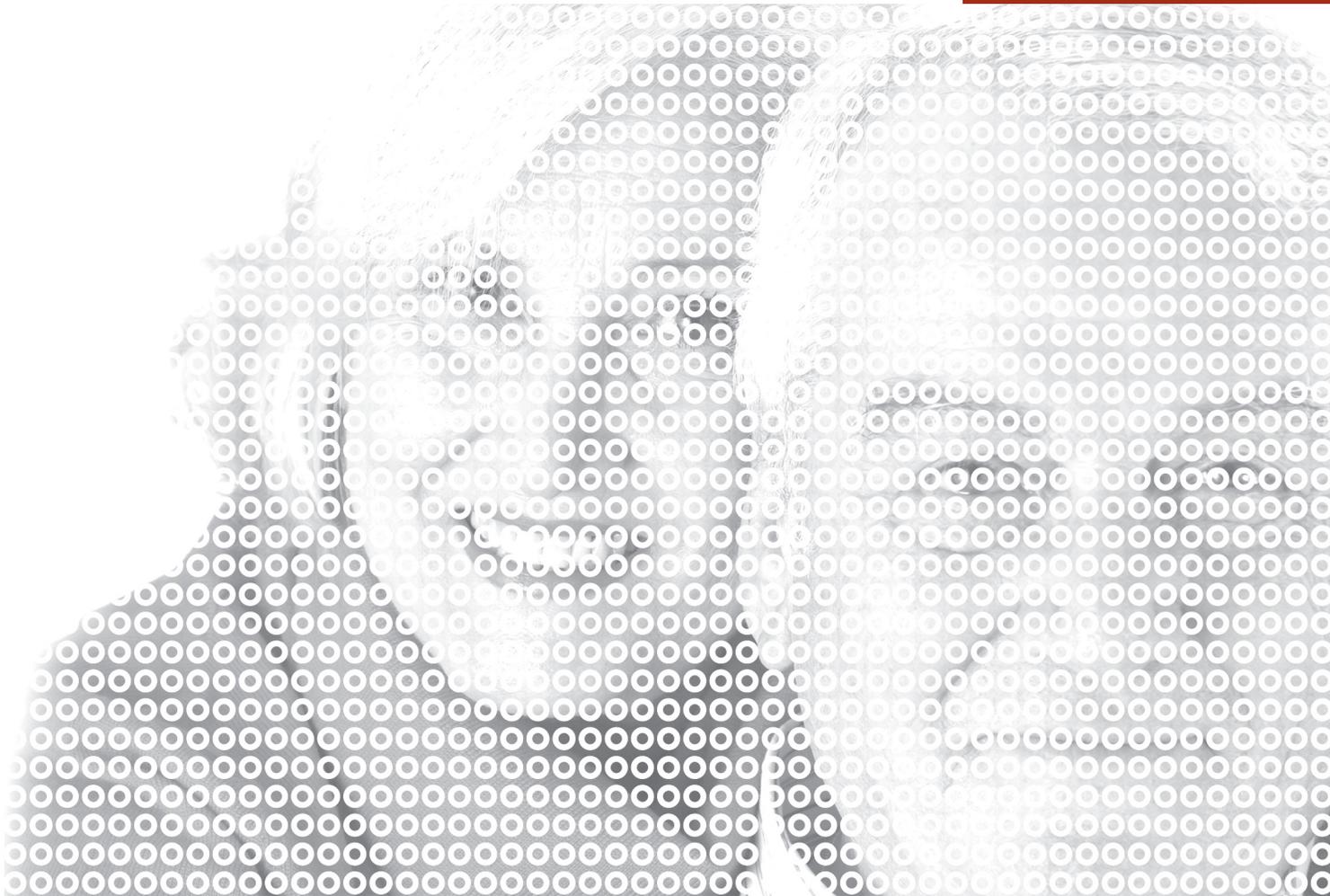


SUITABILITY AND FEASIBILITY OF A COLORECTAL CANCER SCREENING PROGRAM IN QUÉBEC

Executive summary and conclusions of the report of the scientific
committee established by the Institut national de santé publique du Québec

OCTOBER 2008



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Direction des systèmes de soins et politiques publiques
Programmes de dépistage, génétique et lutte au cancer

*Institut national
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EXECUTIVE SUMMARY

Randomized comparative trials have shown that screening can reduce the mortality from colorectal cancer. However, due to difficulties of implementation, as observed in various countries, the expected benefits might not be achieved. The Committee recommends that the following conditions be met prior to implementing a provincial program:

Accessibility to colonoscopic examinations should be governed by the implementation of clinical, quality and performance standards that will be applied to all clientele in all services offering this examination in Québec.

Individuals with a high risk of colorectal cancer, primarily those identified by a family history of colorectal cancer, should be so informed, and they should have access to screening that corresponds to their specific risk.

A demonstration project to show the feasibility of a program targeting average-risk individuals should be carried out before implementing a program at the provincial level.

The effectiveness of the colorectal cancer screening program for average-risk individuals must meet the following requirements:

The target population must be restricted to persons aged 50 to 74. Each person must be invited individually and must be provided with information, tools and, when needed, support for making an informed decision whether or not to participate in screening.

The screening program must be integrated with a global policy to combat colorectal cancer, which will include a primary prevention component designed to promote healthy lifestyles associated with a lower risk of colorectal cancer.

Screening must be based on a fecal occult blood test (FOBT) every two years, followed by a complete colonoscopy if the result is positive. The choice between the guaiac test and the immunochemical test must be based on the results obtained during the demonstration project.

FOBTs must be available without requiring referral from a family physician. The tests must be analysed in a central laboratory meeting high quality assurance criteria.

The screening program must provide for monitoring mechanisms and for the measurement of performance and quality indicators. It must also be shown that it has no significant negative impact on the other aspects of colorectal cancer control or on clinical services (colonoscopy, for example).

CONCLUSIONS

ROLE OF SCREENING IN COLORECTAL CANCER CONTROL

- Colorectal cancer is a disease that is suitable for a screening intervention integrated within a global policy of colorectal cancer control.
- Because of its natural history and the high probability of cure when it is diagnosed and treated at an early stage, colorectal cancer is an appropriate target for screening.
- When implemented as part of an organized program, screening must be integrated with the other pillars of cancer control, namely, primary prevention, treatment and palliative care.
- Primary prevention targeting physical activity and a healthy diet must be strongly supported. This approach has the potential to be highly effective in reducing the burden caused by this cancer, without generating negative effects and with lower costs, while also helping to combat other major pathologies.
- The remarkable decline in mortality from colorectal cancer achieved in Québec, especially over the past decade for men, must be maintained. When the causal factors behind this phenomenon have been identified, they might even be applied systematically, so as to maximize the gains generated thereby.

SUITABILITY OF COLORECTAL CANCER SCREENING IN QUÉBEC

Under certain conditions, a colorectal cancer screening program is suitable for Québec.

- Colorectal cancer is the second greatest cause of cancer deaths in Québec.
- Screening must distinguish two populations that are not impacted to the same degree by

colorectal cancer. The so-called “high-risk” group is primarily made up of individuals related to persons who have been diagnosed with colorectal cancer. The “average-risk” group is made up of asymptomatic individuals aged 50 or older without such a family history.

- Clinical practice guidelines recommend that individuals at a high risk of colorectal cancer be evaluated to determine their exact degree of risk, and that they be screened and monitored by colonoscopy. Several international studies have shown that “opportunistic” screening does not adequately address the needs of high-risk individuals.
- Québec should set up an information system allowing individuals diagnosed with colorectal cancer to register their family members. In this way, family members could receive adequate information on their degree of risk and on clinical recommendations. Family members of a person who has been diagnosed could also register themselves directly in the system.
- High-quality scientific data show that mortality from colorectal cancer can be reduced by screening based on a guaiac fecal occult blood test (FOBTg) performed every two years on average-risk individuals aged 50 to 74. Individuals with a positive result must undergo a colonoscopy for diagnostic confirmation.
- The reduction in mortality from colorectal cancer varied between 15 and 18% over 10 years in average-risk populations aged 50 to 74 with a participation rate of 60%. One study has shown that the reduction amounted to 27% among participants. The risk of death from colorectal cancer for an individual participating in screening was 0.6%, compared to 0.8 and 0.9% for the control groups. Thus one life was saved for approximately every 500 participants, among

whom between 20 and 40 colonoscopies were required.

- A meta-analysis indicates the possibility of an excess mortality from causes other than colorectal cancer among the individuals screened. This observation is not statistically significant, but as a precaution, very close monitoring of forthcoming results should be maintained.
- Diagnostic confirmation by colonoscopy, needed for individuals with a positive result on the FOBT, can lead to complications. At diagnostic colonoscopy, more than 50% will have no detected precursor and 80 to 90% will have no diagnosis of cancer. Although complications from colonoscopy are very rare, especially complications that might lead to death, a program must guarantee the minimization of risks, especially by ensuring that those who administer colonoscopy have had adequate training and that they undertake a minimal number of colonoscopies annually.
- Screening of average-risk individuals by an FOBTg every two years does not seem to entail overdiagnosis, but the low specificity of the test enables detection of only 50 to 55% of cancers present.
- In a survey carried out in Québec, a large majority of individuals aged 50 to 74 indicated that they would participate in a screening program. The family doctor's recommendation is a major determinant of the subject's intention to participate.
- According to current estimates, the cost effectiveness of colorectal cancer screening in an average-risk population could be better than that for breast cancer screening.

ETHICAL CONCERNS

Ethical concerns at the individual and societal levels are exacerbated by the fragile balance between the benefits and the negative effects.

- A program must provide each individual with accurate and comprehensible information on the benefits and the risks, support the individual's decision-making process and encourage healthy lifestyles associated with a reduction in the risk of colorectal cancer.
- A program should be part of a global policy on colorectal cancer control that prioritizes its actions and the deployment of its resources, so as to insure that (1) diagnostic and therapeutic services are accessible to individuals who are symptomatic and have been diagnosed, (2) screening is offered to individuals with a family history of colorectal cancer, and (3) a screening program exists for average-risk individuals.
- The assignment of resources to an eventual screening program must not be prejudicial to other individuals who need the same health-care services (colonoscopies, cancer treatments, gastroenterology, etc.).
- The implementation of very rigorous quality and performance assurance programs is indispensable to maintain the balance in favour of the benefits of screening. For the sake of fairness, all individuals, regardless of whether they are participants in the screening program, must receive services of the same quality and performance.

SCREENING TEST

- The decision concerning the screening test (type and manufacturer) used in an eventual program for average-risk individuals must be subjected to an in-depth analysis based on data that will have to be collected through a demonstration project.

- All the evidence concerning the efficacy of colorectal cancer screening in reducing colorectal cancer mortality was obtained by using the FOBTg, which remains the preferred technology for most of the organized programs now under way.
- The test must be shown to be sufficiently effective when it is used in the target population in Québec and when it is analyzed by a laboratory operating in a manner similar to that anticipated for a program. The test selected for a program must have shown a specificity of at least 95%.
- Immunochemical tests (FOBTi) are now offered by manufacturers to replace the guaiac test (FOBTg). Several characteristics make FOBTi an attractive option: possibility of automation, easier quality control, and higher detection rate for cancers and adenomas. However, not all of the parameters of its effectiveness are known within the context of a screening program. By comparing the FOBTg and FOBTi in a demonstration project, it will be possible to make a better informed choice.

DEVELOPMENTS IN KNOWLEDGE AND TECHNOLOGIES

Developments in knowledge and technologies could modify the analysis concerning the best and most suitable screening option in a few years.

- The results of clinical studies concerning the use of screening sigmoidoscopy are expected in one to two years. Even if the superiority of this method has been demonstrated, its use will be problematic due to the human and material resources it requires to carry out the initial screening examination and subsequent diagnostic and therapeutic colonoscopies.

- No other clinical screening method is currently being evaluated in randomized comparative studies. However, new imaging technologies (virtual colonoscopy or ingestible video capsules) are already available for screening or will be offered in the near future.

NEED FOR A DEMONSTRATION PROJECT

- If the decision is made to implement an organized screening program, the first step will be to carry out a demonstration project.
- Determination of the clinical characteristics of the target population and organization of services are the two essential parameters that must be evaluated by means of a small-scale project before such a program can be implemented for the general population.
- Definition of the demonstration project and analysis of the results must be supervised by an independent scientific committee.
- The demonstration project must allow the evaluation of the viability of the program framework, the capacity of health services to adjust, and the various terms and conditions of a screening program that is based on an FOBT every two years, followed by a complete colonoscopy if the result is positive.
- The goals of the demonstration project will be to:
 - Validate the application of the screening program's framework.
 - Determine the effectiveness of the organizational procedures and identify the causal factors thereof.
 - Evaluate the effectiveness of the methods used to invite individuals to participate in screening and to distribute FOBT test kits.
 - Evaluate the effectiveness of the information procedures concerning the quality of participants' decision-making.

- Compare the use of the FOBTg and FOBTi in separate groups of individuals aged 50 to 74 in order to assess the performance (participation, positivity, detection, interval cancers) and the advantages of laboratory management (standardization, quality assurance, impact on resources) associated with each test.
- Measure the costs in order to produce a cost-efficiency analysis specifically for the Québec context and the proposed framework.

PROGRESSION TOWARD A SCREENING PROGRAM

If the decision is made to implement an organized screening program, such a program must set priorities so as to guarantee everyone the same quality and performance of services and ensure that all patients, including non-participants, are treated equitably.

- Phase 1: Insure accessibility to colonoscopy within an appropriate time frame for individuals for whom this examination is clinically required (individuals who are symptomatic or are being monitored for a diagnosed disease).
- Phase 2: Systematically offer screening to high-risk individuals, i.e., those with a family history of colorectal cancer.
- Phase 3: Finalize the parameters of the screening program's framework based on the results of the demonstration project, and implement the screening component for average-risk individuals in regions where phases 1 and 2 have been implemented satisfactorily.

FEASIBILITY OF AN ORGANIZED PROGRAM

The resources needed for an organized screening program cannot be precisely determined before results have been obtained

from the demonstration project. However, the feasibility of a population-based program of colorectal cancer screening is also dependent on solving issues currently encountered in clinical services. These issues primarily concern access to colonoscopy services and, to a lesser degree, primary care services and pathology laboratory services.

- Before implementing a colorectal cancer screening program in Québec, current issues concerning accessibility, quality and performance of colonoscopy services must be resolved.
- A program should be structured in such a way that it supports the activity of health-care professionals, and also takes charge of as many of the administrative and organizational tasks as possible.
- Primary care services must be supported so that they can assume their role where they are needed.
 - The family physician should be the entry point for the screening of high-risk individuals in order to evaluate the nature of the risk, inform the patient, and orient him or her toward the appropriate clinical services.
 - Although a recommendation by the family physician can increase a patient's willingness to participate in a screening program for average-risk individuals, accessibility to general practitioners is currently insufficient in Québec to satisfy the entire target population. A sufficiently wide array of means must be explored in order to meet the population's varied needs. For example, primary care nurses, pharmacies, Info-Health and other existing services could play an active role.
 - The family physician should be informed of his/her patient's decision to participate in a screening program and should

systematically receive the results of tests and examinations.

- The requirements for quality, performance and uniformity in FOBT analysis can be achieved only if there is a single central laboratory, or two at most to ensure that there is a back-up.
- Colonoscopy services should be equipped with quality and performance assurance programs so as to increase their capacity, while maintaining effectiveness and efficiency.
 - Current colonoscopy capacity in Québec appears insufficient. International studies have shown that a substantial capacity in colonoscopy can be ensured by following clinical practice guidelines, particularly those concerning the frequency of monitoring examinations.
 - Variability in the organization of services and the information deficit on colonoscopy referrals, time frames and complications should be corrected.
 - The annual number of colonoscopies per physician is a factor that promotes quality, improves performance, and minimizes complications. A minimum threshold for annual colonoscopies per colonoscopist should be adopted in Québec. Currently, only 42% of colonoscopists perform at least 160 colonoscopies annually.
 - Standards for colonoscopy practice must at a minimum document that the caecum has been reached, as well as recording withdrawal time. Detection levels for polyps, adenomas, advanced adenomas and cancers are essential for evaluating performance.
 - Qualified physicians from specialties other than gastroenterology should be encouraged to perform colonoscopies. Outside urban areas, surgeons, internists and other specialists assume a greater share of colonoscopies, thereby increasing

accessibility. Depending on the region, the number of gastroenterologists performing colonoscopies varies from 16 to 4 per 10,000 individuals aged 50 to 74.

FUNCTIONS OF AN ORGANIZED PROGRAM

A colorectal cancer screening program for average-risk individuals will require a detailed framework.

- Responsibility for defining, implementing, evaluating and periodically adjusting the framework lies with the health-care system, as well as with associations of health-care professionals.
- Management and coordination must be provided by a central structure.
- The program should provide support to the regions and to hospital centres during implementation of the various phases.
- The program should organize an information system for collection, redistribution and analysis of clinical and organizational data.
- The program must maintain scientific expertise in order to:
 - Validate the scientific quality of the quality and performance assurance programs, the indicators, the practice guidelines, and the evaluation and monitoring plans.
 - Guarantee the scientific quality of the protocols for demonstration projects and for the organized program.
 - Analyse the results of the demonstration project.
 - Guarantee scientific intelligence, particularly in order to shore up the scientific foundations of the program, based on advances in knowledge and clinical practices.

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