Nurses Collaborate to Improve Cancer Screenings in Rural Areas

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ONCOLOGY NURSE CHAMPION
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Clinical Insights
Multiple Myeloma and Cervical Cancer
IN ER+/HER2- METASTATIC BREAST CANCER (mBC)

CAN IMPROVING ER ANTAGONISM AND DEGRADATION UNLOCK A BRIGHTER FUTURE?

Complex mechanisms of estrogen receptor (ER) signaling have been associated with tumor growth.1-3
In ER+/HER2- mBC, the ER pathways are involved in tumor progression and treatment escape mechanisms that enable endocrine resistance.$^{1,2,4,5}$

To strengthen the fight against resistance, could advancements in ER antagonism and degradation help decrease the ER pathway’s downstream effects?


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Supporting Patients With Cancer
From Beginning to End

Cancer care encompasses multiple phases. Nurses supporting patients with cancer need to guide them through multiple processes before, during, and after active treatment. Despite this, there is still an unmet need for comprehensive survivorship care plans. Our Nurse’s Note highlights this issue and comments on the future of survivor care.

Similarly, short-term care plans can also be difficult to navigate. Our feature story offers guidance for oncology nurses who educate caregivers about postoperative recovery for patients with lung cancer. For a comprehensive view of how The University of Texas MD Anderson Cancer Center’s patient experience program has helped facilitate navigation across a spectrum of care-related points, flip over to our Partner Perspective page.

Best treatment doesn’t always begin at diagnosis, either. Even before the COVID-19 pandemic, discrepancies in health care and preventive screenings have existed across disadvantaged communities. The health care barriers presented by the pandemic have only exacerbated these issues. Our cover story showcases the strategies and methods that oncology nurses can use to help increase screenings in rural areas, whereas our featured The Vitals podcast offers an expert opinion on health equity and the impact of COVID-19.

No matter which community an oncology nurse serves, the relationship between nurse and patient continues to be one of the most important connections a patient can experience throughout their treatment. In this issue, we highlight 2 Oncology Nurse Champions who have gone above and beyond to make their patients’ cancer journey a little better. Please join us in thanking Kristin Rupp, BSN, RN, OCN, Desert Regional Medical Center’s Comprehensive Cancer Center, and Sarah Donahue, MPH, AOCNP, University of California San Francisco Health, for their dedication and service. You can find their detailed stories in our Oncology Nurse Champion column.

In our Clinical Insights section, we provide coverage from the European Society for Medical Oncology Congress 2021 and from the 18th International Myeloma Workshop. Read about the potential for pembrolizumab (Keytruda) plus chemotherapy to become the new standard of care in the frontline setting of cervical cancer and better understand how the addition of daratumumab (Darzalex) to lenalidomide (Revlimid) and dexamethasone resulted in superior progression-free and overall survival compared with lenalidomide and dexamethasone alone. After catching up on our favorite conference highlights, be sure to take the online quiz on onc nursingsnews.com for continued education credit. Lastly, this issue also spotlights the recent FDA approvals of mobocetrux (Eskkyria) for NSCLC with EGFR exon 20 insertion mutations and abemaciclib (Verzenio) for HR+, HER2- high-risk early breast cancer.

There is not 1 phase of cancer care that outweighs another in importance. Each component needs the other to be effective. In this issue, we highlight the different ways an oncology nurse can help assist in that process from start to finish.

As always, thank you for your service and for reading.

Michael J. Hennessy
Chairman and Founder
### Clinical Insights

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Adding Pembrolizumab to Chemotherapy May Be New Standard of Care for Frontline Treatment of Advanced Cervical Cancer

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Interested in joining our Advisory Board? Contact Lindsay Fischer, lfischer@mjlifesciences.com.
Survivors Need Research-Based Interventions and Stronger Coordination Across Care Continuum

With estimates pointing to 26.1 million cancer survivors by 2040, the care of these individuals will need to be more than a care plan in their electronic medical record.

What does it mean to be a cancer survivor? The National Cancer Institute (NCI) defines a survivor as “one who remains alive and continues to function during and after overcoming a serious hardship or life-threatening disease. In cancer, a person is considered to be a survivor from the time of diagnosis until the end of life.”

There are many types of survivors, including those living with cancer with continuous treatment and those free from cancer. Because of new screening tools and treatments, there has been tremendous progress in life expectancies for those living with cancer. Subsequently, there is now a large community of cancer survivors in the US.

The American Cancer Society reported that there are currently 16.9 million cancer survivors in the US, which accounts for approximately 5% of the population. In addition, 18% of these survivors have lived with their disease for over 20 years. The most common cancers associated with this population are breast, prostate, and colorectal.

As the number continues to grow for cancer survivors, oncology nurses require well-developed education about what it means to be a cancer survivor. Moreover, as it is estimated that there will be 26.1 million survivors by 2040, the care of these individuals will need to be more than a care plan in their electronic medical record.

The NCI Office of Cancer Survivorship (OCS) was not established until 1996. Cancer survivor Ellen Stovall helped establish the OCS to enhance the quality and length of survival of all persons with cancer to prevent, minimize, or manage adverse events of cancer and its treatment. Two decades later, the American College of Surgeons Commission on Cancer (CoC) created survivorship standards in the United States. These 2016 standards created questions for many oncology practices regarding whom could establish and update care plans for all cancer survivors. Why are the CoC’s new survivorship standards so important? Many facilities see the CoC accreditation as providing value to their programs for the patient, family, and community.

The early standards (standard 3.5) received criticism for allowing practices to “check a box” instead of providing comprehensive survivorship care and programs. However, the newest standard CoC (4.8) now places the emphasis on the actual program and the process of delivering survivorship care. This standard states that a survivorship program should include a team of providers and a survivorship coordinator, as well as services that include survivorship care plans, seminars for survivors, and rehabilitation, nutritional, and psychological services.

In addition, care of patients via technology has been pushed to the forefront by the pandemic and has yielded great success. There are many apps designed for survivors with a focus on health and wellness from both a physical and psychological perspective. However, further development of cancer survivorship apps for adolescent, young adult, and older adult survivors will be necessary if this technology is to become a component of long-term care planning.

As a longtime oncology nurse and cancer survivor, I am thrilled at the rising number of survivors and people thriving after cancer. We have come so far. However, oncology nursing needs to embrace the survivorship movement by providing research-based interventions with equality for all patients.

Patients are asking for transitional and continuous care to be coordinated and available for all patients with cancer. Survivorship care should be focused on new and current programs, education, and rehabilitation services, and nutritional, and psychological services. The current emphasis on survivorship programs should involve a team approach with a focus on delivering the care with flexibility. There should be no time restrictions on survivorship care. Be open to assist.

For nurses who support cancer survivors—you are doing amazing work. Keep moving your patients toward their best lives. Thank you for all you do.

References are available on OncNursingNews.com.

Patricia Jakel, MN, RN, AOCN
Co Editor in Chief
Oncology Nursing News®
FDA Approves Mobocertinib for NSCLC With *EGFR* Exon 20 Insertion Mutations

The FDA has green lit mobocertinib for the treatment of adult patients with locally advanced or metastatic non–small cell lung cancer with an *EGFR* exon 20 insertion mutation.

By Lindsay Fischer

The FDA has approved mobocertinib (Exkivity) for the indication of adult patients with locally advanced or metastatic non–small cell lung cancer (NSCLC) whose disease harbors an *EGFR* exon 20 insertion mutation, as detected by an FDA-approved test, either following or beyond platinum-based chemotherapy. This first-in-class, oral tyrosine kinase inhibitor (TKI) is the first-approved oral therapy engineered to target *EGFR* exon 20 insertion mutations, according to Takeda Pharmaceutical Company Limited, the manufacturer of the small molecule TKI.¹

“*EGFR* exon 20 insertion–positive NSCLC is an underserved cancer that we have been unable to target effectively with traditional EGFR TKIs,” said Pasi A. Jänne, MD, PhD, Dana-Farber Cancer Institute, in a press release. “The approval of Exkivity marks another important step forward that provides physicians and their patients with a new targeted oral therapy specifically designed for this patient population that has shown clinically meaningful and sustained responses.”

The regulatory decision is based on findings from the phase 1/2 trial of Exkivity (NCT02716116). In the trial, 114 patients with *EGFR* exon 20 insertions, who had been previously treated with platinum-based therapy, received mobocertinib at a 160-mg dose. Findings revealed an overall response rate of 28% through an independent review committee (IRC) and 35% through investigator analysis. The median duration of response (DOR) was 17.5 months, the median overall survival (OS) was 24 months, and the median progression-free survival (PFS) was 7.3 months. DOR, OS, and PFS were all determined by an IRC.

Notable adverse events from the study drug included diarrhea, rash, nausea, stomatitis, vomiting, decreased appetite, paronychia, fatigue, dry skin, and musculoskeletal pain. Patients and providers should be aware that there is a risk of interstitial lung disease/pneumonitis, cardiac toxicity, and diarrhea associated with the drug.

“Patients with *EGFR* exon 20 insertion–positive+ NSCLC have historically faced a unique set of challenges living with a very rare lung cancer that is not only underdiagnosed but also lacking targeted treatment options that can improve response rates,” added Marcia Horn, JD, executive director of the exon 20 Group at the International Cancer Advocacy Network.

“As a patient advocate working with *EGFR* exon 20 insertion–positive NSCLC patients and their families every day for nearly 5 years, I am thrilled to witness continued progress in the fight against this devastating disease and am grateful for the patients, families, health care professionals, and scientists across the globe who contributed to the approval of this promising targeted therapy.”

A confirmatory trial will determine continued approval for the indication.

References are available on OncNursingNews.com.

COVID-19 PANDEMIC EMPHASIZES DISPARITIES IN CANCER CARE

By Lindsay Fischer

FOR THIS EPISODE OF THE VITALS, we spoke with Chastity Washington, MPH, CHES, director of the Center for Cancer Health Equity at The Ohio State University, about how the COVID-19 pandemic has exacerbated preexisting disparities in cancer care. Washington spoke to Oncology Nursing News® about the direct and indirect impacts of COVID-19 on disadvantaged communities, vaccine hesitancy among those communities, and more.

“We’ve seen [that] a lot of people of color were the ones most impacted by COVID-19, which has had some impact on cancer patients and their outcomes. [It is] still being studied exactly what the extent of that is, but they’re [people] who are in those essential service jobs. So they’re getting COVID-19 more often, they’re using public transportation—all those things that existed before COVID-19 and were causing those disparities were just compounded.”

“A lot of what can be done is going to be outside of the scope of a clinical practice. It’s going to be trying to help those patients connect with resources, help them understand how to use telehealth and telemedicine, [and] spending that extra time walking [them] through that process or connecting [them] to the resources [for] services.”

“We’re going to see so much more mortality in the years to come [because of those delays], particularly in breast and colorectal cancer screening. So encouraging patients to get back in for routine screenings, ensuring them it’s safe, [and] reminding them of the protocols we’re taking to make sure they will be safe when they come in for those screenings will go a long way.”
NEW to decrease the incidence of chemotherapy-induced myelosuppression in patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC)

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FDA BREAKTHROUGH THERAPY DESIGNATION

INDICATION

COSELA is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

*COSELA was evaluated in 3 randomized, double-blind, placebo-controlled clinical studies. The Pivotal Study (Study 1) evaluated COSELA or placebo administered prior to treatment with E/P/A in 107 patients with newly diagnosed ES-SCLC not previously treated with chemotherapy. In this study, COSELA significantly reduced the primary endpoints of incidence (adjusted relative risk [aRR] 0.038 [95% CI, 0.008, 0.195], P<0.0001) and duration in Cycle 1 (mean difference -3.8 [95% CI, -4.9, -2.3], P<0.0001) of severe neutropenia and significantly decreased the rate of all-cause chemotherapy dose reductions (aRR 0.242 [95% CI, 0.079, 0.742]. The incidence of Grade 3/4 anemia was 19% and 28% (aRR 0.663 [95% CI, 0.336, 1.310]) and RBC transfusions on/after 5 weeks were 13% and 21% (aRR 0.642 [95% CI, 0.294, 1.404]) with and without COSELA, respectfully.

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**WHILE CHEMOTHERAPY TARGETS CANCER CELLS**

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**CONTRAINDICATION**
- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

**WARNINGS AND PRECAUTIONS**

**Injection-Site Reactions, Including Phlebitis and Thrombophlebitis**
- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

**Acute Drug Hypersensitivity Reactions**
- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade ≤1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

**Interstitial Lung Disease/Pneumonitis**
- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK) 4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

**Embryo-Fetal Toxicity**
- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.

**ADVERSE REACTIONS**
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

To report suspected adverse reactions, contact G1 Therapeutics at 1-800-790-GITX or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This information is not comprehensive. Please see the Brief Summary of Prescribing Information on the adjacent page.
**COSELA** (trilaciclib) for injection, for intravenous use

**Initial U.S. Approval:** 2021

**BRIEF SUMMARY OF PRESCRIBING INFORMATION**

**INDICATIONS AND USAGE**

COSELA is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered concurrently with a platinum-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

**DOSE AND ADMINISTRATION**

**RecommendedDosage**

The recommended dose of COSELA is 240 mg/m2 per dose. Administer as a 30-minute intravenous infusion completed within 4 hours prior to the start of chemotherapy on day 1 of each 21-day cycle.

**Contraindications**

COSELA is contraindicated in patients with a history of severe hypersensitivity reactions to trilaciclib. Reactions have included anaphylaxis and urticaria.

**Warnings and Precautions**

**Pharmacokinetics**

A drug interaction study was performed in healthy volunteers receiving COSELA concurrently with dexamethasone, amifostine, and etoposide. The Severity Grade* *(NCI CTCAE v4.03x)

**ADVERSE REACTIONS**

The most frequent significant adverse reactions are described elsewhere in the table:

- Injection-Site Reactions, including phlebitis and thrombophlebitis
- **Interstitial Lung Disease/Pneumonitis**
- **Hypokalemia**
- **Hypophosphatemia**
- **Dalfampridine**
- **Drug Interactions**

**Effect on Other Oral Contraceptive Drugs, Certain OITC, MATTE, and MATE 2K Substrates**

COSELA is an inhibitor of OCT2, MATTE, and MATE 2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATTE1, and MATE-2K substrates in the kidney (e.g., dalfampridine).

**DRUG INTERACTIONS**

**Effect on Other Oral Contraceptive Drugs, Certain OITC, MATTE, and MATE 2K Substrates**

COSELA is an inhibitor of OCT2, MATTE, and MATE 2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATTE1, and MATE-2K substrates in the kidney (e.g., dalfampridine). Refer to the prescribing information for these concomitant medications for assessing the benefit and risk of concurrent use of COSELA.

**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

**Lactation**

**Geriatric Use**

**Drug Interactions**

Advises patients of the signs and symptoms of injection-site reactions, including phlebitis and thrombophlebitis. Advise patients to immediately report new or worsening respiratory symptoms.

**Drug Interactions**

Advises patients to immediately report new or worsening respiratory symptoms.

**Dosage and Administration**

**Pharmacokinetics**

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**USE IN SPECIFIC POPULATIONS**

**Pregnancy**

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Advises patients of the signs and symptoms of injection-site reactions, including phlebitis and thrombophlebitis. Advise patients to immediately report new or worsening respiratory symptoms.

**Drug Interactions**

Advises patients to immediately report new or worsening respiratory symptoms.
The FDA has approved abemaciclib (Verzenio) as an adjuvant therapy in combination with endocrine therapy (tamoxifen or an aromatase inhibitor) to treat hormone receptor (HR)-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score of greater than or equal to 20%, as determined by an FDA-approved test, according to a press release by Eli Lilly and Company.1

“Women and men living with high-risk HR-positive, HER2-negative early breast cancer want to do all they can to reduce the risk of the disease coming back, with the hope of living free of cancer. The approval of [abemaciclib] provides a new treatment option to help them do just that,” said Jean Sachs, MSS, MLSP, CEO of Living Beyond Breast Cancer, in the release. “This approval brings new optimism to the breast cancer community.”

The regulatory decision is based on findings from the randomized, open-label, 2-cohort, multicenter, phase 3 monarchE trial (NCT03155997), designed to evaluate abemaciclib plus standard endocrine therapy vs standard endocrine therapy alone in adult patients with HR-positive, HER2-negative, node-positive, resected early breast cancer with clinical and pathological features consistent with a high risk of disease recurrence. Patients were treated with either 2 years of abemaciclib 150 mg twice daily plus standard endocrine therapy or with standard endocrine therapy as a monotherapy. Patients in both cohorts were prescribed adjuvant endocrine therapy for 5 to 10 years.

The primary end point was invasive disease-free survival (iDFS), defined as the length of time before the breast cancer returns, new cancer develops, or death, and has already met a prespecified interim analysis in the intent-to-treat population. Patients receiving abemaciclib have demonstrated superior iDFS compared with those treated with endocrine therapy as a monotherapy.

Overall survival data are not yet ready for analysis and investigators are continuing to conduct additional follow-ups.

In addition, no new safety signals were detected in the monarchE trial. Safety and tolerability were assessed across 5591 patients, in whom the most common adverse events were diarrhea, infections, fatigue, nausea, headache, vomiting, stomatitis, dizziness, rash, and alopecia. Laboratory abnormalities to monitor include an increase in creatinine, a decreased white blood cell count, decreased neutrophil count, anemia, lymphocyte count decrease, platelet count decrease, increased alanine aminotransferase level, increased aspartate aminotransferase level, and hypokalemia.

Patients should receive blood counts and liver function tests prior to initiating treatment with abemaciclib. These tests should continue every 2 weeks for the first 2 months, monthly for the following 2 months, and so on, as clinically indicated. Patients taking this medication will also require monitoring for thrombosis and pulmonary embolism.

Patients should be taught to immediately initiate antidiarrheal therapy, increase oral fluids, and notify their health care providers at the first sign of loose stools. The labeling for the drug includes precautions for diarrhea, neutropenia, interstitial lung disease, hepatotoxicity, venous thromboembolism, and embryo-fetal toxicity. In addition, patients should understand that this drug poses serious risk to a fetus. The label urges patients to plan accordingly by using effective contraception.

“The design and results of the monarchE study are practice-changing and represent the first advancement in adjuvant treatment of HR-positive, HER2-negative breast cancer in a very long time,” said Sara M. Tolaney, MD, MPH, Harvard Medical School, Dana-Farber Cancer Institute, and investigator on the monarchE study. “This FDA approval for Verzenio in combination with endocrine therapy in the early breast cancer setting has the potential to become a new standard of care for this population. We are encouraged by the marked reduction in the risk of recurrence even beyond the 2-year treatment period in these patients, and I’m grateful to be able to offer this as a treatment option to my patients.”

References are available on OncNursingNews.com.
Excellence Is in the Details:
Oncology Nurse Champion Sarah Donahue

Sarah Donahue, MPH, AOCNP, shares what drew her to oncology, the daily challenges she faces as a nurse practitioner, and her advice to new oncology nurses on how to overcome those barriers.

By Lindsay Fischer

When it comes to comprehensive oncology care from the nurse practitioner’s perspective, the “excellence is in the details,” according to Sarah Donahue, MPH, AOCNP, a nurse practitioner on the breast team at University of California San Francisco Health. Donahue originally thought she wanted to go the geriatric route focusing on reducing cardiac risk factors when she was in school for her master’s, but after some clinical experience in an infusion center, she knew oncology was the perfect path for her career.

Bound for Oncology
Donahue fell in love with oncology when she was a student. Her mother, who is an oncologist, offered her some clinical experience by working at her infusion center during the summer.

She said she immediately felt comfortable caring for the older patients at the center. “I think I am an old soul or something,” she said, adding that she was also impressed by the science behind the treatments. “The science was fascinating to me. Put that together with the social issues that come up around having cancer…it’s a lot more emotional, [but] it was also really exciting for me, and it brought together the science and social [components] perfectly.”

The Nurse as a Teacher
“I love to teach,” Donahue said. “I like to take something really complicated and make it as simple as possible.”

“She is committed to communicating the interpretation of scan and laboratory results to our patients, particularly now that results are released immediately to the patient, which can cause significant anxiety, and she is very attentive to management of toxicity and pain, providing clear information and potential strategies,” said coworker Hope S. Rugo, MD, FASCO, professor of medicine and director of breast oncology and clinical trials education at the University of California, San Francisco Helen Diller Family Comprehensive Cancer Center.

Donahue said she tries her best to imagine not having any sort of medical background when talking with patients. She will often ask her patients to repeat back her explanations so she can gather a sense of their understanding. She is also very thoughtful about her wording. She prefers words that are palpable and not scary.

“There’s a bit of finesse when you’re talking about scans in cancer. [You need] to give the patient the information they need but also not scare them,” she said. For example, she prefers to use words like stable or maintain instead of not progressing because it allows the patient to feel calm, even though the cancer is still present.

The Different Angles of Supportive Care
As a nurse practitioner, Donahue is used to approaching supportive care from a variety of viewpoints. There are the “obvious” pillars of care, like ensuring patients arrive for treatments, monitoring for medication adherence, and actively managing adverse events, but cancer care also involves more complex assistance that needs to be managed. Donahue explained how she must constantly evaluate her patients, not just for symptoms but for psychological components, family stress, transportation issues, and more. “It is all interconnected,” she said.

She said there are days when it feels as if every patient requires a high level of data collection, which is part of why the workload for nurse practitioners can feel overwhelming at times.

The best thing a nurse can do in this situation is remain calm and focus on the details, she said. If a patient states they are experiencing diarrhea, she asks when: First thing in the morning? In the afternoon? Exactly when are they taking their Imodium? She will tell them, “We’re going to figure it out together because I can’t help you unless I know exactly what’s going on.” She also added that her patients often learn to take notes between visits so they can explain to her exactly what they are experiencing.

A Final Message
Donahue acknowledged that supportive oncology care often feels as though it is nonstop; one of the biggest challenges is learning to “turn it off” when she is not in the clinic. She is grateful for her family for helping her practice separating herself from work when she goes home.

“Her commitment to patient care is exemplary,” Rugo said. “Sarah is always willing to step in to manage an issue [even] when she is not in [the] clinic, and this commitment showed clearly throughout the pandemic despite her need to juggle the care of her 2 young children. Sarah is a true Oncology Nurse Champion.”

Donahue’s message to fellow oncology nurses is this: “It’s an honor to care for these patients and to be a part of their cancer journey. The end result could be the same, but if you can make them feel heard, treat their symptoms, [and] improve their quality of life, that is 100% worth it and rewarding.”
The Best Profession in the World: Oncology Nurse Champion Kristin Rupp

Kristin Rupp, BSN, RN, OCN, reminisces about the experiences that made her the nurse she is today and how she continues to pay it forward.

By Lindsay Fischer

After 30 years of experience being an oncology nurse, Kristin Rupp, BSN, RN, OCN, “wouldn’t trade this profession for the world.”

“I know I’ve made the right choice,” she said in an interview with Oncology Nursing News®. Rupp, a seasoned oncology nurse “with a wealth of experience and a heart of gold,” according to her coworkers, has spent the past 15 years at the Desert Regional Medical Center Comprehensive Cancer Center in Palm Springs, California, where she works full time in the oncology infusion suite and assists in the satellite clinics weekly. Although she is known to have fantastic managerial skills, her coworkers especially appreciate her heart for the patients and her knack for putting them at ease.

“She has been recognized locally by her peers and our hospital administration as a nurse of distinction,” said Timothy Tyler, PharmD, director of pharmacy, lab, and oncology supportive care at the Desert Regional Medical Center Comprehensive Cancer Center, “but most of all, she is loved by her patients and fellow clinicians as someone who goes beyond what is expected and is truly exemplary.”

Preparing the Next Generation

Rupp was positively influenced by a variety of encouraging and inspiring mentors when she was still a novice oncology nurse. Today, she helps the next generation of nurses by having assisted at a nursing school in her community and by frequently volunteering to precept nursing students. According to Rupp, one of the most inspiring parts of preparing the next generation of nurses is witnessing their interactions with patients. “[They] see how amazing our patients are, how brave they are, what they are going through...[and say], ‘Hey, you know what? This isn’t so scary. And you know what? I’m going to think about oncology nursing.’ To me, that’s priceless,” Rupp said.

When students interact with patients with cancer, it can have a huge impact on them as they realize these individuals will have to live with their disease for the rest of their lives, and in some cases, may have to navigate end-of-life issues. However, she enjoys seeing how many of her students find themselves ready to tackle the world of oncology supportive care once they garner experience. “I love the students,” she said. “I love their enthusiasm. I love [how] they’re scared and frightened [when they come in, but] when they go back to their class, they say, ‘Gosh, that was great.’”

A Personal Connection

Rupp recognizes that cancer care not only involves treating the disease itself, but also involves offering supportive care, managing adverse events, and often supporting the needs of the patient and the family caregivers. By imagining the situation from the patient’s perspective, she is able to try to understand what they might be experiencing.

“I look at these challenges, and [I think], ‘how would I want to be treated? Or how would I want my family members to be treated?’ We want to look at the situation as a whole and address the needs individually,” Rupp said.

Rupp’s professional and personal experiences have even intertwined at times. Her career was significantly affected through losing both her brother and mother to lung cancer. “As an oncology nurse, it hit home in my heart,” Rupp said. She explained that although she knows she tried to be the best nurse, sister, and daughter she could be, the loss continues to weigh on her. At the end of the day, she recognizes that this experience strengthened her ability to connect with the patients and caregivers she supports.

“I can feel and know the hurt that folks are going through. I had been an oncology nurse for a long time, but when it gets into your inner circle...it’s a whole different story. I am sad I lost them, but [to see] how brave they were to have gone through what they went through—I see things in a whole different light because of it.”

Patient Support in a Pandemic

Rupp said one of the biggest challenges in the past year was helping patients overcome the feeling of isolation. “Think of how difficult it must be to go to your first chemotherapy appointment and not have your loved one with you” she said. “Think about the nurse talking about all of this medication, [adverse] effects, and instructions of what to do at home. There’s only so much you can absorb if you don’t have that extra set of ears or extra set of eyes.”

Oncology nurses were forced to adapt during the COVID-19 pandemic, she concluded. They had to use a lot of patience to provide the level of emotional support required by their patients. Upon reflecting over the past almost 2 years, Rupp describes excellence in oncology nursing as “when you can sit with someone, hold their hand, laugh, cry, talk about life and death... have the most intimate conversations without a thought of the pandemic.”

Her advice to peers is to know they’ve chosen the best profession in the world, and to be the best oncology nurses they can be.
ZEJULA is the only once-daily oral PARP inhibitor maintenance monotherapy approved for all eligible first-line platinum responders with advanced ovarian cancer, regardless of biomarker status \(^1\-^4\)

**Indication**

ZEJULA is indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.

**Important Safety Information**

**Myelodysplastic syndrome/acute myeloid leukemia** (MDS/AML), including some fatal cases, was reported in 15 patients (0.8%) out of 1,785 patients treated with ZEJULA monotherapy in clinical trials. The duration of therapy in patients who developed secondary MDS/cancer therapy-related AML varied from 0.5 months to 4.9 years. These patients had received prior chemotherapy with platinum agents and/or other DNA-damaging agents including radiotherapy. Discontinue ZEJULA if MDS/AML is confirmed.

**Hematologic adverse reactions** (thrombocytopenia, anemia, neutropenia, and/or pancytopenia) have been reported in patients receiving ZEJULA. In PRIMA, the overall incidence of Grade ≥3 thrombocytopenia, anemia, and neutropenia were reported, respectively, in 39%, 31%, and 21% of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 4%, 2%, and 2% of patients. In patients who were administered a starting dose of ZEJULA based on baseline weight or platelet count, Grade ≥3 thrombocytopenia, anemia, and neutropenia were reported, respectively, in 22%, 23%, and 15% of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred, respectively, in 3%, 3%, and 2% of patients. Do not start ZEJULA until patients have recovered from hematological toxicity caused by prior chemotherapy (≤ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months, and periodically thereafter. If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA, and refer the patient to a hematologist for further investigations.

**Hypertension and hypertensive crisis** have been reported in patients receiving ZEJULA. In PRIMA, Grade 3-4 hypertension occurred in 6% of patients receiving ZEJULA vs 1% of patients receiving placebo, with no reported discontinuations. Monitor blood pressure and heart rate at least weekly for the first two months, then monthly for the first year, and periodically thereafter during treatment with ZEJULA. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Manage hypertension with antihypertensive medications and adjustment of the ZEJULA dose, if necessary.

**Posterior reversible encephalopathy syndrome** (PRES) occurred in 0.1% of 2,165 patients treated with ZEJULA in clinical trials and has also been described in postmarketing reports. Monitor all patients for signs and symptoms of PRES, which include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. Diagnosis requires confirmation by brain imaging. If suspected, promptly discontinue ZEJULA and administer appropriate treatment. The safety of reinitiating ZEJULA is unknown.

**Embryo-fetal toxicity and lactation:** Based on its mechanism of action, ZEJULA can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months after receiving their final dose of ZEJULA. Because of the potential for serious adverse reactions from ZEJULA in breastfed infants, advise lactating women not to breastfeed during treatment with ZEJULA and for 1 month after receiving the final dose.
**5.4 Posterior Reversible Encephalopathy Syndrome**

Posterior reversible encephalopathy syndrome (PRES) occurred in 0.1% of 2,165 patients treated with ZEJULA in clinical trials and has also been described in postmarketing reports [see Adverse Reactions (6.2)]. Signs and symptoms of PRES include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging.

Monitor all patients treated with ZEJULA for signs and symptoms of PRES. If PRES is suspected, promptly discontinue ZEJULA and administer appropriate treatment. The safety of reinstating ZEJULA in patients previously experiencing PRES is not known.

5.5 Embryo-Fetal Toxicity

Based on its mechanism of action, ZEJULA can cause fetal harm when administered to a pregnant woman [see Clinical Pharmacology (12.1) of full prescribing information]. ZEJULA has the potential to cause teratogenicity and/or embryo-fetal death since niraparib is genotoxic and targets active division cells in animals and patients (e.g., bone marrow) [see Warnings and Precautions (5.2) and Nonclinical Toxicology (13.1) of full prescribing information]. Due to the potential risk to a fetus based on its mechanism of action, animal developmental and reproductive toxicity studies were not conducted with niraparib.

Aprosia pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 6 months after the last dose of ZEJULA (see Use in Specific Populations (8.1)).

**5.6 Allergic Reactions to FB&D Yellow No. 5 (Tartrazine)**

ZEJULA capsules contain FB&D Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FB&D Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

**6 ADVERSE REACTIONS**

The following clinically significant adverse reactions are described elsewhere in the labeling:

- **MDS/AML** [see Warnings and Precautions (5.1)]
- **Bone marrow suppression** [see Warnings and Precautions (5.2)]
- **Hypertension and cardiovascular effects** [see Warnings and Precautions (5.3)]
- **Posterior reversible encephalopathy syndrome** [see Warnings and Precautions (5.4)]

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 with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common adverse reactions of all grades in >10% of 1,314 patients who received ZEJULA in the pooled PRIMA, NOVA, and QUADRA trials were nausea (65%), thrombocytopenia (60%), anemia (56%), fatigue (52%), constipation (39%), mucositis (34%), vomiting (33%), neutropenia (31%), decreased appetite (24%), leukopenia (24%), insomnia (23%), headache (23%), dyspnea (22%), rash (21%), diarrhea (18%), hypertension (17%), cough (10%), dizziness (14%), acute kidney injury (11%), urinary tract infection (8%), and hemoptysis (11%).

First-Line Maintenance Treatment of Advanced Ovarian Cancer

The safety of ZEJULA for the treatment of patients with advanced ovarian cancer following first-line treatment with platinum-based chemotherapy was studied in the PRIMA trial, a placebo-controlled, double-blind study in which 726 patients received niraparib or placebo. Among patients who received ZEJULA, the median duration of treatment was 11.1 months (range 0.3 to 29 months).

**5.1 Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)**

Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), including cases with fatal outcome, have been reported in patients who received monotherapy with ZEJULA in clinical trials. In 1,765 patients treated with ZEJULA in clinical trials, MDS/AML occurred in 15 patients (0.8%). The duration of therapy with ZEJULA in patients who developed secondary MDS/cancer therapy-related AML varied from 0.5 months to 4.5 years. All these patients had received previous chemotherapy with platinum agents and/or other DNA-damaging agents including radiontherapy. Discontinue ZEJULA if MDS/AML is confirmed.

5.2 Bone Marrow Suppression

Hematologic adverse reactions, including thrombocytopenia, anemia, neutropenia, and/or pancytopenia have been reported in patients treated with ZEJULA [see Adverse Reactions (6.1)].

In PRIMA, the overall incidences of grade 3 thrombocytopenia, anemia, and neutropenia were reported in 39%, 31%, and 21%, respectively, of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred in 4%, 2%, and 2%, respectively, of patients. In patients who were administered a starting dose of ZEJULA based on baseline weight or platelet count, grade 3 thrombocytopenia, anemia, and neutropenia were reported in 22%, 23%, and 15%, respectively, of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred in 3%, 3%, and 2%, respectively, of patients.

In NOVA, grade 3 thrombocytopenia, anemia, and neutropenia were reported in 29%, 25%, and 20%, respectively, of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred in 3%, 1%, and 2%, respectively, of patients.

In QUADRA, grade 3 thrombocytopenia, anemia, and neutropenia were reported in 39%, 27%, and 12%, respectively, of patients receiving ZEJULA. Discontinuation due to thrombocytopenia, anemia, and neutropenia occurred in 4%, 2%, and 1%, respectively, of patients.

Do not start ZEJULA until patients have recovered from hematological toxicity caused by previous chemotherapy (Grade 2). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time. If hematological toxicities do not resolve within 28 days following interruption, discontinue ZEJULA and refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics [see Dosage and Administration (2.3) of full prescribing information].
Patients Receiving ZEJULA with Dose Based on Baseline Weight or Platelet Count in PRIMA: Among patients who received ZEJULA with the dose based on weight and platelet count, the median duration of treatment was 11 months (range: 1 day to 16 months). Serious adverse reactions occurred in 27% of patients receiving ZEJULA. Serious adverse reactions in ≥2% of patients were anemia (8%) and thrombocytopenia (7%). No fatal adverse reactions occurred. Permanent discontinuation due to adverse reactions occurred in 14% of patients who received ZEJULA. Adverse reactions resulting in permanent discontinuation in ≥2% of patients who received ZEJULA included thrombocytopenia and anemia (5% each) and nausea (2.4%). Adverse reactions led to dose reduction or interruption in 72% of patients, most frequently from thrombocytopenia (40%), anemia (23%), and neutropenia (15%). Table 3 and Table 4 summarize adverse reactions and abnormal laboratory findings in the group of patients who received ZEJULA.

Table 2: Abnormal Laboratory Findings in ≥25% of All Patients Receiving ZEJULA in PRIMA

<table>
<thead>
<tr>
<th>Abnormal Laboratory Finding</th>
<th>ZEJULA (n=484)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>87%</td>
<td>66%</td>
<td>29%</td>
</tr>
<tr>
<td>Platelets</td>
<td>74%</td>
<td>13%</td>
<td>37%</td>
</tr>
<tr>
<td>Leukocytes</td>
<td>71%</td>
<td>36%</td>
<td>9%</td>
</tr>
<tr>
<td>Glucose</td>
<td>66%</td>
<td>57%</td>
<td>3%</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>51%</td>
<td>29%</td>
<td>7%</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>46%</td>
<td>21%</td>
<td>1%</td>
</tr>
<tr>
<td>Creatinine</td>
<td>40%</td>
<td>23%</td>
<td>0%</td>
</tr>
<tr>
<td>Magnesium</td>
<td>36%</td>
<td>34%</td>
<td>1%</td>
</tr>
<tr>
<td>Aspartate aminotransferase</td>
<td>35%</td>
<td>17%</td>
<td>1%</td>
</tr>
<tr>
<td>Alanine aminotransferase</td>
<td>29%</td>
<td>17%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Maintenance Treatment of Recurrent Ovarian Cancer

The safety of monotherapy with ZEJULA 300 mg once daily has been studied in 367 patients with platinum-sensitive recurrent ovarian, fallopian tube, and primary peritoneal cancer in the NOVA trial. Adverse reactions in NOVA led to dose reduction or interruption in 69% of patients, most frequently from thrombocytopenia (40%), anemia (23%), and neutropenia (15%). Table 5 and Table 6 summarize the common adverse reactions and abnormal laboratory findings, respectively, observed in patients treated with ZEJULA in NOVA.

Table 3: Abnormal Laboratory Findings in ≥25% of All Patients Receiving ZEJULA Based on Baseline Weight or Platelet Count in PRIMA

<table>
<thead>
<tr>
<th>Abnormal Laboratory Finding</th>
<th>ZEJULA (n=367)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemoglobin</td>
<td>81%</td>
<td>70%</td>
<td>21%</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>70%</td>
<td>36%</td>
<td>6%</td>
</tr>
<tr>
<td>Platelets</td>
<td>63%</td>
<td>15%</td>
<td>18%</td>
</tr>
<tr>
<td>Glucose</td>
<td>63%</td>
<td>56%</td>
<td>2%</td>
</tr>
<tr>
<td>Neutrophils</td>
<td>60%</td>
<td>27%</td>
<td>15%</td>
</tr>
<tr>
<td>Lymphocytes</td>
<td>52%</td>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>Alkaline phosphatase</td>
<td>43%</td>
<td>17%</td>
<td>1%</td>
</tr>
<tr>
<td>Magnesium</td>
<td>44%</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>Creatinine</td>
<td>41%</td>
<td>22%</td>
<td>0%</td>
</tr>
<tr>
<td>Aspartate aminotransferase</td>
<td>31%</td>
<td>19%</td>
<td>1%</td>
</tr>
<tr>
<td>Alanine aminotransferase</td>
<td>28%</td>
<td>15%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Adverse Reactions Reported in ≥10% of Patients Receiving ZEJULA in NOVA

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ZEJULA (n=367)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>54%</td>
<td>21%</td>
<td>1%</td>
</tr>
<tr>
<td>Anemia</td>
<td>50%</td>
<td>23%</td>
<td>1%</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>36%</td>
<td>15%</td>
<td>1%</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>28%</td>
<td>11%</td>
<td>5%</td>
</tr>
</tbody>
</table>

The following adverse reactions and laboratory abnormalities have been identified in ≥1 to <10% of the 367 patients receiving ZEJULA in the NOVA trial and not included in the table: tachycardia, peripheral edema, hypokalemia, bronchitis, conjunctivitis, gamma-glutamyl transferase increased, blood creatinine increased, blood alkaline phosphatase increased, weight decreased, depression, and epistaxis.

Treatment of Advanced Ovarian Cancer after 3 or More Chemotherapies

The safety of monotherapy with ZEJULA 300 mg once daily has been studied in QUADRA, a single-arm study in 463 patients with recurrent high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who had been treated with 3 or more prior lines of therapy. The median duration of overall study treatment was 3 months (range: 0.03 to 32 months). For the indicated QUADRA population, the median duration was 3 months (range: 0.1 to 30 months). Fatal adverse reactions occurred in 2% of patients, including cardiac arrest. Serious adverse reactions occurred in 43% of patients receiving ZEJULA. Serious adverse reactions in ≥3% of patients were small intestinal obstruction (7%), vomiting (6%), nausea (5%), and abdominal pain (4%). Permanent discontinuation due to adverse reactions occurred in 1% of patients who received ZEJULA. Adverse reactions led to dose reduction or interruption in 73% of patients receiving ZEJULA. The most common adverse reactions (≥5%) resulting in dose reduction or interruption of ZEJULA were thrombocytopenia (40%), anemia (21%), neutropenia (11%), nausea (13%), vomiting (11%), fatigue (9%), and abdominal pain (5%). Table 7 and Table 8 summarize the common adverse reactions and abnormal laboratory findings, respectively, observed in patients treated with ZEJULA in QUADRA.

Table 4: Abnormal Laboratory Findings in ≥25% of All Patients Receiving ZEJULA Based on Baseline Weight or Platelet Count in PRIMA

<table>
<thead>
<tr>
<th>Abnormal Laboratory Finding</th>
<th>ZEJULA (n=367)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decreased hemoglobin</td>
<td>81%</td>
<td>70%</td>
<td>21%</td>
</tr>
<tr>
<td>Decreased neutrophils</td>
<td>70%</td>
<td>36%</td>
<td>6%</td>
</tr>
<tr>
<td>Decreased platelets</td>
<td>63%</td>
<td>15%</td>
<td>18%</td>
</tr>
<tr>
<td>Decreased glucose</td>
<td>63%</td>
<td>56%</td>
<td>2%</td>
</tr>
<tr>
<td>Decreased neutrophils</td>
<td>60%</td>
<td>27%</td>
<td>15%</td>
</tr>
<tr>
<td>Decreased lymphocytes</td>
<td>52%</td>
<td>30%</td>
<td>5%</td>
</tr>
<tr>
<td>Increased alkaline phosphatase</td>
<td>43%</td>
<td>17%</td>
<td>1%</td>
</tr>
<tr>
<td>Decreased magnesium</td>
<td>44%</td>
<td>30%</td>
<td>0%</td>
</tr>
<tr>
<td>Increased creatinine</td>
<td>41%</td>
<td>22%</td>
<td>0%</td>
</tr>
<tr>
<td>Increased aspartate aminotransferase</td>
<td>31%</td>
<td>19%</td>
<td>1%</td>
</tr>
<tr>
<td>Increased alanine aminotransferase</td>
<td>28%</td>
<td>15%</td>
<td>2%</td>
</tr>
</tbody>
</table>

Common Terminology Criteria for Adverse Events version 4.02.

Adverse Reactions in ≥10% of Patients Receiving ZEJULA in NOVA

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ZEJULA (n=367)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>61%</td>
<td>29%</td>
<td>0.6</td>
</tr>
<tr>
<td>Anemia</td>
<td>50%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>30%</td>
<td>20%</td>
<td>2%</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>17%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The following adverse reactions and laboratory abnormalities have been identified in ≥1 to <10% of the 367 patients receiving ZEJULA in the NOVA trial and not included in the table: tachycardia, peripheral edema, hypokalemia, bronchitis, conjunctivitis, gamma-glutamyl transferase increased, blood creatinine increased, blood alkaline phosphatase increased, weight decreased, depression, and epistaxis.

Adverse Reactions Reported in ≥10% of Patients Receiving ZEJULA in NOVA

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>ZEJULA (n=367)</th>
<th>Placebo (n=169)</th>
<th>Placebo (n=86)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thrombocytopenia</td>
<td>61%</td>
<td>29%</td>
<td>0.6</td>
</tr>
<tr>
<td>Anemia</td>
<td>50%</td>
<td>25%</td>
<td>0%</td>
</tr>
<tr>
<td>Neutropenia</td>
<td>30%</td>
<td>20%</td>
<td>2%</td>
</tr>
<tr>
<td>Leukopenia</td>
<td>17%</td>
<td>5%</td>
<td>0%</td>
</tr>
</tbody>
</table>

The following adverse reactions and laboratory abnormalities have been identified in ≥1 to <10% of the 367 patients receiving ZEJULA in the NOVA trial and not included in the table: tachycardia, peripheral edema, hypokalemia, bronchitis, conjunctivitis, gamma-glutamyl transferase increased, blood creatinine increased, blood alkaline phosphatase increased, weight decreased, depression, and epistaxis.
The following adverse reactions have been identified during postapproval use of ZEJULA. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Blood and Lymphatic System Disorders:** Pancytopenia.

**Immune System Disorders:** Hypersensitivity (including anaphylaxis).

**Nervous System Disorders:** Posterior reversible encephalopathy syndrome (PRES).

**Psychiatric Disorders:** Confusional state/disorientation, hallucination, cognitive impairment (e.g., memory impairment, concentration impairment).

**Respiratory, Thoracic, and Mediastinal Disorders:** Non-infectious pneumonitis.

**Skin and Subcutaneous Tissue Disorders:** Photosensitivity.

**Vascular Disorders:** Hypertensive crisis.

**USE IN SPECIFIC POPULATIONS**

**8.1 Pregnancy**

**Risk Summary**

Based on its mechanism of action, ZEJULA can cause fetal harm when administered to a pregnant woman [see Clinical Pharmacology (12.1) of full prescribing information]. There are no data regarding the use of ZEJULA in pregnant women to inform the drug-associated risk. ZEJULA has the potential to cause teratogenicity and/or embryo-fetal death since niraparib is genotoxic and targets actively dividing cells in animals and patients (e.g., bone marrow) [see Warnings and Precautions (5.2) and Nonclinical Toxicology (13.1) of full prescribing information]. Due to the potential risk to a fetus based on its mechanism of action, animal developmental and reproductive toxicology studies were not conducted with niraparib. Apprise pregnant women of the potential risk to a fetus.

The background risk of major birth defects and miscarriage for the indicated population is unknown. 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.

**8.2 Lactation**

**Risk Summary**

No data are available regarding the presence of niraparib or its metabolites in human milk, or on its effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during treatment with ZEJULA and for 1 month after receiving the final dose.

**8.3 Females and Males of Reproductive Potential**

ZEJULA can cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1)].

**Pediatric Use**

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

**8.5 Geriatric Use**

In PRIMA, 39% of patients were aged 65 years or older and 10% were aged 75 years or older. In NOVA, 35% of patients were aged 65 years or older and 8% were aged 75 years or older. No overall differences in safety and effectiveness of ZEJULA were observed between these patients and younger patients but greater sensitivity of some older individuals cannot be ruled out.

**8.6 Renal Impairment**

No dose adjustment is necessary for patients with mild (CrCl ≥ 60 mL/min) to moderate (CrCl 30 to 59 mL/min) renal impairment. The degree of renal impairment was determined by creatinine clearance as estimated by the Cockcroft-Gault equation. The safety of ZEJULA in patients with severe renal impairment or end stage renal disease undergoing hemodialysis is unknown.

**8.7 Hepatic Impairment**

For patients with moderate hepatic impairment, reduce the starting dosage of niraparib to 200 mg once daily [see Dosage and Administration (2.4) of full prescribing information]. Niraparib exposure increased in patients with moderate hepatic impairment [total bilirubin >1.5 x upper limit of normal (ULN) to 3.0 x ULN and any aspartate transaminase (AST) level]. Monitor patients for hematologic toxicity and reduce the dose further, if needed [see Dosage and Administration (2.3) of full prescribing information].

For patients with mild hepatic impairment (total bilirubin <1.5 x ULN and any AST level or bilirubin <ULN and AST≥ULN), no dose adjustment is needed.

The recommended dose of ZEJULA has not been established for patients with severe hepatic impairment (total bilirubin >3.0 x ULN and any AST level) [see Clinical Pharmacology (12.3) of full prescribing information].

**17 PATIENT COUNSELING INFORMATION**

Advises the patient to read the FDA-approved patient labeling (Patient Information).

**Melody Fabulous Syndrome/Atlantic Fabulous Syndrome**

Advise patients to contact their healthcare provider if they experience weakness, feeling tired, fever, weight loss, frequent infections, bruising, bleeding easily, breathlessness, blood in urine or stool, and/or laboratory findings of low blood cell counts or a need for blood transfusions. This may be a sign of hematological toxicity or MDS or AML, which has been reported in patients treated with ZEJULA [see Warnings and Precautions (5.1)].

**Bone Marrow Suppression**

Advises patients that periodic monitoring of their blood counts is required. Advise patients to contact their healthcare provider for new onset of bleeding, fever, or symptoms of infection [see Warnings and Precautions (5.2)].

**Hypertension and Cardiovascular Effects**

Advises patients to undergo blood pressure and heart rate monitoring at least weekly for the first 2 months, then monthly for the first year of treatment and periodically thereafter. Advise patients to contact their healthcare provider if blood pressure is elevated [see Warnings and Precautions (5.3)].

**Posterior Reversible Encephalopathy Syndrome**

Inform patients that they are at risk of developing posterior reversible encephalopathy syndrome (PRES) that can present with signs and symptoms including seizure, headaches, altered mental status, or vision changes. Advise patients to contact their healthcare provider if they develop any of these signs or symptoms [see Warnings and Precautions (5.4)].

**Dosage Instructions**

Inform patients on how to take ZEJULA [see Dosage and Administration (2.2) of full prescribing information]. ZEJULA should be taken once daily. Instruct patients that if they miss a dose of ZEJULA not to take an extra dose to make up for the one that they missed. They should take their next dose at the regularly scheduled time. Each capsule should be swallowed whole. ZEJULA may be taken with or without food. Bedtime administration may be a potential method for managing nausea.

**Embryo-Fetal Toxicity**

Advises females to inform their healthcare provider if they are pregnant or become pregnant. Instruct females of the risk to a fetus and potential loss of the pregnancy [see Warnings and Precautions (5.5) and Use in Specific Populations (8.1)].

**Contraception**

Advise females of reproductive potential to use effective contraception during treatment with ZEJULA and for at least 6 months after receiving the last dose [see Use in Specific Populations (8.8)].

**Lactation**

Advises patients not to breastfeed while taking ZEJULA and for 1 month after the last dose [see Use in Specific Populations (8.8)].

**Allergic Reactions to FD&C Yellow No. 5 (Tartrazine)**

Advises patients that ZEJULA capsules contain FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons or in patients who also have aspirin hypersensitivity [see Warnings and Precautions (5.6)].

**ZICLIBS 03/2021**

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Nurses Collaborate to Improve Cancer Screenings in Rural Areas

Longer travel times and fewer available resources can make rural cancer care particularly challenging, but oncology nurses may play a crucial role in promoting screenings in these areas.

By Ellen Rice Tichich, MFA, MSN, RN, NPD-BC
Improving cancer screening in rural areas poses certain challenges not always seen in more populated settings. However, oncology nurses are adept at way-finding, particularly when the need is great. Early detection and treatment of cancer saves lives, yet for residents living in outlying and rural areas, risk factors for developing cancer tend to be greater than in urban areas, whereas screening rates are lower. Factors contributing to these disparities include differences in accessibility to care, lifestyle, culture, and financial stability.

The COVID-19 pandemic, which resulted in delays of care across the geographical spectrum, hit rural areas hard, as financial strain forced out some providers or led to closures of numerous clinics and hospitals. While the impact of the pandemic on cancer detection and treatment is not yet fully known, the need to improve screening in rural areas remains unquestionably urgent.

So what can be done to address this issue? To answer this question, Oncology Nursing News® spoke with several oncology nurses who took on the challenge to improve rural cancer screening. Their efforts are inspiring and underscore the value of collaboration, innovation, and determination.

Carol Estwing Ferrans, PhD, RN, FAAN, is professor emerita at the University of Illinois Chicago College of Nursing. She has coauthored numerous publications addressing rural cancer care, including an article with lead author Leslie Carnahan, MPH, PhD, on rural cancer disparities. She shared with us her experience and success improving cancer screening and early detection in the Chicago area and described disparities inherent in rural communities.

With grant money awarded from the National Institutes of Health (NIH), Ferrans and her colleagues set out to reduce late-stage breast cancer diagnoses, particularly among African American women in Chicago. “Fear is a huge barrier to screening,” Ferrans said. “When people are afraid of what screening may reveal, they are reluctant to participate. We addressed this barrier by producing a 14-minute video, ‘Beating Breast Cancer,’ featuring 5 beautiful African American women—all breast cancer survivors—telling their stories.”

The video, in addition to allaying fear, was created to clear up misconceptions pertaining to breast cancer and resonate with the intended target audience. As women responded to the cancer screening promotion, they were shown the video or provided the link to watch at home. The intervention worked. Thousands of women throughout Chicago responded, not only by completing cancer screening but also by following up as when recommended. The 5-year campaign and other such efforts were so successful, Chicago saw a 14% reduction in breast cancer death rates for African American women, more than any other major city in the US.

Motivated by the impressive results of the work done in Chicago, Ferrans has now shifted her attention to rural Illinois, where she will be working to reduce disparities alongside colleague Yamile Molina, PhD, MS, MPH, who is spearheading the effort and seeking additional NIH grant money. Regarding barriers to care in rural communities, Ferrans explained that the work they’ve done has shown 4 primary drivers of cancer disparities. Lack of insurance stands as a major factor. “We think about farmers with large farms, and [although] they may have wealth tied up in their farms, people in rural areas often struggle with collective poverty and no insurance,” Ferrans said. Migrant workers are another concern, as they often have language barriers and are also without insurance. Culturally, there is a rural reluctance to go on public aid or use government resources, making these issues tricky to address. For people with insurance, their deductibles are often too high or screening isn’t covered. Some make too much money for Medicaid but not enough for insurance and slip between the cracks.

Lack of cancer resources in the community, such as mammography centers and oncology specialists, poses another challenge. Clinic closures and consolidations further reduce screening and treatment access. “It’s difficult when few specialists are available. Wait times are long, [and] it might take 2 months to see a specialist or have an initial visit,” Ferrans said. “Delays in detection can advance cancer, setting up for later-stage diagnosis.”

Residents in rural communities may also face long travel times and associated fuel costs. Some have little or no time off from work or unreliable transportation.

The fourth disparity driver is fear, and although it’s not unique to residents in rural areas, it may be experienced differently. Rural residents may delay medical evaluation after finding symptoms, especially as COVID-19 continues to make its way through these communities. For many, the fear of cancer in addition to a COVID-19 diagnosis can be immobilizing.

“Nurses are making a difference. Nurses are doing what nurses do. They build relationships in the community, and they build trust. They fill the gaps. They understand the strength and value of family.”

Carol Estwing Ferrans, PhD, RN, FAAN
These barriers may seem insurmountable, but Ferrans was quick to point out the hope and good news. "Nurses are making a difference. Nurses are doing what nurses do. They build relationships in the community, and they build trust. They fill the gaps. They understand the strength and value of family," she said.

The same approaches used in urban areas can be used in rural settings when tailored and targeted for the community. These include personal engagement and communicating via phone, Zoom, and telehealth technologies. Residents in rural communities are used to communicating via these methods because of the distance factor, even more so since the pandemic. Ferrans suggests creating videos specifically for the rural audience and their concerns.

Nurses can guide people to resources, allay their fears, confront misconceptions, direct them to safety net resources, get them fast-tracked to medical care, and connect them to free or low-cost screening programs and diagnostic follow-ups. "Nurses are doing this work, we just need more," Ferrans said. "They have a unique role and the tools in their pocket. We have reason for hope."

Carnahan's work also focuses on rural disparities from a holistic approach, including working on Centers for Disease Control and Prevention (CDC)-funded programs for breast and cervical cancer screening and early detection and cancer prevention program evaluations for the Illinois Department of Public Health, and the development and implementation of a community engagement strategy for the forthcoming 2022-2027 Illinois Comprehensive Cancer Control Plan. She works in Chicago but maintains connections in the rural space and is working on a number of statewide evaluation projects. Through her work, Carnahan found that local programs often do not go far enough to address the financial disparities of underinsurance, but national programs are in place to help meet these gaps in coverage. The National Breast and Cervical Cancer Early Detection Program is one example.

"Nurses are positioned to facilitate the linkage between patients, programs, and resources," Carnahan said. In rural communities, some of the outreach and support services available provide transportation to screening services, which can address one of the barriers to care. When patients worry about who will pay for a biopsy if needed, nurses can discuss the different available resources and ensure patients’ financial concerns are addressed. Carnahan urges use of telehealth for risk assessment, for which primary care nurse involvement can be helpful.

Partnering with public health nurses and helping develop and sustain a strong nursing workforce will be vital as the fallout from COVID-19, including delayed screenings, becomes more evident.

Marsha Woodall, DNP, MBA, RN, is a professor and Nurse Administrator Division chair at Madisonville Community College in Kentucky. She is the lead author of an article on improving education and screening in a rural population.4 Her insight on improving cancer screening in rural settings demonstrates how impactful interventions can be when using a carefully targeted and tailored approach.

Woodall had participated in rural community outreach before, handing out pamphlets and informational brochures, signing up residents for screening, and chatting with community members during monthly events. Her booth featured a bagged cancerous lung that residents could see and touch, along with a walk-through depiction of a real colon with cancerous nodules. Although the approach was attention grabbing and engaging, follow-through was poor in response to screening tests handed out.

For her doctoral project, Woodall chose to employ a different and much more effective approach. She scheduled a meeting with the Madisonville mayor and asked for permission to visit every city department over 3 weeks to provide education about colorectal cancer. Focused on this target population, Woodall, along with a nurse navigator from Baptist Health Deaconess Madisonville, educated 193 city employees at the sewer plant, trash, water, and electric departments. Sessions were scheduled to align with department meetings during day, evening, and night shifts, making it convenient for employees to attend. They provided basic education and written materials about colon cancer.

"They seemed to really be engaged," Woodall said. "A few shared stories of a relative or friend that had been diagnosed with colon cancer and spoke out about the importance of screening."

Half the attendees took home fecal immunochemical tests provided by the oncology nurse navigator, which detect occult blood in the stool. Twenty-nine submitted their tests, a return rate double that of the earlier community booth event. Eight tests were positive and were referred for follow-up.

Woodall encourages nurses to make it easy for rural residents to learn about cancer and participate in cancer screening. "Make it as hassle free and convenient as possible," she said. She also stresses the importance of collaboration.

"It takes a team effort, but increasing cancer screening in rural communities is absolutely doable by utilizing a targeted approach and exercising persistence."  Ellen Rice Tichich, MFA, MSN, RN, NPD-BC, is a health care writer and board-certified nursing professional development specialist.

Research has identified 4 primary drivers of cancer disparities in rural areas

1. Lack of insurance
2. Cultural reluctance to go on public aid or use government programs
3. Lack of cancer resources
4. Fear of cancer

References are available on OncNursingNews.com.
Daratumumab-Lenalidomide-Dexamethasone Combination May Become Preferred Treatment for Transplant-Ineligible Patients With Newly Diagnosed Multiple Myeloma

Because of the favorable efficacy and safety profiles of daratumumab plus lenalidomide and dexamethasone, investigators speculate that the combination may become the new standard of care in multiple myeloma treatment.

By Darlene Dobkowski, MA

Recent findings showed that older patients with newly diagnosed multiple myeloma demonstrated superior progression-free survival (PFS) and overall survival (OS) when treated with daratumumab (Darzalex) plus lenalidomide (Revlimid) and dexamethasone (D-Rd) compared with lenalidomide and dexamethasone (Rd).

The presentation at the International Myeloma Society’s 18th International Myeloma Workshop, held September 8 to 11, 2021, in Vienna, Austria, focused on updated efficacy and safety data for D-Rd compared with Rd at a median follow-up of nearly 5 years in the phase 3 MAIA study (NCT02252172). The updated results, part of a prespecified interim OS analysis, followed a primary analysis that occurred at a median follow-up of 28 months.

“Those results, when looking at D-Rd, both for PFS and OS and a relatively good safety profile, I would say, are now establishing D-Rd as a new standard of care for patients who are not transplant eligible,” said Philippe Moreau, MD, professor of clinical hematology at University Hospital Hôtel-Dieu in Nantes, France, in a presentation of the findings.

Investigators analyzed data from 737 patients with newly diagnosed multiple myeloma. These patients were ineligible for high-dose chemotherapy and autologous stem cell transplantation because of their age (>65 years) or the presence of comorbidities. Patients were randomly assigned to receive D-Rd (n = 368) or Rd (n = 369). Patients had a median age of 73 years (range, 45-90 years). The primary end point was PFS, with key secondary end points including OS, among others. Longer treatment times resulted in much greater differences in PFS between the D-Rd and Rd groups.

There was no significant difference in median PFS between D-Rd and Rd among patients either treated for either less than 9 months or treated for 9 to 18 months (P = .3579 and P = .2480, respectively), but D-Rd produced a robust benefit in patients treated longer than 18 months (median PFS not reached and 54.8 months, respectively; HR, 0.57; 95% CI, 0.43-0.76; P < .0001). The 5-year PFS rates among patients treated longer than 18 months were 64.4% and 44.6%, respectively.

At a median follow-up of 56.2 months, the D-Rd group had a significant 32% reduction in the risk of death compared with the Rd group. Median OS was not reached in either group (HR, 0.68; 95% CI, 0.53-0.86; P = .0013). The estimated 5-year OS rate was 66.3% in the D-Rd group compared with 53.1% in the Rd group. Median PFS was not reached in the D-Rd group, whereas those assigned to Rd had a median PFS of 34.4 months (HR, 0.53; 95% CI, 0.43-0.66; P < .0001).

The investigators found that patients in the D-Rd group tended to remain on treatment longer than those in the Rd arm, with median treatment durations of 47.5 months and 22.6 months and with 42% vs 18% of patients remaining on study treatment, respectively. Patients in the D-Rd arm were less likely than the Rd arm to discontinue because of disease progression (27% vs 34%) or adverse events (AEs) (13% vs 23%). Longer follow-up did not result in new safety concerns. The most common grade 3 or 4 treatment-emergent adverse event AE was neutropenia, occurring in 54.1% of patients in the D-Rd group and 37.0% in the Rd group.

References are available on OncNursingNews.com.
Adding Pembrolizumab to Chemotherapy May Be New Standard of Care for Frontline Treatment of Advanced Cervical Cancer

Data presented at the ESMO Congress 2021 suggest that pembrolizumab in addition to chemotherapy with or without bevacizumab may become new standard of care in the frontline setting of cervical cancer treatment.

By Kristi Rosa

Adding pembrolizumab (Keytruda) to chemotherapy with or without bevacizumab (Avastin) was shown to effectively improve survival rates among patients with persistent, recurrent, or metastatic cervical cancer in the phase 3 KEYNOTE-826 trial (NCT03635567). Data from the trial’s first interim analysis were presented as part of the Presidential Symposium during the European Society for Medical Oncology Congress 2021, held September 16 to 21, 2021.

Platinum-based chemotherapy has been the standard treatment for patients with persistent, recurrent, or metastatic cervical cancer, with the preferred regimen being platinum-based chemotherapy, paclitaxel, and bevacizumab. Although prior studies have demonstrated the efficacy of PD-1 inhibitors, such as pembrolizumab and cemiplimab (Libtayo), as monotherapy in patients with previously treated cervical cancer, no data have been available regarding whether the addition of a PD-1 inhibitor to chemotherapy, with or without bevacizumab, would improve outcomes. To this end, investigators launched the double-blind KEYNOTE-826 trial, which enrolled patients with persistent, recurrent, or metastatic cervical cancer that was not amenable to curative treatment.

In the subset of patients with a PD-L1 combined positive score (CPS) of 1 or higher, the median progression-free survival (PFS) in the investigative (PEM) and control (PBO) arms was 10.4 months (95% CI, 9.7-12.3) vs 8.2 months (95% CI, 6.3-8.5), respectively (HR, 0.62; 95% CI, 0.50-0.77; P < .001). Median overall survival (OS) was not reached (NR) vs 16.5 months (95% CI, 14.5-19.4) with placebo (HR, 0.67; 95% CI, 0.54-0.84; P < .001).

In the group of patients who had a PD-L1 CPS of 10 or higher, the median PFS with pembrolizumab plus chemotherapy with or without bevacizumab was 10.4 months (95% CI, 8.9-15.1) vs 8.1 months (95% CI, 6.2-8.8) with chemotherapy with or without bevacizumab (HR, 0.58; 95% CI, 0.44-0.77; P < .001). The median OS was also NR (95% CI, 19.1-NR) in the PEM arm vs 16.4 months (95% CI, 14.0-25.0) in the PBO arm (HR, 0.61; 95% CI, 0.44-0.84; P = .001).

“Adding pembrolizumab to chemotherapy with or without bevacizumab provides statistically significant, clinically meaningful improvements in PFS and OS in patients with persistent, recurrent, or metastatic cervical cancer. The significant benefit was observed in all primary analysis populations and was generally consistent across protocol-specified subgroups,” lead study author Nicoletta Colombo, MD, director of the Gynecologic Oncology Division at the University of Milan-Bicocca in Milan, Italy, stated in a presentation of the findings. “Data from KEYNOTE-826 suggest that pembrolizumab plus platinum-based chemotherapy with or without bevacizumab may be a new first-line standard of care for the treatment of patients with this disease.”

Eligible patients had an ECOG performance status of 0 or 1 and could not have previously received systemic chemotherapy. Prior radiotherapy and chemoradiotherapy were allowed. A total of 617 participants were randomized 1:1 to receive pembrolizumab at 200 mg every 3 weeks for up to 35 cycles plus paclitaxel and cisplatin or carboplatin every 3 weeks for up to 6 cycles with or without bevacizumab at 15 mg/kg every 3 weeks (n = 308). The PBO arm (n = 309) received the same regimen, but with placebo instead of pembrolizumab. Patients in both arms had the option of adding bevacizumab to their regimen, and 63.1% received this drug. Stratification factors included metastatic disease at diagnosis (yes vs no), PD-L1 CPS (<1 vs ≥10), and planned bevacizumab use (yes vs no). The dual primary end points of the study were investigator-assessed OS and PFS per RECIST v1.1 criteria; secondary end points comprised overall response rate, duration of response, 12-month PFS, and safety. Patient-reported outcomes were evaluated using the EuroQoL EQ-5D-5L Visual Analog Scale score and served as an exploratory end point. In the all-comers population, the median age between the arms was 50.5 years (range, 22-82). Moreover, 43.3% of patients had an ECOG performance status of 1, 72.3% had squamous cell disease, and 48.3% had previously received chemoradiation or radiation.

The safety profile of the pembrolizumab regimen was manageable. The rates of all-cause and treatment-related grade 3 or higher and serious adverse events (AEs) were all numerically greater in the immunotherapy-containing arm. However, patients receiving pembrolizumab were generally on treatment longer than those receiving placebo, said Colombo. The most frequent all-cause AEs of any grade reported on the PEM and PBO arms included anemia (61.2% vs 53.4%, respectively), alopecia (56.4% vs 57.9%), nausea (39.7% vs 43.7%), diarrhea (35.5% vs 29.8%), and fatigue (28.7% vs 27.2%), among others. The most common immune-mediated AEs of any grade were hypothyroidism (18.2% vs 9.1%, respectively) and hyperthyroidism (7.5% vs 2.9%).

“Approximately one-third of patients on the [PEM] arm discontinued any treatment component due to an AE,” Colombo said. “The incidence of AEs leading to death was similar in the treatment arms. The incidence of immune-related AEs was higher in the [PEM] arm.”

References are available on OncNursingNews.com.
The Oncology Nurse’s Role in Preparing Patients and Caregivers for Postoperative Recovery

As minimally invasive surgery for lung cancer increases in popularity, more patients are recovering at home, expanding the need for personalized caregiver education.

By Linda Childers

Although surgery is an option for some patients with lung cancer, unmet needs related to postoperative recovery can negatively affect a patient’s quality of life and increase the family caregiver’s burden, explained Virginia Sun, PhD, MSN, RN, associate professor in the Division of Nursing Research and Education at City of Hope, a cancer research and treatment organization near Los Angeles, California.

To address these needs, Sun and her colleague, Jae Kim, MD, assistant professor and chief of the Division of Thoracic Surgery at City of Hope, launched a 5-year study in 2018 focusing on how to best support family caregivers after a loved one has undergone surgery for lung cancer.

Sun and Kim developed the study after working on a previous research project that showed although standard intervention and education methods, such as videos and printed materials, were helpful for patients, they weren’t as helpful for caregivers.

Sun’s study examines the differences between a caregiver control arm that receives traditional education materials and one that receives these materials as well as face-to-face sessions with an oncology nurse to help address specific patient and caregiver needs and problems.

Although some oncology centers have nurse navigators that work with family caregivers, that isn’t the case with all medical centers. Sun said it’s important for all oncology nurses to ensure good outcomes for patients with lung cancer by ensuring their caregivers are well prepared.

With an increase in minimally invasive surgery for lung cancer, the length of hospital stays has decreased, with patients now typically spending 2 to 3 days in the hospital after minimally invasive surgery. Although many patients prefer to recover at home, Sun said when caregivers aren’t adequately prepared, patients with lung cancer can experience complications that result in being readmitted to the hospital.

Caregiver preparation often consists of videos and print materials developed by groups, such as the American Society of Clinical Oncology. Although those resources are informative, caregivers often need more personalized support, Sun said.

“Oncology nurses can help families and family caregivers by simply asking them about their needs and how they are doing,” she said. “Many family caregivers report they’ve never been asked about their needs. A simple question can lead to improved assessment, provision of relevant information, and referrals for support to families.”

Sun recommended that oncology nurses determine who will be the primary family caregiver for a patient, and whether there will be more than 1 family member taking on this role, and assess their knowledge needs and caregiving preparedness. “Most family members are interested in how they can better prepare for the day of surgery and the recovery process, and what to expect during these times,” Sun said. “If possible, nurses can think about how we can best use the preoperative period to educate and prepare families for what’s ahead and also encourage caregivers to think about their own self-care plan, as many family caregivers may be coping with their own illness.”

Empowering Caregivers

Shayne Cardozo, RN, nurse coordinator for the thoracic surgery and oncology clinic at the University of California, San Francisco Health, works with many patients with lung cancer and their family caregivers and strives to give them the information and support they need after they’re discharged from the hospital.

“The quality of life for these patients with lung cancer should be the same or better after surgery,” Cardozo said. “We stress an active recovery where, after receiving approval from their doctor, they engage in walking and deep breathing exercises. The more they can do, the faster they will recover.”

In addition, Cardozo demonstrates how to properly use devices, such as an incentive spirometer, so patients can expand their lungs to help them breathe more deeply and fully. Doing this, as well as regular breathing and coughing exercises, also helps patients to keep their lungs active during their recovery and prevents complications, such as pneumonia.

Cardozo also works with patients to develop a personal plan to treat postsurgery pain and address common adverse events, such as constipation caused by pain medications. “At-home patients tend to fall behind on their pain medications,” she said. “Many are fearful they will become addicted to pain medications, so it’s important to let them know prescription opioids are generally safe when prescribed by their doctor and taken for a short period of time.”

Cardozo sees the role of a family caregiver as that of a personal trainer who offers encouragement and support to their loved ones by ensuring they follow postoperative instructions, take their medications, and practice breathing exercises. She also advises caregivers to call her in the event they have questions or if their family member experiences a fever, discharge from the incision site, chest pain, or shortness of breath.

Sometimes the most important tool that oncology nurses can provide is reassurance. “Caregivers need to feel empowered that they are part of the health care team and have the tools and answers in place to care for their loved one,” Cardozo said.

References are available on OncNursingNews.com.
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Involvement in clinical trials and referrals for patient enrollment are factored into the standard regimen of care for oncology advanced practice providers (APPs) associated with academic centers and large cancer institutions. However, for those in the community setting, several barriers to clinical research prevent APPs and their patients from taking part in experimental therapies.1

According to data from the American Society of Clinical Oncology’s (ASCO) annual Practice Census, the number of oncology practices in the United States that have reported employing APPs increased from 52% in 2014 to 81% in 2017.2 3 A collaborative effort of ASCO, the American Academy of Physician Assistants, the Association of Physician Assistants in Oncology, the Advanced Practitioner Society of Hematology and Oncology, and the Oncology Nursing Society led to the identification of 5350 oncology APPs practicing in the United States, with the possibility of that number being close to approximately 7000.

APPs are involved in various aspects of care including roles as nurse practitioners (NPs), physician assistants (PAs), and other licensed, nonphysician providers such as clinical nurse specialists, certified nurse midwives, and certified registered nurse anesthetists.2 NPs are regulated and licensed by state nursing boards, although requirements for recertification and continuing education vary.4 Furthermore, approximately half of states authorize NPs to independently practice without the need for oversight,5 6 and all states grant full prescriptive authority for NPs.5 Additionally, PAs are also regulated by state medical boards and must practice with a supervising physician, with extent of physician supervision varying by state.6 7 PAs are able to write prescriptions in all states.8

**APPs In Clinical Trials**

APPs associated with institutions often fill roles in clinical trials as primary investigators (PIs), subinvestigators, study coordinators, and/or in the delivery and monitoring of therapies for patients. Results from a 65-item survey of attitudes, beliefs, and roles of oncology APPs in clinical research that was distributed via the Association of Community Cancer Centers (ACCC) demonstrated that oncology APPs are engaged and interested in clinical trials, and believe clinical research is important to improve care. However, they may not be used to their full scope.9 Barriers include a lack of time, inadequate awareness of clinical trials, and underrepresentation on research committees. Recommendations for realizing the potential of APPs include research-related education, more complete integration as a member of the multidisciplinary cancer care team, and federal and state policy and regulatory changes.

“I work with 1 other oncologist, and we keep a portfolio of our available trials,” shared Christa Braun-Inglis, MS, APRN, FNP-BC, AOCN, of the University of Hawaii Cancer Center in Honolulu, in an interview. “I’ll see a patient for treatment counseling, and I’ll assess whether or not [a patient is] eligible for either a treatment trial or symptom management trial that we have available. [The oncologist and I] have this workflow where she will introduce the trial during the consult and then I’ll pick up from there during the treatment counseling, and I will decide whether or not they are eligible and interested in enrolling in the trial.”

Braun-Inglis, who is the primary author of the study and an oncology NP, emphasized that her experience with clinical trials and clinical research has been in the community setting at the University of Hawaii Cancer Center. She explained that she functions within the National Cancer Institute (NCI)-sponsored Community Oncology Research Program, where she is PI on several quality-of-life, symptom control cancer care delivery protocols.

She also noted that she provides clinical support to the research coordinators.

Laura J. Zitella, MS, RN, ACNP-BC, AOCN, of the University of California San Francisco Helen Diller Family Comprehensive Cancer Center, said she works at an academic medical center with a very robust clinical trials program. “My primary role is the clinical care of patients, and in that role I take care of patients who are receiving standard-of-care treatments,” Zitella said. “But I also take care of patients who are enrolled in clinical trials. I am a subinvestigator on clinical trials that are related to the patient population that I care for.”

Zitella, a hematology/oncology NP, said she includes clinical trials in treatment discussions with patients and communicates with the primary trial investigator and the clinical research coordinator to enroll patients in trials. “I am involved with consenting and performing research procedures, and ordering study drugs, and all of the other processes that go along with being [enrolled in] a clinical trial,” she said. “It’s very common for APPs at academic medical centers to be involved with clinical research and to be subinvestigators on clinical trials for the patient population that they take care of.”

Lisa A. Kottschaide, MSN, APRN, CNP, an NP at Mayo Clinic in Rochester, Minnesota, said, “Oncology APPs can play a number of roles in clinical research. Some things that come to mind include patient recruitment and management on clinical trials [or] serving as principal investigators on certain trials and coinvestigators. Additionally, APPs can participate in NCI cooperative groups and institutional research committees. I belong to our cancer center’s scientific review committee and our data safety monitoring board.”

**Current Challenges for APPs**

In the community setting, Braun-Inglis noted that very few APPs are enrolling their patients in trials even though they can do so for trials...
in the symptom management/quality-of-life cancer care delivery space. Based on the survey findings, over 70% of APPs would like to have a larger role in clinical research (Figure 2). “I want us to really participate to the extent that our licensure, our scope, and our role within our institutions will allow,” she said.

Braun-Inglis also emphasized that there is no formal training available for APPs at this time, but access to initiatives could be beneficial in 4 areas:

- How to assess a patient for a trial in everyday practice
- How to become a good investigator and follow good clinical practice
- How to review a study protocol for feasibility and scientific integrity
- How to play a role in protocol development and leadership

This year, the Advanced Practitioner Society for Hematology and Oncology (APSHO) launched a research and quality task force to identify needs within the APP community, with a goal to develop curricula that APPs can access. “We still see only 3% to 5% of adult oncology patients going on trials,” Braun-Inglis said. “Here we are, a group of health care providers that has grown exponentially in the last 10 years. We are not being routinely engaged in this process. I think the interest is there; now [the question is]: How do I do this at my practice?”

Zitella noted that an area of opportunity for oncology APPs is to be educated and aware of clinical trials and to be able to discuss them as a potential treatment option for patients. “There are a number of organizations trying to increase awareness and education about clinical trials for APPs, including APSHO and ACCC,” she said. “I think that if people are involved with professional organizations, go to meetings and network with other oncology APPs, and hear about what other people are doing...that makes a difference.”

**APPs Can Shape the Future of Clinical Trials**

Currently, APPs are not able to order drugs or treatments for Cancer Therapy Evaluation Program (CTEP)-sponsored trials or any drug that holds an investigational new drug application, all of which contribute to a substantial barrier in practice.

In September 2020, the NCI developed a guideline that allows APPs to sign for drugs.
for nontreatment trials. “Even though there is that guideline that exists now, it’s still fuzzy,” Braun-Inglis explained. “You meet barrier after barrier. Our whole platform is to allow us to practice at the top of our licensure and scope within the realm of trials and not have the trial or the sponsor of the trial limit our practice. I’m hoping in the next couple of years or even a year that we’re going to see the changes come from the CTEP-sponsored trials. My real push is to make APPs leaders for other trials because we do all those things every day. There is no reason that we shouldn’t have a significant amount of involvement.”

Zitella said there has been a significant shift in the past year because the NCI clarified some of the responsibilities of nonphysician investigators. “All cooperative groups now have nursing committees, and I think that we are going to see more progress in integrating APPs into those roles,” Zitella said. “I think the other area where we’re going to see a lot of progress is integrating the patient; this is a key element for the future of clinical trial design. Academic medical centers, professional organizations, cooperative groups, and the NCI are really trying to partner with community oncology practices to make it easier and more feasible to conduct clinical research and to have them be a part of clinical trials.”

Kottschade noted that clinical trials in oncology are often the best option for patients for treatment, and in some cases, the only option and that APPs will affect the extent to which clinical trials are leveraged in the community setting. “The use of APPs in the community setting will expand access for patients to be enrolled on clinical trials, through increased awareness, education, and access,” she said.

Braun-Inglis added, “I would love for APPs to take a look at their practice, look at the clinical research available in their practice, and really evaluate [how they can be] practicing at the top of their scope and licensure.”

Zitella emphasized the importance of always considering clinical trials as treatment options. “Even if you don’t work in clinical trials, being aware of them, knowing where to find them and feeling comfortable discussing them with patients, is really important because patients are relying on us for our opinion and for our knowledge,” she said.

References are available on OncNursingNews.com.

Cancer Care Costs US Billions—Mostly in Drug Expenses

Medication is the biggest expense for breast, lung, lymphoma, and colorectal cancers.

By Todd Shryock

Pennsylvania State University College of Medicine investigators have found that the 15 most prevalent types of cancer in the US cost approximately $156.2 billion in 2018, with medication representing the biggest expense for breast, lung, lymphoma, and colorectal cancers.

The investigators examined a database that included statistics on cancer care for the 402,115 privately insured patients with cancer below the age of 65 in the US. The aim of the study was to gather data to help understand how money is being spent on cancer care, which has traditionally been difficult to track, mainly because the US has different ways to cover health care costs, such as private insurance for people younger than 65 years of age and Medicare for people 65 and over.

“Cancer is a leading cause of death, actually overtaking heart disease as the leading cause of death in the US over the past few years,” said Nicholas Zaorsky, MD, MS, researcher and assistant professor from the departments of radiation oncology and public health sciences at Penn State Cancer Institute, in a statement. “But it’s still unknown what we pay for in cancer care. As a team, we wanted to look at what private insurances are paying for each kind of cancer and for each type of service.”

The investigators assessed a database that included 38.4 million types of Current Procedure Terminology codes for the 15 cancers, including breast, prostate, colorectal, lung, lymphoma, melanoma, uterus, head and neck, bladder, kidney, thyroid, stomach, liver, pancreas, and esophagus cancers. The cohort study used 2018 data, the most recent complete numbers available, from the IBM Watson Health MarketScan.

The sample included 27.1 million privately insured individuals, including patients with the most prevalent cancers.

Breast cancer incurred the most services, about 10.9 million services and procedures, followed by colorectal cancer, which had approximately 3.9 million services listed in the database. Breast cancer was also the most expensive type of cancer, costing a total of $3.4 billion, followed by lung cancer and colorectal cancer, which were both estimated to incur around $1.1 billion in costs.

Drug costs represent the most expensive category for treating patients with cancer. Approximately $4 billion was spent on cancer related drugs, which is twice the $2 billion spent on surgeries. Other direct costs included diagnostic tests, hospital fees, and physician fees.

Pathology and laboratory tests accounted for the highest number of services performed in the study, although the drug therapies cost more than these services.

Investigators noted that these figures highlight discrepancies between the spending associated with different types of cancer but does not offer an explanation to justify these variations.

For example, pancreatic cancer is one of the deadliest cancers, yet the total cost of care devoted to pancreatic cancer is relatively low compared with indolent prostate cancer.

Future research should seek to determine which services are of the most and least value to patients, factors/parameters, etc, that may or may not be directly correlated with higher costs. Furthermore identifying areas of high out-of-pocket costs will also be an important part of reshaping policy to ease patient burden and improve quality of life for patients with cancer.

REFERENCE
Transitions in care can be a complicated process for a patient with cancer. Comprehensive programs are needed to help engage patients and their families on multiple levels and always ensure safe care.

The University of Texas MD Anderson Cancer Center, a National Cancer Institute-designated comprehensive cancer center, takes great pride in its ability to respond to patients who are most in need. Therefore, MD Anderson created a comprehensive call center available 24/7 to improve the patient experience. The comprehensive program seeks to utilize the right level of staff at the right time with the right service. This has been created through “askMDAnderson,” a comprehensive call program designed by patients for patients, which is staffed with operators, health information specialists, nurses, and associated providers to address each level of care.

AskMDAnderson also increases patient satisfaction by providing discharge phone calls for all patients discharged from inpatient, outpatient surgery, and the emergency department.1

Different Levels of Service
The operators represent the first level of service. This team handles over $1 million worth of calls per year. Operators provide patients and families with directions, visitor guidelines, parking details, meal distributions, COVID-19 testing, password reset assistance, code blues, and merit call at all locations. They keep patients and families informed of the most updated information to ensure confidence throughout their cancer journey.

The second level of service is the health information team and referring provider team. These teams are designed to ease the referral process. Patients and referring physicians can call whenever they want, and the staff gladly walks them through the referral process, discusses research protocols, and estimates when the person will be seen by a physician. These teams provide a critical information link to prospective patients and their family members for all transitions in care needs, as well as education about MD Anderson’s services, programs, treatments, and clinical trials to prospective patients, families, and health care providers. They also assist patients in assessing the electronic medical record and video visit or any electronic medical record inquiry.

Houston is a very competitive market, and although patients want the best cancer center nationally, they want quick service as well. This team assists 2500 referrals each month and is available 24/7.

Patient Care During the COVID-19 Pandemic
The COVID-19 pandemic resulted in strict visitor restrictions, mandated testing and/or quarantine for patients, trepidation of coming to the emergency center or hospital, and panic among those with fever, coughs, or sore throats. These are all symptoms of COVID-19, but they are also sequela of medical treatments for chronic illnesses, such as cancer. Consequently, AskMDAnderson became a vital source of information and education for patients and their families in real time. Timely answers to questions and education about safety procedures and symptom triage has allayed fears and helped make patient visits efficient and effective.

Two new clinical programs were launched in 2019. These included discharge phone calls after all inpatient, outpatient, and emergency department visits and an After Hours Clinical Support program, which is designed to help the patient and physicians on call after the centers have closed. In the current COVID-19 era, the askMDAnderson clinical team became available 24/7.

Due to the complexity of clinical presentation and limited provider-based resources, patients with cancer and their families often telephone their physician or cancer clinic to seek advice.2 Furthermore, when patient care shifts from an inpatient to outpatient setting, there is need for oncology nurses to not only know about disease processes and clinical patient care but also be skilled in telephone nursing triage.3 The After Hours Clinical Support enables patients to speak with a nurse when clinics are closed, rather than paging a provider and waiting for a call back. These clinically trained nurses manage patient issues and concerns that are within their scope, but they will also refer issues to the provider when necessary.

Research has shown activities like these elevate the quality of care patients receive.4,5 Such activities also lower the overall costs of care of an organization and protects the time and capacity of emergency centers and hospitals to care for their most critical patients.6,7 This results in a safer, more efficient, less expensive, and better experience for patients.

In the initial 6 months of the new program, specific clinical services provided feedback about the algorithms utilized to determine when to page the physician on call. Despite the need to change some of the algorithms, incremental improvements were already seen in readmission rates, which decreased by 1%. In addition to care coordination, working to protect the health of a uniquely vulnerable cancer population, the cancer network was able to share best practices for entrance screening, critical patient surge preparations, telehealth visit transitions, and personal protective equipment use.

Cancer care cannot stop during a pandemic. Furthermore, the amount of information patients need to successfully navigate their cancer journey can be daunting. Programs like the askMDAnderson call center help alleviate some patient stress and provide critical information. Broad implementations of similar programs may help facilitate easier navigation across health access barriers moving forward.

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References are available on OncNursingNews.com.
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