COLORECTAL CANCER

Quality in the technical performance of screening flexible sigmoidoscopy: recommendations of an international multisociety task group

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Background: Flexible sigmoidoscopy (FS) is a complex technical procedure performed in a variety of settings, by examiners with diverse professional backgrounds, training, and experience. Potential variation in technical quality may have a profound impact on the effectiveness of FS on the early detection and prevention of colorectal cancer.

Aim: We propose a set of consensus and evidence based recommendations to assist the development of continuous quality improvement programmes around the delivery of FS for colorectal cancer screening. **Recommendations:** These recommendations address the intervals between FS examinations, documentation of results, training of endoscopists, decision making around referral for colonoscopy, policies for antibiotic prophylaxis and management of anticoagulation, insertion of the FS endoscope, bowel preparation, complications, the use of non-physicians as FS endoscopists, and FS endoscope reprocessing. For each of these areas, continuous quality improvement targets are recommended, and research questions are proposed.

Colorectal cancer is the second leading cause of cancer death in the USA.¹ Colorectal cancer screening performed with flexible sigmoidoscopy (FS) has been associated with reduced incidence and mortality from colorectal cancer in cohort studies,² case control studies,³⁻⁷ and a randomised controlled trial.⁸ FS is performed in diverse environments, including dedicated hospital based endoscopy units, outpatient physician offices, and endoscopic ambulatory surgery centres.

FS is a complex technical procedure that requires training and experience to ensure accuracy and safety.9 The US Multi-Society Task Force on Colorectal Cancer developed these recommendations for the technical performance of FS and for continuous quality improvement in FS screening in conjunction with several international experts on the use of FS. The Task Force is comprised of representatives of the American College of Gastroenterology, the American College of Physicians-American Society of Internal Medicine, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy (ASGE). Investigators performing three large randomised clinical trials of FS provided additional expert opinion (prostate, lung, colorectal, and ovarian trial of the US National Cancer Institute (Robert E Schoen),10 11 the UK Flexible Sigmoidoscopy Trial (Wendy Atkin),12 and the Norwegian Colorectal Cancer Prevention trial (Geir Hoff)^{13 14}).

The focus of these recommendations is on the quality of FS in relation to screening and prevention of colorectal cancer. Thus the recommendations do not address every diagnostic or therapeutic use of FS. These recommendations address the intervals between FS examinations, documentation of results, training of endoscopists, decision making around referral for colonoscopy, policies for antibiotic prophylaxis and management of anticoagulation, insertion of the FS endoscope, bowel preparation, complications, the use of nonphysicians as FS endoscopists, and FS endoscope reprocessing. For each of these areas, the underlying evidence base is reviewed, continuous quality improvement targets are recommended, and research questions are proposed (tables 1, 2).

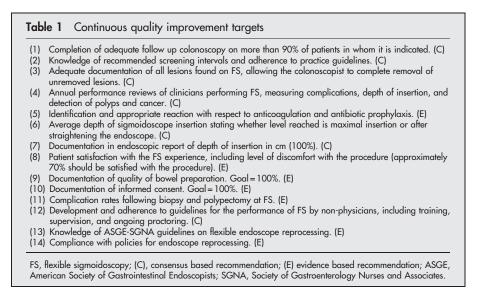
The purpose of this paper is: (1) to provide evidence and consensus based standards for the performance of high quality screening FS and (2) to facilitate the development of constructive programmes in continuous quality improvement. Continuous quality improvement should be part of every FS screening programme.

We propose the following course of action for endoscopists found to have substandard performance, given the limitations of the current evidence base, understanding the danger of misjudging the results of patient selection as poor performance. Merely providing feedback on individual performance can be expected to result in significant improvement in performance, for individuals and collectively for all endoscopists involved. Endoscopists with suboptimal performance, who fail to improve after feedback of information, may require more direct intervention. The exact mechanism of this intervention has not been well studied. For these types of programmes to be successful it is crucial to explicitly state that the aim is not to punish. The responsibility for improvement of individual practitioners lies with the institution in which they practice, to provide opportunities to reach a sufficient level of proficiency by learning from other colleagues or attending formal courses. In the end, there may remain a small group of individuals unable or unwilling to take the necessary course of action to improve. The best method of dealing with these providers will have to be made on a case by case basis.

METHODS

Task Force members developed a list of major categories to be included in this paper, and a full PubMed Medline search

Abbreviations: FS, flexible sigmoidoscopy; FOBT, faecal occult blood test; TA, tubular adenoma; AA, advanced adenoma; SGNA, Society of Gastroenterology Nurses and Associates; ASGE, American Society of Gastrointestinal Endoscopists



was last performed on 15 July 2004 for English language articles with the MeSH terms "sigmoidoscopy" and "mass screening" published since 1980. The reference lists of identified articles were scanned for other articles of interest. Recommendations for relevant articles were also sought from the experts on the panel. Abstracts of information presented at international meetings are referenced only when necessary. Each author had an opportunity to review drafts of this position paper and had an opportunity to make meaningful revisions in the content.

INTERVALS

Endoscopists performing screening FS should know the sensitivity of FS compared with other screening tests, and the intervals at which screening FS is recommended. For average risk screening, FS every five years is one of several acceptable screening options.^{15–18} Other options include annual faecal occult blood testing (FOBT), annual FOBT combined with FS every five years, double contrast barium enema every five years, and colonoscopy every 10 years.

Advanced neoplasms or cancers may be found in the interval between screening examinations19 20 because of limited test sensitivity or rapid cancer progression. The aim of screening is to reduce the risk of dying from colorectal cancer or developing the disease. No screening strategy can eliminate this risk entirely. Any screening approach carries risks and costs and these must be balanced with the risk of missing potentially important precancerous or cancerous neoplasms. Because screening is directed at people without symptoms, avoidance of harm from screening is paramount. A 10 year interval between FS examinations is supported by two case control studies of FS screening demonstrating similar risk reduction for 10 year or longer screening intervals as more frequent intervals, including one in the rigid sigmoidoscopy era.4 7 Additional supporting evidence is provided by a study showing that significant neoplasms were rare five years after a negative colonoscopy.²¹

Differential sensitivity for FS and colonoscopy for the distal colon has never been demonstrated but the five year interval for FS screening is chosen in most guidelines because unsedated FS patients may become uncomfortable during

Table 2 Areas for future research related to performance of flexible sigmoidoscopy

- What is the degree of adherence to recommended intervals between FS examinations among both (1) gastroenterologists and non-gastroenterologists?
- (2) Is there a clinically meaningful difference between a 5 year interval between FS examinations and a 10 year interval?
- What portion of the adenoma bearing cohort can safely have a follow up colonoscopy delayed until after the (3) age of 60 years?
- Would a single FS between age 50–59 years successfully stratify the population according to subsequent risk of colorectal cancer, guiding the need for subsequent screening or surveillance? (4)
- What will be missed by delaying this initial examination until after the age of 60 years? (5)
- How many examinations are necessary to achieve and maintain technical procedural competence? What defines a complete FS insertion, based on clinically important outcomes? (6)
- (7)
- What should be done when a screening FS is incomplete or suboptimal? (8)
- What technical improvements could improve the ease, speed, and safety of FS?
- (10) Do smaller diameter endoscopes improve FS performance or patient satisfaction? (11) What is the preferred bowel preparation for flexible sigmoidoscopy, balancing preparation quality, patient satisfaction, and safety?
- (12) Are there differences in rates of missed cancer or advanced lesions by non-physicians compared with generalist and specialist physicians?
- (13) Do patient preferences vary for physician v non-physician providers of FS?
- (14) To what degree do office based primary care providers performing FS adhere to endoscope reprocessing guidelines? (15) What is the incidence of preventable transmissible infection related to FS procedures and are these events
- related to inadequate compliance with reprocessing guidelines?
- (16) Can disposable sheath endoscopes be a feasible means of delivering flexible sigmoidoscopy in high volume with reduced risk of transmitting infection?

the procedure, impairing thorough examination of the colonic mucosa. The typically less complete bowel preparation for FS compared with colonoscopy may also limit complete visualisation. FS examiners may have less experience interpreting colonic findings compared with specialists who usually perform colonoscopy. In situations where an experienced endoscopist performs a complete examination on a well prepared patient and comfortably achieves an adequate examination, a 10 year interval between screening flexible sigmoidoscopies may be justified,¹⁷ although more research on this issue is needed. While the incidence of clinically detected colorectal cancer during the five years after a negative screening flexible sigmoidoscopy may be low,²⁰ ²² advanced lesions may be found on repeat examination done as soon as three years after a negative initial screen.¹⁹ Many of the advanced lesions detected after an apparently negative FS will be in regions of the colon beyond the reach of the FS endoscope; a fraction will also be found in the distal colon.

DOCUMENTATION

The performance of FS requires that findings must be documented adequately enough to allow other clinicians to provide appropriate follow up for the patient. The size (in mm), number, and location of any lesions found on FS, especially lesions that are incompletely removed, must be recorded in the procedure report (table 3), and in any communication between the sigmoidoscopist and the colonoscopist. Other necessary items include depth of insertion (in cm, and ideally with a straightened endoscope) with estimation of the colonic segment. Additional findings such as diverticulosis and haemorrhoids, whether a retroflex view has been obtained, and qualitative estimation of the preparation should also be recorded. Examination of the anal canal and the perianal area should also be made and comments included if abnormal.

REFERRAL FOR COLONOSCOPY

The glandular structure of adenomas can be characterised as either tubular or villous. If more than 80% of the polyp contains tubular elements, the polyp is classified as a tubular adenoma (TA). If more than 80% of the polyp contains villous elements, it is classified as a villous adenoma. If neither tubular nor villous elements exceed 80%, then the polyp is classified as a tubulovillous adenoma. Most adenomas are TAs.

In most studies, an "advanced adenoma" (AA) is defined as an adenoma with high grade dysplasia, villous elements, or ≥ 1 cm in size (as estimated using an open biopsy forceps). As patients with one or two TAs smaller than 1 cm are clearly not at increased risk of subsequent colorectal cancer,²³ the focus of screening and surveillance has shifted progressively towards the AA and cancer, and away from the finding of a single TA. AAs have a greater risk of transforming into cancer, and patients with resected AAs have a greater risk of having recurrent AAs and cancers.^{23 24} Furthermore, advanced histology in adenomas found at FS predicts an increased likelihood of finding advanced proximal colonic neoplasia in the proximal colon.²⁵⁻²⁹

The decision to perform colonoscopy based on the findings at FS remains an area of debate, which is complicated by the fact that biopsy is not universally available at FS.³⁰ Patients with only hyperplastic polyps in the distal colon should be considered to have had a normal examination. Patients are at increased risk of advanced proximal neoplasia or subsequent development of colorectal cancer if multiple (\geq 3) TAs are found, if the adenomas are advanced, or if a positive family history is present.23 27 Age 65 years or older is also associated with increased risk for advanced proximal neoplasia.27 31 32 Additional screening with FOBT, barium radiography, or colonoscopy may be justified in older patients, as an alternative to FS. If a large polyp (>1 cm) is found at flexible sigmoidoscopy, colonoscopy is generally indicated to complete removal of this lesion and to exclude synchronous proximal neoplasia. The majority of polyps 1 cm or larger in size are adenomas, and it is not necessary to perform biopsies to determine whether colonoscopy is indicated.

The risk of proximal AAs and cancer among patients with 1 or 2 small (<1 cm) distal adenomas found on flexible sigmoidoscopy is less than 10%.²⁵⁻²⁹ ³³⁻³⁵ This risk may not be higher than that of the general population but may still be high enough to warrant colonoscopy, depending on patient preferences, age, comorbidity, and resource availability.

TRAINING IN FS

Cognitive and technical skills are both required for screening FS. Trainees develop skills at variable rates due to differences in manual dexterity, interpretative skills, clinical judgment, and quality of instruction. Prospective studies are limited as to the most appropriate method to train clinicians to perform screening FS.³⁶ Clinicians of multiple backgrounds have been trained in FS, including primary care physicians, registered nurses, nurse practitioners, and physician assistants.

Training should begin with instruction in basic anatomy and typical pathological findings in the distal colon and rectum. Didactic study can include review of textbooks or compact disks on the performance of FS.³⁷ A formalised training programme may allow determination of competency in the performance of FS.³⁸ Understanding the indications and contraindications for FS are part of the cognitive process. Initial hands-on training begins with time spent becoming familiar with the technical aspects of handling the sigmoidoscope by practising on a plastic model. In an endoscopy unit, the trainee spends time observing both colonoscopic and sigmoidoscopic examinations to become familiar with the basic anatomy of the colon and the appearance of normal and abnormal findings. Hands-on experience during actual

Element	Examples and comments
Informed consent	The procedure, its indications, risks, benefits and alternatives were explained to the patient, who had an opportunity to ask questions, and indicated a desire to proceed.
Preparation quality	Good, fair, poor
Size, number and location of lesions	Size: in mm diameter; location in cm from the anal verge and in estimate colon segment
Presence of other abnormalities	Diverticulosis, haemorrhoids, inflammatory findings
Performance of retroflexion	May not be feasible or safe in all patients
Disposition	Barium enema or colonoscopy to be done soon, repeat sigmoidoscopy i 5 or 10 years, further follow up based on recommendations of primary care provider, clinicians identified as providing follow up care

procedures begins by first withdrawing the instrument under direct supervision. Once the trainee can perform the withdrawal successfully, he or she can begin to advance the scope. Training then progresses through several stages along a continuum of graded responsibility and reduced supervision. Cold biopsy techniques should be part of the training process.³⁹

Short courses in FS are adjuncts or starting points in the training process and do not substitute for mentored training by an experienced proficient endoscopist.⁴⁰ Computer simulation of FS is available and a recent study demonstrated that a virtual reality sigmoidoscopy training system was a valid discriminator of FS experience.⁴¹ However, virtual reality simulators are not a substitute for traditional bedside teaching.⁴²

A minimum of 15–25 supervised procedures was recommended in studies performed in the 1980s,^{43 44} but in reality more examinations may be needed. The ASGE position paper on FS recommended 25 supervised procedures before competency with the 60 cm instrument is assessed.⁹ The Society of Gastrointestinal Nurses and Associates (SGNA) as well as the Society of American Gastrointestinal Endoscopic Surgeons also recommend 25 supervised procedures.^{45 46} Others have suggested that 50–100 supervised procedures are needed to effectively train clinicians with no previous endoscopic skills.^{47 48} Furthermore, a minimum number of FS should be done yearly to maintain proficiency.

ANTIBIOTIC PROPHYLAXIS AND ANTICOAGULATION

FS with or without biopsy or polypectomy is associated with a low risk of bacteraemia. However, patients may be considered on a case by case basis for antibiotic prophylaxis if they have high risk conditions for endocarditis (for example, prosthetic heart valve or history of endocarditis) and during the first year after placement of a synthetic vascular graft. Antibiotics are not recommended prior to FS to prevent infection of prosthetic joints or orthopaedic prostheses. The issue of antibiotic prophylaxis is discussed in detail elsewhere.^{49 50}

Therapeutic anticoagulation with warfarin is associated with an increased risk of bleeding after polypectomy but not after mucosal biopsy.⁵¹ Management of anticoagulation before and after the procedure depends on the risk of thromboembolism and is discussed in detail elsewhere.⁵¹ Anticoagulants, antiplatelet agents, or non-steroidal anti-inflammatory medications do not need to be stopped prior to FS, as long as polypectomies are deferred to colonoscopy.

FS INSERTION

The goal of FS is to examine as much of the distal colon as possible based on the limits of FS endoscope length (usually 60-70 cm) or to the limits of patient tolerance. In general, high levels of patient satisfaction can be achieved with FS screening,⁵² and the use of carbon dioxide instead of air for colon insufflation is associated with reduced post procedural discomfort and reduced risk for cautery related complications. Insertion depths in women are less than in men,⁵³⁻⁵⁵ possibly due to anatomical differences between genders. The use of a thinner diameter upper endoscope to perform FS may be better tolerated than standard sigmoidoscopes.⁵⁶ Prior abdominal surgery is also associated with reduced depth of insertion,53 and prior history of hysterectomy is associated with reduced polyp detection at screening FS.⁵⁷ Patients should not be subjected to excessive discomfort in order to achieve a predefined level of adequate insertion. Anatomical factors, preparation quality, or variations in patient tolerance all may limit insertion depth. The definition of an adequately inserted screening FS is subjective and not currently defined. In the screening setting, the decision to perform colonoscopy or other tests after an incomplete FS should be individualised, based on degree of risk for colorectal cancer, the limiting factor (preparation quality ν anatomical barriers) patient preferences, and available resources.

Localising the depth of FS insertion by anatomical segment is unreliable. The rectum is usually traversed by the distal 10–20 cm of the FS endoscope. The procedure report should document the depth of insertion of the FS endoscope in centimetres from the anal verge, ideally with a straightened endoscope. Smaller diameter "paediatric" FS endoscopes are available that are more flexible than standard diameter scopes. It is not clear that these differences make a clinically important difference in patient satisfaction or in depth of insertion.⁵⁸

ADENOMA DETECTION

Endoscopy is not perfect. Miss rates for small adenomas on colonoscopy may be substantial, and occasionally polyps ≥1 cm are missed.^{59 60} Adenoma detection rates may vary widely between different examiners, within similar patient populations.^{61 62} Adequate colonic distension, adequate suctioning and cleaning, and adequate time spent examining the colonic mucosa all correlate with higher detection rates.^{61–63} The prevalence of adenomas in a given population will vary according to the age and sex of those being screened. Adenoma detection may be a useful surrogate marker for the quality of an examination but has not yet been proven to correlate directly with differences in colorectal cancer incidence or mortality in a FS screening programme.⁶⁴ The use of dye spray to enhance detection of flat and diminutive lesions in the distal colon tends to lead to increased detection of smaller and non-neoplastic lesions, and the clinical benefit may be minimal.65 66

PREPARATION

The FS procedure report should document the quality of preparation and any impairment in the endoscopist's confidence attributable to preparation, but there is no standardised system for describing bowel preparation. An adequate examination is one that allows confidence that mass lesions other than small (≤ 5 mm) polyps were generally not obscured by the preparation. Recommended intervals for screening and surveillance assume adequate preparation.

Most FS units use sodium phosphate enemas to prepare patients for FS. The use of oral agents with an enema preparation has demonstrated improved preparation quality when the enemas are combined with an oral laxative, such as magnesium citrate or oral sodium phosphate.^{67–70} Caution should be exercised to avoid electrolyte disturbances and dehydration with the use of oral osmotic agents, particularly in the elderly and in those taking diuretics.⁷¹ When preparation quality is suboptimal, it is incumbent upon the endoscopist to make adequate arrangements in the follow up of the patient. Options include repeating the examination with a modified preparation, shortening the interval between screening examinations, or pursuing an alternative screening strategy, such as FOBT or double contrast barium enema.

COMPLICATIONS AND INFORMED CONSENT

Perforation related to FS occurs rarely. Recent reports suggest that perforations occur in 1 in 25 000–50 000 FS examinations.^{12 54 72} The expected rate of major post polypectomy bleeding is <1%.⁷³⁻⁷⁵ The risk of major bleeding from mucosal biopsy is near zero, even among patients who are therapeutically anticoagulated.⁵¹ Perforation may result from either mechanical rupture of the colon from instrument passage, barotrauma, or from polypectomy or other therapeutic procedures. The most important rule to avoid mechanical perforation is not to push forcibly against the sensation of

fixed resistance. Forceful perforation is less likely in FS compared with colonoscopy as FS patients are usually not sedated, and less force is applied to colonic loops by the endoscope shaft.

It is desirable for individuals performing FS to be proficient in performing endoscopic biopsies. The risk of explosion associated with the use of electrocautery, while small, is real, and an important reason to avoid the use of hot biopsy forceps or monopolar electrocautery snares in air insufflated patients.^{76–80} Polyps larger than 2 mm or smaller than 7 mm can be removed safely with a cold snare. Smaller flat polyps, not easily grasped with a snare, can be removed piecemeal with cold biopsy forceps. The use of carbon dioxide insufflation instead of air eliminates the risk of combustion.^{81 82} Cold snaring is particularly attractive for polyps <7 mm in size, based on endoscopist discretion, as anecdotal data suggest no risk of perforation and a very low risk of post polypectomy bleeding.^{83 84} Thus cold snaring may be an effective way to remove small polyps and nearly eliminate associated complications.

It is acceptable to obtain consent for FS on the day of the procedure, preferably prior to entering the examination room. Informed consent for FS should focus on three possible adverse outcomes.

- Perforation and the probable need for surgical repair if this occurs.
- Missing a significant neoplasm (including, but not limited to, lesions beyond the reach of the sigmoidoscope).
- Post polypectomy and post biopsy haemorrhage.

NURSE AND PHYSICIAN ASSISTANT **ENDOSCOPISTS**

A large and consistent evidence base supports the use of nonphysicians for sigmoidoscopy. In several studies, average depth of insertion, polyp yield, complications, procedure time, and patient satisfaction were all similar for non-physicians, non-gastroenterologist physicians, and gastroenterologists.^{54 85-88} In settings where fee for service reimbursement is not an issue, such as the Department of Veterans' Affairs Medical Centers and prepaid medical groups, the use of non-physicians has become commonplace.

FLEXIBLE SIGMOIDOSCOPE REPROCESSING

Guidelines for endoscope reprocessing have been reviewed in detail elsewhere,89 and have recently been updated.29 The ASGE-SGNA guidelines recommend manual precleaning of endoscopes, with a 20 minute submersion in a 2.4% glutaraldehyde solution.⁹⁰ A recent highly publicised series describing patient to patient transmission of hepatitis C via colonoscopy⁹¹ has raised public awareness and concern. Other infections related to gastrointestinal endoscopy include salmonella, pseudomonas, and hepatitis B.92 Based on survey data, it is apparent that even gastroenterology specialists may not be uniformly aware of disinfection practices.93 The quality of endoscopic reprocessing can vary and, in general, manual reprocessing is inferior to the use of automatic endoscope reprocessing machines.94 Bacterial contaminants can be detected in samples obtained from endoscopes cleaned according to current guidelines.95 One possible solution for clinicians performing FS without access to disinfection facilities is the use of the disposable sheath flexible sigmoidoscope.96-98 This device has the advantage of also limiting staff and patient exposure to hazardous chemicals, such as glutaraldehyde. This endoscope is only available as a fibreoptic instrument, and is technically more difficult to use than video flexible endoscopes.

FS remains an important tool for screening and prevention of colorectal cancer. It can be delivered in high volume, by a variety of examiners, safely, and with high patient satisfaction. The effectiveness of FS depends on the quality of examination. We anticipate that a constructive process of continuous quality improvement that educates endoscopists in optimal technique, procedure documentation, specimen acquisition, and endoscope reprocessing could improve patient outcomes. The recommendations and rationale for continuous quality improvement made in this document are evidence based where possible and consensus based where no evidence exists. The Task Force recommends that all of the targets recommended above be periodically reviewed in continuous quality improvement programmes. Findings of deficient performance can be used to educate endoscopists, and additional monitoring can be undertaken to document improvement in performance. Furthermore, we recommend that both academic and community based programmes report the results of their reviews of adherence to these continuous quality improvement measures in the peer reviewed medical literature.

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- EDITOR'S QUIZ: GI SNAPSHOT

An upper abdominal swelling causing nausea and vomiting

Clinical presentation

A 75 year old woman was admitted to Elche University General Hospital for further evaluation of nausea and vomiting related to meals for one month. She had previously been well with no history of liver disease, dysphagia, or peptic ulcer. On routine physical examination an abdominal mass was discovered in the right upper quadrant and epigastrium. Results of laboratory studies and liver function tests were normal. Also, she had never been abroad and had no contact with livestock. Upper endoscopy showed extrinsic compression of the gastric lesser curve. A helical computed tomography scan was therefore done.

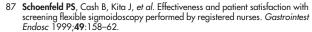
Question

What does this investigation show (fig 1)? See page 842 for answer This case is submitted by:

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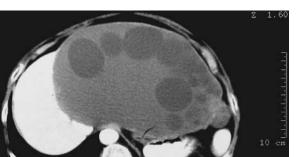


Figure 1 Helical computed tomography scan.

Robin Spiller, Editor