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2. Answer questions from patients regarding emerging cancer detection technologies.

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Cancer Screening in the United States, 2014
A Review of Current American Cancer Society Guidelines
and Current Issues in Cancer Screening

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Each year the American Cancer Society publishes a summary of its guidelines for early cancer detection, a report on data and trends in cancer screening rates, and select issues related to cancer screening. In this issue of the journal, we summarize current American Cancer Society cancer screening guidelines. In addition, the latest data on the use of cancer screening from the National Health Interview Survey is described, as are several issues related to screening coverage under the Patient Protection and Affordable Care Act, including the expansion of the Medicaid program. CA Cancer J Clin 2014;64:30-51. © 2014 American Cancer Society, Inc.

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Introduction
In this yearly report, we provide a summary of the current American Cancer Society (ACS) cancer screening guidelines, a summary of guidance to health care professionals and the public related to early cancer detection tests that are not yet recommended for mass screening due to uncertainty about the balance of benefits and harms, and the most recent data on adult cancer screening rates and trends.

The ACS monitors the medical and scientific literature on an ongoing basis for new evidence that could lead to a change in cancer screening guidelines, or information about screening that should be conveyed to clinicians and the public. Under the new guidelines development process, the ACS will initiate an update of guidelines at least every 5 years, or sooner if new evidence warrants an update.1,2 The annual guideline reviews, as well as the more detailed cancer screening guideline updates, are published as stand-alone articles and are available online at cacancerjournal.com. Table 1 shows the recent history of guidelines updates, as well as those currently in progress.3-15

In this update of ACS cancer screening guidelines, we describe the current guidelines; current issues shaping screening for breast, colorectal, and lung cancer; the most recent data on cancer screening from the National Health Interview Survey (NHIS); and preventive health coverage under Medicaid.

Screening for Breast Cancer
Breast cancer is the most common cancer, the second most common cause of death from cancer in women in the United States, and the leading cause of premature mortality from cancer in women as measured by total years of life lost.16,17 In 2014, the ACS estimated that there would be 232,670 cases of invasive breast cancer and 62,570 cases of ductal carcinoma in situ diagnosed in...
US women, and 40,000 deaths.17 After a period of declining incidence (1999-2005) in the age-adjusted incidence rate of breast cancer,15 there has been an average annual percentage increase of 1.1% from 2005 through 2009.16 Age-adjusted breast cancer mortality rates have declined about 2% per year over the period 1998 through 2009.16

ACS guidelines for breast cancer screening in average-risk women were last updated in 2003,3 and screening guidelines for women at very high risk were last updated in 2003,3 and screening guidelines for women at very high risk were last updated in 2003 (Table 2).4 At this time, the ACS is in the process of updating the breast cancer screening guidelines for women at both average and high risk.

The current guidelines for the early detection of breast cancer in average-risk women consist of a combination of regular clinical breast examination (CBE) and counseling to raise awareness of breast symptoms beginning at age 20 years, and annual mammography beginning at age 40 years.

Between the ages of 20 and 39 years, average-risk women should undergo CBE every 3 years, and annually after age 40 years. CBE should take place during periodic health examinations, and ideally prior to mammography after age 40 years so that any suspicious palpable abnormality detected during the examination can prompt a diagnostic versus screening examination. When CBE is performed in women of any age, it is an opportunity to discuss the value of early breast cancer detection and answer any questions a woman may have about her own risk, other issues related to breast disease, and questions related to conventional or new imaging technologies. Clinicians should regularly inquire about a family history of breast and ovarian cancers in first-degree and second-degree relatives on both the maternal and paternal side of the family going back 3 generations, describe the effect of family history on breast cancer risk, and emphasize the importance of updating the family history if there has been a change. Attention to family history beginning in the patient’s 20s and after is important not only because of the opportunity to identify a patient who may benefit from pedigree assessment and genetic counseling, but also because significant percentages of women underestimate or overestimate the contribution of family history to their own risk.18 During these discussions, clinicians also should emphasize the importance of awareness and recognition of breast changes, and if changes are perceived, the importance of seeking consultation promptly.

Although ACS guidelines do not recommend routine breast self-examination (BSE), neither do they recommend against it. A woman may choose to perform regular BSE, occasional BSE, or not perform BSE at all. If a woman chooses to perform regular or periodic BSE, she should receive instructions in the technique and periodically have her technique reviewed. As with mammography, women should be informed about the potential benefits, limitations, and harms (principally the possibility of a false-positive result) associated with BSE.

The ACS recommends that average-risk women should begin annual mammography at the age of 40 years. Women should be informed that early breast cancer detection with mammography is associated with a reduced risk of dying from breast cancer and less aggressive treatment, including the opportunity for breast-conserving therapy, avoidance of extensive lymph node dissections that increase the risk of lymphedema, and not requiring chemotherapy. Women should also be informed of the importance of adhering to a schedule of regular screening to ensure the greatest likelihood of having a growing breast cancer detected while it is still small and localized to the breast. The informed decision-making process should include a discussion about the limitations and harms associated with breast cancer screening. Mammography will not detect all breast cancers, and some breast cancers detected with mammography may still have poor prognosis.

The harms associated with breast cancer screening include the potential for false-positive results, which can result in anxiety,
Beginning at age 40 y, annual CBE should ideally be performed prior to mammography. Whether a woman ever performs 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.

For women in their 20s and 30s, it is recommended that CBE be part of a periodic health examination, preferably at least every 3 y. Asymptomatic women aged ≥40 y should continue to receive a CBE as part of a periodic health examination, preferably annually.

### TABLE 2. ACS Recommendations for the Early Detection of Cancer in Average-Risk, Asymptomatic Individuals

| CANCER SITE | POPULATION | TEST OR PROCEDURE | FREQUENCY |
|-------------|------------|-------------------|-----------|
| Breast      | Women ages ≥20 y | BSE | It is acceptable for women to choose not to do BSE or to do BSE regularly (monthly) or irregularly. Beginning in their early 20s, women should be told about the benefits and limitations of BSE. Whether a woman ever performs 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. |
| Cervix      | Women, aged 21-65 y | Pap test and HPV DNA test | Cervical cancer screening should begin at age 21 y. For women aged 21-29 y, screening should be done every 3 y with conventional or liquid-based Pap tests. For women aged 30-65 y, screening should be done every 5 y with both the HPV test and the Pap test (preferred), or every 3 y with the Pap test alone (acceptable). Women aged >65 y who have had ≥3 consecutive negative Pap tests or ≥2 consecutive negative HPV and Pap tests within the last 10 y, with the most recent test occurring within the last 5 y, and women who have had a total hysterectomy should stop cervical cancer screening if they no longer have a cervix and are without a history of CIN2 or a more severe diagnosis in the past 20 y or cervical cancer ever. Women at any age should not be screened annually by any screening method. |
| Colorectal  | Men and women, ages ≥50 y | FOBT with at least 50% test sensitivity for cancer, or FIT with at least 50% test sensitivity for cancer, or | Annual, starting at age 50 y. Testing at home with adherence to manufacturer’s recommendation for collection techniques and number of samples is recommended. FOBT with the single stool sample collected on the clinician’s fingertip during a DRE in the health care setting is not recommended. Guaiac-based toilet bowl FOBT tests also are not recommended. In comparison with guaiac-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. |
|            |            | Stool DNA test, or Interval uncertain, starting at age 50 y. |
|            |            | FSIG, or Every 5 y, starting at age 50 y. FSIG can be performed alone, or consideration can be given to combining FSIG performed every 5 y with a highly sensitive guaiac-based FOBT or FIT performed annually. |
|            |            | DCBE, or Every 5 y, starting at age 50 y. |
| Colonoscopy |            | Every 10 y, starting at age 50 y. |
| CT colonography | Every 5 y, starting at age 50 y. |
| Endometrial | Women, at menopause | At the time of menopause, women at average risk should be informed about the risks and symptoms of endometrial cancer and strongly encouraged to report any unexpected bleeding or spotting to their physicians. |
| Lung        | Current or former smokers aged 55-74 y in good health with at least a 30 pack-y history | LDCT | Clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about lung cancer screening with apparently healthy patients aged 55-74 y who have at least a 30 pack-y smoking history, and who currently smoke or have quit within the past 15 y. A process of informed and shared decision-making with a clinician related to the potential benefits, limitations, and harms associated with screening for lung cancer with LDCT should occur before any decision is made to initiate lung cancer screening. Smoking cessation counseling remains a high priority for clinical attention in discussions with current smokers, who should be informed of their continuing risk of lung cancer. Screening should not be viewed as an alternative to smoking cessation. |
| Prostate    | Men, aged ≥50 y | DRE and PSA | Men who have at least a 10-y life expectancy should have an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer, after receiving information about the potential benefits, risks, and uncertainties associated with prostate cancer screening. Prostate cancer screening should not occur without an informed decision-making process. |
| Cancer-related checkup | Men and women, aged ≥20 y | 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. |

ACS indicates American Cancer Society; BSE, breast self-examination; CBE, clinical breast examination; Pap, Papanicolaou; HPV, human papillomavirus; FOBT, fecal occult blood test; FIT, fecal immunochemical test; DRE, digital rectal examination; FSIG, flexible sigmoidoscopy; DCBE, double-contrast barium enema; CT, computed tomography; LDCT, low-dose helical CT; PSA, prostate-specific antigen.

*Beginning at age 40 y, annual CBE should ideally be performed prior to mammography.

*The stool DNA test approved for colorectal cancer screening in 2008 is no longer commercially available. New stool DNA tests are presently undergoing evaluation and may become available at some future time.
and when abnormal findings cannot be resolved with additional imaging a biopsy will be required to rule out the possibility of breast cancer. A majority of biopsies are benign. Finally, some breast cancers detected by mammography may not be progressive (ie, they would not have been detected in a woman’s lifetime had she not undergone mammography, a phenomenon known as overdiagnosis). Estimates of the rate of overdiagnosis are highly variable, ranging from 0% to over 50%. Estimating the rate of overdiagnosis is extremely difficult, and requires comparing the incidence of breast cancer in a group exposed to screening with a group not exposed to screening over a long duration of time, and adjusting for factors that influence incidence rates such as the lead time associated with screening and contemporaneous trends in breast cancer incidence. Puliti et al have shown that extreme estimates of overdiagnosis principally are due to methodological failures to adjust for these known influences on breast cancer incidence. The more credible estimates (ie, those that have adequate follow-up and properly adjust for lead time and trends in breast cancer incidence) indicate that the magnitude of overdiagnosis is small (approximately 6%) and mostly confined to ductal carcinoma in situ.

There is no specific upper age at which mammography screening should be discontinued. Rather, the decision to stop regular mammography screening should be individualized based on the potential benefits and harms of screening within the context of overall health status and estimated longevity. As long as a woman is in good health and would be a candidate for breast cancer treatment, she should continue to be screened with mammography.

In 2007, the ACS issued new guidelines for women who were known or likely carriers of a BRCA mutation and other rarer high-risk genetic syndromes, or who had been treated with radiation to the chest for Hodgkin disease. Annual screening mammography and magnetic resonance imaging (MRI) starting at age 30 years is recommended for women with a known BRCA mutation, women who are untested but have a first-degree relative with a BRCA mutation, or women with an approximately 20% to 25% or greater lifetime risk of breast cancer based upon specialized breast cancer risk estimation models capable of pedigree analysis of first- and second-degree relatives on both the maternal and paternal side. While MRI may eventually prove to be advantageous for women at elevated risk due to other combinations of risk factors, at this time recommendations for annual screening mammography and MRI are based strictly on known or estimated high-risk mutation carrier status or a history of high-dose radiation therapy at a young age.

To estimate the risk of breast cancer in women with a significant family history who have not undergone genetic testing and do not have an affected relative who has tested positive, health professionals should use specialized software that can address family history in first- and second-degree relatives on both the maternal and paternal side. There are several models that can estimate risk based on complex family histories and assist clinicians in estimating breast cancer risk or the likelihood that a BRCA mutation is present, including the Claus model, the Tyrer-Cuzick model, the BRCAPRO model, and the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) model. While the Breast Cancer Risk Assessment Tool (ie, the Gail model) provides a good, generalized measure of short- and long-term risk based on a woman’s age, ethnicity, history of breast biopsy and breast cancer, age at menarche, parity, and age at first live birth, it does not have the capacity to analyze detailed family histories including first- and second-degree relatives on both the maternal and paternal side. A link to supplemental material related to these models is included in the online publication (onlinelibrary.wiley.com/doi/10.3322/canclin.57.2.75/supplinfo). As noted in the original article, and highlighted in a more recent investigation, each of these models is unique and will identify some women at higher risk who will not be identified by the other models. Thus, as noted previously, there may be value to considering the unique features of each model and using more than one for risk estimation in the clinical setting.

It has been known for some time that breast density was a risk factor for breast cancer, and that the sensitivity of mammography is lower in women with heterogeneously dense or very dense breasts. What has been less clear is whether this information should be communicated to women, whether it would be useful for risk modification, and whether screening algorithms and modalities should differ for women with significant breast density. Today, there is a general sense that women should be informed about their level of breast density, and that consideration of supplemental imaging is reasonable when significant mammographic density precludes concluding with confidence that a screening mammogram is normal due to the possibility that abnormalities may be obscured by dense breast tissue. A Connecticut organization, Are You Dense?, has been promoting state and federal legislation that requires that women with significant breast density be informed on their mammography reports that breast density is a risk factor for breast cancer and for a missed cancer during mammography screening, and that women with significant breast density should consider supplemental imaging. For example, in California, the Health and Safety Code was amended, effective April 1, 2013, by Senate Bill 1538 with the following language:

123222.3. (a) A health facility at which a mammography examination is performed shall, if a patient is categorized by the facility as having heterogeneously
dense breasts or extremely dense breasts, based on the Breast Imaging Reporting and Data System established by the American College of Radiology, include in the summary of the written report that is sent to the patient, as required by federal law, the following notice: Your mammogram shows that your breast tissue is dense. Dense breast tissue is common and is not abnormal. However, dense breast tissue can make it harder to evaluate the results of your mammogram and may also be associated with an increased risk of breast cancer. This information about the results of your mammogram is given to you to raise your awareness and to inform your conversations with your doctor. Together, you can decide which screening options are right for you. A report of your results was sent to your physician.32

As of this time, 12 states have passed similar legislation,33 federal legislation has been introduced,34 and the National Mammography Quality Assurance Advisory Committee has endorsed adding similar language to the current federal requirements for reporting the results of mammography examinations.35

The increase in the cancer detection rate associated with supplemental imaging would seem to be sufficiently compelling for it to have become a standard of care many years ago, and not to have necessitated legislation to require health care professionals to inform women about breast density and propose shared discussions about supplemental imaging. However, opinions are mixed not only about whether benefits outweigh harms, but which women actually need supplemental imaging and whether providers of breast imaging services are prepared to adequately triage patients.

In the American College of Radiology Imaging Network (ACRIN)/National Cancer Institute (NCI) 666 trial women with heterogeneously or very dense breast tissue in at least one quadrant underwent screening mammography and physician-performed ultrasonographic examinations in randomized order by a radiologist who was naive to the previous examination results.36 Mammography detected 7.6 cancers per 1000 women screened, and the addition of ultrasound increased the cancer detection rate to 11.8 cancers per 1000 women screened, an increase of 4.2 cancers per 1000 women screened, of which most were small invasive cancers. However, this improved rate of detection was accompanied by a substantial decrease in the positive predictive value of a recommendation for biopsy, which dropped from 22.6% for mammography to 11.2% for mammography plus ultrasound (276 biopsies yielded 31 cancers). In general, the response to this study focused more on the large increase in negative biopsies associated with supplemental ultrasound and less on the value of the added cancer yield.

The limitations of mammography for women with significant breast density are well established, and evident in the lower mammographic sensitivity and higher interval cancer rate in women with dense breast tissue.37 As noted above, in the years since the American College of Radiology Imaging Network/NCI 666 trial was published, other studies have shown an increased yield in the cancer detection rate associated with supplemental ultrasound or MRI, although systematic reviews have concluded that the evidence base is insufficient to clearly reconcile whether supplemental imaging for women with dense breast cancer be recommended.38 Varying methodologies, populations studied, and comparison groups make comparative analysis challenging. However, other factors are commonly cited as barriers to implementing systematic supplemental imaging, including inconsistent insurance coverage, inadequate resources, concerns about the cost-effectiveness of supplemental handheld ultrasound and especially MRI, and the increase in false-positive biopsies associated with the addition of any supplemental imaging.38,40 While each of these concerns is legitimate, advocates’ insistence on improved communication about the increased risk associated with breast density and the increased risk of a missed cancer has resulted in the limitations of mammography in women with dense breast tissue receiving increasing attention. Newer technologies, including the penetration of digital mammography, digital breast tomosynthesis (DBT), and 3-dimensional (3D) automated breast ultrasound, and having screening ultrasound performed by technologists may hold some potential to obviate some of the current challenges that presently are cited as barriers to supplemental imaging. Digital mammography has shown superior sensitivity in women with dense breast tissue, which could somewhat reduce the estimated percentage of women who need supplemental imaging.31 DBT, which uses x-rays and a digital detector to generate a series of tomograms (cross-sectional slices) to provide 3D images of the breast, received premarket approval for screening by the US Food and Drug Administration in 2011.42 Although the data still are limited, DBT appears to offer advantages over full-field digital mammography, including both increased sensitivity and a reduction in the recall rate,43 with the latter showing significant reductions in the rate of false-positive results in women with dense breasts.44 Automated 3D ultrasound also was recently approved by the US Food and Drug Administration and has shown promise as a less operator-dependent and faster throughput device for supplemental ultrasound compared with handheld ultrasound, although too little data are available to draw definitive conclusions.45,46 Ultimately, it remains to be determined how routine screening protocols will be altered by new state legislation, but state legislation and the potential to
improve the detection of breast cancer in women with dense breasts means that this challenge will receive considerable attention going forward.

Screening for Cervical Cancer

The ACS estimates that 12,360 women will be diagnosed with invasive cervical cancer, and 4030 women will die from the disease in 2013.17 Cervical cancer incidence and mortality rates have declined since the introduction of the Papanicolaou (Pap) test in the mid-20th century, and rates continue to decline to this day.16 For the period 2001 through 2010, cervical cancer incidence rates have decreased at an average annual rate of 2.0% per year in women aged younger than 50 years, and by 3.1% per year in women aged 50 years and older. Over the same period, deaths rates have declined at an average annual rate of 1.3% in women aged younger than 50 years and 1.9% in women aged 50 years and older.16 In 2012, the ACS, the American Society for Colposcopy and Cervical Pathology, and the American Society for Clinical Pathology issued joint guidelines for cervical cancer screening based on a systematic evidence review and using a collaborative process that included 25 organizations (Table 2).7 Similar recommendations were released in 2012 by the US Preventive Services Task Force (USPSTF).47 Recommendations for the use of prophylactic human papillomavirus (HPV) vaccines, including policy and implementation issues, were published in January 2007.6

The screening guidelines recommend different surveillance strategies and options based on a woman's age, her screening history, other risk factors, and the choice of screening tests. Specifically:

- Screening for cervical cancer should begin at age 21 years. Women aged 21 to 29 years should receive cytology screening (with either conventional cervical cytology smears or liquid-based cytology) every 3 years. HPV testing should not be used for women in this age group (although it can be used to follow women diagnosed with atypical cells of undetermined significance). Women aged younger than 21 years should not be screened regardless of their age of sexual initiation.
- For women aged 30 to 65 years, the preferred approach is to be screened every 5 years with the combination of HPV testing and cytology ("cotesting"). It is also acceptable for women to continue to be screened every 3 years with cytology alone.
- Women who have had their cervix removed should not get screened, unless they have a history of cervical intraepithelial neoplasia 2 (CIN2 or a more severe diagnosis. Women who have undergone a subtotal (supracervical) hysterectomy should be screened following the recommendations for average-risk women who have not undergone a hysterectomy.
- Women with a history of CIN2 or a more severe diagnosis should continue to follow routine screening recommendations for women ages 30-65 for at least 20 years, even if screening extends beyond age 65 years.
- Women who are immunocompromised by immunosuppressive therapy following organ transplantation, chemotherapy, or chronic corticosteroid treatment or those who are HIV positive should be tested twice during the first year after diagnosis/treatment and annually thereafter, according to guidelines from the US Public Health Service and the Infectious Disease Society of America.48
- There is no specific age at which to stop screening for women with a history of cervical cancer or in utero exposure to diethylstilbestrol, and women who are immunocompromised (including those who are HIV positive). While the update in the guideline did not address immunocompromised women, earlier ACS guidelines relied on the joint recommendations from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. Women in these risk groups should undergo annual cervical cancer screening for as long as they are in reasonably good health and would benefit from early detection and treatment.49
- Recommended screening practices should not change on the basis of HPV vaccination status.

Vaccination Against HPV

The ACS recommends routine HPV vaccination principally for females aged 11 to 12 years, but also for females aged 13 to 18 years to “catch up” those who missed the opportunity to be vaccinated or who need to complete the vaccination series. The guidelines state that there are insufficient data to recommend for or against the universal vaccination of females aged 19 to 26 years. Women in this
age group who are interested in undergoing vaccination should talk with a health care professional about their risk of previous HPV exposure and the potential benefit of vaccination. Screening for CIN and cancer should continue in both vaccinated and unvaccinated women according to current ACS early detection guidelines for cervical cancer.

There currently are 2 HPV vaccines available in the United States: a quadrivalent vaccine that protects against infection by HPV types 6, 11, 16, and 18 and a bivalent vaccine that protects against HPV types 16 and 18. The principal difference between the 2 vaccines is the additional protection against genital warts provided by the quadrivalent vaccine. According to the 2011 National Immunization Survey of Teens (NIS-Teen), 53% of US female adolescents aged 13 to 17 years initiated the HPV vaccination series with either the quadrivalent or bivalent vaccine (ie, had at least one of 3 shots as recommended for the HPV vaccine), and 34.8% had completed 3 doses.50 Unfortunately, the most recent update of NIS-Teen showed coverage was similar in 2012 (53.8%) compared with 2011.51 As of 2012, 53.8% of adolescent girls aged 11 to 17 years had received one dose, 43.4% had received 2 doses, and 33.4% had received all 3 recommended doses. In 2012, the CDC estimates that 84% of unvaccinated girls had missed at least one opportunity to receive the HPV vaccine during a health care encounter. The CDC report notes that if the HPV vaccine had been administered during health care visits when another vaccine had been received, coverage rates for receiving more than one dose (3 doses are recommended) would have reached 92.6%.51 The CDC also interviewed parents who reported no intention to vaccinate their daughters within the coming 12 months (23% of parents) to assess the main reason that they were avoiding vaccination. In order of magnitude, the most common 5 reasons parents rejected vaccination was their perception that the vaccine was not needed (19.1%) or not recommended (14.2%), safety concerns (13.1%), lack of knowledge about the vaccine or the association between HPV and cervical cancer (12.6%), and finally that their daughter was not sexually active (10.1%).51 As the authors noted in the report, both failure to administer the vaccine during health care encounters and parental misperceptions about the value and need for the HPV vaccine represent missed opportunities for clinicians to educate parents and increase vaccine coverage.

Screening and Surveillance for the Early Detection of Adenomatous Polyps and Colorectal Cancer

In 2014, the ACS estimates that 136,830 new cases of colorectal cancer (CRC) will be diagnosed in women and men, and 50,130 individuals will die from this disease.17 CRC incidence and mortality rates have been declining for the past 2 decades, largely attributable to the contribution of screening to prevention and early detection. Guidelines for screening and surveillance for the early detection of adenomatous polyps and CRC in average-risk adults were updated in 2008 in an evidence-based consensus process that included the ACS, the US Multi-Society Task Force on Colorectal Cancer (USMSTF) (which represents the American College of Gastroenterology, American Gastroenterological Association, and American Society for Gastrointestinal Endoscopy), and the ACR (Table 2).12 Recommendations for adults at increased and high risk were last updated in 2001,6 and in 2006 the ACS and the USMSTF issued a joint guideline update for postpolypectomy and post-CRC resection surveillance.10

Recommended CRC screening tests are grouped into 2 categories: 1) tests that primarily detect cancer, which include both the guaiac-based fecal occult blood tests (gFOBTs) and fecal immunochemical tests (FITs), and testing stool for exfoliated DNA; and 2) tests that can detect cancer and advanced lesions, which include the endoscopic examination and radiological examinations (ie, flexible sigmoidoscopy [FSIG], colonoscopy, double-contrast barium enema, and computed tomography colonography [CT colonography or virtual colonoscopy]). This distinction is intended to help primary care physicians support informed decision-making and to contribute to public understanding of the features, advantages, and disadvantages that distinguish these 2 groups of screening tests. Furthermore, the guidelines state that while all recommended tests are acceptable options, the prevention of CRC is the greater priority in screening.

Screening options may be chosen based on individual risk, personal preference, and access. Average-risk adults should begin CRC screening at age 50 years with one of the following options: 1) annual high-sensitivity gFOBT or FIT, following the manufacturer’s recommendations for specimen collection; 2) FSIG every 5 years; 3) colonoscopy every 10 years; 4) double-contrast barium enema every 5 years; or 5) CT colonography every 5 years. Stool DNA testing, which also was among the recommended options in the 2008 update, is no longer commercially available for screening. The use of flexible sigmoidoscopy for screening in the U.S. has declined sharply over the past decade. CT colonography is not broadly covered for screening. For these reasons, the vast majority of CRC screening in the U.S. is performed with either gFOBT, FIT, or colonoscopy. Single-panel gFOBT in the medical office using a stool sample collected during a digital rectal examination (DRE) is not a recommended option for CRC screening due to its very low sensitivity for advanced adenomas and cancer.52 For similar reasons, the guideline recommends discontinuing the use of older, lower-sensitivity versions of the guaiac test in
favor of newer, high-sensitivity gFOBT or FIT. An additional option for regular screening is annual stool blood testing (gFOBT or FIT) with FSIG performed every 5 years. Health professionals should provide guidance to adults about the benefits, limitations, and potential harms associated with screening for CRC, including information on test characteristics and requirements for successful testing. For example, when advising patients about gFOBT or FIT, it is important to stress that unless there is a commitment to annual at-home testing with adherence to the manufacturer’s instructions, the limited sensitivity observed with one-time testing would make stool testing a poor choice. In contrast, evidence from randomized clinical trials and modeling have shown that a commitment to annual screening with high sensitivity tests can result in a reduced risk of developing CRC and a reduced risk of dying from CRC that rivals colonoscopy.

The ACS and other organizations recommend more intensive surveillance for individuals at higher risk of CRC. Individuals at higher risk of CRC include: 1) individuals with a history of adenomatous polyps; 2) individuals with a personal history of curative-intent resection of CRC; 3) individuals with a family history of either CRC or colorectal adenomas diagnosed in a first-degree relative, with differing recommendations based on the relative’s age at diagnosis; 4) individuals at significantly higher risk due to a history of inflammatory bowel disease of significant duration; or 5) individuals at significantly higher risk due to the known or suspected presence of one of 2 hereditary syndromes, specifically hereditary nonpolyposis colon cancer (Lynch syndrome) or familial adenomatous polyposis. For these individuals, increased surveillance generally means a specific recommendation for colonoscopy, and may include more frequent examinations and examinations beginning at an earlier age. As noted above, an update in recommendations for follow-up colonoscopy for individuals with a history of adenomatous polyps or a personal history of curative-intent resection of CRC was issued in 2006 jointly by the ACS and the USMSTF. The USMSTF has since updated recommendations for colonoscopy surveillance after screening and polypectomy.

Over the past several years, a growing number of studies have used different methodologies to demonstrate the benefits of CRC screening. In 2010, the United Kingdom trial of once-only FSIG reported a 23% reduction in CRC incidence and a 31% reduction in CRC mortality after a median of 11.2 years of follow-up. No reduction in CRC incidence or mortality associated with proximal CRC was observed. In 2012, Schoen et al reported results from another study of FSIG that was part of the NCI’s Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial. After median follow-up of 11.9 years, the investigators observed a 21% reduction in CRC incidence and a 26% reduction in CRC mortality compared with the usual-care group. Mortality from CRC in the distal colon was reduced by 50% compared with the group of patients who received usual care, while no reduction in deaths from proximal CRCs was observed. In both the PLCO and UK studies, the lack of an observed reduction in the incidence or mortality associated with proximal lesions is due principally to the limited reach of FSIG.

In 2012, Zauber et al reported on the long-term follow-up of the National Polyp Study, which had previously demonstrated a substantial reduction in CRC incidence associated with prior colonoscopy, and nearly 20 years later (median follow-up, 15.8 years), the investigators observed 53% fewer deaths from CRC based on observed versus expected mortality.

Nishihara et al evaluated the protective effect of endoscopy (FSIG and colonoscopy) on CRC incidence using data from 2 long-term prospective cohort studies: the Nurses’ Health Study, which enrolled 121,700 US nurses aged 30 to 55 years in 1976, and the Health Professionals Follow-Up Study, which enrolled 51,529 US male health professionals aged 40 to 75 years in 1986. After 22 years of follow-up, both FSIG and colonoscopy were associated with a reduced incidence of CRC, although the protective effect of FSIG only was observed in the distal colon. Likewise, both tests were associated with a reduced risk of dying from CRC (41% and 68%, respectively), although again, FSIG only was associated with a reduced risk of dying from distal CRC. Polypectomy was associated with a 43% reduction in incident CRC, negative FSIG was associated with a 40% lower incidence of CRC, and negative colonoscopy was associated with a 56% lower incidence of CRC. The fact that negative endoscopy was associated with significantly lower incident rates of CRC adds to the evidence that screening tests also can identify lower-risk cohorts who may eventually be selected for less-intensive screening.

Shaukat et al recently reported long-term follow-up results of the Minnesota Colon Cancer Control Study, 20 years after Mandel et al first demonstrated the efficacy of screening for CRC. After 30 years of follow-up, the original observations largely had been maintained (ie, 32% fewer deaths from CRC associated with annual screening with gFOBT and 22% fewer CRC deaths associated with biennial screening).

In Spain, a large prospective randomized controlled trial (RCT) is currently comparing FIT performed every 2 years with one-time colonoscopy. The first round of screening was completed in 2011, and the main study outcome is CRC mortality at 10 years of follow-up, which will be measured in 2021. In an interim report describing participation rates, diagnostic findings, and complications after the first round of screening (based on an intention-to-treat
analysis of eligible participants), Quintero et al reported that overall participation rates were higher in the group randomized to receive FIT (34.2%) compared with the group invited to colonoscopy (24.6%), while the cancer detection rate was similar in each group (0.1%; 30 cancers vs 33 cancers, respectively). The advanced adenoma detection rate was twice as high in the group invited to colonoscopy (1.9%) compared with the group invited to FIT (0.9%). However, the intention-to-treat analysis in a study with low overall rates of attendance obscures important differences in the baseline results. When examined by exposure to screening, the rate of advanced neoplasia (cancer and advanced adenomas) in the group attending colonoscopy was 4 times higher than that in the group undergoing FIT (10.3% vs 2.7%), and thus results of the study in both the intention-to-treat analysis and by exposure to screening must be considered in terms of the prospective nature of the study and the results from 4 additional rounds of stool testing in the group invited to FIT that had yet to take place at the time the study was published. At this point in time, the most important finding of the study is the higher uptake rate in the FIT arm compared with the colonoscopy arm. Studies in the United States have also demonstrated increased adherence to screening recommendations among patients who are offered stool tests. Inadomi et al found that 38% of individuals who received a recommendation for colonoscopy completed a screening examination within 6 months, compared with a 67% rate of completion among those offered gFOBT and 69% among those given a choice between the 2 screening tests.67 Gupta et al assessed the impact of mailed FIT kits compared with mailed colonoscopy invitations in a group of underserved patients, and found increased adherence to FIT (40.7%) versus colonoscopy (24.6%).68

These studies add to the literature demonstrating the value of the screening tests currently recommended for CRC screening, with one exception: the use of a low-sensitivity stool test in the Minnesota trial although, per protocol, rehydration was used, which increased test sensitivity and contributed to better long-term outcomes. Although 3 of the studies described herein demonstrated a reduced incidence and mortality associated with FSIG, exposure to FSIG in these studies typically occurred many years ago, and the availability and use of FSIG in the United States today is uncommon. While there are numerous recommended options for CRC screening, the tests commonly in use in the United States are colonoscopy and testing with either gFOBT or FIT. Although colonoscopy is the dominant CRC screening test in use in the United States, evidence suggests when given a choice, a significant percentage of adults elect to undergo stool testing.67-70 Modeling studies also have shown that a lifetime of screening with high-sensitivity FOBT or FIT results in nearly equivalent outcomes in terms of life-years gained when compared with colonoscopy, provided that adherence to stool testing is high, a finding that should be emphasized when counseling patients about testing options.23

The findings from these recent studies also suggest a new direction for tailored screening. As noted earlier, negative findings on endoscopy are associated with a reduced risk of CRC, suggesting that hybrid strategies of screening (ie, different schedules and different tests based on assessment of risk) have real potential. Moreover, modeling also suggests the potential for hybrid strategies in average-risk adults. Dinh et al recently used the Archimedes model to simulate a prospective trial of 100,000 adults aged 50 to 75 years who were followed over a period of 30 years with colonoscopy, FIT, and a combination of the 2 tests.71 Positive FIT tests were followed by colonoscopy, and adults with polyps identified on colonoscopy followed ACS recommendations based on findings.12 Without screening, the model estimated that over the 30-year period there would be 6004 cases of CRC and 1837 deaths. Colonoscopy performed every 10 years was the most effective single-test screening strategy, achieving a reduction in CRC incidence of 76% compared with no screening, whereas annual FIT decreased CRC incidence by 68%. However, the hybrid strategy of annual FIT from age 50 to 65 years followed by 1-time colonoscopy at age 66 years was associated with a 73% reduction in incidence. All strategies increased quality-adjusted life-years (QALY), and all were cost-saving compared with no screening. Colonoscopy every 10 years gained 11,500 QALYs, and saved $111.5 million per 100,000 person-years. In contrast, the combination of annual FIT from age 50 to 65 years followed by 1-time colonoscopy at age 66 years was only slightly inferior to colonoscopy in terms of QALYs (300 fewer QALYs) and saved $126.8 million per 100,000 person-years, largely through reduced numbers of colonoscopies.

The combination of data from long-term studies, recently launched prospective trials, and modeling ultimately may provide for approaches to CRC screening that will produce similar outcomes at lower costs compared with what many regard as the prevailing gold standard (ie, colonoscopy every 10 years). These strategies may involve hybrid screening protocols as described above, or single-modality studies applied differently from what is currently recommended in existing guidelines. An organized approach to screening with a hybrid screening method potentially could reduce current rates of both overscreening and underscreening, while still offering a menu of testing options to patients. This potentially could be quite effective in increasing screening rates and reducing incidence and mortality, particularly if steps are taken to systematize screening in a way that supports adherence.

Without organized programs that could rationally and effectively increase both access and regular adherence to high-sensitivity stool testing, hybrid programs probably
Testing for Early Prostate Cancer Detection

Prostate cancer is the most common cancer, apart from skin cancer, diagnosed in men in the United States, with an estimated 233,000 new cases and 29,480 deaths expected in 2014. In 2010, the ACS updated its 2001 guideline for the early detection of prostate cancer. The 2010 guideline states that men who have at least a 10-year life expectancy should have an opportunity to make an informed decision with their health care provider about whether to be screened for prostate cancer with DRE and serum prostate-specific antigen (PSA), after receiving information about the benefits, risks, and uncertainties associated with prostate cancer screening (Table 3). Prostate cancer screening should not occur without an informed decision-making process. Men at average risk should receive this information beginning at age 50 years. Men at higher risk, including African American men and men with a family member (father or brother) diagnosed with prostate cancer before age 65 years, should receive this information beginning at age 45 years. Men at appreciably higher risk (multiple family members diagnosed with prostate cancer before age 65 years) should receive this information beginning at age 40 years. Men should either receive this information directly from their health care providers or be referred to reliable and culturally appropriate sources. Patient decision aids are helpful in preparing men to make a decision whether to be tested. For men who are unable to decide, the screening decision can be left to the discretion of the health care provider, who should factor into the decision his or her knowledge of the patient’s general health preferences and values. Asymptomatic men who have less than a 10-year life expectancy based on age and health status should not be offered prostate cancer screening. For men who choose to be screened for prostate cancer after a process of shared or informed decision-making: 1) screening is recommended with the serum PSA with or without DRE (DRE is recommended along with PSA for men with hypogonadism, due to the reduced sensitivity of PSA); 2) for men whose PSA is less than 2.5 ng/mL, screening intervals can be extended to every 2 years (screening should be conducted yearly for men whose PSA level is 2.5 ng/mL or higher); and 3) a PSA level of 4.0 ng/mL or higher has historically been used to recommend referral for further evaluation or biopsy, which remains a reasonable approach for men at average risk of prostate cancer. For PSA levels between 2.5 ng/mL and 4.0 ng/mL, health care providers should consider an individualized risk assessment that incorporates other risk factors for prostate cancer, particularly for high-grade cancer, which may be used for a referral recommendation. Factors that increase the risk of prostate cancer include African American race, family history of prostate cancer, increasing age, and abnormal DRE findings. A prior negative biopsy lowers risk. Methods are available that merge this information to achieve an estimate of a man’s overall risk of prostate cancer and, more specifically, of his risk of high-grade prostate cancer.

The importance of informed and shared decision-making has been a central element of ACS recommendations on prostate cancer screening since 1997 and especially since 2001. In fact, the importance of making an informed decision about screening for early prostate cancer detection before testing takes place is a cross-cutting theme in most guidelines. However, studies have shown that informed

### TABLE 3. Core Elements of the Information to be Provided to Men to Assist With Their Decision About Prostate Cancer Screening

| Core Elements of Information |
|-------------------------------|
| Prostate cancer is an important health concern for men: |
| - Screening with the PSA blood test alone or with both the PSA and DRE detects cancer at an earlier stage than if no screening is performed. |
| - Prostate cancer screening may be associated with a reduction in the risk of dying from prostate cancer. However, evidence is conflicting and experts disagree about the value of screening. |
| - For men whose prostate cancer is detected by screening, it is currently not possible to predict which men are likely to benefit from treatment. Some men who are treated may avoid death and disability from prostate cancer. Others who are treated would have died of unrelated causes before their cancer became serious enough to affect their health or shorten their lives. |
| - Depending on the treatment selected, the treatment of prostate cancer can lead to urinary, bowel, sexual, and other health problems. These problems may be significant or minimal, permanent or temporary. |
| - The PSA and DRE may have false-positive or false-negative results, meaning men without cancer may have abnormal results and undergo unnecessary additional testing, and clinically significant cancers may be missed. False-positive results can lead to sustained anxiety about prostate cancer risk. |
| - Abnormal results from screening with PSA or DRE require prostate biopsies to determine whether the abnormal findings are cancer. Biopsies can be painful, may lead to complications such as infection or bleeding, and can miss clinically significant cancer. |
| - Not all men whose prostate cancer is detected through screening require immediate treatment, but they may require periodic blood tests and prostate biopsies to determine the need for future treatment. |
| - In helping men to reach a screening decision based on their personal values, once they understand the uncertainties, risks, and potential benefits, it can be helpful to provide reasons why some men decide for or against undergoing screening. For example: |
| - A man who chooses to be screened might place a higher value on finding cancer early; might be willing to be treated without a definite expectation of benefit; and might be willing to risk injury to urinary, sexual, and/or bowel function. |
| - A man who chooses not to be screened might place a higher value on avoiding the potential harms of screening and treatment, such as anxiety or risk of injury to urinary, sexual, or bowel function. |

PSA indicates prostate-specific antigen; DRE, digital rectal examination.
and shared decision-making measures are inconsistently used and that, when discussions do take place, the content is highly variable, incomplete, and falls short of accepted standards. Moreover, compared with clinicians in academic settings, community-based clinicians are more likely to endorse annual PSA testing as a standard of care. In an effort to address these shortcomings, the 2010 ACS guideline provides detailed recommendations on the core information related to screening and treatment that should be shared with men to enable them to make a truly informed decision.

In the 2010 NHIS, a nationally representative sample of men aged 50 to 74 years were asked questions about discussions with their physicians regarding the advantages, disadvantages, and uncertainty about the benefits of PSA screening for prostate cancer. Nearly two-thirds of men reported no discussion with their physician that would even minimally qualify as shared decision-making related to prostate cancer screening; nearly 28% reported partial shared decision-making with one or more of the 3 elements, with a discussion of advantages being more common than one of the disadvantages; and 8% reported past physician-patient discussions of all elements related to shared decision-making about prostate cancer screening. While the absence of shared decision-making was more common in men who reported no PSA testing, 39% of men who reported high-intensity screening (4-5 tests within the previous 5 years) reported no shared decision-making.

Educational interventions directed toward physicians have shown improved delivery of information recommended for shared decision-making. Wilkes et al randomized 120 primary care physicians in 5 group practices and 712 male patients aged 50 to 75 years into a control group that received standardized educational materials and 2 intervention groups: one that received a Web-based educational program without patient activation and another that received the Web-based educational program and patient activation, during which patients viewed a Web-based program that provided both information about PSA testing and encouragement to actively participate in screening decisions. Compared with control group physicians, those physicians who received the educational intervention were more likely to engage in discussions about prostate cancer screening with activated patients and were more likely to remain neutral in their recommendations. The investigators concluded that the 20- to 30-minute Web-based intervention combined with the interactions with a small number of activated patients provided the catalyst to favorably modify their shared decision-making behavior.

The failure to adhere to recommendations for shared decision-making is multifactorial, and includes a lack of demand by adults who have confidence that screening tests inherently are beneficial; a lack of time during health professional-patient encounters; a lack of knowledge and training in supporting shared decision-making; a lack of currency in state-of-the-art knowledge about benefits, limitations, and harms; and concerns about medical-legal liability. To address these challenges, the CDC convened a consensus panel to prioritize strategies to achieve more effective communication concerning benefits, harms, and patient value preferences related to prostate cancer screening. To improve the quality and frequency of shared decision-making, the panel endorsed targeting reimbursement to reward shared decision-making; the development of effective, technology-assisted, clinical setting tools; reframing messages to improve clarity; previsit decision interventions; the effective use of electronic medical records to measure delivery of shared decision-making; and additional training in the delivery of shared decision-making, including making training a component of reaccreditation.

The current ACS early detection recommendations for prostate cancer were published in 2010 following an extensive review of the evidence related to screening, including 2 recently published, long-term, multicenter, RCTs of screening with PSA and DRE: the European Randomized Study of Screening for Prostate Cancer and the PLCO screening trial. Based on evidence from these RCTs and other studies, the ACS determined that the balance of benefits and harms related to the use of PSA for the early detection of prostate cancer still was uncertain and the existing evidence was insufficient to support a recommendation for or against the routine use of PSA screening. In 2012, the USPSTF released new recommendations on screening for prostate cancer. In 2008, the USPSTF recommended against prostate cancer screening in men aged 75 years and older, but concluded that there was insufficient evidence to recommend for or against prostate cancer screening for men aged 50 to 74 years (C rating). In 2012, having evaluated largely the same evidence considered in the ACS review, the USPSTF concluded with moderate certainty that the harms of PSA testing outweigh the benefits and on that basis recommended against PSA-based screening for all men.

The basis for the USPSTF’s new recommendation was “convincing evidence” from the multicenter trials that the number of men who avoid dying from prostate cancer due to screening is, at best, very small, while the harms related to the treatment of screen-detected cancers were judged to be at least moderate. These estimated harms included incontinence and erectile dysfunction in 200 to 300 of 1000 men treated with surgery or radiotherapy, and death in 5 of 1000 men within one month of prostate cancer surgery. The USPSTF made no distinction in their recommendations between men at average risk of prostate cancer and men known to be at an increased risk of developing and dying from prostate cancer (African Americans and men with family history of prostate cancer). While the USPSTF acknowledged that African American men and men with a family history of the disease are at an increased risk of...
developing and dying from prostate cancer, they noted that the gaps in the evidence regarding the potential benefits of screening also apply to these men.

The differences between the ACS and USPSTF recommendations can be attributed in large part to differences in how each organization evaluated the recent evidence from the RCTs. The ACS judged the initial interim analyses from the European Randomized Study of Screening for Prostate Cancer and PLCO as informative but not definitive. In contrast, the USPSTF has been criticized for reaching a definitive conclusion based on incomplete data.86

In 2013, the American Urological Association (AUA) conducted a systematic review of over 300 studies, and also chose to emphasize values and preferences expressed in the clinical setting during physician–patient discussions rather than a public health approach, which presumably refers to placing priority on shared decision-making versus judgments about the balance of benefits and harms at the population level.75 For men aged 55 to 69 years, the AUA concluded that the quality of the evidence for benefits associated with screening was moderate, while the quality of the evidence for harms was high. Shared decision-making is recommended for men aged 55 to 69 years, a group for whom the AUA has judged the benefits may outweigh the harms. For men in this age range who choose to undergo screening, a screening interval of 2 years is preferred to reduce potential harms. For men aged younger than 55 years and older than 70 years, the AUA concluded that there was insufficient evidence to conclude that benefits outweighed harms. The panel recommended against PSA screening in men aged younger than 40 years; recommended against routine screening from age 40 to 54 years; specifically in average-risk men, and argued that screening decisions should be individualized for African American men or men with a strong family history; strongly recommended “shared decision-making for men age 55 to 69 years that are considering PSA screening and proceeding based on a man’s values and preferences”; and, finally, recommended against routine PSA screening in men aged 70 years and older or in men who do not have a life expectancy of 10 to 15 years.75

While there are clear differences in each organization’s recommendations, the ACS, USPSTF, and AUA also share a number of similarities. Each acknowledges that many men are harmed by undergoing screening that leads to the detection and treatment of prostate cancers that would never have become clinically apparent (overdiagnosis and overtreatment), or are so slow-growing that death from another cause is a higher probability. Although recommending against PSA screening, the USPSTF acknowledges that some men will continue to request screening and some physicians will continue to offer it. Like the ACS and AUA, they state that screening under such circumstances should respect patient preferences. There is also agreement that screening for prostate cancer in the absence of discussion and shared decision-making is not consistent with the evidence and should not take place.

It should be acknowledged that a significant percentage of the harms associated with testing result in large part from a failure to adhere to guidelines. Carlsson et al have endorsed 3 principles to measurably improve PSA screening outcomes.86 First, avoid PSA screening in men with a limited life expectancy. The ACS recommends that a man have at least 10 years of projected longevity or PSA testing is not appropriate.13 Second, avoid treatment in men who do not need treatment. This is a more challenging issue, and more research is needed to distinguish with confidence low-risk prostate cancers from those that truly need curative therapy. However, new data from the PIVOT (Prostate Intervention Versus Observation Trial) and other prospective studies comparing long-term outcomes may prove to be informative about choosing between curative therapy versus active surveillance.87 Greater guidance to support treatment decisions is needed. Third, men who need treatment should be referred to high-volume centers so that the risk of treatment-related complications is reduced.

### Screening for Endometrial Cancer

In 2013, the ACS estimates that 52,630 women will be diagnosed with endometrial cancer, and 8590 women will die from this disease.17 In 2001, the ACS concluded that there was insufficient evidence to recommend screening for endometrial cancer in women at average risk, or those 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.8 The ACS recommends that women at average and increased risk should be informed about the potential benefits, harms, and treatment-related complications. Women at very high risk of endometrial cancer due to: 1) known Lynch syndrome genetic mutation carrier status; 2) a substantial likelihood of being a mutation carrier (ie, a mutation is known to be present in the family); or 3) the absence of genetic testing results in families with a suspected autosomal dominant predisposition to colon cancer should consider beginning annual testing for early endometrial cancer detection at age 35 years. The evaluation of endometrial histology with endometrial biopsy is still the standard for determining the status of the endometrium.88 Women at high risk should be informed that the recommendation for screening is based on expert opinion, and they also should be informed about the potential benefits, harms, and limitations of testing for early endometrial cancer detection.

### Screening for Lung Cancer

Lung cancer is the most common cancer affecting both men and women, accounting for 14% of all new diagnoses...
TABLE 4. Eligibility Criteria for the National Lung Screening Trial

| Age                  | 55-74 y, with no signs or symptoms of lung cancer. |
|----------------------|--------------------------------------------------|
| Smoking history      | Active or former smoker with a 30 pack-y history (a pack-y is the equivalent of 1 pack of cigarettes per d per y. One pack per d for 30 y or 2 packs per d for 15 y would both be 30 pack-y). |
| Active smoker        | If active smoker, should also be vigorously urged to enter a smoking cessation program. |
| Former smoker        | If former smoker, must have quit within the past 15 y. |
| General health exclusions | Metallic implants or devices in the chest or back. Requirement for home oxygen supplementation. Prior history of lung cancer or other lung cancer symptoms. |

from cancer and an estimated 222,210 new cases in 2014.\textsuperscript{17} Lung cancer also is the leading cause of death from cancer in men and women, accounting for an estimated 159,260 deaths in 2014, which is approximately 27\% of all cancer deaths in the United States.\textsuperscript{17} Death from lung cancer is the leading cause of premature mortality from cancer, with an estimated 2.37 million years of life lost in 2010.\textsuperscript{16} Historically, there has been a concerted effort to reduce the burden of disease by preventing the uptake of cigarette smoking; promoting smoking cessation; and investigating various approaches to detecting lung cancer early in its natural history, including screening for lung cancer with chest x-ray (CXR) or sputum cytology. Studies of CXR screening have produced disappointing results in part due to study design limitations, but also the inherent limitations of CXR to detect small lesions in the lung. In contrast, early investigations of screening for lung cancer with low-dose helical CT (LDCT) demonstrated considerably greater sensitivity for the detection of small pulmonary nodules,\textsuperscript{89} leading to the initiation of RCTs in the United States and Europe.

In the United States, the National Lung Screening Trial (NLST) was launched in 2002, randomizing 53,454 adults aged 55 to 74 years who were at high risk of lung cancer into 2 arms: one that would be invited to 3 rounds of annual LDCT screening and one that would be invited to 3 rounds of annual CXR. Participants were current or former smokers (quitting within the past 15 years) who were in reasonably good health and had at least a 30 pack-year history of smoking. In 2010, the NCI announced that the study had observed 20\% fewer lung cancer deaths in the LDCT arm compared with the CXR arm, and that there was no evidence that adverse events associated with lung cancer screening were sufficiently common to question the balance of benefits and harms.\textsuperscript{90}

Findings from the NLST established that lung cancer mortality in specific high-risk groups can be reduced by annual screening with LDCT.\textsuperscript{91} Although the evidence is convincing, it needs to be appreciated that organizations issuing new lung cancer screening guidelines are doing so with limited information from the NLST and ongoing RCTs in Europe and elsewhere.\textsuperscript{92} Furthermore, there is uncertainty about capacity; expertise; and the prevalence of expert, multispecialty groups in the United States to provide lung cancer screening and follow-up, and to do so with a high level of quality. Because cancer screening tests commonly are associated with both benefits and adverse events, and because the NLST results would likely stimulate great interest in lung cancer screening, the ACS issued interim guidance on lung cancer screening in 2011, stating that “adults between the ages of 55-74 who meet the eligibility criteria of the NLST and are concerned about their risk of lung cancer may consider screening for early lung cancer detection.”\textsuperscript{2} Rather than a direct recommendation for screening, the guidance emphasizes shared decision-making prior to making a decision about lung cancer screening.

Following the announcement of the NLST results in late 2010, the ACS joined with the American College of Chest Physicians, the American Society of Clinical Oncology, and the National Comprehensive Cancer Network to produce a systematic review of the evidence related to lung cancer screening with LDCT.\textsuperscript{93} Both RCTs and observational studies were included in the review, which focused on literature published from January 1996 through April 2012. The systematic review focused on evidence related to the benefits and harms associated with LDCT screening for lung cancer, groups likely to benefit from screening, and settings in which screening was most likely to be effective. In developing this guideline, which is an update of the interim guidance, particular weight was given to the NLST based on its larger study size, and the fact that it has shown a statistically significant difference of 20\% fewer lung cancer deaths in a group invited to screening with LDCT versus CXR. Greater details related to the evidence underlying the updated recommendations are available in the systematic evidence review\textsuperscript{91} and the updated guidelines.\textsuperscript{14}

The updated recommendations emphasize that clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should ascertain the smoking status and smoking history of their patients aged 55 to 74 years (Table 4) and should initiate a discussion about lung cancer screening with patients aged 55 to 74 years who have at least a 30 pack-year smoking history, currently smoke, or have quit within the past 15 years, and who are in relatively good health. Core elements of this discussion should include the benefits, uncertainties, and harms associated with screening for lung cancer with LDCT (Table 5). Adults who choose to be screened should follow the NLST protocol of annual LDCT screening until they reach age 74 years. CXR should not be used for cancer screening.
TABLE 5. Key Discussion Points for the Process of Shared Decision-Making Related to Screening for Early Lung Cancer Detection With LDCT

- Benefit: Screening with LDCT has been shown to substantially reduce the risk of dying from lung cancer.

- Limitations: LDCT will not detect all lung cancers or all lung cancers early, and not all patients who have a lung cancer detected by LDCT will avoid death from lung cancer.

- Harms: There is a significant chance of a false-positive result, which will require additional periodic testing and, in some instances, an invasive procedure to determine whether an abnormality is lung cancer or some non-lung-related incidental finding. Fewer than one in 1000 patients with a false-positive result experience a major complication resulting from a diagnostic workup. Death within 60 d of a diagnostic evaluation has been documented, but is rare and most often occurs in patients with lung cancer.

- Individuals who value the opportunity to reduce their risk of dying from lung cancer and who are willing to accept the risks and costs associated with undergoing LDCT and the relatively high likelihood of the need for further tests, even tests that have the rare but real risk of complications and death, may opt to be screened with LDCT every y.

- Individuals who place a greater value on avoiding testing that carries a high risk of false-positive results and a small risk of complications, and who understand and accept that they are at a much higher risk of death from lung cancer than from screening complications, may opt not to be screened with LDCT.

When possible, adults who choose to be screened should enter an organized screening program at an institution with expertise in LDCT screening, with access to a multidisciplinary team skilled in the evaluation, diagnosis, and treatment of abnormal lung lesions. If an organized, experienced screening program is not accessible but the patient strongly wishes to be screened, they should be referred to a center that performs a reasonably high volume of lung CT scans, diagnostic tests, and lung cancer surgeries. If such a setting is not available and the patient is not willing or able to travel to such a setting, the risk of harms associated with lung cancer screening may be substantially higher than the observed risks associated with screening in the NLST, and therefore screening is not recommended. Referring physicians should help their patients identify appropriate settings with this expertise.

At this time, very few government or private insurance programs provide coverage for the initial LDCT preformed for lung cancer screening. This likely will change soon based on release of an updated recommendation statement from the USPSTF giving lung cancer screening for adults aged 55 to 80 years with at least a 30 pack-year history who are current smokers or who have quit within the past 15 years a “B” rating, which means there is high certainty of moderate net benefit, or moderate certainty that the net benefit is moderate to substantial. These recommendations are quite similar to those of other organizations that have issued lung cancer screening guidelines and thus are likely to be widely endorsed during the comment period. Under the Patient Protection and Affordable Care Act of 2010 (ACA), a B rating for a preventive service will be covered with no out-of-pocket costs for adults enrolled in most commercial insurance programs.

Clinicians who decide to offer screening bear the responsibility of helping patients determine if they will have to pay for the initial test themselves and helping the patient know how much they will have to pay. In light of the firm evidence that screening high-risk individuals can substantially reduce death rates from lung cancer, both private and public health care insurers should expand coverage to include the cost of annual LDCT screening for lung cancer in appropriate high-risk individuals.

Smoking cessation counseling constitutes a high priority for clinical attention in patients who are currently smoking. Current smokers should be informed of their continuing risk of lung cancer, and referred to smoking cessation programs. Screening should not be viewed as an alternative to smoking cessation.

Clinicians should not discuss lung cancer screening with LDCT with patients who do not meet the recommended criteria (Table 4). In those cases in which the risk seems to approximate or exceed the NLST eligibility criteria in one category but not another, clinicians will need to use their best judgment in deciding whether to engage the patient in a discussion about screening. If lung cancer screening is requested, these patients should be informed that at this time, there is too much uncertainty regarding the balance of benefits and harms for individuals at younger or older ages and/or with less lifetime exposure to tobacco smoke and/or with sufficiently severe lung damage to require oxygen (or other health-related NLST exclusion criteria), and therefore screening is not recommended.

Testing for Early Ovarian Cancer Detection

Although the annual incidence of ovarian cancer is low compared with breast cancer and precursor lesions of the cervix, it is the most lethal of the gynecologic cancers. Fewer than one-half of women diagnosed with ovarian cancer survive longer than 5 years, and although the 5-year survival of localized ovarian cancer is greater than 90%, only 15% of all patients are diagnosed with localized disease.

Screening and diagnostic methods for ovarian cancer include pelvic examination, CA 125 antigen as a tumor marker, transvaginal ultrasound (TVU), and, potentially, multimarker panels and bioinformatic analysis of proteomic patterns. The sensitivity and specificity of pelvic examination for the detection of asymptomatic ovarian cancer are poor and do not support physical examination as a screening method. CA 125 has limited sensitivity and
specificity (ie, while CA 125 levels are increased in many women with ovarian cancer, only one-half of early ovarian cancers produce enough CA 125 to cause a positive test, and noncancerous diseases of the ovaries, other cancers, and other noncancerous influences also can increase the blood levels of CA 125).96-98 TVU is capable of detecting small ovarian masses and may distinguish some benign masses from some malignant adnexal masses, although it still poorly predicts which masses are cancers and which are due to benign disease. As an independent test, ultrasound has shown poor performance in the detection of ovarian cancer in women at average or high risk.99 There are ongoing attempts to develop a blood test for ovarian cancer based on measuring genes, proteins, or multiple marker assays that may be present in higher or lower amounts in women with ovarian cancer compared with women who do not have ovarian cancer, but this work is still experimental and, however promising, prospective validation studies still will be required.100,101 At this time, the lack of supporting evidence indicating that any one or combination of these strategies is efficacious has prevented organizations from issuing recommendations for ovarian cancer screening.

Two large prospective randomized trials, one in the United States and the other in the U.K., have been studying screening average-risk women with a combination of CA 125 and TVU. The US trial, the PLCO cancer screening trial,102 reported results in 2011.103 In the PLCO trial, 78,216 women aged 55 to 74 years were randomized to a group offered 6 annual rounds of screening with CA 125 and TVU for 4 years (n = 39,105) or a group that received usual care (n = 39,111). Participants were followed for a maximum of 13 years, with mortality from ovarian cancer as the main study outcome. At the conclusion of the study, the number of deaths from ovarian cancer was similar in each group (ie, there were 3.1 ovarian cancer deaths per 10,000 women-years in the group invited to screening vs 2.6 deaths per 10,000 women-years in the control group [relative risk, 1.18; 95% confidence interval, 0.82-1.71]). The authors concluded that simultaneous screening with CA 125 and TVU was not associated with a reduction in ovarian cancer mortality compared with usual care.103 However, the authors also noted that the absence of a stage shift in the group invited to screening compared with the control group suggests that the screening protocol in the PLCO trial may not have been sensitive enough to diagnose ovarian cancer sufficiently early to alter its natural history. However, for each of the 2 tests under evaluation, lower cutoff values would result in higher false-positive rates. An alternative approach, which is currently under evaluation in the UK Collaborative Trial of Ovarian Cancer Screening, is assessing the efficacy of multimodal screening including annual CA 125 screening with a risk of ovarian cancer algorithm (ROCA) and TVU as a second-line test versus annual screening with TVU only.104 The ROCA measures changes in CA 125 over time rather than with a single cutoff point, and is believed to improve sensitivity for smaller tumors without measurably increasing the false-positive rate. PLCO investigators retrospectively evaluated CA 125 screening values in the PLCO study group to determine if calculating ROCA scores rather than using a fixed CA 125 cutoff would have more favorably affected the trial’s outcome. While the use of ROCA scores in the simulation was associated with fewer deaths in the intervention arm, the difference between deaths in the intervention group and control group still was not statistically significant. The authors caution that this simulation does not rule out the possibility of observing a benefit from using ROCA scores in the ongoing UK Collaborative Trial of Ovarian Cancer Screening.105

Currently, no organization recommends screening average-risk women for ovarian cancer. Based principally on the results of the PLCO trial, in 2012 the USPSTF recommended against screening for ovarian cancer (D recommendation), concluding that there was adequate evidence that annual screening with TVU and CA 125 does not reduce ovarian cancer mortality, and that likewise there was adequate evidence that screening for ovarian cancer can lead to important harms, mainly surgical interventions in women without ovarian cancer.106

In 1994, a National Institutes of Health Consensus Panel concluded that women with 2 or more first-degree relatives diagnosed with ovarian cancer should be offered counseling about their ovarian cancer risk by a gynecologic oncologist (or other specialist qualified to evaluate family history and discuss hereditary cancer risks) since these women have a 3% chance of being positive for an ovarian cancer hereditary syndrome.107 The panel further advised that women with a known hereditary ovarian cancer syndrome, such as mutations on BRCA1 and BRCA2, including breast-ovarian cancer syndrome, site-specific ovarian cancer syndrome, and Lynch syndrome, should receive annual rectovaginal pelvic examinations, CA 125 determinations, and TVU until childbearing is completed or at least until age 35 years, at which time prophylactic bilateral oophorectomy is recommended. Although women with these hereditary syndromes are estimated to represent only 0.05% of the female population, they have a 40% estimated lifetime risk of ovarian cancer.

**Cancer Screening and Primary Care**

Periodic encounters with clinicians, either for acute care or for health maintenance visits, offer the potential for health counseling, cancer screening, and case finding.108,109 When individuals see a clinician for a preventive health examination, there is an opportunity for more comprehensive
counseling and testing and indeed, it has been consistently observed that individuals who have had a recent preventive health examination are more likely to have undergone cancer screening.110 A preventive health examination is an opportunity to provide a referral for screening or, if appropriate, to perform the test in the office, and it is an opportunity for case-finding examinations of the thyroid, testicles, ovaries, lymph nodes, oral region, and skin. In addition, self-examination techniques or increased awareness about the signs and symptoms of skin cancer, breast cancer, or testicular cancer can be discussed based on the patient’s interest. Health counseling may include guidance about smoking cessation, diet, and physical activity; shared decision-making about cancer screening; or testing for early cancer detection for cancer sites where population-based screening is not yet recommended and there is insufficient evidence to recommend for or against screening. Whereas in the past the ACS recommended a “cancer-related checkup” in a manner that implied a stand-alone examination, the recommendation now stresses that the occasion of a general periodic health examination provides a good opportunity to address examinations and counseling that could lead to the prevention and early detection of cancer (Table 2).

Surveillance of Cancer Screening: Colorectal, Breast, Cervical, and Prostate Cancers

In a previous report, we detailed national trends in cancer screening for the period between 1987 and 2005 based on the NHIS.111 In 2012, we provided updated national cancer screening estimates based on the 2010 NHIS, showing the extent of change (percentage increases or decreases) in cancer screening prevalence for 2 time periods (2005–2008 and 2008–2010). Using the most recent survey data (2010), we describe differences in cancer screening by race and ethnicity and 2 socioeconomic indicators (having health insurance and educational attainment) strongly associated with access to and use of medical/preventive services (Table 6). Since there are no updated survey results since 2010, we are reproducing the most recent data for the convenience of the reader.

Discussion

ACS guidelines for average-risk adults endorse screening for breast cancer, cervical cancer, and CRC based on clear evidence that screening reduces morbidity and mortality. At this time, informed and/or shared decision-making is recommended for adults considering prostate cancer screening based on the uncertainty of the balance of benefits and harms. New lung cancer screening guidelines also stress shared decision-making, but emphasize that primary care physicians should assess the current and former smoking status of their patients aged 55 to 74 years and, if they meet general health and smoking history criteria that would have made them eligible for the NLST, a discussion about lung cancer screening should then be initiated. A direct recommendation for lung cancer screening is not recommended at this time by the ACS or any other organization because of the need for discussions about the potential benefits and harms, and also because of the need to identify patients and refer them to high-quality local services. However, the ACS recommendations are direct that health care professionals should assess their patient’s smoking history and initiate discussions about lung cancer screening and smoking cessation if appropriate.

Each of these screening recommendations has different age, sex, risk, and testing interval requirements. Screening adults at high risk of these cancers requires both the proper identification of high-risk status based on a detailed assessment of family history or other considerations, and the application of a protocol that commonly involves beginning screening earlier and with different protocols than those recommended for average-risk adults.

Achieving high rates of cancer screening is a persistent challenge in both organized and nonorganized (ie, opportunistic) systems.112 In the United States, where opportunistic screening predominates, fulfilling the cancer screening needs of average- and high-risk adults requires a multifactorial combination of infrastructure, incentives, and systems to identify, contact, and follow the target population. Furthermore, health professionals must be aware of the screening recommendations for adults at average and high risk; the underlying evidence and logic for including and excluding individuals from invitations to screening; and the benefits, limitations, and harms associated with screening. Adults also need to have a basic awareness of what they can and cannot expect from screening, and understand what is expected of them in terms of preparation, follow-up, and adherence. Finally, financial and other access barriers to screening and follow-up care must be minimized.

The ACA includes provisions for the coverage of 16 adult preventive services, including breast cancer, CRC, and cervical cancer screening, without any patient cost-sharing (ie, no copay or requirement to meet a deductible) for individuals with new health insurance plans or policies beginning on or after September 23, 2010. This common feature of plans should contribute to increased rates of screening since out-of-pocket costs have been shown to be a significant deterrent to the use of preventive services.113 However, there have been reports that some patients undergoing breast cancer and CRC screening are being charged for screening examinations that they expected would be covered under the ACA’s provision against cost-sharing for preventive services that had received an A or B rating from the USPSTF. It is important to note that federal regulators have clarified the issue of copays associated with CRC
screening for the private insurance market in a set of Frequently Asked Questions (FAQ) issued to address common inquires about cost-sharing and the coverage of preventive services under the ACA. The FAQ, issued on February 20, 2013, stated: “…polyp removal is an integral part of a colonoscopy. Accordingly, the plan or issuer may not impose cost-sharing with respect to a polyp removal during a colonoscopy performed as a screening procedure.”

### TABLE 6. Prevalence (%) of Recent Cancer Screening Examinations Among US Adults by Race and Ethnicity, Health Insurance Coverage, and Educational Level, NHIS, 2010

| US ADULTS                         | RACE AND ETHNICITY                                                                 |
|-----------------------------------|------------------------------------------------------------------------------------|
|                                  | YEAR 2005*                           | YEAR 2008*                           | ABSOLUTE % CHANGE | YEAR 2010 | ABSOLUTE % CHANGE | WHITE, NON-HISPANIC | BLACK, NON-HISPANIC | HISPANIC | ASIAN AMERICAN |
|                                  | %     | SE    | %     | SE    | (2008 - 2005) | %     | SE    | %     | SE    | %     | SE    | %     | SE    |
| Colorectal cancer (adults aged ≥50 y) |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Either a FSIG or colonoscopyb     | 46.8  | 0.6   | 53.2  | 0.6   | 6.4        | 59.1  | 0.6   | 5.9   | 0.7   | 61.5  | 0.7   | 55.5  | 1.7   | 47     | 1.8   | 45.9  | 2.3   |
| FOB T home kitc                   | 12.1  | 0.4   | 10    | 0.4   | -2.1       | 8.8   | 0.3   | -1.2  | 0.4   | 9.2   | 0.4   | 8.4   | 0.9   | 5.6    | 0.7   | 7      | 1.4   |
| FOB T or endoscopyd               | 43.1  | 0.6   | 50.2  | 0.6   | 7.1        | 56.4  | 0.6   | 6.2   | 0.7   | 58.5  | 0.7   | 53    | 1.6   | 45.3   | 1.8   | 44.5  | 2.2   |
| Breast cancer (women aged ≥40 y)  |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Mammogramg                        | 51.2  | 0.6   | 53    | 0.7   | 1.8        | 51    | 0.7   | -2    | 0.7   | 51.5  | 0.9   | 50.6  | 1.6   | 46.5   | 1.7   | 47.7  | 2.8   |
| Cervical cancer (women aged ≥18 y) |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Pap testf                         | 79.6  | 0.4   | 78.3  | 0.5   | -1.3       | 76.4  | 0.5   | -1.9  | 0.6   | 77.7  | 0.6   | 77.8  | 1.1   | 73.4   | 1.1   | 66.1  | 2     |
| Prostate cancer men aged ≥50 y    |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| PSAg                             | 40.7  | 0.9   | 44.1  | 1     | 3.4        | 41.3  | 0.9   | -2.8  | 1     | 44.4  | 1     | 35.2  | 2.4   | 24.3   | 2.3   | 34.4  | 4.7   |

| HEALTH INSURANCE | EDUCATIONAL LEVEL (NO. OF YEARS OF EDUCATION) |
|------------------|-----------------------------------------------|
| HAVE HEALTH INSURANCE | NO HEALTH INSURANCE | ≤11 YEARS | 12 YEARS | 13 TO 15 YEARS | ≥16 YEARS |
|                   | %     | SE    | %     | SE    | %     | SE    | %     | SE    | %     | SE    |
| Colorectal cancer (adults aged ≥50 y) |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Either FOB T or colonoscopyb       | 62.2  | 0.6   | 18.8  | 2.5   | 2.5        | 43.9  | 1.3   | 54.2  | 1     | 63.1  | 1.1   | 69.2  | 1     |
| FOB T home kitc                    | 9.2   | 0.4   | 1.6   | 0.3   | 0.3        | 5.8   | 0.6   | 6.8   | 0.5   | 11    | 0.7   | 10.4  | 0.7   |
| FOB T or endoscopyd                | 59.4  | 0.6   | 17.8  | 2.5   | 2.5        | 42.1  | 1.3   | 51.9  | 1     | 59.5  | 1.1   | 66.7  | 1     |
| Breast cancer (women aged ≥40 y)   |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Mammogramg                        | 55    | 0.8   | 16.9  | 2.4   | 2.4        | 37.7  | 1.7   | 48.5  | 1.3   | 53.3  | 1.3   | 57    | 1.5   |
| Cervical cancer (women aged ≥18 y) |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| Pap testf                         | 80    | 0.5   | 55.8  | 2.2   | 2.2        | 62.5  | 1.6   | 71.6  | 1.1   | 81    | 0.9   | 85.5  | 0.8   |
| Prostate cancer (men aged ≥50 y)  |                                  |                                    |                    |          |                      |                    |          |            |          |            |        |            |            |
| PSAg                            | 49.5  | 1     | 13.9  | 3.6   | 3.6        | 26.2  | 1.9   | 34.8  | 1.6   | 43    | 1.8   | 53.9  | 1.7   |

NHIS indicates National Health Interview Survey; SE, standard error; FSIG, flexible sigmoidoscopy; FOB T, fecal occult blood test; Pap, Papanicolaou; PSA, prostate-specific antigen.

*Prevalence estimates for 2005 and 2008 are shown here to describe differences in the absolute percentage change in cancer screening use with respect to most recent data for 2010. Prevalence is weighted and age adjusted using the 2000 Census.

bRecent sigmoidoscopy within the preceding 5 y or colonoscopy within the preceding 10 y.

c Recent FOB T using a home test kit performed within the preceding y.

d Recent FOB T using a home test kit performed within the preceding y OR recent sigmoidoscopy or colonoscopy within the preceding 10 y.

e Women aged ≥40 y who had a mammogram within the last y.

fWomen who had a Pap test within the preceding 3 y with intact uteri.

gA PSA test within the past y for men who had not been told they had prostate cancer.

Source: National Health Interview Survey 2005, 2008, and 2010 (National Center for Health Statistics, Centers for Disease Control and Prevention, Atlanta, GA).
Increased insurance coverage for millions of Americans also is a feature of the ACA. Under the ACA, in 2014, increased insurance coverage will be made available through tax credits for lower-income adults that can be used to purchase coverage through health insurance exchanges. Beginning in 2014, states can also choose to expand their Medicaid programs, which will create 2 categories of Medicaid eligibility within those states: those who qualified under traditional Medicaid and those who are newly eligible for Medicaid. Under the law, in 2014, states can choose to expand their Medicaid programs using a new national coverage floor based on income. “The newly eligible” will include individuals younger than 65 years of age, including both parents and adults without dependent children. Coverage of A-rated and B-rated services for existing adult Medicaid beneficiaries remains optional for states, although there is a financial incentive within the law to encourage states to cover them. States that choose to cover all A and B services and recommended vaccines without cost-sharing in both fee-for-service and managed care standard benefit packages will earn a 1% increase in federal matching funds for expenditures relating to those services.

Given these changes, it is an important policy priority to better understand current state Medicaid program coverage of preventive services, including cancer screening. The National Colorectal Cancer Roundtable, the ACS Cancer Action Network, and the American Heart Association commissioned the George Washington University Center for Health Policy Research to conduct an in-depth, state-by-state assessment of Medicaid services. The researchers sought to answer several questions, including: 1) which of the specified USPSTF A-rated and B-rated services are covered by state Medicaid programs; 2) what restrictions exist in relation to these services and treatment items; and 3) what information do Medicaid programs provide to enrollees about their benefits.

Wilensky and Gray reviewed available documents in each state, including provider manuals, state statutes and regulations, policy pronouncements, boilerplate managed care contracts, information on Medicaid Web sites, information provided to Medicaid beneficiaries, and fee schedules/billing codes. In addition, they contacted individuals in Medicaid offices to fill in or clarify information about state coverage of preventive services. They observed that the quality and detail of the information varied significantly by state and, as such, identifying coverage for specific preventive services was often difficult, and in many instances the researchers could not clearly conclude whether a state covered a specific preventive service. Furthermore, some states technically offer coverage but fail to offer a wellness examination, meaning that a beneficiary has limited opportunity to access the preventive service unless they are ill and could access the service while being treated for their illness. Wilensky and Gray also concluded that part of the confusion around coverage stemmed from the inconsistent use of concepts such as “prevention” and “medical necessity.” For instance, a Medicaid program might technically cover a service, but only if it is deemed “medically necessary,” which is a term of art used by insurers and without a clear definition. Covering preventive services when they are “medically necessary” goes against the population-based approach to screening, which recommends screening based on a person’s age, sex, asymptomatic status, and screening schedule. For example, it would be appropriate to say a woman is eligible for a screening mammogram based on the accepted screening recommendations (eg, annually starting at age 40 years), not a patient’s individual characteristics and symptoms. Finally, there is considerable confusion among the states regarding both the requirements and benefit around expanding coverage to include USPSTF-recommended preventive services. As such, most state Medicaid agencies had not taken action to cover USPSTF services in order to receive a Federal Medical Assistance Percentages bump.

Beginning in 2014, a large number of US residents will suddenly have access to recommended preventive health services, including cancer screening, without copays as a result of the ACA and the small majority of states that have elected to opt into the Medicaid expansion. It is hoped that this improved access to care will have a near-term and highly visible effect on disparities in cancer screening rates associated with a lack of health insurance.

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