
**PILOT PROJECT COMPARING
PRIMARY CARE PHYSICIAN RECRUITMENT TO
PUBLIC HEALTH UNIT PROGRAM RECRUITMENT FOR
COLORECTAL SCREENING BY FECAL OCCULT BLOOD
TESTING IN ONTARIO**

MARCH 3, 2003

Submitted to the Ontario Ministry of Health and Long-Term Care by
Cancer Care Ontario and Institute for Clinical Evaluative Sciences

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Introduction

In 2001, the Canadian Preventive Task Force published a strong recommendation (level ‘A’) for the use of fecal occult blood testing (FOBT) for colorectal screening (CS) among persons age 50 and older, because of the reduction in colorectal cancer deaths achievable by FOBT.ⁱ

Randomized controlled trials have proven that FOBT may detect invisible amounts of blood in feces, shed by asymptomatic colorectal cancer, leading to diagnosis and treatment of the cancer at more curable stages compared to diagnosis and treatment of symptomatic cancer, and hence, a significant reduction in mortality from CRC.

In December, 2002 the National Committee on Colorectal Cancer Screening comprised of members from provinces and key organizations from across the country, released its final report following 2 years of deliberations. One of the key recommendations was that:

“Colorectal cancer screening should be made available to Canadians. In order to ensure quality screening which maximizes benefits and minimizes potential risks, ideally screening should be within an organized and structured environment, with the following elements in place:

- a. clear, concise and understandable information for patients and physicians on the risks and benefits of screening and on the administration of the test.
- b. informed consent following personal consultation with family practitioner or equivalent
- c. standardized protocols and procedures with a single entry test and options for follow-up
- d. systematic tracking and evaluation of all screening invitations (if used), testing frequency, results (including false positive and false negative rates), follow-up, and outcomes”ⁱⁱ

Even though there now exists strong evidence that colorectal screening with FOBT reduces colorectal cancer mortality, the participation of the target population in screening is low. Estimates of participation rates in the eligible age group are approximately 15% from data collected from Ontario’s Rapid Risk Factor Surveillance System.ⁱⁱⁱ

No jurisdiction has implemented a comprehensive colorectal screening program at this point in time. However, pilots of colorectal screening programs are underway in the United Kingdom, Italy and Australia and a number of provinces in Canada are considering their options for establishing pilots, consistent with the National Committee recommendations, in their jurisdictions.

This is a proposal to the Ontario Ministry of Health and Long Term Care (MOHLTC), from the Division of Preventive Oncology of Cancer Care Ontario (CCO) and the Institute for Clinical Evaluative Sciences in Ontario (ICES), to undertake a pilot project comparing two methods of recruitment to colorectal screening in asymptomatic average risk 50 to 75 year old individuals in Ontario. Primary care physician – based recruitment (Supported Usual Care) is compared with public health program – based recruitment (Public Health Strategy).

Any approach to organized colorectal screening in Ontario will need to proceed with consideration of the health care system infrastructure that exists and build on this. This pilot project works with and builds on the current roles of key primary care and public health services. It will collect useful evaluation data to help guide future deliberations on how the Ontario MOHLTC should proceed to reduce the burden of illness and mortality from colorectal cancer, which is responsible for over 6000 new cases and 2200 deaths each year.

This information will complement the work of other colorectal screening projects that are in progress, such as the work of Marshall et al on how individuals rate their preferences on different screening modalities and what factors impact their decision-making.^{iv} The project is based on FOBT as the screening modality, in keeping with the recommendation of the Canadian Task Force on Preventive Health Care. While FOBT is the screening test with the most complete randomized controlled trial evidence of mortality reduction, the project will collect information on physician and patient preferences and attitudes about other screening modalities such as colonoscopy.

Compliance with follow-up diagnostic procedures after an abnormal (positive FOBT) screening result is an important issue which affects the outcome of screening. It has been noted in many jurisdictions that organized breast screening programs have resulted in increased awareness of and attention to appropriate follow-up for screen-detected abnormalities. While compliance with follow-up was high in the randomized controlled trials of FOBT, it has been found to be lower in settings when follow-up is not organized. This pilot project will develop educational materials addressing diagnostic procedures as well as screening recommendations. Actual compliance to follow-up will be evaluated to determine what is the compliance rate in both arms and whether the broader public health strategies have an effect.

Objectives

The main objective is to compare the rate of participation of eligible individuals in FOBT screening between a supported usual care arm and a public health strategy arm. The project will collect data to address several specific objectives, as follows:

Specific Objectives:

- (1) to compare participation rates, as measured by the submission of a completed FOBT kit to the laboratory, between two distinctly different approaches to recruitment (supported usual primary care compared to public health strategy).
- (2) to describe variation in these rates among the diverse geographic, sociodemographic, and linguistic communities of Ontario, including the North and among non-English speakers.
- (3) to describe attitudes about screening with FOBT compared to other approaches among primary care physicians, public health units, and persons eligible for screening.

- (4) To determine the compliance with follow-up medical investigations for those who test positive, including a comparison between the two arms.

Other information obtained in the course of the project will be of interest to the MOHLTC and will be useful to planners and decision-makers, including:

- information on waiting times and accessibility to diagnostic services,
- implementation issues for the health care system and colorectal screening program initiatives from the perspective of physicians and public health units,
- documentation of the feasibility and effectiveness of various public health strategies to promote screening,
- feasibility of using the existing administrative databases at ICES to evaluate colorectal screening.
- Information related to the costs and health services utilization impacts of different recruitment options.

Methodology

Eligible individuals for FOBT screening are asymptomatic average-risk men and women between the ages of 50 and 75. These individuals will be recruited either through the usual care arm involving primary care physicians or through the public health strategy arm involving health units.

Participating primary care practitioners will be identified through a process involving the Ontario College of Family Physicians, the Ontario Medical Association and the Ontario MOHLTC. No primary care physicians in the supported usual care arm will be selected from geographic areas which are involved in the public health strategy arm.

Participating public health units will be identified through a process involving the Association of Local Public Health Agencies (ALPHA) and the Ontario MOHLTC. There was support for the pilot project from health unit representatives invited to a consultation meeting held in December, 2001 and ALPHA has written a letter of support which includes a resolution passed by its Board supporting the pilot project (Appendix 1). No public health unit will be selected from geographic areas where primary care physicians are recruited.

A start-up period to identify all physician and health unit participants, develop the supported usual care arm information packages, public health strategy arm recruitment activity plan for each health unit, educational materials, study FOBT requisitions and consent forms will take place over 3-4 months. Orientation of all participants and the laboratories involved in each participating jurisdiction will take place at that time, also. The recruitment intervention will take place over a period of 12 months, beginning at the end of the start up period.

As soon as the project is approved by the MOHLTC to proceed, a project office with staffing will be set up along with the Project Steering Committee, comprised of CCO,

ICES, MOHLTC and other key stakeholders. The project team, lead by CCO and ICES, will manage the project and practical challenges arising from the implementation phase. It will be guided and assisted by the Project Steering Committee. Written reports on project implementation and budget status will be submitted to the MOHLTC by CCO bi-annually.

Description of Recruitment in the Supported Usual Care Arm

Participating primary care physicians will be given the latest information on colorectal screening recommendations, including the Canadian Task Force on Preventive Health recommendation for colorectal screening by FOBT, and a summary of up-to-date information about colorectal screening and the management of positive test results. They will be advised to recommend FOBT to eligible patients during office visits scheduled for preventative care or for other purposes. They will provide eligible patients with the following: educational information about colorectal cancer, FOBT, early detection, information on the pilot project, and a study FOBT requisition with consent form to take to the laboratory.

Description of Recruitment in Public Health Strategy

Each public health unit will develop or use existing broadly based community networks, including primary care physicians, local screening and prevention advocacy groups, service clubs and community cultural and social organizations, to educate the community and promote colorectal screening by FOBT. The networks will help facilitate publicity, recruitment, and compliance in the local area. The specific strategies of each participating health unit will be developed together with the study office and could involve an expansion of existing promotional approaches for breast screening and healthy lifestyles promotion. There will be centralized production of health promotion materials that could be used by all health unit sites. Approaches used may include the following:

- (1) mass media (e.g. newspapers, website, radio and television spots)
- (2) information packages distributed to family physicians, public health unit staff, and community groups and organizations (e.g. professional associations, unions, major corporations, senior citizen centres, service clubs, Royal Canadian Legion, cultural / religious and recreational centres)
- (3) information booths at major community health events or settings
- (4) presentations to community groups, physicians and other health professionals
- (5) access to FOBT study requisition, study consent forms and educational information (fact sheets, pamphlets, educational videos), and test kits through the public health unit for eligible individuals and primary care physicians in the health unit area
- (6) collaborative screening initiatives with other community stakeholders such as hospitals, pharmacies, community health centres, and voluntary associations.

Completion of the FOBT by Participating Individuals

All initially recruited participants will receive a guaic-based FOBT collecting kit with 3 slides (Hemocult/(Beckman Coulter) or hema-screen (Immunostics)) and instructions on collection and diet restrictions to reduce false positives when they take their requisition forms and consent to the laboratories. FOBT testing will be carried out according to laboratory standard practices in the laboratory. Both commercially available test kits are currently in use in the community labs and they have been shown to have similar test characteristics.

Follow-up of positive FOBT results

All FOBT results will be sent to the primary care physician. Positive FOBT reports of subjects recruited by the public health strategies will be accompanied by a form letter explaining the patient's participation in the study and including the recommended options for the follow-up of a positive FOBT. Follow-up of positive FOBT will be at the discretion of the primary care physician. Compliance with follow-up of positive FOBT will be monitored by a search for relevant billing claims in the ICES databases.

In situations where the participant does not have a family physician (in the public health arm), community physicians will be recruited by the health unit to participate in providing follow-up for those study participants that test positive on their FOBT screen. This approach is used in the Ontario Breast Screening Program and was also implemented in the northern Ontario nurse practitioner pilot project. As a default, the pilot will employ a medical director to assist with a number of issues including acting as the physician-of-record, if needed.

Surveys

Participating primary care physicians will be surveyed with a questionnaire before and after the 12 month intervention period about their attitudes and preferences about colorectal screening by FOBT and also their experiences with patient access to barium enema, sigmoidoscopy and colonoscopy.

A sample of eligible participants will be surveyed with a questionnaire before they submit their FOBT about their level of knowledge and attitudes about the FOBT and other screening modalities. These participants will be surveyed once more following their screening episode to determine their attitudes and perspectives on FOBT screening at that time, including their intent to participate in future FOBT screening, after the pilot project is over.

Data collection

The laboratories will return all submitted consent forms and all FOBT test results to the study office. This would occur monthly and via electronic transmission where feasible. Survey questionnaires from participants, delivered to the lab at the same time as the return of the FOBT kit, will also be sent by the labs to the study office. Completed physician surveys will be returned by mail to the study office.

All data will be held at ICES. A secure database will be constructed based on the encrypted Ontario Health Insurance Numbers of all participants with a positive FOBT. Follow-up procedures that are carried out following the completion of the FOBT will be identified by linkage of this secure database with the OHIP billing and hospitalization files held at ICES.

Data confidentiality, privacy and security

All personal data will be stored electronically in a password-protected database. Names, addresses, phone numbers will be deleted once the screening cycle has been completed. OHIP numbers will be encrypted and stored at ICES following the stringent ICES data security and confidentiality procedures.

Key outcomes

- (1) Screening participation rates in each arm of the project
- (2) Compliance with follow-up procedures in those individuals who have a positive FOBT result
- (3) Relative frequency of use of each of the diagnostic medical procedures that are utilized in the follow-up of a positive FOBT result
- (4) Time period to complete a diagnostic procedure from the time of the positive FOBT result
- (5) Perceptions and experiences of participating physicians with regard to FOBT, other screening modalities and access to diagnostic procedures
- (6) Perceptions and attitudes of individuals about FOBT before and after they have completed the test

Secondary outcomes will be more descriptive and provide further depth into the findings above. These will include an assessment of the feasibility (barriers and facilitators) of various public health strategies to promote colorectal screening and how this differs in the different settings in Ontario, cost implications of recruitment strategies and their impact on service utilization. In addition, key options and recommendations from public health units and physicians for any consideration of programmatic screening will be compiled as well.

Instruments for measuring outcomes

1. Survey questionnaire for physicians, pre and post
2. Survey questionnaire for eligible participants, pre and post
3. FOBT results on all participants who complete an FOBT
4. ICES held databases – OHIP billings database, hospitalization database

Sample size and power calculation

Sample size calculations have been based on the most difficult comparison to detect, that is, a difference in the rate of compliance with follow-up medical investigations following a positive FOBT in each of the two arms of the pilot. The educational approaches implemented in the two arms will likely affect the compliance to follow-up and the estimated sample size will allow a difference between the two arms to be detected.

We propose that each arm of the pilot project have an eligible screening population of 220,000. One population will consist of eligible patients of approximately 450 participating primary care physicians who will see them during routine office visits. The other population will consist of eligible Ontarians residing within six public health units (either all or part of each health unit's geographic area, depending on population size). Therefore, the total eligible population will be 440,000.

We assume that 34% (74,800 in each arm) of eligibles will receive standard educational information plus a study FOBT requisition and consent form during the one-year period. We assume that 23% (50,600 in each arm) of eligibles will pick up a FOBT kit. We assume that 17% (37,500 in each arm) of eligibles will return completed FOBT kits to the laboratory (recruitment rate). We assume that 2% of the 75,000 tests (both arms) will be positive (1500), and that, among those, the baseline compliance with follow-up medical investigations is 50%.

Based on the preceding assumptions, we will have 90% power (two-sided alpha = 0.01¹) to detect a 20% difference in the rate of compliance with follow-up medical investigations following a positive FOBT between the two strategies. We will have 90% power (two-sided alpha = 0.01) to detect a 6% difference in the recruitment rate.

¹ An alpha of 0.01 has been chosen to allow a limited number of additional comparisons requested by the Ministry, such as a comparison of FOBT kits picked up but not submitted to the laboratory between the two arms. These other comparisons, while not related to the main objectives, may be of interest to the Ministry and other planners.

Research Ethics Review

The pilot project proposal and the consent form will be submitted for ethics review by the Sunnybrook and Women's Health Sciences Centre Research Ethics Board prior to the implementation of the intervention.



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Providing leadership in public health management

Dr. Terry Sullivan
VP Preventive Oncology
Cancer Care Ontario
620 University Avenue
Toronto, Ontario M5G 2L7

Dear Dr. Sullivan,

Re. Colorectal Cancer Screening Pilot Project

On behalf of member Medical Officers of Health, Boards of Health and Affiliate organizations of the Association of Local Public Health Agencies (alPHa), I am writing in support of Cancer Care Ontario's proposed Colorectal Cancer Screening Pilot Project.

The Mandatory Health Programs and Services Guidelines (MHPSG), under which our members provide their services, already require them to carry out specific activities under the Early Detection of Cancer program to maximize the use of breast and cervical cancer screening services.

These screening services are actively promoted by public health as an effective tool in the reduction of mortality from these types of cancers, as they meet the criteria against which their worth is measured:

- The burden of illness warrants implementation of screening services
- The natural history of the condition is understood
- The screening test effectively distinguishes between those with and without the disease
- Effective treatment is available and accessible for the early detected stage
- The benefits of screening outweigh the risks.

Our members believe that screening for colorectal cancer meets these criteria, and in 2001 endorsed a Resolution calling on the Government of Ontario to approve and fund Cancer Care Ontario's Colorectal Cancer Screening Pilot Project with a view to the establishment of a more complete program in the future. This Resolution is attached, along with the relevant portions of a letter sent to the Minister of Health and the Director of the Public Health Branch, and the response.

Ontario Boards of Health are obligated by the MHPSG to work with their communities to increase the use of breast and cervical cancer screening programs through needs assessments, increased access, and raising awareness of the availability and importance of these services

among health professionals and community residents. The establishment of a colorectal screening program would thus benefit from a pre-existing set of promotion activities required of Ontario's boards of health.

Our members are by definition strong advocates of programs and standards that enable residents of their communities to realize their fullest health potential through health promotion and disease prevention. Their support of a colorectal cancer-screening program as an effective component of this goal is on record. We look forward to assisting Cancer Care Ontario in this initiative in whatever way we can.

Sincerely,



Andrew Papadopoulos, BAsC, MBA
Executive Director

Encl.

2001 alPHa RESOLUTION NO. A01-11

TITLE: Colorectal Cancer Screening

SPONSOR: Regional Municipality of Durham

WHEREAS colorectal cancer is the leading cause of mortality in Ontario, ranking second as a cause of cancer deaths in 1998; and

WHEREAS there are protocols in place that reduce the number of false positives; and

WHEREAS Cancer Care Ontario's Expert Panel on Colorectal Cancer Screening recommended in its March 1999 report that an organized colorectal cancer screening program be established in Ontario; and

WHEREAS both Cancer Care Ontario and alPHa have endorsed the Expert Panel's recommendations; and

WHEREAS on January 11, 2001, Cancer Care Ontario submitted to the Ontario Ministry of Health and Long-Term Care a proposal to establish a colorectal screening pilot project which incorporates all of the changes to earlier versions that were required by the Ministry;

NOW THEREFORE BE IT RESOLVED that the Association of Local Public Health Agencies (alPHa) urges the Government of Ontario to approve and fund Cancer Care Ontario's Colorectal Cancer Screening Pilot Project so that the project can be implemented and evaluated as soon as possible and by so doing, lay the groundwork for the establishment of a future organized Ontario colorectal cancer screening program.

***Status of Resolution:* Endorsed by the alPHa membership June 12, 2001**

August 21, 2001

The Honourable Tony Clement
Minister of Health and Long-Term Care
10th Floor, Hepburn Block
80 Grosvenor Street
Toronto ON M7A 2C4

Dear Minister Clement,

RE: Resolutions from alPHa Annual Conference (June 10-12, 2001)

On behalf of member Medical Officers of Health, Boards of Health, and Affiliate organizations of the Association of Local Public Health Agencies (alPHa), I am writing to introduce the resolutions endorsed this past June by our membership for consideration and anticipated action by your ministry.

No. A01-11 Colorectal Cancer Screening

In March 1999, Cancer Care Ontario's Expert Panel on Colorectal Cancer Screening called for the establishment of an organized screening program on colorectal cancer. Many in the health community applauded this recommendation. In January 2001, Cancer Care Ontario proposed that a colorectal cancer screening pilot project be established. alPHa and its members therefore request that the Province approve and fund the pilot project proposal immediately in order to establish a foundation for a future colorectal screening program.

Thank you for your attention to the above. We look forward to a reply at your earliest convenience.

Sincerely,

Andrew Papadopoulos, BAsC, MBA
Executive Director

Enclosures

cc. Dr. Colin D'Cunha, Chief Medical Officer of Health

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and Long-Term Care
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FEB 19 2002

REC
FEB
ALPHA

Mr. Andrew Papadopoulos
Executive Director
Association of Local Public Health Agencies (alPHA)
425 University Avenue, Suite 502
Toronto ON M5G 1T6

Dear Mr. Papadopoulos: *Andy*

Re: Resolutions from alPHA Annual Conference 2001

Thank you for your letters dated October 22, 2001, addressed to Minister Clement and myself in which you share the resolutions adopted by the alPHA membership at the 2001 Annual Conference.

Please find attached responses to the resolutions pertaining to the Ministry of Health and Long-Term Care. As for Resolution A01-5 on "Healthy Babies, Healthy Children Program Funding", we have shared it with the Office of Integrated Services for Children. Resolution A01-17 on "Dental Care for Seniors in Need" we have shared with the Ontario Seniors' Secretariat. With regards to Resolution A01-19 on "Ontario Works Allowances and Adequate Nutrition", I note that you have already directed this to the attention of the Minister of Community and Social Services.

I would also like to take this opportunity to thank you for meeting with Public Health Branch staff on November 20, 2001. As always, the discussion was informative and useful. We appreciate your support for the accountability framework and look forward to working with you in the future. As pertains to your three-pronged funding proposal, we note that given the current fiscal climate, alPHA has volunteered not to pursue it at this time.

We appreciate the effort on the part of your Association to bring public health issues to the Minister's attention.

Yours sincerely,

Colin O. Cunha
Colin O. Cunha, MBBS, MHSc, FRCPC
Director, Public Health Branch
Chief Medical Officer of Health

c: Dr. Lynn Noseworthy, President, alPHA
The Honourable Mike Harris, Premier of Ontario
The Honourable Tony Clement, Minister of Health and Long-Term Care
The Honourable Chris Hodgson, Minister of Municipal Affairs and Housing
Dr. Doug Galt, MPP, Northumberland
Alex Hukowich, Executive Officer, Haliburton-Kawartha, Pine Ridge District Board of Health

Attachment

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And further that alPHa urges the Government of Ontario to specifically strengthen Section 9 of the Tobacco Control Act to further protect Ontarians from second-hand smoke exposure by ensuring that all workplaces and all public places are smoke free;

No: A01-9 Strengthening of the Tobacco Control Act Section 3

Now therefore be it resolved that the Association of Local Public Health Agencies (alPHa) urges the Government of Ontario to strengthen the Ontario Tobacco Control Act through specifically amend Section 3 of the Tobacco Control Act to strengthen controls on access to tobacco by under-ages youth;

Response: The renewed Ontario Tobacco Strategy (OTS) is built on a range of initiatives that utilize a variety of strategies to achieve the OTS goals of prevention, protection and cessation. Reducing tobacco use is a complex challenge and requires a multi-pronged approach. The Ministry is currently reviewing options for strengthening all components of OTS, including the Tobacco Control Act (TCA).

No: A01-11 Colorectal Cancer Screening

Now therefore be it resolved that the Association of Local Public Health Agencies (alPHa) urges the Government of Ontario to approve and fund Cancer Care Ontario's Colorectal Cancer Screening Pilot Project so that the project can be implemented and evaluated as soon as possible and by do doing, lay the groundwork for the establishment of a future organized Ontario colorectal cancer screening program.

Response: A colorectal cancer screening pilot proposal is currently under development by Cancer Care Ontario (CCO) with input from the Ministry to ensure that the questions which need to be answered with respect to a potential future publicly funded population - based screening program for colorectal cancer are addressed in the pilot. A number of criteria must be met before a decision is made to implement an organized mass screening program for any health condition. These criteria include, but are not limited to: the accuracy of the screening test; how acceptable the tests (screening and follow-up diagnostic tests) are to the population; and whether the health care system is capable of responding (resources) to the demands of a screening program.

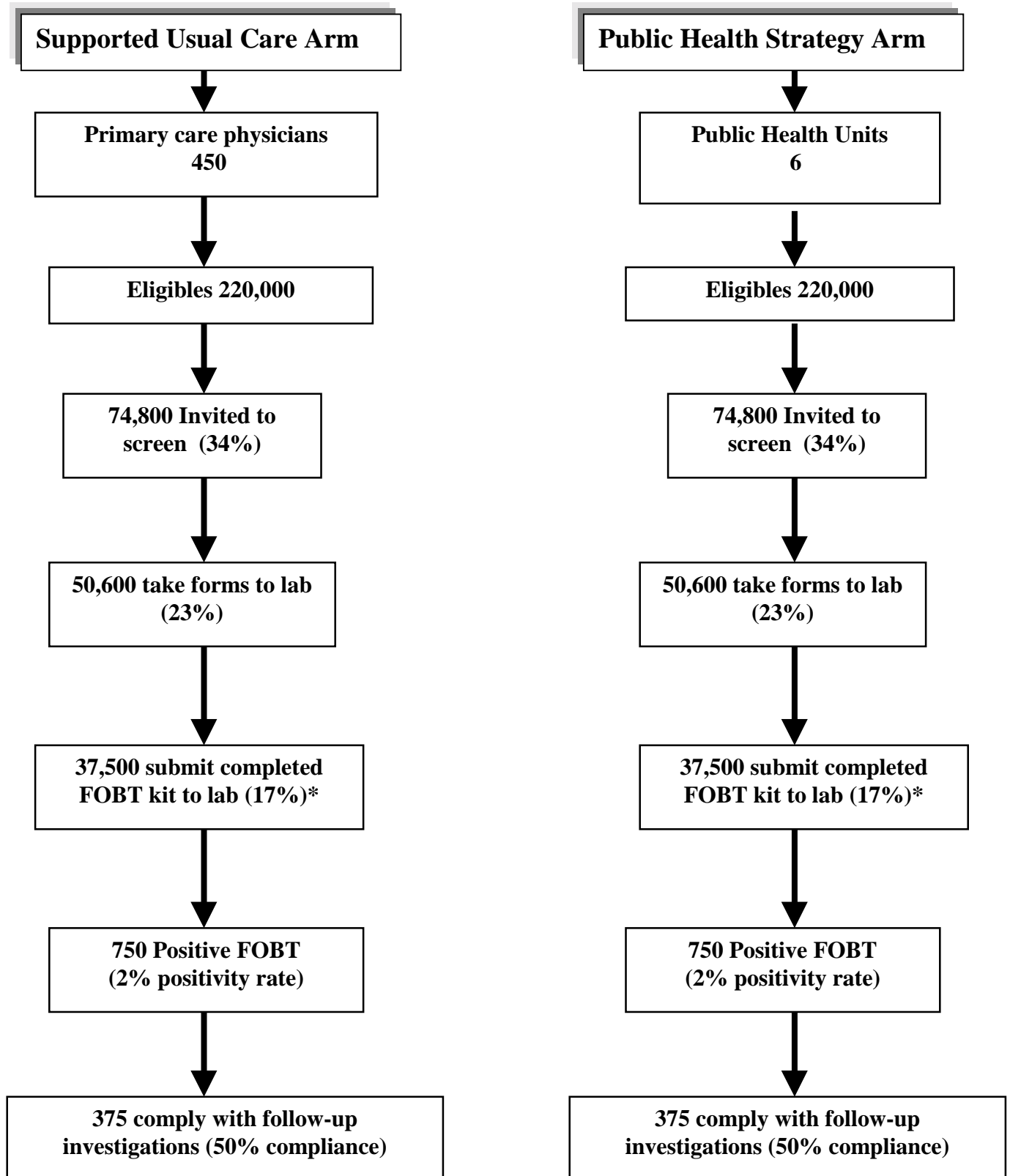
No: A01-17 Dental Care for Seniors in Need

Now therefore be it resolved that the Government of Ontario establishes and fully funds all costs associated with a "Dental Care for Seniors in Need of Treatment Program" to be administered by boards of health in accordance with the Report of the Advisory Committee on Dental Care for Seniors in Need;

Response: As you may be aware, at this time there is no plan to expand the Children In Need Of Treatment (CINOT) dental program to include seniors. Because resolution no. A01-17 involves seniors, Public Health Branch will share a copy with the Ontario Seniors' Secretariat.

Appendix 2

NUMBERS OF PARTICIPANTS



References

ⁱ Recommendation statement from the Canadian Task Force on Preventive Health Care. CMAJ 2001 Jul 24; 165.(2):206.-8. 201;165:206-08

ⁱⁱ http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ncccs-cndcc/ccsrec_e.html, accessed February 27, 2003

ⁱⁱⁱ <http://www.cehip.org/rfss/>, accessed February 27, 2003

^{iv} Personal contact with Dr. John Marshall, McMaster University