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ASTRO news

AMERICAN SOCIETY FOR RADIATION ONCOLOGY

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Features

Inside

SHARPEN YOUR EDGE AGAINST CANCER.

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BY LISA A. KACHNIC, MD, FASTRO

EDITOR'S*notes*

Challenges of navigating the cancer care continuum amidst the Boston blizzards: TALES FROM A SAFETY NET HOSPITAL

ARTIC *ASTRONEWS* BLAST: record snowfalls of more than six feet shut down Boston. The mayor suspends public transportation and closes all schools and highways for days. However, radiation oncology staff and the patients they care for do not have the luxury of multiple snow days. As outcomes may be compromised if our patients have prolonged treatment breaks, we all don ski garb, with the addition of our New England Patriots Super Bowl 49 champ hats, brave the inclement elements and somehow get to the hospital … and for the patients that were only able to receive three of five weekdays of radiation, we also offer Saturday treatments.

Does this all sound challenging? Well, imagine experiencing such barriers to cancer care throughout the entire year. This is what it is like at a safety net hospital. At Boston Medical Center (BMC), where I have worked for the past 15 years, about three-quarters of our patients experience different sociocultural beliefs and practices, lack any secondary education, are uninsured or underinsured, and are considered at the poverty level in Massachusetts. In addition, more than 30 percent speak primary languages other than English. As such, standard management tasks such as completing the diagnostic work-up, cancer therapy and follow-up are all frequently compromised due to patient non-compliance. For example, in my early years at BMC, 15 to 20 percent of our daily treated patients just didn't show up for their radiation due to complicated social barriers. These vulnerable patients lack the time to care for their cancer due to domestic/family responsibilities, no available transportation, fear of losing their minimum wage, often uninsured part-time job, and a lack of trust in their cancer care providers. They also have notable co-morbidities challenging their treatment completion and eligibility for most national trials.

To address these barriers and overcome cancer care disparities, the National Cancer Institute created the Cancer Disparities Research Partnership Program in 2002 with a main focus on patient navigation (see "Patient navigation programs help address health disparities" on page 12). BMC initiated a cancer care patient navigation and support program in 2007, largely supported by an NCI Minority-based Community Clinical Oncology Program (MB-CCOP) award, for which I was the principle investigator. Our patient navigation model uses peer health educators who perform four core functions: 1) patient identification; 2) identification of barriers to care; 3) implementation of an individual cancer care plan and identification of patients for clinical studies; and 4) long-term tracking for treatment and follow-up compliance. Peer navigator services also include helping patients to make and keep appointments; arranging for interpreter services, child care and transportation; providing emotional support; assisting with insurance issues; helping with housing; and/or addressing issues of domestic violence. Since initiating

these services, our no-show rate for patients receiving radiation has significantly decreased to less than 5 percent.

We have also leveraged this patient navigation program to assist in clinical trial enrollment. First, through our monthly protocol screening meeting, we work to choose studies that are relevant to the patient population we serve and design investigator-initiated protocols to meet these needs. Our lay navigators are also educated on trials open for enrollment, so that they may, in turn, educate the practicing primary physicians; this is critical for cancer prevention or cancer care delivery trials. We also employ on-site clinical trial nurse navigators in our cancer center who attend all of our multidisciplinary cancer conferences and have access to the cancer providers' schedules to actively screen every cancer patient we serve for a prevention, treatment, symptom management or survivorship trial, often utilizing our 35 language interpreter services, and our peer lay navigators to arrange transportation and social support. All recruitment-related patient encounters use an informal conversational approach. Although prospective research on similar methods is ongoing, we believe that an informational, non-threatening approach is very effective in initiating a conversation with our vulnerable patients about clinical trials, securing their cooperation for cancer-control research.

Depending on the complexity of the study and the potential risks and benefits, two to three visits are often required for trial enrollment. In our experience, these face-to-face meetings have proven superior to other outreach approaches. During one of the meetings, the clinical trial nurse navigator responsible for the study reviews the consent form with the patient and family members, detailing the treatment plan, risks, benefits, alternatives, costs, etc. The patient and family members are then given multiple opportunities to ask questions. The clinical trial staff generally use one or two additional in-person meetings to reinforce study specifics, ensure patient understanding and address potential barriers. All visits are conducted in conjunction with the patient's scheduled visits in the hematology/oncology, radiation oncology or the multidisciplinary oncology clinics. Through this navigation infrastructure, BMC noted a 250 percent increase in NCI cancer clinical trial enrollment in 2013, with an overall rate of clinical study enrollment of 20 percent, approximately half representing minority accrual.

With our navigators (lay and nurses), BMC has also developed a formal survivorship program. We have more than 20 cancer support groups and specialty services including an active Complementary Alternative Medicine Program and one to two large-scale free screening efforts per year. The American Cancer Society and the LIVE**STRONG** Foundation have been wonderful supporters (see "Survivorship programs help support cancer patients throughout journey" on page 16). Currently, we are constructing a survivorship template in our electronic medical record so that we may meet the American College of Surgeon's Commission on Cancer's new program requirements. While this is the right thing to do for our patients and their primary care providers, it is quite challenging. The developing ASTRO survivorship cancer plan template, described on page 20, will be paramount in our successful implementation.

I only wish that ASTRO may provide support in ridding the 101 inches of snow and ice off of my roof. For those in the Northeast, especially New England, stay warm and be safe!

Dr. Kachnic escaped the Boston weather to enjoy her beloved New England Patriots secure a rollercoaster victory in sunny Phoenix during Super Bowl 49.

Dr. Kachnic is chair of the department of radiation oncology at Boston Medical Center and professor of radiation oncology at Boston University School of Medicine. She welcomes comments on her editorial, as well as suggestions for future ASTROnews *topics, at astronews@astro.org.*

BY BRUCE G. HAFFTY, MD, FASTRO
CHAIR, BOARD OF DIRECTORS

CHAIR'S*update*

CLINICAL PRACTICE STATEMENTS: CAN WE KEEP UP WITH THE DEMAND?

CLINICIANS ACROSS ALL OF MEDICINE are increasingly dependent on clinical practice statements in a variety of formats, including guidelines, consensus statements, best practices, practice standards, appropriateness criteria, white papers and other guidance, to influence practice and clinical decision-making. While clinical trials and peer-reviewed literature provide the basis for much of our clinical decision-making, clinical practice statements, typically generated by teams of experts and supported by professional societies and organizations, provide an important mechanism for gathering, analyzing, synthesizing and ultimately making recommendations based on the best available evidence and literature.

The value of these clinical practice statements to practitioners is reflected by the fact that guidelines, consensus and practice statements are among the most highly referenced and quoted articles in the medical literature. This is true across all of medicine, including radiation oncology. It is not only reflected in the cited literature, but also in ASTRO's member survey. Clinical practice statements were ranked by our membership as the third-highest priority out of all of ASTRO's functions, behind only our publications and educational products, and it was ranked first, second or third by 74 percent of members.

Given that clinical practice statements are such a high priority and valued function within our own specialty and throughout medicine, I wanted to take this opportunity to review ASTRO's approach in this arena. One of the major changes ASTRO has made during the past few years was the creation of a new council structure, when it became clear that issues surrounding clinical care, quality and accreditation should fall under a dedicated council (Clinical Affairs and Quality Council) within ASTRO's structure. Committees dedicated to guidelines and clinical practice statements were then reformed and restructured within this newly created council, along with other committees dedicated to the general domain of clinical affairs and quality.

ASTRO then developed specific policies and procedures within this area, which continue to develop and evolve as needed. While it is likely, given the importance, priority and rapid development of practice statements and guidelines, that our approach and specific products will change over time, ASTRO continues to strive to meet the needs of our specialty by providing as many quality practice guidelines and statements as possible.

GUIDELINES DEVELOPMENT

One of the major events that shaped guideline development was the 2011 Institute of Medicine (IOM) report, "Clinical Practice Guidelines We Can Trust" (available online at www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx), which established rigorous standards in producing guidelines. Guidelines generated by professional medical societies and organizations are generally supported by a relatively high level of evidence and are most likely to directly impact clinical care and decision-making; therefore, the rigor applied to the process of guideline development is an important step to assure that these guides to clinical decision-making are unbiased and reflect the best available evidence. While practice guidelines produced through the years have served a significant need and likely improved patient care, analysis of guidelines in

oncology and other fields of medicine, published in high-impact journals from highly respected organizations during the past decade revealed a relatively low compliance with current IOM standards.

In response to the need for a rigorous approach to guideline development, ASTRO established policies and procedures for guideline development which adhere, as closely as possible, to the IOM standards. Given the multidisciplinary nature of oncologic practice, guidelines are often developed in collaboration with other societies. Therefore, it is important that ASTRO be involved from the beginning and collaborate and coordinate with other organizations to ensure the ultimate guideline product will comply as closely as possible to IOM standards. We are confident and take pride that our current process largely fulfills IOM standards for those products we refer to as guidelines.

Development of formal guidelines follows this rigorous process, and given the complexity of development, they are both time consuming and costly and need to be prioritized. The process of creating and ultimately approving a guideline typically takes 12 to 18 months. Clearly, it is not possible to produce guidelines for every clinical scenario, particularly within radiation oncology where our specialty covers such a broad spectrum of disease sites. Nor is it appropriate to develop guidelines when there is not high-level evidence in the literature to support a guideline.

OTHER PRACTICE STATEMENTS

There are a variety of other mechanisms beyond formal guidelines that societies employ to address the needs of their specialty in practice guidance, ranging from consensus panel statements, best practices, practice standards, appropriateness criteria, white papers and literature reviews. Depending on the specialty, these products take on many forms and would not be expected to fully adhere to IOM guideline development standards, though many of these same principles should and will apply.

CONSENSUS PANEL STATEMENTS

Consensus statements most closely resemble guidelines, and the terms are informally used interchangeably. The evidence supporting consensus panel statements is usually not as robust as the literature supporting guidelines. However, because consensus panel statements are often used to support clinical decision-making and impact directly on patient care, it is important in developing consensus statements that IOM standards are adhered to as much as possible, particularly regarding conflict of interest, systematic review, panel composition and external review of the document. While ASTRO has only published a few consensus statements in recent years, our process does comply with these criteria, and when asked by other societies to participate in consensus panels or guidelines panels, ASTRO requests that their process follow IOM standards as closely as possible.

BEST PRACTICES

Best practices at ASTRO are currently used to define the appropriate use of radiation therapy in selected clinical scenarios. The process involves use of the RAND/UCLA appropriateness criteria methodology, which combines the best available literature and expert opinion from a multidisciplinary panel. Panel members vote on the level of appropriateness for a particular approach in a given clinical scenario. Generally, best practice statements address clinical practice questions of how to treat in a particular situation where there is not high-level evidence. Many of the same principles of the IOM standards are used in best practices, including panel selection, conflict of interest, systematic reviews, public comments and external review of the document.

Continued on Page 8

Clinical practice statements provide an important mechanism for gathering, analyzing, synthesizing and ultimately making recommendations based on the best available evidence and literature.

Continued from Page 7

CHAIR'S*update*

WHITE PAPERS

ASTRO has an extensive array of committees, composed primarily of our volunteers and supported by ASTRO staff, covering a broad range of issues and topics within our five councils. Often, these committees propose white papers to address overarching issues of particular interest to the Society that do not fit neatly into practice statements. Specifically, ASTRO attempts to place clinical practice issues into one of the products noted above, avoiding white papers directly related to clinical care. However, some white papers focus on certain aspects of clinical care, particularly as they may relate to quality assurance. These white papers provide guidance for our members, our specialty and our patients on a variety of topics. While white papers are not expected to adhere to IOM standards as much as guidelines and consensus statements, we do require conflict of interest (COI) disclosure, assure that the chair/senior author does not have a COI, attempt to have broad representation, and require external review, and often public comment.

MODEL POLICIES

While clinical practice statements are designed to offer guidance on treatment decision-making, a model policy's primary purpose is to provide guidance on appropriate coverage of certain technologies. Although model policies do not necessarily directly address clinical treatment decisions, a rigorous process is followed in developing model policies. This includes an extensive literature search as well as panel/committee composition that addresses COI, expertise and diversity. Ultimately, the policy is used to support insurance coverage for certain technologies and procedures in the delivery of radiation therapy services. These model policies generally reflect, based on the review of the literature and committee discussion, ASTRO's position on insurance coverage for specified technologies in delivering radiation for given clinical conditions.

CONCLUSION

Clinical practice statements are a high priority for our specialty. Extensive resources are required to produce all of these products, and ASTRO strives to adapt to the increasing demand for clinical practice statements to help guide clinical decision-making and quality patient care. Of course, resource allocation in terms of volunteer and staff time limits the number of products that can be developed, and ASTRO has developed policies and procedures for prioritizing clinical practice statements. ASTRO members can suggest topics for clinical practice statement development online at www.astro.org/CPTopic. We also continue to engage and collaborate with other professional societies in developing appropriate clinical practice statements to guide oncologic care. As our work in this arena continues to expand, we are confident that the ultimate goal of improving patient care and outcomes will be met.

Dr. Haffty is professor and chair of the Department of Radiation Oncology at Rutgers-Robert Wood Johnson Medical School and New Jersey Medical School and associate director of the Rutgers Cancer Institute of New Jersey. He welcomes comments on this column at astronews@astro.org.

SOCIETY NEWS

ASTRO accepting nominations for 2015 recognition awards

ASTRO has opened nominations for its annual recognition awards. Presented at the Awards Ceremony at the Annual Meeting, these three categories of awards honor individuals who have made substantial contributions to the field of radiation oncology.

GOLD MEDAL

The Society's highest distinction is the Gold Medal. This award honors members who have made outstanding contributions to the field of radiation oncology, including research, clinical care, teaching and service. Gold Medal Award recipients may be selected from any of the scientific disciplines represented by ASTRO's members. The nomination submission deadline for the Gold Medal Award is April 30, 2015.

ASTRO FELLOWS

The ASTRO Fellows designation is granted based on length of ASTRO membership and commendable service to ASTRO and to the field of radiation oncology. To be considered, nominees must have at least 15 years of active ASTRO membership and service to ASTRO must add up to 10 years. Other factors considered include leadership and service, research, patient care and education. The nomination submission deadline for the Fellows program is May 15, 2015.

HONORARY MEMBER

Honorary Membership in ASTRO is the highest recognition the Society confers on notable cancer researchers and leaders in disciplines other than radiation oncology, radiation physics or radiobiology. The nomination submission deadline for Honorary Membership is April 30, 2015.

For more information on ASTRO's recognition awards, visit www.astro.org/recognitionawards.

THREE ASTRO STAFF MEMBERS RECEIVE PROMOTIONS

THREE ASTRO STAFF MEMBERS recently were recognized with promotions: Emily Wilson was promoted to executive vice president; Dave Adler was promoted to vice president of advocacy; and Anne Hubbard was promoted to director of health policy.

As executive vice president, Wilson will provide strategic guidance to ASTRO's Board of Directors, CEO and staff to ensure the organization is meeting the goals of the Society's strategic plan.

In his role as vice president of advocacy, Adler will oversee ASTRO's Government Relations and Health Policy departments, which are responsible for ASTRO's legislative and regulatory advocacy efforts.

As director of health policy, Hubbard will lead ASTRO's efforts to analyze payer reimbursement policy decisions and will continue to serve as ASTRO's staff advisor to the AMA's CPT Editorial Panel and RVS Update Committee.

IN MEMORIAM

ASTRO has learned that the following members have passed away. Our thoughts go out to their family and friends.

Thomas J. Weatherall, MD
H. Rodney Withers, MD, DSc, FASTRO

The Radiation Oncology Institute (ROI) graciously accepts gifts in memory of or in tribute to individuals. For more information, call 1-800-962-7876 or visit www.roinstitute.org.

SOCIETY NEWS

Companies elected to ASTRO's Corporate Advisory Council

ASTRO's Corporate Membership has elected the following companies to serve on the 2015 Corporate Advisory Council: Accuray and ViewRay Inc. are newly elected and Bogardus Medical Systems, Standard Imaging, Sun Nuclear and Varian Medical Systems have been re-elected for new terms.

Through a synergistic relationship between ASTRO and its corporate members, the Council focuses on issues and initiatives of mutual concern in radiation oncology to increase awareness of radiation therapy and advance the science and practice of cancer treatment and patient care. Together with ASTRO leadership, the Council convenes several times a year via conference call and holds an in-person meeting at ASTRO's Annual Meeting. Discussion topics range from CPT codes and reimbursement activity to the Sunshine Act. Patient safety, MOC and interoperability (IHE-RO) are other important topics.

The Council is a smaller, representative group of the corporate membership-at-large, with an appropriate proportional mix from the corporate membership base. Seats on the Council are held by high-level decision makers within the corporations and are equally balanced between large and small corporations to represent a broad cross-section of the industry.

All corporate members can nominate their company to serve on the Council. Nominations are accepted every fall with elections conducted during the winter. For more information about the Council and/or Corporate Membership, please contact Joanne DiCesare at 703-839-7398 or joanne.dicesare@astro.org.

CORPORATE ADVISORY COUNCIL

Company	Representative	Term Expires
Bogardus Medical Systems Inc.	Jeff Carlin	2015
Alliance Oncology	Greg Spurlock	2015
Elekta	James Hoey	2015
Revenue Cycle Inc.	Ron DiGiaimo	2015
CIVCO	Nat Geissel	2016
D3 Oncology Solutions	Ron Lalonde, PhD	2016
Vantage Oncology	Michael Fiore	2016
Sun Nuclear	Jeff Simon	2016
Standard Imaging Inc.	Raymond Riddle	2017
Accuray	Kelly Londy	2017
Varian Medical Systems	Kolleen Kennedy	2017
ViewRay Inc.	Chris Raanes	2017

Corporate Advisory Council members met in San Francisco during ASTRO's 56th Annual Meeting.
Front Row (from left): Laura Thevenot; David C. Beyer, MD, FASTRO; Bruce D. Minsky, MD, FASTRO; Colleen A.F. Lawton, MD, FASTRO; Deborah A. Kuban, MD, FASTRO; Jeff Simon, Sun Nuclear; Lawrence B. Marks, MD, FASTRO; Michael Fiore, Vantage Oncology.
Back Row (from left): Tim R. Williams, MD, FASTRO; Ron DiGiaimo, Revenue Cycle; Nat Geissel, CIVCO; James Hoey, Elekta; Greg Spurlock, Alliance Oncology; Ron Lalonde, PhD, D3 Oncology Solutions; Jeff Carlin, Bogardus Medical Systems; Raymond Riddle, Standard Imaging; Don Goer, PhD, IntraOp Medical.

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Patient navigation programs help address health disparities

BY BRITTANY ASHCROFT, COMMUNICATIONS MANAGER, BRITTANYA@ASTRO.ORG

ADDRESSING HEALTH CARE DISPARITIES that medically underserved, low-income, ethnic and minority populations face is an ongoing challenge. In an effort to strengthen NCI research programs to help reduce the negative consequences of cancer disparities across the United States, the National Cancer Institute's (NCI) Radiation Research Program (RRP) created the Cancer Disparities Research Partnership (CDRP) program.

The goal of the program, which issued its first two five-year grants in 2002 and an additional four five-year grants in 2003, was to address health disparities in minority and underserved populations through increasing clinical trial participation. When the five-year grants expired in 2009, the previous CDRP grantees were invited to reapply for additional funding. Those renewed grants ended in 2014.

One of the main elements used by grantees to help increase enrollment in clinical trials was a patient navigator program in which navigators were trained to meet the individual needs of specific disparity populations. Funding for the CDRP patient navigators was provided by NCI's Center to Reduce Cancer Health Disparities for the first funding period only.

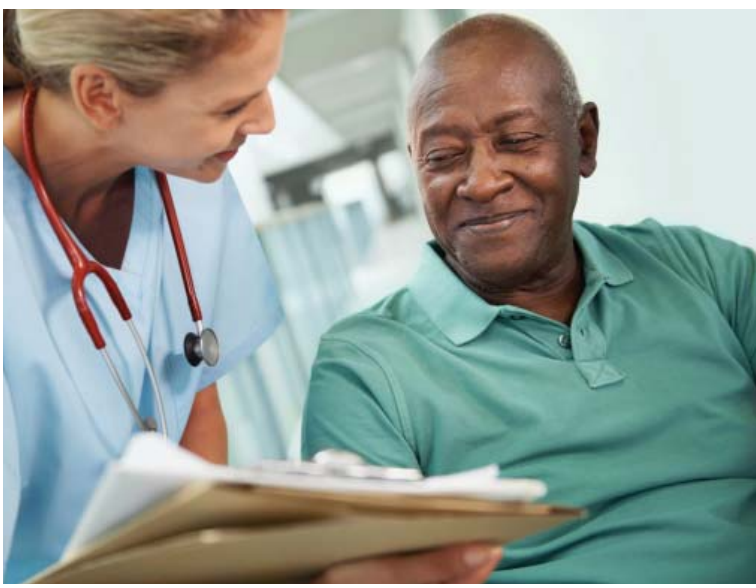
"Patient navigation has been around for decades," said Bhadrasain Vikram, MD, branch chief of the Clinical Radiation Oncology Branch at NCI. "The NCI's Center to Reduce Cancer Health Disparities has been trying to quantitatively assess how patients do better when they have a navigator to help walk them through the health care system. The CDRP was specifically designed to assess if the addition of a patient navigator to other efforts in health disparity communities would increase accrual in clinical trials."

CDRP grantees used different models of patient navigation including a lay navigator, in which community members who are not health care professionals serve as navigators; a professional navigator, in which health care professionals who are medically trained serve as navigators; and a combination program, which uses both professional and lay navigators.

"Each grantee had specific, different models of patient navigation that the organization used to see if they could increase accrual to clinical trials," said Rosemary Wong, PhD, CDRP program director. "We have seen, based on research, that access to a patient navigator program decreased time delays in completing radiation treatment and would lead to better outcomes."

According to Dr. Wong, the CDRP was successful because the number of minority and underserved patients treated in NCI clinical trials increased. Grantees also expressed that the patient navigation element of the CDRP helped improve cancer care because more patients completed treatment, and there was an established rapport between patients and health care providers.

In addition to measuring the "hard metrics" of success, such as increased participation in clinical trials, C. Norman



Coleman, MD, FASTRO, RRP associate director, explained that programs are looking at "soft metrics" as well.

"How do you declare success? There are hard metrics, and then there are soft metrics, like developing trust in the community and having people understand information better, that you can't necessarily measure in a survey, so it's a challenge when people try to measure the success of these programs," he said.

Patient navigation programs are important for disparity populations because these groups tend to present with more advanced disease. Reaching out to patients during screening programs or immediately after a cancer diagnosis through a navigation program can increase their access to clinical trials.

"Patients didn't enroll in trials in part because eligibility for cooperative group trials may not include people with advanced stage disease encountered in the disparities setting," Dr. Coleman said. "In that these tumors may still be curable and local palliation is necessary, there is a unique opportunity for radiation oncology to lead in clinical trials for the advanced diseases that disparity populations tend to see."

Three CDRP grantees shared their experiences and the impact the grant and a patient navigation program had on their patients.

NEW HANOVER REGIONAL MEDICAL CENTER

New Hanover Regional Medical Center, located in Wilmington, North Carolina, is the largest health care service provider in southeastern North Carolina and has a patient population that is largely African-American and has high rates of poverty. The goal of the project at New Hanover Regional Medical Center was to increase the accrual of African-American and other underserved patient populations in southeastern North Carolina into NCI-sponsored clinical trials, in addition to growing the organization's clinical trials infrastructure, increasing the number of oncologists actively involved in clinical research that addresses underserved populations and helping eliminate barriers to cancer care through a patient navigation program.

"We were interested in developing a robust oncology clinical trials program at New Hanover Regional Medical Center and within our group, Coastal Carolina Radiation Oncology," said Patrick Maguire, MD, a radiation oncologist and the principal investigator for the grant. "Our oncology clinical trials education during the period of the grant funding consisted of two main parts: outreach predominately in the African-American community and a patient navigator within the Zimmer Cancer Center to help direct patients."

The patient navigator program at New Hanover Regional Medical Center, which is open to all patients with cancer, uses a professional navigator model. The navigators work with a community advisory board to inform the community about

Continued on Page 14

"The CDRP was specifically designed to assess if the addition of a patient navigator to other efforts in health disparity communities would increase accrual in clinical trials."

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"We have seen, based on research, that access to a patient navigator program decreased time delays in completing radiation treatment and would lead to better outcomes."

cancer and clinical trials. Patient navigators assist patients with applying for federal, state and private assistance for treatment costs, accessing transportation and improving family and social support systems.

"Patient navigator programs have tremendous potential to improve cancer care and survivorship, particularly for patients who are from underserved populations," Dr. Maguire said. "Having patient navigator services as a key component of CDRP funding allowed hospital administration and staff to see the benefits to patients and to the community."

Now that CDRP funding has ended, New Hanover Regional Medical Center will continue to offer patient navigator services for patients receiving cancer care as a result of support from the center's administration.

"The CDRP was a wonderful initiative from NCI," Dr. Maguire said. "It afforded people of southeastern North Carolina, particularly African-Americans, the poor and the elderly, enhanced cancer care overall and a more robust oncology clinical trials program that continues beyond the CDRP grants."

RAPID CITY REGIONAL HOSPITAL

Rapid City Regional Hospital, located in Rapid City, South Dakota, is a nonprofit regional medical center serving approximately 100,000 Native Americans from the surrounding communities and reservations. The patient population experiences high poverty and some of the highest cancer mortality rates in the United States.

The goal of the project at Rapid City Regional Hospital was to decrease cancer incidence and mortality and to improve the quality of life of people with cancer in the community. Some patients the hospital serves live up to four hours away from the cancer center, so the patient navigator program at Rapid City Regional Hospital uses community research representatives who work on the reservations to give patients immediate access to assistance.

"Native Americans tend to present with more advanced stages of cancer, and, therefore, suffer from higher cancer mortality rates," said Daniel Petereit, MD, a radiation oncologist at Rapid City Regional Hospital and the principal investigator for the grant. "Clinical trials were a big part of the grant for us. We also developed shorter treatment regimens since many patients live from 75 to 200 miles away from the cancer center."

Rapid City Regional Hospital's patient navigator program, called Walking Forward, is unique in that it combines the lay and professional navigator model. Lay navigators (community research representatives) are members of the reservation with which they work and serve as the liaison between the health care professionals and the reservation. Professional navigators are based at the hospital and help patients overcome barriers to care, such as seeking out social or financial support.

"The patient navigator program was critical because we hired Native American navigators who lived in the community, and they helped with education and increased awareness. They are really the ones on the front line, getting the message to the community," said Dr. Petereit. "Getting into communities really takes someone to take the time. Having community representatives who wanted to put the message out about the program and that cancer is potentially curable if caught early helps because if patients hear that message, even those with more advanced disease believe there is still hope and still things we can do for them."

Dr. Petereit has seen the direct impact the grant and the hospital's patient navigator program has had on patients. Through surveys, patients have expressed an increased satisfaction with the process and their care and have shown increased compliance rates.

"We were able to document that we improved satisfac-

tion via surveys we conducted with cancer patients pre- and post-navigation," Dr. Petereit said. "They said they had improved experiences with the health care system and showed improved compliance."

UPMC MCKEESPORT HOSPITAL

Radiation Oncology Community Outreach Group (ROCOG) is the collaboration of five community hospitals (UPMC McKeesport, Jameson Hospital, Somerset Hospital, Mercy Hospital and the Murtha Cancer Center) spanning three health care systems, led by UPMC McKeesport Hospital, located in McKeesport, Pennsylvania, a nonprofit, acute care community hospital. The partners in ROCOG serve a diverse population of isolated, rural, poor communities; inner-city, poor African-American communities; the elderly; and the Amish, which tends to be an underserved population.

The goal of the project at UPMC McKeesport Hospital was to improve accrual to clinical trials, to create a sustainable clinical trials infrastructure at each site and to provide patient navigator services. The CDRP grant at UPMC McKeesport Hospital was a bit different than at the other grantee locations in that it connected three hospitals and five community centers in a partnership.

"In western Pennsylvania, we saw most cancer patients presenting with late-stage and stage 4, metastatic breast, prostate and colorectal cancer," said Dwight E. Heron, MD, professor of radiation oncology, otolaryngology, and head and neck surgery, and the principal investigator for the grant. "We asked the logical question: Why were so many patients presenting late-stage diseases in these communities compared to counterparts in other regions? This was the perfect opportunity to address disparities region-wide and encompass different centers. Once we started services, we noticed that the Amish were a group that was typically overlooked."

UPMC McKeesport Hospital's patient navigator program uses a professional model that helps patients with transportation services, insurance and adhering to treatment schedules. The patient navigator at the hospital is also the tumor registrar.

"This is important because every time someone was diagnosed with cancer, the patient navigator could start the process of reaching out to them to help them along the way," Dr. Heron said. "This is especially important for rural poor and urban minorities who have challenges in accessing cancer services in a timely fashion. The patient navigator walks them through each step—consult, treatment and post-treatment."

Dr. Heron and the rest of the grant team worked to make sure patients and the community saw this as a community effort and not a researcher coming in, gathering data and then leaving. The hospital partnered with a regional health group and a consumer advocacy group to reach the community directly.

"We partnered with these groups to bring a stronger message about what we were trying to do," Dr. Heron said. "The goal was to be sustainable, to raise the quality of care and to reduce health disparities. The project was a very novel experiment on the part of NCI, and it demonstrated the power of partnerships. We transformed the ways the community accesses health care, and we strongly believe we've had a lasting impact."

Survivorship programs help support cancer patients throughout journey

BY BRITTANY ASHCROFT, COMMUNICATIONS MANAGER, BRITTANYA@ASTRO.ORG

The Commission on Cancer (CoC), established by the American College of Surgeons in 1922, is a multidisciplinary accreditation program and is comprised of professional organizations that work to improve survival and the quality of life for cancer patients.

Based on the 2005 Institute of Medicine report, "From Cancer Patient to Cancer Survivor: Lost in Transition," *CoC phased-in a new standard for accreditation for 2015 that requires accredited centers to provide patients with a comprehensive survivorship plan.*

ASTRO spoke to CoC's four member organizations in the advocacy/patient-based arena that provide survivorship support, including survivorship care plans.

AMERICAN CANCER SOCIETY

The American Cancer Society (ACS) offers a multitude of resources for survivors through its website and a 24-hour hotline staffed by trained cancer information specialists. In addition, ACS is currently collaborating with the George Washington University Cancer Institute on the National Cancer Survivorship Resource Center, which is funded by a five-year cooperative agreement from the Centers for Disease Control and Prevention.

"ACS has a long history of being committed to the welfare of cancer survivors," said Richard Wender, MD, chief cancer control officer at ACS. "The National Cancer Survivorship Resource Center has given us the opportunity to tackle one of the most important gaps, which I think everybody is struggling with right now, and that is how do we make survivorship the standard of care that every patient receives and make it part of the care system."

The National Cancer Survivorship Resource Center aims to increase access to information, resources and support for survivors as they transition out of treatment and throughout the remainder of their cancer journey. The Survivorship Center has also developed clinical care follow-up guidelines and educational resources to facilitate survivorship care by primary care clinicians as their patients' transition out of the oncology setting.

"We are focused on helping survivors as they transition out of the oncology team's care and are developing resources to support survivors from that point of the journey forward," said Rebecca Cowens-Alvarado, MPH, cancer control mission director at ACS. "ACS's research demonstrates that survivors commonly express concerns about fatigue, recurrence, depression

and late effects of treatment. The Survivorship Center is working to identify and develop resources to address these concerns."

The National Cancer Survivorship Resource Center has helped develop additional resources in three areas: 1) research to better understand what survivors are experiencing in the first two years post-treatment; 2) conducting a randomized controlled trial of Stanford University's *Cancer: Thriving and Surviving* self-management program aimed at helping post-treatment survivors better manage their health and wellness; and 3) improving the information available to primary care clinicians to help them better understand what survivors are facing as they transition out of treatment and improve the care coordination with the oncology team.

"There's a large number of cancer survivors—14.5 million now, and we expect to see almost 19 million in the next decade—who may experience one or more long-term or late effects of treatment," Cowens-Alvarado said. "It's a group of people that may not know what they need until they actually need it. We hope that through our efforts people will become more aware of what they might expect after treatment ends, and more people will have their needs met."

ACS also works closely with CoC, particularly in helping providers prepare survivorship care plans, in addition to co-managing the National Cancer Data Base.

"ACS understands survivorship and can assist CoC-accredited cancer centers in meeting the new CoC standard on providing a comprehensive survivorship care plan," said colon and rectal surgeon Alan Thorson, MD, clinical professor of surgery at Creighton University and the University of Nebraska in Omaha, Nebraska, and former president of ACS. "Collaboration between ACS and CoC is long-standing and a testament to the power of mutually beneficial associations. In this case, there is the potential to have a meaningful impact on the entire survivorship experience for cancer patients by facilitating the plan process and improving overall cancer care."

"It is interesting that somehow the oncology world suddenly woke up to this [survivorship needs] because the needs have always been there," Dr. Wender said. "I think what really shifted is the number of people who are going to live so many years following cancer. It's the voice of cancer patients themselves who have reported these needs."

For more information on ACS, visit www.cancer.org.

CANCER SUPPORT COMMUNITY

Cancer Support Community (CSC), created in 2009 when The Wellness Community and Gilda's Club Worldwide merged into one organization, provides psychosocial support to patients through community-based centers, hospitals, community oncology practices and the organization's website.

CSC offers support in-person for patients close to a CSC affiliate and online and telephone support for patients who are not close enough for an in-person visit. CSC counselors, who are all licensed mental health professionals, can help survivors locate resources, provide counseling and offer support through the experience. The organization also holds support groups focused on various topics, including specific disease sites, getting back into the workforce, exercise and medication.

"We welcome people because we know the most critical time is when the oncology team tells them, 'We will see you in a year or six months,'" said Sara Goldberger, LCSW-R, senior director at CSC. "When treatment is over, that doesn't mean a person's experience with cancer is over." *Continued on Page 18*

"For patients to really be engaged in their own care and to be a partner in their own care, they need to advocate for themselves."

CSC also offers the Cancer Transitions: Moving Beyond Treatment program. Developed in 2006 with the LIVE**STRONG** Foundation, Cancer Transitions is a six-week program offered in person and online. The goal of the program is "to support and empower survivors as they transition from active treatment to post-treatment." Any survivor may participate in the program; however, it is specifically designed for patients who have completed treatment in the last 24 months.

The Cancer Transitions program includes information on the benefits of exercise, nutrition, emotional support and medical management. Participants use the Cancer Transition workbook and the National Cancer Institute's Facing Forward: Life After Cancer Treatment booklet, accompanied by additional interactive content, during the program.

"We were seeing a need for activities geared toward post-treatment patients," Goldberger said. "Cancer Transitions started as the Return to Wellness program. We did more research and development on that program, and, at the same time, LIVE**STRONG** was looking at community organizations and funding them. LIVE**STRONG** saw this as a good program to work collaboratively on. We are currently looking at broader use of the program, and we keep expanding access to it."

As one of the few support organizations focused on providing psychosocial support, CSC also works closely with CoC to help develop standards and best practices.

For more information about CSC, visit www.cancersupportcommunity.org.

LIVESTRONG FOUNDATION

The LIVE**STRONG** Foundation, established in 1997 as the Lance Armstrong Foundation, provides cancer support services and advocates for policies to improve access to care and quality of life. The foundation provides a variety of survivorship programs and tools, including navigation services, a guidebook and planner, brochures tailored to specific patient groups and audiences, and a care plan that patients can complete.

"The LIVE**STRONG** Foundation provides survivorship support through educational tools that empower people with knowledge and resources and through navigation services to help them meet the emotional, practical and physical concerns related to the cancer experience," said Emily Eargle, director of navigation services at the LIVE**STRONG** Foundation.

LIVE**STRONG**'s cancer navigation services allow patients to connect with navigators who can provide them with the appropriate tools and partners who, in turn, provide expert services in a variety of areas, including counseling, treatment decision-making, understanding long-term and late effects, clinical trial matching, and insurance needs, among other topics.

Also connected to LIVE**STRONG**'s navigation services is the LIVE**STRONG** Guidebook Planner and Journal, a two-volume set. The first volume provides patients with information to help them make informed decisions about their health care team and day-to-day needs. The second volume contains worksheets and calendars to help patients keep track of information and stay organized.

"This resource helps people take control of their cancer experience by providing them with information about what to expect, what questions to ask and how to make care decisions based on what is important to them," Eargle said.

The LIVE**STRONG** Foundation also has developed a series of brochures on survivorship that are tailored for various audiences, including multicultural, African-American, American Indian/Alaskan Native, Hispanic/Latino, Asian American and several other audiences. The Living After Cancer Treatment brochure series provides information on the physical, practical and emotional concerns of survivors and lists resources for survivors to seek support.

"People experience cancer differently for a number of reasons, some of those being their personal values, language, cultural experiences and ethnic identity," said Sarah Arvey, PhD, director of research and evaluation at the LIVE**STRONG** Foundation. "The Living After Cancer Treatment series presents culturally and linguistically relevant information as patients make the transition from active treatment to post-treatment survivorship."

Recognizing the need for patients to have a survivorship care plan, the LIVE**STRONG** Foundation launched the LIVE**STRONG** Care Plan, powered by Penn Medicine's OncoLink. The care plan is a Web-based application that creates survivorship care plans for providers and survivors and is customized using details from a person's type of cancer and the type of treatment they received (e.g., radiation therapy chemotherapy, surgery, etc.).

The care plan is also continuously updated to reflect new and evolving clinical guidelines and recommendations.

"Many cancer survivors finish their treatment and do not know what treatment they received, how that treatment may affect their health needs or what steps to take to ensure they maintain their health after surviving cancer," Dr. Arvey said. "A survivorship care plan is a roadmap for patients that they can use and share with other providers, both oncologic and non-oncologic, to facilitate care coordination and promote improved health outcomes over time."

For more information about the LIVE**STRONG** Foundation, visit www.livestrong.org.

NATIONAL COALITION FOR CANCER SURVIVORSHIP

The National Coalition for Cancer Survivorship (NCCS) is a policy organization focused on "advocating for quality cancer care for all people touched by cancer." NCCS, founded by cancer survivors in 1986, advocates on behalf of cancer survivors and their families and caregivers and also offers a variety of resources to enable survivors to become self-advocates.

The NCCS website contains information to assist survivors at any point on their journey, from diagnosis and during treatment to post-treatment, long-term and late effects, and end of life.

"For patients to really be engaged in their own care and to be a partner in their own care, they need to advocate for themselves," said Shelley Fuld Nasso, MPP, NCCS's chief executive officer. "Our system is fragmented, and patients may see a number of different physicians, so it often doesn't feel coordinated. No one is really advocating for patients unless they do it. Skills of self-advocacy are ones we really don't have if we haven't been through a cancer diagnosis. Once you are the patient, everything is different."

NCCS focuses on policy issues to encourage delivery and payment reforms that provide access to cancer care planning services and coordinated care, and promoting the adoption of care planning and coordination into clinical practices.

One of the policy issues NCCS advocates for is the inclusion of a treatment summary and a survivorship care plan for all patients, beginning at diagnosis, through treatment and during the transition to post-treatment and beyond.

"What we see as one of the reasons survivorship care plans are not adopted into practice is because it's not paid for," Nasso said. "We believe one way we can make sure this planning is adopted into practice is to make sure the cancer care payment system supports it."

In addition to promoting self-advocacy and working on policy issues related to improving the quality of cancer care, NCCS is part of the Journey Forward program, developed through a partnership with NCCS, UCLA Cancer Survivorship Center, the Oncology Nursing Society, Anthem and Genentech. Journey Forward offers a publicly available software program to efficiently create a comprehensive survivorship care plan that includes contact information for the patient's care team, a brief summary of the diagnosis and treatment plan, schedule for follow-up tests and surveillance, psychosocial assessment information on managing ongoing symptoms and what to expect after treatment. The care plans are shared with the cancer survivor, the oncology provider, the primary care provider, and other specialists and members of the health care team.

One of the things that makes the Journey Forward Survivorship Care Plan Builder unique is that patient data can be imported directly from several cancer registry software programs into the Journey Forward software, eliminating the need for inputting all of the data by hand. This development saves time and allows several cancer registry providers to export information, including staging and treatment regimen, directly to the Journey Forward Survivorship Care Plan with fewer inaccuracies and inefficiencies.

NCCS is also working with CoC to improve the quality of care and services for patients.

"We believe our membership in CoC helps to ensure people have access to quality care that is coordinated and to make sure patients' voices are heard," Nasso said. "We worked diligently to make sure survivorship care planning was included in CoC's accreditation standards. It's an important priority for us."

For more information about NCCS, visit www.canceradvocacy.org.

ASTRO prepares survivorship care plan template to help members meet Commission on Cancer standard

BY BRIDGET KOONTZ, MD, RONALD CHEN, MD, MPH, AND THEODORE DEWEESE, MD

THE AMERICAN COLLEGE OF SURGEONS COMMISSION ON CANCER (CoC) has mandated that CoC-accredited cancer programs implement survivorship care plans (SCPs) into their programs. CoC accreditation is often sought by cancer programs as independent recognition for meeting certain quality standards set by the American College of Surgeons. Its endorsement of SCP use has increased attention to the role of a formalized care plan delivered to patients at completion of treatment.

Standard 3.3 of *Cancer Program Standards, 2012: Ensuring Patient-Centered Care, v. 1.2.1*, requires phasing in of SCPs over the next four years, so that by 2019, accredited programs must provide all curative-intent patients who have completed active therapy with a SCP including a summary of treatment and a follow-up plan[1]. These SCPs provide individualized plans for patients that include adjuvant therapy and surveillance recommendations and guidelines for maintaining overall health. Meeting this standard at the time of visitation will be a necessary part of the accreditation process; programs that fully integrate SCPs ahead of schedule will be eligible for special recognition.

Attempts to integrate SCPs have outstripped research into the document's effectiveness. However, research that does exist notes that SCPs in particular aid to educate primary care providers (PCPs) on uncommon but significant side effects; two-thirds to three-quarters of PCPs report inadequate training on chemotherapy and radiation therapy side effects[2-3]. Other small studies indicate that PCPs are at risk for overuse of surveillance testing[4] and that SCPs can facilitate practice change in about 50 percent of patients[5]. Early randomized results show no improvement in patient knowledge or satisfaction[6]; however, they did demonstrate potential benefit to PCPs, although initial SCPs were found to be too long to be practical[7]. Therefore, goals and recommended minimum components of an SCP were recently updated by the American Society of Clinical Oncology's Survivorship Care Planning Workgroup (which included Dr. Chen and Arthur Liu, MD, PhD, as radiation oncology representatives) to aid in the adoption of widespread SCP use[8].

The SCP is divided into two parts: a treatment summary, including contact information of providers, diagnosis and stage, and broad overview of treatment; and a follow-up care plan, including recommendations for adjuvant therapy, follow-up/surveillance testing schedule, description of significant and/or rare late effects pertinent to the individual, a review of important psychosocial concerns and resources, and a general statement encouraging healthy behaviors.

In December 2013, ASTRO's Board of Directors approved the Clinical, Translational and Basic Science Advisory Committee proposal to survey ASTRO members on issues related to cancer survivorship. This survey was designed to assess the current use of SCPs in the radiation oncology clinic as well as the readiness of ASTRO members to fulfill the CoC requirement of providing survivorship care plans to their patients. Highlights of the survey included the percentage of radiation oncologists who currently use SCPs, services that are provided after treatment completion and barriers that prevent radiation oncologists from using SCPs. The survey demonstrated a strong need for an SCP "template" specific to radiation oncology. The development of an effective radiation oncology-specific template would additionally need to consider the unique aspects of different patient and disease populations. Subsequently, in June 2014, the Board of Directors approved dissemination of these

> The template, written in a language that patients can understand, will provide a consistent, discipline-wide practice to increase patient dialogue regarding their treatment and follow-up care.

survey results via a published manuscript and creation of a radiation oncology-focused SCP template.

The SCP template was available for public comment earlier this year, and the template is anticipated to be published for the public this spring. While many radiation oncologists currently create a treatment completion note and provide some type of follow-up care, the template, written in a language that patients can understand, will provide a consistent, discipline-wide practice to increase patient dialogue regarding their treatment and follow-up care. The document will also spur greater communication between the radiation oncologist and other care providers, including the PCP, who may be less versed in surveillance schedules or presentation of radiation's late effects. The SCP template will cover CoC requirements including a summary of diagnosis and treatment, what patients can expect after treatment regarding recommended clinical visits and testing, and potential key late effects.

The two-page SCP template was also designed to minimize burden for the physician or other health care professional to complete. An additional, third page of the template will contain the technical details of radiation treatment commonly included in treatment completion notes, so that one document can serve the dual purpose of an SCP and completion note, avoiding duplicate work for the radiation oncologist.

Dr. Koontz is an associate professor of radiation oncology at Duke Cancer Institute and medical director of Duke Regional Radiation Oncology Services in Durham, North Carolina.

Dr. Chen is an associate professor in the Department of Radiation Oncology at the University of North Carolina at Chapel Hill in Chapel Hill, North Carolina.

Dr. DeWeese is the Sidney Kimmel Professor and chair of the Department of Radiation Oncology and Molecular Radiation Sciences at the Johns Hopkins University School of Medicine in Baltimore.

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XOFIGO® IS INDICATED *for the treatment of patients with castration-resistant prostate cancer (CRPC), symptomatic bone metastases and no known visceral metastatic disease.*[1]

Give your patient's standard

EARLIEST ONSET OF SYMPTOMS[a]

BEST STANDARD OF CARE

- In ALSYMPCA, best standard of care was defined as local EBRT, treatment with glucocorticoids, ketoconazole, or antihormonal agents[2]
- Xofigo is not recommended in combination with chemotherapy[1]

30%
REDUCED RISK OF DEATH vs PLACEBO PLUS BEST STANDARD OF CARE[1]

START NOW
WITH 6 INJECTIONS OF
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EBRT=external beam radiation therapy; OTC=over-the-counter.
Not an actual doctor. Model used for illustrative purposes only.

[a]In the ALSYMPCA trial, symptomatic was defined as regular analgesic use, including OTC, or use of EBRT to treat bone pain.

Important Safety Information

- **Contraindications:** Xofigo is contraindicated in women who are or may become pregnant. Xofigo can cause fetal harm when administered to a pregnant woman
- **Bone Marrow Suppression:** In the randomized trial, 2% of patients in the Xofigo arm experienced bone marrow failure or ongoing pancytopenia, compared to no patients treated with placebo. There were two deaths due to bone marrow failure. For 7 of 13 patients treated with Xofigo bone marrow failure was ongoing at the time of death. Among the 13 patients who experienced bone marrow failure, 54% required blood transfusions. Four percent (4%) of patients in the Xofigo arm and 2% in the placebo arm permanently discontinued therapy due to bone marrow suppression. In the randomized trial, deaths related to vascular hemorrhage in association with myelosuppression were observed in 1% of Xofigo-treated patients compared to 0.3% of patients treated with placebo. The incidence of infection-related deaths (2%), serious infections (10%), and febrile neutropenia (<1%) was similar for patients treated with Xofigo and placebo. Myelosuppression—notably thrombocytopenia, neutropenia, pancytopenia, and leukopenia—has been reported in patients treated with Xofigo.

  Monitor patients with evidence of compromised bone marrow reserve closely and provide supportive care measures when clinically indicated. Discontinue Xofigo in patients who experience life-threatening complications despite supportive care for bone marrow failure
- **Hematological Evaluation:** Monitor blood counts at baseline and prior to every dose of Xofigo. Prior to first administering Xofigo, the absolute neutrophil count (ANC) should be $\geq 1.5 \times 10^9$/L, the platelet count $\geq 100 \times 10^9$/L, and hemoglobin ≥10 g/dL. Prior to subsequent administrations, the ANC should be $\geq 1 \times 10^9$/L and the platelet count $\geq 50 \times 10^9$/L. Discontinue Xofigo if hematologic values do not recover within 6 to 8 weeks after the last administration despite receiving supportive care
- **Concomitant Use With Chemotherapy:** Safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Outside of a clinical trial, concomitant use

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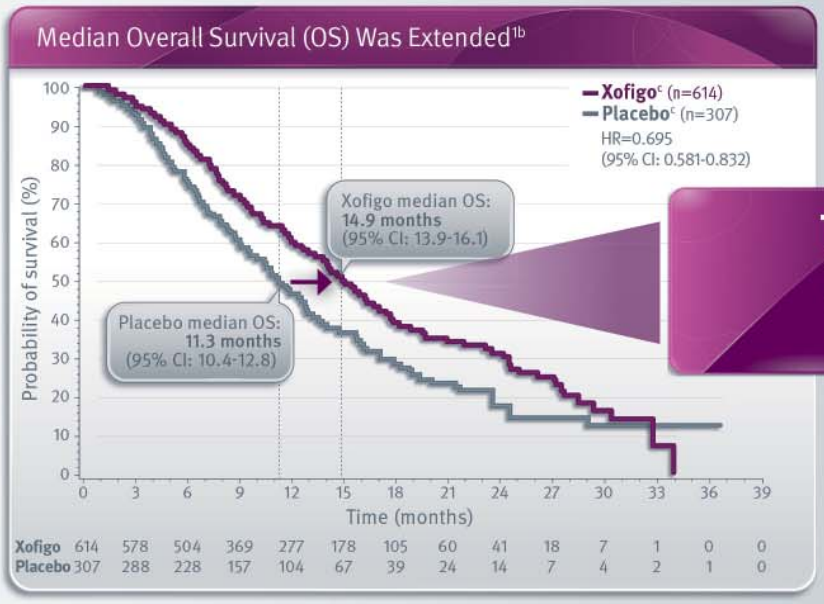
# of care a survival boost[1]



THE XOFIGO BOOST
3.6 month increase in median overall survival[1]

- In a prespecified interim analysis, median overall survival was 14.0 months for Xofigo (95% CI: 12.1-15.8) vs 11.2 months for placebo (95% CI: 9.0-13.2)[1]
  - *P*=0.00185; 95% CI: 0.552-0.875; HR=0.695[1]

[b]An exploratory updated overall survival analysis was performed before patient crossover, incorporating an additional 214 events, resulting in findings consistent with the interim analysis.[1]

[c]Plus best standard of care.[1]

of Xofigo in patients on chemotherapy is not recommended due to the potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes, or hemibody external radiotherapy are administered during the treatment period, Xofigo should be discontinued

- **Administration and Radiation Protection:** Xofigo should be received, used, and administered only by authorized persons in designated clinical settings. The administration of Xofigo is associated with potential risks to other persons from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations
- **Adverse Reactions:** The most common adverse reactions (≥10%) in the Xofigo arm vs the placebo arm, respectively, were nausea (36% vs 35%), diarrhea (25% vs 15%), vomiting (19% vs 14%), and peripheral edema (13% vs 10%). Grade 3 and 4 adverse events were reported in 57% of Xofigo-treated patients and 63% of placebo-treated patients. The most common hematologic laboratory abnormalities in the Xofigo arm (≥10%) vs the placebo arm, respectively, were anemia (93% vs 88%), lymphocytopenia (72% vs 53%), leukopenia (35% vs 10%), thrombocytopenia (31% vs 22%), and neutropenia (18% vs 5%)

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Please see following pages for brief summary of full Prescribing Information.

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1 INDICATIONS AND USAGE

Xofigo™ is indicated for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastatic disease.

2 DOSAGE AND ADMINISTRATION

2.3 Instructions for Use/Handling

General warning

Xofigo (an alpha particle-emitting pharmaceutical) should be received, used and administered only by authorized persons in designated clinical settings. The receipt, storage, use, transfer and disposal Xofigo are subject to the regulations and/or appropriate licenses of the competent official organization.

Xofigo should be handled by the user in a manner which satisfies both radiation safety and pharmaceutical quality requirements. Appropriate aseptic precautions should be taken.

Radiation protection

The administration of Xofigo is associated with potential risks to other persons (e.g., medical staff, caregivers and patient's household members) from radiation or contamination from spills of bodily fluids such as urine, feces, or vomit. Therefore, radiation protection precautions must be taken in accordance with national and local regulations.

For drug handling

Follow the normal working procedures for the handling of radiopharmaceuticals and use universal precautions for handling and administration such as gloves and barrier gowns when handling blood and bodily fluids to avoid contamination. In case of contact with skin or eyes, the affected area should be flushed immediately with water. In the event of spillage of Xofigo, the local radiation safety officer should be contacted immediately to initiate the necessary measurements and required procedures to decontaminate the area. A complexing agent such as 0.01 M ethylene-diamine-tetraacetic acid (EDTA) solution is recommended to remove contamination.

For patient care

Whenever possible, patients should use a toilet and the toilet should be flushed several times after each use. When handling bodily fluids, simply wearing gloves and hand washing will protect caregivers. Clothing soiled with Xofigo or patient fecal matter or urine should be washed promptly and separately from other clothing.

Radium-223 is primarily an alpha emitter, with a 95.3% fraction of energy emitted as alpha-particles. The fraction emitted as beta-particles is 3.6%, and the fraction emitted as gamma-radiation is 1.1%. The external radiation exposure associated with handling of patient doses is expected to be low, because the typical treatment activity will be below 8,000 kBq (216 microcurie). In keeping with the **A**s **L**ow **A**s **R**easonably **A**chievable (ALARA) principle for minimization of radiation exposure, it is recommended to minimize the time spent in radiation areas, to maximize the distance to radiation sources, and to use adequate shielding. Any unused product or materials used in connection with the preparation or administration are to be treated as radioactive waste and should be disposed of in accordance with local regulations.

The gamma radiation associated with the decay of radium-223 and its daughters allows for the radioactivity measurement of Xofigo and the detection of contamination with standard instruments.

4 CONTRAINDICATIONS

Xofigo is contraindicated in pregnancy.

Xofigo can cause fetal harm when administered to a pregnant woman based on its mechanism of action. Xofigo is not indicated for use in women. Xofigo is contraindicated in women who are or may become pregnant. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus *[see Use in Specific Populations (8.1)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Bone Marrow Suppression

In the randomized trial, 2% of patients on the Xofigo arm experienced bone marrow failure or ongoing pancytopenia compared to no patients treated with placebo. There were two deaths due to bone marrow failure and for 7 of 13 patients treated with Xofigo, bone marrow failure was ongoing at the time of death. Among the 13 patients who experienced bone marrow failure, 54% required blood transfusions. Four percent (4%) of patients on the Xofigo arm and 2% on the placebo arm permanently discontinued therapy due to bone marrow suppression.

In the randomized trial, deaths related to vascular hemorrhage in association with myelosuppression were observed in 1% of Xofigo-treated patients compared to 0.3% of patients treated with placebo. The incidence of infection-related deaths (2%), serious infections (10%), and febrile neutropenia (<1%) were similar for patients treated with Xofigo and placebo. Myelosuppression; notably thrombocytopenia, neutropenia, pancytopenia, and leukopenia; has been reported in patients treated with Xofigo. In the randomized trial, complete blood counts (CBCs) were obtained every 4 weeks prior to each dose and the nadir CBCs and times of recovery were not well characterized. In a separate single-dose phase 1 study of Xofigo, neutrophil and platelet count nadirs occurred 2 to 3 weeks after Xofigo administration at doses that were up to 1 to 5 times the recommended dose, and most patients recovered approximately 6 to 8 weeks after administration *[see Adverse Reactions (6)]*.

Hematologic evaluation of patients must be performed at baseline and prior to every dose of Xofigo. Before the first administration of Xofigo, the absolute neutrophil count (ANC) should be $\geq 1.5 \times 10^9$/L, the platelet count $\geq 100 \times 10^9$/L and hemoglobin ≥ 10 g/dL. Before subsequent administrations of Xofigo, the ANC should be $\geq 1 \times 10^9$/L and the platelet count $\geq 50 \times 10^9$/L. If there is no recovery to these values within 6 to 8 weeks after the last administration of Xofigo, despite receiving supportive care, further treatment with Xofigo should be discontinued. Patients with evidence of compromised bone marrow reserve should be monitored closely and provided with supportive care measures when clinically indicated. Discontinue Xofigo in patients who experience life-threatening complications despite supportive care for bone marrow failure.

The safety and efficacy of concomitant chemotherapy with Xofigo have not been established. Outside of a clinical trial, concomitant use with chemotherapy is not recommended due to the potential for additive myelosuppression. If chemotherapy, other systemic radioisotopes or hemibody external radiotherapy are administered during the treatment period, Xofigo should be discontinued.

6 ADVERSE REACTIONS

The following serious adverse reactions are discussed in greater detail in another section of the label:

- Bone Marrow Suppression *[see Warnings and Precautions (5.1)]*

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In the randomized clinical trial in patients with metastatic castration-resistant prostate cancer with bone metastases, 600 patients received intravenous injections of 50 kBq/kg (1.35 microcurie/kg) of Xofigo and best standard of care and 301 patients received placebo and best standard of care once every 4 weeks for up to 6 injections. Prior to randomization, 58% and 57% of patients had received docetaxel in the Xofigo and placebo arms, respectively. The median duration of treatment was 20 weeks (6 cycles) for Xofigo and 18 weeks (5 cycles) for placebo.

The most common adverse reactions ($\geq$ 10%) in patients receiving Xofigo were nausea, diarrhea, vomiting, and peripheral edema (Table 3). Grade 3 and 4 adverse events were reported among 57% of Xofigo-treated patients and 63% of placebo-treated patients. The most common hematologic laboratory abnormalities in Xofigo-treated patients ($\geq$ 10%) were anemia, lymphocytopenia, leukopenia, thrombocytopenia, and neutropenia (Table 4).

Treatment discontinuations due to adverse events occurred in 17% of patients who received Xofigo and 21% of patients who received placebo. The most common hematologic laboratory abnormalities leading to discontinuation for Xofigo were anemia (2%) and thrombocytopenia (2%).

Table 3 shows adverse reactions occurring in $\geq$ 2% of patients and for which the incidence for Xofigo exceeds the incidence for placebo.

Table 3: Adverse Reactions in the Randomized Trial

System/Organ Class Preferred Term	Xofigo (n=600)		Placebo (n=301)	
	Grades 1-4 %	Grades 3-4 %	Grades 1-4 %	Grades 3-4 %
Blood and lymphatic system disorders				
Pancytopenia	2	1	0	0
Gastrointestinal disorders				
Nausea	36	2	35	2
Diarrhea	25	2	15	2
Vomiting	19	2	14	2
General disorders and administration site conditions				
Peripheral edema	13	2	10	1
Renal and urinary disorders				
Renal failure and impairment	3	1	1	1

Laboratory Abnormalities

Table 4 shows hematologic laboratory abnormalities occurring in $\geq$ 10% of patients and for which the incidence for Xofigo exceeds the incidence for placebo.

Table 4: Hematologic Laboratory Abnormalities

Hematologic Laboratory Abnormalities	Xofigo (n=600)		Placebo (n=301)	
	Grades 1-4 %	Grades 3-4 %	Grades 1-4 %	Grades 3-4 %
Anemia	93	6	88	6
Lymphocytopenia	72	20	53	7
Leukopenia	35	3	10	<1
Thrombocytopenia	31	3	22	<1
Neutropenia	18	2	5	<1

Laboratory values were obtained at baseline and prior to each 4-week cycle.

As an adverse reaction, grade 3-4 thrombocytopenia was reported in 6% of patients on Xofigo and in 2% of patients on placebo. Among patients who received Xofigo, the laboratory abnormality grade 3-4 thrombocytopenia occurred in 1% of docetaxel naïve patients and in 4% of patients who had received prior docetaxel. Grade 3-4 neutropenia occurred in 1% of docetaxel naïve patients and in 3% of patients who have received prior docetaxel.

Fluid Status

Dehydration occurred in 3% of patients on Xofigo and 1% of patients on placebo. Xofigo increases adverse reactions such as diarrhea, nausea, and vomiting which may result in dehydration. Monitor patients' oral intake and fluid status carefully and promptly treat patients who display signs or symptoms of dehydration or hypovolemia.

Injection Site Reactions

Erythema, pain, and edema at the injection site were reported in 1% of patients on Xofigo.

Secondary Malignant Neoplasms

Xofigo contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure may be associated with an increased risk of cancer and hereditary defects. Due to its mechanism of action and neoplastic changes, including osteosarcomas, in rats following administration of radium-223 dichloride, Xofigo may increase the risk of osteosarcoma or other secondary malignant neoplasms *[see Nonclinical Toxicology (13.1)]*. However, the overall incidence of new malignancies in the randomized trial was lower on the Xofigo arm compared to placebo (<1% vs. 2%; respectively), but the expected latency period for the development of secondary malignancies exceeds the duration of follow up for patients on the trial.

Subsequent Treatment with Cytotoxic Chemotherapy

In the randomized clinical trial, 16% patients in the Xofigo group and 18% patients in the placebo group received cytotoxic chemotherapy after completion of study treatments. Adequate safety monitoring and laboratory testing was not performed to assess how patients treated with Xofigo will tolerate subsequent cytotoxic chemotherapy.

7 DRUG INTERACTIONS

No formal clinical drug interaction studies have been performed.

Subgroup analyses indicated that the concurrent use of bisphosphonates or calcium channel blockers did not affect the safety and efficacy of Xofigo in the randomized clinical trial.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy Category X *[see Contraindications (4)]*

Xofigo can cause fetal harm when administered to a pregnant woman based on its mechanism of action. While there are no human or animal data on the use of Xofigo in pregnancy and Xofigo is not indicated for use in women, maternal use of a radioactive therapeutic agent could affect development of a fetus. Xofigo is contraindicated in women who are or may become pregnant while receiving the drug. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to the fetus and the potential risk for pregnancy loss. Advise females of reproductive potential to avoid becoming pregnant during treatment with Xofigo.

8.3 Nursing Mothers

Xofigo is not indicated for use in women. It is not known whether radium-223 dichloride is excreted in human milk. Because many drugs are excreted in human milk, and because of potential for serious adverse reactions in nursing infants from Xofigo, a decision should be made whether to discontinue nursing, or discontinue the drug taking into account the importance of the drug to the mother.

8.4 Pediatric Use

The safety and efficacy of Xofigo in pediatric patients have not been established.

In single- and repeat-dose toxicity studies in rats, findings in the bones (depletion of osteocytes, osteoblasts, osteoclasts, fibro-osseous lesions, disruption/disorganization of the physis/growth line) and teeth (missing, irregular growth, fibro-osseous lesions in bone socket) correlated with a reduction of osteogenesis that occurred at clinically relevant doses beginning in the range of 20 – 80 kBq (0.541 - 2.16 microcurie) per kg body weight.

8.5 Geriatric Use

Of the 600 patients treated with Xofigo in the randomized trial, 75% were 65 years of age and over and while 33% were 75 years of age and over. No dosage adjustment is considered necessary in elderly patients. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Patients with Hepatic Impairment

No dedicated hepatic impairment trial for Xofigo has been conducted. Since radium-223 is neither metabolized by the liver nor eliminated via the bile, hepatic impairment is unlikely to affect the pharmacokinetics of radium-223 dichloride *[see Clinical Pharmacology (12.3)]*. Based on subgroup analyses in the randomized clinical trial, dose adjustment is not needed in patients with mild hepatic impairment. No dose adjustments can be recommended for patients with moderate or severe hepatic impairment due to lack of clinical data.

8.7 Patients with Renal Impairment

No dedicated renal impairment trial for Xofigo has been conducted. Based on subgroup analyses in the randomized clinical trial, dose adjustment is not needed in patients with existing mild (creatinine clearance [CrCl] 60 to 89 mL/min) or moderate (CrCl 30 to 59 mL/min) renal impairment. No dose adjustment can be recommended for patients with severe renal impairment (CrCl less than 30 mL/min) due to limited data available (n = 2) *[see Clinical Pharmacology (12.3)]*.

8.8 Males of Reproductive Potential

Contraception

Because of potential effects on spermatogenesis associated with radiation, advise men who are sexually active to use condoms and their female partners of reproductive potential to use a highly effective contraceptive method during and for 6 months after completing treatment with Xofigo.

Infertility

There are no data on the effects of Xofigo on human fertility. There is a potential risk that radiation by Xofigo could impair human fertility *[see Nonclinical Toxicology (13.1)]*.

10 OVERDOSAGE

There have been no reports of inadvertent overdosing of Xofigo during clinical studies.

There is no specific antidote. In the event of an inadvertent overdose of Xofigo, utilize general supportive measures, including monitoring for potential hematological and gastrointestinal toxicity, and consider using medical countermeasures such as aluminum hydroxide, barium sulfate, calcium carbonate, calcium gluconate, calcium phosphate, or sodium alginate.[1]

Single Xofigo doses up to 250 kBq (6.76 microcurie) per kg body weight were evaluated in a phase 1 clinical trial and no dose-limiting toxicities were observed.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies have not been conducted to evaluate the carcinogenic potential of radium-223 dichloride. However, in repeat-dose toxicity studies in rats, osteosarcomas, a known effect of bone-seeking radionuclides, were observed at clinically relevant doses 7 to 12 months after the start of treatment. The presence of other neoplastic changes, including lymphoma and mammary gland carcinoma, was also reported in 12- to 15-month repeat-dose toxicity studies in rats.

Genetic toxicology studies have not been conducted with radium-223 dichloride. However, the mechanism of action of radium-223 dichloride involves induction of double-strand DNA breaks, which is a known effect of radiation.

Animal studies have not been conducted to evaluate the effects of radium-223 dichloride on male or female fertility or reproductive function. Xofigo may impair fertility and reproductive function in humans based on its mechanism of action.

17 PATIENT COUNSELING INFORMATION

Advise patients:

- To be compliant with blood cell count monitoring appointments while receiving Xofigo. Explain the importance of routine blood cell counts. Instruct patients to report signs of bleeding or infections.
- To stay well hydrated and to monitor oral intake, fluid status, and urine output while being treated with Xofigo. Instruct patients to report signs of dehydration, hypovolemia, urinary retention, or renal failure / insufficiency.
- There are no restrictions regarding contact with other people after receiving Xofigo. Follow good hygiene practices while receiving Xofigo and for at least 1 week after the last injection in order to minimize radiation exposure from bodily fluids to household members and caregivers. Whenever possible, patients should use a toilet and the toilet should be flushed several times after each use. Clothing soiled with patient fecal matter or urine should be washed promptly and separately from other clothing. Caregivers should use universal precautions for patient care such as gloves and barrier gowns when handling bodily fluids to avoid contamination. When handling bodily fluids, wearing gloves and hand washing will protect caregivers.
- Who are sexually active to use condoms and their female partners of reproductive potential to use a highly effective method of birth control during treatment and for 6 months following completion of Xofigo treatment.

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ASTRO LAUNCHES PRACTICE ACCREDITATION PROGRAM APPLICATION AND SELF-ASSESSMENT

THE ASTRO ACCREDITATION PROGRAM FOR EXCELLENCE (APEx™) is currently accepting facility applications and recently launched the APEx self-assessment.

APEx provides an objective review by professional peers of essential functions and processes of radiation oncology practices. It offers transparent, measurable, evidence- and consensus-based standards that emphasize a professional commitment to safety and quality.

ASTRO launched the APEx facility application in December 2014. The application is available to single facility and multi-facility radiation oncology practices based in the U.S.

In the application, the radiation oncology practice submits information about its facilities, the annual number of new patients treated, the treatments offered and the equipment the practice uses, as well as a signed facility agreement and HIPAA business associate agreement.

The self-assessment is a beneficial and impactful step of the accreditation program because it promotes the creation of and adherence to processes and policies that improve the quality of care and patient safety.

APEx challenges practices to improve quality and strive for excellence. The self-assessment allows practices to examine and improve their processes as preparations are made for the facility visit. During the self-assessment, the practice receives a comprehensive guide providing step-by-step instructions for completing this portion of the accreditation process. Additionally, the self-assessment Web portal contains abundant resources such as templates, example documents and worksheets. The self-assessment takes approximately six to 12 weeks for a practice to complete. After submission of the self-assessment documentation, including medical record abstraction, policies, supportive materials and a questionnaire, a performance feedback report is provided identifying strengths and gaps in compliance with the standards. The feedback report provides an opportunity for the practice to improve processes and policies and establish quality improvement efforts. For example, the medical record abstraction portion can be used as a group PQI project for MOC purposes.

Once a practice has achieved the designation of "ready" from the self-assessment, the practice progresses to the facility visit. Facility visits are conducted at the main site and satellite sites. APEx surveyors are responsible for objectively evaluating a practice's performance based on the APEx standards. Surveyors include U.S. licensed and board certified medical physicists and radiation oncologists, certified and licensed (where applicable) radiation therapists, dosimetrists, registered nurses and practice administrators. In addition, APEx surveyors must be ASTRO members who have at least five years of U.S. radiation oncology experience post-licensing and who are currently in active practice.

Surveyors are thoroughly trained through a series of 19 competency-based online modules, including an overview of the APEx program, HIPAA, surveyor roles and responsibilities and a detailed review of the program's standards, which are organized around the five pillars of APEx (the process of care, the radiation oncology team, safety, quality management and patient-centered care). Surveyors conduct a facility visit using a Web-based tool. Each survey of a single location practice or main facility will consist of a two-person team (a medical physicist and a radiation oncologist or other member of the radiation oncology team) and will last one day. In the case of a multi-facility practice, the primary team will conduct an in-depth review at the main location, and additional surveyors will conduct expedited reviews of key evidence indicators at the satellite facilities. The satellite site visits will take approximately a half-day to complete. One additional medical physicist will be added for every two satellite facilities. Medical physicists will be used exclusively for satellite facility site visits to confirm appropriate quality assurance activities. Prior to the site visit, the surveyor team will have access to the radiation oncology practice's file including the application and the uploaded facility policies and procedures. To warrant an accurate and fair facility visit, APEx utilizes a surveyor match algorithm based on facility and surveyor correlation of modality, EHR and treatment planning systems, and factoring in a conflict of interest review.

Following completion of the facility visit, a report and supporting documentation will be submitted to the Practice Accreditation Committee. The Committee meets monthly to review accreditation reports. The Committee's final decision is conveyed to applicants. An accreditation determination will be reported to each applicant no more than 60 days after the facility visit. APEx accreditation is renewed every four years.

For more information about APEx or to apply, visit www.astro.org/APEx.

BY THE ARRO EXECUTIVE COMMITTEE

ARRO EDUCATIONAL RESOURCES FOCUS ON PATIENT SAFETY

IT IS IMPORTANT TO RECOGNIZE that the spectrum of patient safety is broad and includes aspects of treatment that are under direct control of the radiation oncologist. Although errors made by the clinician, including mistakes in target volume delineation and suboptimal treatment plans, may be more difficult to identify and prevent than technical errors in dose delivery, these types of errors should not be ignored. In the era of CT-based planning, the lack of a standardized approach to calculate target volume delineation and treatment planning in many disease sites represents a potential safety concern for patients.

Two recent ARRO initiatives have been developed to provide residents access to online educational resources. The ultimate goal is to improve the quality of care delivered to patients by providing residents with an overview of general management principles and user-friendly approaches to target volume delineation and treatment planning for various disease sites.

ARROCases (www.astro.org/ARROCase) are peer-reviewed, publicly accessible online case vignettes that aim to highlight key aspects of radiation therapy. Select cases include a "contour companion," which takes the reader through target volume delineation using representative axial slices. The ARROCase database was launched in 2012 and currently includes 17 cases. Specific safety issues related to each case are often highlighted and discussed. For example, when treating medulloblastoma with craniospinal irradiation, one approach to matching the spine field to the diverging cranial fields is to rotate the couch toward the gantry. Because this "couch-kick" introduces an opportunity for a potentially catastrophic error in treatment delivery, many institutions choose to replace the couch kick with a gap between the brain and spine field as discussed in the medulloblastoma ARROCase.

The ARRO Image Challenge series (www.astro.org/ARROImageChallenge) is a question bank that was also launched in 2012. The questions are in multiple-choice format and use diagnostic and treatment planning images to highlight key concepts in radiation oncology. Many of these questions are directly related to patient safety, including dose constraints and toxicity. Each answer includes a brief explanation with relevant teaching points and references for further reading. In the example provided, a dose-volume histogram (DVH) for a neoadjuvant esophagus plan is shown *(see Figure 1)*.

The question asks which parameter on the DVH is the basis for rejecting the plan. The answer is the combined lung V10, which exceeds 70 percent. As explained in the answer, the combined lung V10 should be ≤40 percent (acceptable variation is ≤50 percent, based on Radiation Therapy Oncology Group 1010).

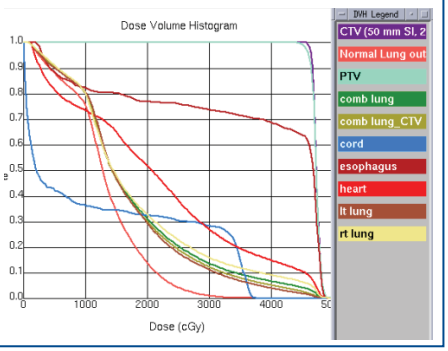
The Residents *e*Contouring Lab Webinar is another educational resource that has been enthusiastically embraced by residents. This series is supported by the ROI del Regato Fund. The *e*Contouring webinars provide residents with contouring instructions from well-respected faculty members. Residents have the opportunity to compare their own contours to those of the instructors in real-time. Pre-registration is required in order to participate; however, residents can also view the webinars on their own time after the event has been recorded.

The content for ARROCases and Image Challenges are provided by the members of the ARRO Education Subcommittee as well as medical students, faculty members and other residents. If you are interested in submitting content, please email arro@astro.org.

Figure 1

51-year-old gentleman with T3N0 esophageal adenocarcinoma is recommended to receive neoadjuvant chemoradiation. A dose of 45 Gy is prescribed to the 98% isodose line using IMRT. The DVH is shown below. Which parameter provides the basis for rejecting this plan?

A. Combined Lung V30
B. Combined Lung V20
C. Combined Lung V10
D. Mean Esophagus Dose



From the ABR

BY PAUL E. WALLNER, DO, FASTRO, DAVID LASZAKOVITS, MBA, AND DONNA BRECKENRIDGE, MA

PUBLIC REPORTING OF PHYSICIAN BOARD CERTIFICATION STATUS

IN THE PAST, member boards of the American Board of Medical Specialties (ABMS) were routinely queried by credentialing agencies and facilities regarding the certification statuses of physician specialists. This information was provided upon request; however, in most cases it was not easily available to any interested party. That somewhat limited transparency has seen a dramatic change in the last several years.

The press frequently reports that "board certification" status (BCS) is one of the most significant factors considered by health care consumers in selection of a provider[1]. However, when queried in greater detail regarding specifics of the designation's meaning, consumers are often unclear. There is general consensus in the press that BCS relates to the provider having obtained initial certification (IC) by one of the 24 member boards of the ABMS, and that this BCS is the sine qua non of "quality." Nevertheless, consumers rarely understand the precise details of how board certification is obtained; they generally assume that all physicians must complete various routine activities to maintain their certification, and that all "board certification" is essentially equivalent. Policy makers, payers and credentialing authorities have also accepted the importance of BCS and maintenance of certification (MOC), which are now actually codified in the Patient Protection and Affordable Care Act of 2010 (PPACA). PPACA has also established a payment incentive for MOC participation as part of the Physicians Quality Reporting System (PQRS)[2-5].

The widespread and increasing use of IC and MOC status as a credential and surrogate for quality intuitively necessitates that the information be generally available to anyone seeking the up-to-date certification status of any physician provider, as well as details regarding the nature of the IC and MOC processes. Each of the 24 ABMS member boards has a publicly available website that provides a level of information regarding the meaning of board certification, their history and details related to certification[6]. As the umbrella organization representing the collective issues and interests of the member boards, the ABMS also maintains an extensive publicly available website (www.certificationmatters.org), which provides detailed information regarding the historical basis of IC and MOC and specifics of the IC and MOC status of individual providers in each of its member boards[7]. The site also provides direct links to member board websites[8].

When anyone queries the ABMS public website regarding provider status, a brief, one-time, non-intrusive registration process is required, with entry of the typical username and creation of a password. When a user enters a provider name and the provider's city/state (non-essential), current certification status will be displayed. IC status indicates the precise certificate(s) granted but not their date(s) of issuance. A second section indicates "Meeting Maintenance of Certification Requirements," listing the various IC certificates held by the provider and a simple "yes" or "no" for the MOC status. Because some of the ABMS member boards continue to have a cohort of diplomates who hold IC without dates of expiration, it was felt that additional clarification was essential, so lifetime certificate holders who are not participating in MOC are reported as "Not Required"[9].

Although board-eligible statuses are not reported on the ABMS or the American Board of Radiology websites, this information may be accessed through the ABR's fulfillment of a "Certification Verification" request (www.theabr.org/verif)[10]. During residency training, candidates have the status of "enrolled, not yet eligible for certification." When candidates for IC complete their residency training, they will be publicly reported as "board eligible – currently not certified, but eligible for certification through MM/DD/YYYY." Under the conditions of a new board eligibility policy, effective January 1, 2012[11], ABR candidates now have six calendar years from the completion of residency training to attain IC. Upon attainment of IC within that time period, they are reported as board certified. Candidates who fail to attain IC within the requisite six years lose their board eligibility status and are reported as "not certified, not board eligible – after expiration of board eligible period without attaining certification." Following completion of a variety of requirements, individuals may return to a six-year interval of board eligibility status.

Management of certification within the osteopathic profession is directly through the parent American Osteopathic Association, with a similar public reporting regimen[12].

Continued on Page 31

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BY BRIDGET KOONTZ, MD, AND BARRY S. ROSENSTEIN, PHD

USING RADIOGENOMICS TO PREDICT RADIATION TOXICITY

GENOMIC SCIENCE has made a huge impact on oncologic care in the past 10 years[1]. These advances that are now in active clinical practice can be predictive of treatment response and of overall prognosis based on tumor genomics. More recently, efforts and research dollars are turning to the work of predicting the adverse effects of treatment by testing the genomics of normal tissue. This knowledge is key to patient-centered care and may allow for dose escalation or de-escalation if the treating physician has a more individualized prediction of tumor and normal tissue response to radiation. This field of research has been termed radiogenomics[2].

The overall goal of radiogenomics is to develop a genomic assay in which the results of a simple, inexpensive and rapid blood test will predict, with a high level of accuracy, the likelihood that a particular cancer patient will develop complications resulting from radiation therapy. This information is informative to the physician and patient and helps guide treatment decisions for each individual. That is, for people predicted to suffer complications from treatment with radiation, alternate therapies or the use of modified radiation dose parameters would be preferred. Using prostate cancer as an example, perhaps active surveillance or surgical choice may represent a better option in men predicted to have increased risk of radiation side effects. Alternatively, for those patients predicted to be at low risk for developing injuries from radiation, then a more aggressive form of radiation therapy using a higher dose could be considered, which may improve the chance for cure of their cancer.

EARLY EFFORTS

Clinicians and radiobiologists have long been aware that certain individuals with relatively rare mutations in certain genes, such as ATM, have greater sensitivity to radiation than others and a greater risk of developing acute and late side effects. Initial efforts to link mutations in certain genes to radiation toxicity was performed through direct candidate gene analysis, where single nucleotide polymorphisms (SNPs) in specific genes whose products were known to play a critical role in radiation-affected pathways, often DNA repair or cell cycle checkpoints, were tested for association with normal tissue toxicities resulting from radiation therapy. Unfortunately, it has been difficult to validate this candidate gene work, which is likely due in part to the overly restrictive nature of these initial studies[3].

In recent years, a genome-wide approach has been adopted in which patients are typically screened for one million or more genetic markers across the genome. This has the advantage of not requiring any *a priori* assumptions as to the genes involved[4]. Using a genome-wide association studies (GWAS) approach, researchers in the field of radiogenomics have made substantial progress in the past few years towards achieving the goal of creating a predictive assay. Much of the credit for the success of this work is due to the establishment of the Radiogenomics Consortium (RGC) in 2009, which is an NCI/NIH-supported cancer epidemiology consortium (http://epi.grants.cancer.gov/Consortia/single/rgc.html) and consists of 188 investigators at 110 institutions in 26 countries[5]. The purpose of the RGC is to bring together collaborators to pool samples and data for increased statistical power of radiogenomic studies. Through the RGC, the size of the research studies has reached the point that genetic markers have been identified and validated in multiple cohorts. It is now anticipated that an assay to predict radiotherapy response will be achieved and implemented in the clinic within the next five years to help guide treatment decisions for cancer patients.

CURRENT STRATEGIES

In recent years, radiogenomics studies have begun to reach the size needed to identify SNPs meeting the strict level of statistical significance needed in genome-wide association studies, in which one million or more genetic markers are being tested and there is a high risk of false positive results[6]. In a study with a total sample size of more than 1,700 radiation therapy patients, SNPs were identified in the *TANC1* gene and validated in two other cohorts to be associated with late adverse effects following prostate cancer radiation therapy[7]. The odds ratio for developing late toxicity associated with a particular SNP in this gene was 6.2 with a p-value of 4.6 x 10-11 in the meta-analysis. The protein encoded by *TANC1* plays a central role in myoblast fusion during myotube formation, which is essential for adult muscle regeneration in response to local damage. Therefore, it is biologically plausible that *TANC1* is

involved in the regeneration of muscle damaged by radiation. Similarly, through a meta-analysis involving four independent cohorts, three additional SNPs have been identified that reached genome-wide significance for association with toxicities resulting from prostate cancer radiation therapy[8]. These SNPs will be included in the predictive instrument that is under development.

GOALS FOR THE NEXT FIVE YEARS

Radiogenomic studies currently underway involve more than 7,000 radiation therapy patients, and the further expansion of studies planned in the next few years to 10,000 or more patients will substantially enhance the statistical power of this work. The goals for the next five years in radiogenomics are to:

1. Validate the SNPs identified in previous GWAS and discover additional SNP associations with adverse effects resulting from radiation therapy for prostate, breast or lung cancer through GWAS meta-analysis of large cohorts using detailed radiation therapy and genotyping data.
2. Build clinically useful multi-SNP predictive models for each form of radiation injury that incorporate radiation dosimetric and clinical factors.
3. Create a low-cost, high-performance genetic assay and companion risk assessment Web-based tool that could be used by physicians in practice and/or genetic testing laboratories to predict risk for developing adverse effects following radiation therapy and help guide treatment decisions for people diagnosed with cancer.
4. Initiate functional/mechanistic studies to elucidate the role of the products of genes affected by SNPs associated with normal tissue toxicities resulting from radiation therapy.

If successful, the practice of radiation oncology may be radically changed by the ability to individualize treatment to the patient's risk of toxicity, as has already occurred for tumor genomic predictors.

This article was submitted on behalf of the Clinical, Translational and Basic Science Advisory Committee.

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From the ABR

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From time to time, candidates and/or diplomates of member boards have requested that their personal certification status not be made available. The general position of the ABMS and its member boards has been that this position is not appropriate nor is it in the public interest.

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JOURNALS

FROM THE NOVEMBER-DECEMBER 2014 ISSUE OF *PRACTICAL RADIATION ONCOLOGY (PRO)*

Choosing Wisely: The American Society for Radiation Oncology's Top 5 List

by Hahn et al and Lawton

The authors highlight five interventions that patients should question, as part of the *Choosing Wisely*® campaign. This initiative fosters conversations between physicians and patients about treatments and tests that may be overused, unnecessary or potentially harmful. An editorial by Colleen A.F. Lawton, MD, FASTRO, puts this initiative in perspective.

HIGHLIGHTS FROM THE *INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY • BIOLOGY • PHYSICS*

DECEMBER 1, 2014

The Adoption of Hypofractionated Whole-Breast Irradiation for Early-Stage Breast Cancer: National and Regional Patterns

by Wang et al, Jagsi et al and Jagsi et al

Hypofractionated whole breast radiation therapy for early-stage breast cancer is now supported by high quality randomized trial evidence and by clinical guidelines. In this edition, three papers look at the patterns of practice across the United States.

Local Control and Toxicity in a Large Cohort of Central Lung Tumors Treated With Stereotactic Body Radiation Therapy

by Modh et al

The use of SBRT to treat central lung tumors is commonly associated with higher rates of severe toxicity. This is now being challenged by new data showing that SBRT can be used centrally as long as dose restraint is observed and dose constraints are respected.

Long-Term Outcomes of Hypofractionation versus Conventional Radiation Therapy after Breast-Conserving Surgery for Ductal Carcinoma In Situ of the Breast

by Lalani et al

Ductal carcinoma in situ represents 25 percent of newly diagnosed breast cancers, and it is unknown if women treated by hypofractionation experience a higher risk of recurrence. In this study, Lalani and colleagues did not find that hypofractionated radiation therapy was associated with an increased risk of recurrence compared to individuals treated with conventional radiation therapy.

Extended Field Intensity Modulated Radiation Therapy with Concomitant Boost for Lymph Node-Positive Cervical Cancer: Analysis of Regional Control and Recurrence Patterns in the PET-CT era

by Vargo et al

An analysis of the National Cancer Data Base reflects what QRRO studies have also shown—a declining utilization of brachytherapy in favor of alternative boost modalities such as IMRT and SBRT.

JANUARY 1, 2015

Defining the Optimal Planning Target Volume in Image-Guided Stereotactic Radiosurgery of Brain Metastases: Results of a Randomized Trial

by Kirkpatrick et al

In this small, randomized trial, the authors sought to identify an optimal margin for SRS of brain metastases. The results suggest that a 1 mm margin is appropriate for image-guided SRS.

Efficacy Endpoints of Radiation Therapy Group Protocol 0247: A Randomized, Phase 2 Study of Neoadjuvant Radiation Therapy Plus Concurrent Capecitabine and Irinotecan or Capecitabine and Oxaliplatin for Patients with Locally Advanced Rectal Cancer

by Wong et al

RTOG 0247 was a clinical trial of neoadjuvant chemoradiation for locally advanced rectal cancer. The authors report long-term outcome endpoints and demonstrate similar efficacy for both arms, suggesting that pathologic complete remission is an unsuitable surrogate for the more traditional survival metrics of clinical outcome.

Is Intermediate Radiation Dose Escalation with Concurrent Chemotherapy for Stage III Non-Small-Cell Lung Cancer Beneficial? A Multi-Institutional Propensity Score Matched Analysis

by Rodrigues et al

Since publication of RTOG 0617, the standard assumptions about dose escalation and an improved outcome in stage III non-small cell lung cancer have been challenged. This comparative effectiveness investigation looked at a large Canadian database and compared those patients treated with standard dose radiation therapy versus those receiving a modest dose escalation.

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