

## Feasibility of colonoscopy screening: discussion of issues and recommendations regarding implementation

Colonoscopy was first discussed as a screening test for individuals at average risk for colorectal cancer in 1988.<sup>1</sup> Since then, there has been slowly but steadily increasing acknowledgment that colonoscopy has the greatest efficacy of currently available screening tests. Recent guidelines and recommendations have endorsed colonoscopy every 10 years as a screening option<sup>2,3</sup> or as the preferred test if resources and expertise are available.<sup>4</sup> Current recommendations for screening colonoscopy are based on estimates of efficacy,<sup>2-7</sup> and the rationale for colonoscopy relative to other available strategies has been reviewed in detail.<sup>4</sup> Cross-sectional studies<sup>8,9</sup> confirm that 5% to 10% of asymptomatic subjects 50 to 75 years old have advanced colonic neoplasia and that many of these individuals would not be identified with other screening tests. Further, initial experience has demonstrated an excellent safety profile for screening colonoscopy, with no perforations in the first 6000 reported examinations.<sup>8-15</sup> Colon screening models have found that colonoscopy may be more cost-effective than other strategies, depending on the range of assumptions used,<sup>16-24</sup> and surveys indicate a significant preference for colonoscopy among patients agreeable to invasive testing.<sup>25</sup> Indeed, safe and efficient application of screening colonoscopy in a compliant population could prevent most colorectal cancers in the United States.<sup>5-7</sup>

As with other screening tests, there are substantial uncertainties regarding compliance and feasibility of screening colonoscopy. Feasibility is particularly problematic because the colonoscopists and infrastructure needed to screen the population may be inadequate. This issue is timely in light of the recent enactment of federal law in the United States, effective July 1, 2001, entitling Medicare beneficiaries to a screening colonoscopy every 10 years. In this commentary, issues pertinent to implementation of screening colonoscopy are discussed. The availability and demand for screening colonoscopy are estimated, and mechanisms are explored whereby these could be increased. Our estimates are based on limited data and are admittedly crude.

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However, these serve to initiate a discussion of feasibility and to suggest practices to be considered for improving availability, as well as issues that require further investigation.

### DEMAND FOR SCREENING COLONOSCOPY

The potential annual demand for screening colonoscopy in the United States can be calculated by dividing the number of adults age 50 to 70 years by the interval recommended for screening (currently 10 years).<sup>2-4</sup> Demographic data suggest there are about 77 million Americans in this age group, with 4 million more added annually.<sup>26</sup> Assuming that 10% of this group would undergo screening colonoscopy in any given year, the maximum number of expected examinations per year is 7.7 million. The actual number of colonoscopies performed in the United States in 1999 was 4.4 million.<sup>27</sup> Thus, the potential demand exceeds the number of colonoscopies currently performed.

For several reasons, actual demand would be substantially less than that suggested by simple calculation. First, compliance with any screening test is never 100%. Compliance with fecal occult blood test (FOBT) and sigmoidoscopy screening is no better than 25% to 30%.<sup>28-31</sup> Compliance could reach 60%, a level similar to that for mammography in women over age 50 years,<sup>32,33</sup> but is unlikely that compliance with colonoscopy would exceed that for mammography. Second, some patients will have had a prior colonoscopy to evaluate GI symptoms. In the Veterans Administration screening colonoscopy study, nearly one-half of prospective screenees had a colon examination within 10 years.<sup>8</sup> Because many underwent sigmoidoscopy or barium enema, some of these individuals would still benefit from screening colonoscopy. A telephone survey of middle income persons in the Pittsburgh area found that 19% of average-risk and 33% of high-risk persons had undergone a full colon examination within 5 years.<sup>34</sup> Based on these data, perhaps one-fourth of patients over age 50 years will have had a complete colon examination. Third, some patients with serious medical problems, particularly those approaching age 70 years, would not be candidates for further screening. Data on recruitment for the Veteran's Administration study suggest this would be about 5% to 10% of subjects.<sup>8</sup> Calculations based on the above assumptions suggest that implementation of colonoscopy screening would create an annual demand for about 2.6 million colonoscopies (Table 1).

The actual demand would be less than 2.6 million because of additional limiting factors. For example, the demand for screening colonoscopy is controlled by reimbursement. Reimbursement for screening

colonoscopy every 10 years has been legislated for Medicare beneficiaries, but this does not mean that private insurers will follow suite. Currently, such coverage is mandated in only 1 of 50 states (Virginia). Some patients and physicians will choose screening tests other than colonoscopy<sup>25</sup>; these will continue to be available and may be preferred by some patients as well as physicians trained in these methods. Thus, the actual demand for screening colonoscopy is likely to be significantly less than 2.6 million procedures per year.

The above considerations are based on a strategy of colonoscopy every 10 years beginning at age 50 years. However, the prevalence of advanced neoplasia doubles between the ages of 50 and 60 years.<sup>8-10</sup> In addition, with increasing age there is a shift to the right colon in the distribution of adenomas, advanced adenomas, and cancer.<sup>35,36</sup> Therefore, the benefit of colonoscopy versus sigmoidoscopy is magnified with increasing age. Taking this into account, one suggested strategy is screening sigmoidoscopy at age 50 and colonoscopy at age 60 years.<sup>4</sup> In fact, sigmoidoscopy at age 50 followed by colonoscopy 10 and 20 years later would achieve a large fraction of the reduction in mortality expected with colonoscopy every 10 years from age 50 and would improve the feasibility of colonoscopy screening in many settings.

Ultimately, the workload associated with a screening colonoscopy program will depend on compliance. This is influenced by many factors, including public awareness of the problem of colon cancer and perceptions of discomfort or embarrassment associated with screening tests. With regard to the interaction between demand and availability for colonoscopy, the reality of imperfect compliance should be considered in discussions of the feasibility of screening colonoscopy. The success of screening will ultimately depend on the success of measures to improve compliance. For example, celebrity endorsements may improve patient awareness.<sup>37</sup> Recent studies have found that videos in physician offices enhance compliance with screening.<sup>38</sup> Improved methods of bowel preparation<sup>39</sup> and sedation,<sup>40,41</sup> which preserve patient comfort and reduce anxiety, may decrease resistance to screening. Indeed, the performance and safety of colonoscopy could be improved in several respects.<sup>42</sup>

## AVAILABILITY OF SCREENING COLONOSCOPY

### Shifting current resources

As noted, 4.4 million colonoscopies were performed in the United States in 1999; implementation of screening colonoscopy would require something less than 2.6 million examinations per year.

**Table 1. Estimation of demand for screening colonoscopy**

| Eligible Americans         | Potential demand (millions) |
|----------------------------|-----------------------------|
| Too ill (5%)               |                             |
| All eligible Americans     | 77                          |
| Minus those too ill (5%)   | 73.2                        |
| Minus 40% noncompliant     | 43.9                        |
| Minus 25% already screened | 25.6/10y or 2.56/y          |

One possible mechanism for increasing the availability of screening colonoscopy is a shift in resources, that is, for practicing colonoscopists to allot more time for colonoscopy. The number of practicing endoscopists in the United States is unknown. Gastroenterologists and colorectal surgeons are almost universally trained in colonoscopy but there are wide variations in numbers of colonoscopies performed by individuals. General surgeons and primary care physicians also perform colonoscopies, particularly in undeserved areas. Little information is available on the time they devote to colonoscopy, their level of training, and whether they could devote more of their practice to colonoscopy. The extent to which colonoscopists could spend more time in endoscopy units performing colonoscopy is uncertain, as is the impact that such a shift would have on other health care services.

Time spent in the endoscopy unit by currently practicing colonoscopists could be increased by adopting an open access system for patients undergoing screening. These patients are by definition asymptomatic and generally healthy. The preprocedure assessment is brief and can readily be accomplished immediately prior to the colonoscopy. Similarly, open access would be suitable for many otherwise healthy patients who undergo colonoscopy because of a positive FOBT or straightforward symptoms such as non-emergent rectal bleeding. Open access reduces time spent by colonoscopists in clinic and allows for increases in time in the endoscopy suite.

A policy of screening colonoscopy will also make endoscopic resources available that are currently used to perform colonoscopy for other indications or for screening flexible sigmoidoscopy. For example, data from the Clinical Outcomes Research Initiative (CORI) indicate that nationally, 10% of colonoscopy procedures are performed for abdominal pain, bloating, and change in bowel habit.<sup>43</sup> However, the proportion of patients with these symptoms without bleeding who have neoplasia is similar to that of asymptomatic populations.<sup>43-45</sup> If these patients undergo routine screening colonoscopy, they will not need a further colonoscopy to evaluate stable symptoms that have no predictive value for cancer, thus shifting workload from evaluation of symptoms to screening.

**Table 2. Effect of shifting resources to screening**

| Indication for colonoscopy (% of workload)             | Current annual volume of colonoscopies* | Potential reduction | Potential new capacity | New workload due to screening |
|--|---|---------------------|------------------------|-------------------------------|
| Surveillance after cancer/adenomas (25%)               | 1,100,000                               | 50%                 | 550,000                | 550,000                       |
| Positive *FOBT (15%)                                   | 660,000                                 | 100%                | 660,000                |                               |
| Abdominal pain, altered bowel habit (10%)              | 440,000                                 | 100%                | 440,000                |                               |
| Abdominal flexible sigmoidoscopy or barium enema (10%) | 440,000                                 | 100%                | 440,000                |                               |
| Flexible sigmoidoscopy by specialists                  | 500,000                                 | 100%                | 250,000                |                               |
|  | Total                                   |                     | 2,340,000              | 550,000                       |
|  | New screening procedures (from Table 1) |                     |                        | 2,560,000                     |
|  |   |                     |                        | 3,110,000                     |

Estimated difference between new demand and supply created by shifting procedures from current use to screening: (3,110,000 – 2,340,000 = 770,000).

\*References 27, 46.

Rectal bleeding is a common indication for colonoscopy (19% of examinations in the CORI database).<sup>46</sup> If patients with this symptom have already had an adequate examination of the colon, further colonoscopy could be replaced in some cases by limited proctoscopy to rule out new rectal and anal pathosis. Likewise, the positive FOBT accounts for about 15% of the current colonoscopy workload.<sup>46</sup> The FOBT would be eliminated for patients willing to accept screening colonoscopy.

Some aspects of current colonoscopy practice would not shift if colonoscopy screening were widespread. Patients with prior advanced neoplasia, hereditary colorectal cancer syndromes, strong family histories of colorectal cancer, and inflammatory bowel disease would still require a colonoscopy at regular intervals.

Flexible sigmoidoscopy is often performed by non-GI specialists. However, it is estimated that gastroenterologists perform about 1 million sigmoidoscopies annually.<sup>46</sup> These examinations are predominantly performed in patients over age 50 years, and about 50% (or 500,000) are performed to screen asymptomatic patients or to evaluate hematochezia or change in bowel habits. Most of these procedures could be replaced with screening colonoscopy. If 1 colonoscopy is equivalent to 2 sigmoidoscopies in terms of time commitment, a capacity for an additional 250,000 colonoscopies could be realized if some resources devoted to sigmoidoscopy were shifted to colonoscopy.

A reduction in the current colonoscopy and flexible sigmoidoscopy workload, as outlined above, could create a capacity of up to 2.3 million screening colonoscopy procedures per year (Table 2). To realize this would require that clinicians place a high level of confidence in previous colonoscopy examinations in patients who have stable symptoms or symptoms with little predictive value for cancer.

The availability of screening colonoscopies could be increased by reducing the use of colonoscopy for sur-

veillance. Currently, surveillance after a diagnosis of adenoma or cancer accounts for nearly 25% of all colonoscopy procedures.<sup>46</sup> Data from the National Polyp Study<sup>47</sup> suggest that 90% of the observed reduction in cancer incidence was due to the baseline examination and polypectomy, with little benefit derived from subsequent surveillance. CORI data suggest that patients undergoing surveillance colonoscopy have lower rates of advanced neoplasia than patients undergoing first examinations for a positive FOBT or asymptomatic screening (unpublished observations). Based on data from recent studies,<sup>8,9</sup> approximately 75% of patients with neoplasia identified at screening are found to have only tubular adenomas less than 10 mm in size. A growing body of data suggests that the risk of finding advanced neoplasia at follow-up examinations in these patients is low and consequently they may need only infrequent surveillance.<sup>48</sup> Ongoing studies, including the National Polyp Study and the Veteran's Administration cooperative study, specifically address the issue of which patients are at risk for the subsequent development of significant neoplasia. Based on current knowledge, our belief is that surveillance intervals can be safely extended beyond 5 years for most patients with tubular adenomas less than 1 cm in diameter. This would substantially reduce the workload related to surveillance and increase the capacity for screening.

It may, however, be argued that screening would identify many more patients with small adenomas for whom surveillance would be undertaken according to current recommendations. Thus, any reduction in surveillance frequency for patients with small tubular adenomas would be offset by the identification of more patients with both low- and high-risk adenomas. If surveillance for most patients with small tubular adenomas could be safely deferred for 10 years, then a substantial reduction (55%) in surveillance colonoscopy would be realized. If one-half of patients with low risk adenomas undergo 1 surveillance examination at 5 years because of new symp-

toms that develop during follow-up, or because of multiplicity of adenomas at baseline, then a 27% reduction in surveillance workload would be realized.

Issues relevant to shifting resources are considered in Table 2. The above considerations, when combined, suggest that a large percentage of the colonoscopies needed for screening could be obtained by shifting examinations from current indications, or that screening colonoscopy could replace the need for many examinations currently performed for other indications. Achieving such a shift would require widespread consensus regarding recommended intervals for surveillance and adherence to these recommendations.

### Increasing the capacity for colonoscopy training

An obvious way to increase capacity is to train more colonoscopists. It is estimated that competence in colonoscopy cannot be assessed until a trainee has completed well over 100 procedures.<sup>49</sup> Any effort to increase the number of trained colonoscopists must not compromise the quality of colonoscopy. High rates of cecal intubation, accurate recognition of pathosis, and low complication rates are essential components of any screening colonoscopy program.

The attainment of competence in colonoscopy requires a long period of dedicated training that is generally only available during a fellowship in gastroenterology.<sup>50</sup> In recent years, there has been a nearly 30% de facto reduction in the number of such fellowship positions in the United States as fellowship programs expanded to 3 years with no increase in the number of available positions. It is unlikely that additional monies to fund new fellowship positions will be forthcoming. Furthermore, most residency programs in Internal Medicine and Surgery would not be able to offer sufficient time for dedicated training. Practitioners (medicine or surgery) could take sabbatical leave for training, but few practice settings offer such an opportunity.

If there are too few trained colonoscopists, perhaps colonoscopy screening could be expanded by training of non-physicians. There is evidence that non-physicians can perform flexible sigmoidoscopy at the same level of competence as physicians.<sup>51-54</sup> However, there is little published experience regarding the performance of colonoscopy by non-physicians.<sup>55</sup> The use of non-physician personnel for screening colonoscopy would require demonstration of the same standards of performance expected of physicians. Further study is needed before colonoscopy by non-physicians can be recommended.

The reality at present, unfortunately, is that there is no available mechanism by which the number of fully trained, competent colonoscopists can be significantly increased.

### Increased productivity and efficiency

A more immediate mechanism by which the availability of screening colonoscopy can be augmented is to increase the productivity of currently trained colonoscopists. A nearly 4-fold variation between individual endoscopists in the number of procedures performed per unit time has been observed recently.<sup>56</sup> Part of this variation is the result of different levels of experience and the intensity with which individual endoscopists work. However, some of the variation relates to the level of support received by individual endoscopists for accomplishing tasks that are ancillary to the actual colonoscopy procedure. For example, the components of a colonoscopy that may involve the colonoscopists include preprocedure assessment, informed consent, establishment of intravenous access, monitoring, sedation, the actual colonoscopy procedure, recovery room assessment, postprocedure discussion with patient and family, and report generation. In addition, before the next procedure can be started, the endoscopy room must be cleaned and prepared for the next patient (room "turnover").

A number of specific measures can be used by individual endoscopists to improve productivity. For example, block scheduling improves efficiency by maximizing the number of procedures that an individual endoscopist can perform per session. Units that do not block schedule generally have an extremely high ratio of endoscopists to procedure rooms. Thus, in these settings the factor limiting procedure volume is not the endoscopist but ancillary resources (i.e., rooms, assistants). Procedure volume can be increased by allocating 2 procedure rooms per endoscopist. This dramatically reduces room turnover times from the perspective of the endoscopist. Individual endoscopists may increase productivity by delegating the informed consent process and/or a recovery room visit to ancillary personnel. Alternate approaches to sedation can also be used to increase productivity including administration of anesthetic agents by nurse anesthetists or anesthesiologists, bolus administration of sedative and analgesics drugs,<sup>57</sup> and administration of sedative drugs by registered nurses. Administration of anesthesia by nurse anesthetists and anesthesiologists improves the efficiency of colonoscopy but it is not cost-effective. Endoscopy units should assess their support of individual endoscopists and whether they provide endoscopists with the resources and opportunity to optimize efficiency and procedure volume.

### QUALITY ISSUES

The critical success factor for a screening colonoscopy program will be the quality of colonoscopic

examinations. Adequate training of colonoscopists, high cecal intubation rates, careful examination technique (high sensitivity for neoplasms), and effective and safe polypectomy are crucial to maximization of the impact of screening colonoscopy on colorectal cancer incidence and mortality while minimizing procedure-related morbidity and mortality. Continuous quality improvement programs directed to these end points will be essential to all screening colonoscopy programs.<sup>58</sup>

### SUMMARY

The demand for screening colonoscopy will be much less than simple population-based calculations would suggest. However, the demand will be substantial and hopefully will increase with better public awareness and improvements in colonoscopy. The availability of colonoscopy to meet this demand can likely be met by implementation of several measures: (1) reduced use of colonoscopy for post-polypectomy and postcancer resection surveillance; (2) replacement by screening colonoscopy of some flexible sigmoidoscopy by gastroenterologists and colonoscopy for low-yield indications; (3) open access for screening colonoscopy; (4) training of current colonoscopists in measures that improve efficiency. Effective implementation of these measures would require a significant effort to ensure compliance of practicing colonoscopists with recommended intervals for screening and surveillance. Importantly, improved efficiency in delivery of screening colonoscopy will require an investment in endoscopic facilities and resources to allow individual endoscopists to become efficient. Full exploitation of these measures is likely to produce sufficient availability of colonoscopy to meet the rising demand. These mechanisms, in our opinion, are more feasible than training additional colonoscopists. Further, the wisdom of training large numbers of colonoscopists is uncertain, given that accurate, cost-effective noninvasive testing for colorectal cancer will almost certainly eventually appear. This would position colonoscopy in only a therapeutic role, thereby reducing the need for colonoscopists. Thus, shifting endoscopic resources and improving the productivity of existing endoscopists are perhaps the most feasible and appropriate mechanisms for meeting the anticipated demand for screening colonoscopy, given that the duration of this demand is uncertain.

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