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Organizational and management model of colorectal cancer screening with an integrated questionnaire method: results of a pilot project in the Russia

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ABSTRACT *AIM: to evaluate the effectiveness of an organizational and managerial model for CRC screening based on the integration of questionnaire for primary risk stratification and relevant systemic solutions.*

PATIENTS AND METHODS: the pilot CRC screening project involved 960 patients — employees of industrial and educational institutions. The organizational and managerial model algorithm included: coordination and monitoring, work with project participants, controlled quality at all stages, identification of "anchor" medical organizations, and interdisciplinary interaction via telemedicine technologies. Participant stratification for subsequent colonoscopy was performed using an original questionnaire developed by the staff of the National Medical Research Center for Coloproctology. For comparative analysis, a quantitative faecal immunochemical test (FIT) was also used in all cases.

RESULTS: after educational lectures, 872 (90.8%) respondents expressed willingness to further participation in the screening program. Of the 280 individuals invited to the second stage, 164 participants (58.6%) consented to participate. All second-stage participants (n = 164) underwent colonoscopy. Indications for deep checkup were present in 127 out of 164 individuals (77.4%). Indications were high risk according to the questionnaire (n = 100), positive FIT result (n = 34). In 7 patients, a combination of positive results was detected for both stratification methods. The remaining 37 out of 164 participants (22.6%) had no formal indications for colonoscopy (negative FIT and low risk according to the questionnaire) and underwent the examination at their own request. According to colonoscopy findings, neoplasms were detected in 95 out of 164 cases (57.9%) (malignant in 2.4%, benign in 55.5%). For the questionnaire method, sensitivity was 73.7% (95% CI: 63.6–82.2), and specificity was 56.5% (95% CI: 44.0–68.4). For the faecal immunochemical test (FIT), sensitivity was 24.2% (95% CI: 16.0–34.1), and specificity was 84.1% (95% CI: 73.3–91.8). As an independent stratification method, the questionnaire identified 3 out of 4 cases of malignant neoplasms (75.0%), whereas FIT identified 2 out of 4 cases (50.0%). The most significant advantage of the questionnaire was demonstrated in the context of secondary prevention of colorectal cancer. Using the questionnaire, polyps were diagnosed in 67 out of 91 patients (73.6%), while FIT detected polyps in only 21 out of 91 patients (23.1%), $p < 0.001$. In 5 patients (5.5%), positive results were found for both methods. Additionally, in 8 patients with benign neoplasms who underwent colonoscopy at their request, stratification results were negative (low risk according to the questionnaire and negative FIT).

CONCLUSION: the implementation of a combination of widely available primary risk stratification tools (questionnaire) and high-tech solutions (artificial intelligence for endoscopic data analysis) will optimize the approach to screening programs for large populations and enhance their effectiveness.

KEYWORDS: *colorectal cancer screening, questionnaire, personalized approach, organized screening, telemedicine technologies*

CONFLICT OF INTEREST: *the authors declare no conflict of interest*

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INTRODUCTION

To achieve the national goal of increasing life expectancy, one of the crucial values is the optimization of organizational processes in the healthcare system aimed at improving prevention programs. Expanding the availability of screening, raising public awareness and a systematic approach to its implementation contribute to reducing morbidity and mortality from malignant neoplasms. And for a number of oncological diseases, screening allows for secondary prevention, preventing the disease and saving the resources of the healthcare system [1]. Thus, screening for colorectal cancer (CRC), as one of the most common malignant diseases in Russia, is extremely actual [2].

At the same time, it is important to understand that screening is not only an examination method, but also an optimally structured organizational process. The population-based effectiveness of screening can be achieved only if it is implemented as a comprehensive multi-stage system, rather than as a disparate set of diagnostic procedures. Thus, without a centralized, well-structured program (at the national or regional level), the coverage of the population will be spontaneous and low, the main purpose of screening will not be achieved, which will lead to an irrational use of economic and human resources [3].

Recently, many countries have developed and implemented national programs dedicated to the early detection of colorectal cancer. In the Russian Federation, CRC screening is not an independent integrated system, but is only one of many measures included in the medical examination program [4]. In our opinion, this is due to the risk of reducing the efficiency of using available resources. Thus, the absence of a single coordination center (monitoring center), systematic educational work with the population, and well-developed routing may not allow achieving the expected screening results. This situation is aggravated by a shortage of personnel, low motivation of the population, as well as limited economic resources.

Thus, the current model of CRC screening in Russia requires addressing two key issues: the choice of optimal methods and the development of an organizational system that ensures a continuous, well-established process from inviting the respondent for examinations to treating the identified pathology.

AIM

Aim to evaluate the effectiveness of the organizational and managerial model of CRC screening based on the integration of the questionnaire method for stratification of risk groups, as well as relevant system solutions.

PATIENTS AND METHODS

The methodology of this study is based on successful organizational solutions tested during previous pilot projects. The accumulated positive experiences were analyzed, and the most relevant practices were integrated into the design of the current work. Before the pilot project was implemented, the main stages of the organizational process were identified, as well as the methods of colorectal cancer screening were selected. For the first time, the questionnaire was used as an independent stratification method in the implementation of CRC screening.

The algorithm of the organizational and managerial model included: coordination and monitoring, work with the population, controlled quality at all stages, identification of 'anchor' medical organizations, interdisciplinary interaction and logistics.

Coordination and Monitoring

A single Screening Center was created, providing monitoring, data accumulation for all stages of screening, routing and active call of participants. Color booklets with detailed descriptions of all stages of screening and colorectal preparation were prepared for employees of enterprises, as well as a dedicated Screening Center hotline, through which participants could receive answers

to any questions that arose during the examination, was established.

Working with Population

The staff of the RNMRC of Coloproctology of the Ministry of Health of Russia gave a series of lectures for all participants, where the importance of timely diagnosis and the stage of the program were fully explained. In addition, special attention was paid to high-quality preparation for colonoscopy. Coloproctologists explained the principles of preparation for endoscopic examination not only in lectures, but also repeatedly, at consultations immediately before the appointment for examination. The coloproctologist also identified possible contraindications to the invasive procedure. It is worth noting that the administration of the organizations participating in the pilot project released employees from work on the day of the endoscopic examination, which was an important moment for making a decision on participation in the screening.

Controlled Quality at All Stages

A unified approach to all diagnostic methods was adopted. All the studies were conducted exclusively on high-resolution, expert-grade equipment with a narrow-spectrum inspection function that meets international standards for screening colonoscopy. A prerequisite was to conduct a photo documentation of the study.

To prepare for the endoscopic examination, a single preparation based on polyethylene glycol of domestic production was used. When performing endoscopic examination in order to minimize the risk of missing neoplasms, the ArtInCoL medical artificial intelligence system of domestic production was used [13]. All participants were offered a colonoscopy under total intravenous anesthesia (TIA). Special attention was paid to the training, which was equally completed by both participants (for the correct implementation of procedures) and doctors (for developing skills to a high-class level). Master classes for endoscopists, scientific and practical conferences for oncologists, endoscopists, coloproctologists, internists, laboratory diagnostics doctors and morphologists were organized. In addition, representatives of the selected 'anchor' medical organization visited the leading endoscopic centers in Russia in order to exchange experience in terms of the organization of outpatient and inpatient endoscopic services, patient routing schemes.

A clear **algorithm for interdisciplinary interaction** was built, 'anchor' medical organizations and the routing of patients with possible pathologies were identified in advance, including using the possibilities of remote consultations using telemedicine technologies. Remote consultations have become a link that ensures the integration of medical organizations into a single network. The implemented approach has also made it possible to provide high-quality medical care to a cohort of patients with other identified nosologies of non-tumor origin. Thus, the continuity of the treatment and diagnostic process for this category of patients was achieved, while maintaining continuity in patient management.

As part of the screening examination, participants were stratified and followed by colonoscopies. The main method of stratification was a questionnaire using an original questionnaire developed by the staff of the RNMRC of Coloproctology [5]. In this study, the questionnaire was an independent screening tool for CRC. A quantitative fecal immunochemical test (FIT) was also used to conduct a comparative analysis of all project participants.

The results of the survey were processed by the staff of the RNMRC of Coloproctology on the basis of a developed nomogram, where the results of the survey, amounting to 54% or more, were accepted as a high risk [6]. A FIT score of 100 ng/ml or higher was considered positive. At the next stage, high-risk individuals were invited to undergo a colonoscopy based on the results of a positive FIT survey. Before the study, all the participants consulted a coloproctologist, who determined the indications and contraindications for colonoscopy, as well as explained in detail and in an accessible

form the need to follow a diet and quality preparation for the study.

The tactics in detecting epithelial neoplasms of the large intestine were determined by the clinical recommendations "Colon and rectal polyp" (K62.1, K63.5, D37.4, D12.0, D12.1, D12.2, D12.3, D12.4, D12.5, D12.6, D12.7, D12.8) [7].

Employees of 4 large enterprises of the Astrakhan region, aged 40 years and older, were invited to participate in the pilot project of CRC screening. It is important to emphasize that younger people could also participate in the project at their request.

Thus, the educational lecture series gathered an audience of 960 people, of whom 872 (90.8%) people expressed their willingness to participate and successfully passed the first stage of screening.

Of them, there were men — 234/872 (26.8%), women — 638/872 (73.2%). The number of people aged between 18 and 40 was 106/872 (12.2%) people.

RESULTS

According to the results of the first stage, a high-risk level was determined in 216/872 (24.8%) people, and a positive FIT result was detected in 35/872 (4.0%) people. At the same time, the coincidence of the results of stratification techniques was observed in 8 (0.9%) cases. In addition, 37 respondents with a negative FIT value and a low level of risk decided to continue participating in the pilot project. Thus, 280/872 (32.1%) people were selected for the second stage. It is important to emphasize that during the implementation of the endoscopic stage, poor preparation of the large intestine with a score of 5 or less on the Boston scale was noted only in 1 (0.6%) case.

At the second stage of the study, a comparative analysis of the effectiveness of various stratification methods (questionnaires and FIT) for the formation of risk groups was carried out. Of the 280 people, invited to the second stage, 164 (58.6%) patients agreed to participate. All the participants in the second stage (n = 164) underwent colonoscopy. 127/164 (77.4%) people had indications for an in-depth examination. The indications were established on the basis of: high risk according to the questionnaire (n = 100), positive FIT result (n = 34). A combination of positive results was observed in 7 patients using both stratification methods. The remaining 37/164 (22.6%) participants had no formal indications for colonoscopy (negative FIT and low risk according to the questionnaire) and underwent an examination at their own request.

Of the total, 95/164 (57.9%) examined patients had neoplasms during colonoscopy. Of them, 4/164 (2.4%) patients had malignant neoplasms, 91/164 (55.5%) had benign ones. All the cases with detected colorectal cancer corresponded to the early forms of the disease (stages I, II). All the patients with stage I (n = 3) of the malignant process were referred to an oncological dispensary for medical care. A patient with an identified stage II (n = 1) was referred to the RNMRC of Coloproctology through a remote consultation using telemedicine technologies (TMT). It should be noted that due to the built-in routing system, including the use of TMT, appropriate medical care was provided to all patients on time.

Treatment of patients with identified benign neoplasms in 65/91 (71.5%) cases was carried out simultaneously during screening colonoscopy, complications after polypectomy were not recorded in any case. In the remaining 26/91 (28.5%) patients, neoplasm removal was required in a 24-hour hospital.

The assessment of the practical significance of stratification techniques was carried out, in which the conclusion of colonoscopy served as a reference method. The detection of neoplasms of the large intestine (benign and malignant) was considered a significant result.

The sensitivity and specificity calculations were carried out applicable to all neoplasms of the large intestine (colorectal cancer and benign neoplasms). For the questionnaire method, the sensitivity was 73.7% (95% CI: 63.6–82.2), and the specificity was 56.5% (95% CI: 44.0–68.4), the

prognostic value of a positive result (PVPR) was 70.0% (95% CI: 60.0–78.8), the prognostic value of a negative result (PVNR) was 60.9% (95% CI: 47.9–72.9).

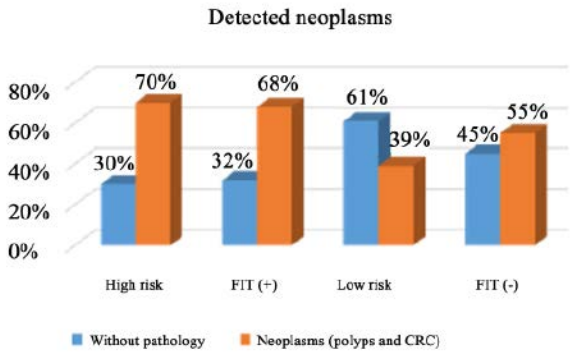

Figure 1. *Correlation between questionnaire results and colonoscopy findings*

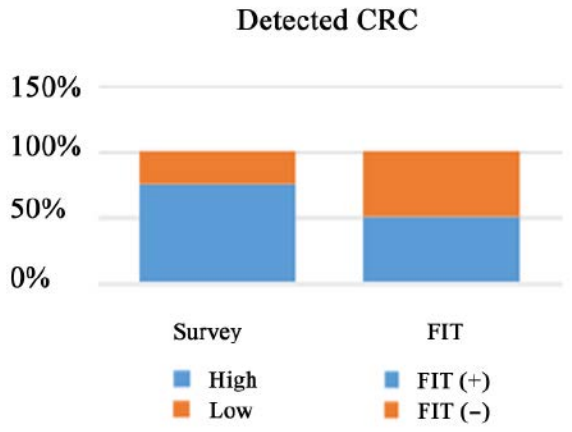

Figure 2. *Share of detected colorectal cancer cases using different stratification methods*

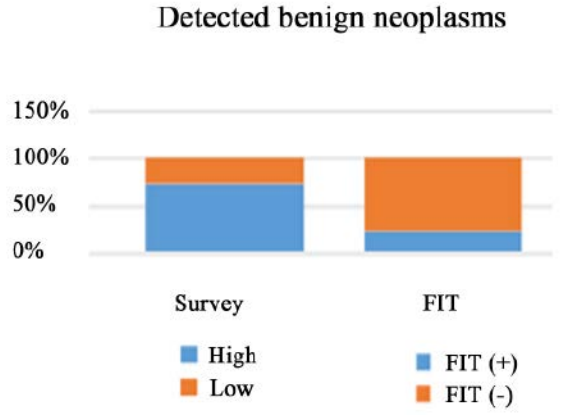

Figure 3. *Share of detected benign neoplasms using different stratification methods*

For the FIT stratification method, sensitivity was 24.2% (95% CI: 16.0–34.1), specificity was 84.1% (95% CI: 73.3–91.8), the prognostic value of a positive result (PVPR) was 67.6% (95% CI: 49.5–82.6), the prognostic value of a negative result (PVNR) — 44.6% (95% CI: 35.9–53.6) (Table 2). 95% CI was calculated by Klopper-Pearson's method in R-Studio version 4.3.2 using the GenBinomApps library (Fig. 1).

It should be emphasized that among patients with CRC, only in one case the results of the questionnaire and FIT gave the same positive result; in 2 cases, the questionnaire showed a high risk, while FIT was negative, and in 1 case FIT was positive and the risk was low. Thus, the questionnaire method revealed 3 (75.0%) out of 4 cases of MN, the FIT method — 2 (50.0%) out of 4 (Fig. 2). Among those who underwent colonoscopy at their own request, CRC was not detected in any case.

If we talk about the detected benign neoplasms (BN), they were diagnosed in 91 participants. Of them, 67 (73.6%) people had a high risk according to the questionnaire, 21 (23.1%) people had a positive FIT, while 5 (5.5%) patients had a coincidence of positive results of both methods. In another 8 patients with BN who underwent colonoscopy at their own request, the results of stratification were negative (low risk according to the questionnaire and negative FIT). Thus, out of 91 cases of BN, 67 (73.6%) people were selected by the questionnaire method, and 21 (23.1%) by the FIT method, $p < 0.001$ (Fig. 3).

Among the group of participants ($n = 37$) who had no indications for colonoscopy (negative FIT and low risk according to the questionnaire) and underwent the procedure at their own request, no significant pathology was detected in 29/37 (78.4%) cases, and benign neoplasms of the large intestine were detected in 8/37 (21.6%) patients.

DISCUSSION

In conditions of limited financial resources and the need to maximize the coverage of the target audience, the preliminary stratification of the

population becomes particularly relevant to determine the priority groups to be colonoscoped. The rational use of resources in the implementation of screening programs dictates the need for a step-by-step approach using stratification methods.

In the present study, a questionnaire using an original questionnaire was used as a tool for personalized stratification at the first stage. Of the 4 cases of colorectal cancer detected during colonoscopy, 3/4 (75.0%) people were included in the risk group formed by the questionnaire method, and 2/4 (50.0%) patients — by the FIT method.

The most significant advantage of the questionnaire is demonstrated in the context of secondary prevention of colorectal cancer, namely in the detection of benign neoplasms. Of the 91 cases of BN, 67 (73.6%) people were selected using the questionnaire, and 21 (23.1%) were selected using the FIT method.

It is noteworthy that the use of only one immunochemical test would have led to a significant number of undiagnosed neoplasms: two cases of cancer would have remained undetected, as well as polyps of at least 70 (66.9%) patients.

In addition, the analysis demonstrates that even with optimal organizational support for the screening program, behavioral factors remain a key barrier limiting its final effectiveness. Thus, at the initial invitation stage, about 10% of the target population refused to participate even before the questionnaire and immunochemical test were conducted. Among those who passed the first stage and had indications for performing a colonoscopy, the failure rate reached 40%. And considering that the rate of positive FIT results in the population was only 4.0%, the final number of participants who actually completed the verification study turned out to be extremely small. Such dynamics of losses at the screening stages casts doubt on the expediency of implementing a program based solely on FIT, due to its low final effectiveness.

In contrast, the use of questionnaires as a primary selection tool made it possible to achieve significantly higher coverage at the second stage: the proportion of people invited for colonoscopy was 24.8%, which is an order of magnitude higher than the same indicator for the FIT strategy. This ensures a higher final turnout for the second stage and, consequently, increases the overall effectiveness of screening. Thus, the choice of the primary risk stratification method is of critical importance for the final results of the program, and in conditions of limited public commitment, it seems more promising to use a questionnaire screening method that minimizes losses at the stages of the diagnostic algorithm.

It is important to note that the proposed technique is characterized by simplicity of application and low cost, which makes it easy to extrapolate to the population level. The combination of these advantages — high sensitivity to precancerous conditions, economic accessibility, and ease of scaling — allows us to consider the original questionnaire as the preferred tool for the first stage of CRC screening in Russia.

The results of the pilot project demonstrated the effectiveness of the organizational decisions taken.

The creation of a single Screening Center has made it possible to ensure the passage of a full cycle of screening activities from inclusion in the program to receiving the necessary treatment for all participants.

Working with the population has led to high rates of participation in screening events. Thus, more than 90% of the people who attended the lectures participated in the screening of CRC, which is probably due to the increased awareness of the population about this problem. In addition, it was important to consult a coloproctologist, when all the stages of preparation for endoscopic examination were explained in detail, which made it possible to minimize the number of studies with inadequate preparation. According to the world literature, poor intestinal cleansing before the procedure remains an urgent problem, and is registered in 17–25% of cases [8–11]. According to the results of this pilot project, only 1/164 (0.6%) case

was registered in which the participant was sent for re-preparation. One of the key points was the quality control of screening at all stages. At the endoscopic stage, ArtInCoL artificial intelligence was used, which made it possible to increase the proportion of detected benign neoplasms to 55.5%, this indicator demonstrated a significant increase of more than 10% compared to previous pilot projects [5,6,12].

Well-established interdisciplinary cooperation and a well-developed routing algorithm, including the use of telemedicine technologies, have played an important role in ensuring timely medical care for all patients with identified pathological changes in the large intestine.

CONCLUSION

The results of the pilot project confirm the expediency of organizing CRC screening as a well-coordinated system, implying the integration of disparate elements into a manageable, clinically effective system. The introduction of a combination of widely available tools for primary risk stratification (questionnaires) and high-tech solutions (artificial intelligence for analyzing endoscopic data) will optimize the screening program for a large population and increase its effectiveness.

AUTHORS CONTRIBUTION

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