

## Screening Flexible Sigmoidoscopy: Is It Worthwhile?

### An Affirmative View

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The following ten observations are offered in support of the value of screening flexible sigmoidoscopy in everyday family practice.

1. Society and its agent, the medical profession, value early detection of disease because these groups feel that health enhancement or cure is more likely with early detection.<sup>1-6</sup> Secondary prevention of cancer is a perceived benefit, the validation of which has not been scientifically proven beyond all reasonable doubt. That policy frequently proceeds in the face of doubt or opposition does not invalidate a policy that has been established through a good-faith consensus of physician-educators, scholars, clinicians, and the public.

2. Without implying unanimity, consensus exists regarding certain aspects of the natural history of colorectal cancer in the United States.<sup>7-10</sup> The disease is deadly and causes significant morbidity and human misery. Death is not sudden, and family suffering is an unmeasurable reality.

3. The adenoma-carcinoma sequence has been observed, reported, published, and accepted in multiple investigations by many scientists at various reputable institutions.<sup>11-14</sup> As a disease, the prognosis for colorectal cancer is inversely related to the degree of anatomical spread. Patients with cancer limited to the bowel wall have five-year survival rates of greater than 90 percent, whereas those patients with disseminated disease will have five-year survival rates of 30 to 50 percent. In controlled screening trials for colorectal cancer, a greater number of cancers having staging levels associated with a more favorable prognosis is found in the study group.<sup>15-20</sup> None

of these trials has studied sigmoidoscopy exclusively as the only diagnostic method.

4. Detection of premetastatic carcinoma is an accepted form of secondary prevention of premature death from a variety of cancers including those of the breast, rectum, stomach, cervix, uterus, and colon, among others. The US General Accounting Office has criticized inflated claims of survival success on the basis of lead time bias, length bias, selection bias, and other biases for various guidelines in all these tumors.<sup>21</sup> For women aged 50 years or more, randomized controlled trials have provided positive evidence regarding decreased mortality from breast cancer for physician breast examination and mammography. For self-breast examination and for women aged 35 to 50 years, however, guidelines lack these confirming data. As the US Preventive Services Task Force points out, "recommendations may be made on other grounds."<sup>22</sup> Studies are in progress, but the recommendations and guidelines for cancer screening continue with wide support from professional societies, hospitals, accredited nonprofit organizations, and others. Where studies have discredited previously accepted screening tests, such as the chest x-ray examination for early detection of lung cancer, these groups have responsibly withdrawn these recommendations. Inferential and epidemiologic data are so strong with respect to some cancers, however, such as cancer of the uterine cervix, that randomized trials would not be considered ethical.

5. The prevalence of colorectal cancer is tangible, but its importance is subjective.<sup>23</sup> As a public health entity, the yearly incidence of colorectal cancer is sufficient to merit application of private and public funds for diagnosis and treatment. Although inequities of access exist, patients with diagnosed cancer of any type are entitled to receive care even if it is ultimately subsidized by public funds. Disability associated with diagnosed colorectal cancer generally qualifies patients for assistance and retroactive public medical insurance benefits. This established public

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health policy has been created by government acting on its social values. Debate for support or rejection of public policy considers, but does not exclusively rely upon, scientific data. A reductionist world view of all phenomena as mathematical or molecular events is a powerful tool for analysis. Information is not synonymous with wisdom, however. In a strict scientific sense, much of what physicians do can be challenged.<sup>24</sup>

6. As a diagnostic procedure for the detection of colorectal cancer, 35-cm flexible sigmoidoscopy and 65-cm short colonoscopy have been accepted as diagnostic improvements.<sup>25-27</sup> Depending on insertion depth, the 65-cm colonoscope has a sensitivity of 50 to 80 percent. By providing a means for direct visualization and tissue acquisition, with the option of photographic and video documentation, specificity exceeds 99 percent. The high predictive value of a positive finding is thus extremely useful. The negative predictive value has improved, and further improvement is probable as primary care physicians use longer instruments. Sensitivity and specificity for this procedure are far superior to those for fecal occult blood screening, which is more widely recommended.<sup>7-9</sup> Fecal occult blood screening also has its critics.<sup>28-30</sup>

7. As Frame<sup>31</sup> has previously stated, the major objections to screening sigmoidoscopy seem to be acceptability and cost. Regarding the former, descriptive data have been published on 450 patients undergoing sigmoidoscopy.<sup>32</sup> At the end of the procedure, 448 indicated they would agree to have the procedure again in one year. Data are now available on over 2,000 patients, and the acceptance rate continues to exceed 97 percent. These are uncontrolled data, but the findings are consistent with other published work.<sup>33-39</sup> No data exist suggesting unacceptability or rejection. Some have suggested that the 35-cm instrument is more comfortable than the 65-cm instrument.<sup>40</sup> Family physicians continue to report favorably on the 65-cm colonoscope and even the 105-cm colonoscopes.<sup>41-44</sup> Using data from equipment manufacturers, approximately 10,000 flexible sigmoidoscopes and short colonoscopes were sold in the United States between January 1, 1986, and December 31, 1987; and of the 80 percent that were sold to primary care physicians, fewer than 5 percent were 35-cm instruments. (Manufacturers' sales data from Welch-Allyn, Pentax, Schott, and Olympus.) Medical literature and sales data therefore suggest that 65-cm short colonoscopy is acceptable in the practices of large numbers of physicians who have integrated flexible sigmoidoscopy-colonoscopy into their practices. The examination may be uncomfortable or embarrassing to large numbers of patients, but the same may be true of breast examinations, mammography, and Papanicolaou smears.

8. In the reductionist model costs and benefits are quantified objectively to assist logic in selecting a best answer. Objective benefits must pass through the subjective

gate of perceived value.<sup>23</sup> Programs and services produce costs, and the costs are borne by those who value the perceived benefits. It is acknowledged that increased quantities of life will increase medical costs, but from the patients' point of view the goal is "to die young at as old an age as possible." The primary allegiance of the physician is to the patient, not to the insurer.

9. Primary care physicians have lowered fees for this service.<sup>27,45</sup> Specialist fees for lower gastrointestinal endoscopy beyond 25 to 40 cm have been set at \$300 to \$500 per procedure. The current average primary care fee is generally much lower because responsible primary care physicians decided to provide this service at a more reasonable cost.<sup>46,47</sup> Reasons for this approach have been described, advocated, and published. In a recent series of primary care physicians contacted through continuing medical education experiences, the majority of the fee schedules are 50 percent below 1980 levels for this service.<sup>41</sup> Family physicians are within their legal rights to bill for limited colonoscopy fees, but most voluntarily choose not to do so. In a period when primary care is viewed as financially less remunerative when compared with other specialties, this lowering of fees by primary care physicians deserves mention and emulation. Data describing projected costs have been debated by Eddy and others.<sup>9,45</sup> In a practice-based study, Rumans et al<sup>48</sup> concluded that costs are not higher than the perceived value of the service. Ganiats and Norcross<sup>49</sup> have alluded to an analysis using the General Health Policy model in which flexible sigmoidoscopy is reported to be 20 times as cost effective as fecal occult blood screening. Hospital-based care for metastatic cancer continues to be fragmented<sup>50</sup> and costly.

10. Further research is needed to determine the extent and frequency of screening flexible sigmoidoscopy. Future studies should determine accurate case finding rates and their association with symptoms. It is notable that Yarborough and Waisbren,<sup>51</sup> Meyer et al<sup>52</sup> and others<sup>53-55</sup> have found a significant diagnostic yield even in their "asymptomatic" patients. The data of Yarborough appear to be primary-care based, with tertiary-care bias thus minimized.

Incidence data (ie, new cases after harvesting of tumors found by the initial screening cycle) will be required to determine the optimal interval for subsequent screening cycles. Until then, there is no strong rebuttal to the three- to five-year interval as proposed by Eddy.<sup>9</sup>

Educational efforts will be required to obtain optimal benefits from available endoscopic techniques. The promulgation of biopsy skills to minimize indirect costs secondary to premature referral and the resolution of the hyperplastic "polyp" dilemma are important researchable issues for primary care internists and family physicians.

Thus, on the issue of sigmoidoscopic screening, sci-



entific relief from ambiguity is not around the corner. Physicians, patients, insurers, and government are likely to be debating the issue for years to come. The debate will be peripheral to the millions of patients, aged 50 years or older, who ask their trusted physician the common question, "Do you think I could have colorectal cancer?"<sup>56</sup> In my view, based upon the above observations, family physicians should be offering, among other things, screening flexible sigmoidoscopy.

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## An Opposing View

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Colorectal cancer is the second leading cause of cancer death in the United States. It is not surprising, therefore, that high priority has been placed on screening and the early detection of this disease. The hope is that early detection will lead to decreased morbidity and mortality. Concern over the consequences of a disease, no matter how important, however, does not justify abandoning the scientific method and recommending new technology with no consideration to cost, acceptability, or efficacy. It is a fact that no method of screening for colorectal cancer has been shown by randomized controlled studies to reduce mortality from this disease. All recommendations for colorectal cancer screening are based on incomplete data and should be critically scrutinized by physicians.

Four methods of screening for colorectal cancer—rectal examination, rigid sigmoidoscopy, flexible sigmoidoscopy, and fecal occult blood testing—have been advocated. Rectal examination is recommended<sup>1</sup> on the basis of tradition without any evidence it is an effective screening test. One has only to compare the 7-cm length of an examining finger with the 150-cm length of the colon to realize rectal examination will miss most cancers.

Two large studies<sup>2,3</sup> are used to support the value of rigid sigmoidoscopy as a screening technique. Gilbertsen<sup>2</sup> studied 18,158 patients in a 25-year study including a total of 103,645 rigid sigmoidoscopies. On initial sigmoidoscopy one cancer was found per 783 examinations. These patients had a 64 percent five-year survival. In 92,000 follow-up sigmoidoscopies only 11 cancers were detected, all localized. This number is only 15 percent of the cancers that would be expected in that population.

Gilbertsen attributed the low incidence of rectosigmoid cancers to the removal of many polyps found by sigmoidoscopy.

Several problems make it difficult to evaluate the value of Gilbertsen's results. There was no control population for direct comparison of the study results. The patients were volunteers for a long-term research project and may not be representative of the national population whose cancer incidence was used as a reference for the study results. The study considered cancers occurring only in the distal 25 cm of the colon. There was no mention of overall colorectal cancer mortality including lesions originating in the proximal bowel.

A randomized controlled study of the multiphasic health examination from the Kaiser Health Plan<sup>3</sup> found decreased mortality from colorectal cancer in the study group screened by rigid sigmoidoscopy and digital rectal examination compared with the control group, which received "usual care." It is hard to attribute this result to the use of routine sigmoidoscopy, as few of the study patients actually had sigmoidoscopic examination. Only 60 percent of the study group showed up for testing each year, and only one third of these (20 percent of the total study population) received a sigmoidoscopic examination.<sup>1</sup>

Indeed, the efficacy of rigid sigmoidoscopy may be a moot point because, in spite of significant promotion by the American Cancer Society and other organizations over the past 30 years, rigid sigmoidoscopy has continued to be unacceptable to most asymptomatic patients. Rodney et al<sup>4</sup> quote several examples of noncompliance with rigid sigmoidoscopy and state, "Rigid sigmoidoscopy is clearly



unacceptable to physicians and patients. Because of non-acceptance it is a non-issue."

Flexible sigmoidoscopy and fecal occult blood testing have both been shown to detect some cancers at earlier stages than found in control populations.<sup>5,6</sup> Flexible sigmoidoscopy using a 60-cm or 65-cm fiberoptic sigmoidoscope will examine two to three times as much of the bowel and detect two to six times as many polyps and two to three times as many cancers as the rigid sigmoidoscope.<sup>7</sup> The major purpose of this discussion is to examine the evidence that flexible sigmoidoscopy is a valuable screening test for colorectal cancer and should be recommended to all asymptomatic adults aged over 50 years at some interval, probably every three to five years.

An understanding of the natural history of colorectal cancer is a prerequisite to the discussion of screening for this disease. Ninety-five percent of cases occur in persons aged over 45 years and 90 percent of cases occur in persons aged over 50 years. Risk factors include family history of colorectal cancer and ulcerative colitis.

It is agreed by experts<sup>8,9</sup> that most colorectal cancer arises from adenomatous or villous polyps. Hyperplastic polyps are not premalignant.<sup>8</sup> Autopsy studies have shown a prevalence of polyps in older adults of 10 to 20 percent.<sup>9</sup> As the incidence of colorectal cancer is 45 cases per 100,000 population (much less than the polyp prevalence of 10 to 20 percent), it is clear that most polyps do not become malignant. Morson<sup>8</sup> estimates that 5 percent of adenomatous polyps and 40 percent of villous adenomas will eventually become malignant. From studies of untreated polyps Morson also states it takes at least five years and probably an average of ten years for a polyp to become malignant. Between 27 and 75 percent of patients with a polyp will have other synchronous polyps.

The distribution of polyps has changed in the last several decades. In a 1946 survey<sup>10</sup> 82 percent of polyps were located in the rectum or sigmoid colon. In contrast, Greene<sup>11</sup> reports data from 1971 through 1980 showing 37 percent of polyps were located proximal to the splenic flexure. A marked shift in the distribution of polyps toward the right side of the colon has occurred.

The natural history of colorectal cancer indicates that although most cancers arise from polyps, most polyps do not become malignant. There is a long lead time from polyp to cancer of five to 15 years, and there has been a recent marked shift in the distribution of polyps and cancers toward the right side of the colon.

Several questions must be answered before a test is considered for recommendation as a routine to be done by all primary care physicians on all patients over the age of 50 years.

1. How sensitive and specific is the test?
2. What is the evidence screening will lead to decreased mortality?

3. What is the cost of screening?
4. Is the test acceptable to most asymptomatic patients?
5. Is the test feasible for physicians and health care providers?
6. How much better is the test compared with other available screening modalities?

Many studies of flexible sigmoidoscopy have been published in the past ten years. Most of these studies discuss sigmoidoscopy for symptomatic patients and do not address issues of screening and prevention of colorectal cancer. In Table 1 is a list of those studies that separate and allow analysis of data involving flexible sigmoidoscopy in asymptomatic patients.

Four of these studies looked at high-risk populations (Bat et al,<sup>18</sup> Bang et al,<sup>19</sup> Ibrahim et al,<sup>16</sup> and Wherry<sup>14</sup>). Two describe findings from patients referred to endoscopy clinics (Lipshutz et al,<sup>12</sup> and Meyer et al<sup>13</sup>). One (Lipshutz et al) did not include fecal occult blood negativity as part of the definition of an asymptomatic person. Only four studies (Johnson et al,<sup>7</sup> Roosevelt et al,<sup>15</sup> Yarborough and Waisbren,<sup>17</sup> and Rumans et al<sup>20</sup>) actually report screening flexible sigmoidoscopy in the community setting.

With the exception of Yarborough's study, which found an unusually high prevalence of polyps and cancers, the data show that on initial flexible sigmoidoscopy significant polyps (adenomatous, or villous greater than 5 mm size) are found in about 8 percent of patients. Cancers are found in 0.4 percent of patients.

These two facts are really all that is known about screening flexible sigmoidoscopy.

Because no outcome or follow-up data are reported by any of the studies, it is impossible to evaluate the sensitivity and specificity of the test. Endoscopy is widely believed to be the "gold standard" for detecting cancers in that portion of the bowel that is visualized. Comparing the length of the colon with the length of the sigmoidoscope, it can be expected that the 40 percent of cancers occurring proximal to the splenic flexure will be missed by flexible sigmoidoscopy. Whether more cancers in the distal bowel will be missed by primary care physicians doing sigmoidoscopy is unknown.

Without outcome data it is also impossible to compare the efficacy of fecal occult blood testing with flexible sigmoidoscopy as a screening test for colorectal cancer. That many polyps and a few in situ cancers were found on sigmoidoscopy in patients who had negative occult blood test results as reported by Bang<sup>19</sup> does not mean these patients would have been cured by sigmoidoscopy and died without it. Given that most polyps will not become cancer and the long progression time from early to invasive cancer, it is possible many cancers and polyps would have been diagnosed at a later but still curable date by fecal occult blood testing.

Only one study, that by Bat et al,<sup>18</sup> includes information



TABLE 1. STUDIES OF FLEXIBLE SIGMOIDOSCOPY IN ASYMPTOMATIC PERSONS

| Author Date                   | Study Setting                     | Number of Patients | Patients with Polyps No. (%) | Patients/Significant Polyps* No. (%) | Number of Cancers No. (%) | Population Denominator | Percent Compliance | Repeat Examinations | Outcome Data |
|-------------------------------|-----------------------------------|--------------------|------------------------------|--------------------------------------|---------------------------|------------------------|--------------------|---------------------|--------------|
| Lipshutz 1979 <sup>12</sup>   | Referred veterans                 | 200**              | 39 (19.5)                    | 19 (9.5)                             | 0                         | ?                      | ?                  | 0                   | none         |
| Meyer 1980 <sup>13</sup>      | Referred gastrointestinal clinic  | 122                | 17 (14)                      | 9 (7.3)                              | 1 (0.08)                  | ?                      | ?                  | 0                   | none         |
| Wherry 1981 <sup>14</sup>     | US State Department               | 417                | 52 (12.4)                    | ?                                    | 0                         | ?                      | ?                  | 0                   | none         |
| Johnson 1984 <sup>7</sup>     | Family practice residency         | 140                | 4 (2.9)                      | 4 (2.9)                              | 0                         | ?                      | ?                  | 0                   | none         |
| Rosevelt 1984 <sup>15</sup>   | Kaiser gastrointestinal clinic*** | 725                | 64 (8.8)                     | 55? (7.5)                            | 3 (0.4)                   | ?                      | ?                  | 0                   | none         |
| Ibrahim 1984 <sup>16</sup>    | Pattern makers†                   | 409                | 44 (10.7)                    | ?                                    | 1 (0.2)                   | ?                      | ?                  | 0                   | none         |
| Yarborough 1985 <sup>17</sup> | Private internal medicine         | 435                | 86 (19.7)                    | 86 (19.7)                            | 19 (4.3)                  | ?                      | ?                  | 0                   | none         |
| Bat 1986 <sup>18</sup>        | Askenazi Jews†                    | 287                | 28 (9.8)                     | ?                                    | 3 (1.0)                   | 1339                   | 21                 | 0                   | none         |
| Bang 1986 <sup>19</sup>       | Pattern makers†                   | 1473               | 220? (15.5)                  | ?                                    | 3 (0.2)                   | 11,700                 | ?                  | 0                   | none         |
| Rumans 1986 <sup>20</sup>     | Private internal medicine         | 252                | 27 (10.7)                    | 27 (10.7)                            | 2 (0.7)                   | ?                      | ?                  | 0                   | none         |

\* Significant polyps are adenomatous or villous polyps greater than 5 mm in diameter (excludes hyperplastic polyps)

\*\* Patients were asymptomatic but not necessarily quiac-negative

\*\*\* Sigmoidoscopies were done by a nurse practitioner

† High-risk population

about the denominator of the population screened. In their study of a high-risk population, 287 of the 1,339 persons (21 percent) offered screening received flexible sigmoidoscopy. The study by Bang et al<sup>19</sup> of high-risk pattern makers does not specifically mention how many persons were offered sigmoidoscopy but does state there were 11,700 eligible members of the union. If all were offered flexible sigmoidoscopy, the compliance would be 12 percent. Brock and Hainer<sup>21</sup> in a family-practice-based study reports a compliance with flexible sigmoidoscopy of 6 percent. Thus although survey reports indicate patients find flexible sigmoidoscopy more comfortable than rigid sigmoidoscopy, there is little evidence that a significant proportion of asymptomatic people will comply with screening flexible sigmoidoscopy.

None of the studies in Table 1 provides any information about the diagnostic yield, efficacy, or patient compliance with repeat follow-up screening sigmoidoscopy, yet repeat examinations are recommended every three to five years.

The cost of flexible sigmoidoscopy is enormous compared with other recommended screening tests; comparable only to the cost of screening for breast cancer by mammography. At \$75 to \$150 per examination, it is ten times more expensive than fecal occult blood testing. Cost as such may not be sufficient reason to exclude a screening

test, but a more expensive test requires greater assurance of efficacy before a recommendation to use it for routine screening is made.

The feasibility of primary care physicians doing large numbers of screening flexible sigmoidoscopies is unknown. There is little doubt many primary care physicians can learn flexible sigmoidoscopy. Not all primary care physicians will be willing or able to include flexible sigmoidoscopy in their practice, however. Crespi et al<sup>22</sup> found one of five physicians could not be trained to do flexible sigmoidoscopy. Rodney et al<sup>23</sup> reports 10 of 18 graduated residents trained to do flexible sigmoidoscopy currently include it in their practice.

Routine screening flexible sigmoidoscopy would place severe time demands on busy practicing physicians. A typical family physician with 3,000 active patients, 1,000 of whom might be aged over 50 years, who works 200 days per year would have to do five sigmoidoscopies every working day to initially screen the population and then two examinations daily just for subsequent screening. If screening flexible sigmoidoscopy is to become a reality, groups of family physicians may need to train physician assistants or nurse practitioners to do the endoscopy so the family physicians can continue to care for the whole person.<sup>15</sup>



In summary, it is known that screening flexible sigmoidoscopy will detect significant polyps in about 8 percent of patients and early cancers in about 0.4 percent of asymptomatic patients on initial examination. It is not known whether such screening will decrease mortality from colorectal cancer or how much better sigmoidoscopy is than fecal occult blood testing. The few available data show poor acceptance of flexible sigmoidoscopy by asymptomatic patients. There are no data about efficacy or compliance with repeat screening sigmoidoscopy. Flexible sigmoidoscopy is a very expensive screening test. It can be taught to primary care physicians but will require reorienting the priorities and direction of their practice. Some primary care physicians will not choose to do flexible sigmoidoscopy and would have to refer patients for this test.

At the present time it is premature to recommend flexible sigmoidoscopy as a routine screening examination for colorectal cancer. Physicians interested in doing flexible sigmoidoscopy should be encouraged to organize their efforts in such a way that needed research information can be generated. Specifically they should know the denominator of the population screened, obtain longitudinal outcome data using controls if possible, and measure patient compliance and efficacy with repeat as well as initial screening flexible sigmoidoscopy.

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