



Working together to improve health care quality, outcomes, and affordability in Washington State.

DRAFT Oncology Care Report and Recommendations

March 2016

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Executive Summary

The Dr. Robert Bree Collaborative was established in 2011 to provide a forum in which public and private health care stakeholders can work together to improve quality, health outcomes, and cost effectiveness of care in Washington State. Cost and quality of cancer care vary greatly in the United States. While evidence-based guidelines exist, adoption has been inconsistent. The Bree Collaborative elected to address this topic and convened a workgroup to develop recommendations from May 2015 to March 2016.

Significant variation in diagnosis, treatment, and supportive care for patients promotes poor outcomes and excessive cost for patients and the health care system. We have two primary focus areas:

1. That all clinics follow the American Society of Clinical Oncology's (ASCO) Choosing Wisely recommendations:
 - Do not use PET [positron emission tomography], CT [computed tomography] and radionuclide bone scans in the staging of early prostate cancer at low risk of spreading.
 - Do not use PET, CT, and radionuclide bone scans in the staging of early breast cancer that is at low risk of spreading.
2. That palliative care be offered alongside active anti-cancer care, as needed. Oncology care should be aligned with a patient's individual goals and values and follow ASCO's position statement of key elements for individualized cancer care. Patients should be apprised of the harms, benefits, evidence, and potential impact of chemotherapy, radiation, molecular therapy, immunotherapy, and surgery at all stages in their illness trajectory.

Unnecessary advanced imaging for staging of low-risk breast and prostate cancer exposes patients to excess radiation, can show false positives that lead to unnecessary treatments, and be costly to the patient and to the overall health care system. Adoption of the Choosing Wisely guidelines has been inconsistent. Barriers to adoption of the ASCO Choosing Wisely guidelines can stem from individual clinician belief and behaviors and from organizational behaviors and structures. Additionally, the larger health care structure can also incentivize clinicians to over-use imaging through fee-for-service reimbursement.

We encourage clinicians and care teams to regularly ask patients, their family members, and friends to discuss their goals of care and work with the care team to tailor care to patient goals. Integration of palliative care as a valued part of overall patient care can help facilitate these discussions and help patients mitigate negative side effects of treatment. However, many health care systems struggle with the growing need for palliative care and face capacity issues. Barriers to integration of palliative care include clinician belief, reimbursement, and current standard practice.

This Report discusses methods of addressing barriers to alignment with ASCO's Choosing Wisely recommendations for advanced imaging and for integrating palliative care alongside active anticancer therapy including implementation strategies for multiple health care stakeholders.

Dr. Robert Bree Collaborative Background

The Dr. Robert Bree Collaborative was established in 2011 by Washington State House Bill 1311 “...to provide a mechanism through which public and private health care stakeholders can work together to improve quality, health outcomes, and cost effectiveness of care in Washington State.” The Bree Collaborative was modeled after the Washington State Advanced Imaging Management (AIM) project and named in memory of Dr. Robert Bree, a pioneer in the imaging field and a key member of the AIM project.

Members are appointed by the Washington State Governor and include public health care purchasers for Washington State, private health care purchasers (employers and union trusts), health plans, physicians and other health care providers, hospitals, and quality improvement organizations. The Bree Collaborative is charged with identifying up to three health care services annually that have substantial variation in practice patterns, high utilization trends in Washington State, or patient safety issues. For each health care service, the Bree Collaborative identifies and recommends best-practice evidence-based approaches that build upon existing efforts and quality improvement activities aimed at decreasing variation. In the bill, the legislature does not authorize agreements among competing health care providers or health carriers as to the price or specific level of reimbursement for health care services. Furthermore, it is not the intent of the legislature to mandate payment or coverage decisions by private health care purchasers or carriers.

See **Appendix A** for a list of current Bree Collaborative members.

Recommendations are sent to the Washington State Health Care Authority for review and approval. The Health Care Authority (HCA) oversees Washington State’s largest health care purchasers, Medicaid and the Public Employees Benefits Board Program, as well as other programs. The HCA uses the recommendations to guide state purchasing for these programs. The Bree Collaborative also strives to develop recommendations to improve patient health, health care service quality, and the affordability of health care for the private sector but does not have the authority to mandate implementation of recommendations.

For more information about the Bree Collaborative, please visit: www.breecollaborative.org.

Cost and quality of cancer care vary greatly in the United States. Significant variation in diagnosis, treatment, and supportive care for patients promotes poor outcomes and excessive cost for patients and the health care system. While evidence-based guidelines exist, adoption has been inconsistent. The Bree Collaborative elected to address this topic and a workgroup convened to develop recommendations from May 2015 to March 2016.

See **Appendix B** for the Oncology Care workgroup charter and a list of members.

Problem Statement

Cancer death rates have declined in the United States from 2002-2011, due in part to great advances in cancer prevention and treatment.¹ However, cost of care has increased significantly, resulting in financial burden on patients and families.² Additionally, patients can be harmed through exposure to unneeded diagnostic tests and subsequent additional radiation and through lack of the patient-centered and supportive care that is found with palliative care.

National surveys show significant financial impact on patients and families due to cancer treatment where of those surveyed 25% used up most or all of their savings.² This rises to 46% among those who were not always insured. Approximately 3% of respondents declared bankruptcy and this rises to 6% among those who were not always insured. Cost and quality can also vary, indicating need for greater standardization and reduction in procedures that do not result in greater patient health.^{3,4}

Significant variation in diagnosis, treatment, and supportive care for patients promotes poor outcomes and excessive cost for patients and the health care system.⁵ The American Society of Clinical Oncology (ASCO) acknowledged this issue and in 2007 established a task force dedicated to investigating the cost and develop guidelines for improving quality of cancer care.⁶ The task force urged oncologists to integrate cost considerations into treatment decision making, but acknowledged that oncologists are often not comfortable discussing cost of care and the lack of robust cost effectiveness data. In 2012, the American Society of Clinical Oncology and the American Board of Internal Medicine partnered as part of Choosing Wisely to identify five tests or procedures “*whose necessity is not supported by high-level evidence*” and developed guidelines around therapeutic effectiveness, use of advanced imaging for staging of low risk breast and prostate cancer, surveillance testing, and prevention of febrile neutropenia.⁷

The Bree Collaborative Oncology Care workgroup choose to develop recommendations and implementation strategies around ASCO Choosing Wisely guidelines for advanced imaging for staging of low-risk breast and prostate cancer and for better integration of palliative or supportive care alongside active anticancer therapy.

1. That all clinics follow the American Society of Clinical Oncology’s (ASCO) Choosing Wisely recommendations:
 - Do not use PET [positron emission tomography], CT [computed tomography] and radionuclide bone scans in the staging of early prostate cancer at low risk of spreading.
 - Do not use PET, CT, and radionuclide bone scans in the staging of early breast cancer that is at low risk of spreading.
2. That palliative care be offered alongside active anti-cancer care, as needed. Oncology care should be aligned with a patient’s individual goals and values and follow ASCO’s position statement of key elements for individualized cancer care. Patients should be apprised of the harms, benefits, evidence, and potential impact of chemotherapy, radiation, molecular therapy, immunotherapy, and surgery at all stages in their illness trajectory.

Definitions

Active Anti-Cancer Care

The use of various modalities to actively treat or reduce a patient's cancer. Goals of anti-cancer care can include cure, prolongation of survival without cure, or palliation (improvement in symptoms and quality of life). While other treatment modalities exist, most anti-cancer care falls within the areas of surgery, radiation therapy, and/or drug therapy, traditionally called "chemotherapy." Symptom management should be included as part of active anti-cancer care.

Chemotherapy

Chemotherapy is the individualized use of drugs to treat cancer. Unlike surgery or radiation therapy, drug therapy is predominantly a systemic rather than a local therapy, in that the chemotherapy agent gains access to the circulatory system. Drug therapy comes in many forms, acts by many different mechanisms, and can be delivered to the circulation in a variety of ways.

End-of-Life Care

End-of-life care is a subset of palliative care but is specific to timing within an illness trajectory.

Hospice Care

Hospice care is an interdisciplinary health care service aimed at supporting patients and their families in the last six months of life provided by a specific hospice care team. End-of-life care may be carried out within hospice care and both are subsets of palliative care. Hospice reimbursement is typically separate from other types of care. The Centers for Medicare and Medicaid describe the differences between palliative care and hospice care here: [www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/infograph-PalliativeCare-\[June-2015\].pdf](http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/infograph-PalliativeCare-[June-2015].pdf)

Patient Decision Aid

Often, shared decision making conversations are enhanced by the use of a patient decision aid. Patient decision aids are defined as *"a written, audio-visual, or on-line tool that provides a balanced presentation of the condition and treatment options, benefits, and harms including, if appropriate, a discussion of the limits of scientific knowledge about outcomes. They include a means to acknowledge that the tool has been fully reviewed and understood."*⁸

The Washington State Legislature passed legislation in 2012 giving the *"Medical Director of the Washington Health Care Authority (HCA) the authority to certify patient decision aids."*⁸ The certification process is currently being developed. The legislation includes language to qualify use of a certified patient decision aid that is used in a shared decision-making process for higher legal protection. More information is available here: <http://apps.leg.wa.gov/rcw/default.aspx?cite=7.70.060>.

Palliative or Supportive Care

The World Health Organization (WHO) defines palliative care as *“an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”*⁹ Oncology care should be aligned with a patient’s individual goals and values. Patients should be apprised of the harms, benefits, evidence, and potential impact chemotherapy, radiation, molecular therapy, immunotherapy, and surgery at all stages in their illness trajectory. We encourage clinicians and care teams to regularly ask patients, their family members, and friends to discuss their goals of care and work with the care team to tailor care to patient goals. Symptom management should be included as a part of this type of oncology care.

There is also a movement to use the term “supportive” rather than “palliative” care to clarify the misconception that palliative care is meant only for the end of life. Some define palliative care as a subset of supportive care, care of any kind designed to support the cancer patient and his/her family and support system in their journey with cancer. In this definition, supportive care encompasses physical, emotional, spiritual, and other identified needs and is not limited by the kind of cancer or the stage of cancer or by goals of therapy (curative, life-prolonging, or palliative).

Shared Decision Making

Shared decision making is a *“collaborative process that allows patients and their providers to make health care decisions together, taking into account the best scientific evidence available, as well as the patient’s values and preferences.”*¹⁰ The American College of Physicians defines shared decision making as a conversation between a patient and health care provider that discusses *“enhancing value by decreasing harms and costs while preserving most benefits.”*¹¹

Shared Decision-Making Resources

- Watch a video from the Institute for Health Care Improvement:
www.ihc.org/education/ihciopenschool/resources/Pages/Activities/VictorMontoriSharedDecisionMaking.aspx
- Learn from the Informed Medical Decisions Foundation slideshow: www.slideshare.net/fimdm/intro-to-shared-decision-making-11486938
- Read the HealthIT.gov fact sheet:
www.healthit.gov/sites/default/files/nlc_shared_decision_making_fact_sheet.pdf

Advanced Imaging for Staging of Low-Risk Breast and Prostate Cancer

The Bree Collaborative recommends that all clinics follow the American Society of Clinical Oncology's (ASCO) Choosing Wisely recommendations:

- Do not use PET [positron emission tomography], CT [computed tomography] and radionuclide bone scans in the staging of early prostate cancer at low risk of spreading.
- Do not use PET, CT, and radionuclide bone scans in the staging of early breast cancer that is at low risk of spreading.

Background

Unnecessary advanced imaging for staging of low-risk breast and prostate cancer exposes patients to excess radiation, can show false positives that lead to unnecessary evaluation and treatments, can be costly to the patient and to the overall health care system, and may have little to no offsetting benefits.¹² Staging is the process of discovering in patients with a diagnosis of cancer the extent of disease and is a critical piece of information guiding prognosis and treatment options. As a general statement, staging attempts to differentiate disease that is either likely truly local, locally advanced but not clearly metastatic or systemic, or identifiably metastatic.

Imaging studies can be used for purposes other than staging such as cancer screening, diagnostic evaluation, assessment of response to treatment, and surveillance in patients whose cancer is no longer evident clinically. Although all of these uses are interesting from a quality of care and value point of view, we are restricting our recommendations to the use of these studies in staging, specifically in patients who appear to have early stage disease. Somewhat complicating this restriction is that a staging study can sometimes serve "double duty" such as being both a diagnostic and staging study.

We define advanced imaging based on technology used as follows:

- Computed tomography (CT) scans. Usually of chest/abdomen/pelvis, sometimes head/brain.
- Bone scans
- Positron emission tomography (PET) and PET scans combined with CT scans in a single instrument/study (PET/CT)
- Magnetic resonance imaging (MRI). MRI is generally not used as a routine systemic staging study for breast cancer and therefore is not specifically addressed in that context. It can be used as a screening modality, and as an adjunct to other studies in surgical decision making. It can also be useful in clarifying abnormalities found on other studies. The use of MRI in the first two contexts above is in flux and at times controversial and will not be included in these recommendations.

Avoiding unnecessary imaging is moving towards becoming the standard of care.

Many professional organizations, including the American Society of Clinical Oncology, through Choosing Wisely, recommend against advanced imaging for staging of early prostate and breast cancer. These recommendations are supported by the American College of Radiology in their appropriateness criteria for stage I breast cancer initial workup and surveillance for local recurrence and distant metastases in asymptomatic women to rule out metastases.

Guidelines available here: <https://acsearch.acr.org/docs/69496/Narrative/>

The American Urological Association also supports these recommendations. Radiographic staging (CT and bone scan) is only recommended for patients with prostate cancer with a Gleason score >7 or a PSA level >20 ng/mL.

Guidelines available here: www.auanet.org/common/pdf/education/clinical-guidance/Prostate-Cancer.pdf.

Prostate Cancer

As part of Choosing Wisely, ASCO recommends: Do not use PET [positron emission tomography], CT [computed tomography] and radionuclide bone scans in the staging of early prostate cancer at low risk of spreading.⁷

Local-stage low risk: less than T1c/T2a or T2 not otherwise-specified prostate cancer with Gleason scores ≤6 or prostate-specific antigen scores ≤10 at diagnosis.¹³ See **Appendix C** for more specific information on prostate cancer staging.

Breast Cancer

As part of Choosing Wisely, ASCO recommends: Do not use PET, CT, and radionuclide bone scans in the staging of early breast cancer that is at low risk of spreading.⁷ Early stage low risk: American Joint Committee on Cancer stage 0, I, II¹⁴

- Stage 0 (ductal carcinoma in situ or DCIS, not invasive cancer)
- Stage I, which is subdivided into IA and IB
- Stage II, which is subdivided into IIA and IIB.

Locally advanced breast cancer is defined as stage III, subdivided into IIIA, IIIB, and IIIC. Metastatic breast cancer (distant spread) is defined as stage IV. See **Appendix D** for more specific information on breast cancer staging.

Harms from overuse of advanced imaging involve potential false-positive results that may lead to unnecessary additional tests or invasive procedures, patient anxiety, excess radiation exposure, and increased costs of \$40-80 million a year.^{15,16,17} Overdiagnosis can lead to overtreatment, or unnecessary treatment, of a disease that would never cause harm in a patient's lifetime.

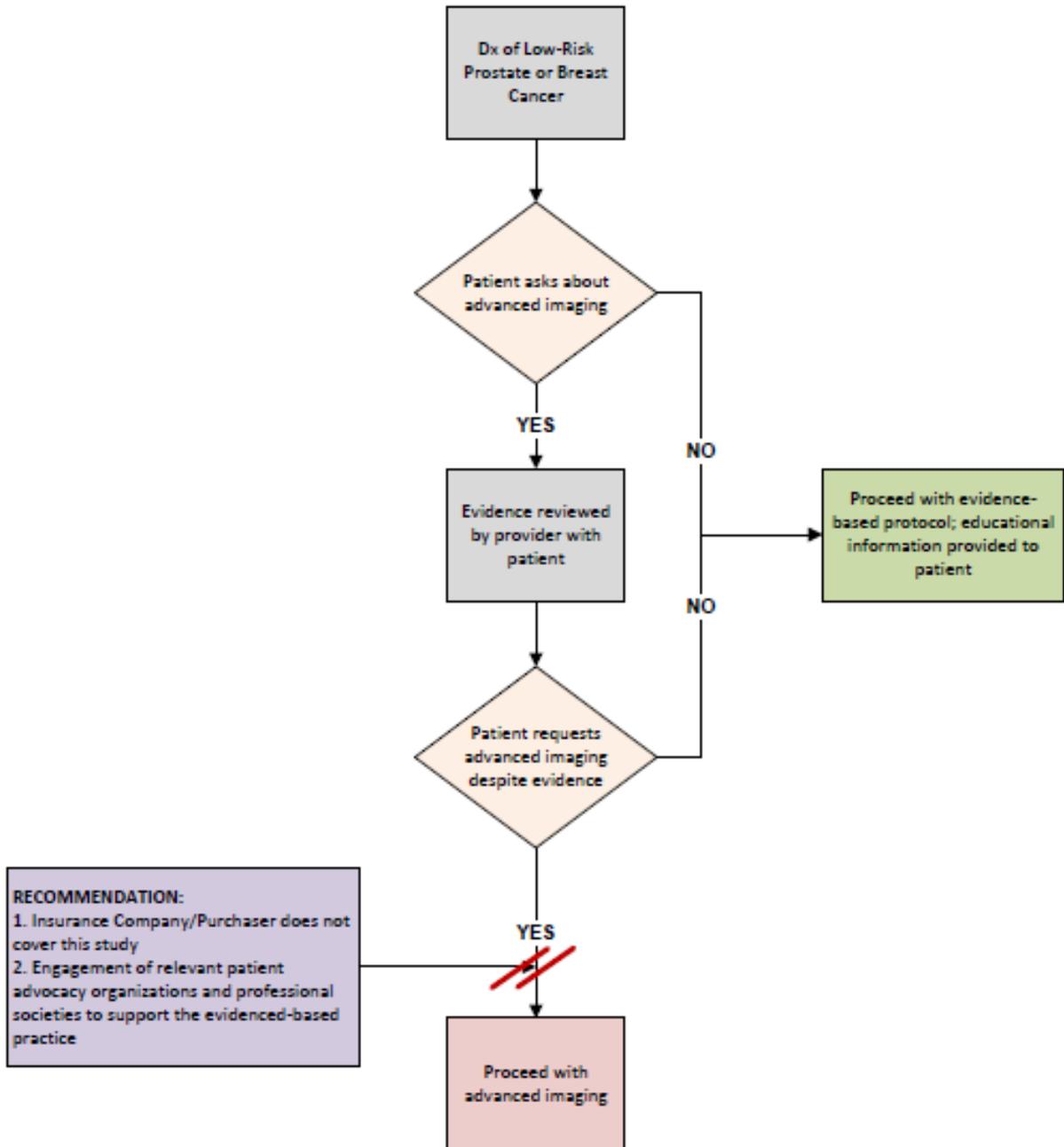
Implementation

Adoption of the Choosing Wisely guidelines has been inconsistent.¹⁸ Research from the Fred Hutchinson Cancer Research Center using Premera Blue Cross data (approximately 20% of Washington state residents) found clinic adherence to the above prostate imaging guidelines at 90% for patients identified as low-risk and 70% for patients with unknown risk status.¹³ Adherence to breast cancer imaging guidelines was dependent on stage and lower among those treating patients with stage II disease; average adherence rates were 78% with stage-specific rates of 0 = 96%, I = 87%, and II = 50%. Cost of care differed between patients whose care followed prostate imaging guidelines and those who did not, \$5,940 vs \$8,423 or a 42% increase, 33% of which can be attributed to nonadherent care. Among breast cancer patients, comparisons of adherent to nonadherent care found costs to be \$20,823 vs \$33,630, or a 61% increase, 19% of which can be attributed to nonadherent care.

The Oncology Care workgroup has developed a best practice care pathway, seen in **Figure 1**, to illustrate an example of a possible pathway of sharing information with patients to adhere to the Choosing Wisely guidelines.

The Fred Hutchinson Cancer Research Center's Hutchinson Center for Cancer Outcomes Research (HICOR) has developed [HICOR IQ](#), *"a database of population-based cancer incidence and survival information and insurance claims data that gives our regional partners continuously updated reporting of trends in oncology... HICOR IQ contains enrollment and claims from Premera Blue Cross and Regence that is securely provided to HICOR and linked to the Cancer Surveillance System to incorporate clinical outcomes data. Future versions will include data from other health plans, healthcare systems and patients in order to more fully capture the patient experience and identify areas for targeted intervention. Partner-specific access will allow for customized data views and monitoring of payer/clinic-specific programs."*¹⁹

Figure 1: Suggested Information Sharing Process for Advanced Imaging in Low Risk Prostate and Breast Cancer



Barriers to adoption of the ASCO Choosing Wisely guidelines stem from individual clinician belief and behaviors and from organizational behaviors and structures, see **Table 1** for more detail. Clinicians may not believe the guidelines to be based in evidence or be beneficial to overall patient health. Others may have concerns about legal issues or be uncomfortable with providing what can feel like less care. Some may be unaware of the guidelines or be uncomfortable interpreting the guidelines and be uncertain about staging and what constitutes cancer at low risk for metastasis. Clinicians may practice in a care team or organization with protocols that conflict with the guidelines. Additionally, the larger health care structure can also incentivize clinicians to over-use imaging via fee-for-service reimbursement.

Table 1: Barriers and Countermeasures to following Choosing Wisely Advanced Imaging Guidelines

	Barriers	Countermeasures
Patient	Wanting to receive advanced imaging for low-risk disease	<ul style="list-style-type: none"> • Discuss the risk of harm and low level of benefit with your patient. Use existing consumer-directed materials, if appropriate, such as those developed by Consumer Reports
Clinician	Being unaware of the guidelines or being unaware of not adhering to the guidelines	<ul style="list-style-type: none"> • Discuss guidelines institution-wide and direct clinician to materials from external organizations such as Choosing Wisely • Use of clinician-level utilization data such as through HICOR IQ to show relative use
	Believing guidelines are not evidence-based or beneficial to overall patient health	<ul style="list-style-type: none"> • Education on research base; sharing patient stories • Engagement with a site-specific clinical champion
	Uncertainty about staging and what constitutes cancer at low risk for metastasis	<ul style="list-style-type: none"> • Education¹ • Decision support tools at point of care²
	Concern about legal repercussions	<ul style="list-style-type: none"> • Discussion of current standard of care aligning with less use of advanced imaging including resources from professional societies • Additional legal protections granted through use of a Washington State-certified patient decision aid
	Being uncomfortable providing what feels like less care	<ul style="list-style-type: none"> • Engagement with site-specific clinical champion, education, connection with peers
Institutional	Care team or organization protocols conflict with the guidelines	<ul style="list-style-type: none"> • Leadership engagement with recommendations
	Reimbursement incentivizes overuse of imaging	<ul style="list-style-type: none"> • Compensation model reform (e.g., bundled payment, outcomes-based reimbursement, non-payment for inappropriate advanced imaging or self-referred advanced imaging)

¹ Refer to Choosing Wisely website if in-house clinical education is not available.

² There are many appropriate decision-support tools on the market. Many tools simply ask the ordering clinician whether the test was meant to be ordered. We do not recommend a specific decision-support tool, but rather that the tool align with the Choosing Wisely Recommendations.

The Susan G Komen Foundation references ASCO's imaging guidelines for breast cancer on their website under "tests not included as part of routine follow-up care."²⁰ The American Cancer Society has been involved with many of the Choosing Wisely committees.

Consumer Reports advises patients:¹²

- **"The greatest risk from imaging tests is that they expose you to radiation. The effects of radiation add up over your lifetime. Having many tests that use radiation can increase your risk of cancer.**
- **Imaging tests can also show a "false positive." This means a test shows something that looks unusual, but after more testing turns out not to be a problem. False positives can lead to stress, more tests, and treatments you don't need.**
- **Imaging tests are costly. They can add thousands of dollars to your treatment costs. If you do not need them, why spend the money?"**

Additionally, patients may want to better understand how long the average patient with the same diagnosis is expected to survive or prognosis. Relative survival rate is often discussed as the percentage of patients who "live at least five years after their cancer is diagnosed" with the assumption that some patients will die of something other than the cancer for which they were diagnosed. Other patient characteristics like age, relative health, specifics of the cancer, and type of treatment also impact prognosis. Prostate and breast cancer five-year relative survival is typically communicated by stage. Numbers below are taken from the American Cancer Society from the National Cancer Institute's SEER database. More information on calculating relative survival: <http://surveillance.cancer.gov/survival/>

Prostate cancer five-year relative survival by stage at time of diagnosis:²¹

- Local = nearly 100%
- Regional = nearly 100%
- Distant = 28.7%

Breast cancer five-year relative survival by stage at time of diagnosis:²²

- 0 = 100%
- I = 100%
- II = 93%
- III = 72%
- IV = 22%

Overall (including all stages of prostate cancer at diagnosis) 99% of men diagnosed with prostate cancer live at least five years post-diagnosis, 98% at least ten years, and 94% at least 15 years.²³ Overall for all breast cancer stages combined, five year survival is 89%, ten year survival is 83%, and the 15-year survival is 78%.²⁴

Stakeholder Implementation Recommendations

Patients

- Access Consumer Reports' education materials about imaging tests for prostate cancer and breast cancer, available here: <http://consumerhealthchoices.org/wp-content/uploads/2013/02/Choosing-WiselyProstateCancerASCO-ER.pdf> and here: <http://consumerhealthchoices.org/wp-content/uploads/2013/02/ChoosingWiselyBreastCancerTestsASCO-ER.pdf>. Information is also available in Spanish.
- Talk to your clinician if you don't feel comfortable with the tests that you are receiving or have questions about your care.

Oncology Care Practices and Clinicians

- Access the [Hutchinson Center for Cancer Outcomes Research IQ](#) database and compare advanced imaging data between your practice and others in Washington State. When available, use HICOR IQ data to compare utilization data between individual clinicians, working with clinicians with high use to align use with best practices.
- Engage practice leadership as advocates for the Choosing Wisely recommendations.
- Engage a site-level champion familiar with the Choosing Wisely recommendations who is willing to discuss the recommendations with other clinicians.

Primary Care Practices and Clinicians

- Develop clear communication pathways with the patient's multidisciplinary oncology care team, sharing notes, treatment protocols, and test results.
- Engage practice leadership as advocates for building relationships with oncology care practices and with the Choosing Wisely recommendations.

Health Plans

- Securely provide patient enrollment and claims data to HICOR for linkage with the Cancer Surveillance System and comprehensive statewide comparison.
- Align appropriateness of advanced imaging care with proper reimbursement that includes safeguards for individual patient exceptions.
- Engage practice leadership as advocates for the Choosing Wisely recommendations.

The Health Care Authority

- Certify patient decision aids aligned with the Choosing Wisely guidelines on advanced imaging as discussed above.

Palliative or Supportive Care

The Bree Collaborative recommends palliative care be offered alongside active anti-cancer care, as needed. Oncology care should be aligned with a patient's individual goals and values and follow ASCO's position statement of key elements for individualized cancer care. Patients should be apprised of the harms, benefits, evidence, and potential impact of chemotherapy, radiation, molecular therapy, immunotherapy, and surgery at all stages in their illness trajectory. When first diagnosed, patients should be asked to describe their goals of care, prognostic awareness, and how much he or she would like to know about prognosis and treatment options.

Background

The World Health Organization (WHO) defines palliative care as *“an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and impeccable assessment and treatment of pain and other problems, physical, psychosocial and spiritual.”*⁹ Oncology care should be aligned with a patient's individual goals and values and follow ASCO's position statement of key elements for individualized cancer care:²⁵

- *“Patients should be well informed about their prognosis and treatment options, ensuring that they have opportunities to make their preferences and concerns regarding treatment and supportive care known.*
- *Anticancer therapy should be discussed and offered when evidence supports a reasonable chance of providing meaningful clinical benefit.*
- *Options to prioritize and enhance patients' quality of life should be discussed at the time advanced cancer is diagnosed and throughout the course of illness along with development of a treatment plan that includes goals of therapy.*
- *Conversations about anticancer interventions should include information on likelihood of response, the nature of response, and the adverse effects and risks of any therapy. Direct costs to the patient in terms of time, toxicity, loss of alternatives, or financial impacts that can be anticipated should also be discussed to allow patients to make informed choices.*
- *Whenever possible, patients with advanced cancer should be given the opportunity to participate in clinical trials or other forms of research that may improve their outcomes or improve the care of future patients.*
- *When disease-directed options are exhausted, patients should be encouraged to transition to symptom-directed palliative care alone with the goal of minimizing physical and emotional suffering and ensuring that patients with advanced cancer are given the opportunity to die with dignity and peace of mind.”*

Patients should be apprised of the harms, benefits, evidence, and potential impact of chemotherapy, radiation, molecular therapy, immunotherapy, and surgery at all stages in their illness trajectory. We encourage clinicians and care teams to regularly ask patients, their family members, and friends to discuss their goals of care and work with the care team to tailor care to patient goals. If the patient consents, caregivers can and should be included in conversations about palliative care services provided to the patient.

Palliative care has been shown to positively impact a patient's life, and in some cases has been associated with longer life.²⁶ Project ENABLE (Educate, Nurture, Advise, Before Life Ends) randomly assigned patients newly diagnosed with gastrointestinal, lung, genitourinary, or breast cancer to usual care or a comprehensive nurse-led telephone-delivered program that included: problem solving, communication and social support, symptom management, and advance care planning.²⁷ Analysis found higher quality of life and improved mood but no effect on number of days spent in the hospital, intensive care unit, or emergency room. When the same program was compared between palliative care provided soon after diagnosis and palliative care delayed by three months, patient-reported outcomes and health services use as described above were not statistically significantly different between the groups, but the earlier intervention group experienced longer survival after diagnosis.²⁸ However, use of early palliative care in the usual care group may have reduced effectiveness of the comparable intervention.

Inclusion of a traditional palliative care model alongside active therapy for newly diagnosed patients with non-small-cell lung cancer has been associated with prolonged survival of two months and clinically meaningful improvements in quality of life and mood.²⁹ Additional analysis found those in the palliative care group to have received half as much intravenous chemotherapy in the final two months of life and a longer amount of time receiving hospice care.³⁰ Key elements of the palliative care visits included: relationship and rapport building, addressing symptoms, addressing patient coping abilities, establishing an understanding of the illness, discussing cancer treatment options, end-of-life planning (including hospice), and engaging family members.³¹ A cluster-randomized trial of early palliative care given at least monthly compared to usual care (with palliative care given when requested) for patients with metastatic cancer in Canada found significantly improved quality of life and severity of symptoms in the intervention group.³² Importantly, all trials show that palliative care is not associated with worse quality of life, an increase in symptoms, or shortened life.

Chemotherapy and radiation therapy have commonly been used in end-stage cancer patients to improve quality of life or prolong life. However, recent research comparing family-reported physical and psychological distress and quality of life for lung, colon, pancreatic and breast cancer patients with solid tumor cancers that had metastasized found similar results among those receiving chemotherapy and those not receiving chemotherapy.³³ For patients reporting lower symptom burden initially, family members of those receiving chemotherapy reported significantly lower quality of life. The Fred Hutchinson Cancer Research Center analyzed Premera Blue Cross claims data for chemotherapy and radiation therapy treatment 90 days prior to death of any cause and providers not using chemotherapy or radiation therapy at 60% 90 days prior to death which increases to 89% 15 days prior.¹³ Among patients receiving nonadherent care, cost was 184% higher (\$50,012 vs \$17,606), 40% directly attributable to nonadherent care. However, the study did not differentiate between therapies provided with curative intent and those provided with palliative intent.

Choosing Wisely addresses palliative care for patients with the recommendation that patients with *“advanced solid tumors who are unlikely to benefit”* should avoid unnecessary anticancer therapy and *“focus instead on symptom relief and palliative care.”*⁷

We define palliative care as follows: Care intended to support a patient who has a serious, life-threatening or life-limiting disease, including cancer. The focus of the care is on quality of life and assisting broadly and holistically with the impacts and implications of disease and treatment on the patient as a whole, including caregivers, family, and friends. A team-based model, care and support can be physical, emotional, and spiritual. Palliative care also focuses specifically on communication and exploration of goals of therapy and patient and family goals, needs, desires, and expectations around choices.

Palliative care is appropriate for patients undergoing life-prolonging care and does not preclude concurrent administration of any specific active anti-cancer therapy. At the patient's request, caregivers can and should be included in palliative care conversations. Palliative care is also not restricted to traditional medicine, nor to strictly medical interventions. More commonly, palliative care is associated with patients for whom no curative treatment is available, recognizing there are specific challenges and needs in caring for patients with a life-limiting disease. During the course of the disease or therapy patients who are being treated with curative intent can become incurable by virtue of disease recurrence or progression.

End-of-life care is a subset of palliative care but is specific to timing within an illness trajectory. End-of-life care may be carried out within hospice care. Hospice care is an interdisciplinary health care service aimed at supporting patients and their families in the last six months of life. A hospice team will work to manage pain and symptoms; assist with the emotional, psychosocial, and spiritual aspects of dying; provide medical supplies; coach the family and friends; and provide bereavement and counseling for surviving family and friends.³⁴ Many studies have shown increased patient, family, friend, and caregiver satisfaction and higher patient quality of life with hospice.^{35,36} When compared to decedents not using hospice, significant Medicare cost savings are seen for patients enrolled for as few as one to seven days, with higher savings for longer enrollment periods.³⁷ Being referred to hospice later on in the illness trajectory is associated with greater unmet needs among family members, but is still associated with higher quality of care than no hospice referral.³⁵

Timing of palliative care initiation, hospice care initiation, and when to stop specific chemotherapy or radiation therapy agents is especially important. Early initiation of palliative care can help facilitate appropriate timing of active anti-cancer care and hospice care transition throughout the care process.^{35,38,39} Hospice services such as bereavement counseling can greatly benefit caregivers and family members. The National Comprehensive Cancer Care Network has developed a distress thermometer for patients that has been used in multiple palliative care trials, available here: www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf, to help determine a patient's need for palliative care.

The National Comprehensive Cancer Network (NCCN) recommends all patients be screened for palliative care needs at their initial visit and rescreened at predetermined intervals.⁴⁰ Glare and Chow adopted the NCCN guidelines into a set of referral criteria⁴¹ and additionally created an 11-item screening tool based on the NCCN screening domains.⁴² Validation studies found high content and construct validity (e.g., higher scores in those closer to death) with a cut-off score of ≥ 5 meant to trigger the oncologist to consider a palliative care consult. Approximately one third of patients met this criteria, greater than the number referred to palliative care through clinical opinion only.

Finding the WHO palliative care guidelines too vague (e.g., lacking information on disease-specific timing and subsequently needed infrastructure), The Department of Palliative Medicine at the University Hospital of Cologne, Germany identified specificity of palliative care early integration based on malignancy of specific cancers (e.g., patients with stage IV melanoma) and standard operating procedures with green and red flags for palliative care.⁴³ The group argues for delivering palliative care at the same time and in the same physical location as active anti-cancer treatment.

Implementation

Palliative care is still finding its place within the health care system. Many health care systems struggle with the growing need for palliative care and face capacity issues. The professionalization of palliative care as a specialty is evolving and demarcations between other specialties growing. Some oncologists may see palliative care as within their scope of practice and be reluctant to refer a patient to this separate specialty. Additionally, stigma especially within oncology in referring a patient to palliative care serves as a barrier as clinicians do not want to “give up” on a patient. Some argue that this messaging is the most important barrier to overcome, focusing on “*palliative care as a means to improve quality of life without decreasing survival [as] essential to make this advocacy agenda more politically tenable.*”⁴⁴ Institutional barriers revolve predominantly around lack of adequate reimbursement for palliative care, shortage of services, and conflicting protocol. See **Table 2** for a presentation of barriers and countermeasures to integration of concurrent palliative and active anti-cancer care.

Table 2: Barriers and Countermeasures to Early Integration of Concurrent Palliative Care and Active Oncology Care³⁸

Barriers		Countermeasures
Patient and Clinician	Perception of palliative care as end-of-life care or as “giving up”	<ul style="list-style-type: none"> • Empower patients with resources on palliative care and end-of-life care (e.g., the Conversation Project) • Use of term <i>supportive care</i> rather than <i>palliative care</i> • Education about definition and scope of palliative care services (e.g., to relieve pain, to connect patients with supports) alongside detailed information on prognosis
Clinician	Concern that palliative care referral would alarm patients and families	<ul style="list-style-type: none"> • Shared decision making tools • Patient education

	Unwillingness and uncertainty of when to initiate palliative care	<ul style="list-style-type: none"> • Clear referral pathways and protocols (e.g., green flags such as initiation of palliative care for patients with stage IV melanoma)⁴³ • Relationship-building between oncology and palliative care centers or palliative care skills building within oncology practice • Increase multidisciplinary collaboration (e.g., developing multidisciplinary care team) including communication with primary care • Communication training in discussing prognosis and care plans with patients
	Uncertainty of who to refer to palliative care	<ul style="list-style-type: none"> • Implementation of valid and reliable screening tools showing individualized palliative care need (e.g., distress screening)
	Concern that pain will not be properly treated outside of active care	<ul style="list-style-type: none"> • Education of proper pain management at all stages of care
Institutional	Shortage of palliative care specialists	<ul style="list-style-type: none"> • Team-based palliative care programs incorporating physician leadership working with advance practice providers
	Care team or organization protocols conflict with the guidelines	<ul style="list-style-type: none"> • Leadership engagement with palliative care integration
	Lack of palliative care financial incentives	<ul style="list-style-type: none"> • Compensation model reform (e.g., bundled payment, outcomes-based reimbursement) to support individualized palliative care
	Inability to pay for concurrent active care and hospice care	<ul style="list-style-type: none"> • Revising hospice reimbursement exclusions to allow for concurrent reimbursement

The Center to Advance Palliative Care has several recommendations for better palliative care reimbursement:⁴⁵

- *“Allocate funding to develop quality measures that address communication, concordance of treatment with patient preferences and goals of care, and care transitions for those with serious illness, multimorbidity and functional and cognitive impairment, and that are applicable across settings for use in new value-based payment models.*
- *Direct CMS to include palliative care measures in all relevant quality- and value-based programs, such as Medicare-sponsored Accountable Care Organization (ACO) measures, the Five-Star Quality Rating System for Medicare Advantage plans and CMS facility-based quality reporting and incentive programs. Measures should include, where applicable, both process and outcome measures to ensure that facilities have adequate resources in place to care for those with serious illness.*
- *As CMMI is selecting and piloting new care models, ensure that palliative care is a component of care, quality measurement and payment for those with serious illness.”*

The Centers for Medicare and Medicaid will be introducing a new payment model for physician practices administering chemotherapy in spring 2016. The two part payment system will include a \$160 monthly per-beneficiary-per-month payment to assist with care coordination and the potential for performance/outcomes-based reimbursement to lower total cost of care and improve quality.⁴⁶ Episodes of care will last six months starting with an initial chemotherapy claim. This type of compensation model reform should be watched closely for benefit, potential harm, and if successful, spread outside of Medicare.

ASCO released recommendations around patient centered oncology payment in May 2015 including recommendations for supplemental, non-visit-based payments with new treatment codes:⁴⁷

- “New Patient Treatment Planning (\$750 per patient)
- Care Management during Treatment (\$200 per patient per month)
- Care Management during Active Monitoring (\$50 per patient per month during treatment holidays)
- Participation in Clinical Trials (\$100 per patient per month)”

However, ASCO recommends oncology practices also take on risk corresponding to the additional payments through:⁴⁷

- *“Avoidance of emergency department visits and hospital admissions for complications of cancer treatment;*
- *Appropriate use of drugs, laboratory testing, and imaging studies, and use of lower-cost drugs, tests, and imaging where evidence shows they are equivalent to higher-cost treatments and tests;*
- *Delivery of high-quality care near the end of a patient’s life; and*
- *Commitment to care consistent with standards of quality defined by ASCO.”*

ASCO also includes discussion of bundled payment models and consolidated payments to replace evaluation and management and infusion payments with new patient payment, treatment monthly payment, and active monitoring monthly payments.

Advance Care Planning

The Bree Collaborative recommends that all Washingtonians be informed about their end-of-life options, communicate their preferences in actionable terms, and receive end-of-life care that is aligned with their wishes, goals, and values. To support this goal the Bree Collaborative convened a workgroup to investigate best practices around end-of-life care that developed five focus areas:

- Increase awareness of advance care planning, advance directives, and Physician Orders for Life Sustaining Treatment (POLST) in Washington State,
- Increase the number of people who participate in advance care planning in the clinical and community settings,
- Increase the number of people who record their wishes and goals for end-of-life care using documents that: accurately represent their values; are easily understandable by all readers including family members, friends, and health care providers; and can be acted upon in the health care setting,

- Increase the accessibility of completed advance directives and POLST for health systems and providers, and
- Increase the likelihood that a patient's end-of-life care choices are honored.

Advance care planning has been shown to be highly beneficial to patient quality of life. In a longitudinal study of cancer patients, discussions between patients and their health care providers about end-of-life wishes were associated with higher quality of death, measured by undergoing ventilation or resuscitation, admission to or death in an ICU in the final week of life, receipt of outpatient hospice care and length on hospice, and amount of physical distress in the final week of life, and lower total costs of care.⁴⁸ Research shows that one of the primary benefits of end-of-life planning conversations is to prepare patients and their families for the decisions they will eventually have to make, even if not directly related to a treatment decision.⁴⁹ Goals of care vary from person to person and within individual patients depending on severity and projected course of illness.⁵⁰ Surrogate decision makers must also be involved in advance care planning conversations. When surrogates are not involved in the planning process, both they and health care providers have been shown to be inaccurate at predicting patients' wishes.^{51,52}

Successful advance care planning should:⁵³

- Assess readiness to discuss goals of care and advance care planning
- Educate the patient, family, and friends on individual health status
- Help the patient choose a suitable surrogate and involve the designated surrogate in the conversation
- Clarify the amount of leeway the surrogate should have in deviating from an advance care plan
- Discuss and clarify values (e.g., If you were in X situation, what would be most important to you)
- Document the advance care plan with an advance directive and POLST if appropriate
- Be an ongoing process to account for changes in patient preference

Advance directives are the written documents generated from advance care planning. These documents should be culturally and linguistically appropriate, be accessible in the medical record, and include:

- A living will/health care directive
 - Consistent with section 030 of the Washington State Natural Death Act.
 - Signed by the declarer in the presence of two witnesses
 - Specify whether the declarer does or does not want to “have artificially provided nutrition and hydration” if the declarer is “diagnosed to be in a terminal condition or in a permanent unconscious condition”
 - Stipulate other specific treatment preferences (if known and applicable to the situation)
- A durable power of attorney for health care
 - Indicating the amount of leeway the surrogate should have in decision-making (e.g., “I want my surrogate to work with my doctors and to use her/his best judgment” vs “I want my surrogate to follow my health care choices on this form exactly.”)⁵⁴
- A written personal statement that articulates the patient's values and goals regarding end-of-life care

Stakeholder Implementation Recommendations

Patients

- Talk with your oncology care team about who your point-person is for questions about your care or any new symptoms that develop.
- Communicate any changes in symptoms to this oncology point-person. Symptoms can be communicated to your primary care provider as well, but should always be communicated to the oncologist charged with your care.
- Develop a plan with your oncologist about how to deal with symptom flare-ups including pain before they happen.
- Access end-of-life care resources and talk about advance care planning with your family and care team. There are many resources available, many are listed here: <http://depts.washington.edu/pallcntr/patient-and-family-resources.html>.
- If you are comfortable, include caregivers and family members in discussions about palliative care measures.

Oncology Care Practices and Clinicians

- Develop an institutional definition of palliative or supportive care and educate clinicians on the difference between palliative or supportive care, active anti-cancer therapy, end-of-life care, and hospice. Some patients may be more comfortable with the term “supportive care.”
- When patients are first diagnosed, ask them to describe their goals of care and talk to the patient about his or her prognostic awareness and how much he or she would like to know about prognosis and treatment options.
- Support the patient as he or she changes in prognostic awareness throughout the course of disease and treatment.
- Screen all patients for palliative care needs at their initial visit and rescreen at predetermined intervals. Caregivers may also be screened for palliative care needs.
- If possible, provide patients with opportunities to participate in clinical trials or other research.
- Develop a multidisciplinary care team to support the patient including clear identification of a specific oncology point-person. This care team and point person should address symptom management with the patient and monitor the patient’s medications, being aware of any potential interactions or side effects. In most cases the point person should be a medical oncologist, however in some settings and for some patients another specialty may be more appropriate (e.g., palliative care specialist, pulmonologist). Make sure that the patient and family members know to contact the oncology point person with any changes in symptoms.
 - The designated oncology point person should be informed about evidence-based oncology care treatments and palliative or supportive care techniques.
 - These recommendations are meant to be inclusive of centers that may not be able to provide palliative or supportive care services separately from oncology care (e.g., from a designated expert). We encourage a member of the multidisciplinary care team to

develop competency in this area and serve in this role. Where this is not possible, patients should be referred to or coordinated with a center where such expertise exists.

- Develop clear communication pathways with the patient's primary care provider, sharing notes, treatment protocols, and test results.
- Develop clear protocols and education on how to identify patients (e.g., through the NCCN distress thermometer) who would most benefit from more intensive palliative or supportive care at initial diagnosis and also how to identify patients who may need a more palliative focus consistently throughout active anti-cancer care (e.g., performing poorly under current anti-cancer therapy regimen).
- Utilize a shared decision-making process, with patient decision aids if possible, to determine whether to continue current anti-cancer therapy regimen with the patient if the treatment is not meeting the patient's goals of care and if no other treatment options could viably meet the patient's goals of care. When appropriate discuss whether transition to hospice might better meet the patient's goals of care.
- Access the [Hutchinson Center for Cancer Outcomes Research IQ](#) database and compare chemotherapy and radiation therapy data in the last 30 days of life between your practice and others in Washington State. When available, use HICOR IQ data to compare utilization data between individual clinicians, working with clinicians to identify patterns of high use.

Primary Care Practices and Clinicians

- Develop clear communication pathways with the patient's multidisciplinary oncology care team, sharing notes, treatment protocols, and test results.
- If the patient contacts primary care with questions about symptoms or to discuss a new symptom, encourage the patient to contact the oncology point person.

Health Plans

- Provide adequate financial support to facilitate care coordination activities and high-quality patient-centered end-of-life care.
- Align appropriateness of care with proper incentives and safeguards for exceptions with good clinical overview.
- Develop quality measures to address communication, concordance of treatment with patient preferences and goals of care, and care transitions for those with serious illness, multimorbidity and functional and cognitive impairment, and that are applicable across settings for use in new value-based payment models.

The Health Care Authority

- Work to certify patient decision aids for advance care planning and for discussing goals of care generally within oncology care.
- Seek to enhance the role of palliative care alongside active anti-cancer therapy

Bree Collaborative | Oncology Care Draft Recommendations

Appendix A: Bree Collaborative Members

Member	Title	Organization
Susie Dade MS	Deputy Director	Washington Health Alliance
John Espinola MD, MPH	Executive Vice President, Health Care Services	Premera Blue Cross
Gary Franklin MD, MPH	Medical Director	Washington State Department of Labor and Industries
Stuart Freed MD	Chief Medical Officer	Confluence Health
Richard Goss MD	Medical Director	Harborview Medical Center – University of Washington
Christopher Kodama MD	President, MultiCare Connected Care	MultiCare Health System
Daniel Lessler MD, MHA	Chief Medical Officer	Washington State Health Care Authority
Paula Lozano MD, MPH	Assistant Medical Director, Department of Preventive Care	Group Health Cooperative
Wm. Richard Ludwig MD	Chief Medical Officer, Accountable Care Organization	Providence Health and Services
Greg Marchand	Director, Benefits & Policy and Strategy	The Boeing Company
Robert Mecklenburg MD	Medical Director, Center for Health Care Solutions	Virginia Mason Medical Center
Kimberly Moore MD	Associate Chief Medical Officer	Franciscan Health System
Carl Olden MD	Family Physician	Pacific Crest Family Medicine, Yakima
Mary Kay O’Neill MD, MBA		
John Robinson MD, SM	Chief Medical Officer	First Choice Health
Terry Rogers MD (Vice Chair)	Chief Executive Officer	Foundation for Health Care Quality
Jeanne Rupert DO, PhD	Medical Director, Community Health Services	Public Health – Seattle and King County
Kerry Schaefer	Strategic Planner for Employee Health	King County
Bruce Smith MD	Medical Director	Regence Blue Shield
Lani Spencer RN, MHA	Vice President, Health Care Management Services	Amerigroup
Hugh Straley MD (Chair)	Retired	Medical Director, Group Health Cooperative; President, Group Health Physicians
Carol Wagner RN, MBA	Senior Vice President for Patient Safety	The Washington State Hospital Association
Shawn West MD	Family Physician	Edmonds Family Medicine

Appendix B: Oncology Care Workgroup Charter and Roster

Problem Statement

Cost and quality of cancer care vary greatly in the United States.^{1,2} Significant variation in diagnosis, treatment, and supportive care for patients promotes poor outcomes and excessive cost for patients and the health care system.³ While evidence-based guidelines exist, adoption has been inconsistent.⁴

Aim

To improve oncology care patient outcomes and reduce unnecessary cost in the State of Washington.

Purpose

The purpose of the Oncology Care workgroup is to propose recommendations to the full Bree Collaborative on improving oncology care diagnostic imaging through:

1. Identifying evidence-based best practices for use of PET, CT, and/or bone scans within two months of diagnosis for staging of early prostate cancer and early stage breast cancer at low risk for metastasis.
2. Identifying evidence-based best practices for use of chemotherapy or radiation therapy in the last 30 days of life.
3. Recommending implementation strategies for widespread adoption of evidence-based best practices.
4. Identifying additional oncology care areas for improvement.

Duties & Functions

The Oncology Care workgroup will:

- Consult members of the Washington State Hospital Association, the Washington State Medical Association, the Washington State Medical Oncology Society, the Washington State Radiological Society, and other stakeholder organizations and subject matter experts for feedback, as appropriate.
- Research evidence-based guidelines and emerging best practices to inform current diagnostic imaging for prostate and breast cancer.
- Meet for approximately nine months, as needed.
- Provide updates at Bree Collaborative meetings.
- Post draft report on the Bree Collaborative website for public comment prior to sending report to the Bree Collaborative for approval and adoption.

¹ Kolodziej M, Hoverman JR, Garey JS, Espirito J, Sheth S, Ginsburg A, et al. Benchmarks for Value in Cancer Care: An Analysis of a Large Commercial Population. *JOP*. 2011 Sep;7(5):301-306.

² Schroeck FR, Kaufman SR, Jacobs BL, Skolarus TA, Hollingsworth JM, Shahinian VB, Hollenbeck BK. Regional variation in quality of prostate cancer care. *J Urol*. 2014 Apr;191(4):957-62.

³ Soneji S, Yang J. New analysis reexamines the value of cancer care in the United States compared to Western Europe. *Health Aff (Millwood)*. 2015 Mar 1;34(3):390-7.

⁴ Malin JL, Schneider EC, Epstein AM, Adams J, Emanuel EJ, Kahn KL. Results of the National Initiative for Cancer Care Quality: how can we improve the quality of cancer care in the United States? *J Clin Oncol*. 2006 Feb 1;24(4):626-34

- Present findings and recommendations in a report.
- Recommend data-driven implementation strategies.
- Create and oversee subsequent subgroups to help carry out the work, as needed.

Structure

The workgroup will consist of individuals appointed by the chair of the Bree Collaborative or the workgroup chair and confirmed by Bree Collaborative members.

The chair of the workgroup will be appointed by the chair of the Bree Collaborative.

The Bree Collaborative project director will staff and provide management and support services for the workgroup.

Less than the full workgroup may convene to: gather and discuss information; conduct research; analyze relevant issues and facts; or draft recommendations for the deliberation of the full workgroup. A quorum shall be a simple majority and shall be required to accept and approve recommendations to send to the Bree Collaborative.

Meetings

The workgroup will hold meetings as necessary. The program director will conduct meetings along with the chair, arrange for the recording of each meeting, and distribute meeting agendas and other materials prior to each meeting.

Name	Title	Organization
Christopher Kodama, MD, MBA (Chair)	President, MultiCare Connected Care	MultiCare Health System
Jennie Crews, MD	Medical Director	PeaceHealth St. Joseph Cancer Center
Bruce Cutter, MD	Oncologist	Medical Oncology Associates
Patricia Dawson, MD, PhD	Medical Director	Swedish Cancer Institute Breast Program and True Family Women's Cancer Center
Keith Eaton, MD, PhD	Medical Director, Quality, Safety and Value	Seattle Cancer Care Alliance
Janet Freeman-Daily	Patient Advocate	
Gary Lyman, MD, MPH	Co-Director	Hutchinson Institute for Cancer Outcomes Research
Rick McGee, MD	Oncologist	Washington State Medical Oncology Society
John Rieke, MD	Radiologist	Washington State Radiological Society
Hugh Straley, MD	Chair	Bree Collaborative
Dick Whitten, MD, MBA	Contractor Medical Director; VP Health Policy	Noridian Healthcare Solutions

Appendix C: Prostate Cancer Staging (ACS/AJCC)¹⁴

The most widely used staging system for prostate cancer is the American Joint Committee on Cancer (AJCC) TNM system based on five categories of information:

- The extent of the primary **tumor** (T category)
- Whether the cancer has spread to nearby lymph **nodes** (N category)
- The absence or presence of distant **metastasis** (M category)
- The PSA level at the time of diagnosis
- The Gleason score, based on the prostate biopsy (or surgery)

There are actually 2 types of staging for prostate cancer:

The *clinical stage* is your doctor's best estimate of the extent of your disease, based on the results of the physical exam (including DRE), lab tests, prostate biopsy, and any imaging tests you have had.

If you have surgery, your doctors can also determine the *pathologic stage*, which is based on the surgery and examination of the removed tissue. This means that if you have surgery, the stage of your cancer might actually change afterward (if cancer was found in a place it wasn't suspected, for example). Pathologic staging is likely to be more accurate than clinical staging, as it allows your doctor to get a firsthand impression of the extent of your disease. This is one possible advantage of having surgery (radical prostatectomy) as opposed to radiation therapy or active surveillance.

Both types of staging use the same categories (but the T1 category is only used for clinical staging).

T categories (clinical)

There are 4 categories for describing the local extent of a prostate tumor, ranging from T1 to T4. Most of these have subcategories as well.

T1: Your doctor can't feel the tumor or see it with imaging such as trans rectal ultrasound.

- **T1a:** Cancer is found incidentally (by accident) during a transurethral resection of the prostate (TURP) that was done for benign prostatic hyperplasia (BPH). Cancer is in no more than 5% of the tissue removed.
- **T1b:** Cancer is found during a TURP but is in more than 5% of the tissue removed.
- **T1c:** Cancer is found by needle biopsy that was done because of an increased PSA.

T2: Your doctor can feel the cancer with a digital rectal exam (DRE) or see it with imaging such as transrectal ultrasound, but it still appears to be confined to the prostate gland.

- **T2a:** The cancer is in one half or less of only one side (left or right) of your prostate.
- **T2b:** The cancer is in more than half of only one side (left or right) of your prostate.
- **T2c:** The cancer is in both sides of your prostate.

T3: The cancer has grown outside your prostate and may have grown into the seminal vesicles.

- **T3a:** The cancer extends outside the prostate but not to the seminal vesicles.
- **T3b:** The cancer has spread to the seminal vesicles.

T4: The cancer has grown into tissues next to your prostate (other than the seminal vesicles), such as the urethral sphincter (muscle that helps control urination), the rectum, the bladder, and/or the wall of the pelvis.

N categories – whether the cancer has spread to nearby (regional) lymph nodes.

- **NX:** Nearby lymph nodes were not assessed.
- **N0:** The cancer has not spread to any nearby lymph nodes.
- **N1:** The cancer has spread to one or more nearby lymph nodes.

M categories – whether the cancer has spread to distant parts of the body. The most common sites of prostate cancer spread are to the bones and to distant lymph nodes, although it can also spread to other organs, such as the lungs and liver.

- **M0:** The cancer has not spread past nearby lymph nodes.
- **M1:** The cancer has spread beyond the nearby lymph nodes.
 - **M1a:** The cancer has spread to distant (outside of the pelvis) lymph nodes.
 - **M1b:** The cancer has spread to the bones.
 - **M1c:** The cancer has spread to other organs such as lungs, liver, or brain (with or without spread to the bones).

Stage grouping

Once the T, N, and M categories have been determined, this information is combined, along with the Gleason score and prostate-specific antigen (PSA) level, in a process called *stage grouping*. If the Gleason score or PSA results are not available, the stage can be based on the T, N, and M categories. The overall stage is expressed in Roman numerals from I (the least advanced) to IV (the most advanced). This is done to help determine treatment options and the outlook for survival or cure (prognosis).

Stage I: One of the following applies:

T1, N0, M0, Gleason score 6 or less, PSA less than 10: The doctor can't feel the tumor or see it with an imaging test such as transrectal ultrasound (it was either found during a transurethral resection or was diagnosed by needle biopsy done for a high PSA) [T1]. The cancer is still within the prostate and has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Gleason score is 6 or less and the PSA level is less than 10.

OR

T2a, N0, M0, Gleason score 6 or less, PSA less than 10: The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound and is in one half or less of only one side (left or right) of the prostate [T2a]. The cancer is still within the prostate and has not spread

to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Gleason score is 6 or less and the PSA level is less than 10.

Stage IIA: One of the following applies:

T1, N0, M0, Gleason score of 7, PSA less than 20: The doctor can't feel the tumor or see it with imaging such as transrectal ultrasound (it was either found during a transurethral resection or was diagnosed by needle biopsy done for a high PSA level) [T1]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor has a Gleason score of 7. The PSA level is less than 20.

OR

T1, N0, M0, Gleason score of 6 or less, PSA at least 10 but less than 20: The doctor can't feel the tumor or see it with imaging such as transrectal ultrasound (it was either found during a transurethral resection or was diagnosed by needle biopsy done for a high PSA) [T1]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor has a Gleason score of 6 or less. The PSA level is at least 10 but less than 20.

OR

T2a or T2b, N0, M0, Gleason score of 7 or less, PSA less than 20: The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound and is in only one side of the prostate [T2a or T2b]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. It has a Gleason score of 7 or less. The PSA level is less than 20.

Stage IIB: One of the following applies:

T2c, N0, M0, any Gleason score, any PSA: The tumor can be felt by digital rectal exam or seen with imaging such as transrectal ultrasound and is in both sides of the prostate [T2c]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor can have any Gleason score and the PSA can be any value.

OR

T1 or T2, N0, M0, any Gleason score, PSA of 20 or more: The cancer has not yet spread outside the prostate. It may (or may not) be felt by digital rectal exam or seen with imaging such as transrectal ultrasound [T1 or T2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor can have any Gleason score. The PSA level is at least 20.

OR

T1 or T2, N0, M0, Gleason score of 8 or higher, any PSA: The cancer has not yet spread outside the prostate. It may (or may not) be felt by digital rectal exam or seen with imaging such as transrectal ultrasound [T1 or T2]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The Gleason score is 8 or higher. The PSA can be any value.

Stage III:

T3, N0, M0, any Gleason score, any PSA: The cancer has grown outside the prostate and may have spread to the seminal vesicles [T3], but it has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor can have any Gleason score and the PSA can be any value.

Stage IV: One of the following applies:

T4, N0, M0, any Gleason score, any PSA: The cancer has grown into tissues next to the prostate (other than the seminal vesicles), such as the urethral sphincter (muscle that helps control urination), rectum, bladder, and/or the wall of the pelvis [T4]. The cancer has not spread to nearby lymph nodes [N0] or elsewhere in the body [M0]. The tumor can have any Gleason score and the PSA can be any value.

OR

Any T, N1, M0, any Gleason score, any PSA: The tumor may or may not be growing into tissues near the prostate [any T]. The cancer has spread to nearby lymph nodes [N1] but has not spread elsewhere in the body [M0]. The tumor can have any Gleason score and the PSA can be any value.

OR

Any T, any N, M1, any Gleason score, any PSA: The cancer may or may not be growing into tissues near the prostate [any T] and may or may not have spread to nearby lymph nodes [any N]. It has spread to other, more distant sites in the body [M1]. The tumor can have any Gleason score and the PSA can be any value.

Appendix D: Breast Cancer Staging⁵⁵

The stage of a breast cancer can be based either on the results of physical exam, biopsy, and imaging tests (called the *clinical stage*), or on the results of these tests plus the results of surgery (called the *pathologic stage*). The staging described here is the pathologic stage, which includes the findings after surgery, when the pathologist has looked at the breast mass and nearby lymph nodes. Pathologic staging is likely to be more accurate than clinical staging, as it allows the doctor to get a firsthand impression of the extent of the cancer.

The TNM staging system classifies cancers based on their T, N, and M stages:

- The letter T followed by a number from 0 to 4 describes the tumor's size and spread to the skin or to the chest wall under the breast. Higher T numbers mean a larger tumor and/or wider spread to tissues near the breast.
- The letter N followed by a number from 0 to 3 indicates whether the cancer has spread to lymph nodes near the breast and, if so, how many lymph nodes are affected.
- The letter M followed by a 0 or 1 indicates whether the cancer has spread to distant organs -- for example, the lungs or bones.

Primary tumor (T) categories:

- **TX:** Primary tumor cannot be assessed.
- **T0:** No evidence of primary tumor.
- **Tis:** Carcinoma in situ (DCIS, LCIS, or Paget disease of the nipple with no associated tumor mass)
- **T1** (includes T1a, T1b, and T1c): Tumor is 2 cm (3/4 of an inch) or less across.
- **T2:** Tumor is more than 2 cm but not more than 5 cm (2 inches) across.
- **T3:** Tumor is more than 5 cm across.
- **T4** (includes T4a, T4b, T4c, and T4d): Tumor of any size growing into the chest wall or skin. This includes inflammatory breast cancer.

Nearby lymph nodes (N; based on looking at them under a microscope):

Lymph node staging for breast cancer has changed as technology has evolved. Earlier methods were useful in finding large deposits of cancer cells in the lymph nodes, but could miss microscopic areas of cancer spread. Newer methods have made it possible to find smaller and smaller deposits of cancer cells, but experts haven't been sure what to do with the new information. Do tiny deposits of cancer cells affect outlook the same way that larger deposits do? How much cancer in the lymph node is needed to see a change in outlook or treatment?

These questions are still being studied, but for now, a deposit of cancer cells must contain at least 200 cells or be at least 0.2 mm across (less than 1/100 of an inch) for it to change the N stage. An area of cancer spread that is smaller than 0.2 mm (or less than 200 cells) doesn't change the stage, but is recorded with abbreviations that reflect the way the cancer spread was detected. The abbreviation "i+" means that a small number of cancer cells (called *isolated tumor cells*) were seen in routine stains or when a special type of staining technique, called *immunohistochemistry*, was used.

The abbreviation "mol+" is used if the cancer could only be found using a technique called *RT-PCR*. RT-PCR is a molecular test that can find very small numbers of cells that cannot be seen even using special stains. However, this test is not often used for finding breast cancer cells in lymph nodes because the results do not influence treatment decisions.

If the area of cancer spread is at least 0.2 mm (or 200 cells), but still not larger than 2 mm, it is called *micrometastasis* (one mm is about the size of the width of a grain of rice). Micrometastases are counted only if there aren't any larger areas of cancer spread. Areas of cancer spread larger than 2 mm are known to affect outlook and do change the N stage. These larger areas are sometimes called *macrometastases*, but are more often just called *metastases*.

NX: Nearby lymph nodes cannot be assessed (for example, if they were removed previously).

N0: Cancer has not spread to nearby lymph nodes.

- **N0(i+):** Tiny amounts of cancer are found in underarm lymph nodes by using either routine or special stains. The area of cancer spread contains less than 200 cells and is smaller than 0.2 mm.
- **N0(mol+):** Cancer cells cannot be seen in underarm lymph nodes (even using special stains), but traces of cancer cells were detected using RT-PCR.

N1: Cancer has spread to 1 to 3 axillary (underarm) lymph node(s), and/or tiny amounts of cancer are found in internal mammary lymph nodes (those near the breast bone) on sentinel lymph node biopsy.

- **N1mi:** Micrometastases (tiny areas of cancer spread) in 1 to 3 lymph nodes under the arm. The areas of cancer spread in the lymph nodes are 2 mm or less across (but at least 200 cancer cells or 0.2mm across).
- **N1a:** Cancer has spread to 1 to 3 lymph nodes under the arm with at least one area of cancer spread greater than 2 mm across.
- **N1b:** Cancer has spread to internal mammary lymph nodes, but this spread could only be found on sentinel lymph node biopsy (it did not cause the lymph nodes to become enlarged).
- **N1c:** Both N1a and N1b apply.

N2: Cancer has spread to 4 to 9 lymph nodes under the arm, or cancer has enlarged the internal mammary lymph nodes (either N2a or N2b, but not both).

- **N2a:** Cancer has spread to 4 to 9 lymph nodes under the arm, with at least one area of cancer spread larger than 2 mm.
- **N2b:** Cancer has spread to one or more internal mammary lymph nodes, causing them to become enlarged.

N3: Any of the following:

- **N3a:** either
 - Cancer has spread to 10 or more axillary lymph nodes, with at least one area of cancer spread greater than 2mm, OR
 - Cancer has spread to the lymph nodes under the clavicle (collar bone), with at least one area of cancer spread greater than 2mm.

- **N3b:** either:
 - Cancer is found in at least one axillary lymph node (with at least one area of cancer spread greater than 2 mm) and has enlarged the internal mammary lymph nodes, OR
 - Cancer has spread to 4 or more axillary lymph nodes (with at least one area of cancer spread greater than 2 mm), and tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy.
- **N3c:** Cancer has spread to the lymph nodes above the clavicle with at least one area of cancer spread greater than 2mm.

Metastasis (M):

- **MX:** Distant spread (metastasis) cannot be assessed.
- **M0:** No distant spread is found on x-rays (or other imaging procedures) or by physical exam.
 - **cM0(i +):** Small numbers of cancer cells are found in blood or bone marrow (found only by special tests), or tiny areas of cancer spread (no larger than 0.2 mm) are found in lymph nodes away from the breast.
- **M1:** Cancer has spread to distant organs. (The most common sites are bone, lung, brain, and liver.)

Breast cancer stage grouping

Once the T, N, and M categories have been determined, this information is combined in a process called *stage grouping*. Cancers with similar stages tend to have a similar outlook and are often treated in a similar way. Stage is expressed in Roman numerals from stage I (the least advanced stage) to stage IV (the most advanced stage). Non-invasive cancer is listed as stage 0.

Stage 0:

Tis, N0, M0: This is *ductal carcinoma in situ (DCIS)*, a pre-cancer of the breast. Many consider DCIS the earliest form of breast cancer. In DCIS, cancer cells are still within a duct and have not invaded deeper into the surrounding fatty breast tissue. *Lobular carcinoma in situ (LCIS)* sometimes also is classified as stage 0 breast cancer, but most oncologists believe it is not a true cancer or pre-cancer. Paget disease of the nipple (without an underlying tumor mass) is also stage 0. In all cases the cancer has not spread to lymph nodes or distant sites.

Stage IA: T1, N0, M0:

The tumor is 2 cm (about 3/4 of an inch) or less across (T1) and has not spread to lymph nodes (N0) or distant sites (M0).

Stage IB: T0 or T1, N1mi, M0:

The tumor is 2 cm or less across (or is not found) (T0 or T1) with micrometastases in 1 to 3 axillary lymph nodes (the cancer in the lymph nodes is greater than 0.2mm across and/or more than 200 cells but is not larger than 2 mm)(N1mi). The cancer has not spread to distant sites (M0).

Stage IIA: One of the following applies:

T0 or T1, N1 (but not N1mi), M0: The tumor is 2 cm or less across (or is not found) (T1 or T0) and either:

- It has spread to 1 to 3 axillary lymph nodes, with the cancer in the lymph nodes larger than 2 mm across (N1a), OR
- Tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy (N1b), OR
- It has spread to 1 to 3 lymph nodes under the arm and to internal mammary lymph nodes (found on sentinel lymph node biopsy) (N1c).

OR

- **T2, N0, M0:** The tumor is larger than 2 cm but less than 5 cm across (T2) but hasn't spread to the lymph nodes (N0).
- The cancer hasn't spread to distant sites (M0).

Stage IIB: One of the following applies:

T2, N1, M0: The tumor is larger than 2 cm but less than 5 cm across (T2). It has spread to 1 to 3 axillary lymph nodes and/or tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy (N1). The cancer hasn't spread to distant sites (M0).

OR

T3, N0, M0: The tumor is larger than 5 cm across but does not grow into the chest wall or skin and has not spread to lymph nodes (T3, N0). The cancer hasn't spread to distant sites (M0).

Stage IIIA: One of the following applies:

T0 to T2, N2, M0: The tumor is not more than 5 cm across (or cannot be found) (T0 to T2). It has spread to 4 to 9 axillary lymph nodes, or it has enlarged the internal mammary lymph nodes (N2). The cancer hasn't spread to distant sites (M0).

OR

T3, N1 or N2, M0: The tumor is larger than 5 cm across but does not grow into the chest wall or skin (T3). It has spread to 1 to 9 axillary nodes, or to internal mammary nodes (N1 or N2). The cancer hasn't spread to distant sites (M0).

Stage IIIB: T4, N0 to N2, M0:

The tumor has grown into the chest wall or skin (T4), and one of the following applies:

- It has not spread to the lymph nodes (N0).
- It has spread to 1 to 3 axillary lymph nodes and/or tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy (N1).
- It has spread to 4 to 9 axillary lymph nodes, or it has enlarged the internal mammary lymph nodes (N2).

The cancer hasn't spread to distant sites (M0).

Inflammatory breast cancer is classified as T4d and is at least stage IIIB. If it has spread to many nearby lymph nodes (N3) it could be stage IIIC, and if it has spread to distant lymph nodes or organs (M1) it would be stage IV.

Stage IIIC: any T, N3, M0:

The tumor is any size (or can't be found), and one of the following applies:

- Cancer has spread to 10 or more axillary lymph nodes (N3).
- Cancer has spread to the lymph nodes under the clavicle (collar bone) (N3).
- Cancer has spread to the lymph nodes above the clavicle (N3).
- Cancer involves axillary lymph nodes and has enlarged the internal mammary lymph nodes (N3).
- Cancer has spread to 4 or more axillary lymph nodes, and tiny amounts of cancer are found in internal mammary lymph nodes on sentinel lymph node biopsy (N3)

The cancer hasn't spread to distant sites (M0).

Stage IV: any T, any N, M1:

The cancer can be any size (any T) and may or may not have spread to nearby lymph nodes (any N). It has spread to distant organs or to lymph nodes far from the breast (M1). The most common sites of spread are the bone, liver, brain, or lung.

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