KEEPING SENIORS HEALTHY: NEW PERSPECTIVE BENEFITS IN THE MEDICARE MODERNIZATION ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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KEEPING SENIORS HEALTHY: NEW PERSPECTIVE BENEFITS IN THE MEDICARE MODERNIZATION ACT

TUESDAY, SEPTEMBER 21, 2004

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:13 p.m., in room 2123, Rayburn House Office Building, Hon. Michael Bilirakis (chairman) presiding.

Members present: Representatives Bilirakis, Hall, Norwood, Shimkus, Brown, Stupak, and Green.

Staff present: Ryan Long, majority professional staff; Melissa Bartlett, majority counsel; Chuck Clapton, majority counsel; Eugenia Edwards, legislative clerk; and Amy Hall, minority professional staff.

Mr. BILIRAKIS. Good afternoon. This hearing will now come to order.

Today the Health Subcommittee will be focusing on a very important issue, the new preventive benefits now being offered by the Medicare program. Coverage of these new preventive benefits, which were authorized by the Medicare Prescription Drug Improvement and Modernization Act of 2003, MMA, is a serious initiative to make Medicare a modern prevention-focused program.

I would like to thank the witnesses who are here before us today: Carolyn Clancy, Dr. Clancy, is Director of the Agency for Health Care Research and Quality, and she will discuss the findings of the United States Preventive Services Task Force. We also have Ms. Janet Heinrich, Director of Health Care, Public Health Issues, at the U.S. Government Accountability Office, GAO. And Dr. Steven Woolf, who I understand is a former resident of the Tampa area—welcome to Washington, Dr. Woolf—who is Executive Vice President for Policy, Development at Partnership for Prevention.

I look forward to hearing from all of you today. I am sure we all do.

Since the program's inception in the mid-1960's, in 1965, Medicare has paid the health care costs for beneficiaries when they are sick. In 1965, this was an appropriate approach to health care.

Today, with rapidly increasing technology, health care is changing from diagnostic to preventive care. However, while the climate has changed, the Medicare program, I think we all would agree, has drug its feet. Over the past few years, Medicare has been incre-

mentally changing to add preventive services to the program. In the 1980's, Medicare began coverage of certain vaccinations. In 1984, Medicare established the U.S. Preventive Services Task Force to make evidence-based recommendations on the appropriateness of preventive services. In 1991, Medicare began coverage for mammography screenings, and the Balanced Budget Act of 1997, BBA, expanded coverage to include colorectal and prostate cancer screenings, pelvic exams, and osteoporosis tests.

With the implementation of MMA beginning in 2005, beneficiaries' access to preventive benefits has been brought to a whole new level. One of the most important new benefits is what we call the "Welcome to Medicare Physical," a complete preventive examination for all new Medicare beneficiaries entering the program. I am particularly proud of this new benefit because I fought for its inclusion from the beginning. My good friend, a gentleman who has been a geriatric physician who retired to Florida many years ago because he had a health problem—thank God he has been with us for a long time down there—came up with this idea. He told it to me years ago and how important it was for beneficiaries to have a complete physical so that their health can be carefully evaluated and any potential problems can be realized. And I am referring to a Dr. William Hale.

Under this new physical, Medicare will now cover influenza and hepatitis B vaccines, mammograms, Pap smears, and pelvic examinations and screening tests for prostate cancer, colon cancer, glaucoma, and osteoporosis. As part of the exam, Medicare will pay for an electrocardiogram, an assessment of a person's risk of depression, hearing and vision tests, and a review of a person's agility to perform routine activities such as bathing, eating, and getting in and out of bed. Additionally, education and counseling for any problems discovered in exams will also be covered.

Other preventive benefit provisions in MMA include Medicare coverage of blood tests for the screening and detection of cardiovascular disease for any individual, and coverage of two diabetes screening tests each year for at-risk beneficiaries.

Over 64 million Americans live with cardiovascular disease, and it is the leading cause of death in this country, and most of those people are over the age of 65. The economic impact of cardiovascular disease in our health care system continues to grow, and according to CDC will reach $368 billion in 2004, including health care expenditures and lost productivity from death and disability.

What makes this even more atrocious is that cardiovascular disease is largely preventable. Expanding Medicare coverage for cardiovascular disease will help seniors who may believe that they are healthy realize potential problems early rather than later. This will increase the health of the individual and reduce the overall cost of health care.

This hearing is, I think, especially timely right now. The Centers for Medicare and Medicaid Services released their Physician Fee Schedule Proposed Rule which contains their proposed guidelines for these preventive benefits in early August, and comments, I guess—were they completed last week? This Friday. Comments are due by this Friday.

Again, thank you for being here today. And I very gladly yield to—I say "gladly," I may be sorry that I used that word—to the ranking member of the subcommittee, the gentleman from Ohio, for an opening statement.

Mr. BROWN. I am never that, Mr. Chairman. Thank you. Thank you for holding the hearing today, and thank you, all three panelists, for joining us, some of you as repeats. Thank you for that.

I appreciate the opportunity to be recognized for an opening statement. The opportunity to make opening statements, which we all took for granted, has long been recognized in this committee as a member's right, was unilaterally and improperly usurped by Chairman Barton last Wednesday, September 15. I suggest in the future that any attempt to gag Democratic members of the subcommittee, which Mr. Bilirakis has never done and I would never expect someone of his integrity to do, but I would hope that any attempt to gag members of the full committee will be counterproductive, and I urge the committee precedent tradition be respected in the future.

Along these lines, Mr. Chairman, I would like to address colleagues on the other side of the aisle who will invariably criticize my opening statement today as a partisan attack. If the Republican majority would dispassionately consider the problems with its new prescription drug law as readily as it promotes the bill's benefits, with tens and tens and tens of millions of taxpayer dollars on television and mailings and all other ways, then our concerns wouldn't be called partisan, they would be called germane. We have been given no such opportunity when it comes to making the most sweeping changes ever to Medicare. American seniors and other American taxpayers don't want an air-brushed sale; they want the truth.

The truth is, the drug law establishes several important preventive benefits, to be sure. It is also true that Congress should not have to mandate coverage of new preventive benefits. Medicare is authorized to cover new diagnosis and treatment benefits without waiting for congressional approval or mandate. Preventive benefits should be treated the same way.

I have sponsored legislation which will enable CMS to approve new preventive benefits through the national coverage process. I hope colleagues on both sides of the aisle will consider cosponsoring this commonsense bill.

Nonetheless, the new preventive benefits are a positive addition to Medicare. Had they been offered as a stand-alone bill, I am sure the bill would have passed with overwhelmingly bipartisan support. But lacing last year's prescription drug law with a couple of new preventive benefits, no matter how attractive, doesn't begin to compensate for the dollars wasted lining the pockets of the insurance industry and the drug companies, or the opportunity wasted, the opportunity to work on a bipartisan basis and add a real drug benefit to Medicare. It doesn't compensate for the time wasted on red-herring discount cards, on HMO experiments, all because the Republican majority and the Republican President don't much like Medicare the way it is, or at least the way it was, and do really like the drug industry and the insurance industry and the way that they both operate; because in the new drug law, Medicare pre-

miums are going to increase by more than 17 percent next year, the highest increase in Medicare history. Seniors will receive a cost-of-living in their Social Security benefits of less than 3 percent. Premiums increase 17 percent.

It didn't have to be that way. The new law, as we know, hands HMOs bonus payments of over $23 billion. Last March, HMOs got their first checks from Federal taxpayers totaling $229 million. In April they got another $229 million. In May they got another $229 million. Yet there was no prescription drug benefit yet. In June, $229 million; July, August, September, all the way through next year, yet still no prescription drug benefit, but plenty of dollars for Medicare HMOs. And, remember, even before these new payments, the Bush administration itself admitted that HMOs were being overpaid. They already said they were overpaid, but now we are giving them $229 million a month. Not that it would have anything to do with political contributions to the President from the insurance industry or to Republican leadership. This bill forces private HMOs regardless of—forces them on seniors regardless of what seniors want and despite the fact that HMOs add billions to Medicare's price tag. The new law prohibits the Federal Government from negotiating volume discounts on RX drugs, as the VA does, a concept that no one I have ever met in Ohio understands, except to be explained away by drug company contributions to George Bush.

Drug industry profits will increase by $182 billion thanks to this new law, with seniors and taxpayers footing the bill. The new law would never have passed if the administration had not lied about the cost of Medicare, had not threatened the Medicare functionary, did not threaten his job if he sang to Congress or the American people about the cost. And—undoubtedly. But we got a bill because we—we got that bill because some people didn't tell the truth. It never would have passed if seniors knew they would be paying dramatically higher Medicare premiums, 17 percent higher, so that the Medicare—that the Republican majority and the President could privatize Medicare, boost the profits of the drug industry, and line the pockets of the HMOs. There are beneficial preventive benefits and a shameful Medicare drug law. That is not a partisan attack, it is simply the truth.

I yield back.

Mr. BILIRAKIS. The Chair would now yield to Dr. Norwood for an opening statement.

Mr. NORWOOD. Thank you very much, Mr. Chairman. I wasn't going to say anything, but I am stimulated to have a remark or two.

First of all, thank you for this hearing. It is very important, I believe, that we continue to point out prevention. In my profession, we have been into that a long, long time. It is high time that we got into that with Medicare.

A couple of points I would make, so Mr. Brown would know. The premium increase that was set out was to help stop the 4.5 percent reduction in fees to our providers, which, had that not been done, access to health care would have drastically been cut. So the Democrats who supported that, we appreciate that, and it is time to bring out at this hearing that that was a good thing.

The Democratic substitute called for increased payments to HMOs. You know, their substitute wasn't any different. So it would be better, just quit being partisan about this bill. There are a lot of good things in this Medicare bill, and I guess to start with, prevention would be at the top of my list.

Second, I am on a number of committees, as we all are, and many of our committees, Mr. Chairman, don't have opening statements other than the chairman and the ranking member. And I don't know about tradition in the Commerce Committee, but that is not a bad rule, particularly 2 months before an election when people aren't really trying to dig into the sense of the problem but are playing politics. And, you know, for me to encourage you to do that on this subcommittee means I don't get to make an opening statement too. But I do want to say that sometimes it is real appropriate not to have an opening statement and listen to the people we have asked to come to Washington to help us learn.

With that, Mr. Chairman, I will——

Mr. BILIRAKIS. Would you yield?

Mr. NORWOOD. I would yield.

Mr. BILIRAKIS. I would just like to say, none of us are happy about the premium increase. We should remember, of course, when Medicare was first devised back in the mid-1960's, it was supposed to be a 50/50 situation; all of the costs would be shared 50 percent by the beneficiaries, 50 percent by the taxpayers, by the government, if you will. And as time went on, that was reduced to something like 75/25. And we passed the law some time back that said that 25 percent would be the share that would be paid by the beneficiaries, and that is a formula type of thing.

And regardless of who might be in the White House and regardless of which party will be in charge this year, it would come out to this dollar figure because it is a flat-out 75/25. And my colleagues know this. And I would hope that they would not play basically political games with that particular point.

I mean, was I distressed when I saw that happening? Of course I was. But it came out to—it is a formula type of a thing.

Having said that——

Mr. NORWOOD. Mr. Chairman, if I could, one last sentence on my time.

Mr. BILIRAKIS. One last sentence.

Mr. NORWOOD. The premium increase also is part of why we can afford to have the preventive benefits. Preventive benefits are lifesaving benefits. It was the right thing to do.

Mr. BILIRAKIS. And I daresay that Mr. Brown's ideas of additional preventive benefits, which I don't think my good friend has directly made me aware of, but if he has, you know, it was at a time maybe when it didn't stick. But that is certainly something that I generally would support, and we just haven't sat down and talked about them specifically. But that would probably also increase the Part B premium in the future with additional preventive benefits added therein.

Anyhow. Mr. Green, for an opening statement.

Mr. GREEN. Thank you, Mr. Chairman. I wasn't planning to enter in on that, but part of that increase that we had in the Medicare bill and was widely reported a few minutes ago, that part of

the increase, that we are paying more dollars for the Medicare+Choice, that actually costs more than regular Medicare for our constituents. But, again, I think that came from CMS when they talked about it.

Mr. Chairman, I just wanted to thank you for the hearing, because there were new preventive benefits in the bill. At the end of the day I voted against the bill because of its incomplete prescription benefit, and in general I believe it does more harm than good to the Medicare program and the beneficiaries who depend on the program for their health care. And I think the proof is in the fewer number of people than expected to take up that benefit.

That being said, the new law does provide three extremely new important preventive benefits: a physical upon enrollment in Medicare; a cardiovascular screening blood test; and a diabetes screening test. Each of these preventive benefits will help save lives, and it is worth noting that in the long run these new benefits will save significant costs for Medicare because we will be able to catch many of these debilitating illnesses in the early stages instead of treating them in advanced stages where costs are skyrocketing.

Without a doubt, an ounce of prevention is worth a pound of cure, and I am pleased that Congress took that message to heart in that bill. Diabetes is a major health problem in my State of Texas, and more than 1 million adult Texans have diabetes. The State estimates that another 500,000 are living with undiagnosed diabetes. The State of Texas, and the district I represent in particular, has a large Hispanic population which studies have shown is at higher risk. That is why I offered the amendment, along with now-Governor Fletcher of Kentucky, to include diabetes screening in the Medicare bill.

And I would like to take this opportunity to once again thank my colleagues for including it at the committee level. And if I had my druthers, Medicare would also include screenings for abdominal aortic aneurysms, known as the "silent killer." Abdominal aortic aneurysms can occur without any symptoms or warnings, and less than 15 percent of the patients with a ruptured abdominal aortic aneurysm survive, and two out of three victims die before they ever reach the hospital. With effective screenings, however, AAA can easily be detected and repaired with a fairly noninvasive procedure. That is why a AAA screening benefit is an excellent candidate for a new Medicare preventive benefit.

My friend Jim Greenwood and I have introduced a bill to cover AAA screenings under Medicare, and I am sure he agrees and will welcome the support of the subcommittee in this effort.

And while we are here today to discuss the implementation and effectiveness of these three preventive benefits, we must realize that there are great additions to Medicare that cannot be examined in a vacuum. There are serious problems with the Medicare program; and as more seniors take advantage of the program's preventive benefits, they are sure to come up against the several roadblocks making these benefits work for them. Physicals don't help seniors if the result is a diagnosis of a disease that must be treated with a prescription drug regimen so expensive that it forces Medicare beneficiaries into a doughnut hole where drugs aren't paid for. And, at the end of the day, a preventive benefit isn't worth the

paper it is written on if the program doesn't provide seniors with the resources to deal with the diagnosis.

I am certainly interested in hearing our witnesses' views on the issues, and I know they will provide us with important insight on the steps we need to take to ensure that new preventive benefits are added to Medicare in a timely manner.

And, again, Mr. Chairman, I appreciate you holding this hearing. And I know for a number of years we have had these hearings on Medicare, not only for the bill that passed last year, but on issues dealing with Medicare. And so I appreciate the opportunity.

Mr. BILIRAKIS. I thank you, Mr. Green. I oftentimes wonder why we can't in a bipartisan manner get together and do something about the method that CBO uses to score, which is something we run into all the time when we talk about things such as preventive health care.

Mr. GREEN. Mr. Chairman, you and I have talked about that, and it sure would be nice if we could set that so we could take advantage of the savings from preventive care. And I know we share that.

Mr. BILIRAKIS. It is crazy, isn't it? They call it the Congressional Budget Office, and yet we don't seem to have any control over them.

In any case, Mr. Hall for an opening statement.

Mr. HALL. Thank you, Mr. Chairman.

I would like to start with—and I have admiration and respect for both the gentlemen present from the minority, but I feel constrained to say that this committee and the chairman of this committee ought to always gag anyone that is politicking at the expense of this committee's very valuable time at this particular time. And as Dr. Norwood has said, and as Mr. Brown and Mr. Green both agreed, the increased payments are not anything that we would enter into but for some reason. And the very reason is that these preventive payments and these preventive benefits save money, considerable money, later. The savings, not today—it looks like a 17 percent increase today, but it is a huge savings down the line. By the time these senior citizens get to that stage, they would have a better life if they had the prevention now. So it is not only saving them money, but it saves in the health of people and the care of people and the love of these senior citizens, these folks that are the treasure that this program benefits.

I was in the Texas Senate in 1963 when Medicare and Medicaid showed its face, and the Members of Congress came down to all the legislators, they came to the Texas legislature and told us about these two great programs that they were going to initiate. One was called Medicare and one called Medicaid. They said if we are not careful, the Medicaid could cost almost a billion dollars a year. Imagine that. And Medicare could cost as much as up to $7 billion a year. I think that was their testimony before our little committee down in Texas.

Well, you know, last year it was $50, $60 billion, and $150 or $160 billion or so. I don't know if those figures are correct, but I think the comparisons are. But for 2005, the Part B premium is going to be more. I don't like that, but I understand it. But, you know, there is a saving grace there. While it is more—and it con-

sists of outpatient hospital services, of home health services, of durable medical equipment—still about three quarters of the 2005 premium increase is due to additional costs for Part B.

And I think the record indicates I believe that all the members of the minority voted for that, in favor of increased physician payments and reimbursements to Medicare Advantage plans, where the major provision that led to the increase in Medicare premium costs, either on the Democrats' substitute, their own substitute for H.R. 1, our own final passage of H.R. 1 conference. So we are not all that far apart.

I think we all realize a lot of this is politics, and I guess it is a political time, but I just think that we need to remember that we, probably most of us, voted for that. And we also need to remember that the beauty of the entire price increase is more than 6 million low-income beneficiaries will see absolutely no premium increase, because they already have their entire premium paid by Medicaid. And the real saving grace to all of it is they can opt out of it. They are not forced into anything. So I don't think we ought to be trying to sell that here 6 weeks before the general election.

I yield back my time.

Mr. BILIRAKIS. I thank the gentleman.

Mr. Stupak for an opening statement.

Mr. STUPAK. Mr. Chairman, while I appreciate the topic of today's hearing, the preventive benefits of the new Medicare law, I believe there are many more important, more urgent topics of concern for American seniors and American taxpayers regarding the new law. Let me list a few.

Topics like cost. Why won't the administration just tell American taxpayers the truth about the cost of this new law? It seems like every day a new cost estimate comes out. The committee deserves a straight answer. Let us face it, the administration did not tell the truth to the American people and Congress when they said the legislation would cost no more than $400 billion over 10 years. Earlier this year, the administration admitted the new law would cost 534 billion over 10 years. This week, a new estimate by the administration says $576 billion. What is the true cost of this bill? And how much of that cost is going to be to big insurance and HMOs as overpayments?

According to a MEDPAC report that was released to Congress last week, Medicare HMOs will get paid 107 percent of what it would cost to care for the same seniors under traditional Medicare. I thought HMOs are supposed to lower our costs. In fact, Medicare spending could be reduced by $50 billion over the next decade by paying private plans 100 percent of what it pays for fee-for-service coverage. The HMOs and CMS need to come before Congress and justify these overpayments. I don't think they can be justified, but I am willing to listen to their explanations. How much is this giveaway to HMOs and prescription drug companies costing American seniors?

We know that Part B premiums are going up, are going to increase by 17.5 percent next year. Seniors deserve to know why they are going to be forced to pay the largest dollar increase in the history of Medicare. We should be discussing how seniors will afford

a 17.5 percent increase next year on top of a 13.5 percent increase this year. We know they can't rely on Social Security.

According to a recent administration analysis, which was hidden until USA Today recently uncovered it—and I am quoting now—a typical 65-year-old can expect to spend 37 percent of his or her Social Security income on Medicare premiums, copayments, and out-of-pocket expenses in 2006. That share is projected to grow to almost 40 percent in 2011, and nearly 50 percent by 2021.

How are seniors supposed to make due? Congress should not go home until the premium issue increase is addressed.

Mr. Chairman, there are a lot of questions that need to be asked about the true cost of this law to both the taxpayers and the seniors and about the quality of benefits. We need to know why 3 million low-income seniors who qualify for the $600 credit under the drug card program have not signed up. We need to know why the administration is not automatically enrolling the only group of seniors I believe may benefit from this otherwise lousy drug card program. And we need to know why, when the Secretary of Human Services, Health and Human Services, is going to use his authority granted to him under the new law to allow the safe importation of prescription drugs by our seniors.

This committee has a lot of questions to ask of the administration on issues of great importance and urgency to our seniors and taxpayers. I hope you allow us an opportunity to ask those questions.

I yield back the balance of my time.

Mr. BILIRAKIS. The Chair recognizes the gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I will be brief.

Thank you for this hearing. You know, it is about time that we started moving Medicare into the modern era, and we are doing that and I think we will find out more with this hearing with the "Welcome to Medicare Physical" as well as the cardiovascular and the diabetes screening that is very important. This is educational. It is educational for us so that we can talk to our seniors, it is educational for the public who will be watching over C-SPAN. The more we learn about it, the better we are all going to be.

And I thank you for coming, Mr. Chairman. I yield back my time.

Mr. BILIRAKIS. I thank the gentleman.

[Additional statement submitted for the record follows:]

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Chairman Bilirakis for holding this important hearing. I would also like to thank our witnesses for coming to testify before the Subcommittee today. I look forward to hearing your testimony, and your views on the new preventive services available to Medicare beneficiaries.

The landmark Medicare legislation passed last year truly deserves the name the Medicare Modernization Act. Medicare is too often behind the curve in responding to changes in the practice of medicine. In 1965, prescription drugs were an afterthought in providing quality medical care. The same was true for preventive benefits. The MMA recognized the changes that have revolutionized health care since 1965, and provided beneficiaries with access to both prescription drugs and preventive benefits.

At its inception, Medicare was designed to treat acute conditions after patients became symptomatic. Since that time quantum leaps have been made in our under-

standing of diseases. Although we don't have a cure for cancer, we do know that when detected early, patients can beat this otherwise fatal disease.

Thirty-nine years ago, too many diabetics faced living with painful diabetic ulcers or having to undergo life-changing amputations. Those dangers still exist, but with early recognition of diabetes and proper management of the disease, most diabetics can avoid serious complications. According to the American Diabetes Association, over 18 percent of Americans age 60 and older have diabetes. With the increasing prevalence of Type II, adult onset, diabetes it is imperative for the quality of life of our seniors that we do a better job of early detection and treatment of this disease. The Medicare Modernization Act will provide seniors at risk for diabetes the appropriate screenings for the disease.

In addition, thanks to the tireless efforts of Subcommittee Chairman Bilirakis, seniors for the first time will receive a "Welcome to Medicare" physical upon their enrollment in the program. The importance of this initial exam cannot be overstated. These examinations will allow seniors to better understand their current health status and take steps to mitigate potential health risks.

Seniors will now also receive regular cardiovascular screenings. According to the American Heart Association, in 2001, over four million seniors were discharged from short-stay hospitals with a first listed diagnosis of cardiovascular disease. Many of those could have avoided hospitalization by early detection of their cardiovascular disease risks.

The new preventive benefits provided by the MMA hold the promise to dramatically improve patient outcomes. They also hold the potential to reduce Medicare spending by identifying and treating conditions before they require expensive acute care.

This year Medicare celebrated its 39th birthday. Thanks to the new benefits provided for in the MMA, seniors will begin to see a Medicare program that is based on the medicine of the 21st century, not an outdated benefits package based on the medicine of decades gone by. Thank you again Mr. Chairman for holding this important hearing.

Mr. BILIRAKIS. Let us go right into the witnesses. Our gratitude for your taking time to be here. I am glad that we have shortened our opening statements, so to speak, so that we can hear from you.

Your written statements, of course, are a part of the record, and hopefully you will complement and supplement them. I will set the clock at 5 minutes, but by all means don't let it rush you. In other words, we want to hear what you have to say. And hopefully, of course, that doesn't mean you double the time, But in any case, whatever. Please help us to better understand what we have accomplished, what we hope to have accomplished regarding preventive health care in this legislation.

Dr. Clancy, please proceed.

STATEMENTS OF CAROLYN CLANCY, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; JANET HEINRICH, DIRECTOR, HEALTHCARE/PUBLIC HEALTH ISSUES, U.S. GOVERNMENT ACCOUNTABILITY OFFICE; AND STEVEN H. WOOLF, EXECUTIVE VICE PRESIDENT FOR POLICY DEVELOPMENT, PARTNERSHIP FOR PREVENTION

Ms. CLANCY. Mr. Chairman and members of the subcommittee, I am really delighted to have the opportunity today to testify about the role of the U.S. Preventive Services Task Force in assessing the effectiveness of preventive health care services. This year marks the 20th anniversary of the Task Force. Composed of 16 private sector experts, the Task Force conducts rigorous impartial assessments of the scientific evidence for a broad range of clinical preventive services. Indeed, its recommendations are considered the gold standard, if you will, for preventive services provided in a clinical setting. The work of the Task Force complements the important

work of CDC's Task Force on Community Preventive Services, which, by its name, as it implies, examines preventive services delivered in community or public health settings.

Before turning to how the Task Force does its work, I want to just make three points to put its work in context:

First, the Task Force focuses on primary and secondary preventive health care services that are delivered in primary care clinical settings. So primary prevention is defined as interventions that reduce the risk of disease in otherwise healthy people. For example, flu shots. Secondary prevention is defined as screening to identify risk factors for disease or to identify disease before it appears, such as cancer or heart disease.

The second point is that the role of the Task Force is to identify those preventive services for which there is good-quality evidence of effectiveness. In medicine, all of us are taught that the first cardinal rule is do no harm. The role of the Task Force is to identify those preventive services for which there is evidence of effectiveness. In other words, that the potential benefits outweigh the potential harms.

The third point is that the Task Force does not speak for AHRQ or for HHS. While the director of AHRQ is statutorily required to appoint its members and support its work, the Task Force is not a Federal advisory body under law. So to date, the Task Force has reviewed over 70 topics in the area of primary and secondary clinical prevention, ranging from taking aspirin to preventing a first heart attack to screening for obesity to screening patients for potential problems with depression.

To determine which topics to review, the Task Force solicits inputs from its members, Federal agencies, professional organizations, and the public. The Task Force then ranks the topics based on the magnitude of the problem as defined by the number of people affected, and they work with outside experts to identify the fundamental questions that should be answered. For example, is a clinical preventive service, whether it is screening, counseling, or chemo prevention, associated with reduced morbidity and mortality? Does early identification of the disease lead to an improved outcome compared to the result that would occur if the disease were not detected early? And so forth.

So this decision framework also takes into account potential harms of these services, such as the possibility of false-positive tests that require further and sometimes invasive and potentially risky follow-up tests.

To rate the quality of the evidence, the Task Force relies on AHRQ to coordinate systematic reviews of the evidence through our Evidence-based Practice Centers program. The Centers first identify all relevant studies, and then they assess the quality of those studies to figure out whether they are of good, fair, or poor quality. They then synthesize the findings. Consistent with our policy and our authorizing legislation, the Centers make no recommendations. That role is left to the Task Force, which establishes recommendation by a formal vote, and how they do this is they assign letter grades.

An A grade means a very strong recommendation; that there is good evidence that the benefits of providing this service substantially outweigh the harms.

A B grade, similar to report cards, means that the Task Force recommends a service if there is at least fair evidence and the benefits outweigh the harms.

A C grade means that the Task Force makes no recommendations for or against if there is at least fair evidence and there is a close balance between the benefits and the harms.

A D grade means that the Task Force recommends against routine use of a service that is ineffective or that the harms outweigh the potential benefits.

And an I grade means that the Task Force finds insufficient evidence to recommend for or against, since the balance of benefits and harms is not known. This I recommendation sometimes causes confusion. The I letter simply reflects that there is insufficient evidence to make a formal recommendation. It is neither a recommendation for nor against providing the service on a routine basis. It may mean that few studies have been conducted or that the existing studies are flawed or contradictory or are not powerful enough statistically to provide conclusive evidence.

Mr. Chairman, supporting the work of the Task Force is just one aspect of AHRQ'S much broader prevention agenda. We have come to appreciate that there is a large gap between what is known and what is actually done in practice, and our work can help in three ways:

First, before we can improve care, we need to understand what is known or the state of the science. AHRQ plays an increasingly important role in synthesizing that knowledge. We now have a formal arrangement to develop such syntheses before each consensus conference sponsored by the National Institutes of Health, and the MMA directs AHRQ to expand its synthesis role. The goal of MMA Section 1013 is to help those who manage and are served by the Medicare, Medicaid, and SCHIP programs to benefit faster from existing knowledge. In addition, we are finalizing three reports related to obesity in the elderly, geriatric surgery, and weight loss programs which we hope will be very useful to public and private sector policymakers.

Second, recent experience demonstrates that knowing the right thing to do is only the first step. The real challenge is ensuring that our broad range of health care delivery systems supports rather than frustrates the effort of harried caregivers to provide state-of-the-art care; that is, to do the right thing. The Institute of Medicine report "To Err is Human," which focused on medical errors and patient safety made it very clear: It takes a dual focus on effective services in effective and efficient ways to organize, manage, and deliver those services.

Third, AHRQ can play a unique role in what is sometimes called tertiary prevention or preventing complications in those with diseases. From my experience as a practicing physician and also from published studies, I can tell you that the critical challenge is not developing management strategies for individual diseases, it is understanding how to reconcile competing recommendations for patients with multiple chronic illnesses. For example, 82 percent of

people with diabetes have at least one other chronic illness. Twenty percent of Medicare beneficiaries have five or more chronic conditions. The perspective that we bring to chronic care management is patient-centered, not disease-specific, and increasingly we are shifting our work to ensure that patients and their caregivers have better information for assessing these critical tradeoffs.

This concludes my prepared remarks, and I would be happy to take any questions.

[The prepared statement of Carolyn Clancy follows:]

PREPARED STATEMENT OF CAROLYN CLANCY, DIRECTOR, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTRODUCTION

Mr. Chairman, I welcome this opportunity to testify about the role of the United States Preventive Services Task Force in assessing the effectiveness of preventive health care services. In fact, this year marks the twentieth anniversary of the Task Force. Now in its third incarnation, the Task Force is widely viewed by primary care clinicians as providing the "gold standard" regarding those preventive services for which there is good quality scientific evidence of effectiveness.

I will also comment briefly on the research and synthesis work undertaken by the Agency for Healthcare Research and Quality (AHRQ). We support the work of the Task Force, a statutory requirement since our 1999 reauthorization, but we also develop new information regarding the effectiveness of preventive health care; synthesize "state of the art" information regarding preventive health care services for patients and their caregivers, and identify approaches for increasing the rates at which effective clinical preventive services are delivered and used.

AHRQ's work provides an important complement to the community-based, public health strategies and interventions that are developed and promoted under the leadership of the Centers for Disease Control and Prevention (CDC). Both CDC and AHRQ also benefit from the work of the National Institutes of Health in developing the basic building blocks that underpin public health and clinical preventive services interventions. Prevention research is a good example of how the Department of Health and Human Services (HHS) is increasingly functioning as "one Department."

As requested, my testimony will provide background information on how the Task Force and AHRQ approach their work in prevention. However, I want to stress that AHRQ maintains a focus on effective preventive services for the elderly. In that capacity, each year we submit to the Congress a report on the latest recommendations of the Task Force. I welcome the opportunity to address any substantive issue following the conclusion of my statement.

THE UNITED STATES PREVENTIVE SERVICES TASK FORCE

Context and Scope

Before turning to how the Preventive Services Task Force undertakes its work, there are 3 points that need to be made regarding the context and scope of its work.

First, the Task Force focuses on primary and secondary prevention. Since the Office of the Secretary established the first Preventive Services Task Force 20 years ago, the Task Force's mandate has focused on the delivery in primary care settings of primary or secondary prevention services. The Task Force was originally created to provide guidance for primary care clinicians in the area of preventive care for apparently healthy individuals. Primary prevention is defined as interventions that reduce the risk of disease occurrence in otherwise healthy individuals. Counseling patients not to smoke and prescribing fluoride to children to prevent cavities are examples of primary prevention. Secondary prevention can be defined as screening to identify risk factors for disease or the detection of disease among individuals who are at risk for that disease. Evaluating blood pressure in adults is an effective way to identify individuals at risk for heart disease and provides an opportunity to intervene before the disease occurs. Screening for colon cancer using colonoscopy to detect pre-cancerous polyps is another example of secondary prevention. The bottom line is that individuals who receive primary or secondary prevention services have no obvious signs of illness; in clinical terms, they are asymptomatic. Consistent with the longstanding commitment by physicians and other health care professionals to "first do no harm," providing services to individuals who are apparently free of disease requires a careful approach to balancing benefits and harms.

By contrast, the Task Force does not address the category of services known as tertiary prevention. Tertiary prevention services are provided to individuals who clearly have a disease and the goal is to prevent them from developing further complications. For example, diabetes care would be considered tertiary prevention in that the care provided is focused on limiting the complications of a disease that is already present. Tertiary prevention interventions are a focus of research by AHRQ and an important component of prevention public policy, but they are not within the purview of the Task Force. Unlike primary and secondary prevention, there are numerous groups who review the literature on medical treatment in order to advise clinicians on the optimal way to treat chronic illnesses. Therefore, it remains critical for a group such as the Task Force to remain focused on the types of preventive service decisions for which most primary care clinicians have limited evidence-based guidance.

Second, the role of the Task Force is to identify those preventive services for which there is good quality evidence of effectiveness. This is a high standard to meet and has implications for interpreting the work of the Task Force and determining what to do in the absence of evidence. The first point to recognize is that good quality scientific evidence takes time. Thus, when the Task Force concludes that there is insufficient evidence upon which to make a recommendation, the Task Force is not concluding that a service is ineffective. It may simply reflect the fact that few studies have been conducted, or that existing studies are flawed, contradictory, or simply not powerful enough statistically to provide good quality evidence. Should a finding of insufficient evidence preclude guidance from Federal agencies, medical societies, or action by policymakers? Not necessarily. Patients and their caregivers often need advice or assistance in the absence of perfect information and there may be an important public health rationale for action before good quality evidence is available. In such cases, guidance from Federal agencies or medical societies or action by policymakers may be appropriate.

Third, the Task Force does not speak for AHRQ or HHS. While the Director of AHRQ is statutorily required to appoint its members, the Task Force is not a Federal advisory body under the law. The Task Force is a body of private sector primary care experts and methodologists. It is configured to provide expertise in the area of primary and secondary clinical prevention to a broad patient population and their primary caregivers. I have included at the end of my testimony, a roster of the current Task Force membership, which includes a mix of internists, family physicians, pediatricians, obstetrician/gynecologists, nurses, and methodologists with expertise in issues of screening, counseling, and prescribing drugs for reducing the risk of disease in the primary care setting.

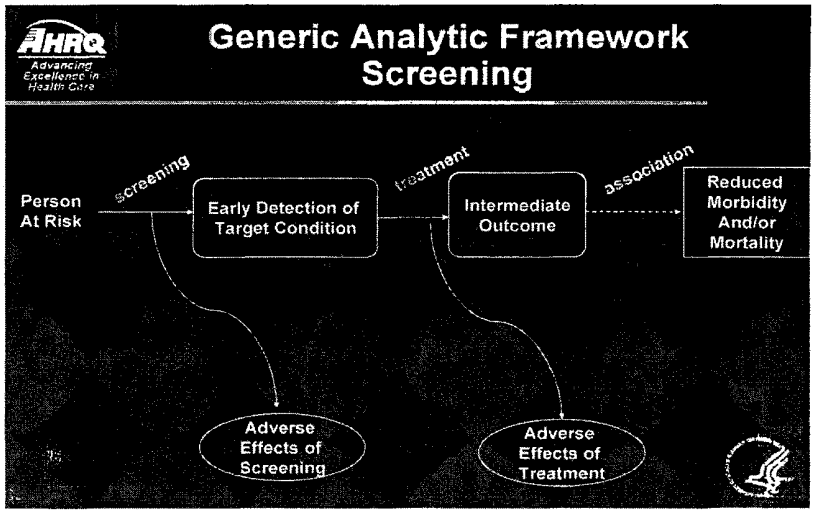
How the Task Force Operates

To date the current Task Force has reviewed numerous topics in the area of primary and secondary clinical preventions, ranging from childhood vision screening to obesity counseling to postmenopausal hormone replacement therapy. This range of topic areas and population age groups reflects the breadth of such interventions encountered in primary care settings. The process that the Task Force uses is as follows:

Topic Selection: To determine which clinical preventive topics to review, the Task Force solicits topics from its members, Federal agencies, professional organizations and the public. The Task Force then prioritizes these topics based on the magnitude of the problem as defined by the number of people affected or the severity of the problem, evolving evidence, and potential impact of the recommendation on primary care practice.

The Framework for Evidence-Based Reviews: For each topic, the Task Force establishes the scope of the review by identifying the specific populations for which evidence will be evaluated. This decision reflects the prevalence of the disease and its manifestation among different groups, expressed in terms of age, gender, and risk status.

The analysis of the scientific literature is guided by the ultimate outcomes on which the Task Force focuses. Is a clinical preventive service—screening, counseling or prescribing drugs to reduce the risk of disease—associated with reduced morbidity and mortality? Does earlier identification of disease lead to an improved outcome compared to the result that would occur if the disease was not detected and treated early? The Task Force then works with external experts to develop the specific key questions for each point in the analytic framework that will illuminate the effectiveness of screening, counseling or treatment on reducing mortality and morbidity. As the graphic below demonstrates, the framework also takes into account potential harms associated with these activities such as false positives, increased anxiety, or adverse effects.



Rating the quality of the evidence: The Task Force relies on AHRQ to coordinate the systematic reviews of the evidence through the Evidence-based Practice Centers (EPCs) supported by the Agency. Before an EPC can synthesize the scientific literature, it must first assess the methodological rigor of each study, asking questions such as:

- Did the investigators use an appropriate research design for the question being asked?
- Did they control for other factors that might affect the outcome (what researchers call "threats to validity")?
- Did they use the right statistical tests and calculate them properly?
- Did the study address services provided in the primary care setting?

After evaluating the relevance and rigor of each individual study, the EPC also considers the consistency of evidence across the entire body of studies. Based on these components the strength of the evidence is categorized as good, fair, or poor and then synthesized. Consistent with its approach in other areas, AHRQ directs its EPCs to identify strengths and limitations of the existing knowledge base, but these evidence reports make no recommendations.

Developing a recommendation: After reviewing the EPC report and considering the overall strength of the evidence and estimates the magnitude of the net benefits (based on the balance of benefits and harms), the Task Force then establishes recommendations by a formal vote. To guide interpretation of its recommendations, it assigns a letter grade to each recommendation, reflecting the strength of the evidence and the magnitude of benefit. The letter grades include:

A—The Task Force strongly recommends a service, there is good evidence, and benefits substantially outweigh the harms.

B—The Task Force recommends a service if there is at least fair evidence, and the benefits outweigh the harms.

C—The Task Force makes no recommendations for or against a service if there is at least fair evidence, and the benefits and harms are closely balanced.

D—The Task Force recommends against routine use of a service that is ineffective or if the harms outweigh the potential benefits.

I—The Task Force found insufficient evidence to recommend for or against a service since the balance of benefits and harms is not known.

The "I" letter grade simply reflects the lack of adequate evidence to make a recommendation; it is neither a recommendation for nor a recommendation against providing the service on a routine basis. A preventive service could receive an "I" letter grade for several reasons: Studies may be lacking, existing studies may be of poor quality, or good-quality studies may have conflicting results. Therefore, an "I" recommendation is a call for additional research that would provide the appropriate evidence base for the USPSTF to make either a positive or negative recommendation.

Two Methodological Issues now under Consideration

Mr. Chairman, there are two methodological issues under consideration by the Task Force that may be of interest to the Committee, and we would welcome your input. The first relates to special populations. The Task Force addresses recommendations across all age groups from birth to death. While the majority of recommendations focus on the adult population, the current Task Force has addressed 13 topics relating to children and adolescents. Challenges exist in making recommendation for these populations for multiple reasons. Defining the clinical endpoint can be difficult in children because the reduction of morbidity and mortality may not be realized until they reach adulthood. The potential benefits or harms of clinical preventive services need to be considered for the child and adolescent as well as their family. Finally, youth often receive services in the school or community setting. To address these challenges the Task Force established the Child Health Workgroup which is currently discussing these issues and is planning a child health expert conference.

The second issue relates to the consideration of costs and cost-effectiveness. With the convening of the current Task Force, members recognized that cost-effectiveness and value are important issues to users of the Task Force recommendations. The Task Force convened a work group to assess approaches for addressing cost and cost-effectiveness. That assessment is still under way. At this point, the Task Force does not consider cost or cost effectiveness as a primary determinate in making its recommendations but rather in selected cases summarizes the cost data for users in the discussion section of its recommendation statement.

THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

Mr. Chairman, supporting the work of the Task Force is but one aspect of AHRQ's much broader prevention agenda. Unlike the Task Force, our agenda includes tertiary prevention interventions in addition to primary and secondary activities. Rather than provide a laundry list of those activities, I would like to highlight three unique strengths that AHRQ brings to all of its work, including the Department's prevention initiatives

In recent years we have come to appreciate that there is a large gap between what is known and what is done in practice. It is reflected in the unacceptably long time line between the funding of pioneering research and the point at which most Americans benefit from that research investment; at least one analyst estimates that it takes 17 years. Our work suggests that there are a number of challenges we must overcome if we are to ensure that Americans benefit more rapidly from our past research investments. Let me highlight just three.

First, it is hard for physicians and their patients to keep abreast of the latest scientific knowledge. The increased pace of publication of new scientific findings also enhances this difficulty. As a practicing physician, I know how difficult it is to determine whether to change my practice on the basis of the latest finding about one of many clinical issues I face. Unless research findings are put into context, my colleagues and I cannot answer for our patients that vital but deceptively simple question: what is known? I am increasingly convinced that AHRQ's role in the synthesis of evidence—which we undertake for (among others) the Task Force, CMS, FDA, and even NIH as a prelude to its consensus conferences—is a vital first step to reducing lag time. We need to understand what is known—the "state of the art"—before we can improve. In the area of prevention, for example, we have completed three important evidence reports on obesity. I expect these reports will be as useful to policymakers as they will be for patients and their caregivers.

- CMS commissioned a technology assessment from us to review and analyze the scientific literature on treatments for obesity in the elderly, including behavioral therapies and dietary counseling.
- At the request of Congress, we developed a report on a cost effectiveness analysis of weight loss programs in the elderly.
- One of our Evidence-based Practice Centers recently completed an evidence report on pharmacological and surgical management of obesity. This report was requested by primary care specialty societies. It will be released in the next few days.

The Medicare Modernization Act (MMA) requires AHRQ to undertake more of this type of work so that those who manage and are served by the Medicare, Medicaid and SCHIP programs can benefit faster from existing knowledge. The MMA also challenges AHRQ to see that physicians and patients can access the information on "what is known" when they need it. We already have an innovative arrangement with the vendor, ePocrates, to provide physicians with fast access on their PDAs to the bottom line of recommendations from the Task Force. Since a growing number

of clinicians rely on their PDAs to help keep them current with the latest science, AHRQ has developed a free Interactive Preventive Services Selector Program for PDAs. Since we made the software available for downloading, the web site has been accessed 7,847 times and the software has been installed on 1,837 Palm-based PDAs and 775 Pocket PC PDAs.

Second, recent experience demonstrates that knowing the right thing to do is only the first step. The real challenge is ensuring that our broad range of health care delivery systems supports, rather than frustrates, the efforts of harried caregivers to do the right thing. AHRQ has a unique dual focus on effective services and effective and efficient ways to organize, manage, and deliver those services. We pioneered the use of preventive services reminder systems and some concepts for workflow redesign to improve the rates at which preventive services were delivered and used. As my colleagues and I work to make AHRQ more of a "problem solving" agency, we will focus increasing attention on options for overcoming those system, organization, and behavioral barriers to increased use of effective clinical services.

In addition, we will soon be announcing a series of grant and contract awards to increase the deployment and use of health information technology—precisely because health information technology can make the right thing to do the easy thing to do. The awards we will be announcing will advance the President's and Secretary's commitment to improve the safety and quality of health care and increase the utilization of preventive services.

Third, as the "baby boomer" generation ages, the ranks of chronic care patients are swelling. AHRQ has and will continue to contribute to efforts to develop and assess specific disease management strategies. But the unique perspective we bring to chronic care management is a patient-centered, not disease-centered, focus. For example, 82% of patients with diabetes have another chronic condition and 20% of Medicare beneficiaries have 5 or more chronic conditions. In our view, the challenge of developing effective individual disease management strategies is easily matched, if not exceeded, by the need to reconcile disparate disease management programs for patients with multiple chronic diseases. Increasingly, our work is shifting to meet this need. The number of multiple chronic care patients will only continue to grow in the years ahead and we need tertiary prevention strategies that can be reconciled at the level of the primary carergiver.

CONCLUSION

Mr. Chairman, this concludes my prepared testimony. I would be happy to answer questions.

Mr. BILIRAKIS. Thank you very much.

Director Heinrich.

STATEMENT OF JANET HEINRICH

Ms. HEINRICH. Mr. Chairman and members of the subcommittee, I too am pleased to be here today as you discuss preventive care benefits for the Medicare population. As you stated, the Medicare program was originally conceived to help pay for people 65 and over who were ill or injured. But over time, Congress has broadened coverage to include specific preventive services such as immunizations or screenings for different types of cancers. Most recently, Congress added coverage for a one-time preventive care examination for new enrollees and other selected preventive services.

As these new benefits are implemented, you have asked about lessons learned from previous research on delivery options. My statement today focuses on the extent to which beneficiaries receive preventive services through physician visits and some of the expected benefits and limitations of delivering services through a one-time prevention examination.

You have just heard about the Preventive Services Task Force and the excellent work that they do. It is clear that Medicare does not cover all of the services that the Task Force recommends. Under the traditional fee-for-service program, there has not been coverage of a regular periodic examination where clinicians might

assess an individual's health risk and provide needed services. Beneficiaries can receive some of these services through office visits for other health problems.

For example, we examined survey data that showed Medicare beneficiaries visited a physician at least six times a year, on average, mainly for illness and medical conditions. Only about 10 percent of the visits occurred when a person is well. Despite how often beneficiaries visit physicians, few people received the full range of recommended preventive services. As we reported, although 91 percent of females in our analysis received at least one preventive service, only 10 percent received screening for cervical, breast, colon cancer, and were also immunized against influenza and pneumonia.

Many beneficiaries may not know that they are at risk of a particular health condition. For example, data from a CDC survey that includes a physical exam showed that 32 percent of persons with an elevated blood pressure were unaware that they might have this condition. This translates into about 6.6 million people who may not have known that they were at risk for high blood pressure.

The new Welcome to Medicare examination may offer an opportunity to correct some of these problems. It could be a means to ensure that health care providers take the time to identify individual beneficiaries' health risks and provide the services appropriate for those risks.

The initial preventive physical exam described in the draft regulations is comprehensive, and provides for a physical exam as well as education, counseling, and referral for separately covered preventive services. Questions remain, however, about how follow-up to beneficiaries will be provided and how they will be encouraged to make informed choices about screening services, immunizations, and avoidance of risky behavior.

It also is unclear if a one-time examination will actually improve beneficiaries' health. For example, one previous CMS demonstration tested health promotion and disease prevention services, such as preventive visits, health risk assessments, and behavioral counseling, to see if this would increase beneficiaries' health or lower health care expenditures. The results showed some increased utilization of preventive measures such as immunizations and cancer screenings, but did not consistently improve beneficiary health or reduce the use of hospital or skilled nursing services.

CMS is exploring an alternative for delivering preventive care that would provide systematic health risk assessments to fee-for-service beneficiaries through a means other than a physician visit. The Medicare Senior Risk Reduction program currently under design will use a beneficiary-focused health risk assessment questionnaire to identify risks. The program will test different approaches to provide feedback and follow-up services, such as referring beneficiaries to community services, including physical activity and social support in changing risk behavior.

In conclusion, current data indicate that many opportunities exist for Medicare beneficiaries to receive preventive care. Our work shows that we also have more to do to deliver preventive services to those beneficiaries who most need them. A one-time pre-

ventive care examination is a good start to reduce the gap in preventive services that beneficiaries receive.

Mr. Chairman, this ends my prepared statement. I am happy to answer questions.

[The prepared statement of Janet Heinrich appears at the end of the hearing.]

Mr. BILIRAKIS. Thank you, Ms. Heinrich.

Dr. Woolf.

STATEMENT OF STEVEN H. WOOLF

Mr. WOOLF. Good afternoon, Mr. Chairman, Mr. Brown, and members of the subcommittee. My name is Steven Woolf. I am a practicing family physician, a specialist in preventive medicine and public health, and a professor at Virginia Commonwealth University.

I am here this afternoon representing Partnership for Prevention where I serve as Executive Vice President. Partnership for Prevention is a national nonprofit, nonpartisan policy research organization committed to helping Americans prevent diseases. We have issued reports and convened national meetings about preventive services under Medicare, have held congressional briefings on the subject, and are now working with CMS on strategies to improve the delivery of preventive care to America's seniors.

Mr. Chairman, you and your colleagues are to be commended for holding today's hearing on the power of prevention to improve the health of America's seniors and to strengthen Medicare.

The inherent logic behind prevention is obvious: The major diseases that claim the lives of Americans and that contribute mightily to the rising cost of health care are caused largely by our health habits, such as smoking, physical inactivity, and poor diet. Preventive services, in which doctors help patients change these behaviors, give vaccines to prevent infectious diseases, and use screening tests to catch them in their early stages, deserve greater attention from policymakers. This was always true, but especially now, a time when Americans are growing older and falling victim to chronic diseases that could have been prevented or made less severe through preventive measures.

It is a mistake to think that seniors are too old to benefit from prevention. Research indicates that seniors will live longer and live healthier if they abandon unhealthy behaviors, get recommended vaccines, and receive certain screening tests.

It is in the interest of our Nation for America's seniors to be healthy instead of infirm, active instead of hospitalized, productive instead of costly, and independent instead of dependent. Prevention makes sense not only for the fundamental reason that it improves health but also for economic reasons. The cost of treating the complications of diseases are enormous. It is better to pay for prevention than to pay for intensive care. As the Governor of Arkansas, Mike Huckabee, has stated: Our health care system should build a fence at the top of the cliff so we can stop sending ambulances to the bottom.

Although prevention was excluded in the law that created the Medicare program 40 years ago, Congress has done much in the past decade to expand coverage for preventive services. Medicare

now covers many of the screening tests and immunizations that medical organizations recommend for seniors, including some of urgent public health importance, such as screening tests for colon cancer and the vaccine that prevents pneumonia.

The Medicare Modernization Act furthered this effort by expanding coverage for cardiovascular and diabetes screening, but also by including coverage for the "Welcome to Medicare" visit. Offering all new beneficiaries a clinical evaluation by their primary care provider is an ideal opportunity to determine the individual needs of patients, remind them about the importance of prevention, and make arrangements for them to receive the counseling, screening, and immunizations that they are due. The visit can help set them off on the right foot.

Partnership for Prevention commends Congress for adding these provisions, but there is far more to be done. Preventive services under Medicare remain deficient. In particular, I will highlight four issues which, in the interest of time, I will state briefly. I expand on these points in my written testimony, and, on request, can provide the subcommittee with our publications on the topic.

First, the very fact that Medicare coverage of preventive service is managed by Congress is itself an issue. When it comes to diagnosing and treating disease, Congress allows CMS to decide what to cover in consultation with the leading experts of the Nation. The same should be true for preventing disease, as the Institute of Medicine recommended in 2000. Requiring an act of Congress to cover each preventive service is not only inconsistent but also inefficient. It slows the delivery of preventive care to America's seniors, compromising their health and costing the system money. The machinery of Congress is not designed for scientific deliberation and is less nimble than CMS in keeping pace with rapid changes in science and technology. Coverage policies that Congress established years ago have become outdated, advocating preventive services that medical groups no longer recommend; yet CMS is compelled by congressional statute to continue offering and paying for them. Partnership for Prevention encourages Congress to direct CMS to make coverage decisions for preventive services, just as it does for diagnostic and treatment services.

Second, although Medicare now covers screening testing and immunizations, it offers little support for clinicians to help patients adopt the behaviors that will prevent disease, a strategy much more likely to save lives. Help with stopping smoking, controlling weight, and eating well, the most effective strategies for improving health and reducing costs for the Medicare program, is not covered under Medicare. The recent decision by CMS to cover obesity treatment is welcomed, but Congress should authorize Medicare to cover counseling for tobacco cessation, physical activity, and healthy diet.

Third, although in theory the "Welcome to Medicare" visit provides an opportunity to deliver or arrange for recommended preventive services, greater structure is needed to ensure that the visit is used to promote evidence-based preventive services that improve health and it is not exploited to use Medicare dollars for services of unproven benefit or potential harm. Not all screening tests are good for you. Some may do more harm than good, which is why expert bodies such as the U.S. Preventive Services Task

Force and most medical organizations recommend only a dozen of the hundreds of screening tests that are in existence. Promoting too many screening tests is not only an expensive proposition but one that is likely to harm the intended beneficiaries.

In draft regulations issued this summer, CMS proposed to configure the "Welcome to Medicare" visit as a comprehensive history and physical examination in which patients would be given a battery of questions and examination procedures. Such comprehensiveness has good intentions but is worthy of further thought. For one thing, the opportunity for Medicare beneficiaries to get comprehensive physicals is already available. It is the opportunity for prevention that the MMA sought to provide. Second, comprehensive evaluations often set off a cascade of diagnostic workups that are of dubious health benefit to patients.

Finally, and most importantly, the distractions introduced by a comprehensive physical can lead physicians and patients into diverse health complaints and crowd out the focus on prevention that the MMA intended. The MMA sought to give beneficiaries an opportunity, at least once during their tenure with Medicare, to focus on prevention; and that worthy goal could be lost if the visit turns into yet another comprehensive physical.

Partnership for Prevention is concerned about overutilization and recommends that the "Welcome to Medicare" visit be designed as a focused prevention visit, not as a comprehensive physical, aimed at promoting a defined set of services that are known to improve health outcomes.

Fourth, and finally, it is not enough to simply add coverage for preventive services. Steps must also be taken to ensure that they are delivered and delivered well. If what Congress has done to expand coverage is to realize its full potential benefits, both beneficiaries and providers must be educated about the importance of prevention and how to make use of the services that Medicare covers, reminder systems for doctors and patients, and modern ideas for quality improvement such as the Medicare Web site that patients can use at home to manage their prevention program, help ensure that patients receive services on time. These tools put patients in charge of their health.

The Medicare program is plagued by racial and ethnic disparities in who receives covered services. And research shows that a systems approach to delivery can do much to reduce such disparities. We therefore encourage data collection activities at CMS to track outcomes and evaluate the performance of preventive care.

Partnership for Prevention seeks to better educate beneficiaries and clinicians about the "Welcome to Medicare" visit and preventive care, and it urges Medicare to encourage, certainly not to impede, the introduction of systems within practices and health care organizations that improve the delivery of preventive care.

Once again, we thank the subcommittee for its commendable efforts to promote prevention, and we look forward to working with you to make Medicare better. I would be happy to answer your questions.

[The prepared statement of Steven H. Woolf follows:]

PREPARED STATEMENT OF STEVEN H. WOOLF, EXECUTIVE VICE PRESIDENT FOR POLICY DEVELOPMENT PARTNERSHIP FOR PREVENTION AND PROFESSOR OF FAMILY MEDICINE, PREVENTIVE MEDICINE AND COMMUNITY HEALTH, VIRGINIA COMMONWEALTH UNIVERSITY

The inherent logic behind prevention is obvious. The major diseases that claim the lives of Americans and that contribute mightily to the rising costs of health care are caused largely by our health habits, such as smoking, physical inactivity, and poor diet. Fully 35% of deaths in the United States are caused by three behaviors: tobacco use, poor diet, and physical inactivity.[1]

Preventive services—in which doctors help patients change these behaviors, give vaccines to prevent infectious diseases, and use screening tests to catch diseases in their early stages—deserve greater attention from policymakers. Our healthcare system expends most of its resources on treating existing disease, but paying for prevention could be much more effective. For example, treatments for cardiovascular disease, once it has already developed, can save 4,000-10,000 lives per year, but helping Americans to stop smoking would prevent more than 400,000 deaths per year.[2]

This was always true but especially now, a time when Americans are growing older and in greater numbers are falling victim to chronic diseases that could have been prevented or made less severe through preventive measures. It is a mistake to think that seniors are too old to benefit from prevention. Research indicates that seniors will live longer and live healthier if they abandon unhealthy behaviors, obtain recommended vaccines, and receive certain screening tests. For example, lifelong smokers who stop smoking at age 50 live an average of 6 years longer than those who continue smoking beyond that age.[3] Prevention can improve function, postpone chronic disease and disability, and avoid premature death.

Prevention makes sense not only for the fundamental reason that it improves health, but also for economic reasons. The costs of treating the complications of diseases are enormous; it is wiser to pay for prevention than to pay for intensive care. In Appendix 1 we outline the cost savings associated with certain screening tests. As the Governor of Arkansas, Mike Huckabee, recently stated, our health care system should build a fence at the top of the cliff so we can stop sending ambulances to the bottom.

Although prevention was excluded in the law that created the Medicare program 40 years ago, Congress has done much in the past decade to expand coverage for preventive services. Medicare now covers many of the screening tests and immunizations that medical organizations recommend for seniors, including some of urgent public health importance such as screening tests for colon cancer and pneumococcal vaccine, which helps prevent pneumonia.

Our nation's leaders have turned the corner in recognizing the need to make Medicare a program that emphasizes prevention. President Bush, speaking in the State of the Union address, said that "Medicare is the binding commitment of a caring society. We must renew that commitment by giving seniors access to preventive medicine."[4] In other speeches, the President has said that Medicare should be as much about keeping seniors healthy as treating them after they become sick. The current Administrator of CMS, Dr. Mark McClellan, said in July that, "we mean it when we say we're shifting the focus of the Medicare program from treating conditions to preventing them."

The Medicare Prescription Drug and Modernization Act of 2003 (P.L. 108-173) affirmed this commitment by expanding coverage for cardiovascular and diabetes screening but also by including coverage for a "Welcome to Medicare" visit. Offering all new beneficiaries a clinical evaluation by their primary care provider is an ideal opportunity to determine the individual needs of patients; remind them about the importance of prevention; and make arrangements for them to receive the counseling, screening, and immunizations to get them up-to-date on preventive care. If properly designed, the visit can start patients off on the right foot and set expectations for an ongoing, comprehensive approach to preventive services. It is an opportunity to encourage patients to be active participants in managing their health and health care needs. Not everything can be done in just one visit, but the clinician and patient can leverage the opportunity to develop a plan for obtaining rec-

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[1] Mokdad et al. Acutal causes of death in the United States, 2000. JAMA 2004;291:1238-45.
[2] Woolf. The need for perspective in evidence-based medicine. JAMA 1999;282:2358-65.
[3] Doll et al. Mortality in relation to smoking: 50 years' observations on male British doctors. BMJ 2004;328:1519.
[4] President George W. Bush, State of the Union Address, January 28, 2003. http://www.whitehouse.gov/news/releases/2003/01/20030128-19.html

ommended services, to arrange follow-up, and to remind patients at a later date when repeat screening or immunizations are due.

Partnership for Prevention commends Congress for adding these provisions. But there is far more to be done; *preventive services under Medicare remain deficient.* In particular, four issues deserve attention:

1. The mechanism for determining coverage of preventive services

It is problematic that decisions about coverage of prevention under Medicare are determined by Congress, service by service. This is not the way that Medicare decides coverage for diagnostic tests and treatments: for those services, Congress directs CMS to decide what to cover, in consultation with the nation's leading medical experts. The same should be true for preventive services, as many experts have recommended. An Institute of Medicine study recommended just such a change in its 2000 report, *Extending Medicare Coverage for Preventive and Other Services.*[5]

The existing model is failing. Requiring an "act of Congress" to cover each preventive service is inefficient and slows the delivery of preventive care to America's seniors—compromising their health and costing the system money. A bill to introduce coverage of Pap smears was introduced annually for 15 years before this benefit was added in 1989. The machinery of Congress is not designed for analyzing science and producing medical guidelines, whereas mechanisms in place at CMS are designed to more nimbly keep pace with the rapid changes that occur in science and technology. The Medicare Coverage Advisory Committee (MCAC), which evaluates effectiveness for CMS, is adept at critically appraising the quality of evidence for new technologies and is quite capable of giving similar advice on the effectiveness of preventive services. As new preventive technologies emerge and as guidelines change, CMS can update coverage policy much faster and with greater scientific rigor than can a legislative body charged with responsibilities for the economy, national security, and other diverse issues.

The legislative mechanism used by Congress to cover preventive services has not performed well in keeping coverage policies current. The provisions written into law are time capsules, reflecting the advice of the time, but many have now become outdated. For example, in 1991, Congress authorized Medicare to cover "baseline mammograms" to be performed on all women at age 35, a practice advocated at the time by the American Cancer Society. But today, no major medical group (including the American Cancer Society) advocates baseline mammograms.[6] In 1998, Congress authorized Medicare to cover colonoscopy screening as often as every 2 years, presumably because of testimony received at the time. But in 2004, no scientific evidence and no major gastroenterological organization supports performing the test this frequently, even for patients at high risk for colon cancer.[7] In 1998 coverage was extended to osteoporosis screening for high-risk women, the group that seemed most likely to benefit. By 2002 the U.S. Preventive Services Task Force had begun recommending screening for all women over age 65, but in 2004 Medicare coverage remains restricted to women at high risk.

Although staff at CMS is aware of these discrepancies, as long as the Congressional statute remains in place, the agency is legally obliged to continue offering and paying for these unnecessary services. CMS publications must inform beneficiaries that these services are covered, thereby disseminating the implicit encouragement that beneficiaries obtain preventive services at a greater frequency—and at greater cost to Medicare—than any medical organization currently recommends.

Experience has therefore taught us that relying on Congressional mandate to cover preventive services under Medicare delays the establishment of coverage for preventive services that are recommended and the elimination of coverage for services that are not recommended. America's seniors deserve a better system.

In a 2003 report, Partnership for Prevention issued a study, *A Better Medicare for Healthier Seniors*[8], which laid out 6 options for Medicare coverage of preventive services:

- Retain the status quo
- Tie coverage to an outside group (e.g., U.S. Preventive Services Task Force)
- Create a Congressional "fast track"

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[5] Institute of Medicine. *Extending Medicare Coverage for Preventive and Other Services.* Washington, DC: National Academy Press, 2000.

[6] Smith et al. American Cancer Society guidelines for the detection of cancer, 2004. CA Cancer J Clin 2004;54:41-52.

[7] Winawer et al. Colorectal cancer screening and surveillance: clinical guidelines and rationale-Update based on new evidence. Gastroenterology. 2003;124:544-60.

[8] Partnership for Prevention. *A Better Medicare for Healthier Seniors: Recommendations to Modernize Medicare's Prevention Policies.* Washington, DC: Partnership for Prevention, 2003.

- Use the regular coverage process
- Introduce a rulemaking change for screening
- Create preventive care accounts

The study concluded that: **Congress should direct CMS to make coverage decisions for preventive services, just as it does for diagnostic and treatment services.** We believe that the ideal option is for decisions about Medicare coverage for preventive services to be incorporated into the current decision-making process at CMS, based on rigorous analysis of scientific evidence. As with other services, CMS could use the MCAC model, obtaining expert advice about coverage from an MCAC panel on preventive care.

We also recommended that CMS be given flexibility to determine which providers and suppliers can be reimbursed for preventive services; that HHS should require greater collaboration on preventive care among all Federal agencies and with state and local agencies; that Congress should support development of evidence-based recommendations for clinical preventive services, health system interventions, community programs, and public and private sector policies; that HHS should maximize data and related analysis to better track and understand beneficiaries' access to and use of preventive services; and that Federal agencies sponsor new research to protect and improve beneficiaries' health.

Our recommendations were supported by all seven living former Secretaries of Health and Human Services (or Health, Education, and Welfare); see Appendices 2-3. Interest in our recommendations has grown in Congress. In May 2003, Representatives DeWine, Leach, and Moran and Senators Graham and DeWine invited Partnership for Prevention to conduct a Congressional briefing. Our recommendations received the attention of Representatives Nancy Johnson, Jim Leach, and Jim Ramstad and of Senator Bill Frist. They were also discussed with the head of the Congressional Budget Office and the staff of Secretary of Health and Human Services Tommy Thompson. We are gratified that these discussions, along with the diligent work of other organizations that share a commitment to prevention, facilitated the expanded focus on preventive services that emerged in the Medicare Modernization Act. We are also pleased that current legislation under consideration in the House and Senate carries forward these recommendations.[9]

2. Lack of coverage for counseling about health behaviors

Preventive services include not only screening tests and immunizations, many of which Medicare now covers, but also the work clinicians do to counsel patients to adopt healthy behaviors, such as stopping smoking, controlling weight, staying physically active, and eating well. Although screening tests can be beneficial in reducing morbidity and mortality from diseases, the benefits of early detection are limited because, by definition, the disease process is already underway. Screening seeks to identify the disease at an early stage, but by then the pathology is already in place and achieving a cure is often an uphill battle.

A more effective strategy than waiting for diseases to develop and attempting to catch them early is to *prevent them from occurring in the first place.* Helping patients to change the behaviors that account for half of all deaths in the United States is thus an urgent public health priority and a prudent economic policy to control the spiraling costs of health care. Accordingly, the Surgeon General and major task forces in the Federal government have urged doctors to make such counseling a routine part of primary care. For example, it is the recommendation of the Department of Health and Human Services and the Surgeon General that all doctors ask all patients, at every visit, whether they smoke; advise them about the importance of quitting; and make arrangements to help them in their quit attempts.[10]

It is therefore problematic that Medicare offers little reimbursement for clinicians to provide such counseling to their patients. The recent decision by CMS to cover obesity treatment is welcome, but tobacco use remains the leading cause of death in the United States.[11] Physical inactivity and unhealthy diets cause cancer and other diseases, even in people who are not obese, and they are essential to prevent obesity. Counseling about tobacco use, regular physical activity, and healthy diet are therefore urgent public health priorities, but Medicare does not provide coverage.

The absence of adequate reimbursement discourages physicians from carving out the time they need with their patients to identify the health behaviors that need attention, provide the information and motivation on which patients rely to make lifestyle changes, arrange for services within the community to facilitate patients'

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[9] Medicare Preventive Services Coverage Act of 2004 (S. 2535 and H.R. 4898).

[10] Fiore et al. *Treating Tobacco Use and Dependence.* Rockville, MD: US Department of Health and Human Services, 2000.

[11] Mokdad et al. Acutal causes of death in the United States, 2000. JAMA 2004;291:1238-45.

efforts, and conduct follow-up calls and visits to provide the encouragement that patients need to maintain changes over time. Neither their efforts, nor the services within the community that can help them, are covered under Medicare, even though these activities pose the most effective strategy to improve the health of the Medicare population and to control spiraling health care costs. Counseling about health behaviors costs far less than the intensive care required for heart disease, cancer, and the others diseases that these behavior changes can avert.

Congress should authorize Medicare to cover counseling for tobacco cessation, physical activity, and healthy diet.

3. The need to control the content of the Welcome to Medicare visit

Although in theory the Welcome to Medicare visit provides an opportunity to deliver or arrange for recommended preventive services, greater structure is needed to ensure that the visit maintains its focus on prevention and is used to promote evidence-based services.

Preventive services that are not evidence-based may result in more harm than good. For example, it seems self-evident that screening for diseases and catching them early must be beneficial, but this is not always the case. Due to the inaccuracies of some screening tests and the rarity of diseases in the general population, the number of people who receive false-positive results may exceed the number of people who have true disease. In some cases the tests used to investigate false-positive results are potentially dangerous. If screening 100,000 people for brain tumors finds two people with the disease but causes 1,000 people to have unnecessary brain surgery or brain biopsies for false-positive test results, the screening program is likely to result in more harm than good. Exposing 1,000 people to the complications of brain surgery for the sake of two people with brain tumors raises daunting ethical questions.

Thus, although hundreds of screening tests are in existence, expert panels that issue guidelines for screening recommend only a handful of screening tests. They refrain not so much out of concerns for costs—these guideline panels are composed largely of health professionals who focus on health outcomes and not economics—but out of a public duty and ethical imperative to ensure that screening is for the good of the population. Promoting too many screening tests is not only an expensive proposition, but one that is likely to harm Americans.

The large consumer market introduced by the millions of seniors who will be entitled to the Welcome to Medicare visit could entice commercial entities and certain specialists to promote services at the expense of the Medicare program. Encouraging clinicians to use the visit for comprehensive assessments is likely to identify issues that prompt further investigations, some involving expensive testing, for which there is little scientific evidence of benefit. To avert the emergence of a Welcome to Medicare "industry" and the exploitation of Medicare dollars for services of dubious value or potential harm, it is important to narrow the scope of the benefit around well-defined services that have been proven to enhance health outcomes.

Below we array the preventive services that the U.S. Preventive Services Task Force recommends for seniors and those covered under Medicare.

	Covered by Medicare	**Not Covered by Medicare**
Recommended by USPSTF	***A***	***B***
	Pneumococcal vaccine Influenza vaccine Hepatitis B vaccine Pap smear Mammography Bone mass measurement Colorectal cancer screening Lipid screening Diabetes screening	Counseling about tobacco use Counseling about healthy diet Counseling about injury prevention Diphtheria-tetanus vaccine Screening for depression Screening for alcohol misuse Hearing screening Visual acuity screening Aspirin prophylaxis
Not Recommended by USPSTF	***C***	***D***
	Pelvic exam Prostate cancer screening Electrocardiograms	

While the Partnership for Prevention welcomes the entry of services into box A, we believe that the services listed in box B should also be covered under Medicare.

Some services in box B, such as counseling about tobacco use, have greater public health urgency than others, such as diphtheria-tetanus vaccination, but all are supported by strong scientific evidence that recipients have improved health outcomes.[12] Such evidence is lacking for the services listed in box C, for which Congress has authorized coverage under Medicare. We believe the resources expended on these services could go farther in improving the health of beneficiaries if applied to the services listed in box B. Box D is empty but represents the hundreds of preventive services for which there is little evidence of benefit.

In draft regulations issued in July 2004, CMS proposed to configure the Welcome to Medicare visit as a comprehensive history and physical examination. Physicians are expected to ask about past hospital stays, operations, allergies, injuries and treatments; to determine current medications and vitamin supplements; to catalogue the patient's family history; to review the patient's travel and work history; and to discuss social activities. They must review the patient's functional ability and level of safety, such as hearing ability, activities of daily living, fall risk, and home safety. For any abnormality identified by these assessments, physicians are to provide physical examination measures, education, counseling, and referrals.

We are concerned about this broad focus for three reasons. First, it is unnecessary. The elements outlined in the regulations are standard components of a "complete physical," for which Medicare beneficiaries were eligible even before the Medicare Modernization Act was passed. At most practices in the United States, new patients complete enrollment forms that ask about past hospitalizations, drug allergies, and the other items listed above, and established patients are often asked to update the information at regular intervals.

Second, a comprehensive battery of questions and examination procedures is likely to set off a cascade of diagnostic workups of dubious health benefit to patients. Many studies have documented that the putative health benefit of such comprehensive assessments is often offset by the harms that result from complications of diagnostic procedures and by the considerable costs induced by follow-up testing and referrals.

Third, the focus on prevention is lost amid the comprehensiveness. The Welcome to Medicare visit is a unique opportunity for a "prevention" visit: to help patients focus on the health behaviors that prevent disease and to identify the screening tests and immunizations for which they are due. A visit preoccupied with comprehensive questions loses this focus on prevention. In the Welcome to Medicare visit, physicians should be asking about tobacco use, not compiling a list of drugs to which patients are allergic. In this visit, physicians should be asking when patients were last screened for breast cancer or immunized against influenza, not learning when an appendectomy was performed. In this visit, patients should be counseled about the importance of physical activity and healthy diet, not arranging referrals for headaches, acid reflux, and other abnormalities that will come to light in a comprehensive history.

We encourage Congress and CMS to authorize coverage of preventive services that are recommended by the U.S. Preventive Services Task Force or other evidence-based bodies. Coverage policies under Medicare, and the content of the Welcome to Medicare visit, should be designed to promote a defined set of services that are known to improve health outcomes. The aims of the Welcome to Medicare visit should focus squarely on prevention, not on offering a "comprehensive physical."

4. Addressing quality, along with coverage, of preventive services

It is not enough to expand coverage for preventive services. Steps must also be taken to ensure that they are delivered, and delivered well. As of 2001, only 60% of beneficiaries over age 65 had received pneumococcal vaccinations, and only 44% had received sigmoidoscopy screening for colorectal cancer. Only 10% of older women were up-to-date on cervical, breast, and colorectal cancer screening. If what Congress has done to expand coverage is to realize its full benefits, both beneficiaries and providers must be educated about the importance of prevention and how to make use of the services that Medicare covers, and systems must be in place to expedite the delivery of these services.

CMS communications to beneficiaries currently focus on describing coverage benefits and little more. To be motivated to take full advantage of the preventive services covered under Medicare, beneficiaries first need to know why prevention matters. They need encouragement to live healthy lifestyles, with messages that remind them about the importance of stopping smoking, staying active, eating well, and controlling their weight. They need to understand why preventive services from

[12] See U.S. Preventive Services Task Force at http://www.ahrq.gov/clinic/uspstfix.htm

their clinician are important, which ones are recommended, and the importance of being "activated consumers" who know what to ask and expect of their doctors.

The Department of Health and Human Services has developed excellent lay resources to answer these questions for consumers, but because they have been developed in "silos" other than CMS (e.g., Centers for Disease Control and Prevention, National Cancer Institute, Agency for Healthcare Research and Quality) CMS staff know little about them, and the CMS website and publications do not mention them to beneficiaries. We believe that CMS communications should be integrated with the work of other components of HHS to disseminate a coordinated health message that encompasses health advice, recommended services to obtain, as well as the details of coverage policy. Partnership for Prevention is currently working with CMS to address these gaps in beneficiary communications.

Communications to providers about the Welcome to Medicare visit should extend beyond traditional correspondence from CMS, which focuses on billing codes and the technical provisions of coverage. To reach and persuade providers, information about the Welcome to Medicare visit should be channeled through their organizations and specialty societies, using their medical journals, newsletters, and annual meetings to discuss the provisions of the new law. The new law provides an opportunity to introduce a "culture shift" toward excellence in the preventive care of seniors, but this will not happen without an organized educational campaign that involves physician organizations. The aims should be to help providers understand how to use the visit to enhance the delivery of recommended preventive services and avoid overutilization of services that are not recommended. Partnership is convening medical specialty societies to carry forward these goals.

The full benefits of the Welcome to Medicare visit cannot be realized without incorporating system solutions within health plans and practice to improve the quality with which preventive services are delivered. Effective measures include standing orders, financial incentives and first-dollar coverage for patients, and feedback reports to providers.[13] Impediments to delivery must be removed, or else reminders will accomplish little in improving care. Obstacles that patients and providers face in obtaining tests, counseling, and referrals must be addressed. Creative strategies, such as using health coaches, social support, and other non-physician outreach workers, can facilitate the delivery of preventive care. Finally, the Welcome to Medicare visit is a moment in time, but preventive care is a continuum. Mechanisms must be in place to connect patients with resources in the community and to reinforce the initial steps taken during the visit with follow-up visits over time.

Reminder systems, both those designed for doctors and reminders sent to patients, are an important reinforcement tool that has been proven to enhance uptake of preventive services. Electronic medical records facilitate such reminders and provide useful tools for tracking adherence to a health maintenance plan, and greater attention is now turning to electronic health systems that give patients greater control over their health. For example, a website service for patients that we wish to test in a demonstration project would be accessed by patients before their Welcome to Medicare visit. After obtaining information from the patient, the website would list the preventive services that are recommended, offer hyperlinks to web pages that explain the meaning of medical terms (e.g., what is a "colonoscopy"?), and direct patients to decision aids to help with complex choices. Patients could print summaries to bring to their appointment, thereby giving doctors a convenient reminder of which services are due. The website would later send patients follow-up emails to remind them to obtain follow-up screening tests or, for example, to contact them in the Fall about obtaining influenza vaccination.

As in other health systems, the Medicare program is plagued by racial and ethnic disparities in patterns of care. For example, in 2002 pneumococcal vaccine was received by 66% of white Medicare beneficiaries above age 65 but by only 51% of African Americans in the same age group.[14] Research has shown that such disparities can be reduced by adopting reminder systems and other "systems approaches" that make delivery of services more uniform.

Finally, the visit provides an opportunity for collecting data that can be used for measuring the effectiveness of services and the performance of plans and providers and tracking utilization over time. These data can be used for research, such as studying the outcomes of different mixes of services for specific subpopulations, based on risk factors, disease, age, gender, race, and ethnicity. The data can also

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[13] Southern California Evidence-Based Practice Center. *Interventions that Increase Utilization of Medicare-Funded Preventive Services for Persons Age 65 and Older.* Baltimore: Health Care Financing Administration, 1999.

[14] Bonito et al. Disparities in immunizations among elderly Medicare beneficiaries, 2000 to 2002. Am J Prev Med 2004;27:153-60.

be used to monitor quality and to apply performance metrics and quality initiatives, such as "pay for performance" programs.

Partnership for Prevention seeks to better educate beneficiaries and clinicians about the Welcome to Medicare visit and preventive care, and it urges Medicare to encourage—certainly not to impede—the introduction of systems within practices and healthcare organizations that improve the delivery and quality of preventive care.

Summary: The Medicare Prescription Drug and Modernization Act updated a program that has served the medical needs of seniors for nearly 40 years, but Medicare is in need of further modernization. There have been tremendous advances in medical science, including knowledge about how to prevent disease and keep people in good health. It is time to make Medicare a program that is as much about helping beneficiaries stay healthy as about treating them when they get sick and need hospitalization.

Partnership for Prevention is a partnership of public and private sector organizations committed to finding solutions to health issues in a nonpartisan and rigorously scientific manner. Our membership includes national employers, nonprofit policy and research organizations, professional and trade associations, voluntary health organizations, health plans, and state health departments. See www.prevent.org for more details.

APPENDIX 1. COST-BENEFIT OF ANALYSIS OF SELECTED SCREENING TESTS

Partnership for Prevention conducted an analysis, using methods employed by the Congressional Budget Office, that assume fee-for-service payment and 2002 dollars:

- Over the first 10 years of coverage, vision screening would result in net savings to Medicare of $148 million. The average net cost per year over the first 10 years would be $18 million.
  - Vision screening would prevent 21,000 hip fractures and 4400 forearm fractures.
- Cholesterol screening would result in net savings of $436 million over 7-10 years of coverage. The average net cost per year over the first 10 years of coverage would be $82 million.
  - Cholesterol screening would prevent 62,362 heart attacks and 44,912 strokes
- Tobacco cessation counseling would begin producing a small net savings to Medicare in the 9th and 10th years of coverage as the savings from long-term quitters in prior years accumulate. The average net cost per year over the first years of coverage would be $19.5 million.
  - Tobacco cessation counseling would save 95,000 life years.
- The average cost per year over 10 years for the Welcome to Medicare visit would be $137 million.

Appendix 2. *Congressional Record*, July 8, 2003

Unfortunately, according to the Mental Health Association the unemployment rate for individuals with disabilities is approximately 75 percent, and for those with psychiatric disabilities it is at almost 80 percent. Some of these statistics can be attributed to those individuals with such severe disabilities that they are unable to work, however much of that percentage is made up of individuals with disabilities who have never had the training or help they need to find the jobs they can do.

The need for a company like Bayaud Industries is clear. Bayaud provides an invaluable link between individuals with disabilities and employment. By being that link they are changing lives on a daily basis. They make a difference every day by opening doors for members of America's disabled community that many of them never knew existed before.

CITIZENS OF LIBERIA

HON. BOBBY L. RUSH

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 8, 2003

Mr. RUSH. Mr. Speaker, tonight, while the President of the United States is visiting Senegal and other countries in Africa, 'I rise to address the House to express my concern for the citizens of Liberia. Liberia is an African nation that was founded in 1820 by freed Black slave men and women from the United States. The nation, considered to be the only U.S. colony in Africa, was founded with a grant of $100,000. Its capital, Monrovia, is named after the United States fifth president, James Monroe. By 1847, thousands of freed slaves had immigrated to Liberia from the United States. They declared independence and the commonwealth of Liberia became the Republic of Liberia.

Liberia's recently-deposed president, Charles Taylor, seized power in 1997 after leading a seven year insurrection, which claimed the lives of thousands of Liberian Africans against his predecessor, Samuel Doe. Taylor, an accused embezzler and protégée of Libyan dictator, Col. Mu'ammar al-Qadhafi, spread terror throughout Sierra Leone, Ivory Coast and Guinea. Taylor's human rights abuses include the use of child soldiers and funding terrorist organizations with money from blood diamond mines.

On June 4, 2003, the United Nations supported an indictment of President Taylor by a Special Court in Sierra Leone, at the same time a group of West African Presidents were meeting with Taylor and others in Ghana to discuss efforts to negotiate a peace agree-

parties in the nation, as well as leaders from religious and women's organizations, have been meeting in Ghana to draw up a peace plan and establish a transitional government expected to run the country for 18 to 24 months before new elections can be held.

The Economic Community of West African States (ECOWAS) Britain and France have asked the United States to lead, at least initially—a peace-keeping operation designed to separate and disarm the warring factions and establish an environment where a transitional government can take control of the country. ECOWAS has pledged 3,000 troops for an intervention force and is asking the United States to pledge 2,000 troops in this effort.

Mr. Speaker, I urge you, and my colleagues support the Liberian people's struggle to return their country to sane and just rule. Liberia has been a friend and a supporter of the United States. It was an ally during the Cold War and a facilitator of covert operations against Col. Mu'ammar al-Qadhafi during the 1980s. It would be a betrayal of that long-held trust to turn our backs on the people of Liberia who have supported us in the past.

Liberia's natural resources are plentiful. The country has iron ore, rubber, timber, diamonds, gold and tin. In addition, in recent years that it has discovered sizable deposits of crude oil along its Atlantic Coast, and it continues to make strides in the agriculture sector. We need to work with the local communities and provide assistance in the areas of development, policing, healthcare.

Mr. Speaker, Liberia has the potential of re-establishing a strong democratic model of liberation and justice for the continent. We must do whatever we can to assist the Liberians—these proud people of liberty—rebuild their beautiful country.

DISEASE PREVENTION IN MEDICARE

HON. JIM RAMSTAD

OF MINNESOTA

IN THE HOUSE OF REPRESENTATIVES

Tuesday, July 8, 2003

Mr. RAMSTAD. Mr. Speaker, I rise today to submit into the Record a letter I have received from seven former Secretaries of the Department of Health and Human Services and its predecessor, the Department of Health, Education and Welfare. The letter, sent to many Members of Congress, and especially to the leadership of both bodies, requests that during our work on Medicare modernization we not forget about the benefits of disease prevention.

The letter specifically references a report by

I encourage my colleagues to read the attached letter, look at the Partnership For Prevention report and consider their recommendations in our further efforts to modernize Medicare.

THE FORMER SECRETARIES OF HEALTH AND HUMAN SERVICES AND HEALTH EDUCATION AND WELFARE
JUNE 25, 2003.

Hon. JIM RAMSTAD,
U.S. Representative, House of Representatives, Washington, DC 20515.

DEAR MR. RAMSTAD, as former Secretaries of Health and Human Services (or Health, Education and Welfare), we write to encourage you to include disease prevention in discussions about Medicare modernization.

Congress created Medicare in 1965 based on the knowledge of health and medicine at that time. Thus, Medicare came into being as a national insurance system to cover hospitalization and visits to clinicians' offices for diagnoses and treatment.

In the nearly four decades since Medicare's creation, considerable research and practice have yielded proven ways to not just diagnose and treat disease, but to prevent it and promote longer, healthier life. Today we know that postponing disability, maintaining social function, and sustaining independence are achievable for seniors through evidence-based health promotion and disease prevention services. It is nearly always preferable, both for the individual and for society, to prevent disease instead of waiting to treat it.

Congress has added selected preventive services to Medicare but has not included other services that are proven effective, nor has it encouraged Medicare to take a comprehensive approach to disease prevention and health promotion for America's seniors.

A recent Harris Poll found that nine in ten American adults want Medicare to be modernized and to put as much emphasis on disease prevention as it does on disease treatment.

The roadmap for this Medicare modernization is laid out in a new Partnership for Prevention (Partnership) report, A Better Medicare for Healthier Seniors: Recommendations to Modernize Medicare's Prevention Policies, which you already have received. These recommendations would move the U.S. toward realization of our nation's two overarching national health goals: increasing life expectancy and improving quality of life, and reducing disparities in health among different segments of the population.

Respectfully yours,

JOSEPH A. CALAFANO, JR.
RICHARD S. SCHWEIKER.
MARGARET M. HECKLER.
DAVID MATHEWS, MD.
LOUIS W. SULLIVAN, MD.
DONNA E. SHALALA, PhD.
OTIS R. BOWEN, MD.

APPENDIX 3. LETTER FROM SEVEN LIVING FORMER HEALTH SECRETARIES

June 25, 2003

The Honorable MIKE DEWINE
Co-Chair
Congressional Prevention Coalition
United States Senate
Washington, DC 20510

DEAR CHAIRMAN DEWINE, as former Secretaries of Health and Human Services (or Health, Education and Welfare), we write to encourage you to include disease prevention in discussions about Medicare modernization.

Congress created Medicare in 1965 based on the knowledge of health and medicine *at that time.* Thus, Medicare came into being as a national insurance system to cover hospitalization and visits to clinicians' office for diagnoses and treatment.

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Congress has added selected preventive services to Medicare but has not included other services that are proven effective, nor has it encouraged Medicare to take a comprehensive approach to disease prevention and health promotion for America's seniors.

A recent Harris Poll found that nine in ten American adults want Medicare to be modernized and to put as much emphasis on disease prevention as it does on disease treatment.

The roadmap for this Medicare modernization is laid out in a new Partnership for Prevention (Partnership) report, *A Better Medicare for Healthier Seniors: Recommendations to Modernize Medicare's Prevention Policies,* which you already have received. These recommendations would move the U.S. toward realization of our nation's two overarching national health goals: increasing life expectancy and improving quality of life, and reducing disparities in health among different segments of the population.

Respectfully yours,

JOSEPH A. CALAFANO, JR., RICHARD S. SCHWEIKER, MARGARET M. HECKLER, DAVID MATHEWS, MD, LOUIS W. SULLIVAN, MD, DONNA E. SHALALA, PHD, and OTIS R. BOWEN, MD

Mr. BILIRAKIS. Thank you, Dr. Woolf.

Isn't it a revelation, really, that we are at least talking about this subject? Only a few years ago we were just concerned about caring for the sick and whatnot, but now we are going well past that, trying to prevent them from getting sick. And I think that in itself is terrific.

Dr. Woolf, if my son who is an internist were sitting there giving your testimony, he would probably say basically the same thing that you have. But that, again, is the ideal and we would hope that we would strive toward that, but obviously we can't do everything that we might think is the right thing to do.

I guess maybe one question to ask is, will seniors utilize these benefits, what they are now and what they may turn out to be? I think Mr. Brown's bill—I haven't studied it, but basically we are thinking preventive health care. And that is good, but we also have to be sure that delivery of these benefits will be available and will be done in the right manner. We have to hope that of course people will take advantage of it.

Dr. Clancy.

Ms. CLANCY. Sure. I think that is about the most important question you could ask. Coverage is the first step. You can't get there without coverage. But as the GAO reports and many other

studies have noted, many of the covered services are underused. This has been a big focus for CMS, trying to figure out how to encourage more of that. And a lot of it does come down to the systems and the settings where people get care.

For example, when I am—a scenario that happens a lot when I see patients, I am sorry to say, is I am seeing a woman and we both agree that it is time for a mammogram, and then we move on to other things, and then she leaves and I forget to give her the piece of paper that she needs to actually get the mammogram, because where I see patients we don't have an idiot-proof system to make sure that it automatically happens. Eventually she gets the service, but it is a distraction, and some people don't come back for the piece of paper and so forth.

So it is that kind of systems approach that is necessary not only in getting the services but also in following up and making sure that people who have abnormal results are correctly identified and referred on when needed, and so forth.

I think a lot of physicians and patients are increasingly aware of this. We clearly have a lot more to do, and it is a big focus of the Agency's work.

Mr. BILIRAKIS. Ms. Heinrich.

Ms. HEINRICH. One question I have is about participation of physicians. When you read through the draft regulations, you see that this physical—comprehensive physical exam and battery of preventive services will be reimbursed at the same rate as a standard new patient evaluation and management fee. And a comprehensive exam like this and the battery of preventive services would take a lot of time. So I think that is a question that has to be asked.

The second, of course, is will the beneficiaries themselves say this is something that I need, that I want, and seek it. And as we have said in our previous studies, the utilization rate is highly variable, and it does depend on race. Minorities utilize these services considerably less than white populations.

Mr. BILIRAKIS. Why is that?

Ms. HEINRICH. I don't think we know the reason specifically. It could be an issue of access, it could be a matter of really knowing and understanding that the benefit exists. And some people, quite honestly, are concerned about even accessing the flu vaccines because they are afraid that they are going to get sick from the flu vaccine. So they are afraid that the intervention will make them sick.

Mr. BILIRAKIS. Dr. Woolf, anything further?

Mr. WOOLF. I think you have asked an excellent question. I think the Welcome to Medicare visit provides a very good leveraging opportunity to try to address this problem by making patients aware of the need for preventive services. The visit could help induce demand.

Many times, clinicians don't deliver preventive services for innocent reasons. Sometimes they forget that a patient is due for them, and there is ample experience in published research suggesting that that kind of demand can be helpful.

Having said that, the agency, CMS, has an uphill battle in organizing an educational campaign to make patients aware of preventive services and the importance of prevention, because this is

something that hasn't been done in the past. We are working with CMS—and Dr. McClellan is very enthusiastically supporting this—to try to change the way communications go out to beneficiaries, to make them more aware of the importance of prevention as a basic concept and then, more specifically, to make them aware of preventive services that are recommended.

Materials and patient education materials that they have not yet developed have been developed by AHRQ and other Federal agencies that they are less familiar with because of the silos in the Federal Government. And we are working to try to link the various agencies together to try to bring out the best-quality information for beneficiaries.

Providers also need education about what this new visit provision means. Without that type of education, it just becomes another billing code and not an opportunity, as we feel it could be, to change the culture of how preventive care is offered to seniors; and with proper education, that can occur.

All that said, the points that have just been made are fundamental. Paying for preventive services is just the starting point, and without the infrastructure for delivering it and following up on the abnormalities that are identified, the great good that could come from this will not be realized.

Mr. BILIRAKIS. Do you all see a good level of cooperation—maybe it is not the right word, but interest, dedication and cooperation on the part of CMS to take into consideration all the advice that you have given; the work that you are volunteering, your group is volunteering, to get this done right; and the education portion, of course, being very significant?

Ms. CLANCY. Without question, since my glass is half full, I thought I would offer a slightly more positive view of this.

A lot of studies have found that doctors and patients are very enthusiastic about prevention. They forget they don't have good systems in place and so forth. But the one nice thing about this Welcome to Medicare visit is, most studies have found that doctors tend to do a much better job in the context of something called a checkup, whether it is a comprehensive physical, whether it is called a health maintenance visit or so forth. So I think I would reiterate Dr. Woolf's point that this gets people off on the right foot.

The other area we are working on closely with CMS is in trying to deploy some of the power of information technology to give people reminders. Ultimately, I think this is going to be powerful for patients, as well. But a lot of times, doctors don't do this because they forget or don't realize the time sequence has come when it is time for someone's next service. And that is fairly easy to correct and reminders make a huge difference.

So I think there are some exciting developments in place Mr. BILIRAKIS. Ms. Heinrich, you would anticipate that the reimbursement to physicians who would conduct this Welcome to Medicare physical would be what, insufficient? Any feeling on that?

Ms. HEINRICH. The observation I make is that you have busy physicians, and the fact that they would not be reimbursed at a rate higher than a regular evaluation, management, first-time visit is not a large incentive. Now there are other incentives at play.

Mr. BILIRAKIS. And that is what you see coming down the pike that they probably would not be reimbursed higher?

Ms. HEINRICH. That is the way the regulation reads now.

Mr. BILIRAKIS. Mr. Brown to inquire.

Mr. BROWN. Thank you, Mr. Chairman.

Dr. Woolf, evidence shows that people with coverage for preventive service logically use those services more than those who don't have coverage. There has been a lot of attention recently to consumer-directed health plans, things such as medical health savings accounts and the like, which have a high deductible and are supposed to encourage consumers/patients to make wiser choices.

Comment, if you will, on what these kinds of plans, these consumer-directed health plans would do to people's utilization of preventive services.

Mr. WOOLF. It is a very interesting question given what appears to be an increasing trend among employers to pursue that kind of product. Frankly, the jury is still out on what impact they would have on preventive services. Most of the experts that are working on this field feel that it is perhaps 2, 3 years before we will have enough high-quality data to know what impact they might have.

The concern is, we have a large body of research going back 20 years to suggest that patients who face deductibles or copayments are less likely to utilize preventive services. And a phenomenon that we used to call "reverse targeting" occurs where the patients most in need of preventive care, who have the greatest risk factors for disease, are often, for socioeconomic reasons, more adversely impacted by the added costs. To the extent that a consumer-driven health plans mimic that phenomenon, they could be at a disincentive to receiving preventive care and adversely affect outcomes.

But there is a counterargument that giving people choices would enable them to concentrate their resources on prevention and thereby prevent disease. A concern that many have is whether patients would have the background and information base to make good choices about how to select preventive services that are a proven value and not be encouraged to invest the resources they have in their accounts on glitzy technologies that promise a lot, but haven't been proven to better their health.

Mr. BROWN. Have you seen—understanding the body of evidence has not accumulated to the degree that you would need to analyze this as thoroughly as you would want, do you see—in these consumer-directed health plans, have you seen special attention paid by the health plan itself to encourage people—to spend from their pot, if you will, their discretionary money to really take advantage of preventive care? Is that something these health plans have pushed effectively or pushed at all?

Mr. WOOLF. I am pleased to see several examples of some of the major vendors of these products offering first-dollar coverage for preventive services and providing a safe harbor, if you will, for preventive services under their plans. I don't know whether that is generalizable and whether all plans in that category are as careful to protect preventive services in that way.

Mr. BROWN. Ms. Heinrich and Dr. Woolf, as the chairman was talking earlier, I introduced legislation to give CMS authority to add preventive benefits to Medicare. We already—Medicare has

broad discretion to add new and promising treatments to Medicare coverage, but doesn't have the discretion to go further and offer preventive benefits.

Ms. Heinrich, would you support giving the Secretary more flexibility to add preventive services?

And, Dr. Woolf, I know your organization has spoken on that.

Would you both just address that issue?

Ms. HEINRICH. We really haven't focused on where the decision for covering preventive services is made, but we have said that it really needs to be science-based. And, certainly, depending on the U.S. Preventive Services Task Force would be a good start.

Mr. BROWN. Dr. Woolf?

Mr. WOOLF. We issued a report last year that outlines detailed recommendations on this issue and looked at a number of different options, and we are trying to address this problem and ultimately concluded that authority for covering preventive services should be transferred from Congress to CMS, just as it is for diagnostic and treatment services.

Mr. BROWN. Thank you, Mr. Chairman.

Mr. BILIRAKIS. I would like to, without objection, offer a document into the record by the Alzheimer's Foundation of America basically making the case that Alzheimer's should be included as part of the Welcome to Medicare preventive health program. And I have reviewed this with Mr. Brown. Without objection, it will be made part of the record.

[The information referred to follows:]

PREPARED STATEMENT OF ERIC J. HALL, CEO, ALZHEIMER'S FOUNDATION OF AMERICA

Chairman Bilirakis, Ranking Member Brown, and distinguished Subcommittee members: On behalf of the Alzheimer's Foundation of America (AFA), thank you for holding this important hearing on preventive benefits enacted as part of the Medicare Modernization Act of 2003 (MMA).

AFA believes the preventive benefits enacted under the MMA represent an important step forward in improving the health of our nation's Medicare beneficiaries. In particular, Mr. Chairman, we support and applaud your efforts to establish an initial preventive screening examination under Medicare.

AFA'S MISSION

An estimated five million Americans currently suffer from Alzheimer's disease, and the number is expected to rise to 16 million by mid-century. It is therefore critical that we all stand together for care as the incidence of this devastating disease continues to rise.

AFA was founded as a nonprofit 501(c)(3) organization to fill a gap that existed on the national front for advocacy of "care . . . in addition to cure" for individuals affected by Alzheimer's disease and related dementias. AFA and its members provide direct services to millions of Americans living with Alzheimer's disease and related disorders nationwide, as well as their caregivers and families. Our goals include improving quality of life for all those affected and raising standards for quality of care.

AFA operates a national resource and referral network with a toll-free hotline, develops and replicates cutting-edge programs, hosts educational conferences and training for caregivers and professionals, provides grants to member organizations for hands-on support services in their local areas, and advocates for funding for social services. It annually sponsors two national initiatives, National Memory Screening Day and National Commemorative Candle Lighting. AFA is also working to promote healthy aging through prevention and wellness education and to expand screening for memory impairment as a tool to facilitate early diagnosis and treatment.

THE IMPORTANCE OF MEMORY SCREENING

Early recognition of Alzheimer's disease and related dementias is essential to maximize the therapeutic effects of available and evolving treatments, and screening for memory impairment is the only way to systematically find treatable cases. Diagnosis in the early stages of the disease is vital, providing multiple benefits to individuals with the disease, families and society. Screening can also be beneficial for individuals who do *not* present a diagnosis of Alzheimer's disease by allaying fears and providing an opportunity for prevention and wellness education.

Memory screening is a cost-effective, safe and simple intervention that can direct individuals to appropriate care, improve their quality of life, and provide cognitive wellness information. With no "silver bullet" for dementia in the immediate future, it is essential to fully use all preventive measures and early interventions. AFA supports a comprehensive strategy that involves both research for a cure, as well as a national system of care that includes cognitive wellness, early detection and intervention, and disability compression.

To advance that objective, AFA launched National Memory Screening Day in 2003 as a collaborative effort by organizations and health care professionals across the country. AFA initiated this effort in direct response to breakthroughs in Alzheimer's research that show the benefits of early medical treatment for individuals with Alzheimer's disease, as well as the benefits of counseling and other support services for their caregivers.

AFA's annual National Memory Screening Day underscores the importance of early diagnosis, so that individuals can obtain proper medical treatment, social services and other resources related to their condition. With no cure currently available for Alzheimer's disease, it is essential to provide individuals with these types of interventions that can improve their quality of life while suffering with the disease.

During National Memory Screening Day, healthcare professionals administer free memory screenings at hundreds of sites throughout the United States. A memory screening is used as an indicator of whether a person might benefit from more extensive testing to determine whether a memory and/or cognitive impairment may exist. While a memory screening is helpful in identifying people who can benefit from medical attention, it is not used to diagnose any illness and in no way replaces examination by a qualified physician.

Our goal is for individuals to follow up with the next steps—further medical testing and consultation with a physician, if the testing raises concerns. The latest research shows that several medications can slow the symptoms of Alzheimer's disease and that individuals begin to benefit most when they are taken in the early stages of memory disorder. This intervention may extend the time that individuals can be cared for at home, thereby dramatically reducing the costs of institutional care.

With early diagnosis, individuals and their families can also take advantage of support services, such as those offered by AFA member organizations, which can lighten the burden of the disease. According to several research studies, such care and support can reduce caregiver depression and other health problems, and delay institutionalization of their loved one—again reducing the economic burden of this disease on society.

In addition, with early diagnosis, individuals can participate in their care by letting family members and caregivers know their wishes. Thus, memory screenings are an important tool to empower people with knowledge and support. Just as importantly, the screenings should help allay fears of those who do not have a problem.

AFA holds National Memory Screening Day on the third Tuesday of November in recognition of National Alzheimer's Disease Month. Broadcast personality Leeza Gibbons is the national advocate for this event. Ms. Gibbons founded *The Leeza Gibbons Memory Foundation* in response to her own family's trial with Alzheimer's. She lost her grandmother to the disease, and her mother now battles with the final stages of Alzheimer's.

This year, National Memory Screening Day will be held on November 16, 2004. Individuals concerned about memory problems will be able to take advantage of free, confidential screenings at hundreds of sites across the country with the goal of early diagnosis of Alzheimer's disease or related dementias. Early diagnosis is critical, because as Ms. Gibbons has noted, "This is not a disease that will wait for you to be ready."

THE NEED FOR FEDERAL LEADERSHIP

As promising research continues in the search for a cure, additional resources are also needed in support of efforts to delay the progression of Alzheimer's disease and

related dementias. The federal government can play a critical role in that regard by providing resources for a public health campaign designed to increase awareness of the importance of memory screening and to promote screening initiatives.

Federal support is essential to expand the scope of ongoing efforts in the private sector. Working in partnership with AFA and other participating organizations, the federal government can leverage its resources cost-effectively to help overcome fear and misunderstanding about Alzheimer's disease and related dementias, to promote public awareness of the importance of memory screening, to expand options for screening nationwide, and to direct Americans to the support services and care available in their local communities.

To that end, AFA is urging the Centers for Medicare and Medicaid Services (CMS) to provide screening for memory impairment as part of the Medicare initial preventive screening examination. CMS included a specific request for public comments on the scope of the exam in its proposed rules; therefore, AFA is recommending that CMS include screening for memory impairment within the proposed definition of a "review of the individual's functional ability, and level of safety, based on the use of an appropriate screening instrument." The proposed rules also state that review of an individual's functional ability and level of safety must address activities of daily living and home safety.

In that context, unrecognized dementia can increase the likelihood of avoidable complications such as delirium, adverse drug reactions, noncompliance, etc. These complications reduce the autonomy of affected individuals, thereby impeding their ability to perform activities of daily living and compromising their safety. In addition, about one-third of elders live by themselves, and these individuals are at greater risks for accidents, injuries, exploitation, and other adverse outcomes. Early identification allows safeguards and home assistance to assure continued maximization of home placement.

For the affected individual, identification of early stage dementia allows early aggressive use of available treatments. Early identification allows optimal therapy with available and emerging medications. Most FDA-approved medications can help slow the progression of symptoms of Alzheimer's disease and related dementias when presented in early stages of dementia.

Once dementia is identified, health care management can be adjusted to incorporate treatment strategies that accommodate a person with cognitive impairment. Issues such as patient education, self-medication, compliance, and hospital care can be adjusted to meet the needs of a mildly demented person who is at risk for common complications such as delirium and depression. Home-based support systems can be adjusted to maximize home placement for these individuals. Safeguards can be taken to prevent avoidable complications such as delirium during hospitalization.

Further, the early identification of dementia supports individual patient rights and self-determination. Mildly impaired individuals are capable of charting the future course of their care and making substantial decisions on issues like end-of-life care, resuscitation, disposition of wealth, etc. Advanced directives can be initiated that incorporate the wishes of individuals with dementia, thereby reducing the burden on the family of surrogate decision-making. Individuals with the disease can also take advantage of social services and other support that can improve quality of life. These include counseling, verbal support groups and cognitive stimulation therapies. These strategies may prolong activities of daily living, and promote a sense of dignity.

Separately, family caregivers also benefit from early identification at several levels. As noted above, early identification reduces the family burden with regard to decision-making, because families can follow the instructions of their loved ones. This process allows family caregivers to benefit early on from support groups, education and other interventions that address their unique and pressing needs. Such knowledge and support can empower them to be better caregivers and can reduce their incidence of depression and other mental and physical health problems. Intervention can also help on an economic front: lightening the burden on primary caregivers, who are also in the workforce, could help reduce employee absenteeism and lost productivity.

Finally, screening can be beneficial for those individuals who do not present a diagnosis of Alzheimer's disease. These negative results can allay fears and provide reassurance. Just as importantly, physicians can take this opportunity to present individuals with prevention and wellness education—a strategy that promotes successful aging.

We would note that use of available screening instruments to identify memory impairment during the Medicare initial preventive physical examination is consistent with current clinical practice guidelines. Individuals with mild cognitive impairment are at higher risk for subsequent development of Alzheimer's disease and related

dementias. General cognitive screening instruments are available and are useful in detecting dementia in patient populations with a higher incidence of cognitive impairment (*e.g.*, due to age or memory dysfunction). Attached for Subcommittee Members' reference is a summary of the relevant American Academy of Neurology practice guidelines for physicians.

Inclusion of screening for memory impairment is also consistent with the recent CMS National Coverage Decision expanding Medicare coverage of Positron Emission Tomography (PET) for beneficiaries who meet certain diagnostic criteria for Alzheimer's disease and fronto-temporal dementia.

AFA believes PET and other neuroimaging devices will be a valuable tool in predicting disease and in steering those with a diagnosis of Alzheimer's or related illnesses to the appropriate clinical and social service resources. Expanded reimbursement for PET studies will drive early intervention for the increasing—and alarming—number of Americans with Alzheimer's disease. Utilization of this technology will become even more critical in the future, as the number of Americans with dementia is projected to triple by mid-century.

CONCLUSION

Expanded screening to facilitate the early identification of memory impairment will produce tangible benefits to society by protecting individuals, improving quality of life, and reducing the costs of health care. Enhancing compliance and protecting individuals with dementia also produces tangible financial benefits to the health care system. Intervention can enable individuals to remain independent longer and can reduce the costs of insurance, absenteeism and lost productivity at work for primary caregivers—currently estimated at $60 billion annually.

AFA commends the Subcommittee's leadership in striving to improve preventive care for our nation's Medicare beneficiaries. We would likewise welcome the opportunity to work collaboratively to improve the quality of life for Alzheimer's patients, their families and caregivers. Please feel free to contact me at 866-232-8484 or Todd Tuten at 202-457-5215 if you have questions or would like additional information.

Thank you for the opportunity to share our views.

National Guideline Clearinghouse
www.guideline.gov

AHRQ

Complete Summary

GUIDELINE TITLE

Practice parameter: early detection of dementia: mild cognitive impairment (an evidence-based review). Report of the Quality Standards Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Petersen RC, Stevens JC, Ganguli M, Tangalos EG, Cummings JL, DeKosky ST. Practice parameter: Early detection of dementia: Mild cognitive impairment (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 May 8;56(9):1133-42. [47 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

- Dementia
- Alzheimer's disease

GUIDELINE CATEGORY

Diagnosis
Screening

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine

Neurology
Psychiatry

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To determine whether screening different groups of elderly individuals in a general or specialty practice is beneficial in detecting dementia

TARGET POPULATION

Persons with mild cognitive impairment

INTERVENTIONS AND PRACTICES CONSIDERED

General Cognitive Screening Instruments

1. Mini-Mental State Examination (MMSE)
2. Kokmen Short Test of Mental Status
3. Memory Impairment Screen
4. 7-Minute Screen

Brief Focused Screening Instruments

1. Clock Drawing Test
2. Time and Change Test

Neuropsychologic Batteries

1. Neuropsychologic Battery
2. Mattis Rating Scale
3. Halifax Mental Status Scale
4. Fuld Object Memory Test

Informant-Based Instruments

1. Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE)
2. Clinical Dementia Rating (CDR)
3. Blessed Dementia Rating Scale (BDRS)

MAJOR OUTCOMES CONSIDERED

- Rates of conversion to dementia for persons classified as having mild cognitive impairment
- Sensitivity and specificity of screening instruments for detection of dementia/cognitive impairment

- Positive and negative predictive values of screening instruments for detection of dementia/cognitive impairment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Panel selection. The Quality Standards Subcommittee identified two team leaders to select committee members to participate in the creation of one or more practice parameters on dementia. The committee determined that three practice parameters were needed: Detection of Dementia, Diagnosis of Dementia, and Management of Dementia. The three practice parameter committees coordinated their literature searches to include key words such as specific forms of dementia and databases that interrelate the three topics. All panel members provided comprehensive disclosures of any real or potential conflicts of interests.

Literature review process. Search terms. Key and index words used were as follows: dementia, pre-senile dementia, senile dementia, vascular dementia, Alzheimer´s disease, early detection, early diagnosis, early stages, early symptoms, health screening, psychologic screening inventory, geriatric assessment, longitudinal studies, retrospective studies, mild cognitive impairment, Mini-Mental State Examination, cognitive impairment, cognitive assessment, and memory tests.

Databases. MEDLINE, EMBASE, Current Contents, Psychological Abstracts, Psych Info, Cochrane Database, and CINAHL Database were searched.

Inclusion/exclusion criteria and process. For the searches, the authors of the guideline sought studies in all languages; however, other types of studies were limited to English only. Studies were restricted to human subjects. Longitudinal prospective studies that evaluated mildly impaired subjects and followed them to detect cognitive impairment from 1991 to early 2000 were reviewed. The authors of the guideline also examined reviews and their bibliographies published from 1994 to November 1999 to identify additional articles. In addition, the authors of the guideline evaluated studies of clinical testing instruments that could be used to identify subjects with cognitive impairment.

Number and disposition of articles. The authors of the guideline identified 1,933 abstracts, which yielded 120 articles. Application of appropriate inclusion/exclusion criteria yielded 74 articles that provided the evidence for this parameter.

NUMBER OF SOURCE DOCUMENTS

74

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification of Evidence

Class I. Evidence provided by one or more well-designed, randomized, controlled clinical trials, including overviews (meta-analyses) of such trials.

Class II. Evidence provided by well-designed, observational studies with concurrent controls (e.g., case control or cohort studies).

Class III. Evidence provided by expert opinion, case series, case reports, and studies with historical controls.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data extraction items. Articles were reviewed by at least two individuals and selected items were coded onto a data extraction form that had the following information: type of article, focus of article (e.g., diagnosis of dementia, early dementia), number of subjects, sex, subject selection method, method of patient characterization, screening instruments used, final diagnostic classification, gold standard for final diagnostic classification, quality of diagnostic methods, formal diagnostic criteria used, diagnostic criteria for Alzheimer´s disease (if applicable), age of population studied (if study dealt with test or instrument), name and value, sensitivity, specificity, positive predictive value, negative predictive value, and final classification of evidence.

Classification of evidence. Each article was assigned to a class of evidence based on a priori definitions. The class of evidence determined whether or not study results were ultimately translated into Standards, Guidelines, or Options.

Development of evidence tables. For all articles, evidences tables were developed. These tables indicate the author and year of the study, level of evidence, main purpose of the study, population, intervention, outcome measure, and result.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Levels of Recommendation

Standard. Principle for patient management that reflects a high degree of clinical certainty. (Usually requires Class I evidence that directly addresses clinical questions, or overwhelming Class II evidence when circumstances preclude randomized clinical trials.)

Guideline. Recommendation for patient management that reflects moderate clinical certainty. (Usually requires Class II evidence or a strong consensus of Class III evidence.)

Option. Strategy for patient management for which clinical utility is uncertain (inconclusive or conflicting evidence or opinion).

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines were approved by the American Academy of Neurology Quality Standards Subcommittee on November 11, 2000, by the American Academy of Neurology Practice Committee on January 6, 2001, and by the American Academy of Neurology Board of Directors on February 24, 2001.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Classification of evidence ratings, I-III, and the levels of recommendations (Standard, Guideline, Option) are defined at the end of the "Major Recommendations" field.

1. Does the presence of mild cognitive impairment predict the development of dementia?

   Conclusion: Studies indicate that individuals characterized as being cognitively impaired but not meeting clinical criteria for dementia or Alzheimer's disease (mild cognitive impairment) have a high risk of progressing to dementia or Alzheimer's disease. If the figures for incident Alzheimer's disease from the general population are used (Table 4 in the original guideline document), one can see that the rates range from 0.2% in the 65 to 69 year age rage to 3.9% in the 85 to 89 year range. The studies of

mild cognitive impairment indicate that the rate of progression to dementia of Alzheimer's disease is between 6 and 25% per year.

Practice Recommendation: Patients with mild cognitive impairment should be recognized and monitored for cognitive and functional decline due to their increased risk for subsequent dementia **(Guideline)**.

2. Does screening at-risk subjects with a specific instrument in a specific setting accurately lead to the diagnosis of dementia?

General Cognitive Screening Instruments

Conclusion: General cognitive screening instruments, which include the Mini-Mental State Examination, Kokmen Short Test of Mental Status, 7-Minute Screen, and Memory Impairment Screen, are useful for the detection of dementia when used in patient populations with an elevated prevalence of cognitive impairment either due to age or presence of memory dysfunction.

Practice Recommendation: General cognitive screening instruments (e.g., Mini-Mental State Examination) should be considered for the detection of dementia in individuals with suspected cognitive impairment **(Guideline)**.

Brief Focused Screening Instruments

Conclusion: Recently, attempts have been made to develop useful screening tools that can be administered in a brief time frame. Caution must be exercised because of the limited scope of these tools.

Practice Recommendation: Brief cognitive assessment instruments that focus on limited aspects of cognitive function (i.e., Clock Drawing Test, Time and Change Test) may be considered when screening patients for dementia **(Option)**.

Neuropsychologic Batteries

Conclusion: Neuropsychologic batteries are useful instruments in identifying patients with dementia, particularly when administered to an increased-risk (by virtue of memory impairment) population. Those neuropsychologic instruments that emphasize memory function are most useful.

Practice Recommendation: Neuropsychologic batteries should be considered useful in identifying patients with dementia, particularly when administered to a population at increased risk of cognitive impairment **(Guideline)**.

Informant-based Batteries

Conclusion: Interview-based techniques (i.e., Blessed Dementia Rating Scale, Clinical Dementia Rating, Informant Questionnaire on Cognitive Decline in the Elderly) may be useful in identifying patients with dementia, particularly when administered to patients who are at increased risk of developing dementia by virtue of age or memory impairment. These instruments emphasize the

importance of obtaining information concerning the cognitive and functional status of persons from an informed source.

Practice Recommendation: Interview-based techniques may be considered in identifying patients with dementia, particularly in a population at increased risk for cognitive impairment **(Option)**.

Definitions:

Classification of Evidence

Class I. Evidence provided by one or more well-designed, randomized, controlled clinical trials, including overviews (meta-analyses) of such trials.

Class II. Evidence provided by well-designed, observational studies with concurrent controls (e.g., case control or cohort studies).

Class III. Evidence provided by expert opinion, case series, case reports, and studies with historical controls.

Levels of Recommendation

Standard. Principle for patient management that reflects a high degree of clinical certainty. (Usually requires Class I evidence that directly addresses clinical questions, or overwhelming Class II evidence when circumstances preclude randomized clinical trials.)

Guideline. Recommendation for patient management that reflects moderate clinical certainty. (Usually requires Class II evidence or a strong consensus of Class III evidence.)

Option. Strategy for patient management for which clinical utility is uncertain (inconclusive or conflicting evidence or opinion).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on a review of the literature. The type of supporting evidence is identified and graded for each recommendation on the early detection of dementia (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved detection of dementia in persons with signs of mild cognitive impairment

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use specific procedures. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all the circumstances involved.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Petersen RC, Stevens JC, Ganguli M, Tangalos EG, Cummings JL, DeKosky ST. Practice parameter: Early detection of dementia: Mild cognitive impairment (an evidence-based review): Report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2001 May 8;56(9):1133-42. [47 references]

ADAPTATION

Not applicable: Guideline was not adapted from another source.

DATE RELEASED

2001 May

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

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GUIDELINE COMMITTEE

Quality Standards Subcommittee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: R.C. Petersen, PhD, MD; J.C. Stevens, MD; M. Ganguli, MD, MPH; E.G. Tangalos, MD; J.L. Cummings, MD; and S.T. DeKosky, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All panel members provided comprehensive disclosures of any real or potential conflicts of interest.

ENDORSER(S)

American Association of Neuroscience Nurses - Professional Association
American Geriatrics Society - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Academy of Neurology (AAN) Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Guideline summary for point of care. Detection, diagnosis and management of dementia. St. Paul (MN): American Academy of Neurology, 2001. Electronic copies: Available from the American Academy of Neurology (AAN) Web site.
- AAN guideline development process. St. Paul (MN): American Academy of Neurology. Electronic copies: Available from the AAN Web site.

PATIENT RESOURCES

The following is available:

- Alzheimer's disease guidelines: a summary for patients, family and friends. St. Paul (MN): American Academy of Neurology. 4 p.

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Neurology (AAN) Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI on February 12, 2002. The information was verified by the guideline developer on September 22, 2003.

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Mr. BILIRAKIS. Mr. Green, you weren't here a moment ago, but you are now, so the Chair will recognize you to inquire.

Mr. GREEN. Thank you, Mr. Chairman. I appreciate the chance and I appreciate your having the committee hearing.

Dr. Clancy, it is my understanding that the U.S. Preventive Services Task Force is currently working on a new recommendation for the abdominal aortic aneurysm screens.

Are you aware of a timeframe for delivering that recommendation?

Ms. CLANCY. November of this year. And we will make sure as soon as it is released, you will get a copy and your staff.

Mr. GREEN. In your testimony, it details two main questions that the task force recommendation process seeks to answer: first, that the task force seeks to determine if the preventive services screening indicates that AAA is associated with reduced risk of morbidity or mortality. The statistics we have on AAA indicate it is a condition that has no symptoms or warning signs, and that less than 15 percent with a ruptured abdominal aortic aneurysm actually survive. It seems to me that preventive services isn't just associated with a reduced risk of morbidity or mortality, that about the only way to reduce that is if you have a preventive test.

And second, in your testimony, the task force determines whether the early identification of the condition leads to an improved outcome compared to the result if these are not detected and treated early. And I think most vascular surgeons would agree that early detection and treatment of AAA would mean catching it before the aneurysm ruptures. And again the relevant statistics that we have are that 85 percent of individuals with a ruptured AAA die. And when caught before the rupture, AAA, it is curable up to 95 percent of the individuals. And, you know, to me, it seems a slam dunk that the task force would understand the need for a screening benefit.

Ms. CLANCY. Let me say I agree with your points. When the official recommendation and specific language is released, you will get a copy, and just also add that I have an uncle who was one of the lucky ones who ruptured his aortic aneurysm a couple of years ago and lives close enough to a major medical center that he made it through, but it was a pretty humbling reminder of what a terrible disease that is.

Mr. GREEN. I have a constituent near the Texas Medical Center who made it there, but it took her 4 weeks of intensive care in the hospital to be able to deal with it, and the cost was outrageous. And they were Medicare beneficiaries, both she and her husband.

I am one of the cochairs of the Congressional Vision Caucus. I am real interested in preventive benefits regarding common vision problems, and I know Medicare typically doesn't deal with it. A preventive benefit to screen for glaucoma is extremely important since approximately half of the individuals aren't aware that they have the disease. And since January 2002, at-risk Medicare beneficiaries have been able to receive these screenings.

Can you give us any information on the statistics or any analysis on the effectiveness of that benefit? If you don't have them today——

Ms. CLANCY. We can look into it and follow up on that.

Mr. GREEN. I appreciate it, one for the caucus but also for our health subcommittee.

Dr. Woolf, cost-sharing deductibles in Medicare can act as a barrier to accessing preventive services. As I understand it, the initial Welcome to Medicare exam is still subject to the deductible, which will soon be increasing by 10 percent and the 20 percent coinsurance.

On top of that, seniors will have the burden, as we discussed in our opening statement, of paying premiums which are increasing by 17 percent. Given that half of all seniors have incomes under 200 percent of poverty, don't you think, for some beneficiaries, such out-of-pocket expense would deter them from seeking this preventive benefit? And do you support eliminating the cost sharing and the deductible for preventive services?

Mr. WOOLF. The evidence indicates Congressman, that the presence of copayments and deductibles does act as a disincentive for the uptake of preventive services. So the science would tell us that that is going to pose a problem, especially for disadvantaged populations.

I can't resist, though, using your earlier questions as a way of responding to Mr. Brown's earlier question, and that is your analysis of the effectiveness of screening for abdominal aortic aneurysms and for glaucoma. I think you are identifying some important analytic arguments. But again, our view as an organization is that the scientific details of how to evaluate the effectiveness of these screening modalities center on issues that experts around the country normally deal with through the process that CMS currently uses for diagnostic and treatment services.

The issue of whether to screen for abdominal aortic aneurysms, for example, turns very much on the likelihood of progression of small aneurysms into large ones and on the performance characteristics of the available screening modalities. Deliberating on these fine technical details in this environment at the same time that you must contend with national security, economy, tax policy and so forth strikes me as inefficient, especially when, in Baltimore, regularly experts convened by CMS deal with much more complex technical issues as they determine whether to cover diagnostic and treatment services.

While I agree with the direction of your intention to cover these preventive services and think many of the scientific arguments have merit, we would encourage the notion of transferring the authority for this type of scientific analysis to CMS.

Mr. GREEN. And if I could follow up, I agree Congress and our country have a lot of concerns, but having had some constituents and family members who—I don't know if we are going to worry about our tax policy or terrorism—but depending on whether my great uncle bleeds from an aneurysm or not, that is our job and our subcommittee here, and we will deal with that. And maybe if we had a different tax policy we would have more resources to deal with it.

Mr. BILIRAKIS. Dr. Clancy's response to you regarding triple-A, now you are in the process of preparing a report in that regard, so you can't tell us where that might be in terms of that particular area?

Ms. CLANCY. Not today, but again, it is just a few weeks off, and because it gets down to debating and being very specific about the details, what size of aneurysm would make a difference and so forth in how often people should get a screening.

Mr. GREEN. And, Mr. Chairman, having talked with vascular surgeons, there are people, when it is discovered, it is not a threat immediately, but by knowing it, they can continue to have it monitored instead of waiting until it bursts and you bleed out.

Mr. BILIRAKIS. Well, there aren't any other members.

Anything further, Mr. Brown?

That being the case, again our gratitude. Your written statements, of course, your testimony here today will be nothing but helpful. But again, keep in mind, we are always open to suggestions.

Dr. Woolf, we sort of have to keep our feet on the ground. We have to be concerned, of course, about accountability and the dollars and things of that nature. So, you know, we can't do everything, as we much as many of us would like to. But any suggestions you may have in addition to what you have made here today that might be helpful to us, fine.

And, you know, the CMS argument, they are making these decisions, that is an interesting point. I don't know, I guess the Secretary decided that obesity should be a covered area, and he has decided that it is a disease, which means apparently he has some control or power in that regard. How far that might go or should go is another question.

Thank you very much. The hearing is adjourned.

[Whereupon, at 3:25 p.m., the subcommittee was adjourned.]

[Additonal material submitted for the record follows:]

WRITTEN TESTIMONY
SUBMITTED ON BEHALF OF THE AMERICAN CANCER SOCIETY

TO THE
UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON ENERGY & COMMERCE
SUBCOMMITTEE ON HEALTH

"KEEPING SENIORS HEALTHY: NEW PREVENTIVE BENEFITS IN THE MEDICARE MODERNIZATION ACT"

SEPTEMBER 21, 2004
2PM

Contact:
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The American Cancer Society would like to thank Congress and particularly Chairman Biliraiks and the House Energy & Commerce Committee for their strong support of an initial physical for Medicare beneficiaries, which resulted in Section 611 of the Medicare Modernization Act (MMA), otherwise known as the "Welcome to Medicare" visit. The Society – along with our partners in the Preventive Health Partnership (PHP), the American Diabetes Association and the American Heart Association – has been a strong advocate for the initial physical because we believe this new benefit will help promote prevention and early detection and will result in lives saved and improved quality of life for our nation's seniors.

Now that Section 611 has been enacted as part of the MMA, we have been working with the Centers for Medicare & Medicaid Services (CMS) on the implementation and with the PHP on outreach initiatives. While we would have liked to testify, the Society appreciates this opportunity to communicate our interest in and perspective on this critical new benefit to the House Energy & Commerce Committee's Subcommittee on Health.

The Society Supports a Comprehensive Physical

Recognizing the strong value of early detection, Congress has already provided Medicare coverage for breast, cervical, colon, and prostate cancer screenings. While screening rates have increased since the coverage became effective, they are still below their optimum levels. Studies have shown that a physician's recommendation is key to increasing screening rates; however, before Section 611 was enacted, Medicare did not cover a routine physical or other type of "wellness visit" where a conversation between a doctor and patient about cancer screening can easily take place. The American Cancer Society advocated for an initial "Welcome to Medicare" visit for new Medicare beneficiaries so that patients and their health care providers could have time dedicated to discussing the patient's health risk as well as recommended disease prevention strategies, such as smoking cessation, better nutrition and increased physical activity, and needed cancer screenings that could either be performed as part of the physical or, if needed, scheduled through a referral. We recognize the challenges Congress faced in creating the benefit and the challenges CMS is now facing with respect to implementation. Overall, the Society is pleased with the completeness of the new physical as outlined in CMS' recent proposed regulation, in particular that it will include a review of a patient's comprehensive medical and social history, which will include reviewing their family history, tobacco use, diet, and exercise. We also appreciate the inclusion of several health measurements, including the patient's height, weight, blood pressure, visual acuity and other factors deemed appropriate by the health care provider based on the patient's examination. While we recognize that patients fill out paper work that captures some of this information prior to their enrollment in Medicare or when they visit a new provider, we feel it is important to use the opportunity presented by the physical for the physician and patient to have a specific discussion about the patient's medical and social history. Many physician practices ask patients to fill out a survey before their first visit. Our hope is that physicians will be able to use the information collected on these types of forms as a discussion tool during the visit.

The need for such a visit is underscored in medical literature. For instance, in a study of 2,775 primary care patients, the strongest factor in whether or not an individual had undergone screening, was whether or not they had a specific visit for a health check-up in the previous

year.[1] In other words, relying on a doctor to mention screening during their sporadic contact with patients is not practical – and does not work. Furthermore, an analysis in the *Annals of Internal Medicine* found that planned visits dedicated to prevention are one of the most effective ways to get people screened.[2] Dedicated check-ups provide the opportunity to plug cracks in the system and assure that patients get their necessary preventive care.

It is our understanding from conversations with Committee staff and CMS that cancer screenings that can be performed by the health care provider during the physical (such as pap smears and prostate-specific antigens) may in fact be performed during the visit instead of requiring a referral. We applaud this approach, as it ensures that patients and physicians can make the most of this visit. However, we feel that there is some ambiguity in the proposed regulatory language regarding this point and have therefore sought clarification from CMS on this specific issue.

Ways in Which the Physical can be Improved

Allow CMS to Add New Preventive Services

As a leading source of cancer screening guidelines, the Society is well-aware that science advances quickly and therefore frequently reviews and updates our guidelines. Currently, Medicare covers the following cancer screening tests, which are inline with the Society's recommendations:

- Breast Cancer Screening: annual mammograms and regular clinical breast exam
- Prostate Cancer Screening: annual digital rectal exam and annual prostate-specific antigen test (PSA)
- Cervical Cancer Screening: pelvic exam every two years and pap smear (either a conventional pap test, or a liquid based-pap cytology tests such as Thin Prep) every two years
- Colorectal Cancer Screening: beneficiaries have the choice of one of five options
  1. annual Fecal Occult Blood Test (FOBT)
  2. Flexible Sigmoidoscopy every four years
  3. Flexible Sigmoidoscopy every four years + annual FOBT
  4. Colonoscopy every ten years for average risk individuals and every two years for those at high risk
  5. Double Contrast Barium Enema as an alternative to flexible sigmoidoscopy or colonoscopy

The Society was very pleased that Congress included a provision in Benefits Improvement and Protection Act of 2000 (BIPA) that not only expanded colonoscopy coverage to include average risk individuals, but also included language that gave the Secretary the authority to update Medicare coverage for colorectal cancer screening "*in consultation with appropriate organizations*." Congress recently also gave CMS this specific authority through the MMA to update cholesterol screening. This type of language wisely gives the Secretary the authority to ensure that Medicare screening benefits are in line with the current state of the science and guideline recommendations.

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[1] Sox CH, Dietrick AJ, Tostenson TD, Winchell CW, Labaree CE. Periodic health examinations and the provision of cancer prevention services, Arch Fam Med. 1997:6:223-30.

[2] Stone EG, Morton SC, et al. Interventions that Increase Use of Adult Immunization and Cancer Screening Services: A Meta-Analysis. *Annals of Internal Medicine*. 2002;136:641-651.

Recently, a new FOBT test – an immunochemical test, or an iFOBT, -- was added to the Society's colorectal cancer screening guidelines, since it was found to be more patient friendly, and likely to be equal or better than guaiac-based tests in sensitivity and specificity. We were very pleased that the BIPA language allowed CMS to update the colorectal cancer screening coverage in a timely and similar fashion to include iFOBT. Given the success that we have had with this language in relation to improving the colorectal cancer screening benefit, we feel that it is important that CMS be given the authority to update other Medicare coverage for preventive services in a similar fashion and would be pleased to work with Congress to this end.

In giving CMS the authority to add preventive services, we would ask that the language regarding with whom CMS consults be kept consistent with the existing colorectal cancer and cholesterol screening language. Congress has previously considered directing CMS to rely solely on the recommendations of the United States Preventive Services Task Force (USPSTF). While USPSTF serves an important function and is widely respected in their guidelines recommendation process, their limited resources have in the past prevented them from being as responsive to current evidence as such organizations as the American Cancer Society.

The USPSTF is known for conducting comprehensive assessments of clinical prevention services; however, the timeliness of these assessments has been cited as a concern by the Institute of Medicine (IOM) in its 2003 report, "Fulfilling the Potential of Cancer Prevention and Early Detection." While the USPSTF updated its prostate, breast, and colorectal cancer screening guidelines in 2002 and its cervical cancer screening guidelines in 2003, the IOM noted that the previous USPSTF guidelines for these vital tests were last issued in 1996 -- a time lag spanning six to seven years. The IOM report concluded that "assessments of prevention services are needed on a continual basis to ensure that public health recommendations are current and incorporate the latest scientific evidence."[3] The report also acknowledged that a significant barrier to USPSTF issuing more timely guidelines is that it has limited resources and that this would have to be rectified before the Task Force could improve its responsiveness

Further, the Society notes that there are screening tests we currently recommend and are covered by Medicare that are not yet recommended by the USPSTF (e.g., liquid based-pap cytology tests such as Thin Prep). The American Cancer Society feels strongly that existing coverage for cancer screening tests should remain intact. Rolling back coverage for tests such as Thin Prep would be a step backwards in bringing the Medicare program up to date with proven disease prevention and early detection strategies.

Remove Cost-Sharing for Preventive Services
The Society also has an interest in removing cost-sharing for the physical and all Medicare covered preventive services. Under MMA, the new physical will be subject to the standard co-insurance and deductible. Since studies have shown that cost-sharing has the effect of reducing the probability of patients using preventive services, we have long advocated for the elimination of cost-sharing for all cancer screenings. The Society is very interested in continuing to work with Congress on efforts to reduce or eliminate cost-sharing for the physical and other covered cancer prevention and early detection services.

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[3] Institute of Medicine. Curry S., Byers T. and Hewitt M., eds. 2003. *Fulfilling the Potential of Cancer Prevention and Early Detection.* Washington, DC: National Academy Press, p. 429-430.

Increase Physician Payment
As the Society has noted in our recent comments to CMS on the proposed Physician Fee Schedule, we are concerned that the payment for this benefit may not be sufficient to compensate physicians for the services provided under the examination. Under the proposed value for the new HCPCS code, G0XX2, a physician must provide several services, including an electrocardiogram, within approximately 45 minutes. Payment for this new HCPCS code will be based on CPT code 99203, *new patient, office or other outpatient visit*, and CPT code 93000, *electrocardiogram, complete*. We would like to see this physical paid using the higher level *new visit* code, CPT code 99205. We are concerned that the current payment may not adequately compensate physicians for their time and could result in shortened visits or visits that fail to include all of the appropriate education, counseling, and referrals. The Society has asked CMS to reconsider the payment for the physical and raise it to a level that will not act as a disincentive for physicians.

Broaden Tobacco Cessation Resources
The Society also has a long-standing interest in tobacco use cessation and strongly advocates for the availability of and access to both cessation counseling and appropriate drug therapies for all of the reported 70 percent of smokers who want to quit. Currently, Medicare does not cover cessation counseling nor does it cover nicotine replacement therapies (NRT). Medicare will begin to cover NRTs available by prescription only once the new prescription drug coverage goes into effect on January 1, 2006. Given the limited cessation-related resources that will be available to patients – at least initially, we have asked CMS for clarification on what physicians will be able to do for patients during the first year of the benefit and later after the prescription drug benefit goes into effect. We appreciate that the new physical presents an opportunity for the physician and patient to begin the discussion about tobacco cessation, and we will continue our work with you to secure coverage for a full cessation counseling benefit. Furthermore, the Society devotes extensive resources to tobacco cessation, including the operation of a quitline in a number of states, and would be pleased to serve as a resource to physicians seeking cessation services for their patients. We note that the report on the Medicare cessation demonstration, "Medicare Stop Smoking Project," should be released shortly, and we look forward to working with Congress and CMS to address its recommendations.

The Importance of Outreach

The Society recognizes that securing coverage for the physical is only half of the battle – we must also do our part to ensure that patients know about the new benefit and use it appropriately. Therefore, the Society is currently focused on using our organization-wide resources to get the word out to patients and physicians that this new benefit exists. We have already begun working on a variety of initiatives on our own and were also recently invited by CMS to begin an outreach partnership with them and our partners in the PHP.

The PHP's ultimate goal is to stimulate improvements in chronic disease prevention and early detection. Together, we strive to raise public awareness about healthy lifestyles and enhance the focus on prevention among health care providers. The PHP has begun a comprehensive public awareness campaign, "Everyday Choices For A Healthier Life," which includes television and

radio PSAs sponsored by The Ad Council, a joint website, an 800-number and educational materials.

With respect to the physical, the Society's education efforts are beginning now so that we can reach as many of those who will become Medicare beneficiaries in the beginning phases of this new benefit as possible, but these efforts will be on-going. Some of the things the Society is already working on include:

- Beginning educating physician memberships and our staff and volunteers by sharing a fact sheet on the physical that we prepared from statutory language. The fact sheet has already been distributed at the American Society of Clinical Oncology's annual meeting and the Primary Care Advisory Meeting, and will be distributed at the American Academy of Family Practitioners annual meeting.
- Sharing Society expertise with CMS by arranging a meeting between CMS staff and our Director of Cancer Screening to discuss the implementation of the physical and to discuss the possibility of helping CMS create a checklist that physicians can use during the physical. The Society has also submitted comments to CMS on the proposed Physician Fee Schedule's implementation of the physical.
- Working to raise media attention about the physical prior to the release of the regulation and again after the proposed regulation was released. The Society will continue to do outreach with reporters as the January 1 implementation date approaches.
- Conducting on-going discussions with CMS about partnership opportunities with the Society and the PHP such as potential joint events with the CMS Administrator that publicize the physical and encourage patients to schedule the visit.

Other resources the Society plans to use to educate beneficiaries include the following:

- Using our "direct channels" such as our website, call center and the cancer survivors network
- Drafting articles on the benefit for our CA Journal and working with various other groups to publicize the physical at other professional meetings in the fall.
- Exploring other possibilities such as creating a Continuing Medical Education course on the physical and considering other ways in which we can work with the American Diabetes Association and the American Heart Association through the PHP to create joint activities.

Conclusion

The Society appreciates the leadership of this Committee in securing coverage for the "Welcome to Medicare" physical and Congress' bipartisan support for the provision. We look forward to working with you and CMS to ensure that new Medicare beneficiaries and their providers are aware of and utilize the opportunity for prevention the physical represents. On behalf of the Society, and the more than 1.3 million Americans who will be newly diagnosed with cancer this year, we thank you for your time and the opportunity to present testimony.

Appendix A: American Cancer Society Guidelines for the Early Detection of Cancer, 2004

CA Cancer J Clin 2004;54:41–52

American Cancer Society Guidelines for the Early Detection of Cancer, 2004

Robert A. Smith, PhD; Vilma Cokkinides, PhD; Harmon J. Eyre, MD

ABSTRACT Each January, the American Cancer Society (ACS) publishes a summary of its recommendations for early cancer detection, including updates, emerging issues that are relevant to screening for cancer, or both. In the spring of 2003, the ACS announced updated guidelines for breast cancer screening, and several other organizations released updated guidelines that we compare with recent ACS updates. Finally, the most recent data pertaining to participation rates in cancer screening are presented by age and sex from the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System, as are U.S. maps profiling states based on the proportion of the age-eligible population not recently screened for breast cancer or colorectal cancer. (*CA Cancer J Clin 2004;54:41–52.*) © *American Cancer Society, 2004.*

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This article is available online at: http://CAonline.AmCancerSoc.org

INTRODUCTION

Four years ago, the American Cancer Society (ACS) began a yearly report on its cancer detection guidelines and current issues related to screening and testing for the early detection of cancer.[1] The first report also included a description of the ACS process for the development or update of a cancer screening guideline. The annual reports have been a summary source for ACS guidelines for the early detection of cancer, but also the background and rationale for guidelines that were updated in the previous year, announcements of upcoming guideline reviews, recent data and issues pertaining to early cancer detection, and a summary of the most recent data on adult cancer screening rates.[1–4]

In 2001, the ACS published revisions in the early detection guidelines for colorectal, endometrial, and prostate cancers, and also an updated narrative related to testing for early lung cancer detection.[2] Guidelines for cervical cancer screening were updated in 2002.[5] In 2003, guidelines for the early detection of breast cancer and a modification of the recommendations for fecal occult blood testing for colorectal cancer screening were published.[6,7]

In addition to providing an overview of existing ACS recommendations for early cancer detection, in this issue we provide (1) a brief summary of updated ACS guidelines for breast cancer screening; (2) a brief update on guidelines and new technologies for colorectal cancer screening; (3) a summary of updated recommendations for cervical cancer screening issued by the US Preventive Services Task Force (USPSTF) and a comparison of USPSTF guidelines and ACS guidelines for cervical cancer screening; and (4) a summary of current screening rates among adults in the United States.

SCREENING FOR BREAST CANCER

The ACS guidelines for breast cancer screening were updated in 2003,[6] and these recommendations are shown in Table 1. The ACS no longer recommends monthly breast self-examination (BSE) beginning at age 20 years, and instead recommends that women should be informed about the potential benefits, limitations, and harms associated with BSE and that they may choose to do BSE regularly, occasionally, or not at all. The change was based on a legacy of limited scientific evidence that cancers detected by women themselves are commonly detected during the formal

TABLE 1 American Cancer Society Recommendations for the Early Detection of Cancer in Average-risk Asymptomatic People

Cancer Site	Population	Test or Procedure	Frequency
Breast	Women, age 20+	Breast self-examination (BSE)	Beginning in their early 20s, women should be told about the benefits and limitations of breast self-examination (BSE). The importance of prompt reporting of any new breast symptoms to a health professional should be emphasized. Women who choose to do BSE should receive instruction and have their technique reviewed on the occasion of a periodic health examination. It is acceptable for women to choose not to do BSE or to do BSE irregularly.
		Clinical breast examination (CBE)	For women in their 20s and 30s, it is recommended that clinical breast examination (CBE) be part of a periodic health examination, preferably at least every three years. Asymptomatic women aged 40 and over should continue to receive a clinical breast examination as part of a periodic health examination, preferably annually.
		Mammography	Begin annual mammography at age 40.*
Colorectal	Men and women, age 50+	Fecal occult blood test (FOBT)†, or	Annual, starting at age 50.
		Flexible sigmoidoscopy, or	Every five years, starting at age 50.
		Fecal occult blood test (FOBT)† and flexible sigmoidoscopy,‡ or	Annual FOBT and flexible sigmoidoscopy every five years, starting at age 50.
		Double contrast barium enema (DCBE), or	DCBE every five years, starting at age 50.
		Colonoscopy	Colonoscopy every 10 years, starting at age 50.
Prostate	Men, age 50+	Digital rectal examination (DRE) and prostate-specific antigen test (PSA)	The PSA test and the DRE should be offered annually, starting at age 50, for men who have a life expectancy of at least 10 years.§
Cervix	Women, age 18+	Pap test	Cervical cancer screening should begin approximately three years after a woman begins having vaginal intercourse, but no later than 21 years of age. Screening should be done every year with conventional Pap tests or every two years using liquid-based Pap tests. At or after age 30, women who have had three normal test results in a row may get screened every two to three years. Women 70 years of age and older who have had three or more normal Pap tests and no abnormal Pap tests in the last 10 years and women who have had a total hysterectomy may choose to stop cervical cancer screening.
Endometrial	Women, at menopause	At the time of menopause, women at average risk should be informed about risks and symptoms of endometrial cancer and strongly encouraged to report any unexpected bleeding or spotting to their physicians.	
Cancer-related check-up	Men and women, age 20+	On the occasion of a periodic health examination, the cancer-related checkup should include examination for cancers of the thyroid, testicles, ovaries, lymph nodes, oral cavity, and skin, as well as health counseling about tobacco, sun exposure, diet and nutrition, risk factors, sexual practices, and environmental and occupational exposures.	

*Beginning at age 40, annual clinical breast examination should be performed prior to mammography.

†FOBT as it is sometimes done in physicians' offices, with the single stool sample collected on a fingertip during a digital rectal examination, is not an adequate substitute for the recommended at-home procedure of collecting two samples from three consecutive specimens. Toilet bowl FOBT tests also are not recommended. In comparison with gualac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly, and are likely to be equal or better in sensitivity and specificity. There is no justification for repeating FOBT in response to an initial positive finding.

‡Flexible sigmoidoscopy together with FOBT is preferred compared with FOBT or flexible sigmoidoscopy alone.

§Information should be provided to men about the benefits and limitations of testing so that an informed decision about testing can be made with the clinician's assistance.

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process of monthly BSE and new data and literature reviews that have questioned the value of routine BSE.[8,9] The consensus among organizations and individuals with expertise in the field of cancer screening is that it is more likely that these cancers are detected during normal activities, thanks to the heightened sense of awareness that has evolved over the past several decades about breast cancer and associated symptoms. Although BSE is one way women can increase their awareness of breast changes, other means to maintain heightened awareness are also possible. Thus, the new guidelines emphasize that clinicians should inform women about breast symptoms, early breast cancer detection, and the importance of prompt reporting of any new symptoms. An extensive discussion related to the underlying evidence and the challenges associated with early diagnosis of palpable masses can be seen in the guidelines update.[6]

The ACS recommendations for clinical breast examination remain unchanged with respect to age-specific periodicity. Clinical breast examination should be performed every three years in women between the ages of 20 and 39 years, and annually for women aged 40 and older. This examination, which should occur during periodic health checkups, provides an opportunity to access risk, to discuss the importance of early detection, to discuss the importance of regular mammography in women aged 40 years and older, and to answer any questions patients may have about their own risk, new technologies, or other matters related to breast cancer. There may be some benefit to performing the clinical breast examination before the mammogram.[6] Women who choose to do BSE can have their technique reviewed during these encounters.

Guidelines for mammography remain unchanged. Women at average risk should begin regular mammography at age 40 years. Women also should be informed about the benefits, limitations, and potential harms associated with screening. The importance of adherence to a schedule of annual mammograms should be stressed.

The update of the breast cancer screening guidelines also addressed issues related to screening high-risk groups, the age to stop screening, and screening with new technologies. Although there are not yet sufficient data to recommend a specific surveillance strategy for women at higher risk, the update states that women at increased risk for breast cancer may benefit from earlier initiation of screening, screening at shorter intervals, and screening with additional methods such as ultrasound or magnetic resonance imaging. With respect to the age to stop screening mammography, the ACS recommends that these decisions should be individualized by considering the potential benefits and risks of screening in the context of overall health status and longevity. The guidelines narrative stressed the tendency of clinicians to underestimate longevity in older women who would still likely benefit from preventive health strategies. As long as a woman is in good health and would be a candidate for treatment, she should continue to be screened with mammography.

SCREENING FOR CERVICAL CANCER

Table 1 summarizes new guidelines for cervical cancer screening published in late 2002.[5] The present guidelines reflect the current understanding of the underlying epidemiology of cervical intraepithelial neoplasia (CIN), and they offer varying surveillance strategies based on new screening and diagnostic technologies that have emerged since the late 1980s.

The ACS recommends that cervical cancer screening should begin approximately three years after the onset of vaginal intercourse, but no later than age 21 years. Cervical screening should be performed annually until age 30 with conventional cervical cytology, or every two years until age 30 using liquid-based cytology, after which screening may continue every two to three years for those women who have had three consecutive, technically satisfactory normal/negative cytology results. Women aged 70 and older with an intact cervix may choose to cease cervical cancer screening if they have had three or more documented, consecutive, technically satisfactory normal/negative cervical cytologic test results and also no abnormal/

positive cytologic test results within the 10-year period before age 70.

The update of the guidelines also addressed screening for cervical cancer in women for whom additional guidance is relevant. Women with a history of cervical cancer, in utero exposure to diethylstilbestrol, or who are immunocompromised (including those who test positive for the human immunodeficiency virus) should continue cervical cancer screening for as long as they are in reasonably good health.

Cervical cancer screening is not indicated for women who have had a total hysterectomy (with removal of the cervix) for benign gynecologic disease. However, women who have had a subtotal hysterectomy should be screened according to the recommendations for women at average risk. Women with a history of cervical intraepithelial neoplasia (CIN) 2/3 who have undergone hysterectomy, or for whom it is not possible to document the absence of CIN 2/3 as an indication for hysterectomy, should be screened until three documented, consecutive, technically satisfactory normal/negative cervical cytology results and no abnormal/positive cytology results (within a 10-year period) are achieved. Women with a history of in utero diethylstilbestrol exposure or a history of cervical carcinoma should continue screening after hysterectomy for as long as they are in reasonably good health and do not have a life-limiting chronic condition.

When the updated guidelines were published,[5] the ACS addressed the use of human papilloma virus (HPV) DNA testing with cytology as a primary screening test for cervical cancer. There are several potential benefits of HPV DNA testing. Women who have negative results of both cervical cytology and HPV DNA tests are further reassured that they are at low risk for cervical cancer. Women who have repeated positive results for high-risk HPV subtypes are at higher risk for cervical cancer and may potentially benefit from more intensive surveillance. Although the Food and Drug Administration (FDA) had not yet approved HPV DNA testing with cytology as a screening test when the guidelines were published in 2002, the ACS recommended, pending FDA approval, that HPV DNA testing with cytology would be reasonable for screening women aged 30 years and older as an alternative to cytologic examination alone. Based on both published and unpublished data reviewed in the guidelines development process, the ACS recommended that cervical cancer screening with HPV DNA testing and conventional or liquid-based cytology could be performed every three years. The ACS guidelines update also stressed the need to develop management algorithms for women with normal/negative cytology results but positive test results for high-risk HPV DNA subtypes.

The ACS discouraged HPV testing any more frequently than every three years and stressed that women who choose to undergo HPV DNA testing should receive counseling and education about HPV. For instance, a positive HPV test result should not be viewed as indicating the presence of a sexually transmitted disease, but rather a sexually acquired infection. Nearly every person who has had sexual intercourse has been exposed to HPV, and the infection is extremely common and usually not detectable or harmful. Testing positive for HPV does not indicate the presence of cancer, nor will the large majority of infections foretell an eventual cancer.

In March 2003, the FDA approved expanded use of Digene Corporation's Hybrid Capture 2 (HC2) HPV DNA test, which can screen for 13 high-risk strains of HPV associated with cervical cancer.

In January 2003, the USPSTF also updated guidelines for cervical cancer screening, with recommendations for average-risk women, women over age 65, and use of new technologies similar to the ACS update.[10] The USPSTF found good evidence that screening with cervical cytology reduces incidence and mortality from cervical cancer, and indirect evidence indicating that most of the benefit can be obtained by beginning screening within three years of onset of sexual activity or age 21 (whichever comes first) and screening at least every three years. The USPSTF recommended against continuing cytologic screening for women aged 65 and older who have had adequate recent screening with normal results, and

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cited ACS criteria for continuing screening in instances where this criteria could not be met.

SCREENING AND SURVEILLANCE FOR THE EARLY DETECTION OF ADENOMATOUS POLYPS AND COLORECTAL CANCER

The ACS guidelines for screening and surveillance for the early detection of adenomatous polyps and colorectal cancer were updated in 2001 (Table 1), and the recommendations for fecal occult blood tests were slightly modified in 2002 with the addition of immunochemical tests.[2,7] The ACS recommends that adults at average risk should begin colorectal cancer screening at age 50, using one of the following five options for screening: (1) annual fecal occult blood test (FOBT); (2) flexible sigmoidoscopy every five years; (3) annual FOBT plus flexible sigmoidoscopy every five years; (4) double-contrast barium enema every five years; or (5) colonoscopy every 10 years. These recommendations are very similar to those issued in the USPSTF guidelines, which were updated in 2002.[11] The USPSTF recommends that clinicians screen all men and women aged 50 years and older for colorectal cancer. The USPSTF concluded that there was fair to good evidence that screening methods, including FOBT, flexible sigmoidoscopy, combined FOBT and flexible sigmoidoscopy, colonoscopy, and double-contrast barium enema were effective at reducing the mortality rate from colorectal cancer, and that individual tests varied with respect to the quality of the evidence, magnitude of benefit, and potential for harms. The USPSTF also concluded that each test met conventional criteria for cost-effectiveness, but that there was insufficient evidence to recommend one test over another based on the balance of potential benefits, cost-effectiveness, and potential harms.

The ACS recommends more intensive surveillance for (1) persons at increased risk due to a history of adenomatous polyps; (2) persons with a history of curative-intent resection of colorectal cancer; (3) persons with a family history of either colorectal cancer or colorectal adenomas diagnosed in a first-degree relative before age 60 years; (4) persons at significantly higher risk due to a history of inflammatory bowel disease of significant duration; or (5) persons at significantly higher risk due to a family history of or genetic testing indicating the presence of one of two hereditary syndromes.

In 2003, a consortium of gastroenterology societies also updated clinical guidelines for colorectal cancer screening and surveillance.[12] The guideline stresses that persons at average risk who are 50 years and older should be screened for colorectal cancer using one of the acceptable options listed previously.

SCREENING FOR ENDOMETRIAL CANCER

In 2001, the ACS concluded that there was insufficient evidence to recommend screening for endometrial cancer for women at average risk, or for women at increased risk due to a history of unopposed estrogen therapy, tamoxifen therapy, late menopause, nulliparity, infertility or failure to ovulate, obesity, diabetes, or hypertension.[2] Rather, the ACS recommended that women at average and increased risk should be informed about risks and symptoms of endometrial cancer at the onset of menopause and strongly encouraged to report any unexpected bleeding or spotting to their physicians (Table 1). However, some women are at very high risk for endometrial cancer due to (1) known hereditary nonpolyposis colon cancer–associated genetic mutation carrier status; (2) substantial likelihood of being a mutation carrier (ie, a mutation is known to be present in the family); or (3) absence of genetic testing results in families with a possible autosomal dominant predisposition to colon cancer. For these women, annual screening beginning at age 35 is recommended due to the high risk for endometrial cancer and the potentially life-threatening nature of this disease. These women should be informed that the recommendation for screening is based on expert opinion in the absence of definitive scientific evidence, and they should be informed about potential benefits, risks, and limitations of testing for early endometrial cancer detection.

SCREENING FOR PROSTATE CANCER

Guidelines for testing for early prostate cancer detection were last updated in 2001 and reflect the importance of shared decision making about testing.[2] The ACS recommends that the prostate-specific antigen (PSA) test and digital rectal examination should be offered annually beginning at age 50 years to men who have a life expectancy of at least 10 years (Table 1). Before making a decision about testing, men should have an opportunity to learn about the benefits and limitations of testing for early prostate cancer detection and treatment of early prostate cancer so that they can make an informed decision with the clinician's assistance. The ACS guidelines panel concluded that men who ask the clinician to make the testing decision on their behalf should be tested. The ACS also stressed that a policy of not discussing testing or discouraging testing in men who request early prostate cancer detection tests is inappropriate.

Men at high risk, including those of African descent (specifically sub-Saharan African descent) and those with a first-degree relative with the disease diagnosed at a younger age (ie, younger than 65 years) should begin testing at age 45. Men at even greater risk for prostate cancer because they have more than one first-degree relative with prostate cancer diagnosed before age 65 could begin testing at age 40. However, if the PSA level is less than 1 ng/mL, no additional testing is needed until age 45. If the PSA is greater than 1 ng/mL but less than 2.5 ng/mL, annual testing is recommended. If the PSA is 2.5 ng/mL or greater, further evaluation with biopsy should be considered. Men at high risk also should be informed about the benefits and limitations of testing for early prostate cancer detection and treatment of early prostate cancer.

TESTING FOR EARLY LUNG CANCER DETECTION

At this time, the ACS does not recommend testing for early lung cancer detection in asymptomatic persons at risk for lung cancer. However, the increase in the use of spiral computed tomography (CT) to test for lung cancer, as well as the millions of chest radiographs in current and former smokers done each year, led the ACS to update their narrative for lung cancer testing in 2001 to ensure that clinicians and patients were aware of the limitations and potential harms associated with testing.[2]

The ACS historically has maintained that persons at high risk for lung cancer due to significant exposure to tobacco smoke or occupational exposures and their physicians may choose to have these screening tests done on an individual basis.[13] The challenge associated with these personal decisions is more complicated today because of favorable findings from investigations using low-dose spiral CT to test for early lung cancer[14,15] and aggressive promotion of these tests to persons at risk. Although these case series reports have demonstrated impressive performance of imaging with spiral CT and positron emission tomography, most organizations that issue screening guidelines likely will require more conventionally definitive results from the ongoing National Cancer Institute and American College of Radiology Imaging Network's collaborative National Lung Screening Trial before issuing guidelines for lung cancer screening.[16] However, because these tests are being aggressively marketed to individuals, the ACS revised the narrative related to lung cancer screening to emphasize the importance of informed decision making for persons who choose to be tested for early lung cancer detection and to recommend that, ideally, testing should be done only in experienced centers that also are linked to multidisciplinary specialty groups for diagnosis and follow-up. Current smokers should be informed that the more immediate preventive health priority is the elimination of tobacco use altogether, because smoking cessation offers the surest route at this time to reducing the risk for premature death from lung cancer.[17]

THE CANCER-RELATED CHECKUP

Periodic encounters with clinicians offer the potential for health counseling, cancer screening, and case finding.[13] These encoun-

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ters may include the performance of or referral for conventional cancer screening tests, as described previously, but also case-finding examinations of the thyroid, testicles, ovaries, lymph nodes, oral region, and skin. In addition, self-examination techniques or increased awareness about signs and symptoms of skin cancer, breast cancer, or testicular cancer can be discussed. Health counseling may include guidance about smoking cessation, diet, physical activity, and shared decision making about cancer screening.

The ACS now recommends that the cancer-related checkup occur during a general periodic health examination, rather than as a stand-alone examination done at a specific interval based on a person's age (Table 1).

SURVEILLANCE OF CANCER SCREENING: COLORECTAL, BREAST, CERVICAL, AND PROSTATE CANCERS

Data Sources and Methods

Each year, this section of the guidelines review reports the most recent prevalence data on the estimated proportion of the US adult population that undergoes specific tests for early cancer detection (Table 2). In addition, a specific topic related to utilization of cancer screening receives special emphasis. This year we are highlighting state-level variations in breast and cervical cancer screening.

These data are from the Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System (BRFSS) for 2002. They represent the most current data for estimating the prevalence of cancer screening in the United States. From its inception, the focus of the BRFSS has been to establish a surveillance system to collect data regarding population-based sociodemographics, health behaviors, and related health care factors known to affect chronic diseases and the health status of the general population.[18] The BRFSS provides state-specific estimates for behavioral risk factors from ongoing statewide telephone surveys of civilian, noninstitutionalized adults aged 18 years or older living in households with a telephone.

The BRFSS is conducted annually in all 50 states, the District of Columbia, and Puerto Rico by state health departments in collaboration with the CDC. The BRFSS survey method includes standardized core questionnaires, complex multistage cluster sampling designs, and random-digit dialing methods to select households with telephones. Data are weighted to provide prevalence estimates representative of the state's adult population. Weighted estimates (prevalence) and the standard error of the estimates were computed for the US population based on the combined state-level weighted data from states participating in the BRFSS in 2002.

Cervical Cancer Screening

In 2002, 86.2% of women aged 18 and older reported having a Pap test in the preceding three years. The high rate of participation in cervical cancer screening reflects a high acceptance of the Pap test among women and their providers as well as the convenience of testing during routine encounters with health care providers. Women who were 18 to 44 years old were more likely to have had a Pap test in the preceding three years compared with women aged 45 and older (88.1% versus 83.4%). In contrast, the prevalence of recent cervical cancer screening is 15% lower among women 65 and older compared with those aged 18 to 44 years (Table 2).

Breast Cancer Screening

In 2002, 61.5% of women aged 40 and older reported having a mammogram in the last year. The proportion of women who reported having a mammogram in the last year was 60.5% among those aged 40 to 64 years and 63.8% among those 65 and older. When considering breast cancer screening with both mammography and clinical breast examination, the estimates are lower, just slightly more than 50%. The proportion of women, aged 40 to 64 years, who reported having both a mammogram and a clinical breast examination in the previous year was

TABLE 2 Prevalence (%) of Recent Cancer Screening Examinations Among US Adults, BRFSS, 2002

	Age	Men Weighted % (95%C.I.)	Women Weighted % (95% C.I.)	Total Weighted % (95% C.I.)
Colorectal Cancer				
Either a flexible sigmoidoscopy or colonoscopy*	50+	41.7 (40.9-42.6)	39.5 (38.8-40.1)	40.4 (40.0-41.0)
Fecal occult blood testing (home kit)†	50+	22.4 (21.7-23.1)	21.4 (20.7-21.8)	21.8 (21.3-22.2)
Breast Cancer				
Mammogram‡	40-64		60.5 (59.8-61.2)	
	65+		63.8 (62.8-64.8)	
Mammogram and clinical breast exam§	40-64		54.9 (54.2-55.7)	
	65+		52.3 (51.2-53.4)	
Cervical Cancer				
Pap test¶	18-44		88.1 (87.5-88.7)	
	45+		83.4 (82.8-84.1)	
	65+		74.4 (73.2-75.5)	
Prostate Cancer				
Prostate-specific antigen (PSA)**	50+	53.7 (52.8-54.6)		
Digital rectal exam (DRE)††	50+	52.0 (51.1-52.8)		

*Recent sigmoidoscopy or colonoscopy test within the preceding five years.

†Recent fecal occult blood test using a home kit test performed within the preceding year.

‡Women 40 and older who had a mammogram in the last year.

§Women 40 and older who had a mammogram in the last year and a clinical breast exam.

¶Women who had a Pap test within the preceding three years.

**A prostate-specific antigen test (PSA) within the past year for men who have not been told they have had prostate cancer.

††A digital rectal examination (DRE) within the past year for men who have not been told they have had prostate cancer.

Source: BRFSS 2002.

54.9%, and the proportion was 52.3% among women ages 65 and older (Table 2).

Prostate Cancer Screening

In 2002, the proportion of men aged 50 and older who reported having a PSA test in the previous year was 53.7%. The proportion of men reporting digital rectal examination in the previous year was 52% (Table 2).

Colorectal Cancer Screening

The proportion of adults aged 50 and older reporting recent colorectal cancer screening with an endoscopic procedure (either a sigmoidoscopy or colonoscopy) was nearly twice that of adults reporting recent screening with an FOBT. In 2002, 40.4% of adults in this age group reported having received either a sigmoidoscopy or colonoscopy procedure within the past five years, whereas the prevalence of having an FOBT within the past year was 21.8%. However, because the nationwide prevalence of colorectal cancer screening is only approximately 50% (ie, 53.1% of adults aged 50 years and older had an FOBT or lower endoscopy, or both), the substantial problem of too many average risk adults not being screened with any of the recommended tests persists.

It is important to note that this comparison represents an estimate of the prevalence of adults who are current with ACS guidelines in terms of the kind of testing they have undergone. However, because the BRFSS does not distinguish between sigmoidoscopy and colonoscopy, persons who had colonoscopy more than five years but less than 10 years before the survey was conducted would not be included in the estimate.[2] No data are available from the BRFSS to estimate use of the double-contrast barium enema. There were no differences in the sex-specific prevalence of colorectal cancer screening (Table 2).

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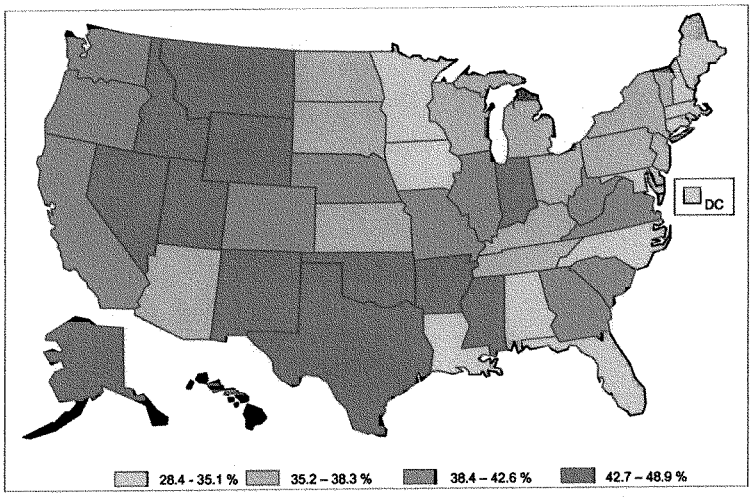

FIGURE 1 Percentage of Women Aged 40 Years or Older Who Reported Not Having Had a Mammogram Within the Last Year, by State, 2002.
Source: Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System, 2002.

STATE-SPECIFIC PREVALENCE IN THE LACK OF UTILIZATION OF BREAST AND COLORECTAL CANCER SCREENING

However good the efficacy of a cancer screening procedure, among the practical elements of its effectiveness is the degree to which the designated population participates in regular screening. This section focuses on state-level variation in lack of utilization of screening for breast and colorectal cancer, which are two of the leading cancers affecting men and women for which there is consensus about the efficacy of screening and for which considerable resources are devoted to efforts to increase screening (Figures 1 and 2, respectively). Specifically, the US maps shown in Figures 1 and 2 illustrate the proportion of each state's age-appropriate population who report not having had a cancer screening test as recommended by the ACS cancer screening guidelines.

State-Specific Prevalence in the Lack of Breast Cancer Screening

Timely mammographic screening among women aged 40 years and older could prevent 30% to 48% of all deaths from breast cancer.[6,19,20] In 2002, approximately 40% of American women aged 40 years and older reported that they had not had a mammogram within the last year. Despite the fact that mammography has been widely available since the late 1980s, in some states the prevalence of lack of mammographic screening among age-eligible women is notable. The state-specific prevalence in the lack of mammographic screening among age-eligible women was greater than 45% in nine states: Alaska, Arkansas, Idaho, Mississippi, New Mexico, Oklahoma, Texas, Utah, and Wyoming, with rates ranging from 45.1% to 48.9% (Figure 1).

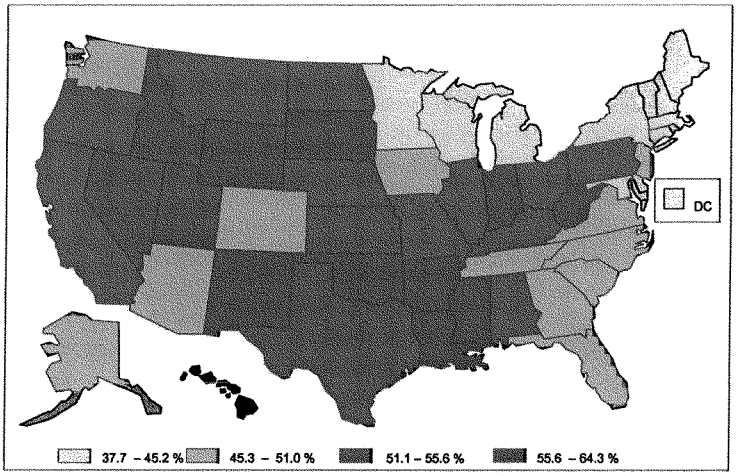

FIGURE 2 Percentage of Adults Aged 50 Years or Older Who Reported Not Having Had Any Colorectal Cancer Screening Test*, by State, 2002.

***No fecal occult blood test in the last year and no endoscopy in the last five years.**
Source: Centers for Disease Control and Prevention, Behavioral Risk Factor Surveillance System, 2002.

State-Specific Prevalence in the Lack of Colorectal Cancer Screening

Colorectal cancer screening could reduce the colorectal cancer mortality rate by 50% or more through early detection of invasive disease and detection and removal of adenomatous polyps.[21] In 2002, 50% of American men and women aged 50 years and older reported that they had not had any colorectal cancer screening (an FOBT within the last year or sigmoidoscopic screening). The state-specific prevalence of not having had any colorectal cancer screening tests (either an FOBT or a sigmoidoscopic examination according to screening guideline intervals) was more than 55% in South Dakota, Utah, Idaho, Hawaii, Louisiana, Mississippi, Nevada, Indiana, New Mexico, West Virginia, Arkansas, Oklahoma, and Wyoming, with rates ranging from 55.6% to 64.3% (Figure 2).

A recent report from the CDC showed slight improvements in the utilization of colorectal cancer screening procedures among persons at average risk between 1997 and 2001: 21% increase in FOBT use within the past year and 29% increase in lower endoscopy within the past five years.[22] Compared with the use of other cancer screening tests, low colorectal cancer screening rates are a function of incomplete diffusion of proven and efficacious methods for screening in the health care systems, low engagement by health care providers in recommending screening to their patients, and lower awareness in the population about the need for and importance of screening.[23–25]

CONCLUSIONS

Guidelines for cancer screening represent evidence-based strategies for reducing the morbidity and mortality rates associated with late-stage diagnosis of specific cancers. To

the extent that these recommendations identify at-risk populations and specify tests, test intervals, and important quality assurance issues, they are blueprints for reducing the number of premature deaths from cancer.[26] The fact that cancer screening is underutilized and that many Americans have limited or no access to cancer screening means that there is a considerable, persistent challenge to identify strategies that would bring the nation closer to achieving the fullest potential of early cancer detection.

A 2003 report from the Institute of Medicine highlighted the need for new strategies to prevent cancer and, when cancer occurs, to detect and treat it at its earliest stages.[27] This report notes that the principal challenges to optimizing the delivery of effective cancer screening services, and reducing inappropriate testing, lie in changing the behaviors of three sectors of society: (1) systems of care, which should make cancer screening available to eligible populations; (2) health care providers, who should counsel patients about recommended cancer screening and assure that screening is performed in a timely manner; and (3) individuals, who should heed the recommendations made by public health agencies and their physicians on screening and obtain recommended screening tests and pursue follow-up tests. Among the recommendations for the nation to make progress in cancer prevention and early detection were specific recommendations related to early cancer detection. That is, there should be: (1) access to and coverage for early detection services by public and private insurers; (2) support for programs that provide primary care to the uninsured and underserved; (3) support for the CDC's National Breast and Cervical Cancer Early Detection Program; (4) the design and implementation of programs to improve health care provider education and training and adherence to evidence-based guidelines for early detection services; and (5) promotion of partnerships between public and private organizations to work toward improving the public's understanding of cancer prevention and early detection with a focus on prevention and early detection of cancer and reduction of disparities in the cancer burden. If key organizations would act on these recommendations with a vision toward improving adherence and efficiency in cancer screening and reducing disparities, then we could anticipate greater reductions in disease burden than we are achieving today.

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The American
Occupational Therapy
Association, Inc.

Occupational Therapy:
Skills for the Job of Living

STATEMENT
AMERICAN OCCUPATIONAL THERAPY ASSOCIATION
SUBMITTED TO THE SUBCOMMITTEE ON HEALTH,
U.S. HOUSE OF REPRESENTATIVES COMMITTEE
ON ENERGY AND COMMERCE
FOR THE HEARING
"KEEPING SENIORS HEALTHY: NEW PREVENTATIVE BENEFITS IN THE MEDICARE MODERNIZATION"
September 21, 2004

The American Occupational Therapy Association (AOTA) submits this statement for the record of the September 21, 2004 hearing. We appreciate the opportunity to provide this information regarding the relationship of occupational therapy services to preventative efforts to keep seniors healthy. It is critical for Congress to be aware of issues regarding America's health needs so that it can develop appropriate national policies to meet society's needs. The topic of this hearing will assist in the development of a better, clearer picture of how to use the benefits of occupational therapy in a preventative manner for America's older population.

In addition, as the Congress reviews expansions of access to important preventative benefits for seniors under the Medicare program, AOTA urges attention to access to currently covered Medicare services for preventative purposes.

AOTA supports guidelines for the new initial preventative physical examination benefit. In particular, AOTA suggests that a review of the beneficiary's functional ability and level of safety is a crucial component of quality care that must be covered. AOTA supports inclusion of mental health and other factors as part of the physical. These factors are key indicators of health and independence and fit squarely within the domain of occupational therapy. In fact, scientific research published in the Journal of the American Medical Association (JAMA) has shown the positive effects of preventative occupational therapy in reducing rates of decline and incidence of need for expensive acute or long-term care. (**Journal of the American Medical Association (JAMA),**
"Occupational therapy for independent-living older adults: A randomized controlled trail." JAMA, Vol. 278, No. 16, p. 1321-1326. 1997". The initial preventative physical examination guidelines should provide information to inform physicians' referrals of the beneficiary when a more extensive evaluation is warranted and also when the initial screening indicates deficits in these areas in which intervention would be medically appropriate.

Occupational therapy is a covered service under Medicare for evaluation and treatment of functional limitations that occur because of illness, injury or disease. It can address and remediate many of the above referenced issues. But there are limitations in coverage that may hinder access to occupational therapy as a preventive service.

Preventive occupational therapy can aid older persons in staying healthier and more independent by helping them to assimilate health-promoting changes into their daily lives. The positive effects of preventive occupational therapy can be maintained over time, helping seniors to age successfully in their own homes and communities and avoid dependence on costly hospitals and nursing homes. Occupational therapists and occupational therapy assistants are part of the injury prevention and care team for older adults, their families, and caregivers. There are a number of preventative areas in which occupational therapists work.

Falls Prevention:

In the United States, 1 of every 3 persons 65 years of age or older falls each year. Older adults are hospitalized for fall-related injuries five times more often than for injuries from other causes. Of those who

fall, 20% to 30% have injuries severe enough to reduce mobility and independence. Occupational therapists play an important role in educating older adults about possible risk factors that they may not have considered in the prevention of falls. Occupational therapists apply the Person-Environment-Occupation Model when addressing falls with older adults. Planning and carrying out daily routines requires older adults to reflect on their health status and mental outlook (person) (e.g., physical abilities, visual limitations, side effects from medications); the physical, external factors affecting performance (environment) (e.g., ice on the sidewalk to the mailbox, height of a closet shelf); and the task or activity they plan to do (occupation) (e.g., getting into the bathtub after knee surgery, cleaning the gutters on the house) and the potential for this activity to contribute to a fall. Fall risks should be assessed as part of the initial physical. But in addition, the guidelines should make physicians aware of the need to refer to occupational therapy for fall assessment and intervention. This is currently a covered Medicare benefit if risk factors are identified.

Vision Rehabilitation:

The demand for occupational therapy for vision rehabilitation is increasing as the population of our country ages. Visual loss can translate into problems with reading, writing, mobility, and activities of daily living. Because the vast majority of visually impaired elderly have some remaining vision, early and appropriate intervention will help maximize the visual abilities of these individuals with the goal of greater independence and self-sufficiency. Macular degeneration, glaucoma, diabetic retinopathy, and cataracts are all diseases of the eye that result in functional limitations occupational therapists address. Occupational therapists conduct evaluations that include acuity testing; contrast sensitivity assessment; effects of glare, color appreciation, and other impairments; and a review of all areas of activities of daily living and how they have been affected by the vision loss. Occupational therapists would identify and implement modifications needed to promote independent function, such as marking of appliance dials, talking clocks, computer scanners for audio reading, positioning of books for reading, and large print calendars and address books. Occupational therapists have much to offer persons with visual deficits, and have the skills for implementing adaptations that maintain function. Occupational therapy is covered under Medicare for the treatment of functional limits resulting from vision loss or reduction. Physician guidelines for the initial physical should highlight vision problems and provide information to inform physician referrals for corrective services such as occupational therapy.

Driving and Mobility:

The number of Americans aged 65 and older is expected to double to 70 million by the year 2030. Millions of older Americans will be driving in the coming decades as they seek to maintain their independence and avoid isolation in suburban and rural communities dependent on the private motor vehicle. Older Americans comprise 12% of all crash fatalities, and drivers over 65 years of age experience more intersection collisions than do younger drivers. The decision by family and friends to intervene in an elder's driving can be very difficult as the older person rejects life without a motor vehicle. Occupational therapists conduct initial evaluations of clients and refer them to programs that provide driving assessments, often provided by occupational therapists. Although all declining performance skills and performance factors cannot be overcome, compensations can be made in some areas by using adaptive equipment (e.g., extra mirrors for clients who cannot turn their heads to check their blind spots) or adopting compensatory strategies. Occupational therapy practitioners have the skills to identify driving issues resulting from illness, injury, disease, or normal aging. As a preventative service, the initial physical exam should identify any driving incidents and then refer for evaluation if appropriate.

Mental Health:

Often forgotten, preventative screening for depression, abuse and other mental health issues among the elderly can help to treat problems before they have serious consequences. Including mental health screening in the initial physical is important to prevent additional and more costly conditions and diseases from occurring. For mental health, too, occupational therapy is a covered Medicare service that addresses functioning in life despite the effects of mental health problems. Physician guidelines should inform about

the availability of Medicare coverage for occupational therapy to address mental health problems and resulting functional limitations.

Existing Limitations in the Medicare Program:

AOTA would like to also mention that some current problems in the Medicare program limit access to occupational therapy and thus limit the preventive benefits of occupational therapy under the current program. Prevention is not just about tests and early identification of disease but is also about ensuring access to services that have a proven impact on lifestyle choices, healthy living, and avoiding illness and injury (such as those resulting from falling, poor driving or limits in self-care).

The "$1500" annual cap on outpatient rehabilitation, imposed by the Balanced Budget Act and currently in suspension through Congressional action, would, if implemented, limit access to occupational therapy that would enable an individual to fully recover from a stroke, to overcome limitations resulting from severe burns, or to achieve independence in self-care to enable living at home. AOTA has worked for many years to repeal this cap and appreciates Congress' willingness to stop implementation. But without Congressional action next year, the cap will be imposed, limiting the healing and preventive benefits of this existing Medicare covered service.

AOTA has also worked for many years to enable occupational therapy to be considered a qualifying service under the home health benefit and thus be available to home health patients in a timely and clinically appropriate manner. We urge the Congress to consider changing this outdated policy and improve the ability of the home care benefit to achieve positive outcomes and save resources in the long run.

The American Occupational Therapy Association represents over 35,000 occupational therapist, occupational therapy assistants, and students of occupational therapy. Occupational therapy is a health and rehabilitation service that helps individuals whose lives have been affected or could be affected by injury, disease, disability or other health risk. Clients who benefit from occupational therapy include infants and children, working age adults, and older persons who are dealing with conditions affecting their ability to engage in everyday activities or "occupations." Occupational therapy is a covered Medicare service for treatment of an illness or injury to recover or improve function. Occupational therapy is also a covered professional service under Medicaid, SCHIP programs, private health insurance, workers compensation and other programs.

United States Government Accountability Office

GAO

Testimony

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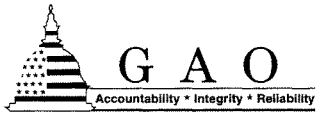
MEDICARE PREVENTIVE SERVICES

Most Beneficiaries Receive Some but Not All Recommended Services

Statement of Janet Heinrich
Director, Health Care—Public Health Issues



GAO-04-1004T

September 2004

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Highlights

Highlights of GAO-04-1004T, a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

MEDICARE PREVENTIVE CARE

Most Beneficiaries Receive Some but Not All Recommended Services

Why GAO Did This Study

Preventive care depends on identifying health risks and on taking steps to control these risks. In contrast, Medicare, the federal health program insuring almost 35 million beneficiaries age 65 or older, was established largely to help pay beneficiaries' health care costs when they became ill or injured. Congress has broadened Medicare coverage over time to include specific preventive services, such as flu shots and certain cancer-screening tests, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added coverage for several preventive services, including a one-time preventive care examination for new enrollees, which will start in 2005.

GAO's work, done before MMA, included analyzing data from four national health surveys to examine the extent to which Medicare beneficiaries received preventive services through physician visits. GAO also interviewed officials from the Centers for Medicare & Medicaid Services (CMS) and other experts and reviewed the results of past demonstrations and studies to assess expected benefits and limits of different delivery options for preventive care, including a one-time preventive care examination.

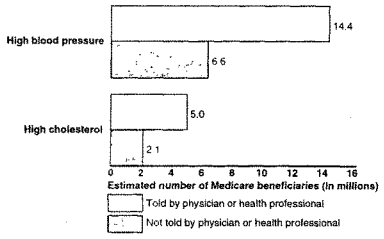
www.gao.gov/cgi-bin/getrpt?GAO-04-1004T.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Janet Heinrich on 202-512-7119.

What GAO Found

Most Medicare beneficiaries receive some but not all recommended preventive services. Our analysis of year 2000 data shows that nearly 9 in 10 Medicare beneficiaries visited a physician at least once that year; beneficiaries made, on average, six visits or more within the year. Still, many did not receive recommended preventive services, such as flu or pneumonia vaccinations. Moreover, many are apparently unaware that they may have conditions, such as high cholesterol, that preventive services are meant to detect. In one 1999–2000 nationally representative survey where people were physically examined and asked a series of questions, nearly one-third of people age 65 or older whom the survey found to have high cholesterol measurements said they had not before been told by a physician or other health professional that they had high cholesterol. Projected nationally, this percentage translates into about 2.1 million people who may have had high cholesterol without knowing it.

Estimated Number of Medicare Beneficiaries Age 65 or Older Who Were Aware or Unaware That They Might Have High Blood Pressure or High Cholesterol, 1999–2000



Source: CDC's National Health and Nutrition Examination survey.

A one-time preventive care examination may help orient new beneficiaries to Medicare and provide further opportunity for beneficiaries to receive some preventive services. Covering a one-time preventive care examination does not ensure, however, that beneficiaries will receive the recommended preventive services they need over the long term or consistently improve health or lower costs. CMS is exploring an alternative that would provide beneficiaries with systematic health risk assessments by means other than visits to physicians. A key component of this early effort involves the coupling of risk assessments with follow-up interventions, such as referrals for follow-up care.

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today as you discuss seniors' health and the preventive care benefits in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Overall preventive care depends heavily on identifying health risks associated with the onset or progression of disease and on taking steps to reduce or mitigate these risks. The Medicare program, in contrast, was established largely to help pay beneficiaries' health care costs when they became ill or injured. Over time, however, Congress has broadened Medicare coverage to include specific preventive services, such as immunizations for influenza and pneumonia and screening tests for certain cancers, that aim to keep an illness or condition from developing or becoming more serious. Most recently, in passing the MMA, Congress added coverage, to start in 2005, for a one-time preventive care examination for new enrollees and for selected other preventive services.[1]

As these new benefits are implemented under MMA, you have inquired about lessons learned from previous research on delivery options for preventive services. Since 2002, we have done a series of reports for Congress that examines the delivery of preventive care services to Medicare beneficiaries. My statement today summarizes some relevant findings from our work done before MMA, specifically:

- the extent to which Medicare beneficiaries receive preventive services through physician visits, and
- some of the expected benefits and limitations of delivering services through a one-time preventive care examination, including discussion of another delivery option being explored by the Centers for Medicare & Medicaid Services (CMS).

My testimony today is based on reports and testimony we have issued since 2002.[2] Our work for these products included a synthesis of

[1]Pub. L. No. 108-173, 117 Stat. 2066.

[2]See U.S. General Accounting Office, *Medicare: Beneficiary Use of Clinical Preventive Services*, GAO-02-422 (Washington, D.C.: April 2002); *Medicare: Use of Preventive Services Is Growing but Varies Widely*, GAO-02-777T (Washington, D.C.: May 23, 2002); and *Medicare: Most Beneficiaries Receive Some but Not All Recommended Preventive Services*, GAO-03-958 (Washington, D.C.: September 2003).

information on preventive care received by people age 65 or older[3] from four nationally representative health surveys;[4] a review of the results of past related research demonstrations and congressionally mandated studies; and interviews with Department of Health and Human Services (HHS) and CMS officials and other experts. This work allows us to discuss the benefits and limitations of the delivery of preventive services through a one-time examination. This body of work was conducted from August 2001 through August 2003 in accordance with generally accepted government auditing standards. In July 2004, we updated information on recommended preventive services and on the status of a CMS effort to explore another delivery option.

In summary, although they typically visit a physician several times during a year, most Medicare beneficiaries receive some but not all recommended preventive services. Our analysis of year 2000 data shows that nearly 9 in 10 Medicare beneficiaries visited a physician at least once that year, and beneficiaries made an average of six visits or more within the year. Despite these opportunities, many beneficiaries did not receive recommended preventive services. In 2000, for example, about 30 percent of Medicare beneficiaries did not receive an influenza vaccination, and 37 percent had never had a pneumonia vaccination as recommended under current guidelines for people age 65 or older. Moreover, many Medicare beneficiaries are apparently unaware that they may have conditions that preventive services are meant to detect. For example, in one 1999–2000 nationally representative survey during which people received physical examinations, nearly one-third of people age 65 or older whom the survey

[3]We focused this work on the people covered by Medicare who are 65 or older—about 86 percent of the entire Medicare population. Besides this age group, Medicare also covered about 5.8 million disabled persons younger than age 65, whom our work did not include. Throughout this testimony, except where otherwise noted, we use the term "Medicare beneficiaries" to refer only to those beneficiaries age 65 or older.

[4]The Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System asks a range of health questions over the telephone, including if respondents received a "routine checkup" within the past year. CMS's Medicare Current Beneficiary Survey collects self-reported data, including whether respondents have received influenza or pneumonia immunizations. CDC's National Health and Nutrition Examination Survey (NHANES) collects data on health conditions by means of both comprehensive health examinations and interviews, where patients self-report information, including whether a physician or other health professional has ever told them that they have a given health condition. Unlike the other surveys, which take a sample of the population, CDC's National Ambulatory Medical Care Survey samples physician practices, collecting detailed information about office visits, including the major reason for the visit and which preventive services were ordered or provided.

found to have high cholesterol measurements said they had not previously been told by a physician or other health professional that they had high cholesterol. Projected nationally, this percentage translates into 2.1 million people age 65 or older who may have had high cholesterol without knowing it.

A one-time preventive care examination may provide an opportunity for beneficiaries to receive some preventive services while orienting new beneficiaries to Medicare. But covering an initial examination does not ensure that beneficiaries receive the recommended preventive services they need. The results of a CMS demonstration conducted in the late 1980s and early 1990s indicated that offering Medicare beneficiaries packages of broad-based preventive services slightly improved the use of some services, such as immunizations and cancer screenings, but did not consistently improve health or lower costs. CMS is exploring an alternative for Medicare preventive care that, by means other than a physician's examination, would provide systematic health risk assessments to Medicare beneficiaries. A key component of this demonstration, which is still in development, is to address concerns that to be effective, risk assessments must be coupled with follow-up interventions, such as referrals for follow-up care.

Background

Preventive health care can extend lives and promote well-being among our nation's seniors. Medicare now covers a number of preventive services, including immunizations, such as hepatitis B and influenza, and cancer screenings, such as Pap smears and colonoscopies. Not all beneficiaries, however, avail themselves of covered preventive services. Some beneficiaries may simply choose not to use these services, but others may be unaware that the services are available or covered by Medicare. Further, for some beneficiaries, certain services may not be warranted or may be of limited value. Appropriate preventive care depends on an individual's age and particular health risks, not simply on the results of a standard battery of tests.

To evaluate preventive care for different age and risk groups, HHS in 1984 established the U.S. Preventive Services Task Force, a panel of private-sector experts. The task force recommends certain screening, immunization, and counseling services for people age 65 or older. Medicare covers some, but not all, of these services (see table 1).

Table 1: Preventive Services Recommended by the U.S. Preventive Services Task Force or Covered by Medicare as of August 2003

Service	Task force recommendation for age 65+	Year first covered by Medicare as preventive service	Medicare cost-sharing requirements[a]
Immunization			
Pneumococcal	Recommends	1981	None
Hepatitis B	No recommendation	1984	Copayment after deductible
Influenza	Recommends	1993	None
Tetanus-diphtheria (Td) boosters	Recommends	Not covered[b]	N/A
Varicella	Recommends	Not covered[b]	N/A
Screening			
Cervical cancer: Pap smear	Recommends against[c]	1990	Copayment with no deductible[d]
Breast cancer: mammography	Recommends[e]	1991	Copayment with no deductible
Vaginal cancer: pelvic exam	Not evaluated	1998	Copayment with no deductible[d]
Colorectal cancer: fecal-occult blood test[f]	Strongly recommends	1998	No copayment or deductible
Colorectal cancer: flexible sigmoidoscopy or colonoscopy[f]	Strongly recommends	1998	Copayment after deductible[g]
Osteoporosis: bone mass measurement	Recommends (women only)	1998	Copayment after deductible
Prostate cancer: prostate-specific antigen test and/or digital rectal examination	Insufficient evidence to recommend for or against	2000	Copayment after deductible[d]
Glaucoma	Insufficient evidence to recommend for or against	2002	Copayment after deductible
Vision impairment	Recommends	Not covered	N/A
Hearing impairment	Recommends	Not covered	N/A
Height, weight, and blood pressure	Recommends	Not covered	N/A
Cholesterol measurement	Strongly recommends	Not covered	N/A
Problem drinking	Recommends	Not covered	N/A
Depression	Recommends	Not covered	N/A
Counseling			
Smoking cessation, injury prevention, dental health	Recommends	Not covered	N/A
Aspirin for primary prevention of cardiovascular events	Strongly recommends	Not covered	N/A

Source: U.S. GAO-03-958 and U.S. Preventive Services Task Force, *Guide to Clinical Preventive Services*, 2nd ed. (Washington, D.C.: 1996) and related updates. According to a task force official, since our 2003 report was issued, the task force has also recommended diabetes screening for people age 65 or older at risk of this disease.

[a]Applicable Medicare cost-sharing requirements generally include a 20 percent copayment after a $100 per year deductible. Specifically, each year, beneficiaries are responsible for 100 percent of the payment amount until those payments equal a specified deductible amount, $100 in 2003. Thereafter, beneficiaries are responsible for a copayment that is usually 20 percent of the Medicare-approved amount. For certain tests, the copayment may be higher. 42 U.S.C. § 1395(a)(1) (2000).

[b]Although the tetanus-diphtheria (Td) and varicella (chickenpox) booster vaccinations are not covered under Medicare as "preventive" services, these treatments might be covered under Medicare if necessary to a beneficiary's medical treatment. Medicare provides coverage for medical treatment and services that are "reasonable and necessary for the diagnosis or treatment of an illness or injury," provided that the services or products used are "safe and effective" and not merely "experimental." 42 U.S.C. § 1395(a)(1)(A) (2000).

[c]The task force recommends against routinely screening women older than 65 for cervical cancer if they have had adequate recent screening with normal Pap smears and are not otherwise at high risk for cervical cancer.

[d]The costs of the laboratory test portion of these services are not subject to a copayment or deductible. The beneficiary is subject to a deductible, copayment, or both for physician services only.

[e]The task force recommends screening mammography, with or without a clinical breast examination, every 1–2 years for women age 40 and older.

[f]Data are insufficient to determine which strategy is best to balance benefits against potential harm or cost-effectiveness. Barium enemas are covered as an alternative if a physician determines that their screening value is equal to or greater than sigmoidoscopy or colonoscopy.

[g]The copayment has increased from 20 to 25 percent for services provided in an ambulatory surgical center.

Medicare's fee-for-service program[5] does not cover regular periodic examinations, where clinicians might assess an individual's health risk and provide needed preventive services. Beneficiaries could and still can, however, receive some of these services during office visits for other health issues.

In late 2003, MMA added coverage under Medicare for a one-time "initial preventive physician evaluation" if performed within 6 months after an individual's enrollment under Part B of the program.[6] Covered services under the examination include measurement of height, weight, and blood pressure; an electrocardiogram; and education, counseling, and referral services for screenings and other preventive services covered by Medicare. MMA also added coverage for various screening tests to identify

[5]"Fee-for-service" is the Medicare arrangement sometimes referred to as the original Medicare plan. Under this option, Medicare pays a health care practitioner for each visit or procedure received by a patient, and a beneficiary can visit any hospital, physician, or health care provider who accepts Medicare patients. Medicare pays a set percentage of the expenses, and the beneficiary is responsible for certain deductibles and coinsurance payments—the portion of the bill that Medicare does not pay. Our September 2003 report indicated that about 84 percent of Medicare enrollees were in the fee-for-service program.

[6]The Medicare Program is divided into three parts. Part A provides hospital insurance coverage, and Part B provides coverage for supplemental medical insurance benefits, such as the preventive health care services discussed above. Part C requires managed care plans participating in the Medicare + Choice program to provide all the basic benefits covered under Parts A and B.

cardiovascular disease (and related abnormalities) in "elevated risk" beneficiaries and diabetes in "at risk" beneficiaries.[7] The new coverage applies to services provided on or after January 1, 2005.

Most Beneficiaries Receive Some but Not All Recommended Preventive Services

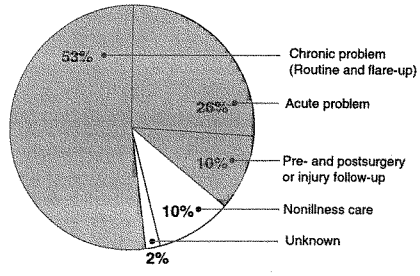
Nationally representative survey data show that Medicare beneficiaries visit physicians often and that most report receiving "routine checkups." These data do not show, however, which specific services were delivered during those "checkups." Despite the frequency of visits, many Medicare beneficiaries do not receive the full range of recommended preventive services. Data also show that many beneficiaries may not know about their risk for health conditions that preventive care is meant to detect.

From 2000 survey data and U. S. Bureau of the Census estimates of people age 65 or older, we estimated that beneficiaries visited a physician at least six times that year, on average, mainly for illnesses or medical conditions. Only about 1 in 10 visits occurred when beneficiaries were well (see fig. 1).[8]

[7]The new preventive care services requirements appear at Pub. L. No. 108-27, §§ 611–613, 117 Stat. 2303-2306 (adding sections 1861(s)(2)(W), (X), and (Y) to SSA) (to be codified at 42 U.S.C. §§ 1395x(s)(2)(W), (X), and (Y).)

[8]Because Medicare's fee-for-service program covers some preventive services, such as immunizations and certain cancer screening tests, it is possible that some of the nonillness visits in 2000 were to obtain such services. In addition, some fee-for-service beneficiaries may be paying for nonillness examinations through other means, such as employer-provided or other supplemental insurance. According to CMS's Medicare Current Beneficiary Survey, in the year 2000 about 41 percent of Medicare fee-for-service beneficiaries had insurance from former employers to supplement their basic Medicare benefit.

Figure 1: Major Reasons for Physician Visits by Medicare Beneficiaries in the Fee-for-Service Program, 2000



Source: CDC's National Ambulatory Medicare Care Survey, 2000.

Note: Numbers do not add to 100 percent because of rounding. The survey defined an "acute problem" as a condition or illness of sudden or recent onset, a "chronic problem" as a preexisting long-term or recurring condition or illness, and "nonillness care" as a general health maintenance examination or routine periodic examination of a presumably healthy person. For chronic problems, the survey reported results separately for "routine chronic problems" and for "chronic problem flare-ups." We combined these results in this figure.

Even though the majority of visits to physicians were to treat illness or health conditions, most Medicare beneficiaries reported receiving what they considered to be "routine checkups." In CDC's 2000 Behavioral Risk Factor Surveillance System Survey, for example, 93 percent of respondents age 65 or older reported that they had received a "routine checkup" within the previous 2 years.[9] This survey did not, however, provide information on which specific services were delivered during those checkups. Data from another survey, enumerating services provided during office visits, indicated that Medicare beneficiaries do receive some preventive services during visits when they are ill or being treated for a health condition.

[9]In 2000, data from CMS's Medicare Current Beneficiary Survey also showed that 88 percent of Medicare beneficiaries reported that they visited a physician at least once that year.

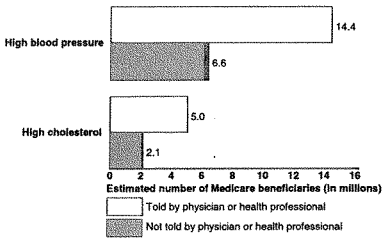
Despite how often Medicare beneficiaries visit physicians, relatively few beneficiaries receive the full range of recommended preventive services covered by Medicare. As we reported in 2002, for example, although 91 percent of female Medicare beneficiaries in our analysis received at least one preventive service, only 10 percent were screened for cervical, breast, and colon cancer and were also immunized against influenza and pneumonia.[10] Our analysis of additional data for our 2003 report showed that many Medicare beneficiaries still did not receive certain recommended preventive services. The task force recommends, for example, that all people age 65 or older receive an annual influenza vaccination and at least one pneumonia vaccination. According to data from CMS's Medicare Current Beneficiary Survey of 2000, however, about 30 percent of Medicare beneficiaries did not receive an influenza vaccination, and 37 percent had never had a pneumonia vaccination.

Many Medicare beneficiaries may not know that they are at risk for health conditions that preventive care could detect—strong evidence that they may not be receiving the full range of recommended preventive services.[11] For example, data from CDC's NHANES for 1999–2000 show that, of beneficiaries participating in this nationally representative survey who, as part of the survey, had a physical examination and were found to have elevated blood pressure readings at that time, 32 percent reported that no physician or other health professional had told them about the condition before. On the basis of this survey, we estimate that, during the period when the survey was conducted, 21 million Medicare beneficiaries may have been at risk for high blood pressure, and an estimated 6.6 million of them may have been unaware of this risk. Similarly, 32 percent of those found by the survey to have a high cholesterol level reported that no one had told them that they had high cholesterol. Projected nationally, this percentage translates into 2.1 million Medicare beneficiaries who may have had high cholesterol without knowing it (see fig. 2).

[10]In January 2003, the U.S. Preventive Services Task Force released new recommendations for the use of Pap smears to screen for cervical cancer. The task force now "recommends against screening women 65 or older who have had adequate recent screenings with normal Pap smears and are not otherwise at increased risk for cervical cancer."

[11]The source of data for this statement was CDC's NHANES of 1999–2000. This survey oversampled; that is, it included a larger number of persons age 60 and older in the sample, providing for a sample size that enabled us to focus our analysis specifically on the Medicare-age population for selected conditions.

Figure 2: Estimated Number of Medicare Beneficiaries Age 65 or Older Who Were Aware or Unaware That They Might Have High Blood Pressure or High Cholesterol, 1999–2000



Source: CDC's National Health and Nutrition Examination survey.

Note: CDC's NHANES measured blood pressure three or four times during its 1-day physical examination. For our analysis, we calculated the average of the blood pressure measurements and applied CDC's definition of high blood pressure: that is, a patient's having an average systolic blood pressure equal to or greater than 140, or an average diastolic blood pressure equal to or greater than 90, or a patient who reported taking hypertension medication. CDC defined high cholesterol as a total cholesterol level equal to or greater than 240.

An Initial Examination May Improve Preventive Care, but Follow-up Is Also Key

A one-time initial preventive care examination covered by Medicare may offer opportunity to deliver some preventive services but alone is not enough to ensure better health among beneficiaries. Information from a CMS demonstration and from other related studies shows that ensuring receipt of follow-up care will be important to improving beneficiaries' health. A proposed CMS demonstration, currently in design, will explore another preventive care delivery option and examine the value of linking beneficiaries to needed follow-up services.[12]

As proponents of a one-time "Welcome to Medicare" examination told us, such an examination could be a means to better ensure that health care providers have enough time to identify individual Medicare beneficiaries' health risks and provide preventive services appropriate for their risks. It could be used to orient new beneficiaries to Medicare and encourage them to make informed choices about providers and plans. Nevertheless, a one-

[12]We confirmed in July 2004 that this CMS demonstration was still in the design phase.

time examination does not ensure delivery of the full range of preventive services. Primary care physicians typically cannot provide services such as mammography screenings for breast cancer or colonoscopies for colon cancer, because these services usually require specialists.

It also is uncertain whether a one-time or periodic examination would be an effective way to improve beneficiaries' health. For example, one previous CMS initiative that included preventive health care visits ended with mixed results. In the late 1980s and early 1990s, the agency conducted a congressionally mandated demonstration to test varied health promotion and disease prevention services, such as free preventive visits, health risk assessment, and behavior counseling, to see if they would increase use of preventive services, improve health, or lower health care expenditures for Medicare beneficiaries.[13] The agency's final report, published in 1998, concluded that the demonstration services were marginally effective in raising the use of some simple disease-prevention measures, such as immunizations and cancer screenings, but did not consistently improve beneficiary health or reduce the use of hospital or skilled nursing services.[14] The report tempered these results by pointing out that the relatively brief period during which the services were provided (roughly 2 years) and the limited number of follow-ups and beneficiary contacts with providers (one to two) may have been inadequate to achieve measurable outcomes.

Determining how to better ensure adequate follow-up once health risks are identified is a concern that a new CMS project aims to evaluate. CMS is exploring an alternative for Medicare preventive care that would provide systematic health risk assessments to fee-for-service beneficiaries through a means other than examination by a physician. In the late 1990s, the agency commissioned the RAND Corporation to evaluate the potential effectiveness of health risk assessment programs. Such programs collect information from individuals; identify their risk factors; and refer the individuals to at least one intervention to promote health, sustain function,

[13]The Consolidated Omnibus Budget Reconciliation Act of 1985 directed CMS (then known as the Health Care Financing Administration) to conduct a 4-year demonstration (*see* Pub. L. No. 99-272, § 9314, 100 Stat. 82, 194–196 (1986)), which was extended for an additional year by the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4164, 104 Stat. 1388, 1388-100.

[14]Donna E. Shalala, *Medicare Prevention Demonstration: Final Report*, RC 87-172 (Washington, D.C.: Department of Health and Human Services, 1998).

or prevent disease.[15] The study concluded that health risk assessment programs have increased beneficial behavior (particularly exercise) and improved physiological variables (particularly diastolic blood pressure and weight) and general health.[16] In addition, the study stated that to be effective, risk assessment questionnaires must be coupled with follow-up interventions, such as referrals to appropriate services. The study recommended that CMS conduct a demonstration to test cost-effectiveness and other aspects of the health risk assessment approach for Medicare beneficiaries.

Following through on the study's findings, CMS has begun designing a demonstration project focused on Medicare fee-for-service beneficiaries, called the Medicare Senior Risk Reduction Program, to identify health risks and follow up with preventive services provided by means other than examinations by physicians. The program will use a beneficiary-focused health risk assessment questionnaire to assess health risks, such as lifestyle behaviors, and use of clinical preventive and screening services. The program will test different approaches to administering health risk assessments, creating feedback reports, and providing follow-up services, such as referring beneficiaries to health-promoting community services including physical activity and social support groups. According to project researchers, the program will tailor preventive interventions to individual risks; track patient risks and health over time; and provide beneficiaries with self-management tools and information, health behavior advice, and end-of-life counseling where appropriate. The design phase had not been finalized as of last week and, according to a CMS official, still required approval from HHS and the Office of Management and Budget.[17]

[15]A typical health risk assessment obtains information on demographic characteristics (e.g., sex, age); lifestyle (e.g., smoking, exercise, alcohol consumption, diet); personal health history; and family health history. In some cases, physiological data (e.g., height, weight, blood pressure, cholesterol levels) are also obtained, as well as a patient's status regarding cancer screens and immunizations.

[16]Southern California Evidence-Based Practice Center/RAND, *Health Risk Appraisals and Medicare* (Baltimore: Centers for Medicare & Medicaid Services, 2001). RAND identified 267 articles, unpublished reports, and conference presentations, of which 27 contained data that project staff deemed necessary to be included as evidence of the effectiveness of health risk assessments.

[17]The demonstration's final cost was uncertain at the time our report was completed in September 2003. CMS was spending approximately $1 million on the developmental work.

Concluding Observations

Current data indicate that many opportunities exist for Medicare beneficiaries to receive preventive care, but many beneficiaries nonetheless fail to receive the full range of recommended services. Although some beneficiaries may not choose to seek these services, others may not be aware that these services are available and covered by Medicare. Our work shows that more needs to be done to deliver preventive services to those beneficiaries who need them, because many people may have a health condition that preventive services can easily diagnose, and yet they may not know that they have this condition.

A one-time preventive care examination will add a dedicated opportunity for delivering preventive care and could help reduce the gap in the preventive services that Medicare beneficiaries receive. At the same time, it is not a panacea. Ensuring that beneficiaries receive needed services and follow-up care is likely to remain a challenge.

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of this Committee may have.

Contact and Acknowledgments

For future contacts regarding this testimony, please call Janet Heinrich at (202) 512-7119. Katherine Iritani, Matt Byer, Ellen W. Chu, Lisa Lusk, and Behn Miller Kelly also made key contributions to this testimony.