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Horizon Scanning Technology Prioritising Summary

Flexible sigmoidoscopy for colorectal cancer screening

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PRIORITISING SUMMARY

REGISTER ID: **000482**

NAME OF TECHNOLOGY: **FLEXIBLE SIGMOIDOSCOPY FOR COLORECTAL CANCER SCREENING**

PURPOSE AND TARGET GROUP: **FOR POPULATION SCREENING OF INDIVIDUALS FROM AGE 50 YEARS**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☐ Yet to emerge
- ☐ Experimental
- ☐ Investigational
- ☐ Nearly established
- ☐ Established
- ☒ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☒ Yes — ARTG numbers 139503, 139504
- ☐ No
- ☐ Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
UK	✓	✓	
Netherlands	✓	✓	
Norway	✓	✓	
Australia	✓	✓	

Flexible sigmoidoscopy (FS) has widespread global use for investigation of the sigmoid (lower colon), often after bowel or rectal symptoms have already occurred. Utilisation of the technology as a screening tool has been the subject of continuing research and debate, but only now are the results of randomised trials becoming available.

IMPACT SUMMARY:

This summary considers emerging evidence for screening using once-off sigmoidoscopy in individuals aged 50 years and older for the earlier diagnosis and treatment of colorectal cancer (CRC). Flexible sigmoidoscopy (FS) is currently

offered as an outpatient procedure through tertiary centres for individuals at high-risk of CRC, or symptoms that may or may not be due to CRC. Various companies manufacture and market flexible sigmoidoscopes. A sigmoidoscope is used to examine the sigmoid (lower colon) and rectum for early signs of cancer and the removal of pre-cancerous polyps, or to investigate alternative causes of rectal bleeding, changes in bowel habit, and other symptoms.[1]

BACKGROUND

CRC, commonly known as bowel cancer, specifically affects the large intestine (colon or rectum) (AIHW 2009). The pathology is typified by a series of cellular mutations in the epithelial layers of the large intestine over time. Mutations at the early stage result in benign polyps that are relatively common in old age, however changes may give rise to benign adenomas that ultimately become malignant as additional mutations occur. Knowledge of specific causes for these mutations is not comprehensive. While a proportion of bowel cancers are thought to be due to hereditary factors, most cases seem to occur sporadically and many are attributed to environmental factors. In Australia, rates of CRC incidence are higher among males than females. This may in some part be due to sex-specific differences in environmental risk factors, some of which may be modified by lifestyle changes. Main risk factors include dietary habits, inadequate physical activity, excess body weight and higher alcohol consumption. Comorbidity with other gastrointestinal conditions may also predispose affected individuals to CRC.

The incidence of CRC is known to increase with age. Ninety-three per cent of people diagnosed in Australia in 2006 were aged 50 or older. CRC may remain latent for many years before showing symptoms, including rectal bleeding, change in bowel habit or anaemia, as these do not often occur until the cancer has become relatively advanced. However, death can be prevented and survival rates can be significantly improved if the disease is detected and treated early. Progression of cellular changes that lead to CRC is relatively slow, thereby making early detection and removal of small cancers, and polyps that may become cancerous, effective in preventing morbidity or mortality from bowel cancer. Clinical trials provide evidence that has shown that regular (two-yearly) screening using FOBT, which can detect evidence of rectal bleeding not visible to the naked eye, can reduce mortality from bowel cancer by 15 to 33 per cent (AIHW 2009).

Despite the overall acceptance of screening for CRC, disagreement exists about the optimal strategy. Guaiac-based FOBT (gFBOBT) has the disadvantage of low sensitivity (11 – 37%) for advanced neoplasia, which may explain limitations to the

[1] Sigmoidoscopy may also be performed with a conventional colonoscope. The colonoscope is longer than a sigmoidoscope and therefore only partially inserted during a sigmoidoscopy, no further than the splenic flexure – the sharp bend under the spleen where the transverse colon joins the descending colon.

impact on CRC mortality for repeated testing. More recently, immunochemical FOBT (FIT) has become available, with better sensitivity and similar specificity as gFOBT for detection of advanced neoplasia. National Health and Medical Research Council (NHMRC) guidelines strongly advocate biennial FOBT screening from age 50 years, while evidence for use of FS is stated to be equivocal under a five-yearly screening regime (ACN 2005). However, current Australian practice under the National Bowel Cancer Screening Program (NBCSP) offers FOBT to those turning 50, 55 or 65 years, of age between January 2008 and December 2010, a strategy that has been regarded as sub-optimal in light of best evidence (Flitcroft et al 2010). However, interest in screening with sigmoidoscopy continues as more evidence for effectiveness over FOBT methods emerges. FS has recently shown higher sensitivity for detection of early neoplastic lesions and the possibility of removing adenomas during the screening procedure (Hol et al 2010), which provides the basis for re-consideration of its place in CRC screening.

CLINICAL NEED AND BURDEN OF DISEASE

CRC is the second most commonly diagnosed cancer in Australia, following prostate cancer, and the second leading cause of cancer death in all persons after lung cancer. In 2006, 3,801 deaths were attributable to CRC, that is, 22 deaths per 100,000 age standardised population (AIHW 2009). The National Cancer Statistics Clearing House (NCSCH) contains data on the incidence of CRC until the end of 2006. In 2006, 13,591 people (7,432 males) were diagnosed with CRC, accounting for thirteen per cent of all diagnosed invasive cancers. The age standardised[2] incidence rate for CRC during 2006 was 62 per 100,000 with the rate for males markedly higher(74 per 100,000) than that for females (52 per 100,000). Incidence of CRC increases sharply from age 45 onwards, with the highest number of cases in people aged 80 years and over (exceeding 400 per 100,000 population). Nonetheless, nearly 30 per cent of new cases occur in persons aged 50 to 65 years. Since the collection of national cancer data began in 1982, incidence of CRC amongst males has doubled, while incidence for females has increased by 80 per cent. Age standardised rates were similar in 1982 and 2006, but because Australia has an ageing population, the burden on the health care system due to new cases of CRC is increasing (AIHW 2009). In 2004 the estimated annual treatment cost for CRC was $235 million (AIHW 2005).

Only provisional data on CRC are available for New Zealand beyond 2007. In 2007, CRC was the second most common cancer by registration and cause of death, accounting for 14.4 per cent of all registrations and 14.7 per cent of all cancer deaths. Between 1997 and 2007, registration rates dropped by 7.6 and 8.5 per cent for males and females respectively, while mortality rates decreased 15.8 per cent for males and 8.7 per cent for females.

[2] Australian 2001 Standardised Population

DIFFUSION

FS has wide-spread diagnostic applications in many countries and is billed in Australia under MBS item numbers 32084 and 32087 (DoHA 2010). However, the use of this technology as a CRC screening tool in average-risk populations is not widely diffused in Australian practice. Rather, the National Bowel Cancer Screening Program promotes the use of FOBT, though not in accordance with NHMRC guidelines which strongly recommend that screening be offered biennially (Flitcroft et al 2010).

COMPARATORS

Guaiac-based and immunochemical FOBT tests are the most common standards by which sigmoidoscopy should be compared. In some instances, a comparison with no screening has been made. Another CRC screening method, which is usually less preferred except in the USA, is colonoscopy. This is despite quantitative modelling analyses, commissioned by the US Preventive Services Task Force and Institute of Medicine, which indicate (in terms of mortality reduction) that any of the methods are appropriate as a screening alternative to colonoscopy. One notable finding of those analyses was that a programme of periodic sigmoidoscopy combined with interval FOBT was as effective as colonoscopy in instances involving fast growing lesions that are missed during intervals between periodic colonoscopy (Ransohoff 2010). Colonoscopy is the most invasive and time demanding method, and has the greatest cost at the baseline investigation level. Further costs of additional morbidity also arise due to the higher complication rate for colonoscopy (Neugut et al 2010). Comprehensive comparison of costs will be feasible only when age range, frequency of screening and overall number of screenings offered in a lifetime are defined and decided on for each of the screening techniques (Castiglione 2010).

SAFETY AND EFFECTIVENESS ISSUES

The literature search for this summary identified a systematic review (Whitlock et al 2008) that assessed safety and effectiveness of FS for screening. The review analysed pooled data on eight studies that assessed clinically significant adverse events associated with sigmoidoscopy. However, data on accuracy of the technique was only extracted from simulated cohort studies. Since results from RCTs are now available, the review will not be further considered here. One Australian case series was identified, but was also omitted given the weight of evidence in higher level studies.

A large RCT (Atkin et al 2010) (level II screening evidence) involving 14 UK centres randomised 170,432 eligible men and women for invitation to FS screening, or to a usual care control group which was not contacted. All had indicated on a previous questionnaire that they would accept an invitation for screening. The objective was to assess whether once-only FS between 55 and 64 years of age can substantially decrease CRC incidence and mortality.. Secondary outcomes were incidence of distal

and proximal cancer[3], all-cause mortality, and mortality due to causes other than CRC. 113,195 people were allocated to the control group and 57,237 to the intervention group (invited to receive FS) of whom 112,939 and 57,099 were included in the final analysis, respectively. Males and females were evenly distributed among both the intervention and control groups. For both groups, mean age was 60 years and median follow-up was 11.2 years. Of the 57,099 persons available for analysis in the intervention group, 40,674 (71%) actually underwent FS. Following screening, 38,525 (95%) were discharged because no polyps or only low-risk polyps were detected, and 2,131 (5%) were referred for colonoscopy after detection of high-risk polyps.[4] From the 170,038 persons in the final analysis cohort, 2,674 CRCs were reported. Of these, 2,588 (97%) were histologically confirmed, while the remaining cases were clinically diagnosed or determined by death certificate alone. A number of these cancers were excluded from analysis, apparently for reasons relating to the tissue or cell type of origin, though this is not clearly explained by the authors. The 2,617 CRCs remaining for analysis were diagnosed among 2,524 participants – 1,818 in the control and 706 in the intervention group. The majority of participants had one CRC (2,438), however 86 participants had two or more cancers, 34 of whom had both proximal and distal cancers. Distal cancers alone were diagnosed in 1,192 controls and 386 persons in the intervention group (126 screen detected). Proximal cancers were diagnosed in 628 controls and 311 persons in the intervention group (14 screen detected).

Intention-to-treat analysis showed that the incidence of CRC for all sites was significantly lower in the intervention than in the control group (Table 1). Incidence of distal cancer (rectum and sigmoid colon) was 36 per cent lower, while proximal incidence showed a non-significant decrease of two per cent for the intervention group. In the per-protocol analysis, which examined groups according to screening attendance, the incidence of CRC among those who did not attend was similar to the rate observed for controls. In those who were screened, incidence (adjusted for non-compliance) was reduced by 33 per cent for all CRC sites and by 50 per cent for the distal colon. There was no reduction in proximal cancer incidence (Table 2). Kaplan-Meier estimates of cumulative incidence for all colorectal and distal cancers in the per-protocol analysis were higher in the intervention than in the control group for the first four years of follow-up. This is due to the early detection of prevalent cancers. After four years, cumulative incidence rates for the control group began to climb above the rate observed for the intervention group. There was no between group difference observed at any follow-up time for proximal CRC.

[3] Proximal cancers are closer to the beginning of the colon, while distal cancers are closer to the end (rectum).

[4] High-risk criteria were defined as: a polyp ≥1cm in diameter; >3 adenomas; tubulovillous or villous histology; severe dysplasia or malignant disease; or ≥20 hyperplastic polyps above the distal rectum.

Table 1 Colorectal cancer incidence and mortality in control and intervention groups (adapted from Atkin et al 2010)

	Control group (n=112,939)		Intervention group (n=57,099)		
	Cases	Rate per 100,000 person-years [95% CI]	Cases	Rate per 100,000 person-years (95% CI)	p-value
Incidence					
All sites	1,818	149 [143,156]	706	114 [106,123]	<0.001
Distal	1,192	98 [92,103]	386	62 [57,69]	<0.001
Proximal	628	51 [48,56]	311	50 [45,56]	0.75
Mortality					
All-cause	13,768	1124 [1106,1143]	6,775	1093 [1067,1119]	0.052
CRC*	538	44 [40,48]	189	30 [26,35]	<0.001
Non-CRC*	13,230	1080 [1062,1099]	6,586	1062 [1037,1088]	0.25
CRC (verified§)	637	52 [48,56]	221	36 [31,41]	<0.001
Non-CRC (verified§)	13,131	1072 [1054,1091]	6,554	1057 [1032,1083]	0.33

*Deaths certified by the Office for National Statistics (UK) by automatic coding. §Cause of death certified by independent expert coder.

Data from the Office for National Statistics (UK) indicated that mortality from CRC was reduced by 31 per cent in the intervention group, as per intention-to-treat analysis (Table 1). Adjusting for people in the intervention group who actually attended screening, the observed mortality reduction was 43 per cent. The investigators calculated the number of people needed to be screened to prevent one CRC diagnosis and one CRC death to be 191 (95% CI [145, 277]) and 489 (95% CI [343, 852]), respectively. Adjustment for independently verified deaths had almost no effect on mortality rates (CRC or non-CRC), however, the number of patients needed to be screened to prevent one CRC death was notably reduced to 402 (95% CI [291, 647]). Rates of all-cause mortality excluding CRC were slightly reduced (NS) among the intervention group compared to the control group, and the authors comment that this indicates FS screening did not have unexpected harms. While serious harms resulting in death would be expected only as a rare occurrence, a confident assessment of safety would need to rely on morbidity as well as mortality data.

One limitation of this study is the two-stage process to recruit eligible individuals only if they responded to an initial questionnaire and indicated they would accept an offer for screening. This means that the compliance rate was higher than would have been expected in a programme targeting the whole population aged 55 to 64 years. The main strength of the study is the long follow-up period, which extended beyond 10 years to demonstrate significant decreases in incidence of distally distributed cancers and the mortality due to CRC. However, screening had no effect on proximal colon cancer incidence, and it appears that determining the proportion of deaths attributable to distal and proximal cancer was beyond the scope of this study. The effectiveness of FS in detecting a sub-group of cancers that may predict possibility of concurrent cancer in the proximal colon was sufficiently addressed, whereas safety of this procedure was not substantiated by morbidity data. Finally, while FS incorporates

polypectomy which contributes to the demonstrated reduction in CRC incidence and mortality by removing pre-cancerous growths, adverse outcomes associated with polyp removal were not addressed (Atkin et al 2010).

Table 2 Colorectal cancer incidence and mortality in control and intervention groups, by randomisation and screening compliance (adapted from Atkin et al 2010)

	Control group (n=112,939)		Intervention group (n=57,099)			
			Not screened (n=16,478)		Screened (n=40,621)	
	Cases	Rate per 100,000 person-years (95% CI)	Cases	Rate per 100,000 person-years (95% CI)	Cases	Rate per 100,000 person-years (95% CI)
Incidence						
All sites	1,818	149 [143,156]	261	152 [134,171]	445	100 [91,110]
Distal	1,192	98 [92,103]	171	99 [85,115]	215	48 [42,55]
Proximal	628	51 [48,56]	87	50 [41,62]	224	50 [44,57]
Mortality						
All-cause	13,768	1,124 [1106,1143]	2713	1,566 [1509,1627]	4,062	909 [881,937]
CRC*	538	44 [40,48]	78	45 [36,56]	111	25 [21,30]
Non-CRC*	13,230	1,080 [1062,1099]	2,635	1,521 [1461,1581]	3,951	884 [857,912]
CRC (verified§)	637	52 [48,56]	94	54 [44,66]	127	28 [24,34]
Non-CRC (verified§)	13,131	1,072 [1054,1091]	2,619	1,512 [1455,1571]	3,935	881 [854,909]

*Deaths certified by the Office for National Statistics (UK) by automatic coding. §Cause of death certified by independent coder.

Randomisation of a large, representative sample (n=15,011) of the Dutch population was undertaken to compare participation and detection rates for guaiac-based FOBT (gFOBT), immunochemical FOBT (FIT) and FS for CRC screening (Hol et al 2010) (level II screening evidence). All persons invited to undergo screening by one of these methods were aged 50 to 74 years and stratified by age, sex and socio-economic status. Of the eligible individuals, 49.5 per cent (2375/4798), 61.5 per cent (2979/4843) and 32.4 per cent (1522/4700) attended gFOBT, FIT and FS, respectively. The results of the various screening techniques are presented in Table 3. Of the 2,351 participants available for analysis in the gFOBT arm, 65 test results were positive and 62 (95%) of these were referred for and underwent complete colonoscopy[5]. Twenty-two (0.9%) advanced adenomas[6] and six (0.3%) CRCs were detected. The positive predictive value (PPV) of gFOBT was 45.2 per cent for advanced neoplasia and 9.7 per cent for CRC. Of the 2,975participants available for analysis in the FIT arm, 143 (4.8%) were positive. Of these, 137 (96%) underwent colonoscopy, which was complete in 134 (98%) instances. Advanced adenomas and CRCs were detected in 59 (2%) and 14 (0.5%) of participants, respectively. The PPV of FIT for advanced neoplasia (53.3%) or CRC (10.2%) was not statistically different from the PPV observed for gFOBT. Of the 1,522 individuals who underwent FS, the

[5] Some colonoscopy procedures were incomplete due to obstructing tumour.
[6] Adenoma ≥10mm, villous histology ≥25%, or high grade dysplasia.

procedure was completed in 1,386 (91%). Eighty-eight (5.8%) examinations were incomplete due to insufficient bowel preparation[7] and 51 (3.4%) failed to obtain adequate insertion of the scope. Participants who had no polyps (n=817; 59%) or non-advanced polyps (424; 31%) were discharged, and the remaining 142 out of 1,386 (10.2%) persons who completed FS were referred for colonoscopy. All but one completed colonoscopy. Of the participants who completed FS, 103 (7.4%) had advanced adenoma and eight (0.6%) had a CRC. One complication was observed within 30 days of FS – a colovaginal fistula attributed to previous diverticulitis and air insufflation during the procedure. Sigmoid resection repaired the fistula without complication. A total of four patients (1.1%) experienced minor rectal bleeding following polypectomy, without need for hospitalisation.

Table 3 Results of screening with gFOBT, FIT and FS (Hol et al 2010)

	n (%)		
	gFOBT	FIT	FS§
Completed screening	2,351 (99)	2,975 (99.9)	1,386 (91)
Positive test result	65 (2.8)	143 (4.8)	142 (10.2)
Colonoscopy performed	62 (95)	137 (96)	141 (99)
Detection rate			
Non-neoplastic polyp	4 (0.2)	7 (0.2)	272 (19.6)
Non-advanced adenoma	12 (0.5)	23 (0.8)	183 (13.2)
Advanced adenoma	22 (0.9)	59 (2.0)	103 (7.4)
Colorectal cancer	6 (0.3)	14 (0.5)	8 (0.6)
PPV (%)			
Advanced adenoma	35.5*	43.1*	Not calculated
Colorectal cancer	9.7	10.2	Not calculated

All values are n (%), unless otherwise specified. §Findings during sigmoidoscopy and colonoscopy. *Values not in agreement with values reported in text of results section.

The participation rates observed for this study indicate that FIT is preferred over gFOBT, while FS was the least preferred method. Beliefs or feelings regarding FS, such as fear and embarrassment (particularly among women) may explain why this test was associated with the lowest uptake of all. This study was conducted in a screening-naive population and it is known awareness does increase participation. The observed strength of FS was its superior detection of advanced adenoma, which was three and seven times higher compared to FIT and gFOBT, respectively. It is a concern that the study results in the text were not in agreement with tabled values of the PPV for gFOBT and FIT to detect advanced adenoma. Furthermore, the PPV of FS to detect advanced adenoma or CRC was not provided, and a rationale for this was not evident. Finally, the tabled values for FS detected adenomas and CRCs are noted to be the findings of sigmoidoscopy *and colonoscopy*. This mixing of results was not

[7] Bowel preparation was by administration of a phosphate enema.

explained in the text of the study which reports results for FS without indication that data are partly generated from colonoscopy findings (Hol et al 2010).

Norwegian investigators (Hoff et al 2009) (level II screening evidence) randomised 55,736 men and women aged 55 to 64 years to compare once only FS with or without FOBT (n=13,823) and no screening (n=41,913). Cumulative incidence and mortality after seven years were the main outcomes of interest. Potential participants were drawn from a population registry and invited directly to attend screening. Fifty per cent (6908) of those screened were asked to provide three consecutive stool samples to study the effect of a supplementary FOBT on compliance. The control group which was offered no screening was not contacted and follow-up was solely registry based. Of the 13,653 people randomised to the intervention group who were eligible for analysis, 8,846 underwent screening, giving a participation rate of 64.8%. It was reported that no severe complications occurred.

At screening, a neoplastic lesion was found in 19 per cent (1685/8846) of people screened and five per cent (440/8846) had high risk adenoma, defined as in the previously assessed studies, or invasive cancer. Out of the 33 prevalent CRCs detected at screening, 17 were in the 6,915 people invited to FS alone (2.5 per 1000 invited) and 16 were in the 6,908 invited for combined FS plus FOBT (2.3 per 1000 invited). Median follow-up of seven years gave a total incidence of 123 and 362 CRCs among the screening group and the control group, respectively. In the screening group, 54 CRCs (7.9 per 1,000) occurred among those who underwent FS alone, and 69 (10.1 per 1,000) occurred in those who received FOBT in addition to FS. Plots of cumulative hazard for colorectal cancer showed no difference between screening groups. However, restricting analysis to attendees and rectosigmoidal cancers (i.e. proximal CRCs) caused the plots to diverge, suggesting a preventive effect of polypectomy on proximal CRC in those who attended screening. Cumulative incidence of proximal CRC was 35 cases in 8,846 attendees (58 per 100,000 person years) and 217 in 41,092 controls (79 per 100,000 person years) (p=0.103). During follow-up, 24 out of 13,653 in the screening group and 99 out of 41,092 in the control group died from CRC. Total CRC mortality in the screening group (as per intention to screen) was reduced by 27 per cent compared to the control group, but this reduction was not significant. The reduction in proximal CRC (37%) was also not significant. Among persons actually screened, a total CRC reduction of 59 per cent (p=0.011) and a proximal CRC reduction of 76 per cent (p=0.016) was observed. Comparing mortality between those who attended screening and those who did not attend for screening demonstrates that for FS to be effective participation rates are important. Analysis restricted to those actually screened represents an impossible best case scenario of 100% participation, and furthermore, introduces the inherent risk of selection bias. Alternatively, as the authors suggest, overall CRC mortality may not have shown a significant reduction at only seven years follow-up. Further reporting at 10 and 15 year end-points remains to be published in order to observe whether a

significant overall reduction in CRC mortality will be reached. Also, despite an apparent reduction in deaths from CRC in people with screen detected cancer (6% of CRC fatalities) compared to controls (32% of CRC fatalities), lead time bias must be considered due to the presence of interval (post-screen detected) cancers, and this prevents formal comparison and conclusions. Finally, cumulative incidence for screening and control groups indicates two possibilities. Either FS is not an effective screening method for reducing incidence, or the progression of precursor lesions to cancer is substantially longer than normally assumed (Hoff et al 2009). Considering the work of Atkin and colleagues (2010), the second possibility is the more consistent conclusion.

COST IMPACT

Cost-effectiveness analysis by the Cancer Institute NSW has reported that the National Bowel Cancer Screening Program would be cost-effective for the health care system if biennial screening with FOBT were to be introduced for individuals turning 55 or 65 years of age, ongoing until the age of 75 years (Bishop et al 2008). It appears, however, that it is yet too early for a well-defined FS screening program to have been proposed, and therefore, comprehensive costing of FS screening remains to be investigated.

The MBS fee for a sigmoidoscopy procedure, as currently indicated in a non-screening context, is $105.20 or $193.45 under items 32084 and 32087, respectively (DoHA 2010). The higher fee for item number 32087 relates to multiple services (the removal of one or more polyps) associated with that item. By comparison, FOBT which is the current screening method in Australia attracts a fee of $8.95 for a single exam under item 66764. Three separately collected and identified specimens in a 28 day period are billed under item 66770 at a fee of $26.90. As previously discussed, morbidity from CRC and the associated costs of treatment continue to increase (AIHW 2009), and screening costs need to be weighed in relation to their impact on reducing the burden of CRC on the Australian healthcare system.

Purchasing a sigmoidoscope with video display capability is possible for US$4,000 and US$5,500, however, peripherals necessary for video display are likely to cost in the order of US$30,000 (HMB 2010). Systems that incorporate an eyepiece for direct viewing without the need for video display are also available. More importantly, however, are the costs of personnel and wider infrastructure that would be required to provide once-off FS screening to Australians of age 50 years and above. For screening purposes, FS would be offered as an outpatient procedure requiring prior consultation and administration of the procedure by a specialist. An anaesthetists' fee may or may not be applicable, as many patients who undergo endoscopy procedures are electing to

do so without sedation[8] (RAH 2009). In countries including the UK and the USA, nurse-led endoscopy has been well described and studies have demonstrated that adequately trained nurses can perform FS at least as competently as gastroenterologists (Moayyedi 2007). By using a work-force of nurses to support FS screening, the number of procedures undertaken by specialists could be minimised, and some cost-savings are foreseeable in this area. However, the issue of funding adequate training would remain as an initial cost-barrier.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

During the final preparation of this report, a discussion paper (Neugut & Lebwohl 2010) on current controversy surrounding CRC screening was published. The authors document a short history on the rise of colonoscopy in the US and the subsequent decline in the use of sigmoidoscopy as a screening technique. Despite the equal endorsement of the two techniques by the US Preventive Services Taskforce, colonoscopy was granted preference in guidelines published by the American College of Gastroenterology. Sigmoidoscopy has been under-utilised due to lower reimbursements than those offered for colonoscopy in the USA. The equally acceptable FOBT, as judged by the Preventive Services Taskforce, is documented as a test which avoids incorrect test results on the basis of cancer distribution (i.e. proximal or distal). The included studies for this summary indicate that sigmoidoscopy shows limited ability for detecting proximal cancers, and despite the supposed benefit of examining the bowel at extended range, evidence to date shows that colonoscopy has equally poor results for the proximal colon (Neugut & Lebwohl 2010). Also, in an Australian context, it appears unlikely that the health care system is adequately prepared for population based FS screening under current work force and infrastructural provisions.

SUMMARY OF FINDINGS

The sources examined are not in complete agreement regarding the effectiveness of FS as a screening tool for CRC. FS screening is a method that incorporates primary prevention by the detection of and removal of adenomas, and secondary prevention by early detection of cancers. Therefore, a successful FS screening program needs to demonstrate a reduction not only in mortality but also in incidence. The study with the longest follow-up and largest patient group (Atkin et al 2010) provided sound evidence of a reduction in CRC incidence and mortality for a group allocated to FS

[8] The advantage of this is prompt discharge of the patient following the procedure without restriction on activities for the rest of the day. This particularly applies to driving a vehicle which is not possible until the day after a procedure undertaken with a sedative injection

screening compared to a control group who were not offered any screening. The work of Hol and colleagues (2010) indicated that FS was superior in the detection of advanced adenoma and CRC compared with FOBT methods, reportedly with minimal complication. When deciding on a screening method, the clinical effectiveness of each strategy needs to be considered with close reference to issues of safety. If FS is to be promoted over FOBT, then determination of whether the level of invasiveness and adverse outcomes are acceptable for the level of benefit gained will be necessary. Comprehensive comparison of costs also remains an issue, since this will be possible only when age range, frequency of screening and overall number of screenings offered in a lifetime are defined and decided on for each of the screening techniques. It is still too early to know comprehensive costing implications of a program of FS screening, as to the evaluators' knowledge, no such program has been specifically defined at this stage.

HEALTHPACT ASSESSMENT:

Based on the high level of evidence it would appear that FS is a screening method that confers significant reduction in incidence of and mortality from CRC when compared to a non-screened population, however resistance to the uptake of this technology is likely due to its invasive nature. The NHMRC are currently in the process of revising the Australian guidelines for the detection of colorectal cancer and therefore HealthPACT have recommended that this document be considered as part of this ongoing process.

NUMBER OF INCLUDED STUDIES

Total number of studies	3
Level II-screening evidence	3

REFERENCES:

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SEARCH CRITERIA TO BE USED:

Sigmoidoscopy, cancer/screening

Flexible sigmoidoscopy

Cancer, colorectal