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Cancer Screening in the United States, 2015: A Review of Current American Cancer Society Guidelines and Current Issues in Cancer Screening

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Each year, the American Cancer Society (ACS) publishes a summary of its guidelines for early cancer detection along with 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 ACS cancer screening guidelines. The latest data on utilization of cancer screening from the National Health Interview Survey (NHIS) also is described, as are several issues related to screening coverage under the Affordable Care Act, including the expansion of the Medicaid program. CA Cancer J Clin 2015;65:30-54. © 2015 American Cancer Society.

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Introduction

In this annual report, the American Cancer Society (ACS) provides a summary of the current ACS cancer screening guidelines and guidance to health care professionals and the public related to early cancer detection, an update of cancer screening rates, and a discussion of select literature and issues related to early cancer detection.

As part of the ongoing guidelines development process, the ACS monitors the medical and scientific literature for new evidence that may support a change in current guidelines or the development of a new guideline and new information about screening that should be conveyed to clinicians and target populations. Under the new guidelines development process, 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 have been available online at bit.ly/CA_Guidelines. Table 1 shows the recent history of guidelines updates as well as those in progress.3-15

In this update of ACS cancer screening guidelines, we describe the current guidelines; a change in our current cervical cancer screening guidelines related to the follow-up of women with a human papillomavirus (HPV)-negative, atypical squamous cells of undermined significance (ASC-US) result; current issues shaping screening for breast, colorectal, and lung cancer; and the most recent data on cancer screening from the National Health Interview Survey.

Screening for Breast Cancer

Aside from skin cancer, breast cancer is the most common cancer in US women. Breast cancer is the second most common cause of death in US women, and the leading cause of premature mortality from cancer in women as measured by total years of life lost.16 In 2015, the ACS estimates that there will be 231,840 cases of invasive breast diagnosed in US women and

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after a period of declining age-adjusted breast cancer incidence rates (1999–2004), there has been an average annual percentage increase of 0.2% from 2004 to 2011.18 Age-adjusted breast cancer mortality rates have declined about 2% per year over the period from 2002 to 2011.18

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 2007 (Table 2).4 An update of the ACS breast cancer screening guidelines will be published in 2015.

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 for women in their 20s and 30s, and annual mammography beginning at age 40 years.

Between ages 20 and 39 years, average-risk women should undergo CBE every 3 years; and, after age 40 years, they should undergo CBE annually. CBE should take place during periodic health examinations and, ideally, before mammography after age 40 years, so that any suspicious, palpable abnormality detected during the examination can prompt a diagnostic examination. When CBE is performed on women of any age, it is an opportunity to discuss the value of early breast cancer detection, the importance of being attentive to breast changes that may be symptoms of breast cancer, and the importance of seeking care right away.19

On the occasion of performing CBE or during other encounters, health care professionals can assess risk, answer questions a woman may have about her own risk, address other issues related to breast disease, and answer questions related to conventional or new imaging technologies. With respect to risk, it is critically important that clinicians should establish and regularly update the patient’s family history of breast and ovarian cancers in first-degree and second-degree relatives on both the maternal and paternal sides of the family going back 3 generations. Clinicians should describe the effect of family history on breast cancer risk and emphasize the importance of the patient’s role in helping keep the family history up to date if there has been a change. Attention to family history beginning in the 20s and afterward is an opportunity not only to identify a patient who may benefit from genetic counseling and pedigree assessment but also to counsel women who may underestimate or overestimate the contribution of family history to their own risk.20

Although ACS guidelines do not recommend routine breast self-examination (BSE), neither do they recommend

| CANCER SITE       | YEAR                  | REFERENCES                        |
|-------------------|-----------------------|-----------------------------------|
| Breast cancer     | 2003: Complete update | Smith 20033                       |
|                   | 2007: Guidelines for MRI use in high-risk women | Saslow 20074 |
|                   | 2015: Update anticipated |                                   |
| Cervical cancer   | 2002: Complete update | Saslow 20025                      |
|                   | 2007: Guidelines for HPV vaccine use | Saslow 20076 |
|                   | 2012: Complete update | Saslow 20127                      |
|                   | 2015: Update related to follow-up of HPV-negative ASC-US | In this article |
| Colorectal cancer | 2001: Complete update | Smith 20018                       |
|                   | 2003: Technology update | Levin 20039                       |
|                   | 2006: Update for postpolypectomy and postcolorectal cancer resection surveillance | Rex 2006, Winawer 200611 |
|                   | 2008: Complete update | Levin 200812                      |
|                   | 2016: Update anticipated |                                   |
| Endometrial cancer| 2001: Guidance for counseling, shared decision making, and high-risk women | Smith 20018 |
| Prostate cancer   | 2001: Guidance for shared decision making related to testing for early detection and screening recommendations for higher risk men | Smith 20018 |
| Lung cancer       | 2010: Complete update | Wolf 201013                       |
|                   | 2001: Guidance for shared decision making | Smith 20018 |
|                   | 2011: Interim guidance on lung cancer screening | ACS, 201114 |
|                   | 2013: Complete update | Wender 201315                     |

ACS, American Cancer Society; ASC-US, atypical squamous cells of undetermined significance; HPV, human papillomavirus; MRI, magnetic resonance imaging.
TABLE 2. American Cancer Society Recommendations for the Early Detection of Breast, Cervix, Colorectal, Endometrial, and Prostate Cancer in Average Risk Asymptomatic Adults and Lung Cancer in High Risk Asymptomatic Adults

| CANCER SITE | POPULATION | TEST OR PROCEDURE | FREQUENCY |
|-------------|------------|-------------------|-----------|
| Breast      | Women ages ≥20 y | Breast self-examination (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 or not 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. |
|             |            | Clinical breast examination (CBE) | For women in their 20s and 30s, it is recommended that CBES be part of a periodic health examination, preferably at least every 3 years; asymptomatic women aged ≥40 y should continue to receive a CBE as part of a periodic health examination, preferably annually. |
|             |            | Mammmography | Begin annual mammography at age 40 y. |
| Cervix      | Women, ages 21-65 y | Pap test and HPV DNA test | Cervical cancer screening should begin at age 21 y; for women ages 21-29 y, screening should be done every 3 y with conventional or liquid-based Pap tests; for women ages 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 in the last 5 y, and women who have had a total hysterectomy (for a benign condition) should stop cervical cancer screening; women at any age should not be screened annually by any screening method. |
| Colorectal  | Men and women, ages ≥50 y | Guaiac-based fecal occult blood test (gFOBT) with at least 50% test sensitivity for cancer, or fecal immunochemical test (FIT) with at least 50% test sensitivity for cancer, or Stool DNA test, or Flexible sigmoidoscopy (FSIG), or Double-contrast barium enema, or Colonoscopy, or CT colonography | Annual starting at age 50 y; testing at home with adherence to manufacturer’s recommendation for collection techniques and number of samples is recommended; FOBOT with the single stool sample collected on the clinician’s fingertip during a digital rectal examination in the health care setting is not recommended; guaiac-based toilet bowl FOBT tests also are not recommended; compared with guaiac-based tests for the detection of occult blood, immunochemical tests are more patient-friendly and are likely to have equal or better sensitivity and specificity; there is no justification for repeating FOBT in response to an initial positive finding. |
| Endometrial | Women, at menopause | | At the time of menopause, women at average risk should be informed about risks and symptoms of endometrial cancer and strongly encouraged to report any unexpected bleeding or spotting to their physicians. |
| Lung        | Current or former smokers (quit within past 15 y) ages 55-74 y in good health with at least a 30 pack-year history | Low-dose helical CT (LDCT) | Clinicians with access to high-volume, high-quality lung cancer screening and treatment centers should initiate a discussion about annual lung cancer screening with apparently healthy patients ages 55-74 y who have at least a 30 pack-year 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 annual 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, ages ≥50 y | Digital rectal examination and prostate-specific antigen test | 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. |

CT, computed tomography; gFOBT, guaiac fecal blood occult blood test; Pap, Papanicolaou. *Beginning at age 40 years, annual CBE ideally should be performed before mammography.
against routine BSE. A woman may choose to perform regular BSE or occasional BSE, or she may choose to 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. Because not endorsing BSE may seem counterintuitive to patients, health care professionals should explain that there is limited evidence supporting the value of routine BSE over a woman’s own heightened awareness of breast changes. In either case, prompt reporting of breast changes that are associated with signs and symptoms of breast cancer is important.

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 significantly reduced risk of being diagnosed with an advanced breast cancer and of dying from breast cancer. Detection of breast cancer while it is still localized to the breast also allows women to avoid chemotherapy altogether. Women should also be informed about 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 a poor prognosis. The harms associated with breast cancer screening include the potential for false-positive results, which mostly can result in short-term anxiety. When abnormal findings cannot be resolved with additional imaging, to rule out the possibility of breast cancer, a biopsy will be required, and while the majority of such biopsies are benign, they can cause short-term discomfort and carry a risk of infection. Finally, some breast cancers detected by mammography, and perhaps more so in the case of ductal carcinoma in situ (DCIS), may not be progressive, i.e., 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%, although the wide range of estimates has been explained by Puliti et al as mostly attributable to variations in study follow-up time and adjustment for screening lead time and trends in incidence. Puliti and colleagues have shown that extreme estimates of overdiagnosis typically are associated with failures to adjust for these known influences on breast cancer incidence. For example, in 2012, Bleyer and Welch estimated that 31% of all breast cancers diagnosed in the United States in 2008 were nonprogressive based on an average annual percentage change (APC) in incidence of 0.25%. Helvie and colleagues examined the same data but noted Bleyer and Welch’s significant underestimation of rising incidence trends over 3 decades based on historical data, which led to a significant overestimation of overdiagnosis in US women in 2008. In fact, Helvie and colleagues concluded that, when the average historic APCs in incidence were estimated based on trends observed in the premammography era, during which the estimated APC increase was 1.3%, there was no support for Bleyer and Welch’s estimates of a high rate of overdiagnosis among US women. 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 much smaller.

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 in 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 guidelines for women who were known or likely carriers of a breast and ovarian cancer susceptibility gene (BRCA) mutation and other rarer, high-risk genetic syndromes or who had been treated with radiation to the chest for childhood cancer. 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 other high risk genetic syndrome with known penetrance, or women with an approximately 20% to 25% or greater lifetime risk of breast cancer based on specialized breast cancer risk-estimation models capable of pedigree analysis of first-degree and second-degree relatives on both the maternal and paternal sides. While MRI eventually may prove to be advantageous for women who are at elevated risk because of 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 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 that has tested positive for a gene mutation associated with an increased
risk of breast cancer, health professionals should use specialized software that can address family history in first-degree and second-degree relatives on both the maternal and paternal sides. There are several models that can estimate risk based on complex family histories and assist clinicians to estimate breast cancer risk, including the Claus model, the Tyrer-Cusick model, BRCAPRO, and the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) model. The BOADICEA model also estimates the risk of someone being a carrier of a BRCA gene, as does BRCAPRO. Although the Breast Cancer Risk Assessment Tool (ie, the Gail model) provides a good, generalized measure of short-term 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 that include first-degree and second-degree relatives on both the maternal and paternal sides, and it does not perform as well across the spectrum of risk compared with more complex risk calculators, such as the Tyrer–Cusick model. A link to supplemental material related to these models is included in the online publication (available at: onlinelibrary.wiley.com/doi/10.3322/canjclin.57.2.75/full). 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.

In 2014, 25-year follow-up results from the 2 Canadian National Breast Screening Studies (CNBSS) were published, showing no significant mortality reduction associated with an invitation to mammography screening. The CNBSS was a randomized trial of breast cancer screening and clinical breast examination among Canadian women ages 40 to 49 years (CNBSS-1) and ages 50 to 59 years (CNBSS-2) who volunteered for the study. Details related to the protocol and early findings are important, because they provide insights into reasons why the trial failed to demonstrate a mortality reduction in the group invited to breast cancer screening. The study was conducted in 15 screening centers in 6 Canadian provinces (Nova Scotia, Quebec, Ontario, Manitoba, Alberta, and British Columbia) from 1980 to 1985. There were 89,835 participants ages 40 to 59 years who, after a physical examination that included CBE, were randomized either to a group that would receive 5 annual invitations to attend mammography screening or to a control group that would not be invited to mammography. Women randomized to be invited to screening also would be invited to receive an annual CBE; so, in both studies, the intervention actually was mammography plus CBE. In the control arms, women ages 40 to 49 years would receive usual care, but women ages 50 to 59 years would be invited to receive an annual CBE. CBE was conducted by nurses with special training in performing physical examination of the breast. The outcome of interest was breast cancer mortality. The first results were published in 1992 after a mean follow-up of 8.5 years. Neither the CNBSS-1 trial nor the CNBSS-2 trial observed a breast cancer mortality reduction associated with an invitation to screening, and none was observed in the CNBSS-2 trial at 13 years of follow-up or in the CNBSS-1 trial at 11 to 16 years of follow-up. At 25 years of follow-up, the investigators combined the 2 study groups into a single evaluation group, and consistent with earlier evaluations, did not observe a lower breast cancer death rate in the groups invited to mammography screening compared with the control group (hazard ratio, 0.99; 95% confidence interval, 0.88-1.12).

Given the enduring challenges to the value of mammography, the response to the results has been contentious, with some asserting that the CNBSS results are definitive evidence that early diagnosis of breast cancer has little value, and others arguing that methodological and protocol decisions largely explain the counterintuitive findings. How do we understand these findings, which are at variance with the other breast cancer screening randomized trials? As Boyd et al and others have pointed out, in the first round of screening, there were more than 3 times the rate of advanced palpable breast cancers in the group randomized to receive an invitation to screening compared with the control group. Boyd et al. have suggested possible explanations for this imbalance, for which there is a only a 3 in 1000 probability that it occurred by chance alone. Even if this imbalance did occur by chance, the simple fact remains that however equal the study and control groups were on other factors, they were not equal with respect to the underlying prevalence of disease in the first round. It is an indication that the randomization process did not produce equal groups for comparison. Second, in the first 5 years of the trial, the majority of a sample of mammograms evaluated by an independent, external group were judged to have only poor or fair image quality. Thus, in the first year and the final year of the screening phase, there was very little difference in the average size of tumors between the study group and the control group (1.91 cm vs 2.1 cm), meaning that the mammography done in this trial performed only slightly better than CBE in detecting smaller tumors. Only 40% of breast cancers diagnosed in the group ages 40 to 49 years and only 53% of breast cancers diagnosed in the group ages 50 to 59 years were detected by mammography alone. In contrast to these findings, Coldman et al published an evaluation of breast cancer mortality trends from 1990 to
2009 in 7 of 12 Canadian breast cancer screening programs representing 85% of Canadian women ages 40 to 79 years.\textsuperscript{58} The investigators obtained data from the screening programs and cancer registries and calculated standardized mortality ratios, comparing observed mortality in participants versus the mortality expected based upon nonparticipants rates. On the basis of these data from nearly 2.8 million women undergoing screening, the average breast cancer mortality rate among participants was 40% (95% confidence interval, 33%-48%) lower than expected, with the range of mortality reductions across provinces varying between 27% and 59%. It is also noteworthy that the average mortality reductions were similar across women in different age groups at the time of program entry; ie, there were 44%, 40%, 42%, and 35% fewer deaths for women ages 40 to 49 years, 50 to 59 years, 60 to 69 years, and 70 to 79 years, respectively.

It is important to appreciate that each of the randomized trials had problems that were unanticipated, each has been criticized, and the investigators of each has defended their study. The important issue is collectively the RCTs have been quite informative, and are the foundation for breast cancer screening policy around the world. In the presence of ongoing challenges to the importance of early breast cancer detection, whether these challenges question the validity of the historic data\textsuperscript{59} or whether greater awareness of symptoms and improvements in therapy have significantly diminished the importance of mammography screening,\textsuperscript{60} it is important to be mindful that the extreme positions about mammography are dwarfed by the experimental evidence\textsuperscript{22} and accumulating observational evidence\textsuperscript{58,61,62} supporting the prognostic advantage of early breast cancer detection. These data continue to persuade national and international commissions to support mammography screening as a public health policy.\textsuperscript{63-65}

### Screening for Cervical Cancer

The ACS estimates that 12,900 women will be diagnosed with invasive cervical cancer and 4100 women will die from the disease in 2014.\textsuperscript{17} Cervical cancer incidence and mortality rates have declined since the introduction of the Papanicolaou (Pap) test in the mid-20th century, and the rates continue to decline to this day.\textsuperscript{18} For the period from 2002 to 2011, cervical cancer incidence rates decreased at an average annual rate of 1.2% per year in women younger than 50 years and by 1.5% per year in women ages 50 years and older.\textsuperscript{18} Over the same period, death rates have declined at an average annual rate of 1.5% in women younger than 50 years and 1.9% in women ages 50 years and older.\textsuperscript{18} In 2012, the ACS, the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology issued joint guidelines for cervical cancer screening based on a systematic evidence review using a collaborative process that included 25 organizations (Table 2).\textsuperscript{7} Similar recommendations were released in 2012 by the US Preventive Services Task Force (USPSTF).\textsuperscript{66} Recommendations for the use of prophylactic HPV vaccines, including policy and implementation issues, were published in January 2007.\textsuperscript{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 ages 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 screening women in this age group (although it can be used as a reflex test for women diagnosed with ASC-US). Women younger than 21 years should not be screened regardless of their age of sexual initiation.

- **For women ages 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 should discontinue screening after age 65 years if they have had 3 consecutive negative cytology tests or 2 consecutive negative cotest results within the 10-year period before ceasing screening, with the most recent test occurring within the last 5 years.**

- **Women at any age should NOT be screened annually by any screening method.**

#### Special Considerations

These recommendations were developed for women at average risk and do not apply to women with a history of cervical cancer; women who were exposed in utero to diethylstilbestrol; women who are immunocompromised by organ transplantation, chemotherapy, or chronic corticosteroid treatment; or women who are positive for the human immunodeficiency virus (HIV). In addition, 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 to 65 years for at least 20 years, even if screening extends beyond age 65 years. 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 ages 11 to 12 years but also for females ages 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 universal vaccination of females ages 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 prevention and early detection guidelines for cervical cancer.

According to the 2013 National Immunization Survey of Teens, 57.3% of US female adolescents ages 13 to 17 years initiated the HPV vaccination series with either the quadrivalent or the bivalent vaccine (ie, they had at least one of three shots as recommended for the HPV vaccine), and 37.6% had completed 3 doses.67 Trend data for the period from 2007 to 2013 showed that HPV vaccine initiation (at least one of the three-dose HPV vaccination series) among US girls ages 13 to 17 years increased by 4.5% per year.68 In 2012, the US Centers for Disease Control and Prevention (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, then coverage rates for receiving more than one dose (three doses are recommended) would have reached 92.6%.69 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 reasons why 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%).69 As the authors noted in the report, both failure to administer the vaccine during health care encounters and parental miscalculations about the value and need for the HPV vaccine represent missed opportunities for clinicians to educate parents and increase vaccine coverage.

HPV vaccination is underused despite the overwhelming evidence for its safety and effectiveness. While HPV vaccination rates have improved, the rate of increase has slowed and no state has met national targets. Physician recommendation is the strongest predictor of receipt of vaccination. Provider education, outreach, and training will lead to increased provider recommendations and improved vaccination coverage. In 2014, the CDC made a major commitment to increase funding through grants and cooperative agreements to various organizations and agencies that ultimately will lead to increased HPV vaccination rates, in large part through coordination of efforts between immunization and cancer-prevention organizations working with providers and health care delivery systems.

Update of Screening Recommendations

There have been 2 new developments since release of the 2012 guideline for cervical cancer screening. The ASCCP released updated guidelines for the management of abnormal screening results in 2013 and included 2 recommendations that differed from the 2012 recommendations. Based on newer evidence from the Kaiser Permanente Northern California (KPNC) database,70 the 2013 management guideline recommended that women with HPV-negative ASC-US results return for screening in 3 years rather than 4 years and stated that HPV-negative ASC-US results are an insufficient basis to allow exit from screening at age 65 years.71 The second development is US Food and Drug Administration (FDA) approval of one HPV test for primary cervical cancer screening, ie, as a stand-alone test without concomitant cytology testing.72 The ACS updated the systematic evidence review performed for the 2012 guideline and considered whether new data on HPV-negative ASC-US results indicated a need for reconsideration of the current screening recommendations for: 1) the interval for rescreening, which currently is 5 years, and 2) the age to exit screening (at age 65 years if a recent Pap result had ASC-US results), as well as new data on primary HPV screening.

Background

The cytologic interpretation of ASC-US represents a category of morphologic uncertainty, and the risk of precancer (CIN2/CIN3) or cancer associated with an HPV-negative ASC-US cytology result is low. Nevertheless, over one million women are diagnosed with ASC-US every year, of whom about half test negative for HPV. Therefore, how to manage patients with these findings is an important issue, both in terms of the interval for follow-up as well as whether to consider this finding a negative result for the purpose of exiting screening at age 65 years. At the screening guideline meeting that led to the 2012 recommendations, participants concluded that an HPV-negative ASC-US result should be treated as normal/negative and has a risk similar to that of a negative cotest result, with a recommended rescreening interval of 5 years. This has an advantage in terms of simplicity and preparation for
moving to HPV primary testing, in which cytology will not be available for women with HPV-negative test results. However, when examining new data from KPNC for the ASCCP management guideline, based on over one million women who were followed for 10 years, the ASCCP guideline panel determined that the risk was not as ultralow as that associated with a negative cotest but, instead, was closer to the risk for a negative Pap test (with no HPV result), which has a recommendation for repeat screening in 3 years. There was also concern that women ages 60 to 65 years with an HPV-negative ASC-US result had a higher risk of invasive cancer than women with a negative cotest result (based on a very small number of cancers). Therefore, keeping in mind the principle of “equal management of equal risks,” the ASCCP guideline panel concluded that an HPV-negative ASC-US result was insufficient for exiting screening. 

Recommendation
The ACS recommends that women with an HPV-negative ASC-US result should return for screening in 3 years, rather than 5 years, consistent with the ASCCP recommendation.

Rationale
This updated recommendation is based on: 1) new evidence from the KPNC data expanded to include 1.1 million women and 2 additional years of follow-up compared with the available evidence when ACS made the recommendation in 2012; 2) the principle of similar management of similar risks, ie, the risk of CIN3+ and of cancer is greater after a negative Pap test compared with that after a negative cotest and is even higher for women with an HPV-negative ASC-US result, although it should be noted that all of these risks are very low (at or below 0.5% over 5 years); 3) the large number of women affected, ie, over 500,000 women with HPV-negative ASC-US results each year; 4) the anticipated move to testing with HPV alone with a 3-year screening interval, in which all women who are HPV-negative would be rescreened in 3 years, although the cytology result would not be known; and 5) the advantage of consistency with other guidelines, ie, ASCCP.

Applying the GRADE framework, as described in Salslow et al, this recommendation is graded as weak. Although it is unlikely that there will be substantial new data that would change the recommended screening interval, the risk associated with HPV-negative ASC-US and, thus, an appropriate interval are still subject to uncertainty and based on very limited data.
test results. The suggestion of elevated cancer risk among women in this age group, which was of concern to the ASCCP guideline panel, was based on a small number of women and a single case of cancer, and additional data are unlikely. The ACS considered the following scenario: if there is adequate negative screening in the past 10 years but one ASC-US result around age 65 years, should a woman exit screening? There are very limited data to address this question. Approximately 0.5% to 1.0% of all women in their 60s will have an HPV-negative ASC-US result (H.A. Katki, personal communication, September, 2014). In addition, with a transition to HPV primary screening, many HPV-negative women potentially will exit screening without knowing that they have ASC-US.

**Recommendation**

As stated in the 2012 guideline, the ACS recommends that women older than 65 years who have evidence of adequate negative prior screening and no history of CIN2+ within the last 20 years should not be screened for cervical cancer with any modality (adequate negative prior screening is defined as 3 consecutive negative cytology results or 2 consecutive negative cotests within the 10 years before ceasing screening, with the most recent test occurring within the past 5 years). Consistent with the 2012 guideline, an HPV-negative ASC-US result should be regarded as negative for the purpose of discontinuing screening.

**Rationale**

The decision not to change this recommendation, in disagreement with the ASCCP recommendation, is based on: 1) sparse data to support a change, 2) the small number of women affected (ie, about 0.5%-1% of all women in their 60s will have an HPV-negative ASC-US result), 3) the unreliability of an ASC-US diagnosis, 4) the very low risk of CIN3+ after an HPV-negative ASC-US result, and 5) the anticipated transition to HPV primary screening, in which HPV-negative women will exit screening without knowing whether they have ASC-US. By using the GRADE framework, as described in Saslow et al,7 this recommendation is graded as weak. Although it is unlikely that there will be substantial new data that would change the recommendation, the available data are very limited.

**Primary HPV Screening**

New data on HPV primary screening from the ATHENA trial that were presented to the FDA in the spring of 2014 support HPV testing alone as an alternative screening strategy.72 Publication of primary HPV screening data in a peer-reviewed journal and publication of interim clinical guidance from multiple societies and organizations for the use of an HPV test that has been approved specifically for primary screening as an alternative to cotesting or cytology alone are pending (articles submitted). More experience and data analysis pertaining to this new strategy will permit a more formal ACS evaluation.

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

In 2015, the ACS estimates that 132,700 new cases of colorectal cancer (CRC) will be diagnosed in women and men and that 49,700 women and men will die from this disease.17 CRC incidence and mortality rates have been declining for the past 2 decades, and this is largely attributable to the contribution of screening to prevention and early detection.82 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 the American Society for Gastrointestinal Endoscopy; and the American College of Radiology (Table 2).12 Recommendations for adults at who are at increased and high risk were last updated in 20018; and, in 2006, the ACS and the USMSTF issued a joint guideline update for postpolypectomy and post-CRC resection surveillance.10,11

Recommended CRC screening tests are grouped into 2 categories: 1) tests that primarily detect cancer, which include both guaiac-based fecal occult blood tests (gFOBTs) and immunochemical-based fecal occult blood tests (FITs) and stool tests for exfoliated DNA (sDNA); and 2) tests that can detect cancer and advanced lesions, which include the endoscopic and radiological examinations, ie, flexible sigmoidoscopy, colonoscopy, double-contrast barium enema, and computed tomography (CT) colonography (or virtual colonoscopy). This distinction is intended to help primary care physicians support informed decision making and to contribute toward public understanding of the features, advantages, and disadvantages/limitations that distinguish these screening tests. Furthermore, the guidelines state that, while all recommended tests are acceptable options, 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 manufacturer’s recommendations for specimen collection; 2) an sDNA test every 3 years; 3) flexible sigmoidoscopy every 5 years; 4) colonoscopy every 10 years; 5) double-contrast barium enema every 5 years; or 6) CT colonography every 5 years. A 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 because of its very low sensitivity for advanced adenomas and cancer. For similar reasons, the guideline recommends discontinuing the use of older, lower sensitivity versions of the guaiac test (such as Hemoccult II; Beckman Coulter, Inc., Brea, Calif) in favor of newer, high-sensitivity gFOBT (such as Hemoccult SENSA; Beckman Coulter, Inc.) or high sensitivity FIT. An additional option for regular screening is annual stool blood testing (gFOBT or FIT) with flexible sigmoidoscopy 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 1-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 testing with high-sensitivity stool 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 for CRC, with the most recent follow-up recommendations having been issued by the USMSTF. Individuals at higher risk for 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 because of a history of inflammatory bowel disease of significant duration; or 5) individuals at significantly higher risk because of the known or suspected presence of a hereditary syndrome, such as Lynch syndrome (hereditary nonpolyposis colorectal cancer) or familial adenomatous polyposis. For these individuals, increased surveillance generally means a specific recommendation for colonoscopy if available and may include more frequent examinations and examinations beginning at an earlier age. The USMSTF also has issued new recommendations for genetic evaluation and management of Lynch syndrome.

In the 2008 CRC screening guidelines update, the ACS included an sDNA test among the recommended high-sensitivity stool tests; however, shortly after the guidelines were issued, the test was withdrawn from the market while the manufacturer focused on development of a second-generation test. In 2010 the ACS guideline was amended to state “the sDNA test that was approved as an option for screening in the ACS’s 2008 CRC screening guideline is no longer available.” In the interim, a second generation sDNA test has been developed and evaluated. The new test differs from the original test in that it is a multistarget test, ie, it combines a hemoglobin immunoassay with an sDNA test which includes quantitative molecular assays for KRAS mutations, aberrant gene methylation, and β-actin (as a reference gene for human DNA quantitation). Performance characteristics of this updated sDNA test were reported in the New England Journal of Medicine in 2014. US and Canadian adults ages 50 to 84 years who were scheduled for screening colonoscopy were recruited to participate. Study participants were required to provide a stool sample and complete their colonoscopy within 90 days of providing informed consent. Results of the sDNA test were compared with an FIT test performed on the same stool sample and a colonoscopy. Of the 9989 participants who could be evaluated, 65 (0.7%) had CRC, and 757 (7.6%) had advanced adenomas or sessile serrated polyps measuring ≥1 cm in greatest dimension on colonoscopy. The sensitivity of sDNA testing for detecting CRC and advanced lesions was 92.3% and 42.4%, respectively, compared with 73.8% and 23.8%, respectively, with FIT. The specificity of the multitarget test was lower (86.6%) compared with FIT (94.9%). The investigators estimated that the number needed to be screened to detect one cancer was 154 with colonoscopy, 166 with the multitarget test, and 208 with FIT. The FDA has approved the multi-target test Cologuard (Exact Sciences Corporation, Madison, Wis) for CRC screening, and the Center for Medicare and Medicaid Services (CMS) has approved reimbursement for Cologuard CRC screening for Medicare beneficiaries who have an average risk of colorectal cancer. Based on the results of that study and the FDA decision, the ACS has removed the qualifying statement that the earlier version of the sDNA test is no longer available, and the guideline table now includes an sDNA test with a screening interval of every 3 years, as recommended by the manufacturer. A full evaluation of the evidence supporting the test will be undertaken, similar to all other recommended CRC screening tests, when the overall CRC screening guidelines are updated.

FIT Concerns
We have stated previously that a competent, office-based system for CRC screening should include an offer of both a structural examination (endoscopy or radiologic examinations) or a stool test, because not all individuals have access to colonoscopy or CT colonography, and a significant fraction of the population prefers stool testing over an invasive procedure. The evaluation in recommendations for stool
testing also led to recommendations to only use high-sensitivity stool testing and to no longer use low-sensitivity stool testing approaches, including in-office testing after a DRE or the use of low-sensitivity take-home tests. Because the evidence indicates that adults prefer FITs over guaiac-based tests, there appears to be growing preference for and use of FIT as the option for stool testing.

Manufacturers that intend to market an FOBT (including FIT) in the United States must submit documentation to the FDA demonstrating that their product is “substantially equivalent” to similar products already cleared for use in the United States. As the advantages of FIT have become increasingly apparent in recent years, there has been a rapid expansion of the number of brands of FIT receiving FDA clearance. Marketing products as “FDA-approved” may be perceived by physicians and the public as an indication that every test meeting this standard is an evidence-based, effective approach for CRC screening. Recent studies have raised concerns regarding the clinical validity, accuracy, and efficacy of some FDA-approved FITs. Inaccurate labeling and promotion of these tests misleads physicians and patients and provides a clear potential for harm to the public. In particular, tests that produce false-negative findings because of low sensitivity may lull patients and clinicians into a false sense of security, causing missed opportunities for cancer prevention and early detection, with an end result of increased cases of CRC, later stages of diagnoses, and increased mortality.

The following concerns have been raised regarding FITs: First, essentially all FITs entering the US market are promoted as tools to screen consumers for CRC, but the FDA currently provides clearance for FITs only for “detection of blood (hemoglobin).” Because sensitivity for blood does not necessarily equate to cancer or polyp detection, these products are not required to demonstrate their suitability or accuracy related to the main purpose for which they are marketed and used. Second, most FIT brands marketed in the United States have no peer-reviewed publications or other scientific evidence documenting their performance characteristics in large, average-risk populations. Third, studies comparing different FIT brands have documented substantial variability in the performance characteristics between brands—especially with regard to the sensitivity of these tests for the detection of cancer and advanced adenomas. Fourth, the collection and analysis of multiple stool specimens has been shown to substantially increase the sensitivity of guaiac-based testing both for cancers and for adenomatous polyps. Although some FIT manufacturers recommend collection and analysis of stool specimens from multiple bowel movements (2 or 3), others indicate that complete and effective screening with their brand requires the evaluation of only a single stool specimen.

Although some FIT brands have demonstrated suitable levels of sensitivity and specificity with the analysis of a single stool specimen, no such data are available for several brands that are nonetheless promoted as single-sample tests. The FDA is reviewing its process for premarket clearance of FITs and plans to address these and other issues through updated guidance to manufacturers and consumers.

New National CRC Screening Goal

The unparalleled benefits of CRC screening to prevent disease and to find it early led the National Colorectal Cancer Roundtable (an organization cofounded by the ACS and the CDC) to propose the ambitious goal of 80% of adults ages 50 years and older in the United States being regularly screened for CRC by 2018 (“80% by 2018”). Launched in March 2014, the 80 by 2018 movement asks organizations to commit to play their part in eliminating CRC as a major public health problem and to work toward this shared goal.

Over 150 organizations, including medical professional societies, nonprofits, health plans, government, health departments, survivors, cancer coalitions, and medical practices, have embraced the goal—and the number is growing every day. Achieving an 80% screening rate by 2018 will require the collaboration of many leaders; it cannot be achieved working in isolation. Health care providers, health systems, communities, businesses, community health centers, government, and every day Americans all have a role to play. Details about the 80 by 2018 initiative and guidance about how to join the effort is available online at nccrt.org/about/80-percent-by-2018/.

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 220,800 new cases and 27,540 deaths expected in 2015. Prostate cancer incidence and mortality rates have been declining in both black men and white men since the early 1990s.

The current ACS guideline for the early detection of prostate cancer was published in 2010 and 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) testing after receiving information about the benefits, risks, and uncertainties associated with prostate cancer screening (see 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 who have had a family member (father or brother) diagnosed with prostate cancer before age 65 years, should receive this information beginning at
TABLE 3. Core Elements of the Information to Be Provided to Men to Assist With Their Decision About Prostate Cancer Screening

| Prostate cancer is an important health concern for men |
|--------------------------------------------------------|
| - Screening with the prostate-specific antigen (PSA) blood test alone or with both the PSA and digital rectal examination (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, 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 that men without cancer may have abnormal results and get 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 the PSA or DRE require prostate biopsies to determine whether or not the abnormal findings are cancer; biopsies can be painful, may lead to complications like 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 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

Adapted from Wolf AMD, Wender RC, Etzioni, RB, et al. American Cancer Society guideline for the early detection of prostate cancer: update 2010. CA: A Cancer J Clin. 2010;60:70-98.13

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 either should receive this information directly from their health care providers or should 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 PSA test with or without DRE (DRE is recommended along with PSA for men with hypogonadism because of 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, and 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 for prostate cancer; for PSA levels between 2.5 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.13 The factors that increase the risk of prostate cancer include African American race, a family history of prostate cancer, increasing age, and abnormal DRE. 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 (Table 3).

The ACS arrived at its current prostate cancer early detection recommendations after an extensive review of the evidence related to screening, including 2 long-term, multicenter randomized controlled trials of screening with PSA and DRE—the European Randomized Study of Screening for Prostate Cancer (ERSPC) and the Prostate, Lung, Colorectal, and Ovarian Cancer Screening (PLCO) Trial.97,98 Based on evidence from these randomized controlled trials and other studies, the ACS determined that the balance of benefits and harms related to the use of PSA for prostate cancer early detection still was uncertain and that the existing evidence was insufficient to support a recommendation for or against the routine use of PSA screening.13 This uncertainty regarding the balance between the benefits and harms associated with screening magnified the importance of informed and shared decision making for men faced with the choice of whether to undergo screening. In an effort to address this challenge, the ACS 2010 guideline included specific recommendations for the core information related to screening, treatment, and potential harms that should be shared with men to enable them to make a truly informed decision,13 and this led to the development and promotion of decision aids for men and their clinicians to assist in these decision-making discussions.99

In 2013, the American Urological Association (AUA) issued an updated guideline on prostate cancer early detection testing.100 After a systematic review of over 300 studies, the AUA concluded that, for men ages 55 to 69 years, the benefits associated with screening for prostate cancer with
the PSA test may outweigh the harms. The AUA also concluded that, for men in this age group, the quality of evidence for benefits associated with screening was moderate, whereas the quality of the evidence for harms was high. On this basis, the AUA guideline 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.” 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 younger than 55 years and older than 70 years, the AUA concluded that there was insufficient evidence to conclude that benefits outweighed harms. The guideline recommended against PSA screening in men younger than age 40 years, against routine screening in average-risk men ages 40 to 54 years, and suggested that screening decisions may be individualized for African American men or for men with a strong family history. The AUA does not recommend routine PSA screening in men ages 70 years and older or in men who do not have a 10-year to 15-year life expectancy.100

In 2012, the USPSTF released new recommendations on screening for prostate cancer. Reviewing largely the same evidence used by the ACS and the AUA, the USPSTF concluded with moderate certainty that the harms of PSA testing outweighed the benefits, and they recommended against PSA-based screening for all men.101 The basis for the USPSTF recommendation was their conclusion that there was “convincing evidence” from the multicenter trials that the number of men who avoid dying of prostate cancer because of screening is, at best, very small, whereas the harms related to the treatment of screen-detected cancers were judged to be at least moderate. The USPSTF made no distinction in their recommendations between men at average risk for prostate cancer and men known to be at increased risk of developing and dying from prostate cancer (African American men and men with a family history of prostate cancer). Although the USPSTF acknowledged that African American men and men with a family history are at increased risk for 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.

Although there are clear differences in each organization’s recommendations, guidelines from the ACS, the AUA, and the USPSTF share several 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 those that 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 the 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.

Despite consistent recommendations for shared decision making across multiple guidelines, studies demonstrate that informed and shared decision-making measures continue to be inconsistently used; and, when discussions do take place, the content is highly variable, incomplete, and falls short of accepted standards.102-105 Overtreatment is acknowledged as a major contributor to the morbidity and mortality associated with prostate cancer screening and treatment. Overtreatment of low-grade prostate cancer (traditionally defined as tumors with a Gleason score ≤6) is common. It is estimated that 40% to 50% of US men diagnosed with prostate cancer are candidates for active surveillance (AS), yet one recent study of men ages 66 years and older with low-risk prostate cancer determined that 80% of these men received curative-intent treatment.106 Avoiding treatment in men who are not likely to benefit could markedly alter the balance of benefits and harms of screening with PSA. Several approaches are being investigated that may someday improve this balance.

One way to significantly lower the rate of overtreatment is to increase the use of AS among risk-appropriate men. Several studies have demonstrated low rates of prostate cancer mortality among carefully selected men with low-risk disease who chose no active treatment at the time of prostate cancer diagnosis.107,108 Evidence related to AS and potential roles for this management approach were explored by a National Institutes of Health (NIH) State-of-the-Science panel. The NIH panel concluded that more research is needed to distinguish with confidence low-risk prostate cancers from those that truly need curative therapy. However, based on the strength of the accumulated evidence, the NIH expert panel concluded that “active surveillance has emerged as a viable option that should be offered to all low-risk patients.”109 However, physician use of AS remains highly variable and is suboptimal in many settings.106

An area of related research involves the use of genomic testing to assist with treatment decisions for men diagnosed with prostate cancer. Studies of biopsy-based multigene expression panels suggest that these tests may offer prognostic value regarding the risk of disease recurrence and death from prostate cancer.110,111 The goals of such testing are to improve the accuracy of risk stratification, allowing some men with clinically localized prostate cancer to consider AS with greater confidence and, thus, avoid unnecessary treatment, and also to identify those men who have more aggressive disease and should consider immediate treatment. However, at the present time, no studies have provided definitive evidence that the addition of gene
expression testing to conventional prognostic factors (age, PSA, Gleason score, and tumor stage) either increases the use of AS or lowers prostate cancer morbidity or mortality. The value of these tests in the management of prostate cancer thus remains uncertain.

The combination of conventional anatomical MRI and functional magnet resonance sequences—known as multiparametric MRI (mp-MRI)—is emerging as an intriguing tool for identifying and managing clinically relevant tumors. MRI has been shown to distinguish small, indolent lesions from higher grade, more clinically significant lesions. Studies have found that mp-MRI can identify suspicious areas and obtain targeted biopsies and that using MRI for guidance during biopsies increases the yield of prostate biopsies. A rapidly expanding area of research involves the use of mp-MRI to identify and grade any suspicious prostate lesions followed by 3-dimensional transrectal ultrasound-guided biopsy on the patient in the urologist’s office. Image-fusion technology superimposes real-time transrectal ultrasound images onto the previously obtained MRI of the prostate, enabling the urologist to obtain targeted biopsy samples from suspicious lesions.

Finally, another proposal for reducing unnecessary treatment of low-grade disease has emerged based on the conclusions of influential researchers and clinicians that the current language used to describe and categorize prostate tumors is contributing to overtreatment of the disease. This has resulted in recommendations for renaming Gleason score 6 tumors as noncancer or modification of the Gleason scoring system to emphasize the indolent nature of Gleason 6 tumors. Whether these recommendations will gain traction in the prostate cancer treatment community remains to be seen.

Screening for Endometrial Cancer

In 2015, the ACS estimates that 54,870 women will be diagnosed with endometrial cancer and 10,170 women will die from this disease. In 2001, the ACS concluded that there was insufficient evidence to recommend screening for endometrial cancer in women at average risk or at increased risk because of a history of unopposed estrogen therapy, tamoxifen therapy, late menopause, nulliparity, infertility or failure to ovulate, obesity, diabetes, or hypertension.

The ACS recommends that women at average and increased risk should be informed about the risks and symptoms (in particular, unexpected bleeding and spotting) of endometrial cancer at the onset of menopause and should be strongly encouraged to immediately report these symptoms to their physicians (Table 2). Women at very high risk for endometrial cancer because of 1) known Lynch syndrome genetic mutation carrier status, 2) the 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 with endometrial biopsy for early endometrial cancer detection at age 35 years. The evaluation of endometrial histology with the endometrial biopsy is still the standard for determining the status of the endometrium. 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

Apart from cancers of the skin, lung cancer is the most common cancer affecting both men and women and accounts for 14% of all new diagnoses from cancer, with an estimated 222,200 new cases predicted in 2015. Lung cancer also is the leading cause of death from cancer in men and women, accounting for an estimated 158,040 deaths in 2015, which is approximately 27% of all cancer deaths in the United States. There have been 20 million deaths because of tobacco since 1964, and tobacco use remains the single largest preventable cause of disease and premature death in the United States (Table 4).

Based on results from the National Lung Screening Trial (NLST) and a systematic evidence review, the ACS issued new lung cancer screening guidelines in 2013. ACS lung cancer screening guidelines 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 ages 55 to 74 years (Table 4) and should initiate a discussion about lung cancer screening with patients ages 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 low-dose CT (LDCT) (see Table 5). Adults who choose to be screened should follow the NLST protocol of annual LDCT screening until they reach age 74 years. Chest x-ray should not be used for cancer screening.

When possible, adults who choose to be screened should enter an organized screening program at an institution with expertise in LDCT screening and 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
with the exception that they extend screening to age 80 years, recommendations mostly are similar to the ACS guidelines, beginning in 2015. The USPSTF is not recommended. Referring physicians should help their patients identify appropriate settings with this expertise.

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

Clinicians should not discuss LDCT lung cancer screening with patients who do not meet the recommended criteria (Table 4). When 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); therefore, screening is not recommended.

In 2014, the USPSTF also issued new lung cancer screening recommendations, giving lung cancer screening a “B” rating and opening the door to insurance coverage under the Affordable Care Act beginning in 2015. The USPSTF recommendations mostly are similar to the ACS guidelines, with the exception that they extend screening to age 80 years (vs 74 years), and they also state that screening should be discontinued once a person has not smoked for 15 years. The USPSTF decision to extend screening recommendations to age 80 years versus age 74 years (per NLST criteria) was based on models suggesting that extending screening to age 80 years would result in an overall 14% lung cancer mortality reduction and a 25% mortality reduction in those eligible for screening based on age and smoking history, with a favorable balance of benefits and harms.

At this time, a growing number of organizations have issued similar lung cancer screening guidelines, although some make allowances for risk factors in addition to exposure to tobacco smoke and allow that the presence of an additional risk factor for lung cancer (family history, occupational exposure, etc) justifies beginning screening at an earlier age and among those with less than a 30 pack-year history (Table 6). Overall, most lung cancer screening guidelines are conservative, in that they generally restrict screening eligibility to the NLST protocol criteria and typically emphasize shared decision making and the importance of screening in a high-quality, multidisciplinary settings. One exception to this trend is the American Academy of Family Physicians (AAFP), which criticized the new USPSTF recommendations and the B rating, concluding that, to the contrary,
there was insufficient evidence to recommend for or against LDCT lung cancer screening. The AAFP expressed concern over recommending LDCT screening based on the results of a single randomized controlled trial, harms associated with the high recall rate and with radiation exposure, and uncertainty over the ability of the average imaging facility to deliver the level of quality that was assumed to be common across NLST study sites. These same concerns were raised by the CMS Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) after hearings held on April 30, 2014. In response to 3 broad questions pertaining to confidence in the evidence supporting the efficacy of LDCT screening for lung cancer and the generalizability of the results to the Medicare population, the MEDCAC gave the CMS a vote of low confidence that the CMS should provide coverage of LDCT lung cancer screening for Medicare beneficiaries. These issues also were summarized in a recent commentary advising the

### TABLE 6. Lung Cancer Screening Recommendations From US Organizations

| ORGANIZATION | YEAR | AGE RANGE, y | MINIMUM PACK-YEARS | FORMER SMOKERS: TIME SINCE CESSATION, y | ADDITIONAL RISK FACTORS CONSIDERED | OTHER CONSIDERATIONS |
|--------------|------|--------------|--------------------|------------------------------------------|-----------------------------------|---------------------|
| USPSTF121    | 2014 | 55-80        | ≥30                | ≤15                                      | No                                | Adults who are candidates for screening should engage in a process of shared decision making; once former smokers have reached >15 y since smoking cessation, they should stop screening |
| AAFP123      | 2013 | —            | —                  | —                                        | —                                 | The AAFP concludes that the evidence is insufficient to recommend for or against screening for lung cancer with low-dose computed tomography (LDCT) in persons at high risk for lung cancer based on age and smoking history |
| ACS15        | 2013 | 55-74        | ≥30                | ≤15                                      | No                                | Adults who are candidates for screening should engage in a process of shared decision making; screening only should be done in an institution that supports multidisciplinary teams and has experience with LDCT imaging; recommend against chest radiograph for screening; strong emphasis on smoking cessation for current smokers |
| ACCP125      | 2013 | 55-74        | ≥30                | ≤15                                      | No                                | Screening only should be done in an institution that supports multidisciplinary teams and has experience with LDCT imaging |
| ASCO120      | 2013 | 55-74        | ≥30                | ≤15                                      | No                                | Screening only should be done in an institution that supports multidisciplinary teams and has experience with LDCT imaging |
| ALA124       | 2012 | 55-74        | ≥30                | ≤15                                      | No                                | No history of lung cancer; screening only should be done in an institution that supports multidisciplinary teams and has experience with LDCT imaging; strong emphasis on smoking cessation for current smokers; recommend against chest radiograph for screening; screening centers should develop ethical practices for advertising and promotion |
| NCCN127      | 2012 | 55-74        | ≥30                | ≤15                                      | Yes                               | Adults with one or more risk factors in addition to smoking history (ie, asbestos or other occupational hazards, radon exposure, family history, personal cancer history, COPD, pulmonary fibrosis) may begin screening if they are age 50 y and have a ≥20 pack-year history of smoking |

AAFP, American Academy of Family Physicians; AATS, American Association of Thoracic Surgeons.; ACCP, American College of Chest Physicians; ACS, American Cancer Society; ALA, American Lung Association; ASCO, American Society of Clinical Oncology; COPD, chronic obstructive pulmonary disorder; NCCN, National Comprehensive Cancer Network; USPSTF, United States Preventive Services Task Force.; “Pack-years” is a unit for measuring smoking history and is calculated by multiplying the number of packs of cigarettes smoked per day by the number of years smoked; ie, one pack-year = one pack per day for one year, or two pack-years = two packs per day for one year. All organizations that endorse screening recommend that candidates for screening should be in good health and should not have any life-limiting comorbidity that would preclude curative treatment.
CMS to postpone national coverage. The authors’ opinions emphasized uncertainty about the benefits of routine screening based on evidence from a single large trial, modeling to determine whether those results were even generalizable to the Medicare population, and the potential magnitude of harms (false-positive results, diagnostic evaluations, complications, anxiety, and radiation exposure). Furthermore, they expressed their expectation that the introduction of screening would be largely uncontrolled, ie, there would be significant deviations from recommended protocols leading to screening in lower risk populations. The authors encouraged the CMS to postpone coverage for LDCT lung cancer screening until better data were available.129

Parker and colleagues responded to the MEDCAC decision in the Journal of Thoracic Imaging, arguing that many of the MEDCAC’s concerns were based on a lack of familiarity/understanding of the data, were at variance with the conclusions of systematic evidence reviews and other expert groups, and were inconsistent with the current evidence.130 For example, concerns about the generalizability of the NLST findings to adults ages 65 years and older can be addressed with the NLST data because there were more than 14,000 adults in the study ages 65 years and older. The National Cancer Institute’s Cancer Intervention and Surveillance Modeling Network data also showed not only a favorable balance of benefits to harms by screening high-risk adults ages 65 years and older but also the added advantages of including high-risk adults in good health up to age 80 years.122 Recently, Pinsky and colleagues directly addressed the performance of LDCT screening in the NLST, comparing outcomes in younger (ages 55–64 years) and older (ages 65–74 years) adults with similar smoking histories.131 Although the false-positive rate was slightly higher in the group ages 65 years and older (27.7% vs 22%), this was not unexpected given the higher prevalence of nodules in this age group, and the positive predictive value was higher in the older versus younger adults (4.9% vs 3%).132 The authors observed a similar low rate of complications in both groups among those undergoing invasive procedures (9.8% in the group younger than 65 years and 8.5% in the group ages 65 years and older). Screening appeared to be more efficient in older adults, with a number needed to screen to prevent one death of 245 in the group ages 65 years and older versus 364 in the adults ages 55 to 64 years. In short, the NLST data did not reveal any worrisome differences that distinguished the older adults from the younger adults in terms of general screening outcomes of interest.

There is some legitimacy to concerns about the generalizability of the evidence base and whether the favorable balance of benefits and harms determined by the NLST investigators119 and by 3 separate systematic reviews120,133,134 will also be achieved in screening outside of research settings. However, all organizations that support the implementation of LDCT screening for lung cancer have stressed the importance of quality, and many already have been providing tools and guidance to support the implementation of high-quality screening. For some years, the Lung Cancer Alliance has promoted the adoption of best practices through their National Framework for Lung Cancer Screening and Continuum of Care,135 and the American College of Radiology has developed criteria for designated lung cancer screening centers136 and a standardized LDCT screening report format that describes both findings and recommendations for management.137 In September 2014, 70 organizations cosigned a letter to the CMS outlining a strategy of protocols, infrastructure, and collaboration to address challenges in delivering high-quality lung cancer screening.138 The ACS also has pledged to be a convener of relevant organizations on a regular basis to monitor progress in implementing lung cancer screening. Thus, the current attention promoting high-quality standards in lung cancer screening presently exceeds what has been in place during the implementation phase of other screening tests. It cannot be emphasized too strongly that these challenges are common across all screening tests, and the absence of organized screening in the United States commonly requires voluntary efforts of this kind to ensure the achievement of high standards.

Encouraging the CMS to delay implementation of coverage for better data begs the question of which particular data would instill greater confidence in LDCT screening and when those data are expected. There is no answer to this question in the official record. However, while concerns about generalizability, quality, and harms are speculative and are not entirely supported by the evidence, not implementing screening means that there is no opportunity to observe how screening in the community compares with screening in experimental settings, nor is there any opportunity to gain experience and learn from that experience. The best strategy for ensuring high-quality LDCT screening for lung cancer is for professional societies, payers, and referring physicians to insist on adherence to best practices and guidelines, medical audits to provide feedback to facilities and personnel, and ongoing evaluation of outcomes. Implementing screening not only will result in experience and evolution of best practices but also will prevent some avoidable deaths from lung cancer.

On November 10, 2014, the CMS proposed that the evidence was sufficient to provide coverage to add a lung cancer screening counseling and shared decision making visit, and if appropriate, coverage for annual screening for lung cancer with LDCT. The CMS has outlined appropriate-ness criteria related to beneficiary eligibility, key elements to be included in the counseling and shared decision making visit, and various quality assurance elements pertaining
to the screening process. Following a public comment period, the CMS will make a final decision about coverage in 2015.139

Testing for Early Ovarian Cancer Detection

Although the annual incidence of ovarian cancer is low compared with that of breast cancer and precursor lesions of the cervix, it is the most lethal of the gynecologic cancers.18 Approximately 21,290 women will be diagnosed with ovarian cancer in 2015, and 14,180 will die from the disease.17 Fewer than half of women diagnosed with ovarian cancer survive longer than 5 years; and, although the 5-year survival rate of patients with localized ovarian cancer is greater than 90%, only 15% of all patients are diagnosed with localized disease.18

Screening and diagnostic methods for ovarian cancer include pelvic examination, cancer antigen 125 (CA 125) 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, whereas CA 125 levels are increased in many women with ovarian cancer, only half of early ovarian cancers produce enough CA 125 to cause a positive test, and noncancerous gynecological diseases, other cancers, and other noncancerous influences also can increase the blood levels of CA 125.140-142 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 because of benign disease. As an independent test, ultrasound has shown poor performance in the detection of ovarian cancer in average-risk or high-risk women.143 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.144,145 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.

Currently, no organization recommends screening average-risk women for ovarian cancer. Based principally on the results of the PLCO study, in 2012, the USPSTF recommended against screening for ovarian cancer.

### TABLE 7. Prevalence (%) of Recent Cancer Screening Examinations Among US Adults: National Health Interview Survey, 2013

| SCREENING EXAMINATION | PREVALENCE ± SE, % | ABSOLUTE CHANGE, % |
|-----------------------|--------------------|---------------------|
|                       | 2005*              | 2008*              | 2010*          | 2013   | 2013-2005  | 2013-2008  | 2013-2010 |
| Colorectal cancer:    |                    |                    |                |        |           |           |           |
| Adults aged ≥50 y     |                    |                    |                |        |           |           |           |
| Endoscopyb            | 46.8 ± 0.6         | 53.2 ± 0.6         | 56.4 ± 0.6     | 55.9 ± 0.5 | 9.1        | 2.7        | −0.5      |
| FOBT home kitc        | 12.1 ± 0.4         | 10.0 ± 0.4         | 8.8 ± 0.3      | 7.8 ± 0.3  | −4.3       | −2.2       | −1.0      |
| FOBT or endoscopyd    | 43.1 ± 0.6         | 50.2 ± 0.6         | 59.1 ± 0.6     | 58.6 ± 0.5 | 15.5       | 8.4        | −0.5      |
| Breast cancer:        |                    |                    |                |        |           |           |           |
| Women aged ≥40 y      |                    |                    |                |        |           |           |           |
| Mammograme            | 51.2 ± 0.6         | 53.0 ± 0.7         | 50.8 ± 0.7     | 51.3 ± 0.7 | 0.1        | −1.7       | 0.5       |
| Cervical cancer:      |                    |                    |                |        |           |           |           |
| Women ages 21-65 y    |                    |                    |                |        |           |           |           |
| Pap testf             | 85.2 ± 0.4         | 84.4 ± 0.5         | 83.0 ± 0.5     | 80.8 ± 0.5 | −4.4       | −3.6       | −2.2      |
| Prostate cancer:      |                    |                    |                |        |           |           |           |
| Men aged ≥50 y        |                    |                    |                |        |           |           |           |
| PSAg                  | 40.7 ± 0.9         | 44.1 ± 1.0         | 41.3 ± 0.9     | 34.5 ± 0.8 | −6.2       | −9.6       | −6.8      |

FOBT, fecal occult blood test; NHIS, National Health Interview Survey; Pap, Papanicolaou; PSA, prostate-specific antigen; SE, standard error. *Prevalence estimates for 2005, 2008, and 2010 are shown here to describe differences in the absolute percentage change in cancer screening use with respect to the most recent data for 2013. †Prevalence is weighted and age-adjusted using the 2000 Census. ‡This includes recent sigmoidoscopy within the preceding 5 years or colonoscopy within the preceding 10 years. §This includes recent FOBT using a home test kit performed within the preceding year. ¶This includes recent FOBT using a home test kit performed within the preceding year, OR sigmoidoscopy within the preceding 5 years, OR colonoscopy within the preceding 10 years. ¶¶These were women aged ≥40 years who had a mammogram within the preceding year. ‰These were women with intact uteri who had a Pap test within the preceding 3 years. These were PSA tests within the past year for men who had not been told they had prostate cancer. Source: National Health Interview Survey 2005, 2008, 2010, and 2013 (National Center for Health Statistics, Centers for Disease Control and Prevention, Atlanta, GA).
(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.\(^{146}\) However, the UK Collaborative Trial of Ovarian Cancer Screening (UKCTOCS) 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.\(^{147}\) 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. The UKCTOCS is expected to report results in 2015.

In 1994, an NIH Consensus Panel concluded that women who have had 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), because these women have a 3% chance of being positive for an ovarian cancer hereditary syndrome.\(^{148}\) The panel further advised that women with a known hereditary ovarian cancer syndrome, such as mutations of \textit{BRCA1} and \textit{BRCA2}, including breast-ovarian cancer syndrome, site-specific ovarian cancer syndrome, and hereditary nonpolyposis colon cancer, 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 checkups, offer the potential for health counseling, cancer screening, and case finding.\(^{149,150}\) However, 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.\(^{151}\) A preventive health examination is an opportunity to provide a referral for screening or, if appropriate, to perform the test in the office. Health counseling may include

| TABLE 8. Prevalence (%) of Recent Cancer Screening Examinations Among US Adults by Race and Ethnicity, Health Insurance Coverage, and Education Level: National Health Interview Survey, 2013 |

| SCREENING EXAMINATION | WHITE, NON-HISPANIC | BLACK, NON-HISPANIC | HISPANIC | ASIAN | YES | NO | SOME HIGH SCHOOL OR LESS | HIGH SCHOOL DIPLOMA OR GED | SOME COLLEGE/ASSOCIATE DEGREE | COLLEGE GRADUATE |
|-----------------------|---------------------|---------------------|----------|-------|-----|----|-------------------------|---------------------------|-------------------------|---------------|
| Colorectal cancer:    |                     |                     |          |       |     |    |                         |                           |                         |               |
| Adults aged ≥50 y     | 58.0 ± 0.6          | 56.5 ± 1.4          | 41.5 ± 1.4 | 48.6 ± 2.3 | 58.8 ± 0.6 | 20.3 ± 2.6 | 40.0 ± 1.2 | 52.6 ± 0.9 | 58.0 ± 1.0 | 65.4 ± 0.9 |
| Endoscopy\(^{1}\)    | 7.4 ± 0.3           | 8.5 ± 0.6           | 8.4 ± 0.8  | 10.9 ± 1.3 | 8.1 ± 0.3  | 2.2 ± 0.4  | 6.8 ± 0.7  | 7.3 ± 0.6  | 8.6 ± 0.6  | 7.9 ± 0.5  |
| FOBT or endoscopy\(^{1}\) | 60.5 ± 0.6          | 59.4 ± 1.4          | 44.9 ± 1.4 | 53.2 ± 2.5 | 61.6 ± 0.6 | 21.9 ± 2.7 | 43.1 ± 1.3 | 55.2 ± 0.9 | 60.7 ± 1.0 | 68.0 ± 0.9 |
| Breast cancer:        |                     |                     |          |       |     |    |                         |                           |                         |               |
| Women aged ≥40 y      | 52.1 ± 0.8          | 52.6 ± 1.8          | 45.9 ± 1.7 | 50.3 ± 2.5 | 54.8 ± 0.7 | 22.3 ± 2.3 | 38.7 ± 1.7 | 47.7 ± 1.3 | 51.9 ± 1.2 | 59.5 ± 1.2 |
| Mammogram\(^{1}\)    |                     |                     |          |       |     |    |                         |                           |                         |               |
| Cervical cancer:      |                     |                     |          |       |     |    |                         |                           |                         |               |
| Women ages 21-65 y    | 82.8 ± 0.6          | 82.3 ± 1.1          | 77.1 ± 1.1 | 70.6 ± 2.0 | 85.2 ± 0.5 | 60.6 ± 1.3 | 68.5 ± 1.6 | 75.7 ± 1.1 | 83.4 ± 0.9 | 87.3 ± 0.8 |
| Pap test\(^{1}\)      |                     |                     |          |       |     |    |                         |                           |                         |               |
| Prostate cancer:      |                     |                     |          |       |     |    |                         |                           |                         |               |
| Men aged ≥50 y        | 36.5 ± 0.9          | 32.9 ± 2.2          | 24.3 ± 2.5 | 26.3 ± 3.7 | 36.2 ± 0.8 | 20.2 ± 5.8 | 23.7 ± 1.9 | 28.6 ± 1.4 | 35.7 ± 1.5 | 43.1 ± 1.5 |

FOBT, fecal occult blood test; NHIS, National Health Interview Survey; Pap, Papanicolaou; PSA, prostate-specific antigen; SE, standard error. "This includes recent sigmoidoscopy within the preceding 5 years or colonoscopy within the preceding 10 years. "This includes recent FOBT using a home test kit performed within the preceding year. "This includes recent FOBT using a home test kit performed within the preceding year, OR sigmoidoscopy within the preceding 5 years, OR colonoscopy within the preceding 10 years. These were women aged ≥40 years who had mammogram within the preceding year. "These were women with intact uteri who had a Pap test within the preceding 5 years. Estimates by education are among women ages 25 to 65 years. These were PSA tests within the past year for men who had not been told they had prostate cancer. Source: National Health Interview Survey 2005, 2008, 2010, and 2013 (National Center for Health Statistics, Centers for Disease Control and Prevention, Atlanta, GA).
guidance about smoking cessation, diet, physical activity, and shared decision making about cancer screening (see Table 2).

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

In this update, we provide updated national cancer screening estimates based on the 2013 NHIS, showing the extent of change (percentage increases or decreases) in cancer screening prevalence for 3 time periods (2005-2013, 2008-2013, and 2010-2013). Between 2005 and 2013, CRC screening increased by 15.5%, whereas cervical and prostate cancer screening declined by 4.4% and 6.2%, respectively. There has been little change in breast cancer screening since 2005. In Table 6, we display cancer screening prevalence by race and ethnicity and 2 socioeconomic indicators (having health insurance and educational attainment) that are strongly associated with access to and use of medical/preventive services. In 2013, CRC screening rates ranged from 44.9% in Hispanics to 60.5% in non-Hispanic whites and were nearly 3 times as high among the insured (61.6%) compared with the uninsured (21.9%). Breast cancer screening rates ranged from 45.9% in Hispanic women to 52.6% in non-Hispanic black women and were twice as high among the insured (54.8%) compared with the uninsured (22.3%). Cervical cancer screening rates ranged from 70.6% in Asian women to 82.8% in non-Hispanic white women and were 25% higher among insured women (85.6%) compared with uninsured women (60.6%) (Tables 7, 8).

**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 who are 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 ages 55 to 74 years; and, if they meet general health and smoking history criteria that would have made them eligible for the NLST, then a discussion about lung cancer screening should be initiated. In effect, this is a recommendation for screening that is initiated with risk assessment and should be accompanied with shared decision making.

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

Achieving high rates of cancer screening is a persistent challenge in both organized and nonorganized (aka, opportunistic) systems. In the United States, in which opportunistic screening predominates, fulfilling the cancer screening needs of average-risk 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 average-risk and high-risk adults; 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 to 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.

Many of the challenges related to identifying adults at higher risk, having an opportunity for informed and shared decision making about screening, being reminded about the schedule for regular screening, and ensuring follow-up of abnormal screening tests can be achieved in diverse settings through adherence to 4 proven strategies: 1) ensuring that patients receive a recommendation to screening, 2) developing a screening policy for the practice and enabling staff to contribute to fulfilling reminders and recommendations for screening, 3) having an office reminder system, and 4) having an effective communication system, including the ability to communicate with patients at various stages of contemplation about screening, shared and informed decision making, and enabling other office team members to contribute. The Primary Care Physician’s Evidence-Based Toolkit and Guide, which was developed by the National Colorectal Cancer Roundtable, summarizes the evidence behind each of these principles, and, although it was principally written to improve CRC screening rates, the summary of evidence-based interventions generally is applicable to all cancer screening. The Guide can be downloaded at no cost at cancer.org/colonmd.

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