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## Objectives

After completion of this program, the reader should be able to:

1. Describe the attributes that characterize both the American Cancer Society (ACS) and U.S. Preventive Services Task Force (USPSTF) and the major components of each organization.
2. Compare and contrast the methods used by the ACS and USPSTF when creating cancer screening guidelines.
3. Identify key differences between current ACS and USPSTF recommendations for breast and prostate cancer screening.

## Abstract

Over the past decades, opportunities for pharmacists to be actively involved in screening, education and referral for patients have grown. As these opportunities have increased, so too has the importance of being knowledgeable about the corresponding recommendations and guidelines. At times, various expert organizations may publish contradicting guidelines for a particular disease state or preventive medicine recommendation. This article focuses on the general background and history of two such expert groups, the American Cancer Society and the U.S. Preventive Services Task Force, and compares the two entities' recommendations for breast and prostate cancer as of April 2017. It is critical for pharmacists and pharmacy students to understand these differences as well as their underlying rationales so as to better advise their patients.

## Key Terms

Preventive Health Services; Early Detection of Cancer; Breast Neoplasms; Prostatic Neoplasms

## Introduction

In recent years, there has been a notable shift toward more patient-centered care in pharmacy practice, allowing pharmacists to establish a more active, clinical role with patients. Thus, pharmacists must be aware of the availability of pub-

lished guidelines and recommendations that assist health care professionals in delivering preventive health care interventions.<sup>1</sup> Expert organizations regularly update their recommendations as new data becomes available, and various organizations may publish contradicting guidelines for a particular disease state or preventive medicine recommendation. It is important for health care professionals to be aware of the discrepancies that exist and the rationale for each so that they may be better equipped to care for patients.

One such example involves breast and prostate cancer screening guidelines issued by the American Cancer Society (ACS) and the U.S. Preventive Services Task Force (USPSTF). This article will discuss how both the ACS and USPSTF conduct research to formulate their respective guidelines regarding screening for both breast and prostate cancer and will compare the two entities' recommendations for breast and prostate cancer as of April 2017.

## The American Cancer Society and the U.S. Preventive Services Task Force

The ACS is one example of an organization that plays an important role in preventive medicine. The ACS primarily is concerned with cancer as a health disparity and focuses on different strategies for cancer prevention and management. The organization is devoted to conducting research, promoting cancer prevention and educating patients about cancer with the ultimate goal of eliminating cancer as a major health problem.<sup>2</sup> Specifically, the ACS's mission statement is to "save lives, celebrate lives and lead the fight for a world without cancer."<sup>3</sup> The ACS is one of the most prominent groups today that aids in cancer prevention and management.

In addition to research, the ACS is also responsible for other aspects of cancer management such as providing support services and promoting advocacy. Patients can access many educational materials through the ACS's website. For support, the ACS provides a telephone hotline number that is available for patients to call at any time of the day. The phone number connects patients to cancer specialists with whom they can speak about a variety of topics such as treatment options, medications, clinical trials and screenings.<sup>4</sup> Lastly, the ACS strives to work with lawmakers and government officials in order to pass laws that affect millions of cancer patients. It has its own nonprofit, nonpartisan advocacy committee known as the American Cancer Society Cancer Action Network (ACS CAN) which is responsible for promoting cancer awareness to government policy makers who can hopefully take actions to make "the fight against cancer a top national priority."<sup>5,6</sup>

The ACS has issued guidelines for cancer screening since 1980 based on evidence-based medicine principles.<sup>7</sup> In 1997, the methodology underwent a complete revision, and the ACS protocol developed nine steps to be followed for creating and formalizing guidelines that incorporate the core stages of guideline development, implementation and evaluation. It was thought that these revisions would create a more formalized approach for deciding which screenings to recommend for all types of cancer. The nine steps are outlined in Figure 1.<sup>7</sup>

This formalized method of guideline development led to the creation of several reliable and effective guidelines; however, many individuals felt that the process could be further improved in terms of consistency, transparency, scientific rigor and communications.<sup>7</sup> In 2011, the ACS again updated their process for guideline development following the publication of guideline standards by the Institute of Medicine (IOM).<sup>8</sup> The IOM's eight principles for guideline development are summarized in Table 1. The ACS and USPSTF both changed their process to align with these same principles.<sup>9,10</sup>

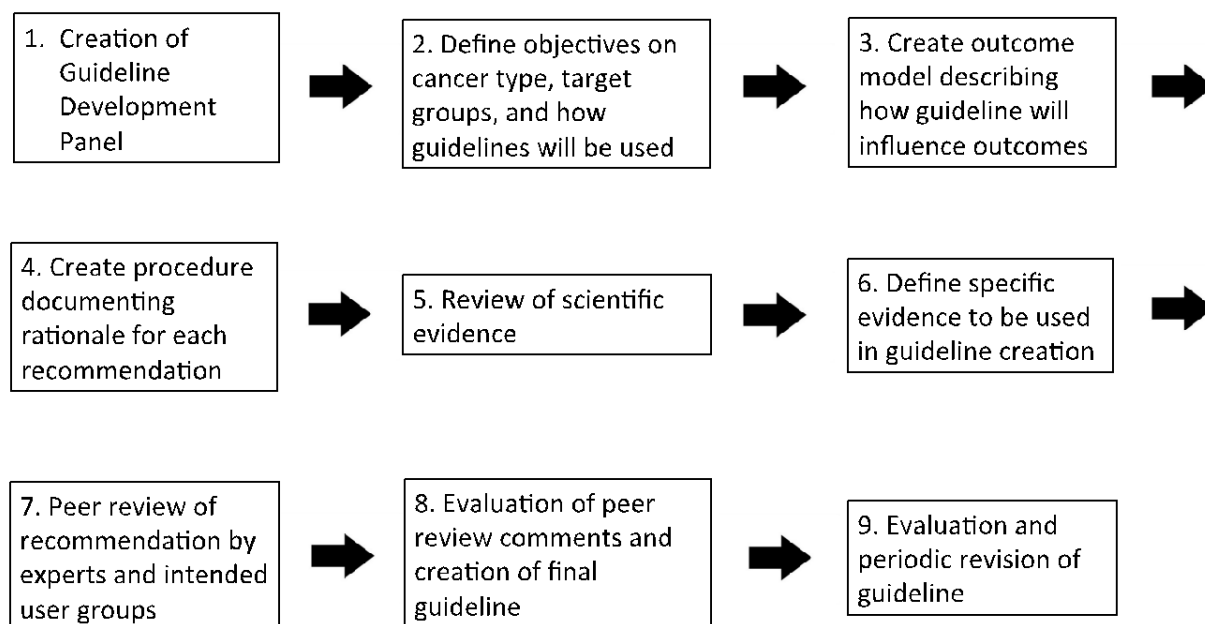
In contrast to the ACS, the USPSTF is, as stated from their website, an "independent organization consisting of a volunteer panel of national experts" whose purpose is to provide "recommendations about clinical preventive services such as screenings, counseling services and preventive medications."<sup>11</sup> The USPSTF's process for creating guidelines for preventive services tends to be somewhat more rigorous than that of the ACS with extra consideration being taken into how primary care physicians help patients decide whether or not they should receive screening. The USPSTF's mission statement consists of the following two components: 1) "Evaluating the benefits and harms of preventive services

in apparently healthy persons on the basis of age, sex and known risk factors for disease," and 2) "Making recommendations about which preventive services should be provided routinely in primary care practice and which should not."<sup>12</sup>

When evaluating a recommendation, the USPSTF categorizes each of its recommendations into one of five different "grades" (A, B, C, D or I).<sup>13</sup> It is recommended that services with a grade of A or B be provided to patients. Grade A indicates that there is high certainty that the net benefit of the service is substantial, while grade B indicates moderate certainty of moderate-to-substantial net benefit. Services classified as grade C are recommended based on individual circumstances. Providing a grade C service to patients should be based on professional judgment and patient preference, as there is moderate certainty of a small net benefit. Grade D indicates that the USPSTF does not recommend the service due to moderate-to-high certainty that the service either has no net benefit or the harms outweigh the benefits. Finally, grade I indicates that current evidence is insufficient to assess benefits versus harms of the service, and patients should understand the uncertainty of benefit before receiving the service.

The definitions of each of these grades have undergone several revisions with the most recent revision taking place in May 2007 and another revision specific to grade C occurring in July 2012.<sup>13</sup> The definitions of each grade correspond to the level of certainty of the "net benefit" of the recommendation as suggested by the USPSTF. Levels of certainty are divided into "high," "moderate" and "low" and are further described and summarized in Table 2. "Certainty" refers to the likelihood that the USPSTF's assessment of the preventive service was correct.

**Figure 1. 1997 Update of the American Cancer Society's Process for Guideline Development.<sup>7</sup>**



**Table 1. Institute of Medicine (IOM) Principles for Guideline Development.<sup>8</sup>**

Standards	IOM Recommendations
Transparency	Process and funding of guideline development should be available to the public.
Conflicts of interest	Commercial, institutional, professional and intellectual conflicts of interest must be openly declared.
Group composition	Multidisciplinary methodological experts, clinicians and patient advocates should be included.
Systematic review of evidence	Guidelines should be based on a systematic literature review that meets standards set by the IOM.
Grading strength of recommendations	Explanation of evidence and reasoning, explanation of benefits and harms and indication of level of confidence in recommendation should be present.
Articulation of recommendations	Recommendations should be clearly stated and actionable.
External review	Draft guidelines should be posted for public comment.
Updating	Guidelines should be updated when new evidence could result in modifying the recommendations.

With each of these grades, it should be noted that a strong emphasis is placed on the balance established between the benefits and harms of the preventive service.<sup>13</sup> For example, if there seem to be slightly more potential benefits than potential harms, the recommendation to use that service will most likely receive at least a grade C. This approach to making a recommendation is part of the reason why the definition for grade C has undergone so many revisions. As stated from their website, the USPSTF's suggestion for practice from a grade C recommendation is to "offer or provide this service for selected patients depending on individual circumstances."<sup>13</sup> A risk-benefit assessment must be conducted, and the overall decision to undergo a screening should be dependent on an individual patient's circumstance. Thus, although it is important for clinicians to examine and evaluate the evidence that either supports or rejects a recommendation, the clinicians must also individualize decision-making

to the specific patient or situation. This consideration of benefits and risks also explains why the USPSTF makes separate recommendations for different populations, including the general adult population, pregnant women and children.

Guidelines created by the USPSTF are population-based. Clinicians can utilize an application known as the Electronic Preventive Services Selector (ePSS) to "identify clinical preventive services that are appropriate for their patients" given patient demographics.<sup>14</sup> The application can be used on multiple platforms such as iPad, Android, iPhone or Windows to identify appropriate preventive services to be offered to specific patients.

The USPSTF follows four major steps when creating its recommendations. The steps can be summarized as follows: 1) topic nomination; 2) draft and final research plans;

**Table 2. U.S. Preventive Services Task Force (USPSTF) Levels of Certainty for Recommendations.<sup>13</sup>**

Level of Certainty	Description
High	Evidence includes consistent results from well-designed, well-conducted studies. Future study results are unlikely to affect conclusions.
Moderate	Although evidence is sufficient to determine effects of preventive service on health outcomes, certainty is affected by multiple factors. Recommendation could change as more information becomes available.
Low	Evidence is insufficient to determine effects of preventive service on health outcomes. More information is needed.

3) draft evidence review and recommendation statement;  
4) final evidence review and recommendation statement. Further details regarding each step of the process are summarized in Figure 2.<sup>15</sup>

Unlike the ACS, the USPSTF is devoted to making recommendations on preventive services for a variety of disease states and not solely for different types of cancer. Both organizations, however, employ the same general approach of using evidence-based medicine in order to formulate their recommendations. So, what exactly makes the USPSTF different from the ACS in terms of how it develops its guidelines? One particular area on which the USPSTF focuses is transparency; the USPSTF places a large emphasis on making it clear to the public exactly how guidelines are developed and the reasons for development. Specifically, the USPSTF has outlined eight main standards explicitly stated for “developing trustworthy clinical practice guidelines” which are modeled after the IOM’s standards for guideline development as described previously.<sup>8,9</sup> While the ACS takes a more targeted approach to developing their guidelines specifically for cancer, the USPSTF exemplifies a more broad, wide-scale approach for guideline creation and focuses on how certain preventive services benefit the patient as a whole with cancer being just one of many possible disease states.

### Breast Cancer Recommendations

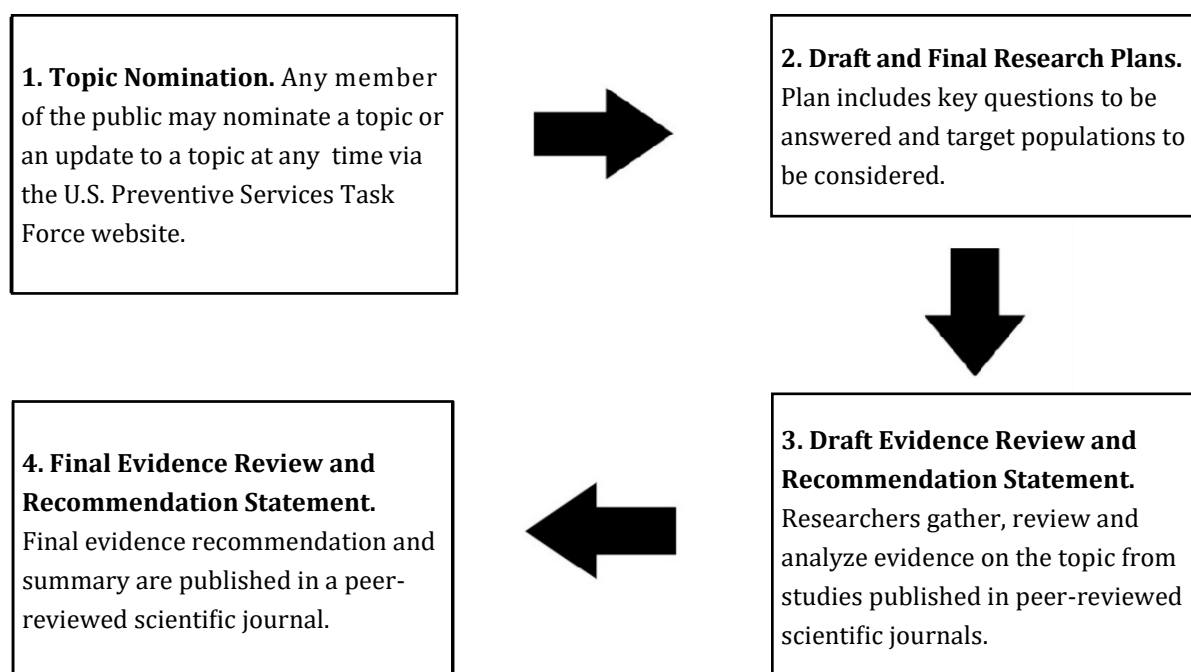
Many different prevention and screening recommendations are available for breast cancer including information about BRCA gene testing, MRI screening, mammography and physical exams as well as different recommendations for women at average risk versus high risk of developing breast cancer. This article focuses on mammography, clinical breast exam (CBE) and breast self-examination (BSE) screening recom-

mendations from the ACS and USPSTF for women at average risk for developing breast cancer.

Breast cancer is relatively common in the United States. One in every eight women in the United States will develop breast cancer in her lifetime.<sup>16</sup> Breast cancer is the second leading cause of cancer death in women in the United States.<sup>17</sup> Mortality in developed countries has decreased over the years; however, it is estimated that 40,290 women died from breast cancer in the United States in 2015. Risk factors for developing breast cancer include female gender, older age and estrogen exposure. Genetics are thought to be a factor in 5 percent to 10 percent of cases.<sup>18</sup> Environmental exposures such as chest radiation therapy or a personal history of abnormal breast biopsies may also increase the risk of developing breast cancer.

Both the ACS and USPSTF have developed guidelines which identify populations that should be screened for breast cancer as well as when and how to screen. Recommendations are specific for average risk and do not address women at increased risk. The remainder of the discussion will focus on recommendations for the average risk woman. Although both groups make similar recommendations, there are a few key differences between the guidelines. The most recent ACS guidelines for women at average risk of developing breast cancer were updated in 2015.<sup>17,19</sup> Per these guidelines, a woman at average risk of developing breast cancer is roughly defined as one without a personal history of breast cancer, chest radiotherapy at a young age or a specific gene that is known to increase the risk of breast cancer such as BRCA. This update was developed using an interdisciplinary team that formulated and addressed five key questions by specifying populations, interventions, comparisons, outcomes, tim-

**Figure 2. U.S. Preventive Services Task Force (USPSTF) Recommendations Development Process.<sup>15</sup>**



ing of outcomes and settings (PICOTS) for each question.<sup>17</sup> For each recommendation the team used Grades of Recommendation, Assessment, Development and Evaluation (GRADE) for assessing the strength of the recommendations. A GRADE of “strong” suggests that most patients would take this course of action, and a clinician would recommend it. “Qualified” suggests the majority of patients would take this course of action, but a risk-benefit analysis may need to be conducted, so clinicians should take the time to discuss options with patients. The evidence used in creating the guidelines consisted of randomized controlled trials, prospective or retrospective cohort studies, case-control or cross sectional studies published in 2000 or later that included 1,000 or more average-risk women, and modeling or simulation studies that allow long-term outcome estimates.

Some of the key questions encompassed the risks and benefits of mammography screening for women of different ages.<sup>17</sup> The ACS guidelines recommend that women with average risk of breast cancer should have the opportunity to start annual screening between the ages of 40 and 44 years (qualified). Women should start mammography screening at the age of 45 years (strong), and continue to be screened annually from the age of 45 to 54 years (qualified). Women 55 years of age and older should be screened annually or biennially (qualified). The guidelines also state that a woman should continue to receive mammograms as long as her overall health is good and her life expectancy is 10 years or more. The ACS did not specify criteria for good health and left the decision to continue screening beyond the age of 74 years up to the provider’s clinical judgment and the patient’s preferences.

In order to determine when to start breast cancer screening, ACS researchers evaluated the five year absolute risk of developing breast cancer for different age groups.<sup>17</sup> They found that the 45 to 49 years of age group had similar risk (0.9 percent) to the 50 to 54 years of age group (1.1 percent), while the 40 to 44 years of age group had lower risk (0.6 percent). Considering the incidence of breast cancer among these groups and the cancer deaths by age at diagnosis, significant differences in terms of mortality benefit of mammography screening and the number of false positives were found between the 40 to 44 years of age group and 45 to 54 years of age groups. Many randomized controlled trials look at 10-year age groups such as 40 to 49 years of age or 50 to 59 years of age and therefore miss some of the differences within those groups. The ACS assessed observational studies in creating these guidelines as well. While observational studies do not provide evidence as strong as randomized controlled trials, these trials found differences between specified ages, most notably between the 40 to 45 years of age group and 45 to 49 years of age group.<sup>20</sup> In a study by Hellquist et al., the researchers observed an 18 percent reduction in mortality for the 40 to 45 years of age group and a 32 percent reduction in the 45 to 49 years of age group with mammography screening. While there are similar false positive findings among women at age 40 years and women at age 50 years, the risk of a false positive mammogram increases when the

screening begins at a younger age due to more screenings over a lifetime.<sup>17</sup> False positives were defined as “recall for additional testing (imaging and/or biopsy) after abnormal CBE or mammography in which further evaluation determines that the initial abnormal finding was not cancer.”

When deciding what time interval to recommend for breast cancer screening, the ACS did not evaluate direct evidence and, rather, relied heavily on observational studies, mathematical models and simulations.<sup>17</sup> Trials have shown that no benefit in mortality was observed unless the screening interval was less than 24 months. While annual screening significantly reduces mortality, it is also associated with increased rates of false positives compared to biennial screening. Biennial screening maintains mortality benefit and has been shown to cut the number of false positives in half compared to annual screenings.<sup>21</sup> In an observational study, White et al. found that there were better outcomes when women from the age of 40 to 49 years had annual screens.<sup>22</sup> This benefit was not seen in women who were 50 years of age or older.

Although no randomized controlled trials have included women aged 75 years or older, modeling and observational studies have shown a reduction in breast cancer mortality related to mammography.<sup>17</sup> This evidence contributed to the ACS’s decision to not define a specific age limit for mammography screening and, rather, define the limit as 10 years or more life expectancy.

The last recommendation in the updated ACS guidelines states that CBE should not be used at any age, as evidence shows that there is a lack of benefit compared to mammography.<sup>17,19</sup> The ACS also states that there is not enough evidence to make a recommendation on routine BSE, which is similar to the 2003 guidelines.

The USPSTF developed guidelines in 2002 for screening women at average risk of breast cancer. Similar to the ACS’s definition, the USPSTF defines “average risk” as a person who is not at increased risk for breast cancer due to an underlying genetic mutation, a history of breast cancer or a history of chest radiation.<sup>18</sup> The USPSTF released a brief update with recommendations in 2009 and 2015.<sup>18,22,23</sup> The 2009 guidelines included evidence from randomized controlled trials, systematic reviews and meta-analyses. These guidelines excluded any trial that did not include mortality as an outcome. The USPSTF used the grading system discussed above in order to classify recommendations.<sup>12</sup>

The most recent update of the USPSTF’s breast cancer screening guidelines recommends that biennial mammography screening be started at age 50 years and continue until age 74 years (grade B).<sup>23</sup> The USPSTF recommends that starting biennial screening before age 50 should be an individual decision, and screening could begin between the ages of 40 and 49 years (grade C). The guidelines also state that there is insufficient evidence to recommend screening in women 75 years of age and older (grade I). The USPSTF recommends against teaching women BSE methods (grade D)

and suggests there is insufficient evidence to make a recommendation for or against CBE beyond 40 years of age (grade I).

The USPSTF concludes that the benefit of biennial screening from age 50 to 74 years is moderate.<sup>1</sup> The mortality benefits increase with age, while the risks associated with screening, such as false positives or detection and treatment of noninvasive cancer, are steady and can decrease with age. The USPSTF suggests the best benefit of screening for breast cancer is achieved for women in their 60s. For women in their 40s, the benefits of screening may outweigh risks; however, the benefit is small. This is why the USPSTF states that screening before age 50 years should be an individual choice. The USPSTF analyzed evidence that suggested benefit was seen if screening was performed every 12 to 33 months.<sup>23</sup> The USPSTF recommends biennial screening because they determined this was likely to have the highest benefit in terms of fewer false positives or other harms, while still maintaining mortality benefit.

Currently, there are no trials comparing CBE without mammography or CBE with mammography compared to mammography alone and, therefore, the USPSTF says that there is not sufficient evidence to make recommendations for or against CBE in the United States (grade I).<sup>18</sup> Trials conducted outside of the United States in regard to teaching women BSE did not show mortality benefit.<sup>24</sup> These trials did illustrate that women may be more likely to have unnecessary biopsies or additional screening done if they performed BSE. Therefore, the USPSTF chose to recommend against teaching women BSE (grade D).<sup>18</sup>

Table 3 highlights some of the differences in breast cancer recommendations between the ACS and USPSTF.<sup>17,23</sup> These differences may stem from how each organization collects and evaluates evidence. For example, the ACS included observational studies that showed a difference between the 40 to 44 years of age group and 45 to 50 years of age group, whereas the USPSTF used randomized controlled trials and other evidence that focused on the 10 year age differences. The ACS is also much more focused on the clinical picture of

the patients and takes things such as cost of therapies and the patient's emotional and physical well-being into consideration in addition to the evidence. The USPSTF, on the other hand, is driven more by evidence, as stated in their guidelines, and does not take into consideration the cost of screening.<sup>17,18</sup>

### Prostate Cancer Recommendations

Prostate cancer is the most common cancer found in men other than skin cancer in the United States.<sup>27</sup> While prostate cancer can be a serious disease, most men diagnosed will not die from it. The ACS and USPSTF both have developed guidelines for men regarding prostate cancer screening.

The ACS uses two specific aims to determine its recommendations: recommendations to providers and patients for screening of average-risk men and recommendations for screening higher-risk men, principally African American men and men with at least one first-degree relative with prostate cancer.<sup>25</sup> These two aims form a recommendation that is most appropriate for each patient population regarding screening tests and frequency of testing that incorporates the patient into the health care decision process.

The ACS guideline for prostate cancer incorporates men into the decision of whether to initiate and continue testing for prostate cancer throughout their life by encouraging patient communication with health care providers.<sup>25</sup> This requires men to have basic background knowledge about prostate cancer. The ACS encourages providers and patients to use screening decision aids to facilitate the process beginning at age 50 years for men with average risk. It is recommended that men with a life expectancy of at least 10 years have an opportunity to make an informed decision about prostate cancer screening. For men at a higher risk, it is recommended that they be provided with the opportunity for an informed decision about screening before the age of 50 years.<sup>25</sup>

When developing guidelines, the ACS looked at two prospective randomized trials: the European Randomized Study of

**Table 3. Differences in Breast Cancer Screening Recommendations from the American Cancer Society (ACS) and the U.S. Preventive Services Task Force (USPSTF).**<sup>17,18,23</sup>

Screening Parameter	ACS Recommendation	USPSTF Recommendation
Age to initiate mammography screening	45 years, give opportunity at 40 years	50 years, may consider for 40 to 49 years
Interval of mammography screening	Annually until age 55 years, then biennially or annually	Biennially
Age to cease mammography screening	None specified, should have a life expectancy of 10 or more years	Not enough evidence for screening beyond 75 years
Clinical breast exam (CBE) recommendation	Not recommended	Insufficient evidence
Breast self-examination (BSE) recommendation	Insufficient evidence	Not recommended



Screening for Prostate Cancer (ERSPC) and the prostate arm of the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial in the United States. The ERSPC and PLCO results did not show a reduction in mortality with screening.<sup>25</sup> While the benefits of prostate cancer screening are uncertain, the problems associated with screening are known. It has been estimated that 23 percent to 42 percent of cancers detected through screening would not have been identified in the absence of screening. This reflects the potential for overdiagnosis, the diagnosis of a disease that will never cause symptoms or death during the patient's expected lifetime, and unnecessary treatment of a disease. It is not possible to predict which men are likely to benefit from treatment of prostate cancer if the cancer is detected through screening. Treatment for prostate cancer can also include many adverse effects such as sexual, urinary and bowel-related complications that could be potentially life-altering.

Evidence shows that periodic testing of prostate-specific antigen (PSA) levels may reduce the likelihood of dying from prostate cancer.<sup>25</sup> However, this must be weighed against the risk incurred from early detection and subsequent treatment, especially in those who would not have experienced effects from the cancer if it had been left undetected. One of the highest reported harms associated with PSA screening is anxiety relating to receiving a positive PSA result, a positive biopsy or a false positive PSA result. Those who receive positive results may also experience adverse or harmful effects from other treatment options such as radiation therapy, hormone replacement therapy and recurrent biopsies.

The ACS concludes that men should be involved in the decision of whether or not to begin prostate cancer screening during their lifetime.<sup>25</sup> Men are encouraged to discuss the importance, potential benefits and risks of various prostate screening options with their providers. If a man decides to undergo prostate cancer screening, the ACS offers the following guidance: the traditional PSA level of 4 ng/mL or greater is considered reasonable to warrant further evaluation; however, it should be acknowledged that there is no true PSA value that distinguishes cancer from noncancer. It is suggested that providers consider the patient individually when making a decision about PSA levels that fall between 2.5 ng/mL and 4 ng/mL, especially in men who have an increased risk for prostate cancer based on nonPSA risk factors. The ACS further recommends that the time between future screenings should be based on the results of the PSA blood test. Patients with PSA levels less than 2.5 ng/mL may only need to be retested every two years, while screening should be done yearly for patients with PSA levels of 2.5 ng/mL or higher.

In contrast to the ACS, the USPSTF currently classifies prostate cancer screening as a grade D recommendation, meaning that the USPSTF recommends against performing prostate screenings.<sup>26</sup> From their research, the USPSTF concluded that evidence illustrates with moderate to high certainty that screening has no benefit or that the harms of screening outweigh the benefits. Past studies have found only a small re-

duction in prostate cancer mortality after 10 to 14 years, thus demonstrating that the benefits of PSA-based screening for prostate cancer do not outweigh the harms.

When determining guidelines, the USPSTF considered the prognosis of prostate cancer.<sup>26</sup> A man living in the United States has a 15.9 percent risk of being diagnosed with prostate cancer during his lifetime. The current lifetime risk of dying as a result of prostate cancer is 2.8 percent, and 70 percent of deaths occur after the age of 75 years. A majority of cases have good prognosis, even without treatment. Furthermore, prostate cancer is rare in men younger than 50 years of age.

Detection of prostate cancer is most commonly done by measuring serum PSA levels. The PSA screening detects asymptomatic cancer in a substantial amount of men, leading to unnecessary treatment as in many cases the tumor would not have progressed or would progress slowly enough such that the patient would remain asymptomatic for his entire life. The rate of overdiagnosis of prostate cancer leading to unnecessary treatment ranges from 17 percent to 50 percent.<sup>26</sup> The rate of overdiagnosis depends on the life expectancy of the patient, any chronic disease states present that would shorten the patient's life span and the number of biopsies taken. As the number of biopsies taken increases, the rate of overdiagnosis increases.

With the risk of over-diagnosis, the USPSTF considered the benefits of early treatment versus the harms when determining their screening recommendations.<sup>26</sup> The primary goal of screening is to reduce the deaths due to the disease and increase the length of life by reducing the development of symptomatic, metastatic disease. Men who have prostate cancer fall into one of three categories: those whose cancer will result in death despite early diagnosis and treatment, those who will have good outcomes in the absence of screening and those for whom early diagnosis and treatment improve survival. Like the ACS, the USPSTF also looked at the PLCO and ERSPC trials when developing their guideline recommendations. Results from the PLCO trial did not show a reduction in prostate cancer mortality, while the ERSPC trial found a reduction in prostate cancer deaths of approximately one death per 1,000 men. The European trial found this reduction in a subgroup of men aged 55 to 69 years in two out of the seven countries included in the study. Statistically significant reduction in mortality was not seen in the other five countries included in the ERSPC trial.

The USPSTF concluded that the benefit of PSA screening and early treatment is minimal with prevention of only zero to one prostate cancer deaths per 1,000 men screened.<sup>26</sup> Due to the minimal benefits seen, the USPSTF also examined the harms related to PSA screening and diagnostic procedures. The PSA tests often produce false positive results (approximately 80 percent) which are associated with negative psychological effects such as constant worry about prostate cancer. False positives also necessitate additional testing which may be accompanied by pain, fever and bleeding. The

**Table 4. Differences in Prostate-Specific Antigen (PSA) Screening Recommendations from the American Cancer Society (ACS) and the U.S. Preventive Services Task Force (USPSTF).<sup>25-27</sup>**

Screening Parameter	ACS Recommendation	USPSTF Recommendation
<b>Age to initiate PSA screening</b>	50 years of age if average risk 45 years of age if high risk 40 years of age if have more than one first-degree relative with early-age prostate cancer	Not recommended
<b>Interval of PSA screening</b>	Yearly if result greater than 2.5 ng/mL	Not recommended
<b>Age to cease PSA screening</b>	None specified; should have a life expectancy of 10 or more years	Not recommended
<b>PSA level recommendation</b>	>4.0 ng/mL reason for further evaluation	Not recommended

USPSTF considered the magnitude of the harms associated with PSA screening as small but influential on the patient's daily life.

Evidence shows that almost 90 percent of men with PSA-detected prostate cancer in the United States undergo early treatment including surgery, radiation or androgen deprivation therapy.<sup>26</sup> Of these men, five out of 100 will die within one month of surgery, and between 10 to 70 men will have serious complications posttreatment but will survive. The evidence that PSA screening leads to overdiagnosis of prostate tumors is of major concern because a man would have remained asymptomatic for the remainder of his life even if he had not been diagnosed with the cancer. Men are therefore being subjected to the harms of treatment for a much longer period of time. As a result, the USPSTF recommends against prostate cancer screening. Table 4 outlines some of the differences in prostate cancer screening recommendations from the USPSTF compared to recommendations from the ACS.

### Conclusion

The ACS and USPSTF are organizations that strive to produce evidence-based recommendations for preventive services that are applicable to the general population as well as specific patient populations. Often, differences in each organization's process for research and evaluation of evidence lead to varying conclusions for guideline recommendations. For breast cancer screening, the ACS and USPSTF make similar recommendations with a few key differences regarding the age to initiate mammography screenings, the age to cease mammography screenings and the interval for mammography screening. For prostate cancer detection, the ACS and USPSTF recommendations differ regarding whether PSA

screening should be performed or not. When offering screening for the early detection of various diseases, it is important that pharmacists and other health care providers review the recommendations published by various groups. In order to appropriately care for patients, health care professionals should understand any discrepancies between the various recommendations and how each organization reached its conclusions so that they may use their clinical judgment to make the best possible decisions for the early detection of disease.

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## Assessment Questions

1. What is the American Cancer Society (ACS) recommended interval of screening for breast cancer in women ages 45 to 50 years?
  - A. Every 24 months
  - B. Every 12 months
  - C. Every 6 months
  - D. Every 36 months
2. Which of these is true regarding breast cancer screening?
  - A. Clinical breast examination (CBE) is recommended by both the ACS and the U.S. Preventive Services Task Force (USPSTF).
  - B. If mammography screening is initiated at the age of 40 years compared to the age of 50 years, there is increased incidence of false positive test results.
  - C. The ACS recommends that women start screening at the age of 50 years, and the USPSTF recommends that women start screening at the age of 45 years.
  - D. Breast self-examination (BSE) technique should be taught to all women starting at the age of 18 years.
3. Which organization classifies its recommendations based on a "grading" scale (A-I) and organizes its level of certainty of the evidence as "high," "medium" or "low"?
  - A. ACS
  - B. USPSTF
4. Both the ACS and the USPSTF try to model their guidelines in line with the standards of which organization?
  - A. Institute of Medicine
  - B. The Joint Commission
  - C. National Academy of Sciences
  - D. American Hospital Association
5. Which organization, in addition to research, deals with other aspects of cancer management such as providing patient support services, encouraging prevention and promoting advocacy?
  - A. ACS
  - B. USPSTF
6. At what age does the ACS recommend to start screening for prostate cancer for the average man?
  - A. 40 years of age
  - B. 45 years of age
  - C. 50 years of age
  - D. The ACS does not recommend screening.
7. At what age does the USPSTF recommend to begin prostate screening for the average man?
  - A. 40 years of age
  - B. 45 years of age
  - C. 50 years of age
  - D. The USPSTF does not recommend screening.
8. According to the ACS, it is recommended that men who have a life expectancy of at least 10 years have an opportunity to make an informed decision about prostate cancer screening.
  - A. True
  - B. False
9. Which patient would be considered to be at average risk of developing breast cancer according to the ACS?
  - A. 42-year-old female with no personal or family history of breast cancer
  - B. 79-year-old female currently in remission who was treated for breast cancer at the age of 50 years
  - C. 23-year-old female known to have the BRCA gene
10. Which of the following statements is correct based on the ACS guidelines for breast cancer screening?
  - A. Women should stop mammography screening at the age of 75 years due to lack of evidence for benefit.
  - B. Women should continue to be screened with mammography as long as they are in good health and have a life expectancy of at least 10 years.
  - C. Women should start biennial screening mammography at the age of 40 years.
  - D. None of the above.



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