Geriatric Assessment, Multidisciplinary Model is Focus of FITNESS Study in Older Adults

he Cancer and Aging Resiliency Clinic—or CARE Clinic at the Ohio State University Comprehensive Cancer Center Arthur G. James Cancer Hospital and Richard J. Solove Research Institute ("The James") is one of only a few hospitals in the nation that provides a unique model of care for older patients with cancer.

The CARE Clinic opened in February 2017 for patients age 65 and older with blood cancer and later expanded to serve patients with solid tumor cancers, such as breast and lung cancers. The clinic is part of the Cancer and Aging Research Group, which joins geriatric oncology researchers in a collaborative effort to design and implement clinical trials to improve the care of older adults with cancer.¹

The care model at The James pairs patients with a multidisciplinary healthcare team who not only review cancer-specific treatment but also assess patients for balance, cognition, hearing, nutrition, medications, symptom management, emotional health, and social issues such as caregiver and safety concerns and financial constraints—all in one visit.

Novel Aging Research and the Multidisciplinary Healthcare Team

The CARE Clinic incorporates novel aging research with subspecialty evaluations by a nurse, pharmacist, case manager, nutritionist, physical therapist, audiologist, and physician to care for patients. One study, the FITNESS study, aims to obtain a Answering the larger question of how to remedy the exclusion of older adults from meaningful cancer research is a crucial aim of the CARE Clinic. Many cancer-related clinical trials have upper age limits or disqualify people for other conditions that older people might have.

better understanding of how seniors age 60 and older tolerate treatments for lung and other cancers and determine which treatments result in worsening disability and functional decline.

"Typically, people arbitrarily pick 65 because that's when you're eligible to enroll in Medicare, but we know that there are some participants who are in their early 60s who chronologically would feel young but physiologically they're much older," Dr. Carolyn Presley, MD, MSH, said. "What is it about the person that can give us an idea of their health status rather than just looking at how old they are?" Dr. Presley is a thoracic geriatric oncologist board certified in both geriatrics and medical oncology. She and hematologist Ashley Rosko, MD, are co-directors of the FITNESS study, which began accruing patients in September 2018. Dr. Presley leads research and clinical teams for the lung cancer cohort, both of which focus on older adults with lung cancer. Dr. Rosko leads the hematology cohort.

The team at the CARE clinic uses the geriatric assessment tool developed by the late Arti Hurria, MD, a leader in geriatric oncology who advanced the specialty field and was a mentor to both Dr. Presley and Dr. Rosko.² The tool is fairly easy to implement into routine oncology care because it is primarily survey based, Dr. Presley said.

Patients in the study fill out a questionnaire about such things as whether they have had any falls, have memory impairment, need help getting dressed, or need help managing their medication. They also do exercises to test their balance and monitor the speed of their gait.

"The study is novel in that it's doing the geriatric assessment at longitudinal time points, or more than one time point, during their treatment," Dr. Presley said. "It's a minimum of at least two times. It could be up to four times, depending on how long they're in the study."

Researchers also will collect blood and stool samples to look at biomarkers of aging and bacteria in the gut microbiome that could be associated with how well treatment is tolerated and how the tumor actually responds to the treatment, Dr. Presley said.

"We really follow them [older patients] more closely for symptoms and side effects and measuring the impact on their daily life more often than we routinely ask about in cancer care," she said. "But we know that living through treatment affects older adults much differently than younger adults, and that's part of what we're trying to understand in this study."

"Most of the study generated in clinical trials that led to the approval of a lot of these newer, super exciting cancer drugs were tested in younger, healthier individuals, and basically everybody now with lung cancer will probably get immunotherapy or targeted treatment, either in place of or in addition to chemotherapy," Dr. Presley said. "But we really don't have a lot of data on how these drugs are tolerated and how the cancer responds to these drugs in older individuals."

Patients have been very open to having a geriatric assessment done. "They want to talk about a lot of these things that we might not necessarily have time to talk about or think that they want to talk about, such as mood, anxiety, depression, mobility, or falls," Dr. Presley said. The study "gives patients the opportunity to talk about those issues."

Doctors are able to ask more questions, which gives them more awareness of what's happening with their patients. "Symptoms are definitely an issue, and balance is another factor that we're able to look at more closely," Dr. Presley said.

Her hope is that the care team "is able to catch side effects earlier and that treatment decisions will be made based on more of the lived experience of getting treatment for lung cancer." "We've encountered some significant toxicities that have resulted in either ending or changing treatment earlier than we would have otherwise," she said. "We are avoiding the worsening of a side effect or we're trying to prevent an irreversible toxicity from these treatments."

For patients in the study, Dr. Presley said that providers are able to capture data earlier, because they are asking patients questions more tailored to older adults: "It's not, 'Do you have nausea, vomiting, diarrhea?' It's a much more nuanced approach."

Study accrual will end in another year, and some results will be available within the next 18 to 24 months.

Breaking Down the Trial Barrier for Older Adults

Answering the larger question of how to remedy the exclusion of older adults from meaningful cancer research is a crucial aim of the CARE Clinic. Many cancer-related clinical trials have upper age limits or disqualify people for other conditions that older people might have.³⁻⁵

"There are two problems: Clinical trials are selecting for the healthiest individuals. If you have any issues with a comorbidity, you are much more likely to be ineligible, and they require a lot more work. There are so many hoops to jump through to get into a clinical trial. For most, it's not worth it because it is a significant time and energy burden for people who already do not feel well," Dr. Presley said. "Those are two things that we were purposefully very mindful about in our studies, so that it doesn't require extra visits. It's all pretty much done the same day that they come in for their regular appointment and treatment, and the inclusion criteria are relaxed, meaning you don't have to be, essentially, a marathon runner to be in the study."

"We have to make it easier, not only for older adults but just for people who don't feel well to get onto clinical trials because we don't think about the treatment burden, the work of the patient that it requires to be in a clinical trial," she continued. "Until we actually address that and relax the inclusion criteria, we're going to continue to exclude older adults from clinical trials."

A Continuing Commitment to Improving Care

The James is continually seeking ways to improve care delivery for their older patients with cancer. The healthcare team at the CARE Clinic has recently initiated a simple yet effective measure to help patients manage their medications by distributing pill boxes.

Early in 2019, Dr. Presley sent her nursing staff to a conference specifically focused on geriatric oncology for oncology nurses. The conference is part of an R25, National Cancer Institute-funded grant, in coordination with the Cancer and Aging Research Group. When they came back, nursing staff took the initiative to develop an "older adult" binder specific to lung cancer.

The James is in the process of building a specific onco-geriatrics program. "That's how dedicated we are to cancer and aging research, and cancer and aging clinical care, because this is really the future of cancer care," Dr. Presley said. "Yes, we can develop all these new, exciting medications and other cancer treatments, but at the end of the day, it's going to be a different story in older adults versus younger adults, and we are very committed to improving the care of older adults with all types of cancer."

"As a healthcare system, just because we treat a lot of patients who are older does not necessarily mean we are good at it. We have a long way to go," she said. "I would really encourage people to try to learn more about the major issues that are affecting older adults. I would say the big issues, at least in cancer, are pain, mood, falls, and polypharmacy, and those are just four main issues, but we have a lot of work to do. We embrace anyone who wants to get involved in that work at Ohio State."

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References

1. Cancer & Aging Research Group. Available online at: mycarg.org. Last accessed August 21, 2019.

2. Piana R. Leader in geriatric oncology, Arti Hurria, MD, FASCO, dies at age 48. Available online at: ascopost.com/issues/november-25-2018/ leader-in-geriatric-oncology-arti-hurria-dies-at-age-48. Published November 25, 2018. Last accessed September 12, 2019.

3. Span P. The clinical trial is open. The elderly need not apply. Available online at: nytimes.com/2018/04/13/health/elderly-clinical-trials. html. Published April 13, 2018. Last accessed September 12, 2019.

4. Singh H, Kanapuru B, Smith C, et al. FDA analysis of enrollment of older adults in clinical trials for cancer drug registration: a 10-year experience by the U.S. Food and Drug Administration. *J Clin Oncol.* 2017;35:10009-10009.

5. Dale W, Mohile SG, Eldadah BA, et al. Biological, clinical, and psychosocial correlates at the interface of cancer and aging research. *J Natl Cancer Inst.* 2012;104:581-589.

ACCC Resources

Addressing the needs of older adults with cancer is critical for the delivery of high-quality, patient-centered care. Through the Multidisciplinary Approaches to Caring for Geriatric Patients with Cancer project, the Association of Community Cancer Centers is identifying



barriers and best practices for serving this growing patient population in order to help support the multidisciplinary team in understanding and proactively preparing for the impact of our graying nation on cancer prevalence and comorbidity burden. Find additional resources and articles at accc-cancer.org/geriatric.

Smitty Proves Age is More Than a Number

Laird "Smitty" Smith is a participant in the FITNESS study at The James under the care of Dr. Presley. After persistent hip pain led him to undergo a battery of tests, he was shocked to learn he had stage 3 lung cancer. The cancer had spread to surrounding lymph nodes and his esophagus.

That was in September 2018. Now he's playing golf up to three times a week with his "buddies," many of whom are cancer survivors themselves and provide a support system for one another.

Smith told Dr. Presley when they first met, "No matter what in life, nothing will ever be as hard as Vietnam." It was during his tour there that Smith was exposed to Agent Orange, a chemical agent that is now a known carcinogen.

Smith attributes his positive attitude and lifestyle to his healing as much as the multidisciplinary cancer care and treatment he receives at The James.

Throughout 5 months of chemotherapy and radiation treatment, he didn't miss a single day of work, walking 9 to 11 miles each day as a manager of 20 buildings in 9 states and 2 countries. He retired on June 14 but said he is busier now than ever.

"I've been busier not going to work than working. I have so much stuff to do, around my house, with doctors' appointments, the VA, The James. I didn't have time before. It's not easy to be retired," Smith said.

He continues to undergo chemotherapy every two weeks and gets a CT scan every two months. On the Thursday and Friday after treatment, he's wiped out, but "then I'm fine," he said. "I can do yard work and play golf. Go to the gym. Everything."

Smith has subsequently changed his diet and lost weight, too. Smith said he eats only organic foods, cut out all meat and dairy, and stopped drinking alcohol, except one glass of red wine on Friday and Saturday nights with dinner.

"You have to keep positive. This thing isn't going to kill me, it's just going to put me down for a while. I'm not too worried about it," Smith said.