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Additional mailing phase for FIT after a medical offer phase: the best way to improve compliance with colorectal cancer screening in France

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Abstract

Background: Compliance with colorectal cancer screening is critical to its effectiveness. The organization of the mass screening program in France has recently been modified with no evaluation of the consequences.

Aims: To evaluate the impact of the way the screening test is delivered on compliance.

Patients and methods: During the first six months of the screening campaign (Ille-Vilaine, Brittany), general practitioners were asked to propose a faecal immunochemical test (FIT), OC-Sensor, to individuals at average risk for colorectal cancer (n=152,097). A subset of non-participants in the medical phase (n=13,071) was randomly chosen to receive a reminder that included the screening test or a simple postal reminder without the screening test.

Results: Compliance was 31% if the screening test was proposed during a medical consultation. In non-participants during the medical phase, it was 45% in those receiving both a reminder and the screening test and 28% among those receiving a simple reminder. An estimated overall participation rate of 54% can be expected if non-participants in the medical phase are sent a reminder together with the screening test.

Conclusion: In France, a compliance rate above the minimum uptake rate of 45% recommended by European Union experts can be achieved if the FIT is mailed to non-participants after the medical free-offer phase.

Key words: colorectal cancer, screening, immunochemical test, compliance

Introduction

Colorectal cancer (CRC) is a major health problem in industrialized countries and meets the criteria necessary for it to be considered for population-based screening[1]. It is one of the most frequent cancers with an estimated 447,000 new cases in Europe in 2012[2]. Five-year survival remains poor[3]. However, when the cancer is limited to the bowel wall it can be cured by complete resection. Furthermore most CRC are preceded by a precancerous lesion, an adenoma, which can be removed during a colonoscopy, and thus prevent CRC[4]. Screening for colorectal tumours at their asymptomatic stage can reduce both CRC incidence and mortality. Like the diagnostic yield and the cost of a screening test, compliance is a major determinant of the effectiveness of a screening programme. Even a highly sensitive screening test will be ineffective if few people perform it. European guidelines for quality assurance in CRC screening recommend a minimum uptake of 45% [5]. To achieve such a participation rate, it has been shown in France, with the Hemoccult test, that both the active participation of general practitioners (GPs) and the mailing of the test to reach those who were not in contact with a GP during the medical free-offer phase was necessary[6]. In 2012, the French General Health Director, independently of any consultation with professionals, decided that there was no reason to make the mailing phase of the screening campaign mandatory. As a result, it was suppressed in most French regions without evaluating the consequences. One of the objectives of the French Cancer Plan is to improve compliance with CRC screening by using the most effective strategy[7]. Thus, the aim of this study was to evaluate the impact of the way the screening test is proposed on participation so as to determine the most efficient screening strategy to be used in the average-risk population in France.

Patients and Methods

An organized screening programme for CRC is currently being carried out in France. It was progressively implemented between 2003 and 2008 and became available throughout the

country in 2009. Initially, subjects aged 50 to 74 at average risk for CRC were invited to perform a guaiac test (gFOBT), the Hemoccult test, biennially[8]. In 2014, the Ministry of Health announced the shift from a g FOBT to an immunochemical test (FIT). A tender was organized to choose a central analysis centre. The proposal had to include a screening test. The biological laboratory CERBA was chosen (95056 Cergy Pontoise Cedex 9) and proposed the OC-Sensor test (Eiken, Tokyo, Japan) as the FIT. Because of administrative and legal delays there was a gap in the shift from the gFOBT (ended in November 2014) to the FIT (started May 2015).

The first 6 months of the screening campaign (May to November 2015) corresponded to the medical free-offer phase. General practitioners (GPs) were asked to propose the screening test to eligible subjects seen at their practice. The screening campaign began by sending to each included subject an invitation letter to perform the screening test and an information brochure. A reminder letter that included a questionnaire to facilitate the identification of excluded subjects was sent 3 months later. GPs were also asked to declare the exclusion criteria and then provided each eligible individual with one screening test consisting of a plastic test tube containing a transportation liquid buffer to prevent the degradation of the globin part of haemoglobin. Each individual was instructed to take one faecal sample using the probe. The probe has a serrated tip which is poked in several different areas of the stool. It is then pulled back into the test tube through a tight membrane to remove the excess stool, which must not enter the buffer. The test is stored at room temperature before mailing. The completed test is sent by mail to the central analysis centre in a prepaid envelope. Patients were instructed to send the test to the central analysis centre as soon as it was completed. The maximum time between faeces deposit and processing of the test has to be less than 6 days.

Subjects who did not complete the test during the medical phase were separated into two groups (figure 1). The first 13,071 individuals who had been given the screening test during

the medical phase but did not do the test were randomly chosen to receive either a reminder with another screening test or a postal reminder only. The second group of subjects did not receive any further invitation. The small proportion of the population who received a reminder after the medical phase was related to the small number of tests available for the reminder-and-screening-test arm. We plan to invite the other non-participants in the medical phase after validation of the results of this pilot study by the health authorities.

To estimate an overall participation rate, we made the hypothesis that the uptake rate in the population who received the reminder with or without the screening test would be the same as that in the non-invited population. The 28,117 individuals who were invited in the medical phase and did not participate in at least the last three screening rounds were considered non-participants because their participation was very low (6). They did not receive the postal reminder but will be invited during any new screening campaign. The estimated population to be invited during the postal phase was thus 76,768.

Results

Between May and December 2015, a total of 162,347 subjects aged 50 to 74 were invited to take part in the seventh screening round of the French organized screening campaign for CRC. They were residents of a well-defined administrative area (Ille-et-Vilaine, Brittany). During this period, GPs offered the FIT (OC-Sensor) free of charge to eligible individuals. The test uses a one-sample strategy with a cut-off value of 150 ng/mL of buffer (or 30 μ g/g of faeces). Overall, 10,250 subjects did not meet the inclusion criteria and were excluded (figure 1).

The overall participation rate was 31%. It was slightly higher in women than in men during the medical invitation phase, while it was higher in men than in women during the postal reminder with and without the screening test (table 1). It varied with age. It was 35% in the 60-69 age group compared with 28% in the 50-59 age group during the medical invitation

phase ($p<0.001$). The effect of age on participation was small during the postal invitation phase.

Among the 13,071 individuals who did not comply with the screening test during the medical phase and who received a reminder, the compliance rate was 50% in those receiving both the postal reminder and the screening test and 28% in those receiving only a postal reminder without the screening test ($p<0.001$) (figure 1). The remaining 91,814 individuals did not receive any further invitation because at this time, the medical phase was not achieved. They will be invited later.

The number of participants during the medical phase (47,212) added to the estimated number of participants among those who would have received a reminder including the screening test (34,853) would have given an overall participation rate of 54% among the 152,097 subjects invited to participate in CRC screening (figure 2).

Discussion

This study conducted in the target population invited to an organized screening programme for CRC with FIT showed that compliance varied depending on the way the screening test was delivered. The distribution of screening tests by primary physicians is not sufficient to achieve the minimum recommended uptake by European Union experts of at least 45% (5). This study showed that sending a reminder with the test is crucial to obtain a high participation rate.

In many countries, the screening test is sent directly by mail to the target population with one or two reminders if necessary. A level of compliance of around 60% and over was reported in the Netherlands [9, 10], and the United-Kingdom[11]. However, in other countries, participation following mailing of the test was low. In Croatia, it ranged from 10 to 30% depending on the area.[12] In the neighbouring Slovenia, it was 33% after a positive answer to a letter of invitation to receive the test at home [13]. Some studies suggest that it is possible

to deliver the screening test in other ways. In Italy, residents of well-defined areas are invited to perform a FIT distributed by pharmacists [14]. It was shown in Serbia that primary care physicians were able to motivate individuals to comply with the screening test[15]. In France, test compliance with Hemoccult was not high enough when the test was given by GPs [6]. This is why the medical distribution phase must be completed by mailing the test to non-participants. This strategy made it possible to reach individuals who were not in contact with a primary care physician during the medical offer phase or those for whom a screening test was not proposed by the GP. One of the important findings of this study was the good participation when the FIT was sent with a reminder letter after the medical distribution phase. It was higher than with the Hemoccult test (around 30%)[6]. Mailing the test is helpful in reaching those who did not get the screening test during the medical free offer phase. Unpublished data suggest that at least 25% of the individuals aged 50 to 74 did not visit their GP over a one-year period. They are excluded from the screening programme in the absence of postal reminder that includes the test. In a population-based organized screening program, it is not ethical for the screening test to be available only to individuals who visit a GP. The design of the FIT received at home is probably the main reason for the improved participation. Efforts were made to make the presentation of the test kit and instructions for use attractive and as simple as possible. Participation in screening during the reminder phase was half as high when a simple reminder (without the test kit) was sent. Clearly, this is not the best strategy to obtain high compliance.

Compliance may become even higher when the problems that occurred as a result of the shift from gFOBTs to FITs have been completely resolved. However, the hypothesis that participation would be similar in the subset receiving a reminder with or without the screening test and in the overall population is a limitation of this study.

In accordance with most studies, participation during the medical phase of the study was slightly higher in women than in men. In contrast, participation was lower in women during the mailing phase of a reminder with or without the screening test. Repeat invitations appear to motivate men more than women. We found, as in other studies, lower compliance in subjects less than 60 and in those aged 70 and over. Compliance is always higher in the 60-69 age groups. These findings may reflect different patterns of behaviour towards illness and screening.

In conclusion, the data reported here suggest that, in France, distributions of the FIT during the medical-offer phase and then by mailing to non-participants are complementary and necessary to reach a participation rate in line with EU recommendations. To meet this objective, the mailing phase of the screening test must be restored urgently.

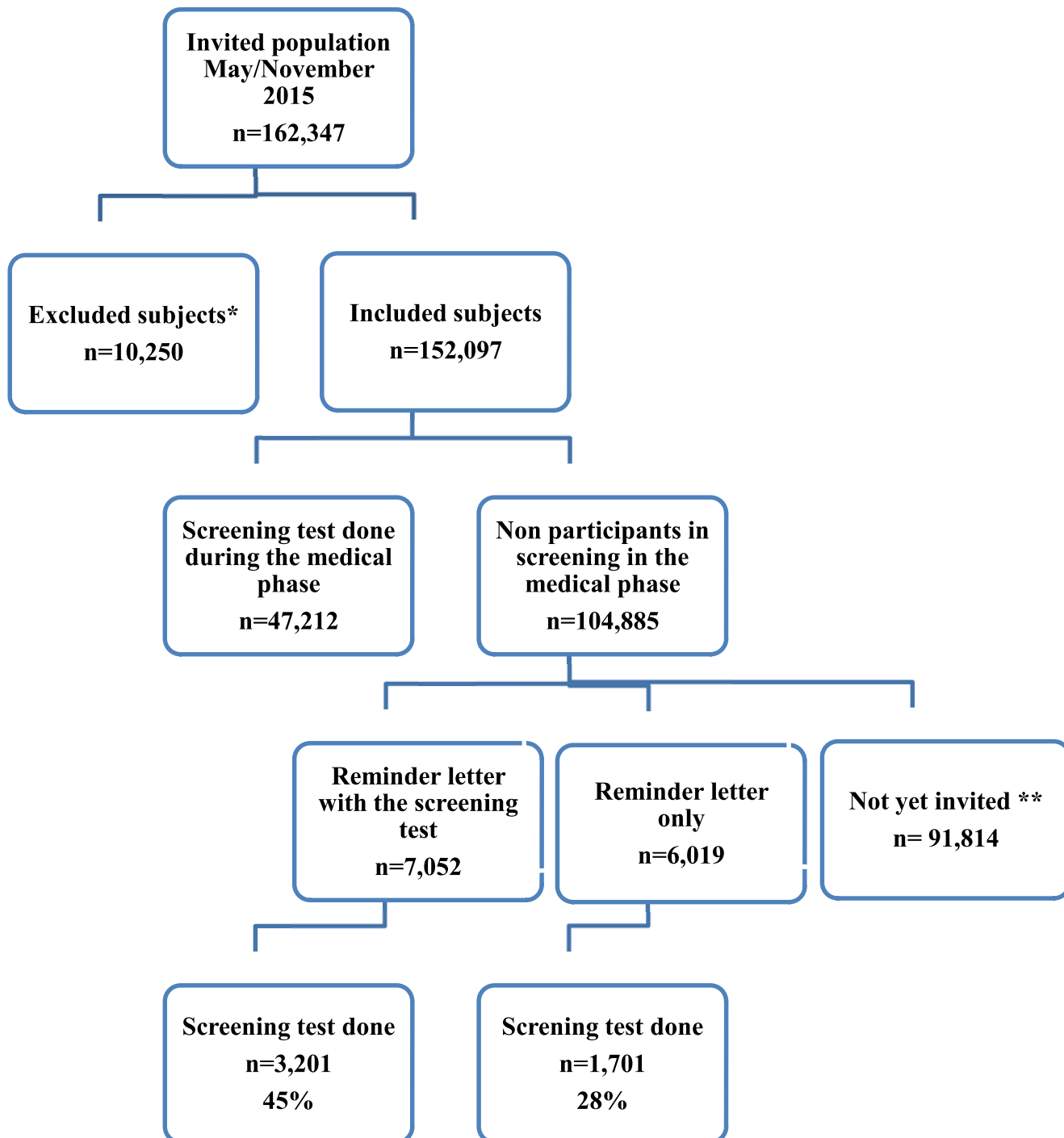
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Table1: Participation (%) during the screening campaign phases by sex and age group

	Medical invitation phase				Reminder letter with the screening test				Reminder letter alone			
	N	%	95% CI	p	N	%	95% CI	p	N	%	95% CI	p
Sex												
males	79,865	29.3	29.0 - 29.6		3,345	47.6	45.9 - 49.3		2,797	29.1	27.4 - 30.8	
females	82,482	32.7	32.4 - 33.0	<0.001	3,707	43.4	41.8 - 45.0	<0.001	3,222	27.5	26.0 - 29.0	0.16
Age												
50-54	41,355	26.9	26.5 - 27.3		1,310	45.9	43.2 - 48.6		1,166	27.0	24.5 - 29.5	
55-59	33,999	28.5	28.0 - 29.0		1,983	44.4	42.2 - 46.6		1,650	27.6	25.4 - 29.8	
60-64	32,305	33.7	33.2 - 34.2		1,567	45.8	43.3 - 48.8		1,305	29.3	26.8 - 31.8	
65-69	30,628	36.0	35.5 - 36.5		1,373	46.6	44.0 - 49.2		1,208	30.3	27.7 - 32.9	
70-74	24,060	31.9	31.3 - 32.5	<0.001	819	44.1	40.7 - 47.5	0.67	690	26.4	23.1 - 29.7	0.22

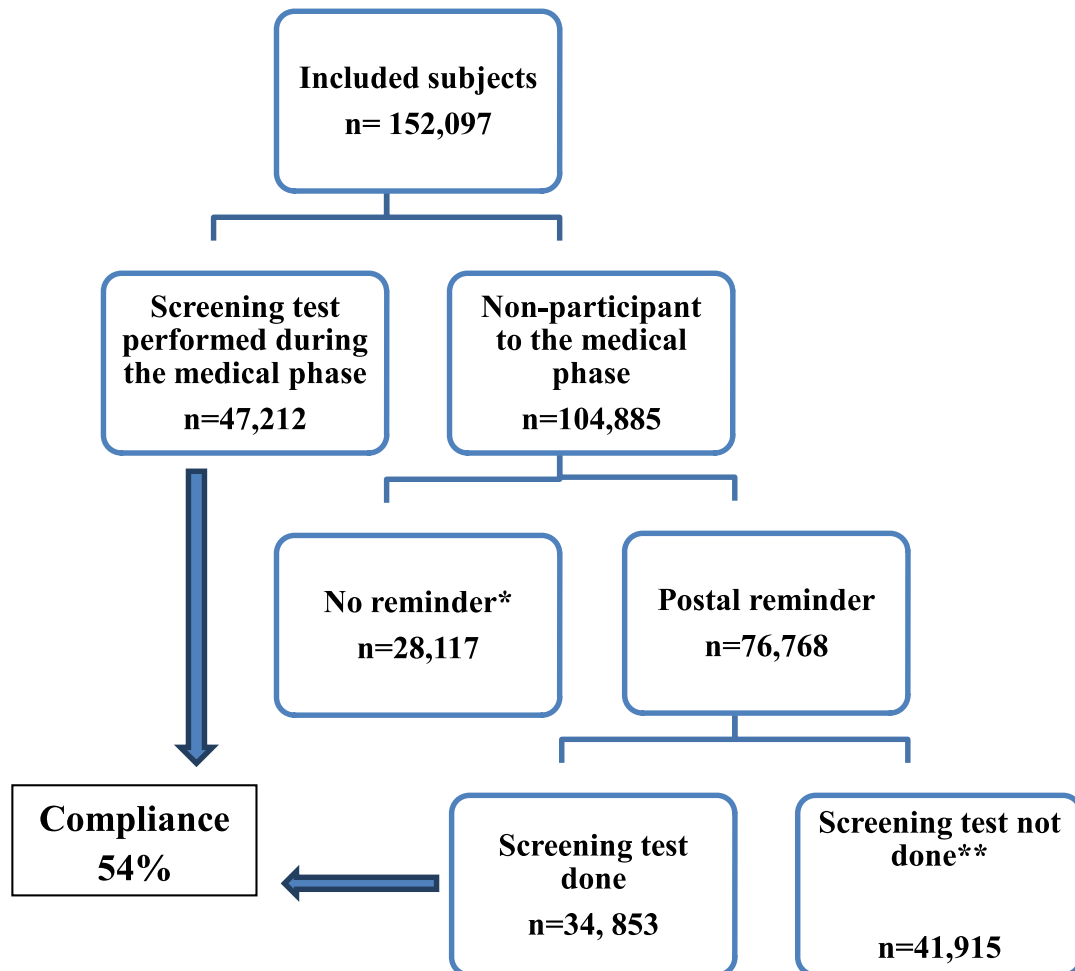
Figure 1 : Study profile



* Population at high risk or very high risk

** will be invited later after validation of the results of the pilot study

Figure 2: Estimation of compliance after the medical phase and postal phase with FIT



* Invited subjects who did not participate to the last three screening rounds or more

** Estimation based on the proportion of FIT performed after the reminder including the screening test in the pilot study