Cost-Effectiveness Analysis of a Navigation Program for Colorectal Cancer Screening to Reduce Social Health Inequalities: A French Cluster Randomized Controlled Trial

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A B S T R A C T

Background: Patient navigation programs to increase colorectal cancer (CRC) screening adherence have become widespread in recent years, especially among deprived populations. **Objectives:** To evaluate the cost-effectiveness of the first patient navigation program in France. **Methods:** A total of 16,250 participants were randomized to either the usual screening group (n = 8145) or the navigation group (n = 8105). Navigation consisted of personalized support provided by social workers. A cost-effectiveness analysis of navigation versus usual screening was conducted from the payer perspective in the Picardy region of northern France. We considered nonmedical direct costs in the analysis. **Results:** Navigation was associated with a significant increase of 3.3% (24.4% vs. 21.1%; P = 0.003) in participation. The increase in participation was higher among affluent participants (+4.1%; P = 0.01) than among deprived ones (+2.6%; P = 0.07). The cost per additional individual screened by navigation compared with usual screening (incremental cost-effectiveness ratio) was €1212 globally

and €1527 among deprived participants. Results were sensitive to navigator wages and to the intervention effectiveness whose variations had the greatest impact on the incremental cost-effectiveness ratio. **Conclusions:** Patient navigation aiming at increasing CRC screening participation is more efficient among affluent individuals. Nevertheless, when the intervention is implemented for the entire population, social inequalities in CRC screening adherence increase. To reduce social inequalities, patient navigation should therefore be restricted to deprived populations, despite not being the most cost-effective strategy, and accepted to bear a higher extra cost per additional individual screened.

Keywords: colorectal cancer screening, cost-effectiveness analysis, patient navigation, social inequalities.

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Introduction

Colorectal cancer (CRC) is the third most common cancer and the second leading cause of cancer deaths in France. In 2012, there were an estimated 42,152 new cases and 17,722 deaths owing to CRC [1]. Nevertheless, this type of cancer is preventable, and an effective, organized screening has existed in France since 2009 for men and women with average risk who are aged between 50 and 74 years. CRC screening, which is based on a fecal occult blood test (FOBT) every 2 years followed by colonoscopy in cases of positive FOBT, has been proved to reduce CRC mortality [2]. The

decrease in CRC mortality could be 14% to 16% among the target screening population if the participation rate were 50% to 60% and the completion rate of colonoscopy after a positive FOBT were 85% to 90% [3]. Nevertheless, although the screening test is covered at 100% by health insurance with no out-of-pocket costs and screening reminders are sent by mail, the national screening rate remains inadequate. This rate was 30% during the period 2013 to 2014, which is much lower than the rate of 45% recommended by current European guidelines [3].

Moreover, low screening participation is closely linked with low socioeconomic status in terms of education level, income,

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and employment status [4–6]. Access to screening for deprived individuals falls more broadly within the context of health inequalities that persist worldwide. Indeed, social inequalities exist between and within countries [7]. In Europe, France is characterized by high social inequalities with respect to mortality, particularly for cancers [8]. These inequalities have worsened in France, including the burden of cancer mortality among people with low education levels [9]. An important step in the issue of health inequalities was taken internationally in 2008 with the publication of a report by the Commission on Social Determinants of Health of the World Health Organization titled "Closing the gap in a generation: Health equity through action on the social determinants of health" [10]. Since then, most European states have undertaken measures to reduce health inequalities [10,11]. Nevertheless, despite the attention given to this problem by political authorities, health inequalities persist. Reducing social inequalities across the entire continuum of care is therefore a fundamental issue worldwide. Screening for CRC is also of concern, and increasing the screening adherence rate is a major public health issue, especially for deprived individuals [11].

Several types of CRC screening promotion strategies have been proposed, ranging from simple postal reminders for health care providers and patients to more sophisticated interventions, including patient navigation. The first patient navigation program was developed in 1990 by Harold Freeman in Harlem, New York City, to assist low-income women in overcoming barriers to breast cancer screening and follow-up care [12]. Since then, patient navigation service programs have become widespread throughout the United States and Canada [13], with the common aim of overcoming financial, logistic, and sociocultural barriers across the care continuum, that is, from screening to therapeutic care. Patient navigators must therefore undertake all possible actions to remove obstacles limiting or delaying the receipt of medical care. The actions of patient navigators are personalized and may include phone calls, making medical appointments, completing medical or administrative paperwork, organizing child care or transportation, language translation, and providing explanations about cancer or screening tests, among others [14].

Navigation programs can be considered at any point along the care continuum, whether at the time of screening, as part of diagnostic or therapeutic management, or during recruitment and retention of patients in clinical trials. The highest evidence for the effectiveness of navigation programs is improvement in screening adherence. Some studies have indeed reported that navigation is associated with improvements in cancer screening for breast, cervical, and colorectal cancers [13,15].

Patient navigator programs offer an interesting way to reduce social inequalities in health and are being implemented in several countries. The question arises of their transferability in France, and more broadly, in Europe, from the perspectives of effectiveness and cost-effectiveness. We therefore set up a prospective randomized trial, the PRogramme d'Accompagnement au Dépistage Organisé (PRADO) study, among the general target population for CRC screening in one region of France, to assess the relevance of addition of a navigation program to the national mass screening program aimed at reducing the social gradient in cancer screening participation. To our knowledge, this is the first patient navigation program conducted in France or in Europe with the objective to increase participation and reduce social inequalities in CRC screening. This article reports the cost-effectiveness analysis conducted from the payer perspective and provides information useful to decision makers when assessing ways to increase CRC screening adherence and reduce social inequalities in health.

Methods

Setting and Population

The PRADO study was a prospective, multicenter, cluster randomized controlled trial that evaluated the impact of patient navigation among the target population for CRC screening. The study was conducted in the three departments of the Picardy region in northern France between April 2011 and April 2013, that is, the duration of a screening campaign round. According to the National Institute of Statistics and Economic Studies (*Institut National de la Statistique et des Etudes Economiques*), the population of Picardy in 2013 comprised 49% men and 51% women, which was equivalent to the national distribution. The population was slightly younger than the overall population of France, with 50% of individuals younger than 40 years compared with 49% nationally, and 22.5% older than 60 years compared with 24% nationally. The economic context was also worse, with an unemployment rate of 11.7% of the working population and a poverty rate of 15.7% compared with 9.8% and 14%, respectively, for the whole of France. The CRC screening adherence rate was 30.1%, which was comparable with the national average of 31%.

Our study area consisted of three French departments collectively comprising 2360 small geographical units for which the socioeconomic level was defined using the Townsend index, which measures material deprivation using indicators related to diet, health, clothing, housing, household facilities, environment, and work.

Clusters were categorized into four strata: urban deprived (UD), rural deprived (RD), urban affluent (UA), and rural affluent (RA). In each department, clusters within each stratum were consecutively randomly assigned to control and intervention arms. A total of 66 clusters were allocated to the intervention arm and 72 clusters to the control arm. The final number of participants included in the study, representing the screening population, was 14,373 in the intervention arm and 14,556 in the control arm. Further details about the study population and strata are presented in Appendix 1 in Supplemental Materials found at http://dx.doi.org/10.1016/j.jval.2017.09.020.

Intervention

Participants in the control arm were screened using the screening modalities of the French national CRC screening program, in which participants aged 50 to 74 years are mailed invitations by the local screening structure to see their general practitioner, who gives them a FOBT kit if it is indicated. Patients can perform the FOBT at home and send it to the laboratory. A first postal reminder is sent by the local screening structure to nonparticipants 3 to 4 months after the initial invitation; at 8 months' time, the FOBT kit is mailed to each nonparticipant at home.

In the intervention arm, patient navigation was added to the national screening program described earlier. Navigation was performed by three specifically trained social workers. Each of them was placed in one of the three departmental screening structures. Participants in the two previous screening rounds, designated "attended," were excluded a priori from the population to be contacted by screening navigators. In addition, navigation was confined to those individuals with an available phone number who did not participate spontaneously during the first 4 months after the initial invitation for screening. Finally, the population eligible for navigation comprised 8105 people: 2259 in the UD stratum, 2086 in the RD stratum, 1599 in the UA stratum, and 2161 in the RA stratum (see Appendix 1 in Supplemental Materials).