected is that the standard deviation of the study (15%) was lower than the value included in the protocol (61%).

The target of this large randomized clinical trial (RCT) was the GP rather than the patient. In most strategies proposed by policy makers, interventions are designed to directly influence patients.8-10 In a previous review focusing on patient participation in CRC screening, Rat et al 9 reported the absolute increase of participation observed for the following interventions: mailing of invitation letters to patients (from 6.2% to 7.0%),19,20 postal mailing of kits (from 3.9% to 24.5%),21,22 written reminders (6.7% to 16.4%).22,23 However, few authors have reported the effect...
Table 5. General Practitioner Characteristics Related to a Higher Patient Participation in Fecal Immunochemical Test Colorectal Cancer Screening (Post Hoc Analysis)*

<table>
<thead>
<tr>
<th>GP Characteristics as Fixed Effects</th>
<th>β Coefficient (95% CI)</th>
<th>Percentage Points</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provision of patient-specific reminders</td>
<td>3.69 (1.88 to 5.52)</td>
<td>3.69 (1.88 to 5.52)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Provision of generic reminders</td>
<td>0.64 (-1.19 to 2.46)</td>
<td>0.64 (-1.19 to 2.46)</td>
<td>.32</td>
</tr>
<tr>
<td>GP age</td>
<td>-1.51 (-2.34 to 0.67)</td>
<td>-1.51 (-2.34 to 0.67)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Male sex</td>
<td>1.15 (-0.49 to 2.78)</td>
<td>1.15 (-0.49 to 2.78)</td>
<td>.16</td>
</tr>
<tr>
<td>Annual No. of medical visits</td>
<td>1.66 (0.82 to 2.51)</td>
<td>1.66 (0.82 to 2.51)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>No. of nonadherent patients on the list</td>
<td>-2.42 (-3.36 to -1.50)</td>
<td>-2.42 (-3.36 to -1.50)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

* According to a general linear mixed-model formula with the general practitioner (GP) as the statistical unit, medical practices as between-random effects, participation in colorectal cancer screening (number of patients screened per number of eligible patients) for each GP, and adjustment for other GP characteristics. All GP characteristics presented in the Table were included in the model. No selection procedure was performed. According to a fixed-effects model, patient participation in fecal immunochemical test colorectal cancer screening can be predicted using the following equation: participation rate = 22.7 + 3.69 (if list) + 0.64 (if generic) + 0 (if control) -1.51 × scale (GP age) + 1.15 (if a man) + 1.66 × scale (annual number of medical visits) -2.42 × scale (number of nonadherent patients on the list).

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participation by only 4% (absolute participation increase) might be regarded as disappointing. Second, the design of this study does not allow a clear report of how providing patient-specific reminders to the GPs positively affects CRC screening participation. A hypothesis is that the physicians concentrated their efforts on these nonadherent patients and customized their communication to the personality and characteristics of each patient to enable shared decision making.6,40 Third, the generalizability of the study findings might depend on the national setting: generating a list of nonresponders requires good data and the resources to create the list. Even in practices with electronic health records, this might not be possible because tests and procedures are sometimes performed outside of the clinic setting and because results are often entered in ways that cannot be captured electronically.

Conclusions

Providing French GPs caring for adults at average risk of CRC with a list of their patients who were not up-to-date with their CRC screening resulted in a small but significant increase in patient participation in FIT screening at 1 year compared with patients who received usual care. Providing GPs with generic reminders about regional rates of CRC screening did not increase screening rates compared with usual care.

REFERENCES