The Cost-Effectiveness of Colorectal Cancer Screening in the Elderly

INTRODUCTION

How cost-effective is colorectal cancer (CRC) screening in the elderly? This question can be answered only by comparing the net health care costs brought about by a screening strategy with the health effects achieved as a result. The health effects of a preventive strategy such as CRC screening include impacts on quality of life as well as on its length. Measuring these two dimensions of health effects is often difficult; some cost-effectiveness analyses include only mortality effects -- life-yeas gained -- and leave quality-of-life improvements implicit; others attempt to capture both dimensions in composite measures such as "wellness years" or "quality-adjusted life years" gained from a preventive strategy.

Estimation of the cost-effectiveness of CRC screening in the elderly is especially difficult because of the uncertainty about whether CRC screening is effective at all in preventing CRC or reducing its lethality. If CRC screening is not effective in reducing CRC incidence or mortality in the elderly, then it is clearly not cost-effective. It is only costly. It may even be both costly and risky, because the screening and followup procedures brought about by a screening strategy carry their own medical risks. However, if CRC screening is effective in reducing cancer incidence and death, then the ratio of net health care costs to a measure of effectiveness can help policy makers determine whether the strategy is worth its costs and risks.

Whether CRC screening can extend the lives of elderly people through prevention or earlier detection of CRCs is not known at present. Indirect evidence does exist, however, about the natural course of the disease, the accuracy of the various screening tests in detecting polyps and CRC, rates of medical complications associated with the screening tests, followup procedures and cancer treatment, and the life expectancy of people with CRC at various stages. Though this evidence is imperfect and has some important gaps, if used judiciously it is possible to explore the potential impact of CRC screening on the health of elderly people. These potential net health impacts can then be compared with the net health care costs associated with screening in elderly people.

To resolve the dilemma posed by uncertainty about net effects, Office of Technology Assessment (OTA) estimated the net health care cost per additional year of life gained from CRC screening using data and assumptions that were in every case pessimistic toward screening. We examined the existing evidence on screening test accuracy, the natural course of the disease in the elderly, medical risks, and costs with the objective of deliberately underestimating the effectiveness and overestimating the costs associated with screening. If the resulting conservative estimate of cost-effectiveness of CRC screening compares favorably with other preventive interventions for the elderly, particularly those that have already been included as Medicare benefits, then confidence that CRC screening is at least as cost-effective as these other services would be high.

The remainder of this chapter describes OTA's analysis of the cost-effectiveness of four alternative strategies for CRC screening and compares the results of that analysis with findings about other preventive services for the elderly and with other studies of CRC cost-effectiveness.

SCREENING, FOLLOWUP, AND SURVEILLANCE STRATEGIES

The National Cancer Institute (NCI) recommends that adults without specific risk factors for CRC begin a program of periodic screening for CRC at age 50 and continue for the rest of their lives. The recommended screening program entails an annual fecal occult blood test (FOBT) and flexible fiberoptic sigmoidoscopy (FSIG) at 3- to 5-year intervals (See table 2). OTA examined four screening schedules, including the NCI schedules, for people beginning at age 65 and continuing until they die or reach the age of 85:

- Regimen 1: Annual FOBT and a sigmoidoscopic examination every 3 years;

- Regimen 2: Annual FOBT and a sigmoidoscopic examination every 5 years;
- Regimen 3: Annual FOBT and ***one*** sigmoidoscopic examination upon entry to Medicare at age 65;
- Regimen 4: Annual FOBT with ***no sig***moidoscopy.

For all regimens, screening was assumed to cease when the individual reaches age 85, although surveillance of people previously found to have polyps would continue for the rest of their lives. Because the lengths of sigmoidoscopes vary, the model was further refined to estimate separately the effectiveness and costs of screening with a 60 cm sigmoidoscope and a 35 cm sigmoidoscope. The longer scope detects a greater proportion of colonic polyps and cancers than the shorter one, but the costs and medical risks of followup and surveillance are higher.

Over the course of their remaining lives, 65-year-old people would undergo repeated screening tests, followup diagnostic testing when the screening tests are positive, polyp removal (polypectomy) when polyps are found as part of the screening or followup tests, and periodic surveillance with colonoscopy after polypectomy to screen for new polyps. In addition, when cancers are found, patients undergo evaluation and treatment for the cancer based on the stage at detection.

The effectiveness and cost of following up on a positive screening test depends on the diagnostic technologies employed. Two alternative followup protocols have been recommended (32,44,47,72,91, 122,143,155). The first is to go directly from a positive screening test to a full colonoscopy with polypectomy if necessary. The alternative is to followup with sigmoidoscopy (if the screening test was an FOBT) and a DCBE. The relative advantages of the two followup procedures are currently subjects of debate (44,53). Comparisons of relative accuracy, procedure risk, patient comfort and cost underlie different conclusions about the two procedures.

In this study OTA assumed a positive screening sigmoidoscop would result in full colonoscopy with polypectomy.[1] All positive FOBT tests were also assumed to result in a diagnostic colonoscopy and, if a polyp is found, polypectomy. Pathological tests are universally recommended for all removed polyps, and the OTA analysis assumed that they will be done.

Once a polyp has been discovered and removed, the patient is typically subject to periodic surveillance by colonoscopy, on the assumption that people previously discovered to have polyps are at higher risk of future recurrence of polyps and cancers (87,114). The American Gastroenterological Society recommends that surveillance begin one year after the polypectomy and, if the first surveillance colonoscopy is negative, that it continue at 3- to 5-year intervals (44). A large multi-center randomized trial funded by the NCI is currently underway to compare the effectiveness of surveillance at 1 year and 3 years vs. 3 years after polypectomy (113). The OTA analysis assumed a surveillance colonoscopy frequency of every 4 years beginning 4 years after the initial polypectomy, but the impact of moving to a 2-year surveillance interval was investigated in a sensitivity analysis reported later in this paper.

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[1] **The procedure costs of colonoscopy are higher than a combination of sigmoidoscopy and DCBE. The average Medicare allowed payment for a sigmoidoscopy and a DCBE together in 1986 was $213 compared to $376 for a diagnostic colonoscopy and $626 for a colonoscopy with polypectomy. The impact on total costs of assuming followup with colonoscopy rather than with FSIG and DCBE may not be to overestime costs, however. Any polyps discovered by DCBE beyond the reach of the sigmoidoscope would be removed through colonoscopy, requiring an additional procedure, and those within the reach of the followup sigmoidoscopy might also require an additional procedure for removal, thereby necessitating a further charge for the polypectomy. Because polyps are present in a high proportion of 65-year-old people (perhaps as many as one-half), basing the cost of diagnostic followup on the assumption that it will always be colonoscopy does not substantially overestimate true costs. It might even underestimate these costs in some circumstances. For example, if 50 percent of all people referred for follow-up from a positive FOBT had polyps, then the average followup cost of the FSIG and DCBE in 1986 would have been $526 [1/2($213 +$626)+ 1/2($213)] compared to $445 [1/2($213) + 1/2($676)] for colonoscopy.**

STRUCTURE AND ASSUMPTIONS OF THE COST-EFFECTIVENESS ANALYSIS

The cost-effectiveness analysis enumerates and estimates the size of the potential health effects and health care costs of CRC screening over the remaining lifetime of a cohort of 65-year-olds. The analysis assumes that these people have not been screened before reaching the age of 65 and that all people in the cohort will fully comply with the screening, followup and surveillance regimen. The 2.1 million people who were 65 years of age in 1989 served as the illustrative cohort for the analysis.

Table 5 arrays the potential effects and costs brought about by any particular CRC screening strategy. Notice that screening potentially affects both costs and outcomes in both positive and negative ways. OTA's analysis estimated the size of each potential category of cost and effect ***except*** those involving changes in quality of life. Individuals vary greatly in perceptions of pain and discomfort associated with particular procedures. Consequently, OTA did not attempt to adjust the analysis for quality of life impacts but recognized that such considerations would and should enter into individual clinical decisions about the value of CRC screening in a particular person[2].

In OTA's analysis a population of 65-year-olds embarks on a screening regimen and begins to incur costs and reap medical effects (measured by additions to or reductions in life expectancy) over the succeeding years. The estimated costs and effects incurred over time are discounted to their net present value.[3] The size of these estimated costs and effects depends on assumptions about the following:

Table 5- Effects and Coats of CRC Screening in the Elderly

Effects
Longer life:
● Removal of polyps prevents cancers that would have been fatal.
● Early detection of CRC reduces death rate from cancers.
Shorter life:
● Detection and removal of polyps carries small risk of colon perforation and death.
● Surveillance with colonoscopy of people previously detected with polyps carries small risk of colon perforation and death.
● Treatment of cancers detected in screening that would have remained latent for the duration of the patient's life carries risk of surgical, medical complications.
Higher quality of life:
● pain associated with cancer or cancer treatment is avoided for those whose cancer would have been clinically detected in the absense of screening.
Lower quality of life:
● Discomfort, pain is incurred from screening, followup, and surveillance procedures.
● Pain of cancer treatment is incurred for those whose cancer would have remained latent for the rest of their lives.
● False positive screening results cause unnecessary anxiety.
costs
Higher costs:
● Screening and followup tests cost money.
● Polyp removal procedures cost money.
● Surveillance procedures for those found with polyps cost money.
● Treatment of cancers that would have remained latent for the duration of the patient's life costs money.
Lower costs:
● Reduction in need for cancer treatment due to prevention of CRC saves costs.
● cost of cancer treatment is reduced due to detection in earlier stages where treatment is less expensive.

SOURCE: Office of Technology Assessment, 1990.

0 natural history of the disease:

the underlying prevalence of polyps and cancers by stage in 65-year-olds;
the incidence of new polyps and cancers at various stages that would be expected in succeeding years in the absence of screening;
the rate at which polyps become cancers and early cancers progress to late cancers;
the rate at which latent cancers become diagnosed clinically;
the life expectancy of people in each year from age 65 to 85 without CRC and with CRC detected in early and late stages;

[2] These quality of life effects, particularly the discomfort of the screening, followup and surveillance procedures themselves, may partly explain why colorectal screening use rates are so low today.

%0 compare outlays occurring in different time periods, they must each be discounted to their to their present value. The discounting of health effects as well as costs is necessary to insure that programs whose benefits lie well in the future will not be found more cost-effective if postponed indefinitely (77). A discount rate of 5 percent per year was used to convert both additional years of life gained (effects) and costs in future years to their value in 1989.

o test accuracy:

the sensitivity and specificity of the screening, followup and surveillance tests in detecting polyps and CRC;

o ***medical risks:***

the rates of colon perforation and death from screening, followup and surveillance;
the rate of surgery-related mortality associated with treatment of cancer;

[0] ***costs:***

the costs of screening, followup, polyp removal, surveillance, and treatment of early and late cancers;
the cost of treating colonoscopy-induced injuries;
the cost of treating surgery-related injuries in patients with cancers that would have remained latent in the absence of screening for the remainder of the patient's life ("lifetime latent" cancers).

Detailed descriptions of the sources of data and rationale for assumptions in each of these areas are presented in appendix C. Table 6 summarizes the critical assumptions underlying the results presented for the pessimistic analysis.

RESULTS

Table 7 shows the results of a cost-effectiveness analysis of the four screening regimens under assumptions that are pessimistic about the cost-effectiveness of CRC screening. Regardless of the screening regimen employed, CRC screening is potentially costly. The present value of the net lifetime health care costs of periodically screening the 1989 population of 65-year-olds could be as high as $1.5 billion to $2.6 billion if all of these people were to fully comply with the screening, followup and surveillance protocols. This net lifetime expenditure amounts to about $737-$1,263 for every person who does comply with the protocols.

The net costs of screening regimens that involve FSIG are much higher than the net cost of an annual FOBT, largely because FSIG is such a sensitive

Table 6-Summary of Assumptions for Coat-Effectiveness Analysis

Accuracy	
FOBT sensitivity for polyps	10%
FOBT sensitivity for CRC	40%
FOBT specificty	96%
FSIG sensitivity for polyps	
– for polyps destined to become clinically detected cancer.	92%
– for polyps destined not to progress	96%
FSIG sensitivity for CRC	92%
Reach of 60 cm FSIG	
– for polyps destined to become clinically detected cancer.	35%
– for polyps destined not to progress	70%
– for CRC	35%
FSIG Specificity	95%
Natural history of the disease	
Percent of all clinically detected cancers that begin as polyps	57%
Number of years for a 5 mm adenoma to progress to CRC	6
Number of years required for a new invasive CRC to progress to late CRC (for CRCs destined to be clinically detected)	1
Number of years required for a late CRC destined to be clinically detected to be detected	1
Percent of CRCs clinically detected in early stage	40%
Prevalence of lifetime latent cancers at age 65	5/1000
Annual incidence of lifetime latent cancers	5/10,000
Medical risks	
Rate of colonoscopy-induced perforation of the large bowel	0.1%
Colonoscopy-induced motility rate	0.02%
Surgery related mortality in patients with primary colorectal cancer surgery	7%
coats	
Cost of FOBT	$3.56
Cost of Screening FSIG	$96
Cost of diagnostic colonoscopy	$411
Cost of colonoscopy with polpectomy	$653
cost of pathology	$51.37
Cost of treating early cancer	$20,000
Cost of treating late cancer	$30,000
Cost of treating colonoscopy-induced perforations	$20,000
Cost of treating colonoscopy-induced deaths	$30,000
Cost of treating fatal complications in early cancer patients	$30,000

SOURCE: Office of Technology Assessment, 1990.

Table 7-Cost-Effectiveness of Colorectal Cancer Screening in the 1989 U.S. 65-Year-Old Population Under Assumptions Unfavorable to Screening[a,b]

	Costs				Effects					Cost Effectiveness
screening Regimen	Costs of screening, followup and surveillance[c,d]	Extra costs of treating lifetime latent cancers[c,f]	Savings in treatment costs[c,d]	Net additional costs of screening	Number of cancers prevented	Years of life gained from reduction in cancer mortality[c]	Years of life lost from operative mortality	Years of life lost from complications of colonosoopy[c]	Net gain in years of life[c]	Cost per year of life gained[c,e]
Regimen 4: Annual FOBT	$1.597 billion	$0.387 billion	$0.450 billion	$1.534 billion	22,756	61,821	12,723	5,340	43,758	$35,054
Regimen 3: Annual FOBT 60cm FSIG on entry to Medicare	$2.526 billion	$0.397 billion	$0.524 billion	$2.399 billion	26,484	72,455	13,316	8,425	50,714	$47,308
Regimen 2: Annual FOBT 60cm FSIG every 5 yrs	$2.705 billion	$0.404 billion	$0.604 billion	$2.504 billion	32,579	81,016	13,567	8,528	58,92'	$42,509
Regimen 1: Annual FOBT 60cm FSIG every 3 Yrs	$2.849 billion	$0.404 billion	$0.623 billion	$2.630 billion	33,549	83,593	13,660	8,610	61,323	$42,892

FOOTNOTES:
[a]For assumptions, see table 6.
[b]Costs shown in table are rounded to the nearest million dollars Underlying calculations carried OUt on exact numbers
[c]Years of life and costs are discounted to present value at a rate of 5 percent per year.
[d]This category includes costs of treating complications of colonoscopy
[e]Compared to no screening.
[f]This category includes costs of treating complications of surgery.

SOURCE: Office of Technology Assessment, 1990.

detector of polyps. Once an adenomatous polyp is detected and removed, a person enters a costly schedule of surveillance by colonoscopy.[4]

The screening procedures alone (FOBT and FSIG) represent a relatively small proportion of the overall cost of the program. For example, screening costs constitute 4 percent of the total costs of screening, followup and surveillance under Regimen 4 (which has no sigmoidoscopy) and 18 percent of the total screening, followup and surveillance costs of Regimen 1, the most intensive screening schedule. Followup and surveillance costs are each a large part of lifetime costs, because 45 percent of the population sooner or later will be subjected to followup and then surveillance under Regimen 4 (FOBT only) and 55 percent would ultimately be placed in surveillance under any screening regimen involving FSIG.

The importance of surveillance as a component of program costs suggests that costs to Medicare are likely to be high even if screening begins well before the person becomes eligible for Medicare. For example, if all people begin CRC screening in keeping with the NCI guidelines at 50 years of age, then many of those with colorectal polyps would already be in a surveillance pool at the time they reach age 65. Though they would not be incurring additional screening and followup costs, they would be in surveillance from the time of entry into Medicare through the rest of their lives.

The net costs of the program could be even higher than those presented here if the schedule of surveillance by colonoscopy were reduced from four years to two. In that case, the total cost associated with screening increases to between $2.3 billion and $3.9 billion, depending on the screening regimen employed (table 8).

[4]**The screening, followup, and surveillance costs shown in Table 7 assume that FSIG screening will be performed with a long (60 cm) FSIG. Use of the shorter (35 cm) FSIG would lower the screening, followup and surveillance costs but would also reduce the effectiveness of screening.**

Table 8-impact of Surveillance Schedule on the Cost-Effectiveness of CRC Screening in the 1989 U.S. 65-year-old Population[a]

	Surveillance schedule			
	Total program costs		Cost per year of life gained [b]	
	4 year	2 year	4 year	2 year
Regimen 4[c]	$1.534 billion	$2.320 billion	$35,054	$58,879
Regimen 3[d]	$2.399 billion	$3.656 billion	$47,308	$80,381
Regimen 2[e]	$2.504 billion	$3.785 billion	$42,509	$70,140
Regimen 1[f]	$2.830 billion	**$3.893 billion**	$42,892	$69,445

ABBREVIATION: FOBT = fecal occult blood test.

[a] Screening with a 60 cm sigmoidoscope.
[b] Cost and years of life gained in the future are discounted to their present value@ a rate of 5 percent per year.
[c] Regimen 4: Annual FOBT; sigmoidoscopy every 5 years.
[d] Regimen 3: Annual FOBT; sigmoidoscopy every 5 years.
[e] Regimen 2: Annual FOBT; sigmoidoscopy once upon entry to Medicare.
[f] Regimen 1: Annual FOBT; no sigmoidoscopy.

SOURCE: Office of Technology Assessment, 1990.

The analysis suggests that in preventing some cancers (between 22,000 and 33,000 depending on the screening regimen) and detecting others in an earlier stage than they would otherwise be detected, substantial savings in health care costs are obtained, but these savings are markedly reduced by the extra costs of treating the many lifetime latent cancers detected through screening. With Regimen 4 (FOBT only) the net saving in cancer treatment cost is only $63 million, a small sum compared to the $1.6 billion spent in screening, followup and surveillance (table 7).

The potential health benefits achieved by this high cost are substantial. Under the assumptions of the OTA analysis, annual FOBT screening would prevent almost 23,000 cases of CRC that are otherwise destined to become clinically manifest sometime during the remainder of the population's life. This represents approximately 17 percent of all cancer incidence expected in the 65-year-old population. In addition to this gain, some cancers that would have manifested themselves in late stages will, under screening, be detected in early stage, with con-

sequent improvements in survival. Taken together, the benefits of prevention and early detection of CRC result in a total gain of between 43,000 and 61,000 additional years of life[5] in the cohort under study (table 7).

The critical measure of cost-effectiveness is the cost per added year of life from a specific CRC screening regimen. As table 7 shows, adopting a CRC screening program for the elderly costs between $35,000 and $47,000 per added year of life gained, depending on the particular screening regimen adopted. Strategy 4 (FOBT only) is the most cost-effective strategy compared to no screening.

The cost-effectiveness of CRC screening depends strongly on the surveillance protocol adopted. The high procedure cost of colonoscopy relative to the screening procedures makes colonoscopy a critical resource whose overuse could render CRC screening much more expensive per year of life gained. As table 8 shows, a 2-year surveillance schedule increases the total costs of the program by almost 50 percent and raises the cost per year of life saved by over 60 percent, to about $57,000 in the case of Regimen 4. In keeping with the pessimistic structure of the analysis, OTA assumed that surveillance colonoscopy adds no health care benefits beyond those achieved by the discovery and removal of the initial polyp in screening. Consequently, the extra costs and risks of more frequent surveillance add only costs and reduce effectiveness without providing any compensating benefits. The National Polyp Study currently underway is intended to determine whether more frequent surveillance does improve outcomes; in the meantime, it is worth noting that the total costs of any CRC screening program are very sensitive to the surveillance schedule.

The cost per year of life saved for each of the screening regimens is based on a comparison with no screening. Ideally, decisions about the frequency of screening with FSIG should be made by comparing the incremental, or additional, costs with the additional health benefits of moving from no FSIG screening or from a less frequent screening interval to the next most frequent screening interval. After all, more frequent screening costs more money. That extra cost should be compared with the extra benefits it provides. Unfortunately, the model is not a reliable estimator of these incremental costs and effects. OTA assumed that cancers destined to be diagnosed clinically (in the absence of screening) progress very rapidly. While this assumption underestimates the effectiveness of any screening regimen compared to no screening, it also overestimates the effectiveness of more intensive or frequent screening compared to less intensive screening regimens. If CRCs destined to be diagnosed clinically progress slowly, then infrequent screening with FSIG should be almost as effective as, and much less costly than, more frequent screening with FSIG.[6] The pessimistic assumptions regarding the speed of polyp and cancer progression (i.e., very fast progression from early to late cancer for those cancers that would become clinically manifest without screening) makes more frequent screening with sigmoidoscopy appear incrementally more effective than it would be if cancers actually progress more slowly.

Because the model is deliberately biased upward in cost and downward in effectiveness when comparing each regimen with no screening, OTA is reasonably confident that, compared to no screening at all, screening according to one of the four schedules provides an added year of life at a cost no greater than, and probably less than, those shown in Table 7. Studies of other preventive services legislated as covered services under Medicare in the past (pneumococcal pneumonia vaccine, cervical cancer screening, and breast cancer screening) have reported lower costs for each additional year of life gained from screening. (36,149,150) However, when both costs and years of life gained were discounted to their present value at an annual rate of 5 percent, as they are in this study, breast cancer screening with mammography was estimated to cost about $34,000 per year of life gained. This is approximately equal to the cost per year of life gained from annual FOBT screening in the elderly under the pessimistic set of assumptions.

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[5] Years of life gained in future years are discounted to their present value at a rate of 5 percent per year.

%0 test this assumption, OTA lengthened the assumed CRC progression rate from one year to three years. As expected, the cost per year of life gained compared to no screening declined, but the additional cost per additional year of life gained from offering more frequent FSIG screening compared to less frequent FSIG screening increased greatly.

To summarize the results of this analysis, under pessimistic assumptions about the potential effectiveness and costs of screening, the discounted cost per year of life gained for FOBT is within the range of cost-effectiveness values calculated for mammography screening in elderly women (36), provided that the post-polypectomy surveillance schedule is no more frequent than every 4 years. Thus, if the assumptions outlined above are as conservative as we believe them to be, CRC screening is as cost-effective as one other preventive intervention that had been covered under Medicare.[7] At the same time, it is impossible to say whether the extra costs of periodic sigmoidoscopy compared to annual FOBT alone are high or low in relation to the extra medical benefits they provide, because the magnitude of those incremental costs varies so greatly with changes in assumptions about the rates of polyp and cancer progression. Indeed, if the great majority of polyps and cancers progress much more slowly than assumed in the model, the incremental cost of regimens 1 to 3 (i.e., those involving FSIG) relative to regimen 4 (FOBT only) would be very high. Yet, the cost per year of life saved ***compared to no screening*** for any of the screening regimens would be even lower than they are in table 7.

Distribution of Effects Across Time and Individuals

The estimated cost per year of life gained represents an average of medical gains and losses incurred by different people at different times in their lives. CRC screening subjects some people to risks of illness and death that they would not have suffered had they not been screened. Those risks are borne relatively early in their remaining lives, whereas the substantial gains from reductions in the incidence and lethality of cancer occur later on. For example, under the pessimistic assumptions, an annual FOBT would detect about 4,200 lifetime latent cancers in year 1, when the 2.1 million 65-year-olds have just enrolled in Medicare; an estimated 300 of these people would die in that year from complications of surgery for CRC. These 300 excess deaths in the first year of screening must be weighed against the 23,000 eases of cancer prevented and the lives saved from early detection of the cancers that are not prevented, both of which occur later in life. To some extent, discounting lives saved in future years to their "present value" takes account of these differences in the time distribution of effects. Yet, the selection of a uniform discount rate for all people, necessary for a public policy analysis, masks wide variation in individuals' preferences for early losses versus late gains in life expectancy. Differing valuations of the tradeoff between risks now and risks later on could make an individual's assessment of the cost-effectiveness of CRC screening very different from the estimates given in this paper.

Sensitivity Analysis

OTA attempted to submit CRC screening to a stringent test of cost-effectiveness by making assumptions that were uniformly unfavorable to screening. For most of the assumptions, we are reasonably confident that the true value is more favorable to screening than the value assumed in the analysis. By combining so many unfavorable assumptions together, the analysis represents a reasonable upper bound on the potential costs per year of life gained from each screening regimen.

Data were very sparse to support several assumptions (Appendix C). The most uncertain and potentially important are the costs of treating early and late cancer; the speed of progression of polyps to cancer; and the sensitivity of FOBT for early cancer. Although OTA attempted to be conservative about each of these assumptions, it is important to know how the results of the cost-effectiveness analysis would change if the true values were at levels even more unfavorable to screening than those assumed in the original analysis.

Costs of Cancer Treatment

The cost-effectiveness model assumed that the additional net costs of treating early and late cancer are $20,000 and $30,000 respectively. The basis for these estimates is tenuous. Higher costs lead to greater savings in the cost of treating cancers that are prevented or detected earlier than they would be

[7] **Mammography was briefly legislated as a covered benefit under Medicare, but because it was legislated as part of the Medicare Catastrophic Health Act of 1988, the provision was repealed when the Catastrophic law was repealed late in 1989.**

without screening but they also increase the costs of treating lifetime latent cancers detected through screening. Consequently, the impact of any change in cancer treatment costs cannot be predicted beforehand. OTA examined how reductions in the cost of early and late cancer treatment would affect the outcome of the analysis.

Table 9 shows the results of changing these values on the estimated cost-effectiveness of regimens 4 and 2. As the table shows, the costs of cancer treatment have little effect on the cost per year of life gained from screening. Even under the extreme assumption that the discounted cost of treating both early and late cancers is only $5,000, the net discounted cost per year of life gained from screening rises from about $35,000 to $37,000 for FOBT.

Speed of Polyp/Cancer Progression

Although most experts believe that the polyp/cancer sequence occurs over a long period of time, it is possible that the most lethal cancers -- those destined to be discovered late and to be least responsive to therapy --progress more quickly, even when they are still polyps. Changing the assumptions about the speed with which polyps that are destined to become clinically detected cancers actually progress from their beginning to early stage cancer has a greater impact on estimated cost-effectiveness than do changes in the cost of cancer treatment. If the polyp/cancer progression time is assumed to be 3 years in length rather than 6 years, the cost per year of life gained from an annual FOBT screen increases to almost $51,000 (table 10). Other screening regimens also become substantially more expensive for the medical benefits they produce.

Table 9-Cost-Effectiveness of CRC Screening Under Differing Assumptions About the Cost of Treating Early and Late CRC[a]

cost of treating early CRC	cost of treating late CRC	Cost per added year of life Regimen 4[b]	Cost per added year of life Regimen 2[c]
$5,000	*$5,000*	$37,150	$45,950
$5,000	$10,000	$35,120	$44,171
$10,000	$15,000	$35,774	$44,210
$10,000	$20,000	$33,745	$42,430
$20,000	*$30,000*	$35,054	$42,509

a Costs and years of life discounted at annual rate of 5 percent.
b Regimen 4 = annual FOBT.
C Regimen 2. annual FOBT + FSIG every 5 years.

SOURCE: office of Technology Assessment, 1990.

Table 10- Sensitivity of Coat-Effectiveness Results to Faster Polyp/Cancer Progression Time[a]

Screening regimen	Cost per year of life gained with 6 year progression time	Cost per year of life gained with 3 year progression time
4	$35,054	$50,992
3	$47,306	$71,547
2	$42,509	$59,751
1	$42,692	$51,666

a Polyp/cancer progression time refers to the number of years for a polyp that is destined to be detected without screening to progress from it's earliest detectable state to invasive cancer.

SOURCE: Office of Technology Assessment, 1990.

FOBT Sensitivity for Early Cancer

OTA assumed that FOBT can detect a cancer (early or late) with a 40 percent probability. (See app. C for the evidence on which this assumption is based.) This is substantially lower than the values used in recent cost-effectiveness studies of FOBT screening (8,39). Although this assumption is on the low end of the existing studies of FOBT sensitivity, most studies of FOBT sensitivity include symptomatic patients, who would be more likely to present with blood in the stool. One study comparing FOBT with sigmoidoscopy in asymptomatic non-elderly people found a sensitivity for cancer of 25 percent (6). OTA examined the impact on costs and effectiveness of using this lower value. As table 11 shows, changing this assumption raises the cost per additional year of life gained by about 23 percent, to $43,000 for screening regimen 4 (FOBT only) but has less proportional impact on regimens that include FSIG.

Table 11- Effect of Lower FOBT Sensitivity on Cost-Effectiveness of CRC Screening

Screening regimen	Cost per year of life gained from screening	
	FOBT sensitivity 40%	FOBT sensitivity 25%
4	$35,054	$43,167
3	$47,306	$55,525
2	$42,509	$48,338
1	$42,692	$46,194

SOURCE: Office of Technology Assessment, 1990.

Comparison With Other CRC Cost-Effectiveness Analyses

Several researchers have analyzed the cost-effectiveness of CRC screening, but none has examined the effectiveness and cost of repeated screens beginning at 65 years of age. Barry, Mulley and Richter (8) examined the cost-effectiveness of a one-time FOBT screen for an asymptomatic 65-year-old who had not been previously screened. The gain in years of life from screening was based on assumed changes in the stage distribution of cancers detected as a result of the screening examination. They found that the net discounted cost[8] per added year of life ranges from about $9,000 to $14,000, depending on the followup procedures used. Their analysis assumed that the prevalence of polyps in this population would be about 18 percent, a substantially lower estimate than OTA used. The low estimate of polyp prevalence reduces the estimated costs of following up positive FOBT examinations. Barry and Mulley also did not include the costs of surveillance following polypectomy, which represent a major component of net health care costs in the OTA study.

England and colleagues (40) studied the effect of a one-time colorectal screening examination in a population of asymptomatic people 40 years and over. The impact of screening on life expectancy was based on assumptions about the shift in the stage distribution of cancers that can be expected from screening. The analysis did not include the costs of surveillance resulting from detection and removal of polyps, and it did not estimate the savings in health care costs that can be expected from improvements in the stage at detection. The authors found that the cost per year of life gained[9] from an FOBT and sigmoidoscopic examination ranged from $19,000 to $21,000.

Allison and Feldman examined a one-time FOBT screen in people 45 years of age and older who were enrolled in an Health Maintenance Organization (HMO) in 1979-1980 (l). The gains in survival from screening were estimated by comparing the stage distribution of CRCs detected in the HMO in 1974 (before screening was available) with that observed in the screened patients in 1979-1980. Savings in medical care costs were netted out of the total cost estimate, but surveillance costs were not included in the analysis. The FOBT was found to cost $765 per person-year of extended life.[10]

In several studies based on a mathematical model of CRC, Eddy and colleagues (33,35,39) estimated the cost-effectiveness of alternative screening and followup strategies for various populations. The impact of screening at various frequencies with different combinations of potential screening tests was calculated based on assumptions about the natural history of polyps and cancer that are similar but not identical to those used by OTA. Costs include screening and followup but not surveillance. Nor did the analyses account for the cost or risk of treating screening-detected cancers that would otherwise remain latent through the remaining life of the screened individual. The net savings in the costs of treating CRC were subtracted from total costs.[11] In the most recent version of the model, Eddy assumed a lower sensitivity of FOBT for polyps than did OTA. Eddy assumed an effective sensitivity for polyps of 19 percent for just the last 2 years before the polyp progresses to invasive cancer. While most of Eddy's other assumptions are more favorable to screening than are OTA's assumptions, this assumption significantly reduces the potential effectiveness of FOBT to prevent cancer compared to OTA.[12] In average risk 50-year-old men, the net discounted cost per additional year of life gained from a screening regimen that would continue to age 75 was estimated at about $19,200 for an annual FOBT and sigmoidoscopy every 5 years, and $25,300 for an annual FOBT and a sigmoidoscopy every 3 years (39).

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[8] The discount rate was 6 percent in that study.

[9] Neither costs nor years of life were discounted in this analysis.

[10] Costs and years of life gained were not discounted in this analysis.

[11] Both costs and increases in life expectancy were discounted at 5 percent.

[12] For example, in OTA's analysis, a cancer that would become clinically manifest in its late stage at age 75 has six chances to be detected (between the ages of 67 and 72), with a 10 percent probability of detection in each year. This corresponds to an overall probability of detection as a polyp of 47 percent, compared to an overall detection probability in Eddy's study of 36 percent.

Discussion

Virtually all cost-effectiveness analyses of CRC screening, including our own, have concluded that this kind of cancer screening delivers substantial benefits with a sizable investment. All of the models, including our own, assume that it is possible to prevent cancer or alter the pattern of mortality from the disease through early detection. Definitive evidence that screening can indeed deliver such effects simply does not exist. Yet, in building from what is known about the polyp and cancer detection capability of the screening tests and the natural course of the disease, we concluded that CRC screening is likely to deliver health benefits at a cost that is roughly in line with those offered by at least one other preventive health service that was covered under Medicare.

The uncertainty about the relative merits of alternative CRC screening strategies is great, however, and the potential costs of screening, followup and surveillance are high. In particular, the incremental cost of each year of life added by sigmoidoscopic screening (on top of an annual FOBT) is unclear and could well be very high. The sigmoidoscopy screening clinical trial currently under development at the National Cancer Institute promises to provide information on the medical effects and net health care costs of sigmoidoscopic screening in older Americans within 10 to 15 years (152).

IMPLICATIONS FOR MEDICARE

OTA's cost-effectiveness analysis followed a cohort of 65-year-olds through the remainder of their lives. The net program costs represent the discounted value of the stream of outlays over the next 30 or more years for people who were 65 years old in 1989. If Medicare were to offer a CRC screening benefit, all elderly people, not just those newly eligible for Medicare in years after coverage begins, would be offered screening. What is the magnitude of the health care costs that would be incurred in any year?

OTA calculated the annual national costs associated with screening, followup and surveillance of three CRC screening regimens beginning in 1989 assuming that all elderly people fully comply with the screening, followup and surveillance protocols. (The savings in health care costs from reductions in cancer treatment and the added costs of treating lifetime latent cancers were not included, but as table 7 showed, these other components of cost are minuscule compared to the costs of screening, followup and surveillance.) For this estimate of the annual national health care bill associated with CRC screening in the elderly, OTA made more realistic (i.e., less pessimistic) about the accuracy of the screening tests and the prevalence and incidence of polyps in the population (table 12).

Costs vary from year to year as the program gears up and the size and age-distribution of the population over 65 years of age changes. In the ninth year of program operation, the annual cost of Regimen 1 with 60 cm FSIG (in 1988 dollars) would be $2.5 billion, and the cost of Regimen 2 would be $2.2 billion. Regimen 4 (FOBT only) would be substantially less expensive to implement ($1.2 billion per year) because it excludes the costs of FSIG and all the followup and surveillance that would have been induced by detection of polyps at sigmoidoscopy. Chart 2 shows the estimated annual cost for each of the three screening regimens during the first nine years of operation of such a program.

If CRC screening were a covered Medicare benefit, Medicare's share of the net cost would be high. Even today, Medicare covers a large but unknown proportion of such costs because all diagnostic, followup, and surveillance procedures are

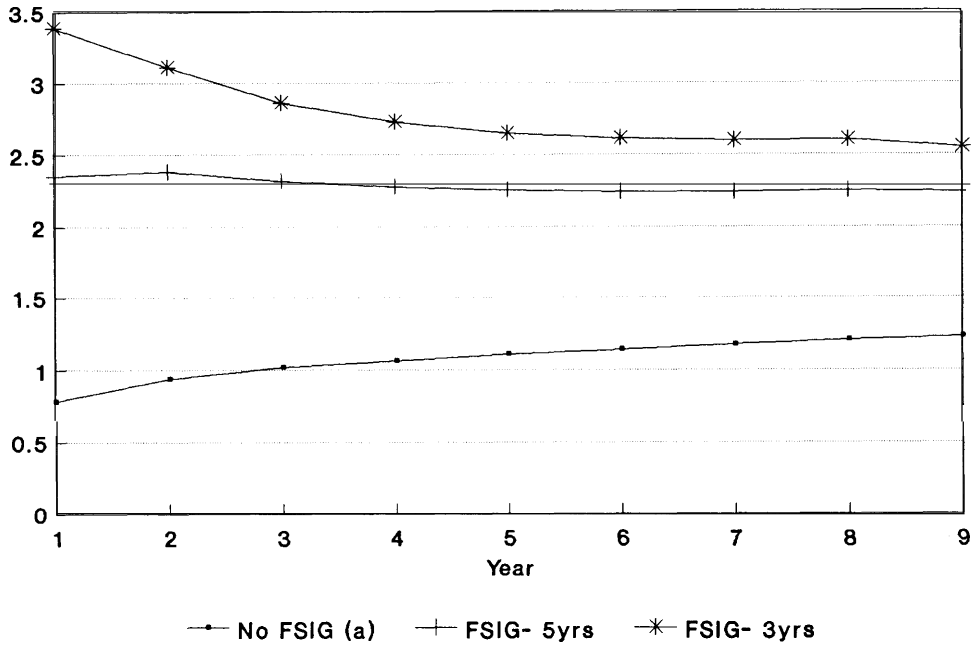
Table 12-Assumptions Underlying Estimates of the Annual National Costs of CRC Screening, Followup, and Surveillance In the Elderly

FOBT sensitivity for polyps	5%
FOBT specificity	98%
FSIG sensitivity for polyps	95%
FSIG specificity	10096
Reach of 60cm FSIG[a]	50%
Reach of 35cm FSIG[a]	30%
Prevalence of polyps[b]	5096

[a] Percent of polyps located within the reach of a FSIG of designated length.
[b] Percent of 65-year-olds with colonic polyps.

SOURCE: Office of Technology Assessment, 19S0.

Chart 2--Annual Cost of CRC Screening, Followup, and Surveillance ($ billions)



(a) all regimens include FOBT annually
SOURCE: Office of Technology Assessment, 1990.

covered Medicare services. The cost of screening alone is just the tip of the iceberg. Medicare allowed under $4 for an FOBT and about $100 for FSIG in 1988 (if performed for diagnostic, not screening purposes).

The annual cost profile outlined in chart 2 represents the net additional cost of screening, followup and surveillance compared to no such procedures in the population. However, a small but growing number of elderly people already receives CRC screening, and Medicare is already paying for the diagnostic followup and surveillance procedures engendered by the screening examinations.[2]

The national cost estimates assume that all elderly Medicare beneficiaries will fully comply with the screening regimen and all followup and surveillance procedures resulting from screening. In reality, the use of CRC screening examinations in the elderly is quite low, and it is unknown how much it will increase by making a combination of FOBT and FSIG a covered Medicare benefit. In 1987, for example, only 34 percent of people 60 years of age or over reported ***ever*** having undergone a screening FOBT test and 7.4 percent reported ***ever*** being screened with proctoscopy (rigid sigmoidoscopy) (152). Whether paying $4 for a FOBT will bring forth substantial additional use is unknown. The actual impact of an FOBT benefit on annual health care costs will depend on the degree to which covering the service will encourage use. Also, if a screening benefit brings about greater increases in use of those at lowest risk of CRC, then the medical benefits projected in the cost-effectiveness analysis would be reduced, and the cost per added year of life would be higher.

[2]**Medicare may be paying inadvertently for some screening procedures if they are billed as diagnostic procedures. Evidence has accumulated that full colonoscopy used as a screening procedure may be paid for by Medicare** in a substantial number of cases (98,151).

Advisory Panel--Project on Preventive Health Services Under Medicare

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NOTE: Advisory Panel members provide valuable guidance during the preparation of OTA reports. However, the presence of an individual on the Advisory Panel does not mean that individual agrees with or endorses the conclusions of this particular report.