OHIO ACADEMY OF FAMILY PHYSICIANS

Breast and Cervical Cancer Practice Improvement Module

Overview

If cancer screening rates could be improved, death from breast and cervical cancers could be decreased (CDC, 2015e). It is estimated that in 2015, approximately 12,900 new cases of invasive cervical cancer will be diagnosed and 4,100 women will die of the disease (Amercian Cancer Society, 2015). In this same year, it is estimated that there will be 231,840 new cases of breast cancer and an estimated 40,290 deaths from the disease (National Cancer Institute, 2015c).

The Affordable Care Act (ACA) will increase access to screening for cervical and breast cancers, especially for underserved and low income women (CDC, 2013). As the United States struggles to bring healthcare costs under control, it is important for physicians to know and incorporate into practice the latest guidelines regarding screening for cervical and breast cancers.

Cervical Cancer

Incidence and Mortality

Since 1980 the incidence of cervical cancer has dropped by 45 percent and mortality by 49 percent (National Cancer Institute, 2014a). However, the disease remains a serious threat to women's health. In the U.S., Hispanic women are most likely to contract cervical cancer (Amercian Cancer Society, 2015) though African American women have the highest mortality rate despite the decline in incidence of the disease (National Cancer Institute, 2014a).

Cervical cancer rarely develops in women younger than 20 years of age (Amercian Cancer Society, 2015). The disease usually manifests itself in midlife, mostly in women younger than 50, though 15 percent of cancer cases have been found in women over 65 (Amercian Cancer Society, 2015). However, It is important to note that cervical cancer rarely occurs over age 65 if the woman was receiving regular screenings (Amercian Cancer Society, 2015).

Cervical cancer incidence and mortality rates vary according to geographic location and socioeconomic status (National Cancer Institute, 2014a). For example, the incidence and mortality rate of cervical cancer are higher in Appalachia Ohio and West Virginia than in other parts of the country (CCHHD, n.d.). Researchers from Ohio State University are conducting transdisciplinary research across the areas of genetics, social networks and tobacco use, the effect of stress on HPV antibodies, and HPV immunization education for parents of young Appalachia girls to understand this phenomenon and thereby reduce cervical cancer incidence and mortality in this region (CCHHD, n.d.).

Risk Factors for the Development of Cervical Cancer

There are several risk factors that play a role in a woman's chance of developing cervical cancer. Some risk factors, like family history, cannot be modified. However, other risk factors,

such as smoking and diet, are modifiable and patients should be counseled as a part of routine care. The most common modifiable risk factor is exposure to the human papilloma virus (HPV).

The prevalence of HPV in the population is so high most people become infected at some point in their lives, although most people will not realize they have acquired the infection (CDC, 2015a, 2015d). While the majority of these infections are asymptomatic, persistent infection can lead to cervical cancer in women and other anogenital cancers, oropharyngeal cancer, and genital warts in women and men (CDC, 2015a; Markowitz et al., 2014). According to the CDC (2015a) each year HPV infection is responsible for 9,000 cancers in men and 17,000 cancers in women.

HPV is the most common sexually transmitted infection in the U.S. A disproportionate burden of infection is seen among adolescents and young adults (Satterwhite et al., 2013). Research has confirmed that the majority of HPV infections occur in women ages 15 to 24 years of age (Hariri et al., 2011; Markowitz et al., 2014; Satterwhite et al., 2013).

Exposure to HPV can occur with any type of intimate sexual contact. It is most commonly spread through oral or vaginal sex. Anyone who is sexually active can acquire the virus, even if they are active with only one person (CDC, 2015c; Markowitz et al., 2014). It may take decades after exposure to the virus for the cancer to manifest itself (Hariri et al., 2015). The HPV vaccine was developed to prevent these HPV related cancers (Hariri et al., 2015).

Screening for Cervical Cancer

Cervical cancer screening will not prevent HPV infection but can prevent most cases of cervical cancer, as well as death attributed to cervical cancer, if women who experience an abnormal screening receive appropriate follow-up care and treatment (Markowitz et al., 2014). The National Cancer Institute states that cervical cancer is preventable and curable when detected in its early stages through screening with a Papanicolaou (Pap) test or co-testing with both the Pap test and a DNA test for HPV (National Cancer Institute, 2014a).

In 2012 the U.S. Preventive Services Task Force (USPSTF), the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), the American Society for Clinical Pathology (ASCP), and the American College of Obstetrics and Gynecology (ACOG) came together to review the evidence related to cervical cancer screening (Markowitz et al., 2014). Based on this evidence all the organizations recommended that screening for cervical cancer should begin at age 21 with cervical cytology (Pap test; conventional or liquid-based). Women between the ages of 21 and 65 should be screened via Pap every three years (Markowitz et al., 2014).

The ACS, ASCCP, and ASCP recommend that women between the ages of 30 and 65 who wish to lengthen the time between tests can be screened for cervical cancer every five years with a combination of Pap and HPV testing (Markowitz et al., 2014). Originally, the USPSTF did not support this recommendation in their draft of the guidelines as they felt there was insufficient evidence to assess the benefit versus the potential for harm (Chustecka, 2011). However,

additional research on the role of HPV testing in cervical cancer became available before the final release of the guidelines. This new evidence prompted the USPSTF to align their recommendations with those of ACP/ASCCP/ASCP (R. Nelson, 2012). The CDC has published a chart [link http://www.cdc.gov/cancer/cervical/pdf/guidelines.pdf] comparing the different agency guidelines.

The USPSTF is currently reviewing its recommendations for cervical cancer screening. The window for public comment on the research plan closed in June 2015 (USPSTF, 2015c). The final plan will provide guidance in the systemic review of the evidence by Evidence-based Practice Center researchers, which will result in the USPSTF Recommendation Statement (USPSTF, 2015c). Table 1 provides a summary of the current USPSTF 2012 recommendations (CDC, 2015b).

Table 1: USPSTF 2012 Guidelines for cervical cancer screening (USPSTF, 2012)*

Population	Recommendation	Grade
Women 21 to 65 (Pap Smear) or 30-65 (in combo with HPV testing)	The USPSTF recommends screening for cervical cancer in women age 21 to 65 years with cytology (Pap smear) every 3 years or, for women age 30 to 65 years who want to lengthen the screening interval, screening with a combination of cytology and human papillomavirus (HPV) testing every 5 years. See the Clinical Considerations for discussion of cytology method, HPV testing, and screening interval.	**A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
Women younger than 30 years, HPV testing	The USPSTF recommends against screening for cervical cancer with HPV testing, alone or in combination with cytology, in women younger than age 30 years.	**D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits
Women younger than 21	The USPSTF recommends against screening for cervical cancer in women younger than age 21 years.	**D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits
Women Older than 65, who	The USPSTF recommends against screening for cervical cancer in women older than age 65 years	**D -** The USPSTF recommends against the service. There is

Population	Recommendation	Grade
have had adequate prior screening	who have had adequate prior screening and are not otherwise at high risk for cervical cancer. See the Clinical Considerations for discussion of adequacy of prior screening and risk factors.	moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits
Women who have had a hysterectomy	The USPSTF recommends against screening for cervical cancer in women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (cervical intraepithelial neoplasia [CIN] grade 2 or 3) or cervical cancer.	**D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits

Immunization to Reduce Risk

There are over 40 types of HPV which can be spread through direct sexual contact (National Cancer Institute, 2015b). HPV spread through sexual contact fall into low-risk HPVs (non-cancer causing) and high-risk HPVs (cancer causing). While over a dozen high-risk HPVs have been identified, HPV types 16 and 18 are responsible for the majority of HPV caused cervical cancers (Lowy & Schiller, 2012).

There are three types of HPV vaccines available in the US – bivalent (HPV2), quadrivalent (HPV4), and 9-valent (9vHPV) (Hariri et al., 2015; Joura et al., 2015; Stokley et al., 2015). Both HPV2 and HPV4 provide protection against HPV types 16 and 18, which are responsible for 70% of cervical cancers (Stokley et al., 2015). HPV4 provides additional protection from HPV types 6 and 11, the cause of 90% of genital warts (CDC, 2010). In February of 2015, ACIP recommended the vaccine 9vHPV, which includes HPV types 6, 11, 16, and 18, and five additional oncogenic types (31, 33, 45, 52, and 58) as one of the three vaccines for use against HPV (Joura et al., 2015; Petrosky et al., 2015).

As of March 2015, ACIP recommends the following immunization schedule for HPV (CDC, 2015f):

- 9vHPV, 4vHPV, or 2vHPV for routine vaccination of females 11 or 12 years of age (can also be given as young as age 9) and females through 26 years of age who have not been vaccinated previously or who have not completed the 3-dose series.
- 9vHPV or 4vHPV for routine vaccination of males 11 or 12 years of age (can also be given as young as age 9) and males through 21 years of age who have not been vaccinated previously or who have not completed the 3-dose series.
- 9vHPV or 4vHPV vaccination for men who have sex with men and immunocompromised men (including those with HIV infection) through age 26 years if not vaccinated previously.

Immunization against HPV to reduce the risk of cervical cancer and other HPV related cancers is a goal of Healthy People 2020. HealthyPeople.gov works with multiple government entities to establish nationwide health goals, and foster improvement in the nation's health priorities by publishing 10-year national health objectives. In December of 2010, the site rolled out Healthy People 2020, a set of goals intended to drive improvement in the nation's health objectives, including increases in adolescent immunization rates and decreases in preventable infectious disease rates (OPDHP, 2015). While progress has been made with some of the established goals, HPV vaccination rates for this age group still fall behind the national goals (Table 2), despite the relative ease of available, reliable resources to support adolescent immunization. In addition, rates vary significantly by region and state, and pockets of under-immunized individuals may pose health risks and challenge our ability to meet national goals (Lieu, Ray, Klein, Chung, & Kulldorff, 2015).

Table 2: Healthy People 2020 targets for adolescent HPV immunization (OPDHP, 2015)

IID-11 Routine Adolescent Vaccination Targets	2008 Baseline	2013 National	2013 Ohio	2020 Target
IID-11.4 Increase the vaccination coverage level of three (3) doses of human papillomavirus (HPV) vaccine for females by age 13 to 15 years	16.6	32.7	25.8	80.0
ID-11.5 Increase the vaccination coverage level of three (3) doses of human papillomavirus (HPV) vaccine for males by age 13 to 15 years	6.9 (Baseline established 2012)	13.5	Unavailable	80.0

Instituting Effective Screening Practices

The Community Preventive Services Task Force (CPSTF) [*]provides recommendations for intervention strategies that increase cancer screening based on systematic reviews of the available evidence. CPSTF (2013) has identified the intervention strategies listed below as effective screening strategies. Table 3 presents the level of evidence for cervical cancer screening.

Client reminders: There is strong evidence which supports sending patients reminders to increase screening rates. These can take the form of an e-email, phone message, letter or postcards. There are additional benefits, supported by the evidence, of combining client reminders with other intervention strategies recommended by the Task Force to promote breast and colon cancer screening.

[*] The Community Preventive Services Task Force and U.S. Preventive Services Task Force (USPSTF) are both expert panels that make prevention-oriented, evidence-based recommendations based on scientific reviews. Their work is complementary, because they focus on different settings.

Small media: Brochures, letters, newsletters, and videos can educate and motivate people to get screened and immunized. These materials can be distributed through community settings or healthcare systems.

One-on-one education: Education by a physician or other healthcare professional can help patients and parents overcome barriers to screening or immunization for cervical cancer. This can be supported by small media and/or patient reminders.

Physician reminders: Adding a note to the patient's medical record can prompt the physician, or other office provider, to talk to the patient about immunization and screening for cervical cancer.

Table 3: Evidence for Client-Oriented Screening Intervention Strategies (CPSTF, 2012)

INTERVENTION STRATEGY	Cervical Cancer
Patient reminders	▲
Patient incentives	●
Small media	▲
Mass media	●
Group education	●
One-on-one education	▲
Reducing structural barriers	●
Reducing patient out-of-pocket costs	●
Provider assessment & feedback	▲
Provider incentives	●
Provider reminder & recall systems	▲
Promoting informed decision making for cancer screening	●

▲ Recommended ● Insufficient Evidence [α]

[α]

▲ **Recommended:** There is strong or sufficient evidence that the intervention strategy is **effective**. This finding is based on the number of studies, how well the studies were designed and carried out, and the consistency and strength of the results.

● **Insufficient Evidence:** There is **not enough evidence** to determine whether the intervention strategy is effective. This does not mean the intervention strategy does not work. There is not enough research available or the results are too inconsistent to make a firm conclusion about the intervention strategy's effectiveness. The Task Force encourages those who use interventions with insufficient evidence to evaluate their efforts.

As there are no approved screening programs for non-cervical HPV-associated cancers, HPV immunization confers an additional benefit for patients against these cancers (Lowy & Schiller, 2012). Even with the HPV vaccine, screening for cervical cancer will remain an important part of women's healthcare, as screening will detect most cervical pre-cancer and cancers not prevented by the current vaccines (Lowy & Schiller, 2012).

Through screening and improved practice patterns, physicians will be able to use every opportunity to recommend HPV vaccine. Answering questions from parents and patients and then offering HPV vaccine will result in a reduction of vaccine-preventable infections and cancers caused by HPV (Stokley et al., 2015).

Breast Cancer

Incidence and Mortality

With the exception of skin cancer, breast cancer is the most commonly diagnosed cancer among women and the second leading cause of cancer death after lung cancer (DeSantis, Ma, Bryan, & Jemal, 2014). Between 2008 and 2012 the number of deaths attributable to breast cancer was 21.9 per 100,000 women (National Cancer Institute, 2015c). The estimated number of deaths due to breast cancer in 2015 is estimated at 40,730 individuals (American Cancer Society, 2015c).

The incidence of breast cancer began to decline in 2000, and then dropped 7 percent from 2002 to 2003 (American Cancer Society, 2015b). Researchers suspect the decline is related, in part, to the decreased use of hormone therapy after menopause as a result of the 2002 published reports from the Women's Health Initiative (WHI), which linked an increased risk of breast cancer and heart disease to hormone replacement therapy (American Cancer Society, 2015b). Based on the most recent data available (2007 to 2011) the incidence of breast cancer remained stable in white women but rose by 0.3 percent per year in black women (American Cancer Society, 2015c). Overall, a U.S. woman has a 12.32 percent chance of developing breast cancer in her lifetime and a 2.69 percent chance of dying from the disease (National Cancer Institute, 2014b).

Risk Factors for Breast Cancer

A woman's level of breast cancer risk depends on multiple factors, some modifiable and some not. Age is the most significant non-modifiable risk factor for women (National Cancer Institute, 2012). The older a women becomes, the greater her chance of developing breast cancer (Table 4) (National Cancer Institute, 2012). Other non-modifiable risk factors include genetic alterations (BRCA1/BRCA2), mammographic breast density, race, and family history (National Cancer Institute, 2012).

Table 4: SEEER[1] Estimates of Developing Breast Cancer by Age (National Cancer Institute, 2012)

Age	Percent	Per Population
30	0.44	1 in 227
40	1.47	1 in 68
50	2.38	1 in 42
60	3.56	1 in 28
70	3.82	1 in 26

Reproductive factors also play a role in breast cancer risk. Age at menarche, parity, age at first birth, breastfeeding, oral contraceptive use, menopausal status, and menopausal hormone therapy influence the amount of time a woman is exposed to circulating estrogen (Endogenous Hormones and Breast Cancer Collaborative Group, 2013; H. D. Nelson et al., 2012). Data collected from studies on breast cancer and hormones in postmenopausal women show a positive association between circulating levels of estrogens and breast cancer risk (Endogenous Hormones and Breast Cancer Collaborative Group, 2002; Kaaks et al., 2005; Zhang, Tworoger, Eliassen, & Hankinson, 2013). It is not yet known if the association is causal, but researchers have determined the existence of plausible biological mechanisms that could explain this effect (Endogenous Hormones and Breast Cancer Collaborative Group, 2013).

Other factors that influence a woman's risk of breast cancer are lifestyle related. These include alcohol consumption, physical activity, and body weight (National Cancer Institute, 2012). Data analysis from the Nurse's Health Study (NHS) has shown that maintaining a healthy weight is the most important modifiable risk factor for the prevention of postmenopausal breast cancer (Tamimi et al., 2014).

Risk Classification

Understanding a woman's level of risk for breast cancer should be obtained through a discussion of personal and family history. Based on history and biopsy results, Hollingsworth et al., (2004) identified three categories of risk for the development of breast cancer. These categories are average risk, elevated/high risk, and very high risk.

Average risk: Women at average risk for breast cancer have no greater than a 1.5-fold relative risk (RR) of developing breast cancer, with a 5-year Gail[2] risk of less than 1.7 percent.

Elevated risk: Women in this category have a relative risk of between 1.5 fold to 4-fold/5-fold for the development of breast cancer.

[1] National Cancer Institute's Surveillance, Epidemiology, and End Results program

[2] The Breast Cancer Risk Assessment Tool is based on a statistical model known as the "Gail model," which is named after Dr. Mitchell Gail, Senior Investigator in the Biostatistics Branch of NCI's Division of Cancer Epidemiology and Genetics. The model uses a woman's own personal medical history, her own reproductive history, and the history of breast cancer among her first-degree relatives (mother, sisters, daughters) to estimate her risk of developing invasive breast cancer over specific periods of time.

Very high risk: Four groups of women fall into the very high risk category: 1) those with a personal history of invasive breast cancer, ductal carcinoma in situ, or lobular carcinoma, 2) women with a personal history of cellular atypia on ductal lavage, nipple aspiration fluid or fine-needle aspiration or breast biopsy showing atypical ductal or lobular hyperplasia and have a first-degree relative with breast cancer, 3) women with a known BRCA 1 or BRCA 2 germline mutation, and 4) women who have undergone breast irradiation before age 20.

Screening Recommendations

The goal of breast cancer screening is to find a lump before it can be felt allowing the cancer to be treated earlier when it is more likely curable (Gøtzsche & Jørgensen, 2013). The U.S. Preventive Services Task Force (USPSTF), the American Cancer Society (ACS), and the American College of Obstetricians and Gynecologists (ACOG) all recommend screening mammograms for breast cancer. However, these recommendations are in a state of flux and a lack of consensus on when to screen exists. As the evidence regarding the benefits and risks of breast cancer screening mounts so do the conflicted feelings of physicians and their patients.

Based on data from simulation models and randomized controlled trials, it is generally agreed that mammography screening can reduce mortality from breast cancer. In one systematic review, screening reduced breast cancer mortality by 15 to 32 percent in women between age 40 and 60, respectively (Pace & Keating, 2014). However, this same review also showed the cumulative risk of false-positive results at approximately 61 percent. A Cochran Review of seven large clinical trials involving over 600,000 women between the ages of 39 and 74 found that some studies – those with the most reliable information – revealed that screening did not reduce breast cancer mortality, while more biased studies found that screening did reduce mortality from breast cancer (Gøtzsche & Jørgensen, 2013).

The controversy surrounding mammography screening centers on a risk versus benefit model. Some women who go through screening will receive a diagnosis of cancer. Breast cancer is a heterogeneous disease – some tumors grow rapidly, some slowly, and others not at all. Mammography cannot differentiate between breast cancer that is fatal and that which is harmless (Elmore & Fletcher, 2012). As a result, women who receive a breast cancer diagnosis, regardless of the type of breast cancer, are more likely to have lumps or breasts removed and to receive unnecessary radiotherapy (Gøtzsche & Jørgensen, 2013).

In their review of the literature Gøtzsche and Jørgensen (2013) assumed that screening reduces breast cancer mortality by 15 percent after 13 years of follow-up. They estimated the level of overdiagnosis and overtreatment at 30 percent. Gøtzsche and Jørgensen (2013) concluded that for every 2000 women screened for breast cancer over a 10 year period, one woman will avoid dying from the disease and 10 healthy women – who would not have been diagnosed if not for screening – will receive unnecessary treatment. Additionally, 200 women will undergo psychological distress for years as a result of false-positive results.

These findings are supported by an analysis of studies by the National Cancer Institute (NCI) (2015a). Based upon solid evidence from randomized clinical trials (RTCs) and population-

based evidence the NCI concluded that screening mammography may lead to a decrease in breast cancer mortality. However NCI also concluded that the magnitude of the benefit, at present, is uncertain. Also based on solid evidence, NCI (2015a) concluded that screening mammography may lead to the following harms:

Overdiagnosis and resulting treatment of insignificant cancers: Through an analysis of descriptive population-based comparisons, autopsy series, and series of mammary reduction specimens, NCI concluded screening can result in a diagnosis of cancers that would never have caused symptoms or death during the woman's lifetime, thereby exposing the woman to the risks of therapy (e.g., surgical deformity, radiation therapy, chemotherapy).

False-positives with additional testing and anxiety: Based on descriptive population-based studies, NCI concluded that on average 10 percent of women who undergo screening will be recalled for further testing. Only five of the 100 women recalled will have cancer. Of U.S. women screened annually over 10 years, approximately 50 percent will experience a false-positive, with between seven to 17 percent undergoing biopsies.

False negatives with false sense of security and potential delay in cancer diagnosis: NCI has concluded, based on descriptive population-based studies that six to 46 percent of women with invasive cancer will have negative mammograms. This is especially true if they are young, have dense breasts, or have mucinous, lobular, or rapidly growing cancers.

Radiation-induced breast cancer: Through an analysis of descriptive population-based studies, NCI found that breast cancer can be caused from radiation-induced mutations, especially if a woman is exposed before age 30 and if the radiation is delivered in high doses (e.g., mantle radiation therapy for Hodgkin disease). In theory, in women aged 40 to 80, annual mammograms may cause up to one breast cancer per 1,000 women.

There is no evidence that clinical breast exam or breast self-examination (BSE) reduces breast cancer mortality, and this exam is no longer recommended (ACOG, 2015; American Cancer Society, 2015a; USPSTF, 2009). All three agencies do state that women should be aware of their own breasts and report any abnormalities to their physician

United States Preventive Services Task Force (USPSTF) Recommendations for Breast Cancer Screening

As stated earlier, USPSTF, ACS, and ACOG guidelines all recommend breast cancer screening. For the purposes of this module the USPSTF recommendations for breast cancer screening will be the applicable guideline. As of the publication date of this module these recommendations are still in draft form. An update will be provided when the draft guidelines are accepted.

The USPSTF (2015b) recommendations (Table 5) for breast cancer screening are applicable to women age 40 and older who are asymptomatic, do not have pre-existing breast cancer or a previously diagnosed high-risk breast lesion, and who are not at high risk for breast cancer due

to a known underlying genetic mutation (BRCA mutation or other familial breast cancer syndrome) or a history of chest radiation at a young age.

Table 5: Draft: Recommendation Summary (USPSTF, 2015b)

Population	Recommendation	Grade [3]
Women ages 50 to 74 years	The USPSTF recommends biennial screening mammography for women ages 50 to 74 years.	B
Women ages 40 to 49 years	The decision to start screening mammography in women prior to age 50 years should be an individual one. Women who place a higher value on the potential benefit than the potential harms may choose to begin biennial screening between the ages of 40 and 49 years. • For women at average risk for breast cancer, most of the benefit of mammography will result from biennial screening during ages 50 to 74 years. Of all age groups, women ages 60 to 69 years are most likely to avoid a breast cancer death through mammography screening. Screening mammography in women ages 40 to 49 years may reduce the risk of dying of breast cancer, but the number of deaths averted is much smaller than in older women and the number of false-positive tests and unnecessary biopsies are larger. • All women undergoing regular screening mammography are at risk for the diagnosis and treatment of noninvasive and invasive breast cancer that would otherwise not have become a threat to her health, or even apparent, during her lifetime (known as “overdiagnosis”). This risk is predicted to be increased when beginning regular mammography before age 50 years. • Women with a parent, sibling, or child with breast cancer may benefit more than average-risk women from beginning screening between the ages of 40 and 49 years.	C

[3] USPSTF Level of Evidence -- **B:** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C:** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. **I:** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Population	Recommendation	Grade [3]
	The Clinical Considerations section contains more information on implementation of the C recommendation.	
Women age 75 years and older	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women age 75 years and older.	I
All women	The USPSTF concludes that the current evidence is insufficient to assess the benefits and harms of tomosynthesis (3-D mammography) as a screening modality for breast cancer.	I
Women with dense breasts	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of adjunctive screening for breast cancer using breast ultrasound, magnetic resonance imaging (MRI), tomosynthesis, or other modalities in women identified to have dense breasts on an otherwise negative screening mammogram.	I

Explaining Risk and New Screening Guidelines

One challenge for family physicians is how to effectively communicate what the new screening guidelines mean on an individual level. Talking with patients about the risk of overdiagnosis and overtreatment of breast cancer requires great care to prevent fear or anger on the part of the patient, however just because the conversation may be difficult is no reason not to have it (Elmore & Fletcher, 2012). Discussion with patients about mammography screening should center on the harm versus the modest benefit and the uncertainty surrounding the relevant weight of the harm/benefit for each individual patient (Pace & Keating, 2014). Women deserve to be fully informed when making decisions about breast cancer screening and physicians are charged with promoting informed screening decisions while taking into consideration the patient's values and preferences (Elmore & Fletcher, 2012; Pace & Keating, 2014). Pace and Keating (2014) provided guidance on discussing screening mammograms with patients in order to promote informed decision making. These discussion points are summarized below.

*Discussion points for screening mammography (*Pace & Keating, 2014):

1. Mammography is not a perfect screening test
    a. Not all cancers will be found
    b. Regardless of whether or not a woman is screened some women will still die
    c. Though cancer may be found, most diagnosed women will be cured regardless of whether or not the cancer was discovered by mammography
    d. Overdiagnosis may occur when some cancers are found that would never have caused problems

e. False-positive results may occur because of a non-cancerous abnormality

2. Benefits of mammography
    a. The number of women who die from breast cancer is decreased through mammography; however the benefit is greatest for those who are at a higher risk because of age or other risk factors.
    b. The number of lives saved varies by age. Based on the best evidence available uncertainty remains about how exact this number is.
    c. For every 10,000 women who undergo screening mammography for the next 10 years, the number of lives saved by age is estimated at:
        - 5 of 10 000 women aged 40 to 49 years
        - 10 of 10 000 women aged 50 to 59 years
        - 42 of 10 000 women aged 60 to 69 years
    d. If a woman's risk for breast cancer is higher than the average patient, she may benefit more from a mammogram.

3. Harms of mammography
    a. More than 50 percent of women who undergo mammography screening for 10 years will have a false-positive result. Of those with a false-positive result, 20 percent will need a biopsy.
    b. If a woman decides to have a mammogram, it is expected that she will have at least one false-positive result where she will be called back for additional imaging and perhaps a biopsy. Most times, nothing is found.
    c. Regular screening may result in overdiagnosis when the results reveal a noninvasive condition (i.e., ductal carcinoma in situ) or an invasive cancer that would never cause a problem. As it is not possible to tell which cancers will cause a problem and which ones won't, they are treated the same as all cancers, which leads to unnecessary treatment for some women.

4. Decision making
    a. It is recommended that women aged 50-74 have a screening mammography every two years
    b. The benefit of starting screening earlier depends on the patient's individual risk factors, values, and preferences.
    c. The feeling of having a false-positive result from screening or being diagnosed with and treated for cancer that would never have caused a problem is different for each woman. Encourage each patient to consider what the experience may mean for her.
    d. Encourage your patient to consider how she might feel if she decides to forgo screening and she is later diagnosed with breast cancer, even when it is likely the mammography would have made little difference.

Conclusion

The USPSTF (2015b) bases its recommendations upon evidence of both the benefits and harms of a service, and an assessment of the balance. The USPSTF recognizes that clinical decisions

involve more considerations than evidence alone and recommends that physicians understand the evidence but individualize decision making to the specific patient or situation.

The USPSTF states the decision to start biennial mammography screening before 50 years of age should be an individual one and should be made with consideration to the patient's values (Pace & Keating, 2014). The USPSTF (2015a) states that "Women deserve to be aware of what the science says so they can make the best choice for themselves, together with their doctor."

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