CANADIAN PARTNERSHIP AGAINST CANCER
PARTENARIAT CANADIEN CONTRE LE CANCER

Screening Action Group

Flexible Sigmoidoscopy Expert Panel - Watching Brief

June 1, 2009

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Purpose of this Document

To provide a concise synthesis of the status of 4 randomized controlled trials (RCTs) of flexible sigmoidoscopy (FS) for colorectal cancer (CRC) screening. This can be used by provincial cancer agencies to respond to the results of the ongoing trials as they are published over this year. The first of the 4 trials to publish results for CRC mortality is expected to present 6 year follow-up results at the beginning of June, 2009. The other 3 trials are likely to publish their results over the next 12 months.

This "watching brief" is intended to provide background information, but not definitive answers or clinical recommendations. The Expert Panel will continue to monitor and review trial evidence as it becomes available, and provide updates to this document.

1.0 Summary of Evidence: FOBT

1.1 Hemoccult FOBT

- Of all the tests available for colorectal cancer (CRC) screening, fecal occult blood testing (FOBT) had the highest level of evidence for efficacy
- There are several published randomized controlled trials (RCTs), which used earlier versions of the hemoccult FOBT (hemoccult or hemoccult II). Hemoccult tests rely on the pseudo peroxidase activity of hemoglobin in stool. These are a type of FOBT referred to as guaiac FOBTs (gFOBTs)
- The results of the gFOBT RCTs were recently pooled and summarized in an updated Cochrane review (see tables below).
- The pooled results suggested that a CRC screening program with biennial gFOBT testing can lead to a 15% reduction in CRC mortality after 12 to 18 years. There was a 25% CRC mortality reduction (RR 0.75, 95% CI 0.66-0.84) for those attending at least one round of gFOBT screening.
- Current provincial CRC screening programs that are underway or in the planning stages may implement biennial or annual screening
- The uptake/compliance with gFOBT in the RCTs was high, with approximately two-thirds attending for at least one round; a high uptake may be challenging to sustain over repeated rounds of screening.
- A UK pilot study, found similar uptake and test characteristics (but without data on CRC mortality) of one-time FOBT, as demonstrated in the RCT in UK.

1.2 Newer FOBTs and FIT

- Hemoccult Sensa, a gFOBT, was developed to improve the sensitivity of hemoccult FOBT
- The Fecal Immunochemical test (FIT) detects human globin.
- The accuracy of the newer FOBTs were recently reviewed in a systematic review for the US preventive Services Task Force (USPSTF); the review concluded that Hemoccult II was less sensitive than FIT for cancer detection and that FIT had similar or less sensitivity than Hemoccult Sensa. The specificity of Hemoccult Sensa was reported to be less than that of FIT, which had similar specificity as Hemoccult II. However the review noted that there are few studies directly comparing different versions of FITs with each other or with regular or high-sensitivity hemoccult tests (Hemoccult Sensa); most of the conclusions were from indirect comparisons.
- An earlier review by the US Multi-Society Task force had concluded that there were no clear patterns of difference between Hemoccult Sensa and FITs. However the experience with use of FIT is rapidly evolving with many ongoing and recently reported studies. A recent study from Netherlands has reported an approximately 10% higher uptake of FIT compared with hemoccult II, likely related to differences in fecal sampling required for the FIT. There are no data on the impact of screening with Hemoccult Sensa or FITs on CRC mortality and/or incidence; but given better test characteristics, a decision analysis conducted for the USPSTF estimated potentially higher CRC mortality reduction with Hemoccult Sensa and FIT.

1.3 Limitations of FOBTs

- No direct harms of FOBT have been demonstrated.
- False positive tests lead to further testing with colonoscopy and the potential of associated complications.
- Another limitation of FOBTs is lower sensitivity (<50%) for advanced adenomas, than that for CRC. Likely because of this limitation, CRC incidence reduction (20%) has been demonstrated in only one RCT using rehydrated FOBT and after 18 years of follow-up.

1.4 Published Randomized Controlled Trials of FOBT

Table 1. Key Features of gFOBT RCTs

	Minnesota	**U.K.**	**Denmark**	**Sweden**	**Comment**
Study population	46,445	152,850	61,933	68,308	European trials randomly allocated subjects to invitation or no invitation for screening. Minnesota study included only those who had agreed to participate.
Ages	50-80	45-74	45-75	60-64	
Screening Cycles	Annual & Biennial	Biennial	Biennial	Biennial	
No. of screening rounds	11 (Annual) 6 (Biennial)	6	9	2	
Follow up years	18	11.7	17	15.5	
Compliance 1st screening (%)	NR	53	67	63	
Compliance (%) (at least one round)	75(Annual) 78(Biennial)	60	NR	70	
Completion of all rounds (%)	46(Annual) 60(Biennial)	38	46	NR	

NR – Not Reported

Table 2. Results of gFOBT RCTs

	Minnesota	U.K.	Denmark	Sweden	Cochrane meta-analysis
Test Positivity (%) Non-rehydrated Rehydrated	 1.4-5.3 3.9-15.4	 1.2-2.7	 0.8-3.8	 1.9 1.7-14.3	
Cumulative Colonoscopy rate (%)	38(Annual) 28(Biennial)	2.6	5.3	6.4	
Sensitivity CRC (%) Non-rehydrated Rehydrated	 80.8 90.2	 57.2	 55	 NR 82	
PPV (%) CRC Non-rehydrated Rehydrated Adenomas Non-rehydrated Rehydrated	 5.6 0.9-6.1 6-11 NR	 9.9-11.9 42.8-54.5	 5.2-18.7 14.6-38.3	 NR NR NR NR	
CRC Mortality RR (95% CI) Annual Biennial	 0.67(0.51-0.83) 0.79 (0.62-0.97)	 0.87(0.77-0.97)	 0.84 (0.73-0.96)	 0.84 (0.71-0.99)	**0.84 (0.78-0.90)**
CRC Incidence Annual Biennial	 **0.80 (0.70-0.90)** 0.83 (0.73-0.94)				
All cause Mortality RR (95% CI)	1.0 (0.97-1.02)	1.0 (0.99-1.02)	1.0 (0.98-1.02)	1.02 (0.99-1.04)	**1.0 (0.99-1.01)**

- The use of rehydrated FOBT, as was done in the Minnesota trial, is not routinely performed in clinical laboratories and is not recommended by any CRC screening Clinical Practice Guideline.
- The sensitivity for CRC given in the table is for a program of annual or biennial testing and not for a single episode of testing. The sensitivity of a single set unrehydrated FOBT when compared to colonoscopy has been reported to be as low as 13 - 25%

2.0 Randomized Controlled Trials of Flexible Sigmoidoscopy Underway

- There are 4 RCTs of flexible sigmoidoscopy (FS) as a CRC screening test; key features are shown in Table 3.
- One trial (NORCCAP) has now published preliminary analysis of cumulative CRC incidence after 7 years and CRC mortality and all cause mortality after 6 years of follow-up (Table 4); the other 3 trials are expected to present preliminary outcome results within the next 12– 18 months.
- In the NORCCAP trial, there was no difference in the 7-year cumulative CRC incidence between the screening and control groups (134.5 vs 131.9 cases per 100,000 person years).
- There was no statistical difference in CRC mortality or all cause mortality between the screened group and control group (Table 4).
- There was a statistical difference in all CRC mortality and rectosigmoid cancer mortality in those who attended screening compared with the control group. This type of analysis is prone to selection bias. Those attending screening may differ from those who did not and from the controls. Those who attended screening may be at lower risk of CRC than the control population ("healthy screenee" effect). For example, they may be of higher socioeconomic status, live a healthier lifestyle or be more vigilant about their health.

Table 3. Key Features of FS RCTs

	NORCCAP	UK FS	SCORE	PLCO
Country	Norway	UK	Italy	US
Lead Investigator	Hoff, G	Atkin, WS	Segnan, N	Weissfeld J
Recruitment	1999 – 2000	1996 – 1999	1995 - 1999	1993 - 2001
POPULATION				
Number randomized	55,736	170,432	34,292	154,000
Setting	2 areas: 1 city, 1 county	14 UK centres	5 areas (Arezzo, Rimini, Torino, Genova, Biella)	10 U.S. cities
Source	Population registry	General practice registry	1. General practice patient registry (A,R,T) 2. Health services registry (G,B)	Public, commercial, screening centre mailing lists
Age (yr)	55-64	55 – 64	55 – 64	55 – 74
STUDY GROUPS				
Randomization	Before invitation	After invitation	After invitation	After invitation
Study Arms[1]	1. FS 2. FS & FIT 3. No screening	1. FS 2. No screening	1. FS 2. No screening	1. FS 2. No screening
UPTAKE				
Responded to invitation[2] (%)	Not applicable	74	83	Not available
Interested in screening (invited)[3] (%)	Not applicable	55	69	Not available
Attended screening (randomized)[4] (%)	67	71	95	83
Attended screening (invited)[5] (%)	67	39	65	Not available
SIGMOIDOSCOPY				
Instrument	140 cm colonoscope	60 cm video-scope	4 centres: 140 cm colonoscope 1 centre: "sigmoidoscope"	60 cm flexible sigmoidoscope
Endoscopist	Not given	Registrar-level gastroenterologists and surgeons	Gastroenterologist	Physicians and nurse practitioners

[1] FS: Flexible sigmoidoscopy FIT: Immunochemical fecal occult blood test
[2] Proportion of individuals who responded to invitation from those with a delivered invitation
[3] Proportion of individuals interested in screening from those with a delivered invitation
[4] Proportion of those interested and eligible individuals who were randomized to FS that attended for F
[5] Proportion of individuals who attended screening from those with a delivered invitation

Screen Frequency	Once only	Once only	Once only	Baseline, year 5
Criteria for Colonoscopy	1. Any polyp ≥1 cm 2. Any neoplasia	1. Any polyp ≥1 cm 2. ≥ 3 adenomas 3. Any polyp with villous component or severe dysplasia 4. Any cancer 5. ≥ 20 hyperplastic polyps above distal rectum	1. Any polyp > 5 mm 2. Any polyp + inadequate bowel prep 3. ≥ 3 adenomas 4. Any polyp with villous component or severe dysplasia 5. Any cancer 6. Clinical judgment of endoscopist	1. Any polypoid lesion or mass
Proportion Requiring Colonoscopy	20.4%	5.2%	8.4%	23.4%

Table 4. Mortality Outcomes of NORCCAP FS Trial

	All CRC Mortality HR (95% CI)	Rectosigmoid CRC Mortality HR (95% CI)	All Cause Mortality HR (95% CI)
All screening group[6]	0.73 (0.47-1.13)	0.63 (0.34 – 1.18)	1.02 (0.98 – 1.07)
Screening attenders[6,7]	0.41 (0.21 – 0.82)	0.24 (0.08 – 0.76)	Not provided

6 = Results are for FS and FS + FIT groups combined
7 = Results should be viewed with caution and are susceptible to the "healthy screener" effect

3.0 How Does FS Screening Compare with Colonoscopy?

- The baseline colorectal adenoma and cancer detection rates for the 4 FS RCTs are shown in Table 6. This table also provides comparable data from 4 studies of colonoscopy screening in average risk individuals. Key features of the colonoscopy studies are summarized in Table 5, below.

Table 5: Key Features of the Colonoscopy Cohort Studies

Study	Lieberman, 2000	Imperiale, 2000	Schoenfeld, 2005	Regula, 2006
Country	USA	USA	USA	Poland
Design	Cohort Study	Cross-sectional Study	Cohort Study	Cross-sectional Study
POPULATION				
Number	3196 of 17732 screened	1994 of 2686 eligible	1483 of 1593 eligible	50,148
Setting	Veterans Affair Study	Eli Lilly employee screening program	Veterans Affairs Study	National Screening Program Database Evaluation
Sex	96.8% Men	58.8% Men	All women	64.1% women
Age (yr)	50-75	50 or older	40-79	40-66
Family History (%)	13.9	n/a	15.7	~20
Complete Colonoscopy (%)	97.9	97.0	98.7	91.1

Table 6. Proportion of Individuals in Whom Colorectal Adenoma and CRC Detected by FS and Colonoscopy Screening

	No Polyps	Any Adenoma	Distal Adenoma	Any advanced lesion	Distal Advanced Lesion	Proximal Advanced Lesion	Any Cancer	Distal Cancer	Proximal Cancer
FLEX SIG RCTS									
UK (%)	75	n/a	12	n/a	n/a	n/a	n/a	0.3	n/a
SCORE (%)	82	n/a	10	n/a	n/a	n/a	0.5	0.5	n/a
NORCCAP (Total cohort) (%)	83	17	n/a	n/a	n/a	n/a	0.3	n/a	n/a
NORCCAP (%) (FS only cohort)	83	n/a	n/a	n/a	n/a	n/a	0.3	n/a	n/a
PLCO (%)	66	31	23	n/a	n/a	n/a	0.4	0.2	n/a
COLONOSCOPY STUDIES									
Lieberman, 2000 (USA) (%)	61	37	23	11	7	5	1.0	0.6	0.4
Imperiale, 2000 (USA) (%)	78	22	8	5	3	3	0.6	0.3	0.4
Schoenfeld, 2005 (USA) (%)	92	20	6	5	n/a	n/a	0.1	n/a	n/a
Regula, 2006 (Poland) (%)	n/a	13	n/a	6	n/a	n/a	0.8	n/a	n/a

- Not all comparison data were presented or could be calculated from the published reports (shown as n/a).
- In the FS trials, the proportion of screened individuals requiring colonoscopy varied from 5% - 23% and depended on how permissive or restrictive the criteria for colonoscopy (see Table 3). The highest colonoscopy rate was in the PLCO study and the lowest in the UK study. Whether the presence of any neoplasia on sigmoidoscopy was an indication for colonoscopy appears to be a major factor in determining the subsequent colonoscopy rate, as can be seen when comparing the NORCCAP and UK trials.
- FS can lead to the detection of proximal adenomas and cancers if there are synchronous distal neoplastic lesions that lead to a complete colonoscopy.
- The proportion of patients with no polyps, distal adenomas, distal advanced adenomas and distal cancers was similar between the FS and colonoscopy studies.
- The data in Table 5 suggest that advanced lesions are more equally distributed between the right and left colon then previously believed.
- The colonoscopy cohort studies suggest that a FS screening strategy would fail to detect 21% - 65% of proximal advanced neoplasia.
- The preliminary CRC incidence and mortality results from the NORCCAP trial were presented in the preceding section.

- These results suggest that those undergoing screening by FS (+/- FIT) have a substantial decrease in mortality from cancers arising in the rectosigmoid (76% mortality reduction) and the entire colorectum (59% mortality reduction). The available data do not allow for the individual contributions of FS and FIT to be determined.
- The mortality reduction of 0.73 reported in the NORCCAP trial in the intention-to-screen analysis is greater than those seen in published RCTs of unrehydrated guaiac-FOBT (see Table 2). However, the result is not statistically significant, at 6 years follow-up.
- Most Clinical Practice Guidelines recommend FS every 5 years. The European trials are all evaluating a single sigmoidoscopy at age 55 – 64 years. If this once in a lifetime sigmoidoscopy strategy is successful, this would significantly reduce the resource needs of a sigmoidoscopy-based screening program.
- Acceptability and anticipated uptake of FS in a population-based CRC screening program in Canada is difficult to anticipate. Very high participation rates were observed in the Norwegian (NORCCAP) and Italian (SCORE) FS trials. However, screening attendance rates were much lower in the UK FS trial (39%).

4.0. Infrastructure/Resources Required to Provide FS Screening

- ENDOSCOPY ROOM: FS is a screening method that involves fiberoptic endoscopy; this requires appropriate setting in which to perform the (unsedated) procedure; in the past the procedures may have been performed in an office setting, but in the current era, this would likely not meet standards for infection control (see below); FS can be done in an ENDOSCOPY SUITE or an Operating Room (OR), but this would require that these resources are available for this purpose; FS may be perceived as displacing colonoscopy if rooms that are currently dedicated for colonoscopy use are used for FS; what is needed is an expansion of capacity, otherwise the introduction of FS could adversely impact access to colonoscopy
- INFECTION CONTROL: reprocessing of the used sigmoidoscope requires the same reprocessing as a used colonoscope (manual cleaning, followed by cleaning in a dedicated "scope washer" and all that this entails) by a individual who is specifically trained to do this (should not be done by casual staff who are not appropriately trained in the cleaning and disinfecting procedures); typically in a large hospital-based Endoscopy Unit, this would be done by a "Endoscopy or Scope Technician"
- EQUIPMENT: FS can be done using a 60 cm long fiberoptic sigmoidoscope, or it can be done using the (longer) colonoscope
- ENDOSCOPISTS: FS can be performed by appropriately trained physicians, such as gastroenterologists, general surgeons, and family physicians (FPs) as well as appropriately trained non-physicians including RNs (RN-FS); few FPs currently perform FS, or have been trained to do FS in Canada; Ontario is piloting RN-FS, and has set up a training program at the Michener Institute in Toronto to train nurses to do FS; a small number of RNs have been trained in this program to date
- ENDOSCOPY ASSISTANTS: Must be trained in assisting with the procedure
- REIMBURSEMENT/FUNDING MODEL: Physicians who perform FS are reimbursed by the provincial health plans, currently; since there is either no fee or an insufficient "technical fee" in the fee schedules (that would cover the costs of providing the service), it is not financially viable for an individual physician or group of physicians to provide FS outside of a hospital setting; if appropriately trained non-MDs were to perform FS screening, presumably they would be salaried, however, the costs of providing the equipment, endoscopy room time, etc would need to be provided

5.0 Policy Implications

5.1. Is the Evidence Enough to Direct Policy Change?

- There are 4 trials underway and the NORCCAP trial is the first to publish preliminary results. Before making a decision to change current policies on CRC screening, should jurisdictions wait for the results of the other FS trials? There is also the issue to consider of how generalizable these trial results will be to the Canadian context, e.g. will uptake rates of 65% shown in the European trials be achievable here? (3 of the 4 trials are from Europe, and the 4th from the US)

5.2. What will be the Impact on the Provision of Other Procedures in use for Screening and Follow-up?

- Trial results (and magnitude of a positive mortality impact) will need to be considered, in the context of (other) existing screening tests and their anticipated benefits
- How much "average risk" primary screening colonoscopy is being done currently needs to be considered in a given jurisdiction
- Unintended consequence of publication of the FS Trial results could be to increase the demand for colonoscopy by the public if there is a view that FS efficacy supports the likelihood of colonoscopy efficacy – even though the trials are not evaluating colonoscopy
- Development of a suitable reimbursement/funding model for FS, if it were to be integrated into existing/planned CRC screening programs
- Resources needed/costs of providing additional and new FS resources will need to be estimated if increased utilization is anticipated. In the past several years utilization trends have shown a decline in utilization of FS.

5.3. What Perspective will Health Care Providers, the Public and Patients Have?

- These groups will respond based on past experience, knowledge, interpretation of the evidence and their own personal values and beliefs. Each group may pressure or lobby for their preferences. For example
    - Family physicians
        - May support FS as it provides more choice for patients. There may be a concern that it will require more of their time to explain options, benefits and risks
        - May view the added option of FS as providing relief on demands for colonoscopy especially if their specialist colleagues endorse it.
        - Will be concerned about local access to sigmoidoscopy
        - Will be influenced by the opinions of the local specialists
    - Gastroenterologists
        - May have concerns that FS will encroach on colonoscopy resources and that colonoscopy will still be preferred because it is a more complete examination

        - If non-MDs are seen as an option for providing FS there may be concerns about reimbursement, liability and potentially that colonoscopy could also be taken over.
    - Public
        - FS could be seen as an attractive screening option as it is more accurate than FOBT yet entails less inconvenience and risk than colonoscopy.
        - The public will continue to be influenced by physician recommendation
        - Patients who have been diagnosed by colonoscopy and advocacy groups may support FS and continue to promote colonoscopy as the more "accurate" tests that will find cancers earlier.
        - If wait times for FS are perceived to be shorter compared to colonoscopy then FS may be preferred.
        - Once in a lifetime testing is unlikely to resonate with the public and may be thought of as done in order to save money

5.4. What are Potential Impacts on the Planning and Implementation of Colorectal Cancer Screening Programs?

For provinces with colorectal cancer screening programs:

- How would FS be added on, or integrated into what is currently underway? These are early days for our provincial screening programs, a consideration would be to wait to see what impact the programs will have as they are fully implemented before making a decision to change
- A determination will need to be made of the added value of adding FS to the existing programmatic screening with gFOBT or FIT, or, in some jurisdictions, colonoscopy. This will involve an assessment of some of the key principles of screening:

    - Test should be suitable – accurate, acceptable, safe and relatively inexpensive; the equipment costs will be a significant factor.
    - Will the public accept the test, will it improve uptake, what are the complication rates, how does the cost/benefit compare with FOBT? Would once-only FS screening appeal to the public and would there be an expectation that it is an option?
    - Agreed policy on whom to treat as patients and what level of abnormality will be referred for further testing. This will determine what percentage of the population screened will require referral to diagnostic facilities (colonoscopy) and whether adequate resources are available.

For Provinces and territories planning their programs:

- The consideration of which screening test(s) to offer in the program may need to include FS.
- Provider reimbursement would need to adequately support equipment purchase and maintenance and sigmoidoscope reprocessing.

Other considerations:

- The importance of ensuring the quality of the endoscopy (both FS and colonoscopy); Quality Assurance (QA) is required for personnel, facilities, and equipment – what processes are currently in place and what would have to be added to the system and at what cost?
- Monitoring and evaluation – what data systems would need to be developed to support addition of FS into a screening program.
- The need to monitor programmatic and opportunistic screening; screening is being introduced in many provinces on a limited basis and so majority of testing is done on an opportunistic basis. To fully understand the extent of CRC screening it is necessary to have centralized capture of screening tests on an individual basis (tests at a minimum – ideally outcomes). Importance of surveillance data and capturing ongoing screening using any method (both within and outside screening programs)

6.0 Cost-Effectiveness of FS Screening

- Effectiveness is not yet established for all different screening modalities so that cost-effectiveness is based upon modeled estimates
- A systematic review of 7 cost-effectiveness analyses of CRC screening methods (including: one-time or annual FOBT; FS every 5 years; colonoscopy every 10 years) in average-risk persons conducted for the USPSTF concluded that: 1) screening for CRC is cost-effective compared with no screening (estimated cost between US $10,000 - $25,000 per life-year saved); and 2) a single optimal strategy could not be determined
- A recent decision analysis, also conducted for the USPSTF did not assess costs (but used the number of colonoscopies as a proxy for resource utilization), reported that, assuming equally high adherence with screening, 4 strategies provided similar life-years gained: 1) annual guaiac FOBT screening with Hemoccult SENSA; 2) annual screening with FIT; 3) FS every 5 years; and 4) colonoscopy every 10 years.

Production of this report has been made possible through a financial contribution from Health Canada, through the Canadian Partnership Against Cancer.

The views expressed herein represent the views of Flexible Sigmoidoscopy Expert Panel.