compliance

Choosing Wisely®Oncology Primer

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irst announced in December 2011. Choosing Wisely (ChoosingWisely. org) is part of a multi-year effort led by the ABIM (American Board of Internal Medicine) Foundation to support and engage physicians in being better stewards of healthcare resources. The overall goal is to help physicians and patients engage in conversations to reduce overuse of tests and procedures and help patients make smart and effective care choices. Participating specialty societies are working with the ABIM Foundation and Consumer Reports to share the lists widely with their members and convene discussions about the physician's role in helping patients make wise care choices.

However, the frequency with which physicians provide tests and procedures on the Choosing Wisely questionable list has not changed much in the years since the start of this national campaign, according to a study published in JAMA Internal Medicine.1 An accompanying editorial co-authored by Cary P. Gross, MD, of Yale University School of Medicine, and David H. Howard, PhD, of Emory University in Atlanta, asserted that clinical decision-making is just one piece of the puzzle when it comes to reducing unnecessary tests or treatments, and that more targeted research, including comparative effectiveness, would help by definitely determining which treatments or services were low-value.

Following are recommendations from several specialty societies; note that even if a cancer program is focused only on one treatment modality, all recommendations should be reviewed. For example, there are

more items relating to imaging of cancer patients in the ASCO recommendations than in other specialty references.

AAHPM Recommendations

The American Academy of Hospice and Palliative Medicine (AAHPM) is the professional organization for physicians specializing in hospice and palliative medicine, nurses, and other healthcare providers. The Academy's core mission is to expand patient and family access to high-quality palliative care and advance the discipline of hospice and palliative medicine through professional education and training, development of a specialist workforce, support for clinical practice standards, and research and public policy. The core purpose of the Academy is to improve the care of patients with life-threatening or serious conditions through the advancement of hospice and palliative medicine. AAHPM offers the following recommendations:2

- 1. Don't delay palliative care for a patient with serious illness who has physical, psychological, social, or spiritual distress because they are pursuing disease-directed treatment.

 Numerous studies, including randomized trials, demonstrate that palliative care improves pain and symptom control, improves family satisfaction with care, and reduces costs. Palliative care does not accelerate death and may prolong life in selected populations.
- 2. Don't recommend more than a single fraction of palliative radiation for an

uncomplicated painful bone metastasis.

A single fraction of radiation to a previously un-irradiated peripheral bone or vertebral metastasis provides comparable pain relief and morbidity compared to multiple-fraction regimens, while optimizing patient and caregiver convenience. Although it results in a higher incidence of later need for retreatment, the decreased patient burden usually outweighs any considerations of long-term effectiveness for those with a limited life expectancy.

 Don't use topical lorazepam, diphenhydramine, or haloperidol gel for nausea.

Topical drugs, such as topical nonsteroidal anti-inflammatory drugs for local arthritis symptoms, can be safe and effective. However, whereas topical gels are commonly prescribed in hospice practice, anti-nausea gels have not proven effective in any large, welldesigned, or placebo-controlled trials. The active ingredients in the gels are not absorbed to systemic levels that could be effective; only diphenhydramine is absorbed via the skin, and then only after several hours and erratically at subtherapeutic levels. It is therefore not appropriate for "as needed" use. The use of agents given via inappropriate routes may delay or prevent the use of more effective interventions.

ASCO Recommendations

In April 2012 the American Society of Clinical Oncology (ASCO) released its initial list of

five key opportunities to improve care and reduce cost for services that are commonly ordered but may not always be appropriate as part of the national Choosing Wisely campaign.³ According to ASCO, these initial five practices are in common use despite the absence of evidence supporting their clinical value:4

- Don't use cancer-directed therapy for solid tumor patients with the following characteristics: low performance status (3 or 4), no benefit from prior evidence-based interventions, not eligible for a clinical trial, and no strong evidence supporting the clinical value of further anti-cancer treatment. Studies show that cancer-directed treatments are likely to be ineffective for solid tumor patients who meet the above stated criteria. Exceptions include patients with functional limitations due to other conditions resulting in a low performance status or those with disease characteristics (e.g., mutations) that suggest a likelihood of response to therapy. Implementation of this approach should be accompanied with appropriate palliative and supportive care.
- 2. Don't perform PET, CT, and radionuclide bone scans in the staging of early prostate cancer at low risk for metastasis.

Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival. Evidence does not support the use of these scans for staging of newly diagnosed low-grade carcinoma of the prostate (Stage Tic/T2a, prostate-specific antigen [PSA] <10 ng/ml, Gleason score less than or equal to 6) with low risk of distant metastasis. Unnecessary imaging can lead to harm through unnecessary

invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

- 3. Don't perform PET, CT, and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis.
 - Imaging with PET, CT, or radionuclide bone scans can be useful in the staging of specific cancer types. However, these tests are often used in the staging evaluation of low-risk cancers, despite a lack of evidence suggesting they improve detection of metastatic disease or survival. In breast cancer, for example, there is a lack of evidence demonstrating a benefit for the use of PET. CT. or radionuclide bone scans in asymptomatic individuals with newly identified ductal carcinoma in situ (DCIS), or clinical stage I or stage II disease. Unnecessary imaging can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.
- 4. Don't perform surveillance testing (biomarkers) or imaging (PET, CT, and radionuclide bone scans) for asymptomatic individuals who have been treated for breast cancer with curative intent.

Surveillance testing with serum tumor markers or imaging has been shown to have clinical value for certain cancers (e.g., colorectal). However, for breast cancer that has been treated with curative intent, several studies have shown there is no benefit from routine imaging or serial measurement of serum tumor markers in asymptomatic patients. False-positive tests can lead to harm through unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and misdiagnosis.

5. Don't use white cell stimulating factors for primary prevention of febrile neutropenia for patients with

less than 20 percent risk for this complication.

ASCO guidelines recommend using white cell stimulating factors when the risk of febrile neutropenia, secondary to a recommended chemotherapy regimen, is approximately 20 percent and equally effective treatment programs that do not require white cell stimulating factors are unavailable. Exceptions should be made when using regimens that have a lower chance of causing febrile neutropenia if it is determined that the patient is at high risk for this complication (due to age, medical history, or disease characteristics).

In October 2013, ASCO announced its second list of five opportunities to improve the quality and value of cancer care. These additional recommendations include:

1. Don't give patients starting on a chemotherapy regimen that has a low or moderate risk of causing nausea and vomiting antiemetic drugs intended for use with a regimen that has a high risk of causing nausea and vomiting.

Over the past several years, a large number of effective drugs with fewer side effects have been developed to prevent nausea and vomiting from chemotherapy. When successful, these medications can help patients avoid spending time in the hospital, improve quality of life, and lead to fewer changes in the chemotherapy regimen. Oncologists customarily use different antiemetic drugs depending on the likelihood (low, moderate, or high) for a particular chemotherapy program to cause nausea and vomiting. For chemotherapy programs that are likely to produce severe and persistent nausea and vomiting, there are new agents that can prevent this side effect. However, these drugs are very expensive and not devoid of side effects. For this reason, these drugs should be used only when the chemotherapy drugs have a high likelihood of causing severe or persistent

nausea and vomiting. When using chemotherapy that is less likely to cause nausea and vomiting, there are other effective drugs available at a lower cost.

2. Don't use combination chemotherapy (multiple drugs) instead of chemotherapy with one drug when treating an individual for metastatic breast cancer unless the patient needs a rapid response to relieve tumorrelated symptoms.

Although chemotherapy with multiple drugs, or combination chemotherapy, for metastatic breast cancer may slow tumor growth for a somewhat longer time than occurs when treating with a single agent, use of combination chemotherapy has not been shown to increase overall survival. In fact, the trade-offs of more frequent and severe side effects may have a net effect of worsening a patient's quality of life, necessitating a reduction in the dose of chemotherapy. Combination chemotherapy may be useful and worth the risk of more side effects in situations in which the cancer burden must be reduced quickly because it is causing significant symptoms or is life threatening. As a general rule, however, giving effective drugs one at a time lowers the risk of side effects, may improve a patient's quality of life, and does not typically compromise survival.

3. Avoid using PET or PET-CT scanning as part of routine follow-up care to monitor for a cancer recurrence in asymptomatic patients who have finished initial treatment to eliminate the cancer unless there is high-level evidence that such imaging will change the outcome.

PET and PET-CT are used to diagnose, stage, and monitor how well treatment is working. Available evidence from clinical studies suggests that using these tests to monitor for recurrence does not improve outcomes and therefore generally is not recommended for this purpose. Falsepositive tests can lead to unnecessary invasive procedures, over-treatment, unnecessary radiation exposure, and incorrect diagnoses. Until high-level evidence demonstrates that routine surveillance with PET or PET-CT scans helps prolong life or promote well-being after treatment for a specific type of cancer, this practice should not be done.

4. Don't perform PSA testing for prostate cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years. Since PSA levels in the blood have been linked with prostate cancer, many doctors have used repeated PSA tests in the hope of findina "early" prostate cancer in men with no symptoms of the disease.

Unfortunately, PSA is not as useful for screening as many have hoped because many men with prostate cancer do not have high PSA levels, and other conditions that are not cancer (such as benign prostate hyperplasia) can also increase PSA levels. Research has shown that men who receive PSA testing are less likely to die specifically from prostate cancer. However, when accounting for deaths from all causes, no lives are saved, meaning that men who receive PSA screening have not been shown to live longer than men who do not have PSA screening. Men with medical conditions that limit their life expectancy to less than 10 years are unlikely to benefit from PSA screening as their probability of dying from the underlying medical problem is greater than the chance of dying from asymptomatic prostate cancer.

5. Don't use a targeted therapy intended for use against a specific genetic aberration unless a patient's tumor cells have a specific biomarker that predicts an effective response to the targeted therapy.

Unlike chemotherapy, targeted therapy can significantly benefit people with

cancer because it can target specific gene products, i.e., proteins that cancer cells use to grow and spread, while causing little or no harm to healthy cells. Patients who are most likely to benefit from targeted therapy are those who have a specific biomarker in their tumor cells that indicates the presence or absence of a specific gene alteration that makes the tumor cells susceptible to the targeted agent. Compared to chemotherapy, the cost of targeted therapy is generally higher, as these treatments are newer, more expensive to produce, and under patent protection. In addition, like all anti-cancer therapies, there are risks to using targeted agents when there is no evidence to support their use because of the potential for serious side effects or reduced efficacy compared with other treatment options.

ASTRO Recommendations

In September 2013, the American Society for Radiation Oncology (ASTRO) released its first list of five radiation oncology-specific treatments that are commonly ordered but may not always be appropriate as part of the national Choosing Wisely campaign.5 The list identifies five targeted treatment options that ASTRO recommends for detailed patient-physician discussion before being prescribed:

1. Don't initiate whole breast radiotherapy as a part of breast conservation therapy in women age \geq 50 with early stage invasive breast cancer without considering shorter treatment schedules.

Whole breast radiotherapy decreases local recurrence and improves survival of women with invasive breast cancer treated with breast conservation therapy. Most studies have utilized "conventionally fractionated" schedules that deliver therapy over 5-6 weeks, often followed by 1-2 weeks of boost therapy. Recent studies, however, have demonstrated equivalent tumor control and cosmetic

outcome in specific patient populations with shorter courses of therapy (approximately 4 weeks). Patients and their physicians should review these options to determine the most appropriate course of therapy.

2. Don't initiate management of low-risk prostate cancer without discussing active surveillance.

Patients with prostate cancer have a number of reasonable management options. These include surgery and radiation, as well as conservative monitoring without therapy in appropriate patients. Shared decision-making between the patient and the physician can lead to better alignment of patient goals with treatment and more efficient care delivery. ASTRO has published patient-directed written decision aids concerning prostate cancer and numerous other types of cancer. These types of instruments can give patients confidence about their choices, improving compliance with therapy.

3. Don't routinely use extended fractionation schemes (>10 fractions) for palliation of bone metastases.

Studies suggest equivalent pain relief following 30 Gy in 10 fractions, 20 Gy in 5 fractions, or a single 8 Gy fraction. A single treatment is more convenient but may be associated with a slightly higher rate of retreatment to the same site. Strong consideration should be given to a single 8 Gy fraction for patients with a limited prognosis or with transportation difficulties.

4. Don't routinely recommend proton beam therapy for prostate cancer outside of a prospective clinical trial or registry.

There is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms of definitive radiation therapy. Clinical trials

are necessary to establish a possible advantage of this expensive therapy.

5. Don't routinely use intensity modulated radiation therapy (IMRT) to deliver whole breast radiotherapy as part of breast conservation therapy.

Clinical trials have suggested lower rates of skin toxicity after using modern 3D conformal techniques relative to older methods of 2D planning. In these trials, the term "IMRT" has generally been applied to describe methods that are more accurately defined as field-in-field 3D conformal radiotherapy. While IMRT may be of benefit in select cases where the anatomy is unusual, its routine use has not been demonstrated to provide significant clinical advantage.

In January 2014, ASTRO formed a group to develop its second Choosing Wisely list, which included representatives from health policy, government relations, and clinical affairs and quality. Based on survey results, the work group submitted a short list of eight items to the ASTRO Board of Directors, from which the Board chose the additional five items listed below:6

- 1. Don't recommend radiation following hysterectomy for endometrial cancer patients with low-risk disease. Patients with low-risk endometrial cancer. including no residual disease in hysterectomy despite positive biopsy, grade 1 or 2 with <50 percent myometrial invasion and no additional high-risk features, such as age > 60, lymphovascular space invasion or cervical involvement have a very low risk of recurrence following surgery. Meta-analysis studies of radiation therapy for low-risk endometrial cancer demonstrate increased side effects with no benefit in overall survival compared with surgery alone.
- 2. Don't routinely offer radiation therapy for patients who have

resected non-small cell lung cancer (NSCLC) negative margins, No-1 disease.

Patients with early stage NSCLC have several management options following surgery, including observation, chemotherapy, and radiotherapy. Patients with positive margins following surgery may benefit from post-operative radiotherapy to improve local control regardless of the status of their nodal disease. However, two meta-analysis studies of post-operative radiotherapy in early NSCLC with node negative or N1 disease suggest increased side effects with no benefit for disease-free survival or overall survival compared to observation.

- 3. Don't initiate non-curative radiation therapy without defining goals of treatment with the patient and considering palliative care referral. Well-defined goals of therapy are
 - associated with improved quality of life and better understanding on the part of patients and their caregivers. Palliative care can be delivered concurrently with anti-cancer therapies and early palliative care intervention may improve patient outcomes, including survival.
- 4. Don't routinely recommend follow-up mammoarams more often than annually for women who have had radiotherapy following breast conserving surgery.

Studies indicate that annual mammograms are the appropriate frequency for surveillance of breast cancer patients who have had breast conserving surgery and radiation therapy with no clear advantage to shorter interval imaging. Patients should wait 6 to 12 months after the completion of radiation therapy to begin their annual mammogram surveillance. Suspicious findings on physical examination or surveillance imaging might warrant a shorter interval between mammograms.

5. Don't routinely add adjuvant whole brain radiation therapy to stereotactic radiosuraery for limited brain metastases.

Randomized studies have demonstrated no overall survival benefit from the addition of adjuvant whole brain radiation therapy (WBRT) to stereotactic radiosurgery (SRS) in the management of selected patients with good performance status and brain metastases from solid tumors. The addition of WBRT to SRS is associated with diminished cognitive function and worse patient-reported fatigue and quality of life. These results are consistent with the worsened self-reported cognitive function and diminished verbal skills observed in randomized studies of prophylactic cranial irradiation for small cell or non-small cell lung cancer. Patients treated with radiosurgery for brain metastases can develop metastases elsewhere in the brain. Careful surveillance and the judicious use of salvage therapy at the time of brain relapse allow appropriate patients to enjoy the highest quality of life without a detriment in overall survival. Patients should discuss these options with their radiation oncologist.

ONS Recommendations

The American Academy of Nursing (AAN) has also engaged in the Choosing Wisely dialogue by creating "Ten Things Nurses and Patients Should Question," which is located on the AAN website.7 While the first five recommendations may not directly impact oncology patients, the second set of five recommendations from the Oncology Nursing Society (ONS) include:

1. Don't use aloe vera on skin to prevent or treat radiodermatitis.

Radiodermatitis can cause patient pain and pruritus that affect quality of life, body image, and sleep. Severe radiodermatitis can necessitate dose reductions or treatment delays that negatively impact the ability to adequately treat the cancer. The incidence of radiodermatitis can be as high as 95 percent, depending upon the population of patients receiving treatment. Studies documenting incidence have primarily occurred in women receiving treatment for breast cancer. Many Internet sites market aloe to individuals for what is commonly termed "sunburn type" reactions from radiation therapy. Research evidence shows that aloe vera is not beneficial for the prevention or treatment of radiodermatitis, and one study reported worse patient outcomes with use of aloe vera. Patients undergoing radiation therapy need to know that aloe vera should not be used to prevent or treat skin reactions from radiation therapy, since it has been shown to be ineffective and has the potential to make skin reactions worse.

2. Don't use L-carnitine/ acetyl-L-carnitine supplements to prevent or treat symptoms of peripheral neuropathy in patients receiving chemotherapy for treatment of cancer.

Peripheral neuropathy is a chronic side effect of some chemotherapeutic agents. This can be a significant quality of life issue for patients, affecting functional ability and comfort. In the public realm, numerous Internet sites that sell herbal and dietary supplements have specifically recommended L-carnitine/ acetyl-L-carnitine for symptoms of peripheral neuropathy. This supplement is available without a physician prescription. Evidence not only has shown use of carnitine supplements to be ineffective, but research also has shown it may make symptoms worse. Current professional guidelines contain a strong recommendation against the use of L-carnitine for prevention of chemotherapy-induced peripheral neuropathy. Nurses need to educate patients not to use this dietary supplement while undergoing chemotherapy for cancer.

3. Don't neglect to advise patients with cancer to get physical activity and exercise during and after treatment to manage fatigue and other symptoms.

During treatment for cancer, up to 99 percent of patients will have fatigue and many individuals continue to experience persistent fatigue for years after completion of treatment. It is the natural tendency for people to try to get more rest when feeling fatigued and healthcare providers have traditionally been educated about the importance of getting rest and avoiding strenuous activity when ill. In contrast to these traditional views, resistance and aerobic exercise have been shown to be safe. feasible, and effective in reducing symptoms of fatigue during multiple phases of cancer care. Exercise has also been shown to have a positive effect on symptoms of anxiety and depression. Current professional guidelines recommend 150 minutes of moderate-level exercise such as fast-walking, cycling, or swimming per week along with 2-3 strength training sessions per week, unless specifically contraindicated.

4. Don't use mixed medication mouthwash, commonly termed "magic mouthwash," to prevent or manage cancer treatment-induced oral mucositis.

Oral mucositis is a painful and debilitating side effect of some chemotherapeutic agents and radiation therapy that includes the oral mucosa in the treatment field. Painful mucositis impairs the ability to eat and drink fluids and impacts quality of life. Oral mucositis can result in the need for hospitalization for pain control and provision of total parenteral nutrition in order to maintain adequate nutritional intake during cancer treatment. Mixed medication mouthwash, also commonly known by other names such as "magic mouthwash," "Duke's magic mouthwash," or "Mary's

magic mouthwash," is commonly used to prevent or treat oral mucositis. These are often compounded by a pharmacy, are expensive, and may not be covered by health insurance. Research has shown that magic mouthwash was reported to cause taste changes, irritating local side effects, and is no more effective than salt and baking soda (sodium bicarbonate) rinses. Instead, frequent and consistent oral hygiene and use of salt or soda mouth rinses can be used.

5. Don't administer supplemental oxygen to relieve dyspnea in patients with cancer who do not have hypoxia.

Reports of the prevalence of dyspnea range from 21 percent to 90 percent overall among patients with cancer, and the prevalence and severity of dyspnea increase in the last six months of life, regardless of cancer diagnosis. Supplemental oxygen therapy is commonly prescribed to relieve dyspnea in people with advanced illness despite arterial oxygen levels within normal limits, and has been seen as standard care. Supplemental oxygen is costly and there are multiple safety risks associated with use of oxygen equipment. People also experience functional restriction and may have some distress from being attached to a device. Palliative oxygen (administration in nonhypoxic patients) has consistently been shown not to improve dyspnea in individual studies and systematic reviews. Rather than use a costly and ineffective intervention for dyspnea, care should be focused on those interventions which have demonstrated efficacy such as immediate release opioids.

Summary

The importance of reducing unneeded testing and medications can be a complicated message, especially for consumers, who have been conditioned to think that "more is better," said Lisa Letourneau, MD, MPH, executive director for Maine Quality

More about ABIM Foundation & the Choosing Wisely Campaign

The mission of the ABIM Foundation is to advance medical professionalism to improve the healthcare system (abimfoundation.org). The foundation achieves this by collaborating with physicians and physician leaders, medical trainees, healthcare delivery systems, payers, policy makers, consumer organizations, and patients to foster a shared understanding of professionalism and how they can adopt the tenets of professionalism in practice. To date, more than 80 national and state medical specialty societies, regional health collaboratives, and consumer partners have joined the Choosing Wisely campaign to promote conversations about

appropriate care. In addition, the campaign will have covered more than 250 tests and procedures that the specialty society partners say are potentially overused and inappropriate, and that physicians and patients should discuss.

The campaign also continues to reach millions of consumers nationwide through a stable of consumer and advocacy partners, led by Consumer Reports, the world's largest independent product-testing organization, which has worked with the ABIM Foundation to distribute patient-friendly resources for consumers and physicians to engage in these important conversations.

Counts, one of the Choosing Wisely grantees.8 She compares the "choosing wisely" message to other public health campaigns such as "don't drink and drive," but acknowledges that "choosing wisely" is more complex because it is not simply a question of convincing the public to stop a specific behavior. The message for patients should always be: "Get the care you need and not the care you don't." OI

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