

**Completed Research: PRACTICE MANAGEMENT RESEARCH**

Abstract #CR02

**Biosimilar Uptake and Cost-Savings Analysis Before and After the Implementation of a Pharmacist-Driven Substitution Program Within a National Community Oncology Network**

**Presenters:** Jenny Li, PharmD, BCPS, BCOP, American Oncology Network; Bradley Winegar, PharmD, American Oncology Network, Fort Meyers, FL

**Co-Authors:** Brooke Peters, PharmD, BCOP; Robert Carr, PharmD, BCPS, BCOP; Camilo Rodriguez, CPhT-Adv, CSPT, PRS; Ashley Kohler-Gerber, CPhT, CSPT; Darell Connor, MHA, FWSPA; Ta'Qyra Freeman, CPhT, CSPT; Kyle Brown; Melody Chang, RPh, MBA, BCOP, American Oncology Network, Fort Meyers, FL

**BACKGROUND:** Providers, payers, and patients all stand to benefit financially from the selection of the most cost-effective biosimilar drugs. As of September 2022, 22 of the 39 biosimilar approvals in the United States are for the treatment of cancer or for the supportive care of patients with cancer. Our organization is a network of community oncology practices, representing 107 physicians at 76 locations across 16 states. Because our network faces formulary selection and reimbursement challenges related to a diverse payer mix across multiple states, we studied the use of regional clinical pharmacists (RCPs) to assist with the selection of the most cost-effective biosimilar drugs.

**OBJECTIVE:** To assess the impact of using RCPs to assist with the selection of the most cost-effective biosimilar drugs.

**METHOD:** In October 2021, our network initiated a pharmacist-driven biosimilar drug substitution program, whereby the RCP acts as a liaison between providers and financial teams to evaluate existing drug orders and their financial impact. The RCP requests biosimilar switches in the electronic medical record (EMR) for financial review. Once approved, the provider confirms the acceptance of the switch and signs off on the order in the EMR. This study evaluated our network-preferred biosimilar drug uptake and associated cost-savings data from April 1, 2021, to April 1, 2022. The outcomes related to biosimilar use, as well as financial impacts on payers, patients, and providers, were assessed before and after the implementation of the RCP-driven biosimilar substitution program.

**RESULTS:** At the end of the study period, preferred drug use was achieved for >90% of bevacizumab, trastuzumab, rituximab, and filgrastim orders. The use of the preferred pegfilgrastim drug increased from <20% to >60% during this study period. Switching to a preferred biosimilar agent occurred in 26% of these cases. Payer preference prevented biosimilar switching in 34% of cases. Payer savings were approximately \$29 million over the 6-month period before the implementation of the RCP-driven biosimilar substitution program and were \$47 million over the 6-month period after implementation. The patient savings were estimated to be approximately \$9500 before implementation and \$30,000 after implementation. Provider savings were approximately \$44 million before the implementation of the RCP-driven biosimilar substitution program and \$90 million after the implementation.

**CONCLUSION:** The use of institution-preferred biosimilar drugs increased across all agents in this study after the implementation of the RCP-driven biosimilar substitution program. Significant cost-savings were noted for providers, payers, and patients. Barriers to switching to institution-preferred drugs included nonmedical switching requirements by payers, patient-assistance and compassionate-use programs, and patient and/or provider preferences.

**Completed Research: CLINICAL/TRANSLATIONAL RESEARCH**

Abstract #CR03

**Bruton Tyrosine Kinase Inhibitors: Real-World Clinical Outcomes in a Diverse Patient Population at a Large Safety Net Hospital**

**Presenters:** Lynnette Henshaw, PharmD, BCOP, Boston Medical Center, Boston, MA; Camille Edwards, MBBS, Boston Medical Center, Boston University Chobanian & Avedisian School of Medicine, Boston, MA

**BACKGROUND:** The use of Bruton tyrosine kinase (BTK) inhibitors has increased over the past several years, changing the treatment landscape of hematologic malignancies, such as chronic lymphocytic leukemia (CLL). Ibrutinib was the first BTK to be FDA-approved in 2013, followed by the next-generation BTK inhibitors acalabrutinib and

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## Abstract #CR03 (Continued)

zanubrutinib, which were approved in 2017 and 2019, respectively. Each BTK inhibitor has its unique side-effect profile as well as its class effects. Real-world, long-term data in diverse patient populations are pertinent for the continued evaluation of safety outcomes and disease management.

**OBJECTIVE:** To describe the real-world use of BTK inhibitors, including treatment-related adverse effects, in a diverse patient cohort.

**METHOD:** This is a retrospective study of patients with hematologic malignancies who received BTK inhibitors between January 2016 and December 2021 at Boston Medical Center (BMC), a large safety net hospital. Using the oncology pharmacy database, we captured all of the prescriptions that were sent during the study period. Patients were excluded if their primary treatment was at another institution or if they did not start their intended therapy. Baseline demographics, therapy information, and safety data were collected after the patients had completed at least 6 months of therapy.

**RESULTS:** A total of 36 patients received treatment at BMC from January 2016 to December 2021 with either ibrutinib (n = 31), acalabrutinib (n = 4), or zanubrutinib (n = 1) in the first-line or relapsed/refractory setting. The median age of the patients was 70 years, and the majority of patients were male (61.1%), black or African American (42%), and diagnosed with CLL (52.8%). Approximately 50% of the patients receiving ibrutinib or acalabrutinib and the 1 patient who received zanubrutinib had a treatment interruption. A total of 19 patients (61.3%) who were receiving ibrutinib discontinued therapy, with 45.2% (n = 14) resulting from treatment-related adverse drug reactions (ADRs). Half of the patients receiving acalabrutinib (n = 2) discontinued therapy, with 25% of the discontinuations resulting from ADRs. Of the patients receiving ibrutinib, a worsening of existing atrial fibrillation (Afib) or new Afib was seen in 6.5% (n = 2) and 9.8% (n = 3), respectively. The patient receiving zanubrutinib had new Afib. None of the patients who were receiving acalabrutinib had Afib. New hypertension was diagnosed in 16.1% (n = 5) of the patients receiving ibrutinib and 25% (n = 1) of the patients receiving acalabrutinib. Worsening of existing hypertension was reported in 6.5% (n = 2) of the patients receiving ibrutinib.

**CONCLUSION:** BTK inhibitors are associated with cardiac adverse events, such as hypertension and Afib, which can develop many months to years after therapy initiation. Knowledge of therapy-related toxicities in diverse populations is essential for appropriate monitoring for the development of adverse events.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

### Abstract #CR04

## Clinical Outcomes in Patients with Tumor PD-L1 <1% Who Received First-Line Nivolumab plus Ipilimumab and 2 Cycles of Chemotherapy versus Chemotherapy Alone for Metastatic NSCLC: Results from CheckMate 9LA

**Presenter:** David P. Carbone, MD, PhD, The Ohio State University Comprehensive Cancer Center, Columbus, OH

**Co-Authors:** Tudor-Eliade Ciuleanu, MD, PhD, Institutul Oncologic Prof Dr Ion Chiricuta and University of Medicine and Pharmacy Iulia Hatieganu, Cluj-Napoca, Romania; Manuel Cobo-Dols, MD, Unidad de Gestión Clínica Intercentros de Oncología Médica, Hospitales Universitarios Regional y Virgen de la Victoria, Malaga, Spain; Michael Schenker, MD, SF Nectarie Oncology Center, Craiova, Romania; Bogdan Zurawski, MD, Ambulatorium Chemioterapii, Bydgoszcz, Poland; Juliana Menezes, MD, Hospital Nossa Senhora da Conceição, Porta Alegre, Brazil; Eduardo A. Richardet, MD, Instituto Oncológico de Córdoba, Córdoba, Argentina; Jaafar Bennouna, MD, University Hospital of Nantes and INSERM, CRCINA, Nantes, France; Ying Cheng, MD, Jilin Cancer Hospital, Changchun, China; Enriqueta Felip, MD, PhD, Vall d'Hebron University Hospital, Vall d'Hebron Institute of Oncology, Barcelona, Spain; Oscar J. Juan-Vidal, MD, Hospital Universitario La Fe, Valencia, Spain;

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## Abstract #CR04 (Continued)

Aurelia Alexandru, MD, Institute of Oncology Prof Dr Alexandru Trestioreanu, Bucharest, Romania; Luis Paz-Ares, MD, Universidad Complutense de Madrid, Madrid, Spain; Shun Lu, MD, Shanghai Lung Cancer Center, Shanghai Chest Hospital, Shanghai, China; Martin Reck, MD, Airway Research Center North, German Center for Lung Research, Grosshansdorf, Germany; Nan Hu, MS, Bristol Myers Squibb, Princeton, NJ; Xiaoqing Zhang, MD, PhD, Bristol Myers Squibb, Princeton, NJ; Diederik Johannes Grootendorst, PhD, Bristol Myers Squibb, Princeton, NJ; Laura Eccles, PhD, Bristol Myers Squibb, Princeton, NJ; Thomas John, MD, Austin Hospital, Heidelberg, Australia

**BACKGROUND:** First-line immunotherapy-based regimens have limited efficacy in patients with metastatic non-small-cell lung cancer (NSCLC) and tumor programmed death ligand 1 (PD-L1) <1%. A high unmet medical need remains in metastatic NSCLC, particularly in patients with squamous metastatic NSCLC or baseline brain metastasis. In CheckMate 9LA (NCT03215706), first-line nivolumab plus ipilimumab and 2 cycles of chemotherapy showed long-term, durable benefit versus chemotherapy in patients with metastatic NSCLC, regardless of tumor PD-L1 status.

**OBJECTIVE:** To report an exploratory analysis of efficacy and safety in patients with tumor PD-L1 of <1% by histology or the presence of brain metastasis.

**METHOD:** Adults with stage IV recurrent NSCLC, ECOG performance score of  $\leq 1$ , and no sensitizing EGFR/ALK alterations were randomized 1:1 to first-line nivolumab (360 mg every 3 weeks) plus ipilimumab (1 mg/kg every 6 weeks) and chemotherapy (every 3 weeks for 2 cycles) or to chemotherapy alone (every 3 weeks for 4 cycles). Overall survival (OS), progression-free survival, objective response rate, duration of response, and safety were assessed in patients with tumor PD-L1 of <1% by histology (nonsquamous or squamous) or by the presence of baseline brain metastasis (by blinded independent central review).

**RESULTS:** Baseline characteristics of the patients with tumor PD-L1 of <1% were generally similar to the intention-to-treat population. With a minimum follow-up of 36.1 months (database lock, February 15, 2022), survival was improved with nivolumab plus ipilimumab and chemotherapy versus with chemotherapy alone in the subgroups of patients with tumor PD-L1 of <1% by histology or by the presence of brain metastasis. The median OS (nivolumab plus ipilimumab and chemotherapy vs chemotherapy) was 18.6 months vs 12.4 months in the nonsquamous disease subgroup (N = 99 vs N = 93, respectively; hazard ratio [HR], 0.74; 95% confidence interval [CI], 0.54-1.02); 15.3 months vs 8.0 months in the squamous disease subgroup (N = 36 vs N = 36, respectively; HR, 0.50; 95% CI, 0.30-0.83); 20.6 months vs 6.9 months in the patients with brain metastasis (N = 17 vs N = 15, respectively; HR, 0.28; 95% CI, 0.13-0.61); and 16.4 months versus 11.2 months in the patients without brain metastasis (N = 118 vs N = 114, respectively; HR, 0.72; 95% CI, 0.54-0.96). A similar clinical benefit of nivolumab plus ipilimumab and chemotherapy in efficacy outcomes will be presented. No new safety signals were observed.

**CONCLUSION:** First-line nivolumab plus ipilimumab and chemotherapy showed long-term, durable clinical benefit in patients with metastatic NSCLC and tumor PD-L1 of <1%, regardless of histology or the presence of baseline brain metastasis. These exploratory results were consistent with previous reports from all randomized patients and further support the use of nivolumab plus ipilimumab and chemotherapy as a first-line treatment option for patients with metastatic NSCLC.

Supported by funding from Bristol Myers Squibb. Previously presented at the European Society for Medical Oncology (ESMO) 2022, Poster #1049P. Thomas John, et al.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

### Abstract #CR05

## Clinical Pharmacist–Initiated Tyrosine Kinase Inhibitor Discontinuation in Patients with Chronic Myeloid Leukemia

**Presenter:** Jared Freml, PharmD, BCOP, Kaiser Permanente Colorado, Denver, CO

**Co-Authors:** Yuliya Byakina, PharmD, BCOP, Bristol Myers Squibb, Portland, OR; Lisa A. Thompson, PharmD, BCOP, Kaiser Permanente Colorado, Denver, CO; Ekim Ekinci, PharmD, BCOP, MS, Kaiser Permanente Colorado, Denver, CO; Jasen Knudsen, PharmD, BCPS, BCOP, Kaiser Permanente Northwest, Portland, OR; Chamath Desilva, MD, Kaiser Permanente Colorado, Lafayette, CO; Soames Boyle, MD, Kaiser Permanente Northwest, Portland, OR; Thomas Delate, PhD, MS, Kaiser Permanente National Pharmacy Services, Denver, CO

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Abstract #CR05 (Continued)

**BACKGROUND:** Tyrosine kinase inhibitors (TKIs) are tolerated relatively well in the treatment of chronic myeloid leukemia (CML), but the wide range of adverse events and the high cost of treatment can make indefinite therapy challenging.<sup>1,4</sup> In recent years, data have shown that patients with CML may tolerate treatment-free remissions after prolonged deep responses to TKIs, leading to the integration of discontinuation recommendations in clinical practice guidelines.<sup>5</sup> Pharmacists have demonstrated ability to assist physicians in optimizing medication management, including treatment discontinuation.<sup>6,7</sup> The use of pharmacists as physician extenders to identify patients with CML who may discontinue TKI therapy may provide patient and healthcare system benefits.

**OBJECTIVE:** To examine the clinical and financial impacts of an oncology clinical pharmacy specialist (CPS)-initiated TKI discontinuation process in a real-world population of patients with CML.

**METHOD:** This retrospective, descriptive analysis included adult patients from 2 integrated healthcare delivery systems who were receiving a TKI between January 1, 2019, and September 30, 2020, and had been screened under collaborative CPS/oncologist TKI discontinuation programs. Using chart data, the CPS systematically reviewed patient charts and obtained information on TKI discontinuation eligibility based on the NCCN guidelines for CML. Patients were followed until December 31, 2020, or until membership termination. The analysis outcomes included the numbers of patients who (1) were existing TKI discontinuation candidates; (2) were future TKI discontinuation candidates; (3) had a managing oncologist who agreed with the pharmacist recommendation that patients were TKI discontinuation candidates; (4) consented to TKI discontinuation; (5) discontinued TKI therapy; (6) resumed TKI therapy; and (7) avoided TKI-related costs (based on last TKI dispensed).

**RESULTS:** The included patients with CML (N = 133) were primarily older, male, and white and had received a TKI for >6 years. In all, 41 (30.8%) and 87 (65.4%) patients were identified as existing and future TKI discontinuation candidates, respectively. The managing oncologists agreed with the pharmacists that 36 of 41 (87.8%) patients were TKI discontinuation candidates, and of these patients, 24 (66.7%) consented to TKI discontinuation, with 23 of the 24 (95.8%) patients discontinuing TKI therapy. A total of 18 of the 23 (78.3%) patients remained off TKI therapy through follow-up. The median TKI cost avoided was \$113,820 per patient. The total TKI medication cost avoided was \$3,054,738.

**CONCLUSION:** The pharmacist-initiated TKI discontinuation programs that were analyzed were associated with systematic screening of patients with CML to formally discontinue TKI therapy and achieved TKI cost avoided. Similar pharmacist-initiated programs could be used in other healthcare settings to provide patient-centered care, reduce oncologists' workload, and minimize financial burden on patients and the healthcare system. Future research to better characterize cost-savings, explore electronic health record tools to assist with the discontinuation of appropriate candidates, and assist with postdiscontinuation BCR-ABL1 monitoring should be considered.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR06

### Evaluation of Chemotherapy-Induced Myelosuppression in Patients with Extensive-Stage Small-Cell Lung Cancer Who Received Trilaciclib: Retrospective Analysis of Florida Community Oncology Practices

Presenters: Lorena Lopez-Gonzalez, G1 Therapeutics, Inc; Michelle Moore, RPh, G1 Therapeutics, Inc

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Abstract #CR06 (Continued)

**Co-Authors:** Lowell Hart, MD, Florida Cancer Specialists & Research Institute, Fort Myers, FL; Augustina Ogbonnaya, MPH, Xcenda, Carrollton, TX; Kristen Boykin, PharmD, Florida Cancer Specialists & Research Institute, Fort Myers, FL; Kathryn Deyoung, MS, Xcenda, Carrollton, TX; Ray Bailey, RPh, Florida Cancer Specialists & Research Institute, Fort Myers, FL; Trevor Heritage, PhD, Florida Cancer Specialists & Research Institute, Fort Myers, FL; Lorena Lopez-Gonzalez, PhD, G1 Therapeutics, Inc., Research Triangle Park, NC; Huan Huang, PhD, G1 Therapeutics, Inc., Research Triangle Park, NC; Michelle Moore, RPh, G1 Therapeutics, Inc., Research Triangle Park, NC; Lucio Gordan, MD, Florida Cancer Specialists & Research Institute, Fort Myers, FL

**BACKGROUND:** Patients with extensive-stage small-cell lung cancer (ES-SCLC) who received chemotherapy frequently have chemotherapy-induced myelosuppression (CIM), leading to the reduced production of white blood cells, red blood cells (RBCs), and/or platelets. Among patients with ES-SCLC who received chemotherapy at Florida Cancer Specialists & Research Institute (FCS) community oncology clinics, the prevalence of grade  $\geq 3$  CIM episodes in  $\geq 1$  or  $\geq 2$  lineages was 62.1% and 33.9%, respectively.<sup>1</sup>

**OBJECTIVE:** To evaluate the CIM outcomes of patients with ES-SCLC who received trilaciclib during chemotherapy at FCS clinics.

**METHOD:** This retrospective cohort study identified adults who received trilaciclib during chemotherapy for ES-SCLC between February 1, 2021, and May 15, 2022, according to FCS-structured electronic medical records. Patients in clinical trials or with  $< 14$  days follow-up (except death) were excluded. Descriptive statistics were reported for the prevalence of CIM episodes by type (anemia, thrombocytopenia, neutropenia) and grade across all chemotherapy cycles with trilaciclib. The CIM episodes included events within 21 days from the start of a treatment cycle with trilaciclib administration.

**RESULTS:** The patients who received trilaciclib (N = 50) were, on average, aged 67.8 years, 56% were female, and 56% were white. During follow-up (median, 2.7 months), 42% of patients had a grade  $\geq 3$  CIM episode in  $\geq 1$  lineage (anemia: grade 3, 18%; thrombocytopenia: grade 3, 20% and grade 4, 6%; neutropenia: grade 3, 24% and grade 4, 4%). Grade  $\geq 3$  CIM episodes in  $\geq 2$  lineages occurred in 18% of patients. Supportive care use (eligibility for RBC or platelet transfusion, granulocyte colony-stimulating factor use, erythropoiesis-stimulating agents use, and intravenous hydration) will also be reported.

**CONCLUSION:** Early real-world outcomes following treatment with trilaciclib suggest a potential for reductions in CIM among patients with ES-SCLC. Future studies are required to confirm the findings.

Previously presented, in part, at 2022 Precision Oncology Summit, October 2022.

1. Hart L, Ogbonnaya A, Boykin K, et al. Burden of chemotherapy-induced myelosuppression among patients with extensive-stage small cell lung cancer: a retrospective study of data from community oncology practices. Poster presented at the Academy of Managed Care Pharmacy Annual Meeting; December 11-14, 2021.

## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR07

### Evaluation of the Safety of the New Alcohol-Containing Formulation of Cyclophosphamide

**Presenter:** Quan Li, BCOP, BCPS, PharmD, MedStar Washington Hospital Center, Washington, DC

**Co-Author:** Tonya Wright, PharmD, MedStar Washington Hospital Center, Washington, DC

**BACKGROUND:** Cyclophosphamide has been available only as a lyophilized powder in a single-dose vial for a long time, and it requires labor-intensive reconstitution. A new liquid formulation of cyclophosphamide was recently approved in a multidose vial for convenient use. However, this new formulation has alcohol as an excipient. Many clinicians are leery to use the new formulation because of the safety concerns regarding the alcohol.

**OBJECTIVE:** To determine if the new formulation of alcohol-containing cyclophosphamide has more central nervous system (CNS) and liver adverse events than the lyophilized powder formulation of cyclophosphamide.

**METHOD:** A multicenter, retrospective chart review was conducted of oncology patients who received cyclophosphamide, either in the lyophilized powder formulation or the alcohol-containing formulation, from April 1, 2021, to December 31, 2021. The exclusion criteria were patient age  $< 18$  years, having advanced liver damage, having

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## Abstract #CR07 (Continued)

liver or brain metastases, or having liver or brain cancer. The primary end points were changes to liver function tests and CNS side effects that happen within 21 days of receiving the cyclophosphamide dose. The secondary end points were treatment delays >7 days or treatment-related hospitalizations.

**RESULTS:** A total of 97 patients were in the lyophilized powder group and 134 patients were in the alcohol-containing group. The lyophilized powder group was predominately white (52.6%), and the alcohol-containing group was predominately black or African American (64.2%;  $P < .001$ ). In all, 68% of the patients in the lyophilized powder group and 85.8% of patients in the alcohol-containing group were women ( $P = .001$ ). No significant differences were seen between the 2 groups for changes to liver function tests (AST,  $P = .179$ ; ALT,  $P = .460$ ). The incidence of CNS symptoms was similar between the groups (50.5% in the lyophilized powder group vs 50% in the alcohol-containing group;  $P = .938$ ). For the secondary outcomes, the treatment delay rate was 3% in both groups, but the hospitalization rate was higher in the lyophilized powder group than in the alcohol-containing group (16.5% vs 6%, respectively;  $P = .01$ ).

**CONCLUSION:** The liquid, alcohol-containing formulation of cyclophosphamide had similar CNS and liver side effects to the lyophilized powder formulation of cyclophosphamide. The use of the liquid, alcohol-containing formulation of cyclophosphamide in adults could be encouraged with close monitoring.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

### Abstract #CR08

## Health System Specialty Pharmacy Integration Impact on Prescription Fill Time

**Presenter:** Angie Wood, PharmD, BCPS, BCOP, CSP, Clinical Oncology Pharmacist, Trellis Rx-North Memorial Health, Robbinsdale, MN

**Co-Authors:** Brian O'Keefe, PharmD, BCOP, Clinical Oncology Pharmacist, Trellis Rx, Parkview Health, Fort Wayne, IN; Jessica Mourani, PharmD, Director, Clinical Outcomes Research, Trellis Rx

**BACKGROUND:** The time from ordering an oral oncolytic to the patient's receipt of the drug can be a source of angst for patients and prescribers who are hoping to avoid delays in treatment. Previous studies report a median time to the access of oral oncolytic agents ranging from 4 to 12 days.<sup>14</sup> The factors that contribute to the lag between the prescription being written and patient access include prior authorizations, financial toxicity, pharmacy review, and delivery time. Health system specialty pharmacies (HSSPs) are uniquely positioned to overcome these barriers. Parkview Health established an integrated specialty pharmacy model to streamline and improve the process for patients in need of oral oncolytics.

**OBJECTIVE:** To compare the time to access oral oncolytic treatments before and after specialty pharmacy integration.

**METHOD:** This retrospective, comparative time-series analysis measures the access time to oral oncolytic drugs for patients before and after the integration of an HSSP at a genitourinary oncology clinic. Access time was defined as the difference in business days between a new order and a patient's receipt of the ordered drug. The integrated specialty pharmacy completed prior authorizations, addressed financial barriers, completed chemotherapy education, and dispensed the therapy or triaged it to the in-network specialty pharmacy. A secondary end point compared the access time of patients filling an oral oncolytic drug prescription at the HSSP versus at an outside pharmacy.

**RESULTS:** A total of 80 patients were identified who had started an oral oncolytic drug before the HSSP integration. The median access time was 7 business days. In all, 82 patients were identified who had started therapy after the HSSP

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## Abstract #CR08 (Continued)

integration. The median access time was 6 business days, resulting in a 15% reduction in the time to therapy after the HSSP integration. The median access time when dispensing through the HSSP was 5 business days versus 9 business days for outside specialty pharmacies, resulting in a 43% reduction in the time to therapy after the HSSP integration. **CONCLUSION:** The integration of an HSSP resulted in a 15% reduction in patient access time, demonstrating the enormous impact that an HSSP can play in avoiding delays to therapy. Furthermore, this study demonstrates the importance of filling a prescription with the integrated HSSP, as demonstrated by the 43% reduction in access time in patients filling their prescription internally.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

## Abstract #CR09

### Invasive Fungal Disease in Patients with Hematologic Malignancies Receiving Micafungin Prophylaxis

**Presenter:** Cory Schulz, DNP, AGACNP-BC, Nurse Practitioner, Johns Hopkins Hospital, Baltimore, MD

**Co-Authors:** Jenica Patel, PharmD, BCPS, Johns Hopkins Hospital, Baltimore, MD; Matthew Newman, PharmD, BCOP, Johns Hopkins Hospital, Baltimore, MD

**BACKGROUND:** Patients with hematologic malignancies have an increased risk for invasive fungal infections (IFIs). Primary antifungal prophylaxis with triazoles or a parenteral echinocandin, such as micafungin, is recommended.<sup>1-3</sup> Triazoles are typically preferred because of decreased rates of IFI.<sup>4,5</sup> However, because of drug-drug interactions, financial barriers, and/or the adverse effects of triazoles, micafungin is used often in clinical practice for select patients.

**OBJECTIVES:** The primary objective was to determine the rates of IFIs amongst patients with hematologic malignancies who received micafungin for primary antifungal prophylaxis. The secondary objectives included identifying pertinent patient characteristics and describing micafungin dosing patterns.

**METHOD:** This was an Institutional Review Board-approved, single-center, retrospective analysis of adult patients with hematologic malignancies who were receiving micafungin for antifungal prophylaxis at a large academic medical center from September 2017 to September 2020. The European Conference on Infections in Leukemia (ECIL) criteria were used to categorize and classify the patients to determine the incidence of IFI. Adult patients (aged ≥18 years) were included if they were receiving treatment for a hematologic malignancy and if they were receiving micafungin as the primary antifungal prophylaxis. Patients were excluded if they had a nonhematologic malignancy, received <4 doses of micafungin, or were receiving micafungin for empiric treatment.

**RESULTS:** A total of 433 patients were reviewed, and 163 patients met the study inclusion criteria. Of the patients selected, 132 (81%) did not have an IFI, 10 (6.1%) had a proven IFI, 3 (1.8%) had a possible IFI, and 18 (11%) had a possible IFI according to the ECIL criteria. The primary oncologic diagnoses observed were acute myeloid leukemia (57%) and acute lymphoid leukemia (21%). Patients received intensive regimens (N = 48; 30%), nonintensive regimens (N = 84; 53%), bone marrow transplant (N = 12; 8%), ATRA and arsenic (N = 8; 5%), and all immunotherapies (N = 8; 5%). For patient host factors, 125 (78%) patients had neutropenia, 22 (14%) were recipients of an allogeneic stem-cell transplant, and 8 (5%) were receiving immunosuppressants. For clinical features, 31 (19%) patients had lower respiratory tract infections, 3 (2%) had sinonasal infections, and no patients had reported tracheobronchitis or central nervous system infections. Most patients received micafungin 100 mg daily for prophylaxis (N = 123; 77%). Alternative micafungin dosing regimens included 100 mg to 150 mg 2 or 3 times weekly.

**CONCLUSION:** The use of micafungin as antifungal prophylaxis can be an alternative treatment for patients who are not ideal candidates to receive triazole antifungals.

Supported by funding from Johns Hopkins Hospital.

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**Abstract #CR09** (Continued)

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**Completed Research: PRACTICE MANAGEMENT RESEARCH****Abstract #CR10****Knowledge Gaps and Educational Needs for Common Cancer Therapy-Related Cardiovascular Adverse Events and Related Drug Interactions**

**Presenter:** Kristen T. Peterson, PharmD, BCOP, Duke University Medical Center

**Co-Authors:** Heather Moore, PharmD, BCOP, CPP, Duke University Medical Center, Durham, NC; Craig Beavers, PharmD, FACC, FAHA, FCCP, BCCP, BCPS, CACP, Baptist Health Systems–Kentucky and Indiana, Louisville, KY; Sarah Hayes, PharmD, BCOP, University of Minnesota Health Systems, Robbinsdale, MN; Israa Yaseen, BPharm, BCCP, BCPS, Bagdad Heart Center–Medical City, Bagdad, Iraq; Preston Skersick, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC; Kelsey Truitt, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC; Sarah Kaspari, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC; Stephen Casselli, PhD, International Cardio-Oncology Society, Tampa, FL; Jo E. Rodgers, PharmD, BCPS, BCCP, FCCP, FHFS, FAHA, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC

**BACKGROUND:** An unprecedented rise in the number of novel oncolytic agents has recently led to a substantial increase in the complexity of cancer management. The real-world use of these therapies has increased the awareness of cancer therapy-related cardiovascular toxicities (CTR-CVTs) and related drug–drug interactions (DDIs), warranting healthcare provider education.

**OBJECTIVE:** To obtain further insight into knowledge gaps and educational needs based on the frequency of observed CTR-CVTs and related DDIs and the perceived ease of their management.

**METHOD:** A 20-question survey was distributed to pharmacists and other healthcare providers using e-mail listservs of targeted professional organizations, including the International Cardio-Oncology Society and the Hematology/Oncology Pharmacy Association. The survey assessed background (eg, training, practice setting), CTR-CVTs, and the related DDIs encountered. In addition, the preferences for future educational topics were assessed.

**RESULTS:** Of 220 survey respondents (102 pharmacists and 118 other healthcare providers, >80% physicians), the majority reported being at academic medical centers (>60% academic, >30% community). Although pharmacists were predominately from North America (96%) and represented cardiology (49%) and oncology/hematology specialties (44%/28%), other healthcare providers were from more diverse regions (Europe, 36%; North America, 28%; South America/other, 25%) and primarily specialized in cardiology (86%). The cancer types varied greatly across all of the healthcare providers. Of 102 pharmacists, 89% were PharmD-trained, and 56% and 33% completed residency and board certification in cardiology or oncology, respectively. In all, 49% of the pharmacists specialized in cardiology and 44% specialized in oncology. The most common CTR-CVTs reported by pharmacists were cancer therapy-related cardiac dysfunction (77%), thromboembolic disease (71%), and hypertension (64%). The most common pharmacodynamic DDIs that were encountered were QT prolongation/torsades de pointes, thromboembolic disease, bleeding, and

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**Abstract #CR10 (Continued)**

hypertension, whereas the pharmacokinetic DDIs were with oral anticoagulants, antiarrhythmic agents, and numerous oncolytic agents. The pharmacists reported the least comfort with managing ibrutinib- or other drug-associated bleeding and arsenic-associated QT prolongation, and the greatest comfort with managing anthracycline- or HER2-targeted therapy-associated cardiac dysfunction. Regarding the recommendations for future education, immune checkpoint inhibitor-associated myocarditis (70%), ibrutinib- or other drug-associated bleeding (61%), and atrial fibrillation (61%) were ranked of highest need. Similar survey results were observed with other healthcare providers.

**CONCLUSION:** This survey indicates that knowledge gaps exist for pharmacists and other healthcare providers for several CTR-CVTs and related DDIs. Future educational initiatives should target these specific areas.

**Completed Research: PRACTICE MANAGEMENT RESEARCH****Abstract #CR11****Multidisciplinary Approach in Maximizing Oncology Clinic Throughput in a Comprehensive Cancer Center**

**Presenter:** Bryna Delman Ewachiw, PharmD, BCOP, Johns Hopkins Bayview Medical Center, Baltimore, MD

**Co-Authors:** Gillian Pullido, MHA, Johns Hopkins Medicine, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Baltimore, MD; Adwoa Nyame, PharmD, Johns Hopkins Bayview Medical Center, Baltimore, MD

**BACKGROUND:** Managing oncology clinic throughput with persistent postpandemic staffing constraints and a lack of resources continues to pose challenges to an already-busy outpatient oncology model. A multidisciplinary group of oncology providers, pharmacists, nurses, and support staff embarked on a quality improvement initiative to improve clinic throughput using a scheduling template software program that was established at other oncology clinics within the health system. Before implementing this software program, patients had their laboratory, provider, and treatment visits all scheduled on the same day, which led to bottlenecks and patient care delays in the phlebotomy area, the infusion room, and the oncology pharmacy but only at certain points of the day.

**OBJECTIVES:** The primary objective was to measure the schedule template compliance rate before and after the intervention, with 85% as the goal. The secondary objective was to measure the rate at which a patient's laboratory visits were decoupled from their treatment dates before and after the intervention.

**METHOD:** Sidney Kimmel Comprehensive Cancer Center (SKCCC) at Johns Hopkins Bayview Medical Center is an academic ambulatory oncology clinic that is primarily focused on the treatment of thoracic malignancies for the Johns Hopkins Health System. From January 2022 through April 2022, the patients' laboratory, provider, and treatment visits were on the same day, and appointments were scheduled by assigning patients to an infusion chair by the scheduling team without a standardized approach. Using a templated schedule software program, which went live in April 2022, patient treatments were scheduled according to the length of the treatment, and all new patients were required to get blood work done before their treatment visit. Standardized patient education and signage reminded patients to have their laboratory work done before their treatment visit. The multidisciplinary group met every week to develop the scheduling templates based on clinic volumes, staffing, and treatment time lengths. The oncology pharmacy team provided scheduling recommendations based on pharmacy technician resources, pharmacy hours, and chemotherapy admixture processes. The scheduling software program set a benchmark target of 85% compliance with the schedule template before and after the go-live date.

**RESULTS:** The mean schedule template compliance rate before we implemented the software was 70% compared with 80% 6 months after the program was used. Regarding laboratory and treatment decoupling, the rate was 40% before the scheduling software was implemented compared with 25% after the software was implemented.

**CONCLUSION:** Incorporating a standardized template for scheduling improved the oncology pharmacy workflow throughput, with enhanced distribution of treatments and the decoupling of laboratories and treatment visits in an outpatient oncology center.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR12

### Optimization of Rasburicase Dose for the Management of Tumor Lysis Syndrome in Community Oncology Practices

**Presenters:** Steven Gilmore, PharmD, BCOP, McKesson Specialty Health, The Woodlands, TX; Melissa Carroll, PharmD, McKesson Specialty Health, The Woodlands, TX

**Co-Authors:** Elizabeth Koselke, PharmD, BCOP, McKesson Specialty Health, The Woodlands, TX; Shannon Hough, PharmD, BCOP, McKesson Specialty Health, The Woodlands, TX

**BACKGROUND:** Tumor lysis syndrome (TLS) is a life-threatening oncologic emergency, resulting in hyperuricemia, hyperkalemia, hyperphosphatemia, and hypocalcemia. Single, fixed-dose rasburicase administration has been evaluated as an effective strategy in the management of hyperuricemia in the hospital setting, but it has not yet been validated within ambulatory community oncology practices. The US Oncology Network (TUSON) is affiliated with approximately 1400 physicians within 500 cancer treatment locations throughout the United States and served as the location for this intervention.

**OBJECTIVE:** To evaluate and optimize the dosing strategy for rasburicase in the management of TLS-associated hyperuricemia in TUSON.

**METHOD:** TUSON reviewed and revised a networkwide guideline to standardize rasburicase dosing from a previously recommended fixed dose of 4.5 mg or 7.5 mg to 3 mg or 6 mg for outpatient rasburicase use for the management and prevention of TLS. Additional updates included changes to the standard order template names and default rasburicase dosing. The electronic health records (EHRs) were reviewed retrospectively. A structured data export from the EHRs was used to evaluate rasburicase dosing in all patients who received a rasburicase dose within TUSON as a primary end point. A retrospective chart review of randomly selected patients evaluated the secondary end points and rasburicase dose, pre- and postrasburicase uric acid levels, and internal guideline concordance. The primary outcome was the mean dose of rasburicase among all patients who received rasburicase treatment over a period of 3 months before and after the guideline revision. The secondary outcomes included the internal guideline concordance, indication, and uric acid normalization (<8 mg/dL) within 24 hours of receiving the rasburicase dose(s).

**RESULTS:** The primary analysis included 291 patients (N = 128 prerevision and N = 163 postrevision). The primary outcome of mean rasburicase dose was reduced in the postrevision population compared with the prerevision population (mean, 6.2 mg prerevision vs 4.5 mg postrevision). A total of 50 patients were included for the secondary analysis, including 25 patients each in the prerevision and postrevision populations. Guideline concordance was identified in 12 patients (48%) and 16 patients (64%), and uric acid normalization occurred in 14 patients (56%) and 16 patients (64%) before and after the guideline revision, respectively. In addition, repeat rasburicase dosing was reduced after the guideline revision (24% prerevision vs 12% postrevision).

**CONCLUSION:** Guideline revision and EHR modification resulted in a 27% reduction in the mean rasburicase dose and a 50% reduction in repeat rasburicase dosing, without a negative impact on clinical efficacy; this is associated with potential cost-savings in a large network of community oncology practices. In addition, guideline concordance increased after revision.

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**Completed Research: CLINICAL/TRANSLATIONAL RESEARCH**

Abstract #CR13

**Pharmacist-Led 14-Day Oncolytic Drug Check-In Protocol****Presenter:** Kristin Hutchinson, PharmD, BCOP, CSP, Trellis Rx, Atlanta, GA**Co-Authors:** Jasmine King, PharmD Candidate, Mercer University College of Pharmacy, Atlanta, GA; Jessica Mourani, PharmD, Trellis Rx, Atlanta, GA; Angie Wood, PharmD, BCPS, BCOP, CSP, Trellis Rx at North Memorial Health, Robbinsdale, MN**BACKGROUND:** Because of their many adverse effects, oral anticancer medications result in high discontinuation rates and low adherence. Although evidence exists that mitigating these adverse effects improves adherence, data demonstrating the impact that health system specialty pharmacy (HSSP) pharmacists have on improving discontinuation rates are lacking.**OBJECTIVE:** To compare discontinuation rates in patients receiving oral anticancer medication before and after a pharmacist-led check-in protocol is put in place to contact patients within 14 days of starting therapy.**METHOD:** A retrospective, multicenter, observational study compared oral oncolytic drug discontinuation rates and reasons of patients across Trellis Rx's partner health systems before and after the implementation of a protocol requiring a pharmacist to contact patients within 14 days of therapy initiation. During this follow-up, adverse event management and mitigation strategies, additional counseling, and question assistance were provided. The providers were contacted when additional supportive care medication was required to mitigate the side effects that the patients reported. The patients were stratified into 2 groups (preprotocol, March 2020-December 2020, and postprotocol, March 2021-December 2021) and were evaluated for the discontinuation rates and reasons as reported by the clinical pharmacist in the Arbor specialty pharmacy technology platform.**RESULTS:** A total of 9414 therapies were evaluated. The preprotocol group (N = 4060 therapies) had an overall therapy discontinuation rate of 40.4% versus 29% in the postprotocol group (N = 5354 therapies). Overall, there was an approximate 11% decrease in oral oncolytic drug discontinuations after the implementation of a pharmacist-led check-in protocol. A total of 6.8% of the oral oncolytic therapy discontinuations in the preprotocol group resulted from drug intolerance versus 2.8% in the postprotocol group.**CONCLUSION:** The high rate of oral anticancer agent discontinuations leads to poor outcomes for patients, including an increased incidence of mortality. HSSP pharmacists play a pivotal role in decreasing oral anticancer drug discontinuation. We have demonstrated this can be done effectively by incorporating a 14-day check-in providing targeted counseling and side-effect mitigation strategies.*Poster previously presented at National Association of Specialty Pharmacy Annual Meeting & Expo: Hutchinson K, Mourani J, Wood A, King J. Comparison of discontinuation rates in patients receiving an oral anticancer agent before and after implementation of a 14-day pharmacist check-in protocol. September 19-22, 2022.**Abstract previously presented at the National Association of Specialty Pharmacy (2022).*

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## Abstract #CR13 (Continued)

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

## Abstract #CR14

### Safety of Rapid Dose Escalation of Venetoclax in Patients with Hematologic Malignancies

**Presenters:** Caroline M. Mejias-De Jesús, PharmD, BCOP, Beth Israel Deaconess Medical Center, Boston, MA; Lauren McGinty, PharmD, BCOP, Beth Israel Deaconess Medical Center, Boston, MA

**Co-Authors:** Verona Abdelmeseh, PharmD, BCOP, Northshore University Hospital, Manhasset, NY; Ajoy Dias, MD, MRCP, Beth Israel Deaconess Medical Center, Boston, MA

**BACKGROUND:** The use of venetoclax has benefited numerous patients and has changed the treatment landscape across several hematologic malignancies. However, it brings several challenges, including prolonged hospitalizations for slow dose ramp-ups with frequent monitoring. There are limited data on the safety of escalating doses more rapidly than is described in initial trials and in the prescribing information, but doing so has the potential to benefit patients and the healthcare system by decreasing the number of admissions and lengths of stay associated with treatment initiation.

**OBJECTIVE:** To evaluate the safety and feasibility of rapid dose escalation of venetoclax in patients with hematologic malignancies.

**METHOD:** A retrospective chart review was conducted for adults in the inpatient setting with hematologic malignancies who received rapid ramp-ups of venetoclax that deviated from the prescribing information recommendations between January 2018 and June 2022 at Beth Israel Deaconess Medical Center. The safety end points included the proportion of patients who had tumor lysis syndrome (TLS) per the Cairo-Bishop criteria and other adverse events (AEs) during the ramp-up. Feasibility was measured by the proportion of patients achieving the target 400-mg dose or an alternative stable dose. Descriptive statistics were calculated.

**RESULTS:** A total of 22 patients received a rapid dose escalation of venetoclax. The median age at venetoclax initiation was 68.5 years (range, 51-87 years). The most common indications included mantle-cell lymphoma (N = 6; 27.3%), relapsed/refractory chronic lymphocytic leukemia (CLL; N = 5; 22.7%), and de novo CLL (N = 4; 18.2%). A total of 10 (52.6%) patients received B-cell receptor pathway inhibitor therapy immediately before receiving venetoclax. All patients started the ramp-up in the inpatient setting with TLS monitoring. The most common schedule (9.1%) was 20 mg on day 1 of week 1, 50 mg on days 2 and 3 of week 1, 100 mg on days 4 through 7 of week 1, 200 mg on days 1 through 7 of week 2, and then 400 mg daily. All but 1 patient received appropriate TLS prophylaxis. In all, 19 (86.4%) patients completed the ramp-up and achieved the 400-mg target dose. A total of 3 (13.6%) patients achieved a stable dose of 200 mg as a result of drug-drug interactions or AEs. The median time to a target or stable dose was 14 days (range, 4-39 days). Laboratory TLS occurred in 1 (4.5%) patient at the 20-mg dose, which resolved without intervention; 2 (9.1%) patients at the 50-mg dose, 1 of which resolved without intervention and the other required treatment with rasburicase and sevelamer; and 1 (4.5%) patient at the 200-mg dose, which resolved without intervention. No clinical TLS was reported. Other AEs included anemia (45.5%), thrombocytopenia (36.4%), and neutropenia (31.8%). No discontinuation of venetoclax occurred during the ramp-up.

**CONCLUSION:** Rapid dose escalation of venetoclax initiated with close inpatient monitoring was tolerated with minimal TLS.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR15

### Safety Outcomes of Oxaliplatin Rapid-Rate Infusion versus Standard-Rate Infusion

**Presenters:** Nick Crozier, PharmD, BCOP, BCPS, MBA, University of New Mexico Comprehensive Cancer Center, Albuquerque, NM; Thao Huynh, PharmD, University of New Mexico Hospital, Albuquerque, NM

**BACKGROUND:** Oxaliplatin is an important part of chemotherapy regimens for colon cancer, but it is associated with significant adverse drug events (ADEs). The National Comprehensive Cancer Network guidelines state that the oxaliplatin dose of 85 mg/m<sup>2</sup> used in FOLFOX may be infused over 85 minutes instead of the standard time of 120 minutes to reduce chair time. To our knowledge, the safety of the rapid-rate infusion has not been fully evaluated. In December 2019, the University of New Mexico Comprehensive Cancer Center (UNMCCC) transitioned to the rapid infusion of oxaliplatin and began administering oxaliplatin over 90 minutes in FOLFOX, FOLFOXIRI, and FOLFIRINOX regimens.

**OBJECTIVE:** To evaluate the safety outcomes of the rapid administration of oxaliplatin by comparing treatment interventions and ADEs in patients who received oxaliplatin at the standard-rate infusion versus those who received the rapid-rate infusion.

**METHOD:** We performed a retrospective, single-center, observational cohort study at the UNMCCC by chart review. Eligibility included adult patients who received oxaliplatin chemotherapy as part of a FOLFOX, FOLFOXIRI, or FOLFIRINOX regimen from January 1, 2018, through June 30, 2021. Patients who were administered other oxaliplatin-containing regimens or who had a prolonged oxaliplatin infusion rate were excluded. The primary outcomes included the incidence of hypersensitivity reaction (HSR) and dose delay, dose reduction, or discontinuation of oxaliplatin because of an ADE. The secondary outcomes included peripheral neuropathy (PN), myelosuppression, and an oxaliplatin-related emergency department visit and/or hospital admission. Research Electronic Data Capture was used for the data collection of the patients' demographics and clinical characteristics, including cancer type and stage, comorbid conditions, medication list, oxaliplatin regimen, infusion rate, oxaliplatin treatment interventions, end-organ function, and ADEs. Statistics were analyzed using SPSS version 28.0.0.0 software.

**RESULTS:** A total of 178 patients were included. The baseline characteristics were similar between the rapid-rate infusion (N = 90) and standard-rate infusion (N = 88) groups. Compared with standard-rate infusion, rapid-rate infusion showed no difference in HSR, dose delay, dose reduction, or the discontinuation of oxaliplatin as a result of ADEs. PN occurred in 72.2% and 42% of patients in the rapid-rate and standard-rate infusion groups, respectively (relative risk for PN, 2.09; 95% confidence interval, 1.43-3.04; *P* < .001), but there were no differences in any other ADE measured.

**CONCLUSION:** Although the rapid infusion of oxaliplatin saved 30 minutes of administration time and was not associated with treatment modifications or a difference in HSR, there was an increase in the risk for PN. Given the lack of available data, the thorough evaluation of each patient's risks for PN along with shared decision-making remain paramount when determining the administration rate for oxaliplatin.

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*Previously presented, in part, at Vizient resident poster session, December 2021, and Western States, May 2022.*

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR16

### Strategies for Implementing an Oral Medication Adherence Intervention

**Presenters:** James Collins, IV, PharmD, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC; Benyam Muluneh, PharmD, BCOP, CPP, University of North Carolina Eshelman School of Pharmacy, Chapel Hill, NC

**Co-Authors:** Michele A. Muir, PharmD, GSK, Chapel Hill, NC; Matthew Foster, MD, University of North Carolina School of Medicine, University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Daniel Richardson, MD, MSc, MA, University of North Carolina School of Medicine, University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill, NC; Lola Olajide, MD, University of North Carolina REX Healthcare, Raleigh, NC; Kaitlyn Buhlinger, PharmD, CPP, University of North Carolina Medical Center, Chapel Hill, NC; Rebecca Sawchak, RN, MSN, AGPCNP-C, University of North Carolina Medical Center, Chapel Hill, NC; Ashley Bryant, PhD, RN, OCN, FAAN, University of North Carolina Lineberger Comprehensive Cancer Center, University of North Carolina School of Nursing, Chapel Hill, NC; Stephanie Jean, PharmD, MS, University of North Carolina Medical Center, Chapel Hill, NC; Jeffrey Reichard, PharmD, MS, University of North Carolina Medical Center, Chapel Hill, NC; John Valgus, PharmD, MHA, BCOP, University of North Carolina Medical Center, Chapel Hill, NC; Maurice Alexander, PharmD, BCOP, CPP, University of North Carolina Medical Center, Chapel Hill, NC; Stephanie Duncan, University of North Carolina Medical Center, Chapel Hill, NC; Walter Laundon, PharmD, MS, BCOP, University of North Carolina REX Healthcare, Raleigh, NC; Julia Rodriguez-O'Donnell, LCSW, OSW-C, University of North Carolina Medical Center, Chapel Hill, NC; Brendan Fitzpatrick, MBA, University of North Carolina Medical Center, Chapel Hill, NC; Michael Tilkens, PharmD, DPLA, University of North Carolina Health, Shared Services Pharmacy, Chapel Hill, NC; Mary-Haston Vest, PharmD, MS, BCPS, University of North Carolina Medical Center, Chapel Hill, NC; Rebecca Jones, PharmD, BCOP, CPP, University of North Carolina REX Healthcare, Raleigh, NC

**BACKGROUND:** Oral anticancer (OAC) agents have transformed cancer care for patients, extending survival and delaying disease progression in certain cases. However, this benefit often requires a medication adherence rate of >90%.<sup>1</sup> Innovative models to improve patient knowledge and adherence to OACs exist.<sup>2-4</sup> However, these models have had varying success, which is limited by a lack of clear strategies to improve their adoption, implementation, and maintenance. Previously, we identified barriers and facilitators to the implementation and maintenance of a medication adherence intervention for OACs to design evidence-based implementation strategies.

**OBJECTIVE:** To design pragmatic and stakeholder-informed strategies for the oral medication adherence program's adoption, implementation, and maintenance.

**METHOD:** We assembled an advisory panel with clinicians (N = 9), administrators (N = 7), and patients (N = 2) in 2 settings (an academic setting and a community cancer center) to design practical strategies for the adoption, implementation, and maintenance of a structured adherence intervention using a systematic approach called implementation mapping.<sup>5</sup> Using focus group discussions and Likert-type surveys, we specified the outcomes and objectives for the intervention, selected implementation strategies, produced implementation protocols and materials, and defined program evaluation outcomes.

**RESULTS:** Overall, 5 qualitative consensus-based discussions and 3 quantitative surveys were conducted with the advisory panel. In all, 10 performance outcomes and 18 performance objectives were identified. A total of 7 participants completed a survey with moderate-to-high agreement (range, 4-5) on all 28 items. Next, we proposed 21 potential strategies to our advisory panel after a series of focus group discussions; 9 participants completed a survey, which yielded moderate-to-high levels of agreement (range, 3.78-5) for all strategies. After the final 2 focus group discussions, this list was refined to 7 distinct strategies (3 for adoption, 3 for implementation, and 1 for maintenance) as necessary for the success of the adherence program. The final produced strategies included (1) formal program commitment documents, (2) key performance indicators, (3) a slide deck justifying the program to leadership, (4) standard operating procedures outlining roles and responsibilities, (5) a workshop on motivational interviewing and adherence, (6) standardized adherence assessment integrated into the electronic health record, and (7) measurable performance indicators and metrics.

**CONCLUSION:** Using implementation mapping, the advisory panel identified 7 strategies that are necessary to overcome previously identified barriers to an OAC adherence program. Future research conducting a preimplementation

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## Abstract #CR16 (Continued)

survey with clinicians, administrators, and patients is necessary to identify the acceptability, appropriateness, and feasibility of the developed implementation strategies from this study followed by a pilot implementation study.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

## Abstract #CR17

### Effectiveness of High-Dose Intravenous Acyclovir in Preventing Cytomegalovirus Infection in Allogeneic Stem-Cell Transplantation Recipients: A Retrospective Study in a Medical Center in Singapore

**Presenter:** Chin Hua Kuan, BSc, BCOP, Singapore General Hospital, National University of Singapore, Singapore

**Co-Authors:** W. P. Yau, PhD, BSc, National University of Singapore, Singapore; A. Ho, MBBS, MMed, FRCP, FRCPATH, Singapore General Hospital, Singapore; Y. C. Linn, MBBS, MRCP, Singapore General Hospital, Singapore; H. Y. Ng, BSc, MSc, BCOP, Singapore General Hospital, Singapore; V. C. Ng, BSc, PharmD, BCOP, Singapore General Hospital, Singapore

**BACKGROUND:** Cytomegalovirus (CMV) is a significant infection after allogeneic hematopoietic stem-cell transplantation (HSCT). In October 2013, our institution started using prophylactic high-dose intravenous (IV) acyclovir (ie, 500 mg/m<sup>2</sup> every 8 hours) for patients who underwent allogeneic HSCT. However, an evaluation is warranted because its use is only marginally supported by guidelines.

**OBJECTIVE:** To evaluate the effectiveness of high-dose IV acyclovir in preventing CMV infection in patients who underwent allogeneic HSCT.

**METHOD:** A retrospective cohort study was conducted in adult patients who underwent allogeneic HSCT between July 2009 and October 2017 and were CMV-seropositive or had a seropositive donor. Patients admitted between October 2013 and October 2017 who received high-dose IV acyclovir (intervention group) were compared with patients who were admitted between July 2009 and September 2013 (controls). The primary end point was the incidence of clinically significant CMV infection, which was defined as CMV disease or CMV viremia leading to preemptive therapy within 180 days after allogeneic HSCT. Specifically, the incidence of CMV disease was identified. The secondary end points included the time to clinically significant CMV infection, the total number of CMV infection episodes (primary and recurrence), and the 1-year all-cause mortality. Poisson regression was used for the primary outcome analysis.

**RESULTS:** Of the 146 patients in the high-dose IV acyclovir group, 82 (56.2%) had CMV infection, whereas 116 (73%) of the 159 control patients had CMV infection. The patients who received high-dose IV acyclovir had a 25% reduction in the risk for CMV infection (adjusted relative risk, 0.75; 95% confidence interval, 0.57-1.00;  $P = .05$ ). The incidence of CMV disease was similar between the groups (4.1% vs 8.8%, respectively;  $P = .261$ ). The significant differences in the secondary end points that favored the intervention group included the time to clinically significant CMV infection (median, 44 days vs 31 days; interquartile range, [IQR], 39-49 vs 27-35;  $P = .002$ ) and the total number of CMV infection episodes (median, 1 vs 2; IQR, 1-2 vs 1-2.75;  $P = .002$ ). However, the 1-year all-cause mortality rate was not statistically significant (27.4% vs 32.1%, respectively;  $P = .46$ ).

**CONCLUSION:** High-dose IV acyclovir use was associated with a 25% reduced risk for CMV infection in patients who had allogeneic HSCT, with borderline statistical significance. Although the study was not powered for secondary

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**Abstract #CR17** (Continued)

end points, the time to clinically significant CMV infection and the total number of CMV infection episodes favored the high-dose IV acyclovir group.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR18**

### Trilaciclib Use and Chemotherapy-Induced Myelosuppression Among Patients with Extensive-Stage Small-Cell Lung Cancer in US Community Oncology Settings

**Presenters:** Lorena Lopez-Gonzalez, G1 Therapeutics, Inc., Research Triangle Park, NC; Michelle Moore, RPh, G1 Therapeutics, Inc., Research Triangle Park, NC

**Co-Authors:** Jerome Goldschmidt, MD, Blue Ridge Cancer Centers, US Oncology Research, Blacksburg, VA; Alisha Monnette, PhD, MPH, Ontada, Woodlands, TX; Divea Venkatesetty, MPH, Ontada, Woodlands, TX; Ping Shi, PhD, Ontada, Woodlands, TX; Huan Huang, PhD, G1 Therapeutics, Inc., Research Triangle Park, NC; Paul R. Conkling, MD, US Oncology Research, Norfolk, VA

**BACKGROUND:** Chemotherapy-induced myelosuppression, which leads to the reduced production of multiple cell lineages (white blood cells, red blood cells [RBCs], and/or platelets), is a major dose-limiting adverse event of chemotherapy. A previous study reported that 56.6% of patients with extensive-stage small-cell lung cancer (ES-SCLC) who received chemotherapy and were in the US Oncology Network (Network) had grade  $\geq 3$  myelosuppression events in  $\geq 1$  lineage and 33% in  $\geq 2$  lineages after chemotherapy initiation.<sup>1</sup>

**OBJECTIVE:** To evaluate the real-world outcomes of patients with ES-SCLC who received trilaciclib in the community oncology setting.

**METHOD:** This retrospective study included adult patients with ES-SCLC who initiated trilaciclib during chemotherapy in Network clinics between February 1, 2021, and April 30, 2022. Patients without evidence of receiving chemotherapy treatment or who were in clinical trials were excluded. The outcomes included myelosuppression events (ie, anemia, neutropenia, thrombocytopenia) and supportive care utilization (ie, eligibility for RBC or platelet transfusion, granulocyte colony-stimulating factor [G-CSF] use) occurring between the first trilaciclib administration and 14 days after the last trilaciclib administration during index chemotherapy.

**RESULTS:** Patients with ES-SCLC (N = 31) received an average of 3.1 cycles (median, 3) of index chemotherapy during the use of trilaciclib and an average of 8.6 administrations (median, 9) of trilaciclib during index chemotherapy. Grade  $\geq 3$  myelosuppression events in  $\geq 1$  lineage occurred in 35.7% of patients (anemia, 7.1%; neutropenia, 28.6%; thrombocytopenia, 7.1%), and 7.1% of patients had grade  $\geq 3$  myelosuppression events in  $\geq 2$  lineages. During the index chemotherapy when trilaciclib was used, 9.7% of patients received G-CSF, 3.2% were eligible for RBC transfusions, and none of the patients were eligible for platelet transfusions.

**CONCLUSION:** Early real-world data in this study suggest that trilaciclib may reduce myelosuppression in patients with ES-SCLC who receive treatment in the community oncology setting. More research is recommended to validate these findings. *Previously presented, in part, at 2022 Precision Oncology Summit, October 2022.*

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**Completed Research: CLINICAL/TRANSLATIONAL RESEARCH**

Abstract #CR19

**Urinary Tract Infections in Patients Receiving Chemotherapy and SGLT2 Inhibitors**

**Presenters:** John Bossaer, PharmD, BCOP, East Tennessee State University Bill Gatton College of Pharmacy, Johnson City, TN; Rachel Rikard, PharmD, University of North Carolina Medical Center, Chapel Hill, NC

**BACKGROUND:** Sodium-glucose cotransporter 2 (SGLT2) inhibitors are associated with an increased risk for urinary tract infections (UTIs). The incidence of UTIs in pivotal trials is up to 9.3% in the general population. Immunosuppressing chemotherapy makes patients more susceptible to infection, causing further concern for getting UTIs with SGLT2 inhibitors. A single trial has been published suggesting that there is not an increased risk for UTIs in patients who have a solid-organ transplant and are receiving SGLT2 inhibitors while using immunosuppressants. However, the risk for a UTI while receiving an SGLT2 inhibitor and chemotherapy is unknown.

**OBJECTIVE:** To describe the incidence of UTIs in patients receiving concomitant SGLT2 inhibitors and chemotherapy.

**METHOD:** The medical records of patients receiving immunosuppressive or myelosuppressive chemotherapy (ie, cytotoxic agents, rituximab, CDK4/6 inhibitors) who also received an SGLT2 inhibitor listed as a home medication in outpatient cancer clinic electronic health records were retrospectively reviewed. The study population included patients with encounters at 2 rural cancer centers between November 1, 2020, and November 1, 2021. The primary outcome was the incidence of UTIs among the study population. The secondary outcomes were to compare SGLT2 inhibitor agents and analyze other UTI risk factors.

**RESULTS:** A total of 540 patients were screened, and 46 patients were included in the study. The majority of screening failures were a result of a lack of cancer treatment or the concomitant use of an SGLT2 inhibitor while receiving treatment. Of the 46 patients, 10 (21.7%) had a UTI (95% confidence interval, 9.8-33.6). This included 8 patients who were receiving empagliflozin and 2 patients who were receiving dapagliflozin. The majority (N = 10) of patients who had a UTI had a solid-tumor malignancy (N = 8) and received chemotherapy alone (N = 6).

**CONCLUSION:** This small, retrospective study suggests that there may be an increase in UTI risk in patients concomitantly taking SGLT2 inhibitors and chemotherapy compared with the general population. Given the high number of screening failures, research collaborators from other cancer centers are needed to provide a more robust analysis of the UTI risk in this patient population.

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**Completed Research: CLINICAL/TRANSLATIONAL RESEARCH**

Abstract #CR20

**Use of Ursodiol for SOS/VOD Prophylaxis in Patients with Acute Leukemia Receiving Gemtuzumab-Ozogamicin or Inotuzumab-Ozogamicin**

**Presenters:** Grace Mosallam, PharmD Candidate Class of 2023, Massachusetts College of Pharmacy and Health Sciences, Boston, MA; Loriel J. Solodokin, PharmD, BCOP, Massachusetts College of Pharmacy and Health Sciences, Dana-Farber Cancer Institute/Brigham and Women's Hospital, Boston, MA

**Co-Authors:** Eric S. Winer, MD, Dana-Farber Cancer Institute; Julia Keating, MS, Dana-Farber Cancer Institute, Boston, MA

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Abstract #CR20 (Continued)

**BACKGROUND:** Sinusoidal obstruction syndrome (SOS)/veno-occlusive disease (VOD) is an often-fatal condition in patients who have had hematopoietic stem-cell transplant (HSCT). Gemtuzumab-ozogamicin (GO) and inotuzumab-ozogamicin (InO), 2 antibody–drug conjugates, are indicated for the management of acute leukemias and have black box warnings for SOS/VOD. Given the paucity of data on ursodiol’s use as SOS/VOD prophylaxis in patients who did not have HSCT, this study assessed the real-world comparative incidences of hepatotoxicity and SOS/VOD in adults with acute leukemia who received GO/InO and did or did not receive ursodiol prophylaxis.

**OBJECTIVES:** The primary objective was to assess the incidence of hepatotoxicity and SOS/VOD in patients who received ursodiol prophylaxis versus those who did not receive ursodiol prophylaxis. The secondary objective was to quantify the time to hepatotoxicity and confirmed SOS/VOD based on the receipt of ursodiol.

**METHOD:** In an Institutional Review Board–approved, multicenter, retrospective chart review of adults (aged  $\geq 18$  years) with leukemia who received  $\geq 1$  dose of GO/InO at the Harvard Cancer Centers between September 1, 2017, and September 1, 2021, the follow-up period was 100 days after the administration of GO/InO. Patients who received HSCT within the 100 days were excluded. The data collection points included anthropometrics; details on the primary malignancy before the HSCT, GO/InO, and ursodiol regimens; hepatic laboratory tests and hepatotoxic concomitant medications; SOS/VOD diagnostic findings; and overall survival. We implemented descriptive statistics and refined analyses via a 2-sided Wilcoxon rank-sum test, a 2-sided Fisher’s exact test, and a log-rank test.

**RESULTS:** Overall, 93 patients were analyzed. In all, 77.4% received ursodiol prophylaxis (26.4% of patients who received GO/73.6% of patients who received InO) and 21.8% did not (100% of GO patients). There were no significant differences in the changes from baseline to the peak values of alanine aminotransferase, aspartate aminotransferase (AST), alkaline phosphate, and total bilirubin within the follow-up period. The patients who did not receive ursodiol, however, had a higher incidence of grade 3 AST hepatotoxicity than their ursodiol counterparts (60% vs 20.8%, respectively;  $P = .015$ ), and the median time to grade 3 AST hepatotoxicity was shorter in the group that did not receive ursodiol than in the group that received ursodiol (22.8 vs 37.8 days, respectively;  $P = .0016$ ). Moreover, 4.2% of patients in the group that received ursodiol had SOS/VOD compared with none of the patients in the group that did not receive ursodiol. Of the 3 patients who had SOS/VOD, 2 (67%) received GO and had very severe classical disease, and 1 (33%) patient received InO and had mild, late-onset disease; all 3 patients were alive by the follow-up period.

**CONCLUSION:** Ursodiol prophylaxis treatment in adults with acute leukemia who were receiving GO/InO is not associated with lower incidences of hepatotoxicity or SOS/VOD. It is, however, associated with a significantly lower incidence of grade 3 AST hepatotoxicity, as well as a longer time to grade 3 AST hepatotoxicity compared with patients who did not receive ursodiol prophylaxis.

Previously presented at the American College of Clinical Pharmacy 2022 Annual Meeting and at the American Society of Health-System Pharmacists 2022 Midyear Clinical Meeting.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR21

### Use of Bevacizumab Originator versus Biosimilar Drugs for Oncology Indications in a Real-World Data Sample

**Presenters:** Bonnie A. Labdi, PharmD, BCOP, The Craneware Group; Rebecca L. Attridge, PharmD, MSc, BCPS, BCCCP, The Craneware Group, Deerfield Beach, FL

**Co-Authors:** Michelle Winkler, PhD, MPH, The Craneware Group; Alec Gilster, BS, The Craneware Group; Samuel G. Johnson, PharmD, BCPS, FCCP, The Craneware Group, Deerfield Beach, FL

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Abstract #CR21 (Continued)

**BACKGROUND:** Biosimilars have significantly changed the landscape of oncology care in the United States. As of September 30, 2022, 39 biosimilars have been FDA-approved, with several others in various stages of development. This study analyzed real-world data over 3.5 years of a bevacizumab originator drug and biosimilar bevacizumab for on- and off-label oncology indications.

**OBJECTIVES:** The primary objective was to evaluate the use of a bevacizumab originator versus biosimilar drugs for oncology indications. The secondary objectives included evaluating the on-versus off-label use for oncology indications, the treatment setting, and the annual and quarterly trends.

**METHOD:** Deidentified real-world dispensations of a bevacizumab originator (Avastin) and biosimilars (bevacizumab-bvzr [Zirabev] and bevacizumab-awwb [Mvasi]) between January 1, 2019, and June 30, 2022, were extracted using Trisus Medication Compare (The Craneware Group; Deerfield Beach, FL). The patients were matched based on ICD-10 diagnosis codes, excluding patients with a nononcology diagnosis or those receiving an originator and a biosimilar. Significance tests were performed for continuous and categorical characteristics using Kruskal-Wallis and chi-square tests, respectively.

**RESULTS:** In total, 10,840 encounters over a 3.5-year time period (bevacizumab, N = 8523; biosimilars, N = 2317) were identified. Bevacizumab accounted for a higher total use (78.6%) than biosimilars (21.4%). A higher proportion of off-label use was seen with the originator drug versus the biosimilar drugs, whereas a higher proportion of on-label use was seen with biosimilars (off-label use, 5.3% vs 4.1%, respectively; on-label use, 94.7% vs 95.9%, respectively;  $P = .02$ ). The most common on-label indications in both groups were colorectal cancer (46.9% vs 41.8%, respectively); ovarian, fallopian tube, or primary peritoneal cancer (27.6% vs 28.2%, respectively); and glioblastoma (10.7% vs 9.8%, respectively). Off-label use accounted for only 5.1% of dispensations, with the most common indication being endometrial cancer (3.5% vs 3.9%, respectively). The use of the originator drug and the biosimilar was higher in urban and outpatient settings than in rural and inpatient settings ( $P = .02$  vs  $P = .04$ , respectively). Nonacademic settings showed higher biosimilar adoption than academic settings (51.8% vs 48.2%, respectively;  $P = .0005$ ). Overall, the annual trends from 2019 to 2022 show that the use of the bevacizumab originator steadily decreased, from 99.9% to 27.3%, whereas biosimilar use steadily increased, from 0.1% to 72.7%.

**CONCLUSION:** This large real-world analysis showed that bevacizumab biosimilar use for on- and off-label indications increased substantially over time. Mvasi, although approved in April 2017, was not launched until July 2019, and Zirabev was unavailable until December 2019, accounting for low biosimilar use in 2019 and early 2020. Decreases in the originator drug and biosimilar drug use dropped in late 2020, which may be attributed to the COVID-19 pandemic.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR22

### Veterans Health Administration Pharmacy Benefits Management Anti-Cancer Stewardship Pilot: Why Switch to a Second-Line Tyrosine Kinase Inhibitor for the Treatment of Chronic Myeloid Leukemia?

**Presenter:** Kourtney D. LaPlant, PharmD, BCOP, Department of Veterans Affairs, VISN 8 Pharmacy Benefits Management, Gainesville, FL

**Co-Authors:** Bernadette B. Heron, PharmD, BCOP, Veterans Health Administration, Pharmacy Benefits Management Services, Hines, IL; Maria J. A. Ribeiro, MD, Atlanta VA Medical Center, Emory University School of Medicine, Winship Cancer Institute, Atlanta, GA; Mark C. Geraci, PharmD, BCOP, Veterans Health Administration, Pharmacy Benefits Management Services, Hines, IL; James Duvel, PharmD, Veterans Affairs Great Lakes Health Care System (VISN 12), Chicago, IL; Samantha McClelland, PharmD, BCPS, Veterans Affairs Great Lakes Health Care System (VISN 12), Chicago, IL; Donna Leslie, PharmD, Veterans Affairs Great Lakes Health Care System (VISN 12), Chicago, IL; Marshall Tague, PharmD, BCOP, Iowa City Veterans Affairs Medical Center, Iowa City, IA

**BACKGROUND:** The Veterans Health Administration (VHA) Pharmacy Benefits Management Anti-Cancer

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## Abstract #CR22 (Continued)

Stewardship (ACS) was established to promote consistent, high-quality, value-based anticancer drug therapy. Chronic myeloid leukemia (CML) was the initial disease of focus, because tyrosine kinase inhibitors (TKIs) account for the second highest outpatient anticancer drug use by prescription fills, with imatinib, the preferred VA formulary TKI, accounting for the highest use. After the initial process of identifying a disease-specific CML cohort was established, regional pharmacist champions performed a pilot medication use evaluation (MUE) with their respective populations to determine why second-line TKI therapy was needed in select veterans.

**OBJECTIVE:** To describe second-line TKI prescribing patterns among VHA patients with CML with focus on the rationale supporting the change. Data findings will help direct future ACS initiatives in CML prescribing.

**METHOD:** A centralized documentation process was established. Pharmacist champions from 2 Veterans Integrated Service Networks (VISNs), VISN 8 Southeastern and VISN 23 North Central regions, answered MUE questions based on chart review of their identified cohort with CML. The responses to the select data points included the documented reason(s) for switching to second-line therapy (adverse drug reaction [ADR], disease progression, identified mutation, inadequate disease response, no reason provided), prior authorized drug request completed (Yes/No), detailed adjudication rationale (if provided), ADR documented in allergy or ADR section of computerized patient record system (CPRS; Yes/No), and if prior authorized drug request approval was via an oncology pharmacy specialist (Yes/No).

**RESULTS:** The data were reviewed for 97 patients (VISN 8, N = 65; VISN 23, N = 38) who were identified as switching to second-line TKI therapy. The documented reason(s) for a change in the chart included 45% mild or moderate ADR, 26% resistance or inadequate response, and 19% disease progression. The prior authorized drug request forms were completed in 66% of the patients and yielded similar reasons. In all, 12 (24%) of the 49 patients with documented ADRs were recorded in the CPRS. Overall, 78% of the prior authorized drug request approvers were oncology pharmacy specialists. Dasatinib was the most common second-line therapy. Data through September 2022 indicate that 30% of the patients received third-line or later therapy.

**CONCLUSION:** The results of this pilot indicate that, despite variable geography, mild-to-moderate ADRs are the most common reason that patients with CML were switched to second-line therapy, followed by resistance or inadequate response in the first-line setting, and disease progression. Despite ADR documentation being the most frequent reason for adjudication, most of these events were not documented as ADRs in the patient chart. Dasatinib was the most common TKI used in the second-line setting, followed by nilotinib. Most prior authorized drug request approvers were oncology pharmacy specialists.

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2. Hochhaus A, Baccarani M, Silver RT, et al. European LeukemiaNet 2020 recommendations for treating chronic myeloid leukemia. *Leukemia.* 2020;34:966-984.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

### Abstract #CR23

## Assessment and Education of Biosimilars Across an Outpatient Oncology Infusion Network

**Presenters:** Alexander Quesenberry, PharmD, BCOP, Baptist Cancer Center/Baptist Memorial Health Care Corp; Hannah Alley, PharmD, BCOP, Baptist Cancer Center/Baptist Memorial Health Care Corp, Memphis, TN

**Co-Authors:** Glenn Roma, PharmD, PhD, BCOP, Baptist Cancer Center/Baptist Memorial Health Care Corp, Memphis, TN; Gregory Sneed, PharmD, BCOP, Sanofi, Cincinnati, OH

**BACKGROUND:** Despite FDA approval in 2016, nationwide biosimilar adoption has been slow. Challenges to biosimilar use are education, buy-in, electronic medical record integration, lack of interchangeability, payer coverage, and conversion.

**OBJECTIVE:** To improve biosimilar utilization through focused education to improve understanding and confidence in using these agents.

**METHOD:** To gauge baseline staff knowledge, we created a modified version of the European Society for Medical Oncology biosimilars in oncology survey. This survey included content assessing knowledge of biosimilars as well as

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## Abstract #CR23 (Continued)

the biosimilar approval pathway. In addition, to assess feelings toward biosimilar use as well as any perceived obstacles or barriers, several items focused on individual opinions and attitudes towards biosimilar agents. Prescribers, nursing staff, pharmacy, ancillary clinical staff, financial counselors, and members of the administration were encouraged to participate in the survey. Following the initial survey, we created and disseminated an educational handout addressing knowledge deficits identified from the survey results. The handout focused on 3 aspects: defining a biosimilar, the biosimilars approval process, and interchangeability. After disseminating the handout, we administered the survey to assess the impact of the education on knowledge and opinions related to biosimilars.

**RESULTS:** A total of 62 employees completed the initial survey, 16% prescribers, 13% pharmacists, 28% nursing staff, and 43% other staff. Regarding the 3 knowledge-based questions: 72% correctly defined a biosimilar, 26% correctly understood the process of interchangeability, and 37% correctly understood the concept of extrapolation of indications. A total of 49 employees completed the post-education survey, 16% prescribers, 31% pharmacists, 12% nursing staff, and 41% other staff. Regarding the 3 knowledge-based questions, 84% correctly defined a biosimilar (12% improvement), 53% correctly understood the process of interchangeability (27% improvement), and 53% correctly understood the concept of extrapolation of indications (16% improvement).

**CONCLUSION:** During fiscal year 2021, Baptist Cancer Center underwent a coordinated biosimilar utilization effort across its 17 clinic locations. This effort focused on preferred biosimilar selection, provider and patient education, electronic medical record incorporation, and routine biosimilar utilization assessment. As a result, Baptist Cancer Center saved \$9 million in fiscal year 2021 in medication expense by using biosimilars 79% of the time and improved clinic staff understanding of biosimilars. This demonstrates that focused educational efforts can beneficially drive use of biosimilars across a medical system.

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## LATE-BREAKING RESEARCH: Practice Management Research

### Abstract #LB01

## Optimizing Corticosteroid Use for Immune-Related Adverse Events at a Community Oncology Practice

**Presenter:** Christin M. Molnar, PharmD, BCOP, Cancer & Hematology Centers of Western Michigan, Grand Rapids, MI

**BACKGROUND:** Immune-related adverse events (irAEs) are a known risk with immune checkpoint inhibitor (ICI) therapy that may lead to significant morbidity and/or mortality in patients. The use of ICI therapies is widespread across many tumor types, which presents an opportunity for interdisciplinary collaboration to ensure safe and effective use. Patients with higher-grade irAEs may be initiated on systemic corticosteroid therapy to mitigate the adverse events (AEs). The proper management of patients throughout their corticosteroid course is essential; this includes upfront education on the potential AEs of corticosteroid therapy, routine reassessment and regrading of the irAE, potential escalation of care, and the initiation of corticosteroid tapering when appropriate. At Cancer & Hematology Centers of Western Michigan, a community oncology practice with 5 clinic locations, we identified a need for standardization and optimization of this process for our patient population.

**OBJECTIVE:** To standardize the use of corticosteroids for irAEs to ensure safe and effective use practice-wide.

**METHOD:** An interdisciplinary team was formed in late 2021 with the goal of assessing and improving the care provided to patients receiving ICI therapies. The team included a physician, a registered nurse, and a pharmacist. The team designed a regimen within the electronic medical record (EMR); this was to be assigned to any patient prescribed systemic corticosteroids for an irAE. The regimen included the corticosteroid order, supportive-care medications at appropriate intervals, scheduled nurse telehealth visits, and scheduled provider (physician or advanced practice provider) visits. In addition, a standard note template for nurse telehealth visits was developed to ensure consistent documentation. After the regimen was built within the EMR, education and training were provided to all clinical staff to ensure an understanding of the new protocol.

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## Abstract #LB01 (Continued)

**RESULTS:** The regimen went active on September 26, 2022. In a 2-month period, the regimen was initiated for 21 patients who were prescribed a systemic corticosteroid for an irAE. The most common irAEs were hepatotoxicity (N = 6), diarrhea/colitis (N = 4), and pneumonitis (N = 3). Of the 70 scheduled nurse telehealth assessments, 58 (82.9%) were completed. The standard documentation template was appropriately used in 35 (60.3%) of the 58 encounters.

**CONCLUSION:** Managing irAEs is a complex process requiring interdisciplinary collaboration. With this initiative, we implemented a method by which a practice such as ours can more effectively manage patients requiring systemic corticosteroids for an irAE. To date, we have identified additional opportunities for improvement, such as ensuring that all assessments and documentation occur per protocol.

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## LATE-BREAKING RESEARCH: Clinical/Translational Research

## Abstract #LB02

## Efficacy of Tixagevimab-Cilgavimab in Preventing SARS-CoV-2 in Patients with Hematologic Malignancies

**Presenter:** James Davis, PharmD, BCOP, Medical University of South Carolina, Hollings Cancer Center, Charleston, SC

**Co-Authors:** Katelynn Granger, PharmD; Kiera Roubal, PharmD; Deidra Smith, PharmD; Kelly J. Gaffney, PharmD, BCOP; Mary McGann, PharmD, BCOP; Alyssa Cendagorta, PharmD; Aswani Thurlapati, MD; Amanda Herbst, PA-C; Lindsey Hendrickson, DNP; Hamza Hashmi, MD; Brian T. Hess, MD, Medical University of South Carolina, Hollings Cancer Center, Charleston, SC

**BACKGROUND:** Despite the use of COVID-19 mRNA vaccines, patients with hematologic malignancies who become infected with severe acute respiratory virus (SARS-CoV-2) have increased risks for morbidity and mortality as a result of a diminished immune response to vaccination, advanced age, the use of immunosuppressive therapies, and immunodeficiency.<sup>1-5</sup> Pre-exposure prophylaxis with tixagevimab-cilgavimab (Evusheld) may be an alternative strategy to decrease the incidence and/or severity of COVID-19 in these patients.<sup>6,7</sup>

**OBJECTIVE:** To determine the real-world efficacy and incidence of COVID-19 breakthrough infections in patients with hematologic malignancy who are receiving pre-exposure prophylaxis with tixagevimab-cilgavimab.

**METHOD:** We retrospectively analyzed the medical records at our institution to define the incidence of COVID-19 infection in patients with hematologic malignancies who received pre-exposure prophylaxis with tixagevimab-cilgavimab from January 2022 to November 2022. COVID-19 infection was defined by confirmed positive SARS-CoV-2 polymerase chain reaction and/or rapid antigen testing.

**RESULTS:** At a median follow-up of 190 days (range 19-289), 351 patients received tixagevimab-cilgavimab. A total of 41 (11.7%) patients had a confirmed COVID-19 breakthrough infection at a median of 90 days (range 3-170) after the administration of tixagevimab-cilgavimab. There were 31 (76%) infections that occurred  $\geq 30$  days after the administration of tixagevimab-cilgavimab. Among infected patients, 21 (51%) were receiving active treatment at the time of infection. In all, 3 (8%), 10 (25%), and 1 (2%) infected patients had undergone an autologous stem-cell transplant, allogeneic stem-cell transplant, or CAR T-cell therapy, respectively. The median time from transplant to infection was 135 days (range, 32-842 days), with 4 (10%) infections occurring before day 100 after the transplant. A total of 8 (20%) patients were hospitalized for severe infections, and 2 COVID-19-related deaths were observed. The majority (61%) of infected patients had received  $\geq 3$  previous COVID-19 vaccinations. Overall, tixagevimab-cilgavimab was well-tolerated, with 2 patients having low-grade adverse reactions, including diarrhea and rash.

**CONCLUSION:** Patients with hematologic malignancies are at risk for breakthrough infections, despite the use of pre-exposure prophylaxis with tixagevimab-cilgavimab, although it should be emphasized that hospitalization and mortality rates were low. Our findings suggest that these patients should maintain a multimodal prevention strategy,

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## Abstract #LB02 (Continued)

including social distancing, vaccination, and treatment with tixagevimab-cilgavimab.

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## LATE-BREAKING RESEARCH: Clinical/Translational Research

## Abstract #LB03

## Potentially Inappropriate Medication Use and Cognition in Older Women with Breast Cancer

**Presenter:** Ginah Nightingale, PharmD, MBA, BCOP, Jefferson College of Pharmacy, Thomas Jefferson University, Philadelphia, PA

**Co-Authors:** Ancy George, MS, Thomas Jefferson University, Philadelphia, PA; Maysa Abu-Khalaf, MD, MBA, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA; Misung Yi, PhD, Sidney Kimmel Medical College, Thomas Jefferson University, Philadelphia, PA; Kristine Swartz, MD, Thomas Jefferson University, Philadelphia, PA; Andrew Chapman, DO, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia, PA

**BACKGROUND:** Older women with breast cancer (aged  $\geq 60$  years) are at high risk for cognitive impairment based on age, the cancer itself, and pharmacologic treatments. Cognitive impairment reduces treatment adherence, compromises functional status, increases the risk of falls, increases hospitalizations, and degrades quality of life. Potentially inappropriate medication (PIM) use increases such risks, yet the literature on its prevalence and impact on cognition in older women with breast cancer is sparse and limited by antiquated criteria (Beers criteria, 2003-2012).

**OBJECTIVES:** To evaluate the prevalence of PIMs and medications with anticholinergic burden in older women with breast cancer using updated criteria, and to explore the associations between PIM use and anticholinergic burden, clinical factors (eg, cognition, comorbidities), and demographic variables.

**METHOD:** This prospective, 24-month pilot study enrolled 40 women with breast cancer, aged  $\geq 60$  years, from the ambulatory clinic at Sidney Kimmel Cancer Center during 2019 to 2021. PIM use was defined by the 2019 Beers criteria. The anticholinergic cognitive burden (ACB) scale was used to define ACB. The short Montreal Cognitive Assessment (s-MOCA) was used as a screening test; the trail making test (Part B) was used to assess executive function and processing speed; and the subjective memory assessment was used to report subjective complaints. Patient demographic and clinical variables were collected.

**RESULTS:** A total of 40 women were included in the baseline analysis. The mean age was 68 years (range, 60-87 years), 26 (65%) patients were white, 28 (70%) were non-Hispanic, 19 (48%) were married, and 33 (83%) had some college or graduated college. In all, 30 (75%) patients had early-stage disease, and 37 (93%) had an ECOG performance status score of  $\leq 1$ . Overall, 23 (58%) patients reported subjective memory complaints and 18 (46%) patients screened positive on the s-MOCA with a score of  $< 13$  points. The mean number of medications was 10.8, including 5.8 prescriptions, 3.6 nonprescriptions, and 1.5 herbal medications. PIM use and anticholinergic burden were common, with 24 (60%) patients using at least 1 PIM, and 23 (58%) using a medication with an ACB score of  $\geq 1$ . The most common PIMs were NSAIDs (N = 16 patients) and benzodiazepines (N = 8 patients). The baseline variables associated with cognitive impairment were a higher number of medications, PIM use, and ACB score.

**CONCLUSION:** PIM use, anticholinergic burden, and cognitive impairment were common in older women with breast cancer in this study. These data suggest that providers should be aware of overusing PIMs and ACB medications associated with causing cognitive harm. Future studies focused on PIM and ACB deprescribing interventions are needed to optimize the medications linked to cognitive health in this population.

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## LATE-BREAKING RESEARCH: Clinical/Translational Research

## Abstract #LB04

## Safety and Tolerability of an Alternative Capecitabine Dosing Schedule in Patients with Colorectal Cancer

**Presenter:** Mei Ka Fong, PharmD, BCOP, Levine Cancer Institute, Atrium Health, Charlotte, NC

**Co-Authors:** Sarah L. Hanson, PharmD, BCOP, Levine Cancer Institute, Atrium Health, Charlotte, NC; Madison Kuch, MHA, Levine Cancer Institute, Atrium Health, Charlotte, NC; Erin Donohue, PhD, Levine Cancer Institute, Atrium Health, Charlotte, NC; Jimmy Hwang, MD, Levine Cancer Institute, Atrium Health, Charlotte, NC; Mohamed E. Salem, MD, Levine Cancer Institute, Atrium Health, Charlotte, NC

**BACKGROUND:** Capecitabine at FDA-approved doses as a single agent, or in combination, is difficult to tolerate for many patients. Since its approval, alternative doses and schedules have been proposed and evaluated.<sup>1,2</sup> For example, capecitabine at 825 mg/m<sup>2</sup> orally twice daily on days 1 through 5 and on day 8 through every 14 days provides an earlier rest period after 5 days instead of 14 days, which may help improve tolerability, but also a higher dose intensity than the original schedule. This schedule has been employed at our institution.

**OBJECTIVES:** To summarize the frequency of dose modifications and the adverse events (AEs) in patients with colorectal cancer who received this alternative dosing regimen, and to evaluate the tolerability of the alternative dosing, as defined by the frequency of AEs and dose modifications.

**METHOD:** We analyzed adult patients with colorectal cancer who received capecitabine dosed twice daily on days 1 through 5 and days 8 through 12, every 14 days, between January 1, 2018, and July 31, 2020. Patients were excluded if they had received capecitabine with radiation, in combination with irinotecan, or if their creatinine clearance was <30 mL/min. The type of adverse event and the frequency of dose modifications, which were defined as either a dose reduction, delay, and/or treatment discontinuation, were collected.

**RESULTS:** A total of 48 patients who received the alternative dosing were reviewed. In all, 28 patients received a combination of capecitabine and oxaliplatin, and 20 patients received single-agent capecitabine. Of the 48 patients, 47 had at least 1 AE, including myelosuppression, palmar-plantar erythrodysesthesia, stomatitis, fatigue, nausea, vomiting, diarrhea, or constipation. A total of 27 (56.3%) patients had a dose modification, with dose reductions in 13 (27.1%) patients and a dose hold or delay in 14 (29.2%) patients. Capecitabine was eventually discontinued as a result of AEs in 7 (14.6%) patients, with 6 of these patients receiving the combination of capecitabine and oxaliplatin. The most common AE was fatigue (68.8%), followed by diarrhea (60.4%). Palmar-plantar erythrodysesthesia was reported in 14 (29.2%) patients. A total of 5 (10.4%) patients had documented myelosuppression.

**CONCLUSION:** This small, retrospective study provides insight into the potential tolerability of using an alternative dosing regimen for patients with colorectal cancer. Further studies are warranted to determine how the frequency of AEs with the alternative regimen compares with the historical dosing. Larger prospective studies would also help determine the potential survival impact of this alternative dosing regimen in patients with metastatic and nonmetastatic colorectal cancer.

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