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Sujha Subramanian, Georgiy Bobashev and Robert J. Morris
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By Sujha Subramanian, Georgiy Bobashev, and Robert J. Morris

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When Budgets Are Tight, There Are Better Options Than Colonoscopies For Colorectal Cancer Screening

Sujha Subramanian (ssubramanian@rti.org) is a senior health economist at RTI International, in Waltham, Massachusetts.

Georgiy Bobashev is a senior research statistician at RTI International, in Research Triangle Park, North Carolina.

Robert J. Morris is a research statistician at RTI International, in Research Triangle Park.

ABSTRACT **A critical challenge facing cancer screening programs, particularly those aimed at uninsured people with low incomes, is choosing the screening test that makes the most efficient use of limited budgets. For colorectal cancer screening, there is growing momentum to use colonoscopy, which is an expensive test. In this study, we modeled scenarios to assess whether the use of fecal occult blood tests or colonoscopy provides the most benefit under conditions of budget constraints. We found that although colonoscopy is more accurate, under most scenarios, fecal occult blood tests would result in more individuals' getting screened, with more life-years gained.**

Colorectal cancer is the third leading cause of cancer-related mortality in the United States. Increasing emphasis is being placed on colorectal cancer screening because early detection can prevent the majority of deaths from this disease.[1,2] Recent estimates are that only half of Americans ages fifty and older receive colorectal cancer screening as recommended, and that only about 24 percent of the uninsured who do not have a usual source of health care and who are eligible for a colorectal cancer screening receive one.[3]

State health departments and federal agencies are in the planning stages for or have begun to implement screening programs for low-income uninsured and underinsured people.[4] One critical challenge faced by these programs is the selection of the screening test that will provide the most efficient use of their limited budgets.

Background On Colorectal Cancer Screening

Currently, several tests are recommended for colorectal cancer screening. Choosing the optimal screening test is a complex undertaking. Programs must consider a variety of factors, including cost, effectiveness, and compliance with screening guideline recommendations. The interplay of all of these factors affects the total number of people who can be screened and the overall benefit gained from screening.

State and federal colorectal cancer screening programs offer organized screening, which means targeted screening of an eligible cohort by invitation. This screening strategy differs from opportunistic screening, which is typically accomplished via routine medical practice and generally provided to those insured by private health plans, Medicare, and Medicaid. Organized screening offers the opportunity to select and provide the tests that will deliver the maximum benefit for the funding available.

GUIDELINES Over the past decade, the U.S. Preventive Services Task Force, the American Cancer Society, the American College of Gastroenterology, and other organizations have published guidelines recommending specific tests for colorectal cancer screening.[1,2,5–7] These guidelines have recommended colonoscopy, sigmoidoscopy, double contrast barium enema, computed tomographic colonography, fecal immunochemical test, and high-sensitivity guaiac-based fecal occult blood tests. These tests vary in their invasiveness, with colonoscopy

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being the most invasive endoscopic procedure and fecal blood tests the least invasive. In addition, the tests differ in their sensitivity to cancers and precancerous lesions, and their cost.

Unlike previous guidelines, the June 2008 guidelines from the American Cancer Society, the U.S. Multi-Society Task Force on Colorectal Cancer, and the American College of Radiology recommend that the primary goal of screening should be to prevent colorectal cancer, rather than merely to detect it.[8] Therefore, tests that can both prevent and detect cancer, which include colonoscopy and computed tomographic colonography, should be preferred to fecal tests. Fecal tests can detect some advanced, precancerous lesions but are principally effective at detecting cancers. The 2008 guidelines do acknowledge that fecal tests may be appropriate in settings with limited resources or when patients prefer these tests.

TWO FREQUENTLY USED TESTS In the United States, the most frequently used colorectal cancer screening tests are guaiac-based fecal occult blood tests and colonoscopy.[9] The use of the latter for colorectal cancer screening has been increasing rapidly during this decade. About 29 percent of all colorectal cancer tests in 2000 were colonoscopies; more than 60 percent were in 2005.[3,10] The fact that the three medical associations mentioned above favor tests that both prevent and detect colorectal cancer has boosted the role of colonoscopy.

Given the growing trend toward the use of colonoscopy for screening, state and federal programs may feel compelled to offer it as the primary screening test for individuals. But colonoscopy is expensive and carries a higher risk of serious complications than other screening tests do, even though the risk is still low in absolute terms.

A key benefit of colonoscopy is that a complete examination of the colon and rectum is possible in a single session. When colorectal polyps or cancers are detected, the polyps can be removed and biopsied immediately. With a positive, guaiac-based fecal occult blood test, a follow-up colonoscopy is required.

Low compliance with follow-up recommendations will reduce the overall effectiveness of guaiac-based fecal occult blood tests. In addition, these tests must be performed more frequently than colonoscopies. The current recommendation for the individual at average risk of colorectal cancer is to have a guaiac-based fecal occult blood test once a year or a colonoscopy every ten years.

In this paper we offer guidance for selecting the appropriate screening test to programs operating under fixed budgets or annual appropriations. We compare the total benefit gained by offering guaiac-based fecal occult blood tests versus colonoscopy under various scenarios. To reflect real-world scenarios, we varied patient compliance with screening recommendations, test performance features, and cost.

Study Data And Methods

We developed a simulation model using AnyLogic software to assess the cost and effectiveness of screening with guaiac-based fecal occult blood tests and colonoscopy.[11] To mimic real-world scenarios, we incorporated features to vary patients' compliance with screening recommendations and follow-up diagnostic testing.

BASE-CASE ESTIMATES Exhibit 1 presents the base-case estimates for test characteristics and the ranges of costs we used in the sensitivity analyses.[5,6,8,12–24] There is variation among the available guaiac-based fecal occult blood tests in terms of their sensitivity, which refers to the proportion of the screened population that has the disease and that tests positive, and specificity, which refers to the proportion of the screened population that is disease free and that tests negative. Therefore, we present separate results for Hemoccult II and Hemoccult SENSA. Both are noninvasive tests that detect blood in stool specimens, but Hemoccult SENSA has higher sensitivity and lower specificity than Hemoccult II.

We looked at costs from the perspective of cancer screening programs that generally assign payments based on the rates that Medicare allows.[23] Therefore, in our cost estimates, we included only direct medical costs—that is, costs related just to the clinical services received. Our estimates were also based on Medicare payment rates whenever possible.

There is ongoing debate about the true cost of performing a guaiac-based fecal occult blood test.[22] Medicare reimbursement is about $5 per test. Although physician consultation is not required for the test to be performed, a physician visit could occur as part of the screening process, and this would increase the cost. We have conservatively assumed that office visits would occur in connection with half of all guaiac-based fecal occult blood tests.

The base-case costs used in this analysis for guaiac-based fecal occult blood tests and colonoscopy were $23 and $699, respectively.

OVERALL COST ESTIMATES We first derived the overall cost estimates assuming 100 percent screening and diagnostic compliance with guaiac-based fecal occult blood tests and colonoscopy. In other words, we assumed that all individuals would undergo screening tests at the

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EXHIBIT 1

Parameters Of The Model Analyzing Colorectal Cancer Screening

Test	Base case (average)	Best case–worst case (sensitivity analysis)[a]
gFOBT Hemoccult II		
Sensitivity for small polyps (≤5 mm)	2	5–0
Sensitivity for medium polyps (6–9 mm)	5	10–0
Sensitivity for large polyps (≥10 mm)	12	20–5
Sensitivity for cancer	40	64–14
Specificity	98	100–90
gFOBT Hemoccult SENSA		
Sensitivity for small polyps (≤5 mm)	7	10–5
Sensitivity for medium polyps (6–9 mm)	12	18–5
Sensitivity for large polyps (≥10 mm)	24	35–10
Sensitivity for cancer	70	79–38
Specificity	92	95–87
Colonoscopy		
Sensitivity for polyps 1[b]	75	85–70
Sensitivity for polyps 2[b]	85	90–80
Sensitivity for polyps 3[b]	95	98–85
Sensitivity for cancer	95	98–85
Specificity	100	—[c]
Complication—perforation	1 per 1,000	0.7 per 1,000
Complication—mortality	0.1 per 1,000	0.05 per 1,000
Screening cost		
gFOBT	$23	$5–$38
Colonoscopy	$699	$400–$1,656
Other costs		
Polypectomy	$184	$100–$500
Complications of endoscopy (perforation)	$24,000	$10,000–$30,000
Lifetime colorectal cancer treatment cost		
Stage 1	$32,700	$20,000–$60,000
Stage 2	$34,400	$25,000–$65,000
Stage 3	$41,600	$30,000–$80,000
Stage 4	$29,400	$20,000–$60,000

SOURCES Studies published in peer-reviewed journals; see Notes 5, 6, 8, 12–24 **NOTES** The estimates for the base-, best-, and worst-case scenarios were derived from relevant literature (see above). gFOBT is guaiac-based fecal occult blood test. [a]Percent of the time that the test can identify polyps or cancer on average, over a range of studies. [b]Represents three different scenarios of diagnostic compliance; see text. [c]Since the specificity is 100 percent (colonoscopy is considered the gold standard) no sensitivity analysis was performed.

EXHIBIT 2

Benefits Of Guaiac-Based Fecal Occult Blood Test (gFOBT) And Colonoscopy For A Screening Program With A Budget Of $1 Million

	Number of people screened	Life-years gained (base-case estimates)
gFOBT		
Hemoccult II	715	50.9
Hemoccult SENSA	604	52.8
Colonoscopy	474	40.9

SOURCE Analysis of output from RTI's Colorectal Cancer Screening Model. **NOTES** The average lifetime cost per person is $1,399, $1,656, and $2,110 for Hemoccult II, Hemoccult SENSA, and colonoscopy, respectively. The average life-years gained per person are 0.071 years (26.01 days) with Hemoccult II, 0.087 years (31.94 days) with Hemoccult SENSA, and 0.086 years (31.47 days) with colonoscopy.

intervals recommended by the guidelines, and that all positive guaiac-based fecal occult blood tests would be followed up by colonoscopies.

We assumed a fixed budget of $1 million for a hypothetical lifetime colorectal cancer screening program that covers the costs of screening, diagnosis, treatment, and surveillance. We then derived the total number of individuals screened and the total benefit in terms of life-years gained. We used the range estimates for sensitivity and specificity to derive results based on the highest and lowest possible effectiveness for guaiac-based fecal occult blood tests. The costs of the different guaiac-based fecal occult blood tests assessed were $5, $23 (base case), $30, and $38.

COMPLIANCE To assess the impact of compliance with guaiac-based fecal occult blood tests, we varied the rate at which individuals complied with recommendations for repeat screening: 40 percent, 60 percent, 80 percent, and 100 percent. We also varied the rate at which individuals with positive guaiac-based fecal occult blood tests underwent follow-up diagnostic colonoscopies: 65 percent, 75 percent, 85 percent, and 95 percent.

COMPARISON OF SCREENING TESTS We compared the various scenarios for guaiac-based fecal occult blood tests with the base-case colonoscopy. Finally, we report the best- and worst-case scenarios to indicate the potential range in the benefits derived. For the best-case scenario, we used the highest effectiveness and lowest cost from Exhibit 1. For the worst-case scenario, we used the lowest effectiveness and highest cost from Exhibit 1.

Study Results

Exhibit 2 presents the number of average-risk individuals ages 50–80 who can be screened, and the life-years gained, when using one of the two guaiac-based fecal occult blood tests versus colonoscopy for a screening program with a fixed budget of $1 million. With 100 percent compliance with screening recommendations and follow-up testing, a total of 50.9, 52.8, and 40.9 life-years for the population of individuals screened are gained with Hemoccult II, Hemoccult SENSA, and colonoscopy, respectively. Fewer individuals are screened with Hemoccult SENSA than with Hemoccult II because more colonoscopies have to be performed with Hemoccult SENSA, given its lower specificity.

As shown in Exhibit 3, at all of the cost levels of fecal occult blood tests assessed—from $5 to $38—these tests offer more benefit than base-case colonoscopy. The horizontal line indicates the life-years gained from colonoscopy at 100 percent compliance with recommendations

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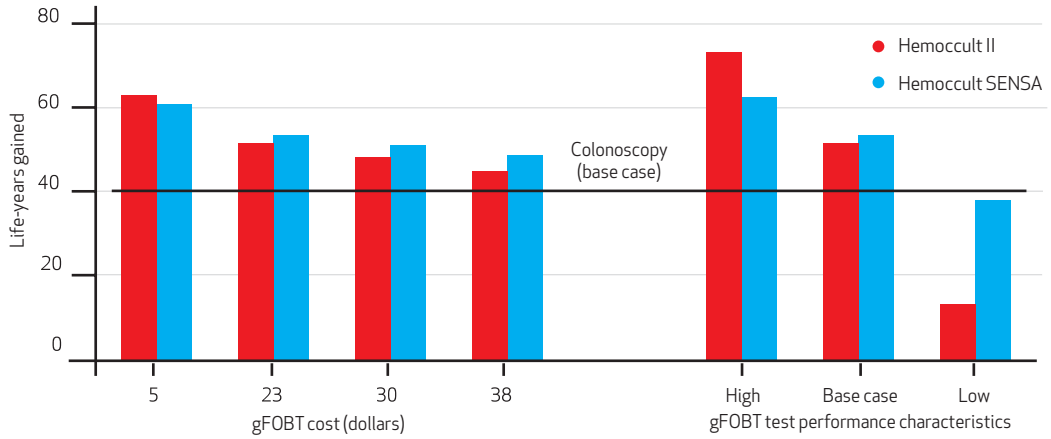
EXHIBIT 3

Life-Years Gained By Varying Guaiac-Based Fecal Occult Blood Test (gFOBT) Cost And Test Performance Characteristics, Based On Funding Of $1 Million For Screening Program



SOURCE Analysis of output from RTI's Colorectal Cancer Screening Model. **NOTES** Cost of colonoscopy was $699 in the base case presented. When varying the cost of gFOBT, the test performance effectiveness modeled was the base-case effectiveness. In estimates varying test performance, the cost of gFOBT was $23.

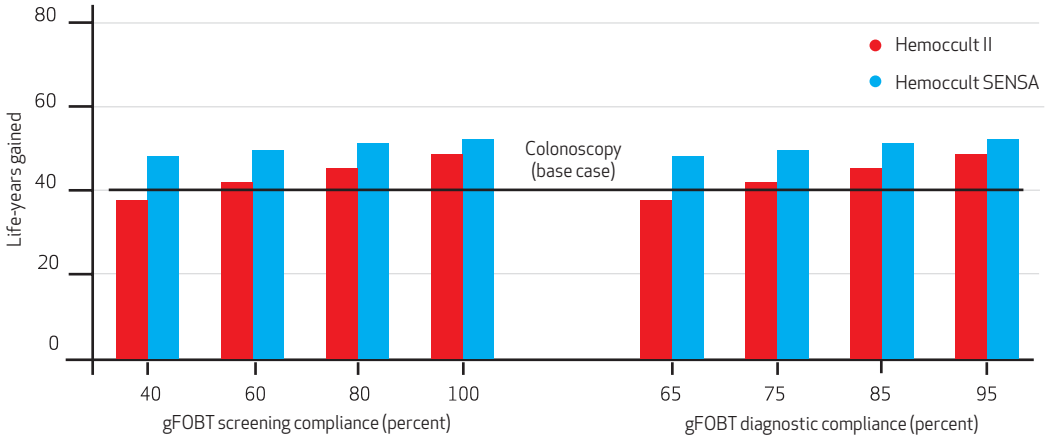
for screening and follow-up testing. In addition, at the high and base levels of guaiac-based fecal occult blood test performance, the life-years gained with both fecal occult tests are higher than gained with colonoscopy.

However, the base-case colonoscopy offers a better value for the screening program when compared with the guaiac-based fecal occult blood tests modeled at the lowest level of effectiveness. Yet the results of the Hemoccult SENSA test at the lowest level of effectiveness are only about 10 percent lower than those for the base-case colonoscopy (37.5 versus 40.9 total life-years gained).

Exhibit 4 presents the total life-years gained in the screening program under different levels of screening and follow-up compliance for guaiac-based fecal occult blood test screening. A program using Hemoccult II, with a screening compliance of 60 percent or higher, will experience more total life-years gained than a program using colonoscopy with 100 percent compliance. Similarly, Hemoccult II will perform better than colonoscopy if at least 75 percent of those with

EXHIBIT 4

Life-Years Gained By Varying Screening And Diagnostic Compliance With Guaiac-Based Fecal Occult Blood Testing (gFOBT), Based On Funding Of $1 Million For Screening Program



SOURCE Analysis of output from RTI's Colorectal Cancer Screening Model. **NOTE** Cost of colonoscopy was $699 in the base case presented, and compliance was 100 percent.

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positive guaiac-based fecal occult blood tests undergo diagnostic follow-up colonoscopies.

Hemoccult SENSA offered better results than colonoscopy at all of the levels of screening and diagnostic compliance we assessed. For Hemoccult SENSA, the findings did not vary greatly when compliance varied. This is because, with lower patient compliance, fewer tests and fewer unnecessary colonoscopies are performed per person screened. At the same time, because the test is less expensive, the funds are available to screen more individuals.

The benefits derived for the worst-case and best-case scenarios range from 16.82 to 74.09 life-years gained for colonoscopy; 6.38 to 152.2 life-years gained for Hemoccult II; and 16.07 to 123.73 life-years gained for Hemoccult SENSA. Lowering the complication rates associated with colonoscopies from 1 per 1,000 (base case) to 0.7 per 1,000 results in 41.7 life-years gained compared to the base case of 40.9 life-years gained.

Discussion

The findings from our analysis provide guidance to colorectal cancer screening programs. They demonstrate how programs with fixed budgets can maximize the number of people screened, as well as the health provided in terms of life-years gained, by selecting the most appropriate screening test.

Under base-case effectiveness and a cost of $23 per test, testing with Hemoccult II is preferred. This is true as long as compliance with repeat testing is greater than 60 percent—in other words, at least 60 percent of those undergoing screening are tested annually—and compliance with diagnostic testing recommendations is more than 75 percent—in other words, at least 75 percent of those with positive test results undergo diagnostic colonoscopy. Under these circumstances of fixed resources, using Hemoccult SENSA results in a higher number of life-years gained than screening with colonoscopy at even 40 percent compliance with screening guidelines and 65 percent compliance with follow-up testing. Under these scenarios, the choice of guaiac-based fecal occult blood tests would allow a program to screen more individuals for colorectal cancer and would thus result in a higher number of life-years gained, compared to the choice of colonoscopy.

We have limited data on compliance with annual guaiac-based fecal occult blood test screening in general, and no reliable data specifically related to the low-income uninsured population. The compliance rate reported in the literature for repeat annual screenings with guaiac-based fecal occult blood tests ranges from 20 percent to 74 percent.[25]

Guaiac-based fecal occult blood tests provide more life-years gained for programs on a fixed budget.

Even when programs adopt measures to increase compliance that result in additional costs—for example, sending annual reminders—guaiac-based fecal occult blood tests may still be the preferred screening test. The use of these tests results in a higher number of life-years gained for a wide range of the costs we assessed. However, it may be challenging to ensure that individuals return every year over the course of decades for screening, and also to ensure that they undergo the recommended follow-up testing. Programs also have to ensure that high-quality screens—performed as instructed and processed correctly to ensure the highest possible sensitivity and specificity—are obtained, to achieve the base-case estimates presented in this study.

Except under the scenario of low test performance (that is, low levels of sensitivity and specificity), for a program with a fixed budget, guaiac-based fecal occult blood tests provide more benefit in terms of total life-years gained than does colonoscopy. Although fewer individuals can be screened with Hemoccult SENSA, that test is preferable to Hemoccult II, as the latter results in a higher cost per life-year saved across the scenarios we examined.

Other types of fecal tests, such as the new fecal immunochemical test (FIT), exhibit performance similar to that of the newer guaiac-based fecal occult blood tests.[15] The fecal immunochemical test has certain advantages because it imposes few or no dietary restrictions. However, it is more expensive than guaiac-based fecal occult blood tests.

Under the majority of the scenarios we analyzed, using guaiac-based fecal occult blood tests rather than colonoscopy as the screening test would result in more individuals' being screened for colorectal cancer. Prior studies have shown that patients and physicians tend to favor tests

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that can be offered to a wider group of the eligible population over those that can be offered to a selected subset, as the former type of test leads to a more equitable distribution of health care resources.[26,27]

In fact, guaiac-based fecal occult blood tests are selected over colonoscopy in the majority of countries that screen for colorectal cancer through programs, pilot studies, or research initiatives—although that is not the case in the United States.[28]

The results for screening colonoscopy presented in this analysis are based on an assumption of 100 percent compliance. In the real world, however, it is likely that not every patient will have a repeat colonoscopy every ten years. Colonoscopy, though, may be the optimal choice in some circumstances.

Colonoscopy is a better screening test in cases where repeated annual testing is not feasible, or where very low compliance with follow-up testing is anticipated. In addition, there is evidence that patients have preferences for specific types of colorectal cancer screening tests, and some individuals or groups might be more likely to be screened if a program used colonoscopy.[25] The selection of that test, however, raises other issues that must be considered, such as whether the program has the capacity to perform the tests and ensure that they are done correctly.

As indicated by the best-case and worst-case scenarios, there is variation in the life-years gained for both the guaiac-based fecal occult blood tests and colonoscopy. Therefore, the anticipated cost and test performance for a specific program needs to be reviewed in light of these findings. Values can differ greatly from the base-case or other scenarios presented in this study and could lead to different conclusions. For example, a lower cost of colonoscopy could make this test preferable, even if higher levels of compliance are achievable with guaiac-based fecal occult blood tests.

Cost-effectiveness models (such as the one reported in this study) that were considered to be too complex in the past can now be generated with relative ease by programs implementing colorectal cancer screening, using sophisticated software that is readily available.

Our model, for instance, has an interactive interface that can be used to vary test parameters and compliance rates to assess their impact on cost and effectiveness with relative ease. In their planning phase, colorectal cancer screening programs should use such tools to make sure that they achieve the maximum benefit possible and to accumulate data over the life of the program, so that the parameter values being used are realistic.

LIMITATIONS OF THE MODEL Although decision-analysis models are useful tools for analyzing health care interventions, there are a few limitations. First, results from colorectal cancer screening models can vary based on the underlying assumptions such as polyp progression.[19] Our model replicates the incidence and stage distribution of polyps in the U.S. population, and our results are similar to those reported by other colorectal cancer screening models. In the standardized analysis performed by the Institute of Medicine,[19] all tests were cost-effective. But the cost per life-years gained was consistently lower for guaiac-based fecal occult blood tests, compared to other tests. Therefore, even when underlying model structures differed, the relative results of these tests compared to others were consistent.

Second, we have presented life-years gained and not quality-adjusted life-years (QALYs) that take into account a person's quality of life. We decided to follow the precedent set by the majority of past modeling assessments of colorectal cancer screening, which have reported effectiveness in terms of life-years gained, and not to subject our findings to potential conflicts surrounding the measurement of quality-adjusted life-years.[29]

Third, we did not include program costs in our assessment, based on our assumption that these costs would not differ depending on the test used for screening. It is possible that the cost of increasing compliance could differ between the tests, as discussed above. Under such a scenario, the difference in program cost between the tests should be included in the cost estimation.

Fourth, this study specifically addressed the issue of test selection under fixed budgets. If there were no budget constraints, a different screening test might be preferable.

CONCLUSION Although colonoscopy is currently emerging as the most frequently performed colorectal cancer screening test in the United States, in many instances it might not be the optimal choice, especially for programs with fixed budgets. Across a broad population, as opposed to for use in a particular individual, the Hemoccult SENSA test can result in more benefit than colonoscopy. Therefore, colonoscopy should not be automatically considered the appropriate choice.

Colorectal cancer screening programs have to systematically assess the choice of screening tests used to maximize the health benefit gained for the funding available. This standard is critical to ensuring that limited funds are expended in an equitable manner, and that the programs work to reduce the disparities in the incidence of and mortality from colorectal cancer. ■

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11 Results are available in an online Appendix, which is available by clicking on the Appendix link in the box to the right of the article online.

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