NOVEMBER 2016 • VOL 7, NO 10

JOURNAL OF ONCOLOGY NAVIGATION & SURVIVORSHIP®

The Official Journal of the Academy of Oncology Nurse & Patient Navigators®

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*Bone complications, also known as skeletal-related events (SREs), are radiation to bone, pathologic fracture, surgery to bone, and spinal cord compression.[2]

References: 1. Hagiwara M, Delea TE, Saville MW, Chung K. Healthcare utilization and costs associated with skeletal-related events in prostate cancer patients with bone metastases. *Prostate Cancer Prostatic Dis.* 2013;16(1):23-27. **2.** Hagiwara M, Delea TE, Chung K. Healthcare costs associated with skeletal-related events in breast cancer patients with bone metastases. *J Med Econ.* 2014;17(3):223-230. **3.** Carter JA, Ji X, Botteman MF. Clinical, economic and humanistic burdens of skeletal-related events associated with bone metastases. *Expert Rev Pharmacoecon Outcomes Res.* 2013;13(4):483-496. **4.** DePuy V, Anstrom KJ, Castel LD, et al. Effects of skeletal morbidities on longitudinal patient-reported outcomes and survival in patients with metastatic prostate cancer. *Support Care Cancer*. 2007;15(7):869-876. **5.** Walker MS, Miller PJ, Namjoshi M, et al. Relationship between incidence of fracture and health-related qualify-of-life in metastatic breast cancer patients with bone metastases. *J Med Econ*. 2013;16(1):179-189.

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The Official Journal of the Academy of Oncology Nurse & Patient Navigators®

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ABOUT THE COVER ART

With a Little Help from My Friends

Pastel by a Person Diagnosed with Cancer
Missouri

My journey began in October 2011, when my doctor called to tell me I had breast cancer. As he was telling me the news, my first thoughts were, "This is not happening to me," and "I am terrified I will not be able to do what I need to do." It's like finding out you are at the edge of dark, scary woods and you need to make correct decisions, which means follow the right path/paths to get to the light, to become a survivor. But as I started my journey, at each step, God, my husband, children, family, friends, and medical staff stepped up and walked beside me, helping me walk the path. Thanks to them, I am a "survivor"!

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The *Journal of Oncology Navigation & Survivorship* (*JONS*) promotes reliance on evidence-based practices in navigating patients with cancer and their caregivers through diagnosis, treatment, and survivorship. *JONS* also seeks to strengthen the role of nurse and patient navigators in cancer care by serving as a platform for these professionals to disseminate original research findings, exchange best practices, and find support for their growing community.

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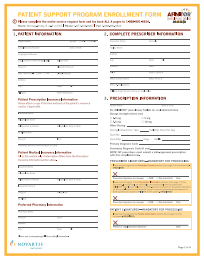

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Calling All Navigators: Join AONN+ and Further Our Progress in Overcoming Barriers to Care!

Dear Navigators,

This month, our Academy of Oncology Nurse & Patient Navigators will convene in Las Vegas for what promises to be an inspiring and entertaining meeting both in our sessions and out! Every year, I look forward to the profound impact the annual meeting has on our collective empowerment as navigators. The general sessions, keynote speakers, and networking social events provide opportunity for professional growth, connection with your colleagues, and re-energized enthusiasm for our chosen careers.

I hope to see many of you there. For all our membership, I ask that you encourage your colleagues to join the academy to help continue our mission of elevating the importance of providing navigation services to all patients with cancer and to further our progress in overcoming barriers to care.

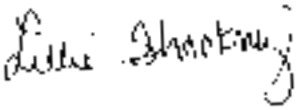
Every year, I look forward to the profound impact the annual meeting has on our collective empowerment as navigators.

In this issue of the *Journal of Oncology Navigation & Survivorship* we feature an original research article by Erin O'Hea, PhD, and colleagues about cancer survivorship planning programs, a critical topic in oncology navigation (page 11).

In addition to news from the American Society for Radiation Oncology, the Palliative Care in Oncology Symposium, and the European Society for Medical Oncology, we also present the quarterly contribution from our Evidence into Practice Committee. This installment focuses on Psychosocial Support Services, with the Novice Navigator section authored by Morgan Finn, RN; Kimberly Foster, MBA, BSN, RN; Marian E. Gilmore, RN, OCN; Pamela Goetz, BA; and Barbara R. McHale, RN, BS, OCN, CBCN, and the Seasoned Navigator section authored by Cheryl Bellomo, MSN, RN, OCN; Tricia Strusowki, MS, RN; and Nicole Delano, MSN, RN (page 31). We are most grateful to this committee of dedicated navigators.

Thank you for your loyal readership and support.

Sincerely,



Lillie D. Shockney, RN, BS, MAS
Editor-in-Chief

University Distinguished Service Professor of Breast Cancer, Depts of Surgery and Oncology; Administrative Director, The Johns Hopkins Breast Center; Director, Cancer Survivorship Programs at the Sidney Kimmel Cancer Center at Johns Hopkins; Associate Professor, JHU School of Medicine, Depts of Surgery, Oncology & Gynecology and Obstetrics; Associate Professor, JHU School of Nursing, Baltimore, MD
E-mail: shockli@jhmi.edu

The Polaris Oncology Survivorship Transition (POST) System: A Patient- and Provider-Driven Cancer Survivorship Planning Program

Erin O'Hea, PhD
Department of Psychiatry, University of Massachusetts Medical School, Worcester, MA
Department of Psychology, Stonehill College, Easton, MA

Juliet Wu, BS
Departments of Emergency Medicine and Psychiatry
University of Massachusetts Medical School, Worcester, MA

Laura Dietzen, MS; Tina Harralson, PhD
Polaris Health Directions, Wayne, PA

Edwin D. Boudreaux, PhD
Departments of Emergency Medicine, Psychiatry, and Quantitative Health Sciences
University of Massachusetts Medical School, Worcester, MA

Background: It is strongly recommended that individuals ending treatment for cancer have a "survivorship plan," and new standards require survivorship planning for accreditation. However, a comprehensive plan is often neglected.

Objective: To present the development and field test results of a web-based, breast cancer survivorship care planning system.

Methods: The Polaris Oncology Survivorship Transition (POST) blends input from the electronic health record (EHR), oncology care providers (OCPs), and patients to create a survivorship care plan (SCP). The content of the POST program was created with the assistance of end-user input (patients, oncologists, and primary care providers (PCPs)) and the full program was piloted on women ending treatment for breast cancer. This paper presents the pilot study that field-tested the POST in a clinical setting. Patients were recruited from outpatient care clinics and chemotherapy units in a comprehensive care center. The study included 25 women ending treatment for breast cancer in the past year, 4 OCPs, and PCPs. Patients received the POST computerized assessment and a tailored SCP.

Results: The POST assists providers in crafting efficient and comprehensive SCPs and was rated highly satisfactory by all end-users.

Discussion: The POST program can be used as a cancer survivorship planning program to assist OCPs in care planning for their patients ending treatment for breast cancer.

Conclusion: This study provides support for incorporating computerized SCP programs into clinical practice. Use of the POST in clinical practice has the potential to improve survivorship planning.

Within the United States, the estimated number of cancer survivors will increase from 14.5 million to approximately 19 million by 2024.[1] The National Coalition for Cancer Survivorship distinguishes between 2 phases of survivorship: 1) intermediate/short-term (posttreatment), and 2) long-term survivorship. In 2015, the American College of Surgeons (ACS)[2] implemented accreditation expectations that include a written or electronic survivorship care plan that is 1) prepared by the OCP; 2) given to patients at treat-

Table 1 POST Patient Assessment Content Areas

Content Area	Number of Items	Sample
Physical Symptoms and Functioning	15	In the past 2 weeks, please rate your FATIGUE or TIREDNESS.
Psychological Distress (Anxiety and Depression)	20	In the past 2 weeks, how often have you felt sad, down, or depressed?
Short-term and Long-term Effects of Breast Cancer	10	Are you having problems with lack of sexual interest or drive (low libido)?
Supportive Care	16	Some patients find it helpful to speak with a counselor about emotional distress that they or their families are experiencing. Would you like to have your information sent to our on-site clinical psychologist?

POST indicates Polaris Oncology Survivorship Transition.

ment completion; and 3) includes a record of care received, important disease characteristics, and a follow-up plan incorporating evidence-based standard of care.

Survivorship care planning has been a highly debated topic in cancer care. Whereas some oncology care experts argue that survivorship planning has the potential to improve quality of life, decrease morbidity and mortality related to future cancers, and enhance patient access to resources to manage the physical, emotional, and social sequelae of cancer treatment,[3-6] others argue that there is a lack of evidence that survivorship care planning actually impacts patient outcomes.[7] One of the reasons for the debate is that there is indeed a lack of methodologically rigorous studies examining the outcomes of care planning, which is likely due to care planning being time-consuming and, thus, not done consistently by OCPs.[8] One exception is a study by Grunfeld and colleagues,[9] which is one of the only randomized controlled trials that has tested outcomes related to survivorship planning and has received much attention because of its null findings. Primary critiques include: a lack of tailored survivorship planning; patients out of cancer treatment for an extended time; extrapolating findings from the Canadian healthcare system to the US system; time of follow-up measurement; and use of non-cancer-specific distress tools.[10,11] Further, Grunfeld's survivorship planning did not include any assessment of the patient's status or needs and neglected to integrate care planning into clinical practice.

The purpose of this paper is to present the findings from a phase 1 STTR (small business technology transfer) study, which funded the development of the Polaris Oncology Survivorship Transition (POST) system. The POST is a computerized, web-based survivorship planning program that generates a tailored SCP. The POST system is the first technology-enabled system to produce tailored survivorship plans fully reflecting the Institute of Medicine (IOM) recommendations[4] and the ACS 2015 requirements. The POST is innovative as it incorporates information from both the OCP and the patient; features readily available "plug in" for 2-way integration with diverse EHRs; provides dynamic, electronic referrals for specialized support service; and facilitates care coordination between OCPs and PCPs. We also discuss our ongoing phase 2 study, which is examining the POST in a randomized controlled trial to determine its impact on patient outcomes as they move into long-term survivorship.

Method

Participants

Twenty-five patients with breast cancer were enrolled in the field study. Inclusion criteria included being 18 years of age or older, female, having a diagnosis of non-metastatic breast cancer, and being within 3 visits of ending active treatment or up to 1 year out of ending active treatment for breast cancer. Patients with other types of cancer, men, and patients with communication difficulties were excluded.

Assessments

The POST Patient Assessment was the main outcome measure for participants and a tool for creating the patient-driven portion of the SCP. We considered the assessment a measure for the study as it assesses important outcome variables described below. In addition, patients completed a Preparing for Life as a New Survivor (PLANS) assessment before and after the Patient Assessment, a feedback/satisfaction survey after reviewing their SCP with their OCP, and a follow-up assessment 1 month after enrollment. OCPs and PCPs also completed follow-up assessments.

The POST Assessments

The POST program incorporates 2 data sources to generate an overall SCP: 1) a Provider Questionnaire populated by information from the EHR, which for this study was entered by a research assistant and OCP, and 2) a computerized Patient Assessment (**Table 1**). The POST SCP is broken down into 2 portions: 1) the provider version of the SCP, and 2) the patient version of the SCP. *Both summaries* consist of 7 sections: 1) Medical Diagnosis and Treatment Summary, 2) Medical Care Plan, 3) Physical Symptoms and Functioning, 4) Psychological Adjustment or Psychological Distress, 5) Short-term and Long-term Effects of Breast Cancer, 6) Supportive Care, and 7) Cancer-Related Health Behaviors. Sections 1 and 2 of both the provider and patient versions of the SCP are generated from the Provider Questionnaire and are *exactly the same in terms of content*. Sections 3 through 7, which are further broken down into subsections, are generated from the patient assessment and vary depending on how the patient responds to the assessment. Also, the patient and provider versions of sections 3 through 7 vary in terms of depth of content, as the patient version is significantly more detailed in terms of psychoeducation and resources.

Section 1 of the SCP provides a comprehensive summary of cancer diagnosis and treatment and other notable medical diagnoses. Section 2 summarizes the patient's plan for the next year, including future scans, tests, and appointments anticipated by the OCP. Sections 3, 4, and 5 include tailored feedback and evidence-based psychoeducation about emotions, relationships, side effects, and lifestyle choices that impact quality of life and health in survivorship. Section 6 is linked to questions regarding social support, spirituality, or financial issues. Finally, section 7 is informed by questions related to diet, exercise, smoking, and alcohol use. This section provides empirically supported information about health behaviors and cancer risks and includes tailored recommendations for behavior change. The "Patient drug information" from uptodate.com was also provided for any current cancer medications taken by the patient. In addition, based on responses from the patient assessment, individuals could request a referral to a psychologist and/or a social worker. For example, individuals with elevated distress were asked if they wanted their information sent confidentially to a psychologist specializing in cancer-related psychosocial issues.

Whereas *both the provider version and patient version of the SCP* contain information on these 7 areas related to survivorship, as stated above, the provider version is very brief and is focused on simply documenting status and symptoms of the patient. Because the provider version would be saved to the EHR, and potentially sent to the patient's PCP, we crafted a brief version of the care plan. Hence, we labeled this brief version the provider version or "provider summary." The provider version is approximately 3 to 5 pages and flags any concerns reported by patients during their assessment (ie, smoking status, high level of depression, sexual problems). (See**Appendix A** for a Provider Version/Summary SCP example.)

Sections 3 through 7, which are further broken down into subsections, are generated from the patient assessment, and vary depending on how the patient responds to the assessment.

The patient version of the SCP is more detailed, providing information and resources depending on the patient's responses to the assessments related in sections 3 through 7. Depending on these responses, a patient version of the SCP can range from 25 to 45 pages. This document can be lengthy because if a patient reports concerns about any of the areas assessed, the POST is programmed to provide the patient with printed materials related to the topic as well as regional and local resources that may help them address the reported concerns. For example, if a woman reports that she is concerned about her weight at the end of cancer treatment, the POST will add a section to the patient version of the SCP that provides her with information taken from good resources (eg, American Cancer Society, National Cancer Institute [NCI]) about cancer risk and obesity, as well as information about best ways to manage weight, and will even include some resources in the area for obesity management treatment. We chose to not include an example of a patient version SCP because of the length of the document, but readers are encouraged to contact the authors if they would like to request an example.

The PLANS

The 17-item PLANS scale was used to assess how prepared and knowledgeable women felt regarding surveillance and care as they entered survivorship.[12,13] Part 1 uses a 4-point Likert scale (strongly disagree = 1 to strongly agree = 4) to determine patients' beliefs regarding their role and their providers' roles during survivorship. Part 2 uses a 10-point Likert scale to measure participants' confidence in ability to care for themselves as

they enter survivorship, with higher scores indicating greater confidence.

Feedback/Satisfaction of POST

The Patient POST Feedback/Satisfaction Survey asked participants about the online assessment process and how they felt about their SCP. Patients were asked how much they agreed or disagreed with 14 items using a 5-point Likert scale (strongly disagree = 1 to strongly agree = 5), open-ended questions, and their ratings for overall satisfaction.

Only estimates of time were documented for each step taken in survivorship planning for the field test because the POST was still in development and was tested in live clinical situations.

Follow-Up Assessment

The 1-month follow-up survey was adapted from a survey developed by Brothers and colleagues[14] to evaluate the clinical utility and impact of survivorship plans and used a 5-point Likert scale (strongly disagree = 1 to strongly agree = 5).

OCP Satisfaction Survey

OCPs evaluated the SCPs by answering how much they agreed or disagreed with statements on a 5-point Likert scale, with higher scores indicating more agreement. They also provided overall satisfaction ratings, feedback about the most useful sections of the SCP, and open-ended comments.

PCP Satisfaction Survey

PCPs were asked about their perception of the SCP's usefulness for evaluating their patient's status and future care needs and other ways that the SCP may have been helpful in transitioning care from the oncology team back to the PCP. Similar to the OCP survey, a 5-point Likert scale was used, with higher scores indicating more agreement.

Procedure

Patients

Enrollment procedures are illustrated in **Figure 1**. Researchers worked with the oncology team to identify potential participants for the field test. All participants went through informed consent procedures and were given the option to send a copy of the provider version of the SCP to their PCP. Participants used an iPad or tablet computer to complete assessments. When the patient portion of the assessment was completed, the OCP completed his or her portion of the POST Provider Questionnaire and checked for inaccuracies. The SCP was then reviewed with the patient and checked for accuracy, and a hard copy was provided to the patient to review at her leisure. After the appointment and SCP review, research staff administered a feedback survey and readministered the PLANS. Any referrals requested for a social worker or clinical psychologist were confirmed with the patient and sent to the appropriate provider. All participants were called 1 month after the initial assessment to complete a follow-up assessment over the phone with a trained research assistant and were remunerated $40.

Only estimates of time were documented for each step taken in survivorship planning for the field test because the POST was still in development and was tested in live clinical situations. Without EHR integration, a research assistant took about 30 to 45 minutes to prepare the Provider Questionnaire, and the OCPs spent about 5 minutes checking and updating the questionnaire after patients completed their assessments. A majority of patients completed their assessments within 10 minutes. It took approximately 10 to 15 minutes to review the SCP with patients at the end of their appointment.

OCPs

OCPs were contacted in person or via e-mail after all participants completed the POST assessment to arrange a time and date to complete a satisfaction survey.

PCPs

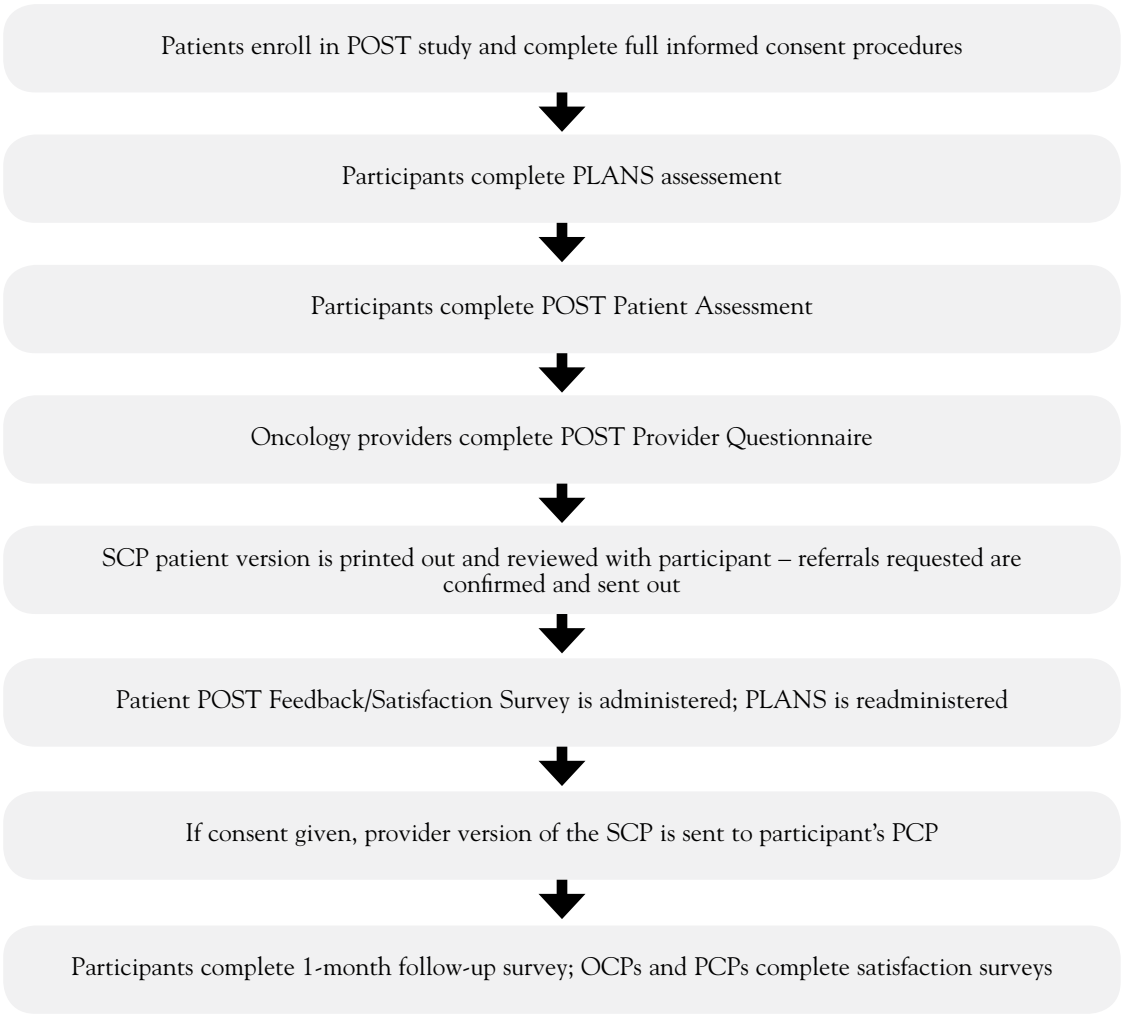
The provider version of the SCPs was sent to the PCPs of the participants who had given permission to share their information. If a PCP was within the hospital network, he or she was e-mailed the SCP and satisfaction survey. If a PCP was outside the network, he or she was sent the SCP via secure fax and contacted via phone by the principal investigator to complete the satisfaction survey.

Results

Data Analytic Plan

Descriptive statistics were determined with demographic data. Means and standard deviations (SDs) were calculated for satisfaction ratings and PLANS scores – pre and post. Wilcoxon signed rank tests were also used for tests of significance. Finally, percentages were calculated for OCP, PCP, and patient follow-up data related to evaluation of the POST program.

Figure 1 POST Patient Enrollment Flow



OCP indicates oncology care provider; PCP, primary care provider; PLANS, Preparing for Life as a New Survivor; POST, Polaris Oncology Survivorship Transition; SCP, survivorship care plan.

Participant Demographics

Twenty-five patients with breast cancer were enrolled in the field test. The mean age at the time of enrollment was 61 years (SD, 13.59), 92% were Caucasian, and 8% were black or African American. No participants were Hispanic or Latina. Three women were enrolled prior to ending active treatment but were within a close enough proximity that the OCP felt they were ready for an SCP. Thirteen women were enrolled within 6 months, and 9 were enrolled within 1 year after ending active treatment for breast cancer.

Patient Outcomes

Baseline and Postintervention Confidence Ratings – PLANS

Twenty-three patients (92.0%) completed the PLANS before taking the patient assessment and after reviewing their SCP. Confidence ratings were equally high before and after the patient assessment (**Figure 2**). At both times, the median of the 5-item average score was 9.40 (range, 6.60-10.00) on a 10-point scale where 10 = "Extremely Confident," $Z = 0.31$, $P = .75$, and $r = .06$. Immediately following the POST, 84% of patients had an

Continued on page 17

Table 2 Patient Follow-up Assessments

Patient Follow-up	Average Rating (strongly disagree = 1 to strongly agree = 5)
Understanding of clinical services	4.11 (n = 22)
The SCP helped in understanding and addressing…	
Your medical concerns	4.14 (n = 22)
Your psychological and/or social concerns	4.20 (n = 20)
Sexual well-being	4.17 (n = 18)
Health risk factors (like smoking and weight)	4.40 (n = 20)
Risk of a second cancer	3.78 (n = 22)
Need for a referral to another medical provider	3.83 (n = 18)
Responsibilities of your healthcare providers	4.23 (n = 22)
Understanding of medical treatment and plan	4.26 (n = 22)
The SCP increased your knowledge of…	
Your cancer and treatment	4.29 (n = 21)
Short-term effects of your cancer treatment	4.11 (n = 19)
Strategies to monitor or manage the short-term effects of cancer treatment	4.37 (n = 19)
Long-term effects of your cancer treatment	4.11 (n = 19)
Strategies to monitor or manage long-term effects of cancer treatment	4.21 (n = 19)
Strategies for reducing risk (like changing health habits or behaviors)	4.27 (n = 22)
Other resources available to you at the clinic or medical center	4.45 (n = 22)
Helpfulness of SCP	4.17 (n = 22)
Since receiving the SCP, the SCP has been helpful regarding…	
Your cancer	4.41 (n = 22)
Planning your own care	4.32 (n = 19)
Fatigue	3.72 (n = 18)
Surgical procedures and side effects	3.94 (n = 18)
Chemotherapy procedures and side effects	4.27 (n = 11)
Radiation procedures and side effects	4.27 (n = 11)
Other treatment procedures and side effects	3.89 (n = 19)
Returning to your daily routine or returning back to the workforce	4.47 (n = 15)
Relationships with family and friends	4.10 (n = 20)
Transitioning out of active treatment and into survivorship	4.26 (n = 19)
	% Endorsed
Have you changed or do you plan on changing any of your health or wellness behaviors?	72.7[a]
Did the SCP influence any of the changes?	50
Did you change your behavior prior to receiving the SCP?	12.5
Have you utilized any supportive services suggested on the SCP?	4.5

[a] Diet and exercise were indicated by all 16 participants who answered yes.
SCP indicates survivorship care plan.

average score of 8 or higher. At follow-up, 91% had similar scores. Ratings of surveillance and coordination were generally high before the Patient Assessment, with a median score of 3.00 on the 4-point scale, where higher scores indicated more favorable responses (range, 2.45-4.00). However, a Wilcoxon signed rank test indicated that scores were significantly higher after assessment and review of the SCP (median, 3.45; range, 2.36-4.00), Z = 2.03, *P* = .04, and r = .42.

Baseline Feedback/Satisfaction of Patient Assessment

Twenty-five patients rated the Patient Assessment immediately after completing it. Sixty-eight percent of the patients were "Very Satisfied" with the assessment process overall, 28.0% were "A Lot Satisfied," and 4.0% were "A Little Satisfied." **Figure 3** provides specific details regarding respondent ratings.

Patient Baseline Feedback/Satisfaction of SCP

Twenty-three patients rated the SCP. Seventy percent (69.6%) of the patients were "Very Satisfied" with the SCP overall, 26.1% were "A Lot Satisfied," and 4.3% were "A Little Satisfied." **Figure 4** provides specific details regarding respondent ratings.

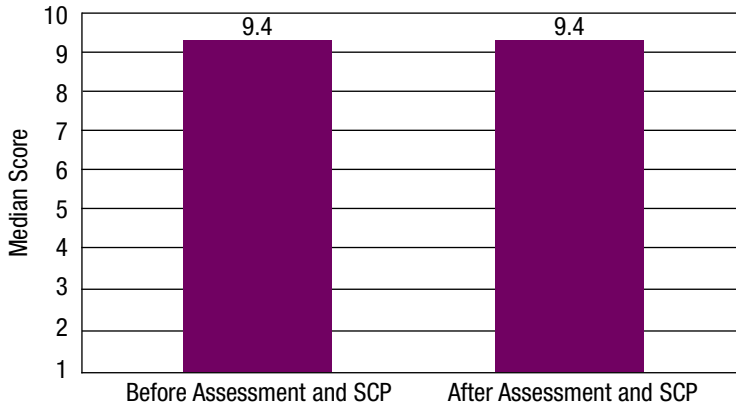
Patient Follow-up

One-month follow-up assessments were completed with 22 of 25 participants (88.0%) over the phone. Two participants were lost to follow-up and 1 withdrew from the study. Questions were posed regarding usefulness of the SCP as well as relevant behavioral changes since baseline. Wilcoxon signed rank tests indicated that satisfaction scores were not significantly different at follow-up compared with ratings immediately following the SCP review (patient assessment, Z = –0.71, *P* = .48, r = –0.15; SCP, Z = –0.82, *P* = .41,r = –0.17). **Table 2** provides additional information about patient feedback at follow-up.

OCP Outcomes

Three oncologists and 1 oncology nurse practitioner completed the satisfaction survey asking about the Provider Questionnaire and SCPs. None had prior formal experience using an SCP in their clinical practice, but all were familiar with existing options such as Journey Forward. See **Table 3** for information about OCP feedback.

Figure 2 PLANS: Baseline and After SCP Confidence Scores



SCP indicates survivorship care plan; PLANS, Preparing for Life as a New Survivor.

PCP Outcomes

Although all PCPs confirmed receipt of the SCP, only 9 of 21 PCPs (42.8%) completed the online satisfaction survey. Therefore, we present their data here to be interpreted with caution. Overall, 44.4% of PCPs were "Very Satisfied" with the POST program, 33.3% were "A Lot Satisfied," and 22.2% were "Somewhat" or "A Little Satisfied." See Table 3 for information about PCP feedback.

The SCPs include a thorough medical summary and plan as well as a psychosocial summary of functioning, and suggestions to improve survivorship functioning over time.

Discussion

The POST is innovative and may be a good resource for providers who are striving to meet the standards surrounding survivorship care planning. First, the POST produces tailored survivorship plans that fully reflect IOM recommendations and ACS requirements. Second, the content and crafting of the assessment and SCP were heavily informed by patients, OCPs, and PCPs. Third, the POST program has the capacity to communicate

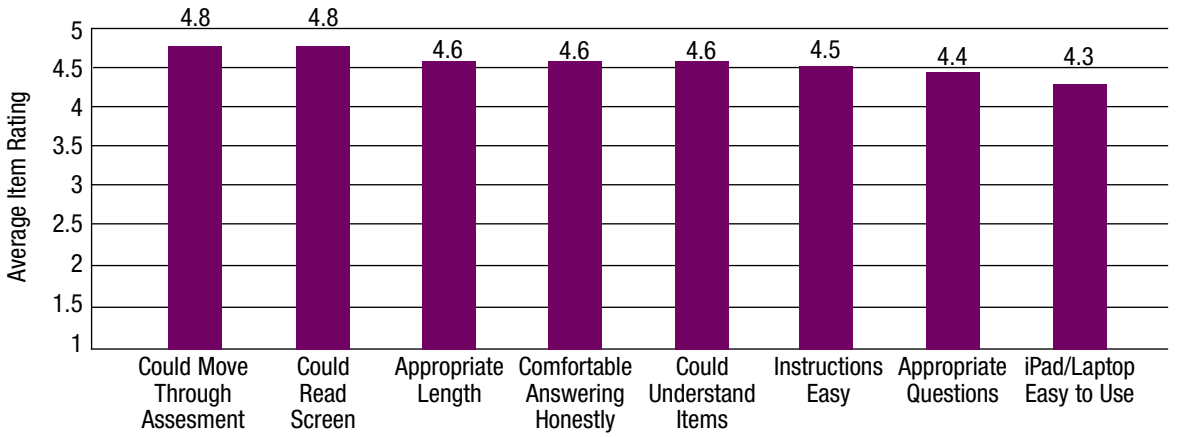
Table 3 OCP and PCP Follow-up Assessments

Healthcare Provider Follow-up	% Endorsed OCP (N = 4)	% Endorsed PCP (N = 9)
Most useful sections of the SCP[a]		
Medical Diagnosis and Treatment Summary	100	66.6
Medical Care Plan	50	55.5
Physical Symptoms and Functioning	25	22.2
Psychological Adjustment	25	33.3
Short-term and Long-term Effects	75	44.4
Supportive Care	25	33.3
Cancer-Related Health Information	25	22.2
Impact on Clinical Practice		
OCP and PCP		
Would consider using the SCP in clinical practice	75[b]	77.8[c]
Would recommend the SCP to colleagues for survivorship planning	75	
PCP-specific		
Having the SCP will benefit clinical interactions with patients		77.8[c]
The SCP helped to stimulate conversation that would not otherwise have come up		66.7[d]
Made clinical decisions based on SCP-provided information		22.2[e]
	Average Rating (strongly disagree = 1 to strongly agree = 5)	
Evaluation of SCP	3.9	4.1
OCP and PCP		
The SCP is easy to read and understand, is comprehensive, is the appropriate length		
OCP-specific		
The POST is an efficient way to put together an SCP		
PCP-specific		
The SCP was efficient and did not generate extra work, increases my confidence to take care of this cancer survivor, gives me a better understanding of my patient's cancer treatment, is something I would like to receive in the future, gives me new information about the patient that I probably would not have had without the plan		

[a] Suggestions for additional content to include in the SCP were: information on the impact of treatment on sexuality, local support groups and young women's issues, and linkages to financial and occupational resources.
[b] One OCP reported reservations about using the POST program as there is "no scientific evidence that cancer survivorship plans are useful or beneficial."
[c] Two (22.2%) were unsure.
[d] Two (22.2%) were unsure and 1 disagreed (11.1%).
[e] Both PCPs answering yes made clinical decisions related to depression.
OCP indicates oncology care provider; PCP, primary care provider; SCP, survivorship care plan.

with the EHR, which significantly impacts efficiency in building survivorship plans. However, it should be noted that the EHR integration was developed after the end of this study and is now part of the POST program during our ongoing, phase 2, NCI-funded, randomized controlled trial. Fourth, the POST is both patient *and* provider driven, whereas most existing programs are simply provider driven. Fifth, the SCPs include a thorough medical summary and plan as well as a psychosocial summary of functioning, and suggestions to improve survi-

Figure 3 Patient Ratings of POST Assessment at Baseline



POST indicates Polaris Oncology Survivorship Transition.

vorship functioning over time. Finally, the POST aids communication and the transfer of care from the oncology team back to the PCP by sending a copy of the SCP to the patients' PCPs. Given that many PCPs do not receive detailed information, and in the worst situation do not receive any information from the oncology team, the POST's automatic transmission of the SCP to the PCP is pioneering.

A key point of this study was clinical implementation, as all SCPs were built in "real time" during the clinic visits. We wanted the study to mirror real-life clinical practice; however, because this was a development and field trial project, we had to rely primarily on the research staff as we were working through programming development iterations while conducting the field trial. The oncology care team was involved with building the medical sections of the SCP and was the group who reviewed the care plans for accuracy. In our ongoing phase 2 study, we have built a protocol that mirrors what we believe is a viable option for oncology treatment centers to do wide-scaled survivorship planning.

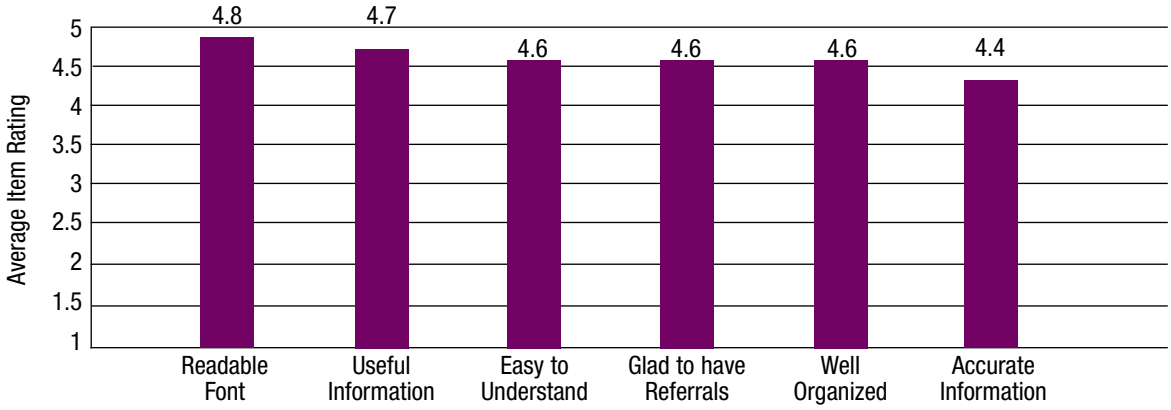
In our protocol, the nurse practitioners/oncology staff build the care plans, including information prepopulated from the EHR, prior to the patient coming in for a "survivorship care planning" visit. There, the plan is reviewed with the patient by a nurse practitioner. After the review, the patient sees her oncologist for 1 final visit during which she has an opportunity to ask questions and address any concerns or information provided in the SCP. The provider then signs off on the SCP, and the briefer provider version of the SCP is both uploaded to the EHR and sent to the PCP. Finally, the patient retains a physical copy of the patient version of the SCP. Results from this study will be disseminated once the study is complete in 2018.

Another important piece of SCP implementation is how to handle patients who have psychosocial needs that are identified in their assessments. For this present study, we were able to make referrals to the on-site psychologist and social worker, who would then contact patients to schedule appointments or visit the clinic if it was an urgent situation. This worked well,

We were able to make referrals to the on-site psychologist and social worker, who would then contact patients to schedule appointments or visit the clinic if it was an urgent situation. This worked well.

and we found that it was very helpful for the psychologist and social worker to be able to review the SCP prior to seeing the patient. However, there are some situations where oncology clinics do not have psychologists on staff to address psychological needs of patients. In these situations, we feel technology can, again, be the answer to connecting patients with resources in their communities. For example, in a different oncology care–related project, our team built the technology to identify psychosocial distress in patients

Figure 4 Patient Ratings of SCP at Baseline



SCP indicates survivorship care plan.

with cancer through a patient-driven, web-based program that could also match a patient's insurance and zip code to a tailored database we built.[15] This aided patients who were not interested in seeing a provider in the cancer center for various reasons. Polaris Health Directions, the technology team that built the POST, has the ability to integrate a similar type of referral system into the POST program.

There are many limitations to this study. The most important is that this study does not show that the POST program is any more efficient than the other planning programs in existence.

We assessed both OCP and PCP outcomes, as we were interested in their perceptions of the clinical utility of the POST program. Although we do not present the data here since the number of providers sampled is very low (OCP = 4, PCP = 9), there was a trend that the OCP felt the SCP was most helpful in building and presenting the medical diagnosis and treatment summary as well as the medical care plan. Further, the majority of both the *OCP and PCP endorsed that they would* consider using the SCP in clinical practice *and* would recommend the SCP to colleagues for survivorship planning. Finally, the PCPs were most likely to report that they felt that having the SCP would benefit clinical interactions with patients, and that the SCP helped stimulate conversation that would not otherwise have come up in their usual interactions with patients. However, the PCPs did not feel that the SCP impacted their decision-making in their clinical encounters.

We also assessed patient ratings regarding confidence for survivorship, before and after review of the SCP. As shown in Figure 2, patient ratings of confidence did not change over time. This was likely because the sample's confidence pre-SCP was very high, which allows for little improvement post-SCP. Figures 3 and 4 provide information about how the patients viewed the assessment and the actual SCP that was generated from the POST program, and it appears the patients had quite favorable reviews of both. It should also be noted that patient ratings of the program remained favorable at the 1-month follow-up (Table 2).

There are many limitations to this study. The most important limitation is that this study does not show that the POST program is any more efficient than the other planning programs in existence. We were unable to achieve the EHR integration when we were conducting the field study and were busy working on the development and testing of the POST program. However, it should be noted that the purpose of a phase 1 STTR is to develop and test programs like the POST, so that by the end of the study there is a streamlined, usable program to test in a phase 2 trial where issues like efficiency can be addressed. We presently have the phase 2 randomized controlled trial under way and are measuring time to

build the SCP compared with other programs, as we feel that the true innovation of the POST 2 is its efficacy and ability to integrate into real clinical practices.

There is much we still do not know about survivorship care planning—its impact on patients, and its impact on clinical practices. Research is needed to determine the potential impact of survivorship planning on health and psychosocial outcomes. Mayer et al[8] suggested 4 broad areas of SCP research: *content, dissemination and implementation, outcomes*, and *improved study methodology*. We need a better understanding of issues that are important to cancer survivors, as well as what strategies we can use to best prepare patients for survivorship.[16]

Developing and delivering an SCP could take between 1 and 4 hours per patient. This time demand can be reduced by integrating planning programs with the EHR or cancer registry.

In terms of dissemination and implementation, there is a great need for studies aimed at developing guidelines for institutional use so cancer centers can comply with IOM recommendations.[6] We need a better understanding of best possible reimbursement pathways, and optimal insurance and payment options.[6] Identifying the best way for OCPs to receive compensation for SCP delivery is essential.[17] Also, as addressed above, a consistent barrier to SCP implementation is lack of time. Developing and delivering an SCP could take between 1 and 4 hours per patient.[18] This time demand can be reduced by integrating planning programs with the EHR or cancer registry. This will be an important piece of future studies as we continue to investigate the best strategies, and potential consequences and benefits, of EHR or cancer registry integration.[19]

Outcomes research related to SCPs should focus on how to best measure important constructs or difficulties experienced by patients.[14] We did not present patient outcomes in this paper as our sample was small and the purpose of the field test was POST program development and utility. Because there is a lack of randomized controlled trials in this area of study, it is difficult to confidently say which issues remain important to the quality of life of survivors over time, and sound methodological studies are needed to determine the important constructs that threaten the well-being of survivors. Finally, more investigation is needed regarding how SCPs can best facilitate communication between medical providers.[17] Gaps in physician understanding must be thoroughly defined to help guide SCP content, and PCP training in survivorship planning may be important for improving care as it transfers from the oncology team back to general medical practice.[20]

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Appendix A

Survivorship Care Plan Provider Summary

Survivorship Care Plan: Provider Version of SCP

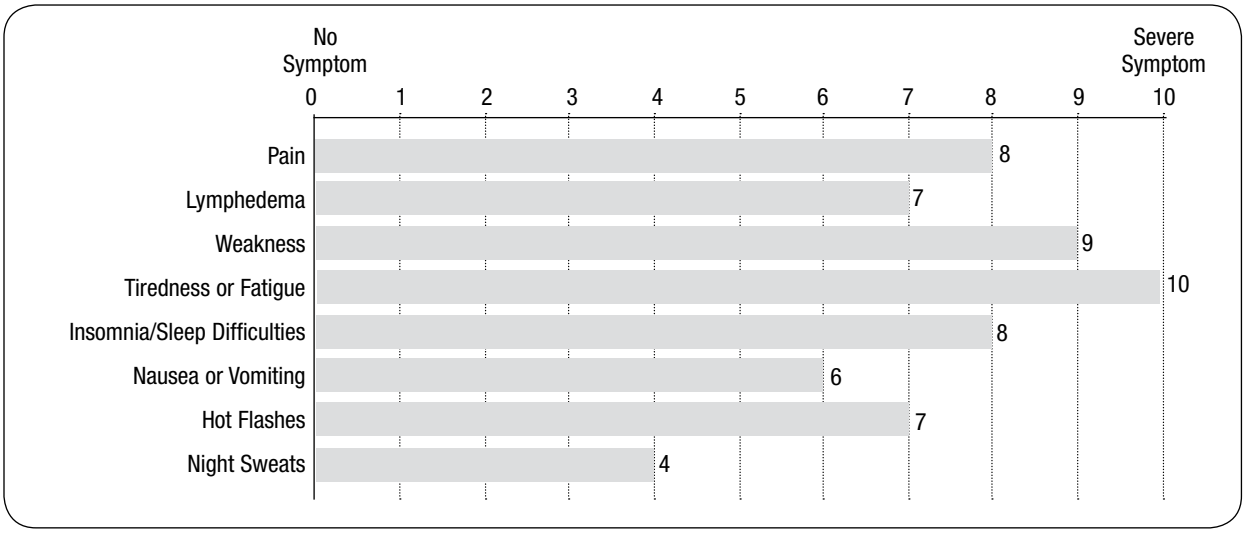
Name: PATIENT, MOCK
DOB: 01/01/1950
Date of Plan: 10/16/2014
SCP Created by: Oncologist, MD

The first part of this Survivorship Cancer Plan (SCP) labeled PROVIDER VERSION is for your medical providers including members of your oncology team and your primary care doctor. The PROVIDER VERSION provides information about your medical diagnoses, treatment and future medical plans. Your oncologist will review this section with you at this visit. The PATIENT VERSION of the SCP has some detailed information about breast cancer survivorship for you to review on your own.

SECTION ONE: Medical Diagnosis and Treatment Summary	
Oncology Treatment Team Medical Oncology (508-334-6200) Dr. Med Onc Radiation Oncology (774-442-5551) Dr. Rad Onc Surgical Oncology (508-334-6200) Dr. Surg Onc	Nursing (508-334-6200) Jane Smith Cosmetic Surgery (508-334-5211) Social Work (774-441-8632) Psychologist (886-597-HOPE)
Primary Care	Name: Primary Care Email: primary.care@university.edu Phone: (555) 664-2442 Fax: (555) 782-6910 Address: 55 Lake Avenue, Worcester, MA 01655
Date of Diagnosis	02/06/2013
Diagnosis	Breast Cancer
Disease Location	Left
Stage of Cancer	Stage IA: T1 N0 M0
Type of Cancer	Estrogen positive AND HER2 positive
Other cancer diagnoses	
Other non-cancer diagnoses	Crohn's disease
Surgery	Lumpectomy with sentinel lymph node biopsy
Reconstruction	None
Prophylactic Surgery	No
Chemotherapy	Neo-adjuvant
Date Chemotherapy Completed	07/20/2013
Radiation	Post Lumpectomy Radiation
Date of last radiation treatment	12/20/2013
Treatment complications	Cardiac dysfunction
Diagnosis of hereditary breast or ovarian cancer symptoms	No
Date of last screening mammogram	06/06/2013
Date of last breast MRI	08/10/2013
Date of last colonoscopy	09/30/2012
Date of last pap smear/pelvic exam	02/16/2014
Date of last bone density scan	02/16/2015

SECTION TWO: Medical Diagnosis and Treatment Summary	
Current Cancer Medications	Tamoxifen
Cancer Recurrence Monitoring?	Regular history, physical examinations and mammography are recommended for breast cancer follow-up. Routine lab work and imaging studies are not recommended as part of ongoing breast cancer surveillance.
5-year plan	Annual screening mammogram Routine clinic visit every 6 months Breast MRI, if indicated PAP as recommended by PCP
Appointments scheduled	Next appointment date: 7/8/15 – Primary Care
Appointments for Patient that need to be scheduled now	
Information about future monitoring/appointments needed	

SECTION THREE: Physical Symptoms and Functioning



SECTION FOUR: Psychological Adjustment

Area	Value (High=Severe)	Info Provided to Patient
NCCN Distress Thermometer (0-10)	6	N/A
Behavioral Health Impairment (anxiety, depression, subjective well-being, functional disability) (0-100)	35	N/A
Depression (0-100)	25	Y
Anxiety (0-100)	10	Y
Functional Disability (0-100)	0	Y

**Scores are percentiles based upon norms for cancer patients in active treatment across different types of cancers*

SECTION FIVE: Short-term and Long-term Effects		
Symptom Area	**Patient Endorsed Difficulty**	**Area**
Lymphedema	Y	N/A
Cognitive Effects	Y	-Problems focusing or paying attention -Feels less sharp mentally
Sexual Dysfunction	Y	-Lack of interest/low libido -Vaginal dryness
Appearance/Body Image	Y	-Unhappy with appearance -Feels less physically attractive
Fear of Recurrence	Y	-Mood affected by thoughts of recurrence
Premature Menopause and/or Infertility	N	N/A

SECTION SIX: Supportive Care		
Item	**Patient Endorsed Difficulty**	**Area**
Family Problems	Y	-Cancer has had bad effect on family's usual pattern of living -Problems with children -Family is still having a hard time with diagnosis and treatment
Finances/Employment/ Practical Problems	Y	-Having financial difficulties -Difficulty paying for medications -Difficulty paying for medical bills -Difficulty going back to work because of physical symptoms -Difficulty managing insurance company
Spirituality/Religiosity	Y	N/A
Relationships/Social Support	Y	N/A

SECTION SEVEN: Cancer-Related Health Information		
Item	**Patient Reported**	**Info Provided to Patient**
Weight at Diagnosis (lbs.)	140	N/A
Most recent weight (lbs.)	142	N/A
Total Weight Gain or Loss (lbs.)	+2	Y
Concerned about weight	Y	Y
Want info about diet/cancer risk	Y	Y
Want info about exercise/cancer risk	Y	Y
Smokes cigarettes	Y	Y
Drinks alcohol	N	Y

Referrals

- **Patient provided a referral to social worker, Mr. John Jones**
- **Patient provided a referral to psychologist, Dr. Erin Boudreaux**

Psychosocial Support Services/Assessment

Cheryl Bellomo, MSN, RN, OCN

Cancer care provides an array of biomedical treatment, but it must also address the psychological and social problems associated with the illness. The cancer experience can have a life-changing impact on many individuals, including the need to accept loss, lack of control in some situations, and fear of recurrence. Psychosocial problems created by or exacerbated by the diagnosis of cancer can include depression and other emotional problems; lack of information or skills needed to manage the illness; lack of transportation or other resources; and disruptions in work, school, and family life. Distress encompasses the emotional, physical, and psychological aspects of facing a cancer diagnosis and treatment.

The National Comprehensive Cancer Network (NCCN) defines distress as "a multifactorial unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment."[1] Distress extends along a continuum ranging from common normal feelings of vulnerability, sadness, and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and existential and spiritual crisis. To deliver high-quality cancer care, patients' psychosocial needs must be addressed and tools/resources/support services provided to improve patient outcomes.

A failure to acknowledge and measure distress can lead to poorer outcomes, including decreased patient adherence. Emotional distress is associated with decreased adherence to treatment, diminished quality of life (QOL), worse survival, higher medical costs, and overall greater burden on the medical system. Studies have shown depression to be a common psychological symptom experienced by patients with cancer. If left untreated or undiagnosed, distress may affect QOL. Many studies confirm that distress is often overlooked and that many patients do not receive appropriate screening or treatment. Bultz and Johansen[2] found that unrecognized depression and anxiety can lead to increased use of emergency departments in an attempt to get relief from distress-related symptoms. This places additional financial burden on not only the patient but the healthcare system as well.

In 2007, the Institute of Medicine (IOM) released *Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs*,[3] a report identifying the seriousness of unmet psychosocial needs faced by patients with cancer and their families. One recommendation was for cancer programs to include distress screening as part of the assessment. The IOM report emphasizes the importance of screening patients for distress and psychosocial health needs as a critical first step to providing high-quality healthcare. It recommends screening as a part of standard clinical care and as a tool for promoting effective patient-provider communication, as well as to support patients by providing personalized information, identifying strategies to address psychosocial needs, providing emotional support, and helping patients manage their illnesses and health.

Studies have shown depression to be a common psychological symptom experienced by patients with cancer. If left untreated or undiagnosed, it may affect QOL.

Building upon this, the American College of Surgeons Commission on Cancer (CoC) required accredited cancer programs to develop a process for distress screening by 2015.[4] CoC Standard 3.2 incorporates distress screening into routine cancer care. The CoC specifies that patients must be screened for distress at least once during a pivotal visit when patients are at greatest risk for distress, such as upon diagnosis, a pre-op or post-op surgical visit, consultation with an oncologist, initiation of chemotherapy or radiation therapy, and transition into either survivorship or hospice care. Periods of increased vulnerability for distress among cancer patients may also include finding a suspicious symptom, during diagnostic workup, awaiting treatment, changing treatment modality, end of treatment, discharge from hospital following treatment, medical follow-up and surveillance, treatment failure, recurrence/progression, advanced cancer, and end of life.

The NCCN created guidelines for distress management. The NCCN Distress Thermometer was developed in 2007 as a visual analog tool for patients to indicate their distress level. The Distress Thermometer is designed to screen for distress and is not a diagnostic tool

for depression or anxiety. Potential sources of distress are listed for patients to self-identify. This single-page tool can facilitate conversations between patients and healthcare providers to better elicit what is contributing to patient concerns and how these issues can be effectively resolved. Asking patients, "How is your stress today on a scale of 1 to 10" opens a dialogue with the oncologist or navigator for a discussion of emotions that is acceptable.

Effective psychosocial care, consisting of a multidisciplinary team approach, has been shown to positively influence patient outcomes and QOL.

According to the NCCN guidelines, patients should be screened during the initial visit and then as clinically indicated throughout the treatment. Scores of 4 or higher suggest a level of distress that has clinical significance. If the patient's distress is mild (score is <4), the primary oncology team may choose to manage the concerns by usual clinical support management. If the patient's distress level is 4 or higher, a member of the oncology team looks at the problem list to identify key issues of concern and asks further questions to determine to which resources (mental health, social work and counseling, or chaplaincy services) the patient should be referred to.

The primary objective/reason for screening for psychosocial distress along the cancer continuum is to address patients' perception of QOL. Effective psychosocial care, consisting of a multidisciplinary team approach, has been shown to positively influence patient outcomes and QOL. The NCCN Distress Thermometer has a secondary benefit of connecting many patients to services that might not otherwise have been identified. Potential benefits of distress screening are that it provides patients an opportunity to partner with their healthcare team, overcomes patients' reluctance to ask for help, destigmatizes the issue and allows patients to share their vulnerabilities, and ensures timely referral to supportive services. Per CoC Standard 3.2, licensed mental health professionals and certified chaplains experienced in psychosocial aspects of cancer should be readily available as staff members or by referral.

Increasing evidence suggests that distress screening alone is not sufficient to improve patient outcomes; another critical component is appropriate, timely, and personalized follow-up referrals. Navigators are instrumental in the development and implementation of a plan for psychosocial health services in their cancer program that supports patients (by providing personalized information, identifying strategies to address psychosocial needs, providing emotional support, helping patients manage their illness and health), links patients and families with psychosocial services, and coordinates psychosocial and biomedical care.

Common barriers to care include lack of social support, financial and insurance concerns, and problems with healthcare communication. Navigators can focus on resolving barriers to care, which can be assessed during interviews with patients, and gathering data on psychosocial, financial, and practical issues. Regular interaction with navigators allows periodic evaluation of the success of intervention to reduce barriers. Clinical health outcomes measurement should include assessment of the psychosocial domain (QOL and patient/family satisfaction) for the continuous evaluation of the navigation program.

Acknowledgment of the supportive role of navigation in addressing all potential concerns, not just coordination of care and side effect management, should help to alleviate distress later if issues arise. Patients, families, and treatment teams should be informed that management of distress is an integral part of total medical care and be provided with appropriate information about psychosocial services in the treatment center and the community. Navigators can strengthen physical and psychosocial adjustment to a cancer diagnosis by identifying and promoting effective coping strategies.

AONN+ Psychosocial Support Services and Assessment Competencies

- Distress screening
- Strategies for coping: disease, treatment, distress/anxiety
- Referrals to psychosocial support and resources

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Tools

NCCN Distress Thermometer. www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf.

Are you following us on social media?

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Use Twitter as a tool to communicate with the AONN+ team and other navigators!

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AONN+ Group: Academy of Oncology Nurse & Patient Navigators
Join the AONN+ Professional Network on LinkedIn to see what your colleagues have to share!

Follow Lillie Shockney on LinkedIn
AONN+ Program Director and Co-Founder
for even more navigation news!

AONN Academy of Oncology Nurse & Patient Navigators

Novice Navigator Psychosocial Assessment/Support Services Psychosocial Domain

Morgan Finn, RN; Kimberly Foster, MBA, BSN, RN; Marian E. Gilmore, RN, OCN; Pamela Goetz, BA; Barbara R. McHale, RN, BS, OCN, CBCN

Delivering psychosocial support to every patient at pivotal points in their care can prove challenging due to several practical factors facing cancer programs across the country. As institutions strive to meet more demanding standards, as well as changes in healthcare reimbursement and financial constraints, program staffs are asked to handle increasing responsibilities. Assessing and addressing psychosocial needs can fall to workers who may not feel they have the time or skill to handle this domain of care. Further, the institution may not have processes or procedures in place to ensure consistent, timely, and appropriate psychosocial care. Nurse navigators, patient navigators, and social workers can collaborate to fill vital roles in direct patient psychosocial care and in developing processes and procedures that improve delivery of that care.

Delivering psychosocial support to every patient at pivotal points in their care can prove challenging due to several practical factors facing cancer programs.

Staffing for navigators, social workers, and other support services varies among institutions in the United States. In this article, we will show a range of examples of how psychosocial care is delivered in cancer programs with differing profiles in terms of staffing and use of technology. AONN+ members who are involved in starting or improving psychosocial services may find ideas or models here that they can incorporate as they develop and expand support programs for their patients.

Barbara R. McHale, RN, BS, OCN, CBCN, is a nurse navigator working at St. Mary's Cancer Treatment Center and Samaritan Hospital Radiation Oncology, St. Peter's Health Partners (SPHP), in Troy, NY.

Description of Facility: St. Mary's Cancer Treatment Center and Samaritan Hospital Radiation Oncology, SPHP, is a community-based cancer center in Upstate New York. It was created by a merger of St. Peter's Hospital (teaching hospital), 3 other community hospitals, and a rehabilitation hospital. St. Mary's Cancer Treatment Center houses medical oncology, and radiation oncology is housed at Samaritan Hospital. The radiation department will be on-site at St. Mary's Hospital in 2018. The cancer center also provides in-house referrals to palliative care, hospice care, Eddy Visiting Nurse Association, geriatric care, and senior living facilities.

Types of Cancer Treated: The center has 1 multisite navigator who works directly with breast, colorectal, head and neck, and lung cancer patients. This navigator also assists patients with pancreatic cancer and lymphoma, and other patients who need assistance or have barriers to care.

Staffing: The system has 1 nurse navigator at St. Mary's Cancer Center and 2 navigators at St. Peter's Hospital. St. Mary's Cancer Center has 1 master of social work (MSW) intern, and the hospital is tracking her utilization by patients to justify hiring a social worker. Samaritan Hospital has 2 social workers in their outpatient mental health department who are available for counseling and a psychiatrist within the mental health department who is available to consult with cancer patients. The oncology RN and the nurse navigator can refer patients to various services: nutrition, social work, and counseling.

Distress Screening: When patients come to St. Mary's Cancer Center or Radiation Oncology for an initial consult, they receive a new patient packet that contains the National Comprehensive Cancer Network (NCCN) Distress Tool. The clinic RN reviews the completed tool and refers any patient with a score of 4 or higher to the social worker, the nurse navigator, the American Cancer Society (ACS) patient navigator, to nutrition, or to counseling. Concerns for patients with a score under 4 are managed by the physician and/or the clinic nurse.

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Boehringer Ingelheim N.E.X.T. Day Session
In Conjunction with the Seventh Annual Academy of Oncology Nurse and Patient Navigators (AONN+) Conference

A SHARED DECISION-MAKING APPROACH TO MANAGING PATIENTS WITH EGFR+ mNSCLC: A CASE-BASED DISCUSSION

Friday, November 18, 2016

9:15–10:30 AM

Aria Hotel, Las Vegas, NV
Room: Juniper 1-2
Convention Center, Level 3

Program Description

This promotional non-CNE symposium, sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., will provide an opportunity to learn more about metastatic NSCLC with common EGFR mutations, including biomarker testing, treatment options, and supportive care via clinical case studies.

EGFR = epidermal growth factor receptor
NSCLC = non-small cell lung cancer

Boehringer Ingelheim

Once a patient has documented specific issues or barriers using the Distress Tool, a further discussion into issues is done by the navigator and/or the MSW intern. They utilize a weekly huddle where the upcoming week of patient appointments are reviewed. At this meeting, where all staff are present, they also discuss inpatients, patients currently being seen with issues/concerns, and upcoming new patients. The discussion covers medical, nutritional, social/counseling, financial, work/disability concerns, clinical trial recommendations, treatment plan of care, and recommendations regarding palliative and/or hospice referrals.

The nurse navigator reviews the Distress Tool with the patients so she can also address issues and barriers. She works closely with the social workers, counselors, and insurance company case managers to make sure that patients receive needed care. The cancer center does not have an electronic medical record (EMR) in the clinic yet, so Excel spreadsheets are used to track data, and Meditech was adapted to include nurse navigation documentation.

The nurse navigator works closely with social workers, counselors, and insurance company case managers to make sure that patients receive needed care.

Patients should be rescreened if there is disease progression or a change in the treatment plan. The cancer center is working on standardizing the rescreen process to more consistently meet the needs of these patients. Once patients complete their treatment, they receive the tool again at a follow-up visit with their oncologist. The completed tool is used to address issues and concerns by the nurse practitioner at the survivorship visit when the patient receives a survivorship care plan.

Patient Feedback: Patient satisfaction surveys have shown that patients are highly satisfied with the care they receive at the cancer center. All surveys have been 4.5 to 5, with 5 being the best. Program staff feel this is due to follow-through, direct contact, and patient adherence to the treatment plan enabled by removal of barriers, quality of life, and coverage of medical costs through grants. Another strength of the cancer program is the close collaboration and care coordination between the surgeons, primary care physicians, medical oncologists, and radiation oncologists.

Integrative Wellness: The cancer program firmly believes that all patients deserve access to integrative health therapies, and that cost should not be a deterrent. Services are available at no cost to the patient through a funded program, "Visions of Strength." The cancer center offers healing touch, massage, yoga, acupuncture (in community by referral), and exercise programs.

Rehabilitation: We work closely with a lymphedema specialist within our system who does baseline assessments and education for our surgical breast patients. The specialist also works with our head and neck cancer patients.

Other Support Resources: The new center has a boutique where patients can purchase supplies, scarves, and hair coverings. A local support organization, 4 my sisters, have a designated area at the cancer center where they provide wigs and makeup to patients. The cost of these services, if not covered by insurance, is underwritten by the Visions of Strength program. At the center, patients can research information at a library, which is staffed by ACS and Hope Club volunteers. SPHP initially used lay navigators from the ACS who came to the hospital twice a week. These navigators were social work students pursuing their MSW. All patients in the infusion area have access to iPads, which are preloaded with educational material, chemotherapy class information, and Netflix access.

As a community hospital–based system, it's important for the navigators to know available resources within the hospital and the community, and to utilize them. Budgets are tight, and it's necessary to gather data to prove the efficacy of positions. Staff refer patients to a program, "To Life," which provides breast cancer education and support, and health and wellness workshops; and the Albany Law Health Clinic, which offers free legal assistance to people diagnosed with HIV/AIDS, cancer, etc. Working collaboratively with other organizations helped the center and their patients receive needed services.

Marian E. Gilmore, RN, OCN, is a nurse navigator at the Dana-Farber/Brigham and Women's Cancer Center in clinical affiliation with South Shore Hospital in South Weymouth, MA.

Description of Facility: The cancer center provides residents south of Boston with the highest level of cancer care in the region. Experts from Dana-Farber Cancer Institute, Brigham and Women's Hospital, and South Shore Hospital collaborate to offer many of the advanced treatments currently offered at Dana-Farber/Brigham and Women's Cancer Center in Boston, including clinical trials exploring new therapies to patients in their local community. For patients requiring care from physicians in specific disease areas, South Shore Hospital can provide a smooth transition to Dana-

Farber/Brigham and Women's Cancer Center in Boston.
Types of Cancer Treated: The nurse navigator works in the Multispecialty Clinic with 12 surgeons who rotate through on a weekly basis in surgical oncology. The multidisciplinary surgical oncology program, provided by South Shore Hospital and Brigham and Women's Hospital, offers care from specialists in gastrointestinal, genitourinary, gynecologic, plastic, and thoracic surgery; neurosurgery; and otolaryngology. The cancer center has a separate Breast Clinic that has 2 breast nurse navigators on staff addressing needs of breast cancer patients.
Staffing: The Multispecialty Clinic offers services with social workers, nutritionists, chaplains, resource specialists, as well as a psychiatrist. South Shore Hospital is located across the street and provides access to financial counselors.
Distress Screening: The oncology nurse navigator utilizes the NCCN Distress Tool on initial consult in the Multispecialty Clinic. Regardless of what the patients' distress score is, the social worker is available to them at all times. Patients are told that scores from 1 to 4 indicate an appropriate level of stress, 5 to 9 moderate stress, and a score of 10 indicates a need to see a social worker before they leave the building. Even those who score 0, and may be in denial, are given the option to see the social worker as well. If the patient scores greater than a 5 and declines social worker support, the nurse navigator follows up within 30 days for re-evaluation and to again offer supportive services.

Once the social worker assesses the patient and determines that the patient needs further counseling, she will refer him/her to the psychiatrist, who is at the clinic 1 day a week. The nurse navigator and social workers meet with the psychiatrist on an ongoing basis to share information regarding patient referrals. Many times the patient is comfortable with the social worker and continues meeting with her.

The team has weekly huddles (prostate-GU/lung/GI) during which all new and ongoing patients are discussed by the surgeon, medical oncologist, radiation oncologist, nutritionist, social worker, chaplain, nurse navigator, and research nurse. All issues are discussed in an open format, and further referrals may be made at this point. The most common barriers that the nurse navigator sees are anxiety about a diagnosis and how to discuss this openly with their families. The Distress Tool is also utilized at any pivotal point in treatment, for example with a recurrence, change in treatment plan, etc. Analysis of the distress screen results shows that there has been a decrease in self-reported stress levels after utilizing services available to them.
Integrative Health: The clinic offers Reiki, acupuncture, massage, and exercise programs, and also offers yoga classes to all patients diagnosed with cancer. Most of these programs request a small fee, and financial assistance is available. Exercise programs are offered at South Shore Hospital (an affiliate facility), and the center also refers patients to the LIVE**STRONG** cancer survivor exercise programs at local YMCAs. The YMCA charges a minimal fee and offers a free 3-month membership. Massage therapy is provided at $20/hour per treatment. Patients are eligible for this service once a month for the rest of their life. (One patient who has been cancer free for over 10 years still comes once a month!)
Spiritual Support: The hospital has a chaplaincy department. Chaplains follow patients treated in-patient and out-patient at the cancer center. The nondenominational chaplain visits patients early in their treatment when they undergo surgery and maintains contact if the patient chooses. The chaplain also makes rounds in medical oncology and radiation oncology and is paged when needed.

The nurse navigator and social workers meet with the psychiatrist on an ongoing basis to share information regarding patient referrals.

Resource Room: The cancer center has a Resource Room with computers with links to Dana-Farber–approved websites and with books/information on every type of cancer. A book exchange is set up where people may donate or take books of interest. Patient, family, and community members have free access to the Resource Room. The program is affiliated with many volunteer groups, who provide afghans and hats. "The Power of the Quilt Project" provides free quilts to patients. There is also a book drop in the Resource Room.
Other Support Resources: A boutique, staffed by certified fitters for breast cancer patients, is housed in the same building with medical oncology, radiation oncology, and the breast center. Wig prosthesis assistance is also provided by experts at the boutique.
Patient Satisfaction: The oncology nurse navigator recently conducted an anonymous survey to learn how patients evaluate navigator services to comply with the Commission on Cancer 3.1 navigation standard. The return rate was greater than 60% with phenomenal results. All scores were a 4 or 5, with 5 being the highest option. The only low scores received were with the comment that "a nurse navigator should be available 24/7"—

an unrealistic expectation, but testimony to the value of the navigator.

Pamela Goetz, BA, is a patient navigator at Sibley Memorial Hospital, a community hospital in Washington, DC.

Description of Facility: Sibley Memorial Hospital, a member of Johns Hopkins Medicine, is a community hospital providing cancer care in Washington, DC; Maryland; and Virginia.

Types of Cancer Treated: The Johns Hopkins Kimmel Cancer Center at Sibley Memorial Hospital treats adults with breast, urologic, prostate, neurologic, head and neck, gynecologic, gastrointestinal, and blood cancers and sarcoma. Additionally, the Johns Hopkins and Children's National Pediatric Radiation Oncology Program at Sibley Memorial Hospital was recently announced; it is the first dedicated pediatric radiation oncology program in Washington, DC.

Patients are referred to reputable community rehabilitation facilities when geography or scheduling issues dictate that other options are needed.

Staffing: Dedicated nurse navigators for breast, gynecologic, and urologic cancers work with patients across the cancer continuum. A patient navigator focuses on care coordination for all newly diagnosed neuro-oncology patients, and in the area of survivorship for all cancer types. Three full-time clinical oncology social workers provide for the psychological, emotional, social, and practical needs for all cancer patients and families in the inpatient and outpatient settings, and short-term supportive counseling is provided for patients and families at no cost by the clinical social workers. A variety of support groups and workshops are facilitated by clinical staff, and 2 nurse practitioners with expertise in palliative care provide services to patients in the outpatient and inpatient settings. Patients are referred to community psychologists, sexual health specialists, and psychiatrists as needed.

Distress Screening: Sibley Hospital program uses the NCCN Distress Thermometer at pivotal points in patient treatment. The tool has been embedded in the EMR, which triggers a nurse or other clinical staff to implement the screening. Initially the screening was conducted by chemo nurses when patients began chemotherapy. The tool is now also being used by the nurses in radiation oncology, with plans to implement it with patients at a posttreatment survivorship consult visit. The goal is to be able to track patients across their treatment trajectory. For patients scoring higher than 6, the EMR makes an automatic referral to a social worker. The electronic screen becomes a part of the patient medical record.

Support Groups: The cancer program offers monthly on-site support groups for patients with advanced brain, breast, or gynecologic cancer, as well as a caregiver support group. These groups are facilitated by the social workers or nurse practitioner. The gyn/onc nurse navigator co-facilitates that group with the social worker. Guest speakers are invited to attend meetings to share information about or experiential practice in yoga, nutrition, meditation, expressive arts, and other support services. Patients with prostate cancer are referred to a support group at Suburban Hospital, a sister hospital in nearby Maryland. Patients are also referred to support groups at local community cancer organizations.

Rehabilitation: The physical impact of cancer treatment can influence patients' mental and emotional status. Rehabilitation helps alleviate both the physical and resulting psychological effects that patients may experience from surgery, chemotherapy, or radiation treatment. Sibley Hospital provides on-site services for patients requiring lymphedema or pelvic floor rehabilitation. Patients are referred to reputable community rehabilitation facilities when geography or scheduling issues dictate that other options are needed.

Patient Education: Patient education occurs in various ways, including through the nurse navigators, a chemo-education class, and in a presurgical class in gynecologic oncology. In addition, cancer-specific teams offer free seminars, in which community members and those already impacted by a diagnosis can learn the latest about screening, diagnosis, treatment, managing a diagnosis, and quality of life.

Integrative Health: The hospital offers free or low-cost weekly classes in restorative yoga for cancer patients/survivors that in addition to providing a mind-body practice also serve to connect survivors with each other, building a sense of community. A weekly chair yoga class gives survivors with balance or mobility issues an opportunity to benefit from the practice. The program also has a free, weekly Mindfulness and Meditation class for anyone impacted by a cancer diagnosis, including caregivers and friends. The facilitator has training in Mindfulness-Based Stress Reduction, and so can employ multiple techniques in mindfulness. After conducting a feasibility pilot, an acupuncture service was established with a community acupuncturist providing service to patients 1 day a week. Patients want-

ing acupuncture need a referral from their oncologist, and the acupuncturist documents in the EMR, allowing collaboration between the providers and the practitioner. Patients who are interested in other integrative services are directed to community providers.

Other Support Resources: The cancer program offers the American Cancer Society's program "Look Good Feel Better," where a trained volunteer cosmetologist demonstrates techniques to combat the skin and hair loss effects of treatment. A certified bra fitter provides fittings for breast cancer patients at the hospital gift shop, where other products designed to support patients can be purchased.

Patient education occurs in various ways, including through the nurse navigators, a chemo-education class, and in a presurgical class in gynecologic oncology.

Sibley Hospital has an Innovation Department, which trains staff to use the Design Thinking process to solve various problems and to inform quality improvement projects. The Design Thinking process involves a process that is focused on getting patient input from the beginning and then iteratively creating and testing prototypes and solutions with all stakeholders. The "Hub" serves all service lines, and the breast cancer program is working on a project to improve the patient experience.

Conclusion

The multidisciplinary team, including the nurse navigator, lay navigator, social workers, financial counselors, and others can effectively collaborate to deliver psychosocial support that is patient-centered and holistic. Distress screening can function as a central point for patient psychosocial assessment, with effective communication among the care team and consistent referrals to in-house and community resources in place to ensure that patient needs are being met. Each institution can find the best way to care for the psychosocial aspect of care based on staffing, accreditations, and needs assessments.

Tools

NCCN Distress Thermometer. www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf.

Seasoned Navigator Case Study Psychosocial Assessment/Support Services

Cheryl Bellomo, MSN, RN, OCN; Tricia Strusowki, MS, RN; Nicole Delano, MSN, RN

The primary objective/reason for screening for psychosocial distress along the cancer continuum is to address patients' perception of quality of life (QOL). Effective psychosocial care, consisting of a multidisciplinary team approach, has been shown to positively influence patient outcomes and QOL. The National Comprehensive Cancer Network (NCCN) Distress Thermometer has a secondary benefit of connecting many patients to services that might not otherwise have been identified. Potential benefits of distress screening are that it provides patients an opportunity to partner with their healthcare team, overcomes patients' reluctance to ask for help, destigmatizes the issue and allows patients to share their vulnerabilities, and ensures timely referral to supportive services. Per the Commission on Cancer (CoC) Standard 3.2, licensed mental health professionals and certified chaplains experienced in psychosocial aspects of cancer should be readily available as staff members or by referral.

The primary objective/reason for screening for psychosocial distress along the cancer continuum is to address patients' perception of quality of life.

Common barriers to care include lack of social support, financial and insurance concerns, and problems with healthcare communication. Navigators can focus on resolving barriers to care, which can be assessed during interviews with patients, and gathering data on psychosocial, financial, and practical issues. Regular interaction with navigators allows periodic evaluation of the success of intervention to reduce barriers. Clinical health outcomes measurement should include assessment of the psychosocial domain (QOL and patient/family satisfaction) for the continuous evaluation of the navigation program and to address gaps in services provided.

Case Scenario

SW is a 44-year-old divorced father with sole custody of 2 teenaged children. SW is self-employed as a landscaper to support his family. After a 2- to 3-week history of abdominal pain and rectal bleeding, he was sent for a colonoscopy. A complete colonoscopy could not be performed as SW was found to have a neoplastic mass of the rectum narrowing the lumen for advancement of the scope. An immediate oncology consultation was arranged. Upon meeting with the medical oncologist, SW was sent for a PET scan, which showed intensive uptake spanning 12 cm of the rectum and uptake within a perirectal lymph node.

Based on the PET scan results, SW discussed the treatment recommendations of neoadjuvant chemoradiation therapy with continuous infusion of 5-fluorouracil for 6 weeks, followed by surgical resection and concluding with adjuvant chemotherapy. SW met with the nurse navigator for chemotherapy and radiation therapy education, as well as for a psychosocial assessment utilizing the NCCN Distress Thermometer. The nurse navigator instructed SW on the role of the Distress Thermometer and encouraged its completion by marking areas of difficulty. SW scored an 8 on a scale of 0 to 10 on the Distress Thermometer. In the areas regarding practical problems, emotional problems, and physical problems, SW marked experiencing difficulty and distress. Based on SW's self-reporting a score of 8 on the Distress Thermometer, he was referred to the oncology social worker by the nurse navigator and contacted within 48 hours.

SW met with the oncology social worker and the nurse navigator to address the areas of difficulty reported on the Distress Thermometer. In the area of practical problems, SW reported difficulty with insurance/financial issues. As a self-employed landscaper and sole provider for his family, SW lacked medical insurance coverage, and he expressed concern regarding his ability to pay medical bills related to his cancer treatment. The oncology social worker and nurse navigator referred SW to the facility's financial counselor, state Medicaid outreach officer, and the local Social Security department. The nurse navigator also referred SW to the national financial assistance resources of Cancer Care and Chronic Disease Fund, and to pharmaceutical drug assistance programs for free drug/drug replacement programs.

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On the Distress Thermometer, SW reported difficulty with emotional problems in regard to treatment decisions and feeling "sadness," "fear," and "worry." In his discussion with the oncology social worker and the nurse navigator, SW expressed his concern about his disease and his treatment affecting his ability to care for his family and loss of "normal" life. SW was encouraged to participate in the cancer center's Coping Skills program facilitated by the oncology social worker to help cancer patients develop skills to cope with the emotional and physical impact of cancer.

Use of the distress assessment tool can effectively guide and assist the nurse navigator in providing high-quality, holistic, and patient-centered care.

SW reported difficulty with "constipation/bowel movements," "eating," and "fatigue" under the physical problems portion of the Distress Thermometer. SW also expressed concern regarding possible side effects of his planned treatment, including neuropathy, diarrhea, and neutropenia, and the effect on his livelihood and QOL. The nurse navigator reviewed education of side effect management and referred SW to the oncology nurse practitioner for supportive care/symptom management and the facility's dietitian for nutritional support.

With the use of the NCCN Distress Thermometer tool, the nurse navigator and oncology social worker were able to identify SW's specific needs and address them accordingly. The nurse navigator and oncology social worker utilized a multidisciplinary approach to address SW's specific needs. Utilization of the distress assessment tool can effectively guide and assist the nurse navigator in providing high-quality, holistic, and patient-centered care.

Conclusion

The open relationship between the patient and the navigator may make it easier for the patient to express his or her concerns. The navigator can assist their patients by 1) listening closely to the patient's concerns, 2) showing interest in the patient's experience with cancer, 3) asking who will provide support during cancer treatments, 4) asking how the patient is adjusting to the cancer and treatment plan, 5) encouraging patients to continue using coping strategies that are successful, and 6) suggesting additional coping strategies to address the patient's concerns. Increasing evidence suggests that distress screening alone is not sufficient to improve patient outcomes. Another critical component is appropriate, timely, and personalized follow-up referrals. Navigators are instrumental in the development and implementation of a plan for psychosocial health services in their cancer program that supports patients (by providing personalized information, identifying strategies to address psychosocial needs, providing emotional support, helping patients manage their illness and health), links patients and families with psychosocial services, and coordinates psychosocial and biomedical care. Navigators can also educate patients and their families on how to use adaptive coping mechanisms, such as deep breathing, mindfulness, and other self-management exercises to decrease distress. Navigators can provide a comprehensive understanding of the patient to other members of the multidisciplinary team and take the lead role in assessing the patient's needs for possible referral to a mental health specialist.

Metrics

Patient Experience Metrics

- **Patient Experience Survey** – percentage of patients extremely satisfied with the patient experience related to navigation services
- **Physician Experience Survey** – number of physicians who received a physician experience survey related to navigation services and outcomes
- **Chemotherapy/Radiation Therapy Patient Experience** – number of patients who received a treatment educational packet from the navigator

Clinical Outcome Metrics

- **Tumor Conference Compliance with NCCN Guidelines** – percentage of treatment plans that followed the NCCN guidelines and recommendations as discussed at the tumor conference
- **Psychosocial Distress Screening** – number of patients who received psychosocial distress screening (compliance with CoC Standard 3.2) at pivotal touchpoints/transitions and interventions; number of patients referred to mental health specialist based on psychosocial distress screening; number of patients who received an evidence-based QOL survey (FACT/City of Hope CSV-QOL) per month with outcomes
- **Patient Pathway and Guideline Compliance** – percentage of patients who were compliant with their treatment plan
- **Monitor Time of Diagnosis to First Treatment**

Modality/Timeliness of Care – number of days from the time the patient is diagnosed until first consultation and treatment plan

- **QOL** – number of patients who received an evidence-based QOL survey (FACT/City of Hope CSV-QOL) at pivotal points throughout the continuum of care and measurement of interventions provided

Business Performance/Return on Investment Metrics

- **Immediate Referrals of Self-Pay Patients for Financial Assistance** – number of self-pay patients referred by navigator for financial assessment/assistance for Medicaid, Medicare, Social Security
- **Medication Coverage** – number of patients eligible and assisted with pharmaceutical assistance programs (ie, copay cards and/or free drug program).

Tools

NCCN Distress Thermometer. www.nccn.org/patients/resources/life_with_cancer/pdf/nccn_distress_thermometer.pdf.

Closing the Racial Divide for Curative Lung Cancer

Racial inequality in healthcare is a long-standing problem that has been studied for decades. The Accountability for Cancer Care through Undoing Racism and Equity (ACCURE) trial, one of the first prospective trials to address racial disparities in access to care, shows that it is possible to improve access to potentially curative care for African American (AA) patients so that they are on a level playing field with white patients. In this multi-institutional trial sponsored by the National Institutes of Health, the ACCURE intervention improved curative treatment rates for uptake of surgical resection and stereotactic body radiation therapy (SBRT) to 96% for both AA and white patients with early-stage lung cancer. Specially trained nurse navigators were essential to the success of this intervention.

The results also showed a spillover effect, meaning that patients not enrolled in the trial may have benefited from staff training and educational sessions cultivating racial sensitivity.

"We saw that the ACCURE intervention—an evidence-based strategic intervention—essentially eliminated racial disparity while improving rates of treatment completion for all races," said Matthew A. Manning, MD, radiation oncologist at Cone Health Cancer Center in Greensboro, NC, in a presentation at the 2016 Annual Meeting of the American Society for Radiation Oncology. "The results also showed a spillover effect of ACCURE at all participating cancer centers," he added, meaning that patients not enrolled in the trial may have benefited from staff training and educational sessions cultivating racial sensitivity.

The ACCURE intervention consists of multiple layers of patient support, including an electronic health record system that alerts clinicians and nurse navigators when a patient misses an appointment or other important milestones in care, such as a biopsy or scan. The staff then contacts the patient to help overcome barriers, for example, the need for a ride or not being available on the day of the appointment due to family factors, Dr Manning explained.

ACCURE utilizes nurse navigators trained about race-related barriers to care, with special training regarding trust and culturally appropriate communication.

The healthcare team is given race-specific feedback on patients' perceptions of care derived from community-based research. The feedback is given in quarterly focus groups offered by Healthcare Equity Education and Training.

The intervention group (ACCURE) included 100 patients with stage I or II lung cancer enrolled in the trial between 2013 and 2015, 25% of whom were AA, compared with 13% in the local population. The primary outcome was rates of receiving surgical resection or SBRT within 4 months of diagnosis.

Baseline data were derived from 2044 patients treated at the cancer center from 2007 to 2011. The control group included 393 patients treated between 2014 and 2015 during the study to assess a spillover effect.

In the baseline group, 64% of AA patients and 76% of white patients received both resection and SBRT between 2007 and 2011. By contrast, in the ACCURE intervention group, 96% of both racial groups received this potentially curative treatment. Rates of treatment also rose in controls: 85% of AA patients and 87% of white patients received both surgery and SBRT from 2014 to 2015.

"Surgical resection was the vehicle of improvement within the ACCURE intervention cohort," Dr Manning said.

Resection alone was received by 55% of AA patients and 61% of white patients in the baseline group, compared with 80% and 79%, respectively, in the ACCURE group and 57% and 55%, respectively, in controls.

Age and disease stage had an impact on treatment rates for both surgical resection and SBRT, but comorbidity affected surgical resection only. Patients younger than 70 years and those with earlier-stage disease were significantly more likely to receive either treatment (P <.05 for both comparisons). Patients with higher comorbidity scores were significantly less likely to receive surgery (P <.05).

"This study suggests that health systems can eliminate racial disparity with systems change through engagement with community organizations," Dr Manning said. He explained that ACCURE was "the brainchild of community organizations that provided antiracism workshops and developed tools for institutions."

Call to Action: Address Patients' Sexual Health

Sexual dysfunction is a common problem for cancer survivors, and nurses can be a part of the solution by addressing this issue, educating themselves, and joining with other health professionals who care about patients' sexual health, says Don Dizon, MD, a medical gynecologic oncologist and Director of the Oncology Sexual Health Clinic at Massachusetts General Hospital in Boston.

A presenter at the 2016 Annual Meeting of the American Society for Radiation Oncology (ASTRO), Dr Dizon told *JONS*, "Nurses and nurse practitioners can be the ones who make a difference in their patients' lives. Nurses can be proactive. Oncologists are often disease focused and treatment focused, and sexual issues get pushed to the side."

Patients should be told before treatment that a diagnosis of cancer and its treatment can affect their sex life. Then when they experience problems, it won't be a surprise.

"Nurses need to be proactive about asking patients about their sexual health. Patients will not volunteer this information if not asked," he continued.

When raising the issue, normalize it, Dr Dizon advised. "Say something like, 'Sexual problems are common among cancer survivors. What is your experience?'" he suggested. "Once you show interest and normalize the discussion, it can be very powerful for patients. I've heard many patients say they experience a huge relief and don't feel so isolated. It's good for them to know they are not the only ones facing these issues," he said.

Common Problems

The obvious problems that arise with cancer treatment include vaginal dryness and pain on intercourse for women and erectile dysfunction for men. However, there are also some not-so-obvious problems, such as a loss of sensation in the residual breast (or the chest wall) for breast cancer survivors. The breast is an erogenous zone for most women, and they may not be prepared for this effect. Men with prostate and other cancers may also struggle with arousal.

"In fact, cancer disrupts the normal cycle of desire, arousal, and fulfillment, which may not make sense to patients," Dr Dizon said. And these changes can lead to a lack of intimacy. Male partners can be frightened by the journey of a female with cancer. Once the partner's treatment is over, men may need to move forward, and part of that includes restarting their sex lives. Men experience intimacy through sexual intercourse, while for women, intimacy is not tied solely to intercourse. The process of rediscovery and finding a "new normal" can take a year or longer for women, which is something their partners may not recognize. So men and women are often not on the same page at the end of active treatment, Dr Dizon explained.

"One of the most important things to talk about with a couple is to define what intimacy means to that couple," Dr Dizon stated.

The obvious problems that arise with cancer treatment include vaginal dryness and pain on intercourse for women and erectile dysfunction for men.

Resources

At the very least, any cancer center can have a library of books and articles on sexual health in cancer survivors. Nurses who are interested in helping patients can read this literature, and patients may want to read books and articles as well. Some authors who have written about this topic, in addition to Dr Dizon, include Anne Katz, PhD, RN, and Michael Krychman, MD.

If possible, nurses should attend conferences on the subject and attend sessions at large cancer meetings that are devoted to sexual health, Dr Dizon advised.

Patients can also take advantage of web-based tools, including a new website called will2love (https://will2love.com/) developed by Leslie Schover, RN, PhD, formerly at MD Anderson Cancer Center in Houston, TX. The American Society of Clinical Oncology's website Cancer.Net also has some information. Counselors versed in cancer-specific sexual health may not be easy to find in most areas of the country except in academic or comprehensive cancer centers.

In his ASTRO presentation, Dr Dizon suggested the PLISSIT approach for nurses and other healthcare professionals: P—give the patient permission to discuss sexual health; LI—provide limited information; SS—give specific suggestions; and IT—refer patients who require intensive therapy.

Immunotherapeutics: Changes in the Landscape of Advanced Cancer Care

Recent approvals of several checkpoint inhibitors across multiple cancer settings have brought more than just new and improved treatments to the clinic. According to David R. Spigel, MD, Chief Scientific Officer at the Sarah Cannon Research Institute, the rapid ascent of immunotherapy has created unexpected problems, too. At the 2016 Palliative Care in Oncology Symposium, Dr Spigel outlined the challenges facing patients and providers alike, including diagnostic uncertainty, treatment-related toxicity, new expectations, and a changing approach to care.

Checkpoint Inhibitors

Those looking for a sign of the times can start with the recent results of the KEYNOTE-024 trial, in which pembrolizumab demonstrated superior progression-free and overall survival compared with chemotherapy as first-line treatment for newly diagnosed advanced lung cancer (in patients who have PD-L1 tumor expression of 50% or more).

These outcomes signal a major shift in how we care for patients, said Dr Spigel, but it's just the tip of the iceberg in terms of drug development. Several checkpoint or PD-1 inhibitors are already in the clinic, approved to treat not only lung cancer but renal cell carcinoma, Hodgkin lymphoma, head and neck cancer, bladder cancer, and melanoma, and more approvals are expected before the end of the year. There are also new drugs coming, including durvalumab, avelumab, and tremelimumab.

At last count, said Dr Spigel, these immunotherapies are being tested in over 17 different cancer settings, and many are likely to find their way into the clinic in the next year or two.

Patient Selection

Despite the obvious clinical benefits, there is still confusion regarding patient selection. Many clinicians are still struggling to figure out which patients should be using these therapies, Dr Spigel reported.

Testing of one diagnostic biomarker, PD-L1, which measures the expression of the PD-L1 protein on tumor cells, is problematic to say the least. There are 4 diagnostic assays available, each with differing definitions of a positive score. Pembrolizumab is the only drug currently on the market that requires up-front selection in the form of PD-L1 testing.

"Data are mixed," said Dr Spigel. "There is increasing evidence that pembrolizumab may be the only drug where PD-L1 testing is necessary. With nivolumab, the other big immunotherapeutic, for example, PD-L1 testing has not proved to be an effective way to select patients for benefit. Whether you have that expression or not, patients seem to benefit."

But there are other biomarkers that may be available to predict benefit, including the number of mutations in a patient's tumor samples, the so-called mutation burden index.

"Patients with high-burden indices seem to benefit from immunotherapy compared to patients who have low indices," he said. "There are no prospective data yet, but this is very intriguing."

Despite the obvious clinical benefits, there is still confusion regarding patient selection. Many clinicians are still struggling to figure out which patients should be using these therapies.

Likewise, data for colorectal cancer have shown that patients with mismatch repair deficiency, the inability to repair defects in DNA damage, have a greater chance of benefiting from immunotherapy than patients with intact mismatch repair.

Clinical factors such as smoking history and history of autoimmunities like rheumatoid arthritis and lupus may predict benefit from these therapies, too, Dr Spigel noted.

Surveillance and Stratification

The greatest challenge facing patients and providers, however, may be unpredictable response once treatment has begun.

"We don't know what's going to happen when we start these therapies," he said. "It could get better from the start, it could get worse, or nothing could change."

Scans at 6 weeks, 8 weeks, or even 3 months may show new lesions in the liver or lung, he explains, but the patient feels fine. Continue to treat these patients,

Continued on page 48

Are You Currently Managing Patients with Unresectable Locally Recurrent or Metastatic HER2+ Breast Cancer?

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Clinical Trial Design

Patients with Pretreated Unresectable Locally Recurrent or Metastatic HER2+ Breast Carcinoma*

Randomized**

- Tucatinib + Capecitabine and Trastuzumab
- Placebo + Capecitabine and Trastuzumab

*Patients must have been previously treated with a taxane, trastuzumab, pertuzumab, and ado-trastuzumab emtansine or T-DM1
**2:1 Tucatinib or placebo in combination with capecitabine and trastuzumab (total enrollment = 180)

Inclusion Criteria: Patients must have been previously treated with a taxane, trastuzumab, pertuzumab, and ado-trastuzumab emtansine (T-DM1). Patients with or without brain metastases are eligible, including patients with asymptomatic untreated brain metastases not needing immediate local therapy and patients with previously treated brain metastases.

Primary Endpoint: Progression-free survival (PFS)

Secondary Endpoints: Duration of response, objective response rate, and overall survival

Recruitment: Enrollment up to 180 patients in multiple centers in the United States, Canada, and Western Europe

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though, and the tumor may begin to regress, a phenomenon called pseudoprogression. Then there are those patients whose scans are neither completely negative nor positive, but who will survive for months and even years in a sort of stalemate with their tumor.

In other words, said Dr Spigel, the classic way to treat cancer, which is to assess whether drugs are working with scans, doesn't apply to immunotherapy. Slow progression might be a worthwhile end point—in addition to disease response.

"Patients can do very well for long periods of time, so doctors have to be quick not to stop therapy," he said. "We need to find a better way to know what to do when we're giving these drugs."

Less Incentive for Clinical Trial Enrollment

Finally, said Dr Spigel, while certainly a blessing, the rapid adoption of immunotherapeutic agents could hinder the development of future treatments.

Clinical trial enrollment is critical for testing the wealth of drugs now in development that may hold even greater promise, including LAG3 and TIM3 inhibitors, costimulatory agents and other immune modulators, CAR-T cells, and vaccines. These must be tested alone and in combinations and sequences, he observed, which certainly strains resources.

Data for colorectal cancer have shown that patients with mismatch repair deficiency have a greater chance of benefiting from immunotherapy than patients with intact mismatch repair.

"It's hard to convince patients to go on clinical trials or doctors to have their patients go on trials," he said, "when it's easier just to give nivolumab or pembrolizumab for whatever tumor they may have."

Novel Techniques for Measuring and Assessing Symptoms

Although symptom management is a cornerstone of high-quality cancer care, according to data presented at the 2016 Palliative Care in Oncology Symposium, clinicians often miss the incidence of patients' symptoms or underestimate their magnitude. Patient-reported outcomes (PROs), which are direct reports from patients themselves about their symptoms, physical functioning, or health state, offer a solution for these oversights, said Ethan Basch, MD, MSc, but have not been used as a standard approach for symptom monitoring.

"Patient self-reporting improves clinical outcomes," said Dr Basch, Director of Outcomes Research Program and Professor of Medicine and Public Health at the University of North Carolina-Chapel Hill. "There is a scientific rationale for integrating PROs into routine oncology care. In the future, electronic health record systems need to better integrate patient-reported outcomes for both data collection and data visualization for clinicians, and standardization is needed for outcomes, metrics, and implementation approaches."

As Dr Basch explained, PROs have been the gold standard for measuring symptoms in cancer clinical research. In clinical trials, he said, patients commonly report their pain using questionnaires that are collected electronically, and a number of published studies have

Despite the mounting evidence, this approach has not been widely adopted, although a growing interest in this area has yielded several initiatives from a number of national stakeholder organizations.

demonstrated that "integrating PROs into routine oncology practice improves communication between patient and providers, patient satisfaction, and health-related quality of life."

Despite the mounting evidence, this approach has not been widely adopted, although a growing interest in this area has yielded several initiatives from a number of national stakeholder organizations. PROs have been implemented in the Oncology Care Model, for example, which is Medicare's demonstration project.

Monitoring Symptoms with PROs: A Randomized Controlled Trial

Dr Basch reviewed results from a randomized controlled trial, published late last year, in which 766 patients receiving palliative chemotherapy for incurable or advanced metastatic cancer were randomly assigned to either a self-reporting system for PROs or standard of care. The intervention arm included 12 common symptoms that patients could report using the web. In addition, whenever a patient reported a severe or new symptom, an automated e-mail alert was sent to the clinical nurse involved in that patient's care.

Feasibility results, said Dr Basch, showed durability of self-reporting over time. On average, 80% of patients eligible to self-report did so at any given time, and this lasted for up to 40 clinic visits or 3 years.

The automated alerts were also a success. Nurses responded with clinical actions to more than three-quarters of the automated alerts sent to them. These clinical actions mostly constituted telephone calls to patients for general advice about symptom management, but they also included referrals to the emergency department (ED) and to other providers. In very rare cases, as a result of these alerts, there was a chemotherapy dose modification or hold, said Dr Basch.

There was a significant improvement in quality of life from baseline to 6 months (34% improvement in the PRO arm vs 18% in standard of care) in patients using the PRO intervention compared with standard of care. Among patients self-reporting their symptoms, there was also a 41% reduction in ED admissions over a 1-year period, compared with 34% in patients receiving standard of care.

Time receiving chemotherapy also differed between arms, said Dr Basch, "presumably due to superior symptom management." Patients engaged in systematic reporting of their symptoms received chemotherapy for 8.2 months versus only 6.3 months for standard of care.

Finally, patients receiving PROs had a longer median survival than those receiving standard of care ($P = .03$).

Research is ongoing in this area, said Dr Basch, but for providers interested in incorporating this approach in their practice today, he recommended downloading the "User's Guide to Implementing Patient-Reported Outcomes Assessment in Clinical Practice," created by the International Society for Quality of Life Research (www.isoqol.org).

Quality Improvement Project Doubles Hospice Length of Stay

A simple quality improvement project to increase duration of hospice care for patients has doubled hospice length of stay, reaching the national median in 1 year. Conducted within the OhioHealth system, this relatively minor intervention suggests that oncologists can change their behavior and refer patients earlier to hospice care.

"We needed to move an entire health system toward more routine, more systematic, and less variable," said Charles F. Von Gunten, MD, PhD, Vice President, Medical Affairs, Hospice and Palliative Medicine for OhioHealth. "It starts with the fact that hospice has been proven to be the best care at the end of life. We also know that enrollment in hospice lowers cost."

As Dr Von Gunten described at the 2016 Palliative Care in Oncology Symposium, the key issue was reaching all eligible patients. "Our novel thought," he said, "was to treat referral for hospice care as a quality measure."

Intervention Design

A survey of the Oncology Clinical Guidance Council, which sets standards of care for the OhioHealth system in central Ohio, found that 67% of council members believed the ideal duration of hospice care for

cancer patients was 90 days, with 27% indicating it should be 45 days. Information obtained from the National Hospice and Palliative Care Organization (NHPCO) by Dr Von Gunten showed the national median to be 44 days.

However, as Dr Von Gunten reported, the median length of stay for patients (N = 176) referred by the 18 private-practice medical oncologists in the OhioHealth system was only 21 days in 2014.

When considered as a whole, the data support the idea that oncologists genuinely want to do right by their patients but are just uncertain about the proper timing for referral to hospice care.

"As expected, we saw variability," he said, "but overall, a big gap was seen, which was fodder for a quality improvement project."

In order to improve these numbers, a letter from the council chairs was sent to each medical oncologist noting the council's opinion about optimal length of stay, the NHPCO national median, and the median length of stay of all patients referred by OhioHealth oncologists. More importantly, said Dr Von Gunten, the oncologists also received a graph detailing the median length of stay of their own patients and those of their peers. One year later, for calendar year 2015, the measurement of median length of stay by oncologist was repeated.

Results

The intervention resulted in much timelier referrals; median duration of hospice care increased to 39.6 days for the 133 patients referred in the first 10 months of 2015. A simple quality improvement approach to improving hospice length of service by oncologists yielded a doubling, he said.

The intervention was not a uniform success. A few physicians failed to improve, and 1 actually decreased. Nevertheless, said Dr Von Gunten, when considered as a whole, the data support the idea that oncologists genuinely want to do right by their patients but are just uncertain about the proper timing for referral to hospice care.

"The major concern among these oncologists was that they were referring patients too early," he said. "Therefore, they often put off these conversations. This project has helped them overcome this concern."

Dr Von Gunten and the council have sent another letter to oncologists detailing these results and will repeat the measurements again next year. He also plans to extend this quality improvement measure to other specialties.

"As a group, physicians are competitive," he said. "Seeing your own performance alongside those of your peers and being compared to benchmarks and standards is the key to changing behavior."

"This simple intervention also shows that treating hospice care as a quality measure is acceptable and actionable," he concluded.

Managing Immune-Related Toxicities

Lynn Schuchter, MD

For many patients with advanced melanoma and lung cancer, checkpoint inhibitors have been a godsend, helping to extend survival to previously unthinkable lengths. While the impression is that checkpoint inhibitors are free of adverse effects, in reality, clinicians strive daily to balance the efficacy and toxicity of these treatments.

At the 2016 Palliative Care in Oncology Symposium, Lynn Schuchter, MD, C. Willard Robinson Professor of Hematology-Oncology at the University of Pennsylvania, Philadelphia, described common toxicities of the 4 FDA-approved immune checkpoint inhibitors—ipilimumab, nivolumab, pembrolizumab, and atezolizumab—and her approach to managing these side effects.

General Toxicities

Before each dose of a checkpoint inhibitor, said Dr Schuchter, patients should be evaluated for the development of toxicities. Although immune-related adverse

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events are generally mild (grades 1/2), with longer follow-up, more uncommon toxicities can emerge, including episcleritis/uveitis, pancreatitis, neuropathies, nephritis, and cardiomyopathies.

"Essentially any organ can be affected by autoimmune complications," said Dr Schuchter. "I have seen 2 patients have wonderful responses to treatment and then die from cardiomyopathy."

Initial management of toxicities usually starts with eliminating other noninflammatory causes and assessing severity. For mild and tolerable symptoms, treatment can typically be continued. With moderate reactions, Dr Schuchter will often hold or omit a dose and begin systemic corticosteroids (0.5-1 mg/kg/day of prednisone or equivalent).

Endocrinopathy management starts with replacing the missing hormones: levothyroxine for thyroid deficiencies and low-dose hydrocortisone for pituitary dysfunction.

"With anti–PD-1/PD-L1 antibodies, doses are *not* reduced," she emphasized. "Rather, schedules are adjusted. When symptoms resolve or return to baseline, steroids can be slowly tapered and treatment can usually be resumed."

When symptoms are severe, therapy is permanently discontinued and systemic corticosteroids initiated (1-2 mg/kg/day).

Specific Symptom Management

Rash/Pruritus

Patients who experience pruritus will report itchy skin, but rash may not be obvious, said Dr Schuchter, who recommended supportive measures (antihistamines, topical steroids) and sun protection for mild pruritus.

For a confluent rash, the recommendation is to hold treatment and consider oral steroids. If the rash is severe, treatment should be discontinued and steroids continued, often intravenously.

Diarrhea/Colitis

Because of the risk of peritonitis, perforation, and life-threatening complications, diarrhea and especially colitis are the most concerning toxicities, said Dr Shuchter, and patients should immediately report changes in bowel movements.

Abdominal pain, mucus or blood in the stool, peritoneal signs, bowel perforation, and ileus are high-risk signs that require urgent care, and colitis may warrant hospitalization for intravenous fluids and steroids.

Dr Schuchter approaches patients with diarrhea by first ruling out *Clostridium difficile*. When drug-related colitis is diagnosed, therapy is very individualized. Mild illness is treated with supportive care and increased monitoring. More serious illness is treated as follows:

- Stools <4 × baseline: loperamide, budesonide
- Stools <7 × baseline: 1 mg/kg prednisone
- Stools >7 × baseline or refractory to oral steroids
  - Hospitalize for IV Solu-Medrol 1-2 mg/kg
  - Consider colonoscopy and CT scan for further evaluation
  - Consider infliximab 5 mg/kg

Endocrinopathies and Hypophysitis

Patients should have a chemistry panel, including thyroid-stimulating hormone (TSH), at baseline and with each treatment, said Dr Schuchter, but a pituitary panel is not necessary unless hypophysitis is suspected on MRI.

Headache related to these conditions can be treated with high-dose steroids. When the thyroid or pituitary gland is affected, the change may be permanent, she reported, but early intervention with high-dose steroids during acute hypophysitis may preserve pituitary function.

Endocrinopathy management starts with replacing the missing hormones: levothyroxine for thyroid deficiencies and low-dose hydrocortisone for pituitary dysfunction. Clinicians should be aware of the potential for adrenal crisis and advise patients to wear medical alert bracelets, she noted.

Hepatotoxicity

Liver function should be evaluated prior to each dose. Mild enzyme elevations can be managed with frequent monitoring. Treatment is held and monitoring is increased when enzymes exceed 2.5 to 5.0 times the upper limit of normal (ULN) or bilirubin is more than 1.5 to 3.0 times the ULN. When levels rise higher than this, however, the drug is permanently discontinued and steroids initiated.

Pneumonitis

A potentially life-threatening event, pneumonitis is more common in patients using anti–PD-1 agents (pembrolizumab and nivolumab) than CTLA-4 inhibitors (ipilimumab). It can present with cough or shortness of breath and can be confused with metastases to the lung.

If pneumonitis is isolated and patients are asymptomatic,

treatment can be continued with close observation, said Dr Schuchter. For symptomatic patients, treatment should be held and high-dose steroids started. Patients with severe symptoms or hypoxia should be hospitalized, treated with steroids, and considered for bronchoscopy. After severe pneumonitis, treatment reinitiation may not be possible.

"Prolonged use and slow taper of steroids can result in its own consequences, including risk of atypical infections, compression fractures, and other steroid-related side effects. Vigilance for these complications is also part of the long-term management of these patients," Dr Schuchter concluded.

Caring About Caregivers: Implementing Formal Caregiver Support Programs

At the 2016 Palliative Care in Oncology Symposium, the message was clear and emphatic: We should care about caregivers as both co-deliverers and co-recipients of healthcare services.

"Despite providing essential home and healthcare services, cancer caregivers are underserved and undervalued while facing a multitude of unmet needs," said J. Nicholas Dionne-Odom, PhD, RN, ACHPN, of the University of Alabama at Birmingham School of Nursing. "There are 2.8 million cancer caregivers performing a variety of invaluable and time-consuming tasks that can take a marked toll on their physical and mental health."

These tasks are related to symptoms, medications, breathing treatments, ostomy, wound care, gastric tube feeding, and catheterizations, among others. Although these nursing services are often performed in a hospital, according to a survey conducted by the National Alliance for Caregiving in partnership with AARP, 72% of cancer caregivers deliver these services at home, despite a lack of preparation or training.

It's not just medical and nursing tasks; caregivers are responsible for appointment coordination, transportation, home maintenance, meal preparation, and activities of daily living. An 11-state survey showed that advanced cancer caregivers work up to 76 hours a week for 18 months.

"It's estimated that advanced cancer caregiving is worth $71,000 a year," said Dr Dionne-Odom. "The idea that this unpaid work could be replaced with paid professionals is unrealistic."

According to a RAND Corporation study, the cost of informal caregiving for the elderly in the United States is $522 billion per year, which is more than the annual Medicare budget, but cancer caregiving poses a serious threat to health as well. Approximately 40% of caregivers experience anxiety, 16% have signs of depression, and 25% are under financial strain, but only half of caregivers are ever asked what *they* need, said Dr Dionne-Odom.

The cost of informal caregiving for the elderly in the United States is $522 billion per year, which is more than the annual Medicare budget, but cancer caregiving poses a serious threat to health as well.

"Caregivers need practical help with home-based activities of daily living, navigating healthcare systems, transportation, finances, balancing the needs of patients with their own, and maintaining their own health. They also need information on cancer diagnosis, progression, prognosis, and management of symptoms and medications. Finally, caregivers need help making end-of-life decisions and managing their own emotional and physical stress," he explained.

Integrating caregiver support in formal healthcare systems remains a huge challenge, said Dr Dionne-Odom, because the system is not incentivized to take care of caregivers, but simple steps can be taken to provide psychosocial support.

"Caregivers often feel underappreciated in their

role," he said. "Simply acknowledging their sacrifice and recognizing them as a member of the healthcare team can go a long way toward making them feel included."

ENABLE III Trial

In the ENABLE III (Educate, Nurture, Advise, Before Life Ends) trial, which took place between October 2010 and March 2013, cancer caregivers were randomly assigned to receive 3 structured weekly telephone coaching sessions, monthly follow-up, and a bereavement call, either early after enrollment or 3 months later.

In the first session, family caregivers were asked to talk about themselves and their experience as caregivers. In the second, self-care and symptom management—for their patients and themselves—were discussed along with dealing with depression, grief, and loss. In the third phone session, the focus was on communication and decision-making: developing a support network, making medical decisions, and implementing advance care planning.

As Dr Dionne-Odom reported, caregivers in the early group had lower depressed mood (P = .02) and lower stress burden (P = .01) at 3 months, with a trend toward improved quality of life (P = .07). These results, he said, confirm what's been anecdotally observed for years: in order to maximize benefits, palliative care for caregivers should be initiated as early as possible.

"If we wait to intervene with family caregivers when they're in the ICU, they are already exhausted and have been down many stressful paths," he concluded. "On the other hand, if we can do this at diagnosis and catch them when they're still relatively healthy and calm, then it's much easier to teach the coping skills they will need later."

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Published Studies Underreport Toxicities Associated with Targeted Therapy and Immunotherapy

Most oncologists' knowledge about toxicities associated with newer therapies comes mainly from clinical trials, but publications of clinical trial safety results may be misleading, according to a study presented at the European Society for Medical Oncology 2016 Congress. The study investigators found suboptimal reporting of adverse events in studies of immunotherapy and targeted therapy published over the past 15 years. In particular, the investigators identified suboptimal reporting of recurrent or late toxicities and the duration of adverse events associated with immunotherapy and targeted therapy.

More than 50% of the reported studies had limitations in the way adverse events were presented, in describing toxicities leading to treatment cessation, and in the follow-up interval assessments.

"Reporting adverse events from clinical trials with new agents is a crucial point, as this will inform physicians and patients regarding the safety profile of that drug and what to expect when starting this therapy in a new patient in everyday clinical practice," said lead investigator Paolo Bossi, MD, Head & Neck Unit at the Fondazione IRCCS Istituto Nazionale dei Tumori, Milan, Italy.

The study was based on a review of 81 trials of targeted therapies and immunotherapies that were approved by the FDA from 2000 to October 2015 for the treatment of solid tumors in adult patients. Each study was assessed using a 24-point score based on the Consolidated Standards of Reporting Trials guidance.

The trials were conducted mainly in colorectal, lung, and breast cancer and in melanoma and involved more than 45,000 patients; 95% of the trials were conducted in advanced cancers. The experimental drug was studied as a single agent in 51% of cases and in combination with chemotherapy in 32%.

The investigators found that more than 90% of the trials had poor scores related to reporting recurrent and late toxicities, as well as in reporting the duration of adverse events; 86% did not adequately report the time the adverse events occurred, and 75% restricted reporting to adverse events that occurred at a frequency above a fixed threshold.

More than 50% of the reported studies had limitations in the way adverse events were presented, in describing toxicities leading to treatment cessation, and in the follow-up interval assessments. One-third of the studies failed to report dose reductions due to adverse events.

"Toxicities of targeted agents and immunotherapy are obviously different from the toxicities we are used to observing and treating due to chemotherapy, and there are some aspects of the toxicities of these newer agents that we are not so well informed about," Dr Bossi said.

The 3 axes of reporting toxicities include frequency, severity, and duration of an adverse event. The duration of an adverse event is not typically considered when a new drug comes to market, he noted.

Dr Bossi said he was encouraged to see a trend toward improved reporting of adverse events in recent years. New instruments are available to help physicians both improve the quality of reporting adverse events and discuss potential toxicities with their patients.

He cited the National Cancer Institute's PRO-CTCAE form, a patient-reported outcome instrument for reporting adverse events. "[This] will allow physicians to collect symptoms as reported by the patients, considering also the severity, intensity, and influence of the symptoms on their quality of life," Dr Bossi said.

Commenting on this study, Nathan Cherny, MD, Shaare Zedek Medical Centre in Jerusalem, noted that evidence shows clinicians underreport adverse events as well as their severity, compared with patient reports.

"These findings lend further support to the proposal to radically reevaluate the collection and reporting of adverse event data to give weighting to patient-reported data," Dr Cherny said.

Quality of Life Improved with Nivolumab versus Chemotherapy

In recent years, the cancer patient's experience has been recognized as an important factor in determining the value of a treatment. According to patient reports, their quality of life (QOL) remained stable on the immunotherapy nivolumab, whereas it significantly deteriorated on chemotherapy, as shown in an analysis of a phase 3 study of platinum-refractory, recurrent, metastatic head and neck cancer.

This is the only study of patient-reported outcomes to be singled out for the Presidential Symposium at the European Society for Medical Oncology (ESMO) 2016 Congress. Results are clinically meaningful, because treatments for head and neck cancer are among the most difficult and painful for patients to tolerate.

In the main CheckMate 141 trial, nivolumab significantly improved overall survival by a median of 2.5 months compared with chemotherapy (investigator's choice of methotrexate, docetaxel, or cetuximab) in 361 patients with platinum-refractory head and neck cancer (P = .01).

The first patient-reported outcomes from CheckMate 141 were presented at ESMO, including functional capacity and symptoms, and included in results published online to coincide with the presentation at ESMO (*N Engl J Med*. 2016; DOI: 10.1056/NEJMoa1602252).

"Squamous cell cancer of the head and neck and its treatment may alter physical appearance and physical ability, impacting functional status and well-being," said coauthor Kevin Harrington, MD, Royal Marsden Hospital, London, UK. "We found on all measures used that patients taking nivolumab remained stable over 15 weeks while those taking chemotherapy significantly worsened, and this was clinically meaningful."

The QOL analysis was based on 129 patients who completed QOL and symptom questionnaires at baseline, 9 weeks, and then at 6-week intervals during treatment.

At week 15, 50% to 68% of patients completed parts of the questionnaires. A 10-point difference from baseline in the EORTC QLQ-C30 module was deemed clinically relevant.

The nivolumab group experienced stable outcomes in physical function, role function, and social function, whereas the chemotherapy group had a statistically significant and clinically meaningful worsening in all domains across the 15 weeks of analysis.

"It is important that patients taking chemotherapy were unable to go about their daily lives, fulfill their roles, and socialize with family and friends," Dr Harrington emphasized.

Symptom burden, fatigue, dyspnea, and appetite loss remained stable over 15 weeks for nivolumab-treated patients, whereas those on chemotherapy fared significantly worse from baseline.

Time to deterioration in symptoms favored nivolumab across all measures, with the exception of financial symptoms, which were similar.

Symptom burden, fatigue, dyspnea, and appetite loss remained stable over 15 weeks for nivolumab-treated patients, whereas those on chemotherapy fared significantly worse from baseline.

On the EORTC QLQ-H&N35 (a cancer-specific QOL measure), a similar pattern was observed. Patients on nivolumab remained stable on measures of symptom burden over 15 weeks, but those on investigator's choice of chemotherapy experienced statistically significant and clinically meaningful deterioration on all measures of pain, sensory problems, and social contact problems.

Programmed death-1 ligand 1 expression levels in patients' tumors did not make any difference in responses on either of the EORTC QOL instruments.

On the EQ-5D visual analogue scale, a generic measure of health status, nivolumab-treated patients were stable, whereas patients receiving investigator's choice of chemotherapy experienced a statistically significantly as well as clinically worsened outcome.

The study was funded by Bristol-Myers Squibb.

"Taking the positive results of nivolumab in improving survival in these patients, and considering the patient-reported outcomes we heard today, nivolumab should be considered standard second-line therapy for recurrent or metastatic squamous cell carcinoma of the head and neck," stated formal discussant Anthony T.C. Chan, MD, Chinese University of Hong Kong.

TECENTRIQ™ (atezolizumab)

Initial U.S. Approval: 2016

This is a brief summary of information about TECENTRIQ. Before prescribing, please see full Prescribing Information.

1 INDICATIONS AND USAGE

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Have disease progression during or following platinum-containing chemotherapy
- Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials *[see Clinical Studies (14.1)]*.

4 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Immune-Related Pneumonitis

Immune-mediated pneumonitis or interstitial lung disease, defined as requiring use of corticosteroids and with no clear alternate etiology, occurred in patients receiving TECENTRIQ. Across clinical trials, 2.6% (51/1978) of patients developed pneumonitis. Fatal pneumonitis occurred in two patients. In 523 patients with urothelial carcinoma who received TECENTRIQ, pneumonitis occurred in 6 (1.1%) patients. Of these patients, there was one patient with fatal pneumonitis, one patient with Grade 3, three patients with Grade 2, and one patient with Grade 1 pneumonitis. TECENTRIQ was held in all cases and five patients were treated with corticosteroids. Pneumonitis resolved in three patients. The median time to onset was 2.6 months (range: 15 days to 4.2 months). The median duration was 15 days (range: 6 days to 3.1+ months).

Monitor patients for signs with radiographic imaging and symptoms of pneumonitis. Administer steroids at a dose of 1 to 2 mg/kg/day prednisone equivalents for Grade 2 or greater pneumonitis, followed by corticosteroid taper. Withhold TECENTRIQ until resolution for Grade 2 pneumonitis. Permanently discontinue TECENTRIQ for Grade 3 or 4 pneumonitis *[see Dosage and Administration (2.2)]*.

5.2 Immune-Related Hepatitis

Immune-mediated hepatitis, defined as requiring use of corticosteroids and with no clear alternate etiology, occurred in patients receiving TECENTRIQ. Liver test abnormalities occurred in patients who received TECENTRIQ. Across clinical trials (n=1978), Grade 3 or 4 elevation occurred in ALT (2.5%), AST (2.3%), and total bilirubin (1.6%). In patients with urothelial carcinoma (n=523) Grade 3 or 4 elevation occurred in ALT (2.5%), AST (2.5%), and total bilirubin (2.1%). Immune-mediated hepatitis occurred in 1.3% of patients. Of these cases, one patient died from hepatitis, five patients had Grade 3, and one patient had Grade 2 hepatitis. The median time to onset was 1.1 months (range: 0.4 to 7.7 months). Of the seven patients with immune-mediated hepatitis, TECENTRIQ was temporarily interrupted in four patients; none of these patients developed recurrence of hepatitis after resuming TECENTRIQ.

Monitor patients for signs and symptoms of hepatitis. Monitor AST, ALT, and bilirubin prior to and periodically during treatment with TECENTRIQ. Administer corticosteroids at a dose of 1-2 mg/kg/day prednisone equivalents for Grade 2 or greater transaminase elevations, with or without concomitant elevation in total bilirubin, followed by corticosteroid taper. Withhold TECENTRIQ for Grade 2 and permanently discontinue TECENTRIQ for Grade 3 or 4 immune-mediated hepatitis *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.3 Immune-Related Colitis

Immune-mediated colitis or diarrhea, defined as requiring use of corticosteroids and with no clear alternate etiology, occurred in patients receiving TECENTRIQ. Across clinical trials, colitis or diarrhea occurred in 19.7% (389/1978) of all patients and in 18.7% (98/523) of patients with urothelial carcinoma. Ten patients (1.9%) developed Grade 3 or 4 diarrhea. Four patients (0.8%) had immune-mediated colitis or diarrhea with a median time to onset of 1.7 months (range: 1.1 to 3.1 months). Immune-mediated colitis resolved with corticosteroid administration in three of these patients, while the other patient died without resolution of colitis in the setting of diarrhea-associated renal failure.

Monitor patients for signs and symptoms of diarrhea or colitis. Withhold treatment with TECENTRIQ for Grade 2 diarrhea or colitis. If symptoms persist for longer than 5 days or recur, administer 1–2 mg/kg prednisone or equivalent per day. Withhold treatment with TECENTRIQ for Grade 3 diarrhea or colitis. Treat with IV methylprednisolone 1–2 mg/kg per day and convert to oral steroids once the patient has improved. For both Grade 2 and Grade 3 diarrhea or colitis, when symptoms improve to Grade 0 or Grade 1, taper steroids over ≥ 1 month. Resume treatment with TECENTRIQ if the event improves to Grade 0 or 1 within 12 weeks and corticosteroids have been reduced to the equivalent of ≤ 10 mg oral prednisone per day. Permanently discontinue TECENTRIQ for Grade 4 diarrhea or colitis *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.4 Immune-Related Endocrinopathies

Immune-related thyroid disorders, adrenal insufficiency, hypophysitis, and type 1 diabetes mellitus, including diabetic ketoacidosis, have occurred in patients receiving TECENTRIQ. Monitor patients for clinical signs and symptoms of endocrinopathies.

Hypophysitis

Hypophysitis occurred in 0.2% (1/523) of patients with urothelial cancer receiving TECENTRIQ. Monitor for signs and symptoms of hypophysitis. Administer corticosteroids and hormone replacement as clinically indicated. Withhold TECENTRIQ for Grade 2 or Grade 3 and permanently discontinue for Grade 4 hypophysitis *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

Thyroid Disorders

Thyroid function was assessed routinely only at baseline and the end of the study. Across clinical trials, hypothyroidism occurred in 3.9% (77/1978) of patients and in 2.5% (13/523) of patients with urothelial carcinoma. One patient had Grade 3 and twelve patients had Grade 1–2 hypothyroidism. The median time to first onset was 5.4 months (range: 21 days to 11.3 months). Thyroid stimulating hormone (TSH) was elevated and above the patient's baseline in 16% (21/131) of patients with a follow-up measurement.

Hyperthyroidism occurred in 1.0% (20/1978) of patients across clinical trials and in 0.6% (3/523) of patients with urothelial carcinoma. Of the three urothelial carcinoma patients, one patient had Grade 2 and two patients had Grade 1 hyperthyroidism. The median time to onset was 3.2 months (range: 1.4 to 5.8 months). TSH was decreased and below the patient's baseline in 3.8% (5/131) of patients with a follow-up measurement.

Monitor thyroid function prior to and periodically during treatment with TECENTRIQ. Asymptomatic patients with abnormal thyroid function tests can receive TECENTRIQ. For symptomatic hypothyroidism, withhold TECENTRIQ and initiate thyroid hormone replacement as needed. Manage isolated hypothyroidism with replacement therapy and without corticosteroids. For symptomatic hyperthyroidism, withhold TECENTRIQ and initiate an anti-thyroid drug as needed. Resume treatment with TECENTRIQ when symptoms of hypothyroidism or hyperthyroidism are controlled and thyroid function is improving *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

Adrenal Insufficiency

Adrenal insufficiency occurred in 0.4% (7/1978) of patients across clinical trials, including two patients with Grade 3, four patients with Grade 2, and one patient with Grade 1. Adrenal insufficiency resolved in two patients.

For symptomatic adrenal insufficiency, withhold TECENTRIQ and administer methylprednisolone 1–2 mg/kg per day IV followed by oral prednisone 1–2 mg/kg per day or equivalent once symptoms improve. Start steroid taper when symptoms improve to ≤ Grade 1 and taper steroids over ≥ 1 month. Resume treatment with TECENTRIQ if the event improves to ≤ Grade 1 within 12 weeks and corticosteroids have been reduced to the equivalent of ≤ 10 mg oral prednisone per day and the patient is stable on replacement therapy, if required *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

Diabetes Mellitus

New onset diabetes with ketoacidosis has occurred in patients receiving TECENTRIQ. Diabetes mellitus without an alternative etiology occurred in one (0.2%) patient with urothelial carcinoma.

Initiate treatment with insulin for type 1 diabetes mellitus. For ≥ Grade 3 hyperglycemia (fasting glucose >250–500 mg/dL), withhold TECENTRIQ. Resume treatment with TECENTRIQ when metabolic control is achieved on insulin replacement therapy *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.5 Other Immune-Related Adverse Reactions

Other immune-related adverse reactions including meningoencephalitis, myasthenic syndrome/myasthenia gravis, Guillain-Barré, ocular inflammatory toxicity, and pancreatitis, including increases in serum amylase and lipase levels, have occurred in ≤ 1.0% of patients treated with TECENTRIQ.

Meningitis / Encephalitis

Monitor patients for clinical signs and symptoms of meningitis or encephalitis. Permanently discontinue TECENTRIQ for any grade of meningitis or encephalitis. Treat with IV steroids (1–2 mg/kg/day methylprednisolone or equivalent) and convert to oral steroids (prednisone 60 mg/day or equivalent) once the patient has improved. When symptoms improve to ≤ Grade 1, taper steroids over ≥ 1 month *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

Motor and Sensory Neuropathy

Monitor patients for symptoms of motor and sensory neuropathy. Permanently discontinue TECENTRIQ for any grade of myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome. Institute medical intervention as appropriate. Consider initiation of systemic corticosteroids at a dose of 1–2 mg/kg/day prednisone *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

Pancreatitis

Symptomatic pancreatitis without an alternative etiology occurred in 0.1% (2/1978) of patients across clinical trials. Monitor patients for signs and symptoms of acute pancreatitis. Withhold TECENTRIQ for ≥ Grade 3 serum amylase or lipase levels (> 2.0 ULN), or Grade 2 or 3 pancreatitis. Treat with 1–2 mg/kg IV methylprednisolone or equivalent per day. Once symptoms improve, follow with 1–2 mg/kg of oral prednisone or equivalent per day. Resume treatment with TECENTRIQ if serum amylase and lipase levels improve to ≤ Grade 1 within 12 weeks, symptoms of pancreatitis have resolved, and corticosteroids have been reduced to ≤ 10 mg oral prednisone or equivalent per day. Permanently discontinue TECENTRIQ for Grade 4 or any grade of recurrent pancreatitis *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.6 Infection

Severe infections, including sepsis, herpes encephalitis, and mycobacterial infection leading to retroperitoneal hemorrhage occurred in patients receiving TECENTRIQ. Across clinical trials, infections occurred in 38.4% (759/1978) of patients. In 523 patients with urothelial carcinoma who received TECENTRIQ, infection occurred in 197 (37.7%) patients. Grade 3 or 4 infection occurred in 60 (11.5%) patients, while three patients died due to infections. Urinary tract infections were the most common cause of Grade 3 or higher infection, occurring in 37 (7.1%) patients.

In a randomized trial in patients with non-small cell lung cancer, infections were more common in patients treated with TECENTRIQ (42%) compared with those treated with docetaxel (33%). Grade 3 or 4 infections occurred in 9.2% of patients treated with TECENTRIQ compared with 2.2% in patients treated with docetaxel. One patient (0.7%) treated with TECENTRIQ died due to infection, compared to two patients (1.5%) treated with docetaxel. Pneumonia was the most common cause of Grade 3 or higher infection, occurring in 6.3% of patients treated with TECENTRIQ.

Monitor patients for signs and symptoms of infection and treat with antibiotics for suspected or confirmed bacterial infections. Withhold TECENTRIQ for ≥ Grade 3 infection *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.7 Infusion-Related Reactions

Severe infusion reactions have occurred in patients in clinical trials of TECENTRIQ. Infusion-related reactions occurred in 1.3% (25/1978) of patients across clinical trials and in 1.7% (9/523) of patients with urothelial carcinoma. Interrupt or slow the rate of infusion in patients with mild or moderate infusion reactions. Permanently discontinue TECENTRIQ in patients with Grade 3 or 4 infusion reactions *[see Dosage and Administration (2.2) and Adverse Reactions (6.1)]*.

5.8 Embryo-Fetal Toxicity

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related rejection of the developing fetus resulting in fetal death. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, advise the patient of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose *[see Use in Specific Populations (8.1, 8.3)]*.

6 ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Immune-Related Pneumonitis *[see Warnings and Precautions (5.1)]*
- Immune-Related Hepatitis *[see Warnings and Precautions (5.2)]*
- Immune-Related Colitis *[see Warnings and Precautions (5.3)]*
- Immune-Related Endocrinopathies *[see Warnings and Precautions (5.4)]*
- Other Immune-Related Adverse Reactions *[see Warnings and Precautions (5.5)]*
- Infection *[see Warnings and Precautions (5.6)]*
- Infusion-Related Reactions *[see Warnings and Precautions (5.7)]*

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.

The data described in Table 1 reflects exposure to TECENTRIQ in Cohort 2 of Study 1. This cohort enrolled 310 patients in a single arm trial with locally advanced or metastatic urothelial carcinoma who had disease progression during or following at least one platinum-containing chemotherapy regimen or who had disease progression within 12 months of treatment with a platinum-containing neoadjuvant or adjuvant chemotherapy regimen *[see Clinical Studies (14.1)]*. Patients received 1200 mg of TECENTRIQ intravenously every 3 weeks until unacceptable toxicity or either radiographic or clinical progression. The median duration of exposure was 12.3 weeks (range: 0.1, 46 weeks).

The most common adverse reactions (≥ 20%) were fatigue (52%), decreased appetite (26%), nausea (25%), urinary tract infection (22%), pyrexia (21%), and constipation (21%). The most

common Grade 3–4 adverse reactions (≥ 2%) were urinary tract infection, anemia, fatigue, dehydration, intestinal obstruction, urinary obstruction, hematuria, dyspnea, acute kidney injury, abdominal pain, venous thromboembolism, sepsis, and pneumonia.

Three patients (0.9%) who were treated with TECENTRIQ experienced either sepsis, pneumonitis, or intestinal obstruction which led to death. TECENTRIQ was discontinued for adverse reactions in 3.2% (10/310) of the 310 patients. Sepsis led to discontinuation in 0.6% (2/310) of patients. Adverse reactions leading to interruption of TECENTRIQ occurred in 27% of patients; the most common (> 1%) were liver enzyme increase, urinary tract infection, diarrhea, fatigue, confusional state, urinary obstruction, pyrexia, dyspnea, venous thromboembolism, and pneumonitis. Serious adverse reactions occurred in 45% of patients. The most frequent serious adverse reactions (> 2%) were urinary tract infection, hematuria, acute kidney injury, intestinal obstruction, pyrexia, venous thromboembolism, urinary obstruction, pneumonia, dyspnea, abdominal pain, sepsis, and confusional state.

Table 1 summarizes the adverse reactions that occurred in ≥ 10% of patients while Table 2 summarizes Grade 3–4 selected laboratory abnormalities that occurred in ≥ 1% of patients treated with TECENTRIQ in Cohort 2 of Study 1.

Table 1: All Grade Adverse Reactions in ≥ 10% of Patients with Urothelial Carcinoma in Study 1

	TECENTRIQ N = 310	
Adverse Reaction	All Grades (%)	Grades 3 – 4 (%)
All Adverse Reactions	96	50
Gastrointestinal Disorders		
Nausea	25	2
Constipation	21	0.3
Diarrhea	18	1
Abdominal pain	17	4
Vomiting	17	1
General Disorders and Administration		
Fatigue	52	6
Pyrexia	21	1
Peripheral edema	18	1
Infections and Infestations		
Urinary tract infection	22	9
Metabolism and Nutrition Disorders		
Decreased appetite	26	1
Musculoskeletal and Connective Tissue Disorders		
Back/Neck pain	15	2
Arthralgia	14	1
Renal and urinary disorders		
Hematuria	14	3
Respiratory, Thoracic, and Mediastinal Disorders		
Dyspnea	16	4
Cough	14	0.3
Skin and Subcutaneous Tissue Disorders		
Rash	15	0.3
Pruritus	13	0.3

Table 2: Grade 3–4 Laboratory Abnormalities in Patients with Urothelial Carcinoma in Study 1 in ≥ 1% of Patients

Laboratory Test	Grades 3–4 (%)
Lymphopenia	10
Hyponatremia	10
Anemia	8
Hyperglycemia	5
Increased Alkaline phosphatase	4
Increased Creatinine	3
Increased ALT	2
Increased AST	2
Hypoalbuminemia	1

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Among 275 patients in Study 1, 114 patients (41.5%) tested positive for treatment-emergent (treatment-induced or treatment-enhanced) anti-therapeutic antibodies (ATA) at one or more post-dose time points. In Study 1, the presence of ATAs did not appear to have a clinically significant impact on pharmacokinetics, safety or efficacy.

Immunogenicity assay results are highly dependent on several factors, including assay sensitivity and specificity, assay methodology, sample handling, timing of sample collection, concomitant medications and underlying disease. For these reasons, comparison of incidence of ATAs to TECENTRIQ with the incidence of antibodies to other products may be misleading.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman *[see Clinical Pharmacology (12.1)]*. There are no available data on the use of TECENTRIQ in pregnant women. Animal studies have demonstrated that inhibition of the PD-L1/PD-1 pathway can lead to increased risk of immune-related rejection of the developing fetus resulting in fetal death *[see Data]*. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, advise the patient of the potential risk to a fetus.

In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Data

Animal Data

Animal reproduction studies have not been conducted with TECENTRIQ to evaluate its effect on reproduction and fetal development. A literature-based assessment of the effects on reproduction demonstrated that a central function of the PD-L1/PD-1 pathway is to preserve pregnancy by maintaining maternal immune tolerance to a fetus. Blockage of PD-L1 signaling has been shown in murine models of pregnancy to disrupt tolerance to a fetus and to result in an increase in fetal loss; therefore, potential risks of administering TECENTRIQ during pregnancy include increased rates of abortion or stillbirth. As reported in the literature, there were no malformations related to the blockade of PD-L1/PD-1 signaling in the offspring of these animals; however, immune-mediated disorders occurred in PD-1 and PD-L1 knockout mice. Based on its mechanism of action, fetal exposure to atezolizumab may increase the risk of developing immune-mediated disorders or altering the normal immune response.

8.2 Lactation

Risk Summary

There is no information regarding the presence of atezolizumab in human milk, the effects on the breastfed infant, or the effects on milk production. As human IgG is excreted in human milk, the potential for absorption and harm to the infant is unknown. Because of the potential for serious adverse reactions in breastfed infants from TECENTRIQ, advise a lactating woman not to breastfeed during treatment and for at least 5 months after the last dose.

8.3 Females and Males of Reproductive Potential

Contraception

Females

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman *[see Use in Specific Populations (8.1)]*. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months following the last dose.

Infertility

Females

Based on animal studies, TECENTRIQ may impair fertility in females of reproductive potential while receiving treatment *[see Nonclinical Toxicology (13.1)]*.

8.4 Pediatric Use

The safety and effectiveness of TECENTRIQ have not been established in pediatric patients.

8.5 Geriatric Use

Of the 310 patients with urothelial carcinoma treated with TECENTRIQ in Study 1, 59% were 65 years or older. No overall differences in safety or efficacy were observed between patients ≥ 65 years of age and younger patients.

8.6 Renal Impairment

Based on a population pharmacokinetic analysis, no dose adjustment of TECENTRIQ is recommended for patients with renal impairment *[see Clinical Pharmacology (12.3)]*.

8.7 Hepatic Impairment

Based on a population pharmacokinetic analysis, no dose adjustment of TECENTRIQ is recommended for patients with mild hepatic impairment. TECENTRIQ has not been studied in patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3)]*.

10 OVERDOSAGE

There is no information on overdose with TECENTRIQ.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Inform patients of the risk of immune-related adverse reactions that may require corticosteroid treatment and interruption or discontinuation of TECENTRIQ, including:

- Pneumonitis: Advise patients to contact their healthcare provider immediately for any new or worsening cough, chest pain, or shortness of breath *[see Warnings and Precautions (5.1)]*.
- Hepatitis: Advise patients to contact their healthcare provider immediately for jaundice, severe nausea or vomiting, pain on the right side of abdomen, lethargy, or easy bruising or bleeding *[see Warnings and Precautions (5.2)]*.
- Colitis: Advise patients to contact their healthcare provider immediately for diarrhea or severe abdominal pain *[see Warnings and Precautions (5.3)]*.
- Endocrinopathies: Advise patients to contact their healthcare provider immediately for signs or symptoms of hypophysitis, hyperthyroidism, hypothyroidism, adrenal insufficiency, or type 1 diabetes mellitus, including diabetic ketoacidosis *[see Warnings and Precautions (5.4)]*
- Meningoencephalitis, myasthenic syndrome/myasthenia gravis, and Guillain-Barré syndrome: Advise patients to contact their healthcare provider immediately for signs or symptoms of meningitis, myasthenic syndrome/myasthenia gravis, or Guillain-Barré syndrome *[see Warnings and Precautions (5.5)]*.
- Ocular Inflammatory Toxicity: Advise patients to contact their healthcare provider immediately for signs or symptoms of ocular inflammatory toxicity *[see Warnings and Precautions (5.5)]*.
- Pancreatitis: Advise patients to contact their healthcare provider immediately for signs and symptoms of pancreatitis *[see Warnings and Precautions (5.5)]*.
- Infection: Advise patients to contact their healthcare provider immediately for signs or symptoms of infection *[see Warnings and Precautions (5.6)]*.
- Infusion-Related Reactions: Advise patients to contact their healthcare provider immediately for signs or symptoms of infusion-related reactions *[see Warnings and Precautions (5.7)]*.
- Rash: Advise patients to contact their healthcare provider immediately for signs or symptoms of rash *[see Dosage and Administration (2.2)]*.

Embryo-Fetal Toxicity

Advise female patients that TECENTRIQ can cause fetal harm. Instruct females of reproductive potential to use effective contraception during treatment and for at least 5 months after the last dose of TECENTRIQ *[see Use in Specific Populations (8.1, 8.3)]*.

Lactation

Advise female patients not to breastfeed while taking TECENTRIQ and for at least 5 months after the last dose *[see Use in Specific Populations (8.2)]*.

Genentech

A Member of the Roche Group

TECENTRIQ™ (atezolizumab)

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990

PDL/121615/0161
Initial U.S. Approval: May 2016

NOW APPROVED

TECENTRIQ™
atezolizumab *INJECTION FOR INTRAVENOUS USE 1200 mg*

THE FIRST AND ONLY FDA-APPROVED ANTI-PDL1 CANCER IMMUNOTHERAPY IN PREVIOUSLY TREATED LOCALLY ADVANCED OR METASTATIC UROTHELIAL CARCINOMA

Indication

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Have disease progression during or following platinum-containing chemotherapy
- Have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

PD-L1=programmed death-ligand 1.

Important Safety Information

Serious Adverse Reactions

Please refer to the full Prescribing Information for important dose management information specific to adverse reactions.

- **Immune-related pneumonitis**, including fatal cases. Permanently discontinue TECENTRIQ for grade 3 or 4 pneumonitis
- **Immune-related hepatitis.** Immune-mediated hepatitis, including a fatal case, and liver test abnormalities have occurred. Permanently discontinue TECENTRIQ for grade 3 or 4 immune-mediated hepatitis
- **Immune-related colitis**, including a fatal case of diarrhea-associated renal failure. Permanently discontinue TECENTRIQ for grade 4 diarrhea or colitis
- **Immune-related endocrinopathies.** Immune-related thyroid disorders, adrenal insufficiency, hypophysitis, and type 1 diabetes mellitus, including diabetic ketoacidosis, have occurred. Permanently discontinue TECENTRIQ for grade 4 hypophysitis. For specific information on dose modifications, refer to Prescribing Information
- **Other immune-related adverse reactions.** Meningoencephalitis, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, ocular inflammatory toxicity, and pancreatitis, including increases in serum amylase and lipase levels, have occurred. Permanently discontinue TECENTRIQ for any grade of meningitis or encephalitis; or myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome. Permanently discontinue TECENTRIQ for grade 4 or any grade of recurrent pancreatitis
- **Infection**, including fatal cases. Severe infections, including sepsis, herpes encephalitis, and mycobacterial infection leading to retroperitoneal hemorrhage have occurred
- **Infusion-related reactions** have occurred. Permanently discontinue TECENTRIQ in patients with grade 3 or 4 infusion reactions
- **Embryo-fetal toxicity.** TECENTRIQ can cause fetal harm in pregnant women. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose
- Advise female patients not to breastfeed while taking TECENTRIQ and for at least 5 months after the last dose

Most Common Adverse Reactions

The most common adverse reactions (rate ≥20%) included fatigue, decreased appetite, nausea, urinary tract infection, pyrexia, and constipation.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

Please see Brief Summary of Prescribing Information on adjacent pages.

Learn more at **TECENTRIQ.com/info**

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TECENTRIQ™
atezolizumab *INJECTION FOR INTRAVENOUS USE 1200 mg*