Oncology Update

WINTER 2023

Mary Lanning HEALTHCARE
Morrison Cancer Center

M. Sitki Copur, MD FACP,
Medical Director

A quarterly newsletter from Mary Lanning Healthcare's Morrison Cancer Center
Local and national cancer authority
The definition of excellence in a comprehensive, academic, community-based cancer program

Welcome to 2023 and the 11th year of the Oncology Update

Dear colleagues,

Happy New Year! We are proud to offer the 11th year of the Oncology Update newsletter in January 2023.

This continuously high-quality publication is now in its second decade of sharing happenings from the local and national hematology/oncology world on a quarterly basis.

With the expansion of our academic, community-based, full-service cancer programs in Grand Island and Hastings, our team now includes you — our distinguished referring healthcare providers in central Nebraska — along with our University of Nebraska and

NCI-designed Fred & Pamela Buffett Cancer Center colleagues.

Our two full-service, state-of-the-art cancer centers, staffed with our exceptional team and local and national affiliations, make us a bridge connecting the western and eastern parts of the state and meeting the long unmet need for academic, community-based cancer care.

In the new year, we look forward to continuing our work together in achieving many more cancer care milestones.

Cheers to a magnificent 2023 full of meaningful achievements, and to many more years to come.

Cordially, *Mehmet Sitki Copur, MD FACP*

Medical Director, Morrison Cancer Center, Mary Lanning Healthcare; Professor, University of Nebraska Medical Center, Adjunct Faculty; mehmet.copur@marylanning.org

Also in this issue

MCC in GI reaches one-year milestone

October 25, 2022, marked the one-year anniversary of our ribbon cutting celebration opening in Grand Island.

In our first year, we proudly served 1,304 medical oncology clinic patients with 175 new consults, 57 radiation oncology clinic patients and 38 new consults, along with 1,522 laboratory encounters and 1,313 infusions/injections. That brings our total number of patients to 4,445.

Our team is honored and thankful for the warm welcome and appreciation of our academic, community-based cancer center by Grand Island and surrounding residents. The best is yet to come.

The Morrison Cancer Center radiation oncology treatment team is excited to expand services to the Grand Island location.

Radiation therapy milestone in GI center

The Morrison Cancer Center team in Grand Island treated its first radiation oncology patient on November 9, 2022.

Radiation therapy is now available on-site in Grand Island at the Grand Island Regional Medical Center Prairie Commons location with the installation of the new, state-of-the-art linear accelerator.

Dr. Randy Duckert (pictured above), MCC's radiation oncologist in Hastings and GI, has 25 years of experience.

The MCC team in Grand Island now is able to deliver a complete list of comprehensive cancer care services including medical oncology, radiation oncology, social work, nurse navigation, occupational therapy, nutrition counseling, pharmacy and specialty surgery consults.

Our experienced providers and exceptional staff look forward to working with patients, families and you, our valued referring providers. We hope to surpass all expectations.

MCC at ACS-CAN Nebaska Policy Forum

Morrison Cancer Center team members Dr. M. Sitki Copur and Chandra Muske were among presenters recently at the American Cancer Society Cancer Action Network (ACS-CAN) Nebraska Cancer Policy Forum.

They talked about barriers to lung cancer screening and shared details of the upcoming MCC lung cancer screening program.

ACS-CAN took place at the University of Nebraska at Omaha Barbara Weitz Community Engagement Center on October 11, 2022. The focus of the forum was discrepancies in access to cancer prevention and finding policy solutions.

Moderated by Laura Schablo-ske, Nebraska Cancer Society Executive Director, sessions also included presenters Dr. Alan Thorson, Amy Behnke and Kelsey Haswell.

MCC director to serve NC2

Morrison Cancer Center director David Jones has been accepted to serve on the Nebraska Cancer Coalition (NC2) board.

The Centers for Disease Control (CDC) established the National Comprehensive Cancer Control Program (NCCCP), which provided money and technical support for development of CCC plans. In 2001, the Nebraska Department of Health and Human Services (DHHS) began receiving funds from the CDC to develop a comprehensive cancer control program, known as the Nebraska Comprehensive Cancer Control Program (NECCCP). One of the primary responsibilities of the program was to implement the state plan by forming partnerships with the cancer community of healthcare professionals, survivors, individuals and organizations. In 2010, the partnership entity of NECCP became a non-profit program known as the Nebraska Cancer Coalition (NC2). Since adopting this model, NC2 has grown into a statewide partnership of more than 350 individuals representing 200 public and private organizations. The NC2 Board of Directors is made up of organizational representatives and individuals from across Nebraska.

Lung cancer screening program update

Work continues on the Mary Lanning Healthcare, Morrison Cancer Center lung cancer screening program.

MLH and MCC have applied for a second grant from the Buffett Cancer Center to help fund the program in addition to investments by MLH and MCC.

Once up and running, the program will serve the Hastings and Grand Island areas. The multidisciplinary team includes primary care providers, pulmonologists, thoracic surgeons, radiologic technologists, radiologists, interventional radiologists, medical and radiation oncologists, plus a dedicated nurse navigator.

The sophisticated software of the electronic records system should be operational soon. It will flag eligible patients, confirm effective tracking and enable adherence to structured nodule reporting, evaluation and referral to the multidisciplinary committee. The team works with primary care providers and the medical community to realize effective lung cancer screening and meet the unmet need for the central Nebraska population.

MCC clinical trials program update

The Morrison Cancer Center clinical trials team is now in the process of securing an Institutional Review Board (IRB) of record after a recent meeting with the University of Nebraska Medical Center clinical trials team.

MCC Clinical Trials Coordinator Joan Meese, RN, has participated in the UNMC workshops for research and clinical trials. She also has completed training through the UNMC's Integrated Cancer Repository for Cancer Research (iCaRe2), which would enable MLH/MCC to be a site for the iCaRe2 registry.

MCC soon will begin enrolling patients in the Breast Cancer Collaborative Registry (BCCR), Pancreatic Cancer Collaborative Registry (PCCR) and Leukemia and Myeloid Neoplasm Registry (LeMN).

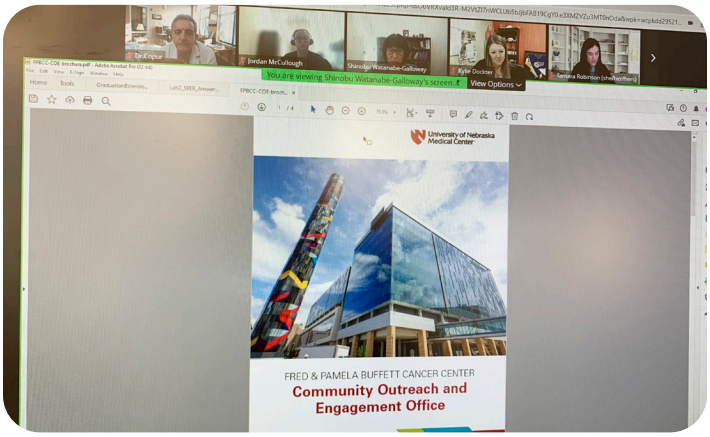
The next steps will be activation of the most suitable clinical trials for central Nebraska patients chosen from the UNMC and National Cancer Institute (NCI) National Cancer Trials Network (NCI-NCTN) portfolio. MLH/MCC is an affiliate member of the NCI cooperative group ALLIANCE through our affiliation with UNMC.

FPBCC Community Advisory Board meets

Dr. M. Sitki Copur presented updates from Mary Lanning Healthcare/Morrison Cancer Center during the November 1, 2022, meeting of the Fred & Pamela Buffett Cancer Center Community Outreach & Engagement (FPBCC-COE) meeting.

Dr. Copur discussed ASCO advocacy summit activities, the launch of a clinical trials program in collaboration with UNMC/Buffett, the lung cancer screening program, NC2 presentation and data on our first year of service in Grand Island.

Agenda items for the meeting included COE updates, launch of a lay cancer patient navigator program, collaboration with One World for colorectal cancer screening, pediatric cancer patient engagement studio work, NC2 monthly statewide webinars, the Buffett cancer center clinical trials brochure, planning for the February 2023 meeting, the role of COE in cancer prevention and control, plus partner updates.



MCC continues legislative efforts

The Morrison Cancer Center continues its fight for our patients not only through scientific, medical and care fronts, but also at the legislative level.

On April 7, 2022, the MCC team participated in the ASCO Advocacy Summit and contacted Nebraska lawmakers, urging them to take action on the Improving Seniors' Timely Access to Care Act (HR3173/S3018), the Telehealth Modernization Act (HR1332/S368), the CONNECT for Health Act (HR2903/S1512), the DIVERSE Trials Act (HR5030/S2706) and research funding for the NIH and NCI for fiscal year 2023. ASCO's feedback to Morrison stated, *"Your meetings with congressional offices on April 7 had a big impact. Since the Advocacy Summit, our legislative asks have already gained several new co-sponsors and we expect more to be added in the coming weeks. Thank you again for your hard work securing this support."*

Following a recent Office of the Inspector General of DHHS report on prior authorization practices in Medicare Advantage plans, Improving Seniors' Timely Access to Care Act had increased momentum. On September 16, 2022, the U.S. House of Representatives passed the act by voice vote. The next step is the Senate. This bipartisan legislation establishes an electronic prior authorization process and reduces the length of time a health plan can consider a prior authorization request; creates a real-time decisions process for routinely approved services; requires plans to report on their prior authorization use and the rate of approvals/denials; and encourages plans to

adopt politics that adhere to evidence-based guidelines.

In addition, the MCC team took part in supporting legislation on "white bagging" practices. The Nebraska Hospital Association (NHA), and a few members of the 340B advisory group, met with District 29 Sen. Eliot Bostar, insurance providers and pharmacy benefit managers to discuss last year's LB943 legislation on "white bagging." After much discussion, key messages surrounding the bill were about patient safety and financial issues for the hospital and patient.

Stories were then compiled about how "white bagging" jeopardizes patient safety. The MCC team submitted to the NHA five examples of patients adversely affected by "white bagging. "

The 2023 ASCO Advocacy Summit will be May 1-2 in Washington, D.C. The MCC team plans to attend.

Local surgeon receives national ACS award

Local surgeon Dr. Caleb Schroeder received the Oweida Scholarship from the American College of Surgeons (ACS) in October 2022.

The scholarship is given to two surgeons in North America each year. It recognizes their work to promote rural surgery. Dr. Schroeder received the award due to his work with the education of surgery residents and his work on telemedicine.

Dr. Schroeder has been working with University of Nebraska Medical Center residents in general surgery since 2016. Hastings is the only location outside of Omaha that the surgeons-in-training

Dr. Caleb Schroeder (left) and Christopher Ellison, President of ACS.

received education during their five-year residency. Rural rotations for residents are not common in the United States despite encouragement from ACS to help meet the anticipated shortage of rural general surgeons.

Dr. Schroeder began working with telemedicine in 2018 and published his results in July 2019. When surgeons across the country began to adopt telemedicine to their practices due to COVID-19, Dr. Schroeder was asked by ACS to share his experiences as a guide for how to urgently include telemedicine in practice.

Dr. Schroeder grew up south of Hastings. He has been practicing in Hastings and surrounding communities since 2015. In September, Dr. Jared Dietze, also a central Nebraska native, joined Dr. Schroeder's practice.

MCC at Husker Harvest Days and Pink Night

The Morrison Cancer Center team took part in Husker Harvest Days (HHD) in September and Pink Volleyball Night in October 2022.

Husker Harvest Days in Grand Island is the world's largest totally irrigated working farm show. For more than 40 years, HHD has provided farm families with a world-class space for networking. The MCC team, featuring Nurse Navigator Chandra Muske, educated attendees about smoking cessation and lung cancer screening.

On Wednesday, October 26, Hastings College, Mary Lanning Healthcare and Macy's Way sponsored Pink Volleyball Night at the Hastings College Broncos volleyball game.

Activities supported local cancer care and raised awareness.

Pink Night t-shirts were made available at MLH, MCC and Hastings College.

Breast navigation process through CNGS

General surgeon Dr. Shellie Faris has developed a breast navigation process involving a certified nurse navigator.

The process supports and guides patients facing abnormal breast imaging/exam results that may require further evaluation or biopsy.

Dr. Faris, who has been practicing at Central Nebraska General Surgery (CNGS) since 2014, works with the nurse navigator to coordinate and schedule a clinical breast exam and biopsy, if indicated. Referring providers benefit because the navigation team obtains necessary prior authorizations.

More than 80 percent of patients referred through the process are not diagnosed with cancer nor do they require surgery. If diagnosis involves a benign process, Dr. Faris manages pathology results with the patient and coordinates surveillance recommendations. If cancer is diagnosed, the goal is to ensure timely initiation of treatment with a focus on patient education, shared decision-making and a multidisciplinary team approach.

Although referrals are welcome at any point in the patient journey, optimally patients are evaluated prior to biopsy. Dr. Faris' initial breast exam provides information that can affect treatment decisions if cancer is diagnosed. The patient's breast exam can be limited by swelling or hematoma from a recent biopsy.

To maintain open communication, the referring provider is updated throughout the patient's continuum of care. A dedicated phone number allows easy access to the nurse navigator and Dr. Faris for both the referring provider and the patient.

To learn more about this process, please see https://www.marylanning.org/news-calendar/latest-internal-news/breast-cancer-navigation.

MCC presenting sponsor at Grace Gala

The Morrison Cancer Center was the presenting sponsor at the fifth annual Mad Hatter's Ball — Grace Gala on October 15, 2022.

The event took place at Boulder Flatts in Grand Island. MCC presented trophies to dance competition winners.

The Grace Foundation's mission is providing financial and emotional support to cancer patients and their families during their fight against the disease. Types of assistance available include gas and grocery cards, help with medical bills and household expenses and professional mental health resources.

New employees join MCC team

Two new radiation therapists have been added to the Morrison Cancer Center team.

Cassidy Stroda joined the Morrison Cancer Center team in October 2022 as a radiation therapist at MCC's Grand Island campus. Stroda graduated from the Mary Lanning Healthcare School of Radiologic Technology in 2019 and the University of Nebraska Medical Center Radiation Therapy Program in August 2022. She and her husband live on a farm near Fairfield with their two daughters.

"It takes a strong mindset and a lot of compassion to work in the field of radiation oncology," Stroda said. "What I love the most is that every patient has a different story to tell and each one is meaningful. We, as therapists, are with the patient every day throughout their course of treatment and relationships are formed in which you learn about them and their lives outside of their diagnosis. What I love most about the Morrison Cancer Center is we are a team that takes part in all of the patient's care. We all assist as their support system."

Stroda

Cecil

Stroda and her family enjoy spending free time going to the lake or traveling. She is currently working toward her Master's Degree in Health Professions Teaching and Technology through UNMC.

Amber Cecil joined the MCC team in November 2022 as a radiation therapist in Hastings. She was born in Virginia. She and her husband, along with their two children, moved to Hastings five years ago. At that time, she began her radiology education, graduating from the Mary Lanning School of Radiologic Technology. She has been working at MCC for more than a year as a student and recently was hired full time.

"I wanted to pursue radiation oncology because it was my passion," Cecil said. "Years later, I graduated from UNMC with my degree and license as a radiation therapist. I am proud to work for a reputable, respectful and highly trained team here at MCC. I am honored to serve Hastings and the surrounding communities. Thank you for trusting me with your loved ones."

Left: Morrison Cancer Center at the Hastings campus: Paige Bishop, Zac VanDiest, Amber Cecil. Right: Morrison Cancer Center Grand Island campus: Heather Hovie and Cassidy Stroda.

Staff highlight: MCC Radiation therapists

Radiation therapists are crucial to the multidisciplinary treatment of cancer. The MCC team is fortunate to have five highly skilled and dedicated radiation therapists operating our linear accelerators in Hastings and Grand Island.

By nature, radiation therapists are problem solvers and critical thinkers who possess the analytical skills necessary to work in a highly complex and rapidly evolving field. They possess communication skills in addition to academic and technical proficiency.

Zac Van Diest, Heather Hovie, Paige Bishop, Cassidy Stroda and Amber Cecil are capable of performing this challenging task. Just like the other amazing MCC team members, they also have the compassion and sensitivity to provide for the physical and psychological comfort of patients.

All of the therapists graduated from the University of Nebraska Medical Center's Radiation Therapy Program with either a Bachelor of Science in Medical Imaging and Therapeutic Sciences Degree or a Post-Baccalaureate Professional Certificate in Radiation Therapy. This is the only program in Nebraska. It graduates six to eight students per year.

Since 2020, the Morrison Cancer Center is a Joint Review Committee on Educational and Radiologic Technology (JRCERT)-certified clinical setting for the UNMC radiation therapy program. This provides an opportunity for central Nebraskans and others who would like to specialize in radiation therapy.

Radiation therapists are responsible for patient evaluation, simulation and daily treatments. Both the Grand Island and Hastings campuses feature state-of-the-art technology with Varian TrueBeam™ linear accelerators. These machines allow treatment of many types of cancer and non-malignant conditions using high energy x-rays. MCC has the capability of treating with brachytherapy, stereotactic body radiotherapy, stereotactic radiosurgery, deep-inspiration breath hold and external beam radiation.

Radiation therapy may be used alone or in conjunction with surgery and/or chemotherapy.

The MCC radiation oncology team has created and implemented a unique process. The team tracks every concurrent medical and radiation oncology patient while undergoing treatments. Heather prepares an Excel spreadsheet for weekly chart rounds and shares it with the entire MCC team. This document includes information to keep the entire team up to date on the patient and his or her cancer journey. This additional information is unique to MCC and highly effective in keeping our providers working together for the highest level of patient safety.

"This easily qualifies for national `best practice,'" Dr. M. Sitki Copur said.

Consolidation therapy with Blinatumomab improves overall survival in newly diagnosed adult patients with B-Lineage Acute Lymphoblastic Leukemia in measurable residual diasease negative remission

Adults with newly diagnosed acute lymphoblastic leukemia (ALL) can achieve a high rate of complete remission (CR) with conventional chemotherapy (CC), but frequently relapse and have suboptimal survival rates even if their measurable residual disease (MRD) status is negative after induction. Blinatumomab (blin) is a bispecific T cell engager molecule that is FDA-approved for patients with relapsed/refractory B-lineage ALL or patients in morphologic CR who are MRD positive (>0.1%).

Patients (pts) between the ages of 30 and 70 with newly diagnosed BCR::ABL1 negative B-lineage ALL were enrolled and initially received 2.5 months of combination induction chemo utilizing a BFM-like regimen adapted from the E2993/UKALLXII clinical trial with extended remission induction, addition of pegaspargase for patients <55 years of age and addition of rituximab for CD20 positive patients.

After remission induction (step 1), if pts were in morphologic complete remission (CR/CRi), they continued on-study and received an intensification course of high dose methotrexate with pegaspargase for CNS prophylaxis (step 2). Subsequently, their remission and MRD status were determined centrally by 6-color flow cytometry with MRD negativity defined as <0.01%.

All patients were then randomized to receive an additional four cycles of consolidation chemo or two cycles of blin for 28 days each cycle followed by 3 cycles of consolidation chemo, another 4-week cycle of blinatumomab (3rd cycle of blinatumomab) followed by an additional cycle of chemo and then a 4th cycle of blinatumomab (step 3).

Patients in each arm received the same number of cycles and doses of chemo. Following completion of consolidation chemo +/- blin, pts were given 2.5 years of POMP maintenance therapy timed from the start of the intensification cycle (step 4). Patients proceeded to allogeneic hematopoietic cell transplant (HCT) at the discretion of the treating physician which was suggested to be done after the first two cycles of blin in the blin arm or at any time following intensification chemo in the control chemo arm. Following the FDA approval of blin for MRD positive disease in March, 2018 pts who were MRD positive after intensification were assigned to the blin arm of the trial and no longer randomized. 772 pts were screened for the trial and 488 were enrolled on step 1 induction therapy. The median age of the pts was 51 years (range 30-70). 224 MRD negative pts were randomized, 112 pts to each arm. 22 pts in each arm proceeded to allogeneic BMT. The CR/CRi rate after induction chemo was 81%. Among the MRD negative pts, at the third interim efficacy analysis, 56 pts had died, 17 in the blin arm and 39 in the control chemo arm.

The upper boundary for efficacy analysis was crossed in favor of blin with a significant improvement in overall survival in favor of the blin arm (median OS: not reached vs. 71.4 months; Hazard ratio 0.42, 95% CI: 0.24 - 0.75; two-sided p=0.003). Median follow-up was 43 months.The addition of blin to consolidation chemo resulted in a significantly better overall survival in pts with newly diagnosed B-lineage ALL who were MRD negative after intensification chemo. No significant safety concerns were noted. The addition of blin to consolidation chem in adult pts aged 30-70 years represents a new standard of care for BCR::ABL1 negative ALL pts.

Ref: Litzow MR et al. 2022 ASH meeting. Plenary session Late Breaking Abstract-1

FDA hematology/oncology drug approvals since last issue

• The FDA approved **atezolizumab** (Tecentriq, Genentech, Inc.) for adult and pediatric patients 2 years of age and older with unresectable or metastatic alveolar soft part sarcoma (ASPS). **December 9, 2022.**

• TFDA approved **olutasidenib** (Rezlidhia) capsules for adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test. **December 1, 2022.**

• The FDA approved a new Monday-Wednesday-Friday dosing regimen for **asparaginase erwinia chrysanthemi** (recombinant)-rywn (Rylaze, Jazz Pharmaceuticals). Under the new regimen, patients should receive 25 mg/m2 intramuscularly on Monday and Wednesday mornings, and 50 mg/m2 intramuscularly on Friday afternoon. It also is approved to be administered every 48 hours at a dose of 25 mg/m2 intramuscularly. **November 18, 2022.**

• The FDA granted accelerated approval to **mirvetuximab soravtansine-gynx** (Elahere, ImmunoGen, Inc.) for adult patients with folate receptor alpha (FRa) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. **November 14, 2022.**

• The FDA approved **tremelimumab** (Imjudo, AstraZeneca Pharmaceuticals) in combination with **durvalumab** (Imfinzi, AstraZeneca Pharmaceuticals) and platinum-based chemotherapy for adult patients with metastatic non-small cell lung cancer (NSCLC) with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations. **November 10, 2022.**

• The FDA approved **brentuximab vedotin** (Adcetris, Seagen, Inc.) in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide for pediatric patients 2 years of age and older with previously untreated high risk classical Hodgkin lymphoma (cHL). **November 10, 2022.**

• The FDA approved **cemiplimab-rwlc** (Libtayo, Regeneron Pharmaceuticals, Inc.) in combination with platinum-based chemotherapy for adult patients with advanced non-small cell lung cancer (NSCLC) with no EGFR, ALK, or ROS1 aberrations. **November 8, 2022.**

• The FDA granted accelerated approval to **teclistamab-cqyv** (Tecvayli, Janssen Biotech, Inc.), the first bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. **October 25, 2022**.

• The FDA approved **tremelimumab** (Imjudo, AstraZeneca Pharmaceuticals) in combination with durvalumab for adult patients with unresectable hepatocellular carcinoma. **October 21, 2022.**

• The FDA granted accelerated approval to **futibatinib** (Lytgobi, Taiho Oncology, Inc.) for adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. **September 30, 2022**.

• The FDA granted regular approval to **selpercatinib** (Retevmo, Eli Lilly and Company) for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test. **September 21, 2022.**

• The FDA granted accelerated approval to **selpercatinib** (Retevmo, Eli Lilly and Company) for adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. **September 21, 2022**.

• The FDA approved sodium **thiosulfate** (Pedmark, Fennec Pharmaceuticals Inc.) to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month and older with localized, non-metastatic solid tumors. **September 20, 2022.**

New 'Ask the Expert' topics posted

The KHAS radio "Ask the Expert" segments for October, November and December can be found on the Mary Lanning website.

Topics for this quarter include leukemia for October by Dr. Tun, cancer patient vulnerabilities for November by Dr. Duckert and lung cancer screening for December by Dr. Copur. The interviews are broadcast on the first Wednesday and last Friday of each month on KHAS radio (1230 AM).

www.marylanning.org/our-services/cancer-care/in-the-news/

Publications since our last issue

- **Copur, M.S., Rupe, A., Kelly, J.** Miscellaneous Chemotherapeutic Agents. De Vita PPO 12th edition 2022. **(Published)**
- **Copur, M.S., Tun, S.M., Wedel, W.,** Vargas, L., Shaheed, M., **Horn, A., Lintel, N., Bronson, R.,** Lavudi S. Unusual dMMR Phenotype Pancreatic Ductal Adenocarcinoma with Germline, and Somatic BRCA2 Mutations in a Jehovah Witness Patient. Clinical Colorectal Cancer 2022. **(Published)**
- **Copur, M.S.,Tun, S.M., Duckert, R.** Perspectives of Community Oncologists About Offering Expanded Access. JAMA **(Published online)** https://jamanetwork.com/journals/ jamanetworkopen/fullarticle/2798001.
- Clark A.S., Hong, F., Finn, R.S.,DeMichele, A.M., Mitchell,E.P., Zwiebel, J., Arnaldez,F.I., Gray, J. Wang, V., McShane, L.M., Rubinstein, L.V., Patton, **D., Copur, M.S., et al.** Phase II Study of Palbociclib (PD-0332991) in CCND 1, 2 or 3 Amplification: Results from the NCI-MATCH ECOG-ACRIN Trial (EAY131) sub-protocol Z1B. Clin Can Res 2022. **(Accepted for publication)**
- **Chu, E., Harrold,L.J., Copur, M.S.** Chemotherapeutic and Biologic Drugs. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2023. **(Accepted for publication)**
- **Copur, M.S., Harrold,L.J., Chu,E.** Guidelines for Chemotherapy and Dosing Modifications. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2023. **(Accepted for publication)**
- **Kuang, C., Copur, M.S., Harrold, L.J., Chu, E.** Common Chemotherapy Regimens in Clinical Practice. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2023. **(Accepted for publication)**
- **Copur, M.S., Harrold, L.J., Chu, E.** Anti-emetic Agents for the Treatment of Chemotherapy-Induced Nausea and Vomiting. Physicians Cancer Chemotherapy Drug Manual Chu De Vita, 2023. **(Accepted for publication)**

Cancer Committee update

The Mary Lanning Healthcare Cancer Committee met November 15, 2022.

Shari Fiala shared progress made in the past few months with Epic reports. Extensive work between the MLH Information Technology Services Department and Nebraska Medicine's Epic team led to the creation of 11 operational reports that did not previously exist.

Thanks to having our patient data-driven reports from the EHR, MCC is better able to track process improvements.

Other significant meeting highlights included implementation of surgical synoptic operative notes and updates on MCC survivorship and clinical research programs.

During the meeting, the committee reflected on 2022's efforts for the cancer program to interact with the community by educating the public about lung cancer prevention.

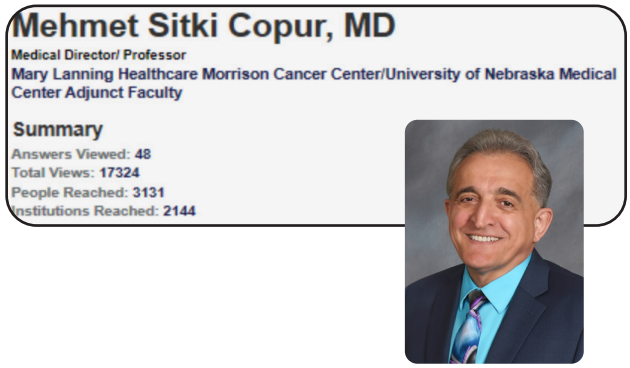
MCC employees and the South Heartland District Health Department attended Kool-Aid Days to share risk factors, including radon exposure, related to lung cancer. Resources were provided for testing homes for high radon levels and affordable test kits were available for purchase.

At Husker Harvest Days, Chandra Muske, MCC Nurse Navigator, also educated the public about lung cancer screening.

Potentially Practice Changing DATA

Fulvestrant plus capivasertib vs. placebo after replapse or progression on an aramatase inhibitor in metastatic, oestrogen receptor-positive, HER2-negative breast cancer

Capivasertib, an AKT inhibitor, added to fulvestrant, was previously reported to improve progression-free survival in women with aromatase inhibitor-resistant oestrogen receptor (ER)-positive, HER2-negative advanced breast cancer. The benefit appeared to be independent of the phosphoinositide 3-kinase (PI3K)/AKT/phosphatase and tensin homologue (PTEN) pathway alteration status of tumors, as ascertained using assays available at the time. Results from the phase 3 CAPItello-291 trial indicated that the combination of capivasertib plus fulvestrant produced improved progression-free survival in patients who have hormone-receptor–positive/HER2-negative advanced breast cancer. 708 postmenopausal adult women with ER-positive, HER2-negative, metastatic or locally advanced breast cancer, who had relapsed or progressed on an aromatase inhibitor, were randomly assigned (1:1) to receive intramuscular fulvestrant 500 mg (day 1) every 28 days (plus a 500 mg loading dose on day 15 of cycle 1) with either capivasertib 400 mg or matching placebo, orally twice daily on an intermittent weekly schedule of 4 days on and 3 days off, starting on cycle 1 day 15. Treatment continued until disease progression, unacceptable toxicity, loss to follow-up, or withdrawal of consent. The median PFS was 7.2 months (95% CI, 7.2-7.4) among those who received capivasertib plus fulvestrant vs 3.6 months in the placebo plus fulvestrant arm (95% CI, 2.8-3.7; HR, 0.60; 95% CI, 0.51-0.71; 2-sided P < .001). In patients who had AKT pathway mutations, the median PFS was 7.3 months (95% CI, 5.5-9.0) in the capivasertib arm vs 3.1 months (95% CI, 2.0-3.7) in the placebo arm (HR, 0.50; 95% CI, 0.38-0.65; 2-sided P <.001). In the non-altered population, the investigator assessed PFS was 7.2 months (95% CI, 4.5-7.4) in the capivasertib arm vs 3.7 months (95% CI, 3.0-5.0) in the placebo arm (HR, 0.70; 95% CI, 0.56-0.88). When PFS was assessed across prespecified patient subgroups, investigators reported a consistent benefit in all groups. Authors concluded that capivasertib addition to fulvestrant extends the survival of participants with aromatase inhibitor-resistant ER-positive, HER2-negative advanced breast cancer. The expanded biomarker testing suggested that capivasertib predominantly benefits patients with PI3K/AKT/PTEN pathway-altered tumors.
Ref: Turner N, Oliveria M, Howell SJ, et al. 2022 San Antonio Breast Cancer Symposium; December 6-10, 2022; San Antonio, TX. Abstract GS3-04.



MCC continues with theMednet

The Morrison Cancer Center continues to be actively involved in theMednet, providing feedback to the oncology community.

MCC has answered more than 48 questions with 17,324 total views.

theMednet is a physician-only online community where expert answers are offered to real-world oncology questions when there are no clear guidelines or published research on the topic.

More than 1,000 academic physicians are recruited based on their research, publications, case volumes, clinical trials and peer recommendations from every cancer center in the United States. The physicians are posed with answering challenging questions from other practicing oncology physicians. The answers are peer-reviewed and indexed, making them accessible through a quick search.

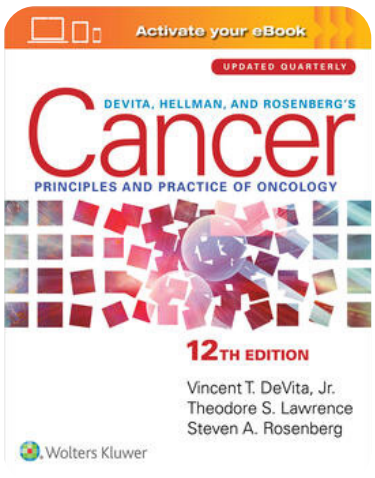
MCC contributes to major cancer textbook

MCC team members M. Sitki Copur; Amber Rupe, PharmD; and Jacqueline Kelly, MD, wrote the chapter "Miscellaneous Chemotherapeutic Agents" in the gold-standard oncology textbook.

"Devita, Hellman and Rosenberg's Cancer: Principles and Practice of Oncology, 12th Edition" provides authoritative guidance and strategies for managing every type of cancer by stage and presentation.

Drs. Vincent T. Devita, Jr., Theodore S. Lawrence and Steven A. Rosenberg oversee an outstanding team of expert contributing authors in this fast-changing field of medicine.

The award-winning reference textbook is continually updated on Health Library and Vital Source platforms for the life of the edition.



Happy holidays from the Morrison Cancer Center

Prostate cancer screening with PSA and MRI followed by targeted biopsy only

Potentially Practice Changing DATA

Screening for prostate cancer is burdened by a high rate of overdiagnosis. The most appropriate algorithm for population-based screening is unknown.

Authors invited 37,887 men who were 50 to 60 years of age to undergo regular prostate-specific antigen (PSA) screening.

Participants with a PSA level of 3 ng per milliliter or higher underwent magnetic resonance imaging (MRI) of the prostate; one third of the participants were randomly assigned to a reference group that underwent systematic biopsy as well as targeted biopsy of suspicious lesions shown on MRI.

The remaining participants were assigned to the experimental group and underwent MRI-targeted biopsy only. The primary outcome was clinically insignificant prostate cancer, defined as a Gleason score of 3+3. The secondary outcome was clinically significant prostate cancer, defined as a Gleason score of at least 3+4. Safety was also assessed. Of the men who were invited to undergo screening, 17,980 (47%) participated in the trial. A total of 66 of the 11,986 participants in the experimental group (0.6%) received a diagnosis of clinically insignificant prostate cancer, as compared with 72 of 5994 participants (1.2%) in the reference group, a difference of –0.7 percentage points (95% confidence interval (CI), –1.0 to –0.4; relative risk, 0.46; 95% CI, 0.33 to 0.64; P<0.001). The relative risk of clinically significant prostate cancer in the experimental group as compared with the reference group was 0.81 (95% CI, 0.60 to 1.1).

Clinically significant cancer that was detected only by systematic biopsy was diagnosed in 10 participants in the reference group; all cases were of intermediate risk and involved mainly low-volume disease that was managed with active surveillance. Serious adverse events were rare (<0.1%) in the two groups. The avoidance of systematic biopsy in favor of MRI-directed targeted biopsy for screening and early detection in persons with elevated PSA levels reduced the risk of overdiagnosis by half at the cost of delaying detection of intermediate-risk tumors in a small proportion of patients.

Ref: Huggosson Jet al. N Engl J Med 2022; 387:2126-2137

The Morrison Cancer Center

Dr. M. Sitki Copur, Medical Director

Now offering on-site radiation therapy in GI

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Some fun from 2022!

Effects on survival of non-myeloablative chemoimmunotherapy compared to high-dose chemotherapy followed by autologous stem cell transplantation (HDC-ASCT) as consolidation therapy in patients with primary CNS lymphoma — results of an international, randomized Phase III trial

Patients with primary central nervous system lymphoma (PCNSL) eligible for intensive treatment approaches are currently treated with high-dose methotrexate (HD-MTX) based induction immuno-chemotherapy followed by consolidative high-dose chemotherapy and ASCT (HDC-ASCT).

However, it is unclear whether overcoming chemo-resistance and subsequently eliminating minimal residual disease may also be achieved by conventional-dose non-myeloablative immuno-chemotherapy, comprising non-cross resistant cytotoxic agents able to cross the brain-blood-barrier.

In this open label, randomized phase III trial newly diagnosed PCNSL, HIV-negative, age 18-65 and adequate organ function patients were given induction of 4 cycles of MATRix regimen (rituximab 375 mg/m2/d days 0 & 5; methotrexate 3.5 g/m2 day 1; cytarabine 2 × 2 g/m2/d days 2 & 3; thiotepa 30 mg/m2 day 4, every 21 days). Stem cell harvest was conducted after the 2nd cycle. Pts achieving at least partial response (PR) after completion of induction were randomly allocated to either arm A with two courses of R-DeVIC regimen (375 mg/m2 day 0; dexamethasone 40 mg/d days 1 to 3; etoposide 100 mg/m2/d days 1 to 3; ifosfamide 1500 mg/m2/d days 1 to 3; carboplatin 300 mg/m2 day 1); or arm B, consisting of HDC with BCNU 400 mg/m2 (day -6) and thiotepa 2 x 5 mg/kg/d days -5 & -4) followed by ASCT. Total 346 pts started treatment, 260 (75%) completed the induction therapy, and 115 and 114 pts were randomly assigned to arm A and arm B, respectively. Median age of the randomized pts was 59 years (range 21 – 70) with 22.3% of pts being 65 years or older.

Distribution of patient characteristics were well balanced between arms. Median follow-up of all registered patients is 44 months (range 0,2-86). 239 of 346 (69%) pts responded to induction treatment, 27% achieved a complete remission (CR) and 52% a partial remission (PR).

Both consolidation strategies were well tolerated: R-DeVIC and HDC-ASCT were completed in 100 (87%) and 111 (97%) pts, respectively. 13 (3.8%) pts died of treatment-related complications during induction treatment, 11 of them due to neutropenic infectious complications. Consolidation treatment with R-DEVIC or HDC-ASCT resulted in a substantial increase of pts with CR (65% in arm A and 68% in arm B, respectively; p= 0.71). To date, there were 79 PFS events: 67 pts experienced progressive disease after randomization (47 for arm A and 20 for arm B). 6 pts died of toxicity during consolidation treatment (2 arm A and 4 arm B), and 6 pts died of unrelated causes while relapse-free (5 arm A and 1 arm B). The 3-year PFS (primary endpoint) differed significantly between the two arms: 79% (95% CI 71-86) after HDC-ASCT and 53% (95% CI 43-62%) after R-DeVIC (HR 0.42; p=0.0003).

The 3-year OS was 86% (95% CI 78-91) for HDC-ASCT arm and 71% (95% CI 61-78) for R-DeVIC arm (HR 0.47; p=0.01). The evaluation of neurocognitive functions showed no difference between arms. Authors concluded that consolidation with HDC-ASCT results in significantly better outcome than non-myeloablative chemoimmunotherapy. This comes along without any measurable negative effect on neurocognitive functions and with an excellent risk-to-benefit ratio. HDC-ASCT is the standard consolidation therapy for fit PCNSL patients.

Ref: Illerhaus G et al. 2022 ASH meeting Late Breaking Abstract-3

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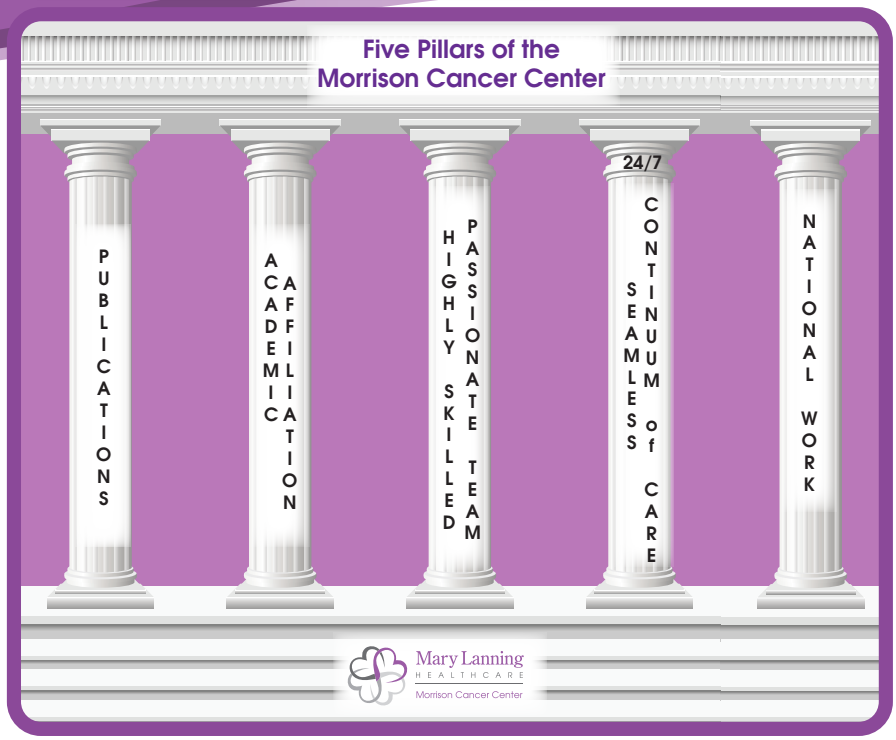

The Morrison Cancer Center team of oncology nurses ("Shark Nurses Team") poses for a picture together during Nurses Week.