## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR01**

# A Pooled Safety Analysis of Loncastuximab Tesirine in Relapsed or Refractory DLBCL in the LOTIS Clinical Trial Program: Incidence, Onset, and Management of Myelosuppression

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**BACKGROUND:** Loncastuximab tesirine-lpyl is an antibody–drug conjugate that includes an anti-CD19 antibody that is conjugated to the alkylating agent SG3199, a pyrrolobenzodiazepine dimer cytotoxin designed to target and kill CD19-expressing malignant B-cells. Loncastuximab tesirine is indicated by the FDA for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after ≥2 previous systemic therapies.

**OBJECTIVE:** To describe the incidence, time to onset, and management of grade ≥3 myelosuppression of patients receiving loncastuximab tesirine for relapsed or refractory DLBCL in the LOTIS-1 and LOTIS-2 clinical trials.

**METHOD:** This pooled safety analysis included patients with relapsed or refractory DLBCL from the phase 1, dose-finding LOTIS-1 clinical trial[1] and the pivotal, single-arm, phase 2 LOTIS-2 clinical trial[2] (data cutoff, March 1, 2021). Loncastuximab tesirine was administered every 3 weeks. LOTIS-1 used doses ranging from 0.015 mg/kg to 0.2 mg/kg, and LOTIS-2 used the approved dose in the prescribing information (0.15 mg/kg for 2 cycles, followed by 0.075 mg/kg for subsequent cycles). Growth factors were permitted, according to ASCO guidelines. Laboratory values were monitored at least weekly for the first 2 cycles and every 3 weeks thereafter. Myelosuppression events were graded according to the Common Terminology Criteria for Adverse Events version 4.0.

**RESULTS:** In the pooled population of patients who received an initial dose of 0.15 mg/kg (N = 215), grade ≥3 neutropenia, thrombocytopenia, and anemia occurred in 69 (32.1%), 43 (20%), and 27 (12.6%) patients, respectively. Febrile neutropenia occurred in 7 (3.3%) patients. In most patients with grade 3/4 neutropenia, the onset occurred in the first 4 months, and in most patients with grade 3/4 thrombocytopenia or anemia, the onset occurred in the first 2 months. Dose delays were the result of grade ≥3 neutropenia, thrombocytopenia, anemia, or febrile neutropenia in 22 (10.2%), 18 (8.4%), 3 (1.4%), and 1 (0.5%) patients, respectively. Treatment discontinuation occurred because of grade ≥3 thrombocytopenia and neutropenia in 5 (2.3%) and 1 (0.5%) patients, respectively. No treatment discontinuation was associated with anemia or febrile neutropenia. Neutrophil growth factors were administered as prophylaxis to 33 (15.3%) patients and as treatment to 56 (26.0%) patients.

**CONCLUSION:** The incidences of grade ≥3 neutropenia, thrombocytopenia, and anemia were <35%, and the incidence of febrile neutropenia was low. Although grade 3/4 neutropenia and thrombocytopenia were among the leading causes of dose delays, the majority of myelosuppression cases were manageable with dose delays and did not require dose reductions or treatment discontinuation.

1. ClinicalTrials.gov. Identifier: NCT02669017. Study of ADCT-402 in patients with relapsed or refractory B-cell lineage non Hodgkin lymphoma (B-NHL). https://clinicaltrials.gov/ct2/show/NCT02669017?term=NCT02669017&draw=2&rank=1.
2. ClinicalTrials.gov. Identifier: NCT03589469. Study to evaluate the efficacy and safety of loncastuximab tesirine in patients with relapsed or refractory diffuse large B-cell lymphoma (LOTIS-2). https://clinicaltrials.gov/ct2/show/NCT03589469?term=NCT03589469&draw=2&rank=1.

## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR02**

# Evaluation of Empiric Double Coverage with Tobramycin for Adult Patients with Febrile Neutropenia

**Presenter:** Amber B. Clemmons, BCOP, PharmD, Clinical Professor, University of Georgia College of Pharmacy, Augusta, GA

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**BACKGROUND:** Appropriate empiric antibiotic use for patients with febrile neutropenia (FN) must balance adequate coverage per local antibiogram and patient factors (eg, history of resistance, clinical presentation), as well as principles of antimicrobial stewardship.[1,2] Based on antibiogram reports showing poor susceptibility of *Pseudomonas* to cefepime, our institution requires the addition of empiric tobramycin therapy for 48 hours (or longer if there is growth of gram-negative organism) for initial management of FN. There is a paucity of data regarding dual antipseudomonal strategy in this setting.[3-6]

**OBJECTIVE:** To evaluate the benefit of tobramycin therapy added to cefepime for empiric treatment of adult patients with FN.

**METHOD:** This retrospective review included adult patients with FN between January 2019 and July 2020. Patients were divided into 3 treatment cohorts: cefepime monotherapy; early dual therapy plus tobramycin therapy added within 48 hours of cefepime initiation, per protocol; and delayed dual therapy plus tobramycin therapy added after 48 hours of cefepime. The primary outcome was adherence to institutional protocol requiring empiric dual treatment with cefepime plus tobramycin. The secondary end points were a comparison of the 3 cohorts regarding hospital length of stay (LOS) and intensive care unit (ICU) LOS; incidence of gram-negative and cefepime-resistant bacteremia, and any gram-negative infection; acute kidney injury; and in-hospital mortality. Statistical analysis included logistic regression, chi-square test, or nonparametric test.

**RESULTS:** Of the 350 patients who received cefepime for FN, 146 (42%) received dual therapy with tobramycin, per protocol. Of those, approximately 80% of the patients discontinued tobramycin therapy by 48 hours. The patient demographics were similar among the 3 groups, except for fewer cases of hematology or transplant, and fewer cases of concomitant vancomycin and hypotension in the cefepime monotherapy group. Overall, the incidence of gram-negative bacteremia was 10%, with resistance to cefepime in 13% of available susceptibility reports. No difference was found among the groups regarding the incidence of gram-negative bacteremia, other gram-negative infections, cefepime resistance, acute kidney injury, ICU admission, or ICU LOS (all $P > .05$). Patients in the cefepime monotherapy group had shorter hospital LOS (6 days + 9.6 days) compared with the early dual-therapy (15 days ± 12.1 days) and delayed dual-therapy (22 days + 14.1 days) groups. Mortality was lower in the cefepime monotherapy cohort compared with the delayed dual-therapy ($P = .04$) but not compared with the early dual-therapy ($P > .05$) groups.

**CONCLUSION:** Overall, no benefits were seen with dual therapy compared with monotherapy groups. Patients who received dual therapy were more likely to have had a transplant or a hematological diagnosis, which might have confounded the LOS and mortality results. In addition, the incidence of gram-negative bacteremia and cefepime resistance was low. Optimal antimicrobial(s) therapy should be dictated by antibiogram, the patient history, and by any risk factors for treatment resistance.

1. Freifeld AG, Bow EJ, Sepkowitz KA, et al. Clinical Practice Guideline for the Use of Antimicrobial Agents in Neutropenic Patients with Cancer: 2010 update by the Infectious Diseases Society of America. *Clin Infect Dis*. 2011;52:e56-e93.

2. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Prevention and Treatment of Cancer-Related Infections. Version 1.2021. July 2, 2021. www.nccn.org/professionals/physician_gls/pdf/infections.pdf. Accessed October 7, 2021.

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**Abstract #CR02** *(Continued)*

3. Lee NH, Kang JM, Lee JW, et al. Cefepime versus cefepime plus amikacin as an initial antibiotic choice for pediatric cancer patients with febrile neutropenia in an era of increasing cefepime resistance. *Pediatr Infect Dis J*. 2020;39:931-936.
4. Zengin E, Sarper N, Çakı Kılıç S. Piperacillin/tazobactam monotherapy versus piperacillin/tazobactam plus amikacin as initial empirical therapy for febrile neutropenia in children with acute leukemia. *Pediatr Hematol Oncol*. 2011;28:311-320.
5. Ponraj M, Dubashi B, Harish BH, et al. Cefepime vs. cefoperazone/sulbactam in combination with amikacin as empirical antibiotic therapy in febrile neutropenia. *Support Care Cancer*. 2018;26:3899-3908.
6. Legrand M, Max A, Peigne V, et al. Survival in neutropenic patients with severe sepsis or septic shock. *Crit Care Med*. 2012;40:43-49.

## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR03**

# Treatment Patterns, Real-World Outcomes, and Resource Use in Patients with Non–MSI-High or Mismatch Repair Proficient Advanced Endometrial Cancer

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**BACKGROUND:** Chemotherapy, the standard of care for patients with advanced endometrial cancer,[1] has suboptimal outcomes. In 2019, novel therapies specific to microsatellite instability (MSI) or mismatch repair (MMR) status changed the treatment landscape in the United States,[2] but real-world outcomes data by MSI or MMR status are sparse.

**OBJECTIVE:** To assess treatment patterns, real-world outcomes, and hospitalization stratified by treatment category, in patients with advanced endometrial cancer and non–MSI-high (MSI-H) or MMR proficient tumors in the United States.

**METHOD:** Endometrial Cancer Health Outcomes (ECHO) is a multicenter, retrospective, chart review US study in which physicians consented to participate and provided de-identified data for adult women with inoperable non–MSI-H or MMR proficient advanced endometrial cancer. Patients had received ≥1 previous systemic therapies and had disease progression between July 1, 2016, and June 30, 2019. Data collected included patient demographics, clinical characteristics, treatment category, clinical outcomes, and hospitalization. Kaplan-Meier analyses were performed to estimate time to treatment discontinuation, real-world progression-free survival (PFS) and overall survival (OS), stratified by chemotherapy or hormonal therapy. The study protocol was approved by the Institutional Review Board.

**RESULTS:** The study included 139 patients (average age, 64 years). Approximately 64% of the patients were white, and 53% had ECOG performance score of ≥2. For second-line therapy, 114 patients received chemotherapy, and 25 patients received hormonal therapy, with a median follow-up of 9 and 8 months, respectively. The median time to treatment discontinuation was 6 months in the hormonal therapy group and 4 months in the chemotherapy group. The median OS since the initiation of second-line therapy in the hormonal therapy and chemotherapy groups was 9 and 10 months, respectively; the median real-world PFS was 6 and 5 months, respectively; and the best overall response to second-line therapy was 24% and 42%, respectively. A total of 16% of the patients had ≥1 hospitalizations (mean length of stay, 6 days for the hormonal therapy group and 7 days for the chemotherapy group); of the hospitalized patients, 41% had an intensive care unit stay (mean, 2 days and 5 days for the hormonal therapy and chemotherapy groups, respectively).

**CONCLUSION:** These results show that there continues to be significant clinical unmet need in patients with non–MSI-H or MMR proficient advanced endometrial cancer in the United States, indicating the need

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**Abstract #CR03** *(Continued)*

for novel therapies that delay disease progression, improve OS, and/or reduce hospitalization rates for this patient population.

1. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Uterine Neoplasms. Version 3.2021. June 3, 2021. Accessed July 7, 2021.
2. Makker V, Green AK, Wenham RM, et al. New therapies for advanced, recurrent, and metastatic endometrial cancers. *Gynecol Oncol Res Pract*. 2017;4:19. doi: 10.1186/s40661-017-0056-7.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR04**

# Development and Implementation of a Pharmacist-Led Virtual Clinic Improve the Management of Patients with Metastatic Breast Cancer Receiving CDK4/6 Inhibitors

**Presenter:** Jodi Taraba, PharmD, MS, BCOP, Breast Clinical Pharmacist, Mayo Clinic, Rochester, MN

**Co-Authors:** Allison Golbach, PharmD, The University of Kansas Health System, Kansas City, KS; Matt Smith, PharmD, Mayo Clinic, Rochester, MN; Kristin Mara, MS, Mayo Clinic, Rochester, MN; Karthik Giridhar, MD, Mayo Clinic, Rochester, MN

**BACKGROUND:** The use of cyclin-dependent kinase (CDK)4/6 inhibitors in combination with endocrine therapy for patients with advanced hormone receptor (HR)-positive, human epidermal growth factor (HER)2-negative breast cancer is rising.[1-5] Managing oral oncology agents remotely, using a patient-centered model, was challenging in our previous practice. Our group developed a pharmacist-led, multidisciplinary virtual clinic to improve the management of patients who are receiving CDK4/6 inhibitors.

**OBJECTIVES:** To evaluate the adherence to recommended laboratory monitoring in patients using palbociclib therapy; to identify areas for optimization, including the development of a pharmacist-led CDK4/6 inhibitor virtual clinic; and to assess the impact of this clinic on adverse events, adherence, laboratory monitoring, and the identification of drug–drug interactions.

**METHOD:** This study included 2 cohorts, a retrospective cohort and a prospective cohort. The retrospective cohort included patients with HR-positive, HER2-negative breast cancer who initiated palbociclib therapy between May 8, 2018, and June 4, 2019; were aged ≥18 years; and had a diagnosis of advanced or metastatic breast cancer. The prospective cohort included patients receiving a CDK4/6 inhibitor—palbociclib, abemaciclib, or ribociclib—who were enrolled in the virtual clinic between May 1, 2020, and April 10, 2021. For both cohorts, the data were collected for up to the first 6 cycles of therapy. The primary outcome was the rate of adherence to recommended CDK4/6 inhibitor therapy, by laboratory monitoring, defined as laboratory blood draws every 2 weeks for the first 2 cycles and before the start of each cycle thereafter ± 3 days. The secondary outcomes included the rate of medication adherence, as reported by the patient, and assessment of potential drug interactions.

**RESULTS:** Patients managed by the virtual clinic were contacted, primarily via phone, every 2 weeks for the first 2 months, then monthly thereafter. These virtual visits included review of laboratory test results, medication adherence, adverse events assessment, medication reconciliation, and screening for drug interactions. Laboratory tests were appropriately done at 462 of 541 time points in the 81 patients in the retrospective cohort, and at 128 of 139 time points in the 28 patients in the prospective cohort (85.4% vs 92.1%; $P = .038$). The patient-reported adherence to the prescribed medication was more than 99%. A total of 38 potential drug therapy problems were identified. The interventions included patient education during therapy administration, thereby increasing adherence, symptom management, drug–supplement interactions, and monitoring of QT interval prolongation.

**CONCLUSION:** The implementation of a pharmacist-led virtual clinic significantly improved adherence to laboratory testing in patients receiving CDK4/6 inhibitor therapy and is now a sustained model in our clinical practice. The development and implementation of interactive care plans to use technology for the management of patients receiving CDK4/6 inhibitors is ongoing.

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**Abstract #CR04** *(Continued)*

1. Finn RS, Martin M, Rugo HS, et al. Palbociclib and letrozole in advanced breast cancer. *N Engl J Med.* 2016;375:1925-1936.
2. Turner NC, Slamon DJ, Ro J, et al. Overall survival with palbociclib and fulvestrant in advanced breast cancer. *N Engl J Med.* 2018;379:1926-1936.
3. Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. *N Engl J Med.* 2016;375:1738-1748. Erratum in: *N Engl J Med.* 2018;379:2582.
4. Slamon DJ, Neven P, Chia S, et al. Phase III randomized study of ribociclib and fulvestrant in hormone receptor–positive, human epidermal growth factor receptor 2–negative advanced breast cancer: MONALEESA-3. *J Clin Oncol.* 2018;36:2465-2472.
5. Goetz MP, Toi M, Campone M, et al. MONARCH 3: abemaciclib as initial therapy for advanced breast cancer. *J Clin Oncol.* 2017;35:3638-3646.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR05**

# Impact of a Remote Oncology Clinical Pharmacist Program in 4 Community Oncology Practices

**Presenter:** Melissa Carroll, PharmD, BCPS, Senior Clinical Pharmacist, McKesson/US Oncology Network

**Co-Authors:** Shannon Hough, PharmD, BCOP, Director, ClinReview and Clinical Content, McKesson/US Oncology Network; Joshua Howell, PharmD, BCOP, Vice President, Pharmacy and Clinical Programs, McKesson/US Oncology Network; Elizabeth Koselke, PharmD, BCOP, Senior Clinical Pharmacist, McKesson/US Oncology Network; Julianna Kula, PharmD, BCOP, Senior Clinical Pharmacist, McKesson/US Oncology Network

**BACKGROUND:** The impact and role of a clinical pharmacist in a community oncology setting is not well-described in the literature. The US Oncology Network recently implemented a centralized clinical pharmacist review program (ClinReview) to provide oncology clinical pharmacist services to community oncology practices.

**OBJECTIVE:** To evaluate the impact of remote clinical reviews by oncology pharmacists in community oncology practices.

**METHOD:** Oncology-trained clinical pharmacists reviewed electronic files for recently placed or modified chemotherapy regimen orders within 4 community oncology practices. The ClinReview pharmacists identified opportunities to modify ordered therapy, based on clinical variables, waste reduction, or financial stewardship. The recommendations were discussed with the treating oncologist at the community oncology practice or modified the regimen, if permitted by approved practice policy. Each pharmacist was appointed at half full-time equivalents. Financial and workload metrics were tracked to monitor the impact of the pharmacist interventions.

**RESULTS:** In 28 weeks, 2234 reviews were documented, and 1038 (46.5%) required modification by a pharmacist. The recommended modifications included 440 (42%) clinical change, 433 (42%) dose rounding, and 165 (16%) medication substitution. The most common clinical changes included 146 (33%) recommendations for additional monitoring, 137 (31%) modifications to supportive care, and 106 (24%) modifications to anticancer medication dose or frequency. Of these clinical recommendations, 235 (53%) were identified by the ClinReview pharmacist as directly influencing patient safety. The clinical pharmacist was remotely integrated into the care team, influencing complex patient care decisions, such as anticancer regimen selection and dosing. The financial impact of the pharmacist resulted in margin improvements totaling $522,473, and a reduction of $2,766,001 in the total cost of care in medication expenses. The expense of the pharmacists during this period was $117,571. To date, the return on investment for the pharmacists compared with the margin improvement was 444%.

**CONCLUSION:** Community oncology practices seek to provide high-value care in a resource-constrained model. An oncology clinical pharmacist is a cost-effective and clinically invaluable member of the care team in community oncology practices. Pharmacists identified opportunities to improve medication safety, drug regimen optimization, and demonstrated substantial financial impact on small-scale budgets in community oncology practices. Oncology-trained pharmacists are chemotherapy experts who are well-equipped to review clinical orders in a complex patient population at risk for medication-related adverse effects.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR06**

# Impact of PGY2 Oncology Pharmacy Residents' Learning Experiences During the COVID-19 Pandemic

**Presenter:** Yun Man, PharmD, BCOP, Medication Use Quality and Policy Specialist, Dana-Farber Cancer Institute, Boston, MA

**Co-Authors:** Megan Menon, PharmD, BCOP, Medication Safety Officer, Pharmacy, Roswell Park Comprehensive Cancer Center, Buffalo, NY; Lijian Cai, PharmD, Chief Pharmacy Officer, Pharmacy, Roswell Park Comprehensive Cancer Center, Buffalo, NY

**BACKGROUND:** The COVID-19 pandemic caused an unprecedented challenge with supply and demand of staff disruption in the healthcare system.[1] The pharmacy residency learning experiences were ultimately affected by the COVID-19 pandemic.[2]

**OBJECTIVE:** To evaluate the impact of oncology pharmacy residents' learning experiences during the COVID-19 pandemic by conducting an inquiry with response measurement from the American Society for Health-System Pharmacists (ASHP)-accredited postgraduate year 2 (PGY2) oncology pharmacy residency programs at National Comprehensive Cancer Network (NCCN) member institutions.

**METHODS:** We surveyed a stratified sample of ASHP-accredited PGY2 oncology pharmacy residencies at 28 NCCN member institutions through the NCCN Pharmacy Directors Forum. The survey included 43 questions and was delivered to the panel participants. The survey was deployed using the web-based survey tool SurveyMonkey, and targeted oncology pharmacy directors who are involved in PGY2 residency training. The representative of each program had the opportunity to complete the survey or to forward it to an alternative delegate within the program, for completion. Requests to participate were sent through e-mail to the participants. The survey included questions related to the oncology learning experience, pharmacy staffing, educational activities, and onboarding process after the emergence of the COVID-19 pandemic in the United States.

**RESULTS:** Of the selected 28 residencies that were sent the survey, 17 residencies completed the survey between February 22 and March 19, 2021, resulting in a 60.7% survey response rate. Participating programs mostly have 2 oncology residents and at least 21 oncology pharmacy preceptors. At the time of the survey, 94% of the respondents reported they had no changes in the numbers and duration of the core and elective learning experiences. In all, 82% of the responding programs continued to have residents on the same staffing hours as before the pandemic. As reported by the survey respondents, the activities that were fully transitioned to virtual reporting included educational responsibility (41%), residents–students teaching encounters (11.76%), and conference presentations (87.5%).

**CONCLUSION:** The oncology pharmacy residency training experience has been affected by the COVID-19 pandemic, with the most significant change reported in shifting the learning experience to a remote format. Flexibility and adaptability are essential for residency programs that are required to undergo rapid structural changes and maintain consistent training experiences for residents.

1. Welles Sasser C, Wolcott MD, Morbitzer KA, Eckel SF. Lessons learned from pharmacy learner and educator experiences during early stages of COVID-19 pandemic. *Am J Health Syst Pharm*. 2021;78:872-878.
2. Moore WJ, Webb A, Morrisette T, et al. Impact of COVID-19 pandemic on training of pharmacy residents and fellows: results from a national survey of postgraduate pharmacy trainees. *Am J Health Syst Pharm*. 2021;78:1104-1111.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR07**

# Integrated Health-System Specialty Pharmacy Support in Reducing Financial Toxicity of Oral Oncolytic Therapy

**Presenter:** Tanner Buchanan, Pharmacy Intern, University of Rochester Specialty Pharmacy, Rochester, NY

**Co-Authors:** Shannon Gowen, PharmD, Clinical Pharmacist, and Jerimiah Moore, PharmD, Clinical Pharmacist, University of Rochester Specialty Pharmacy, Rochester, NY

**BACKGROUND:** Oral anticancer therapy has become an increasingly popular alternative to traditional cancer regimens. As a result, patients have fewer office visits and less medication complications.[1] Although oral therapy is more convenient than intravenous therapy, oral medications come with significant financial barriers, which can limit patient access to, and affect the success of, these regimens.[1,2] In 2019, pharmacists from the University of Chicago Medical Center published an article in the *Journal of Managed Care & Specialty Pharmacy* that drew attention to the increasing need for an oncology specialty pharmacy to assist with reduced financial toxicity, by securing copay assistance for patients with cancer.[3] They reported the results of their study showing that of 75 patients who received financial assistance, the cost-savings ranged from $5 to $13,138 per prescription claim.[3] The high cost burden of oral anticancer medications may result in limited access to therapies, delays in starting treatment, and therapy abandonment.[1]

**OBJECTIVES:** To determine the total financial support obtained by University of Rochester Specialty Pharmacy to help relieve patients from financial toxicity associated with oral oncolytic medications, and to determine the percentage of patients receiving copay assistance support, including independent foundations, manufacturer copay cards, and social work funding.

**METHOD:** This retrospective quality improvement project was granted Institutional Review Board exemption. We reviewed prescription claim data for patients who were prescribed an oral oncolytic through the University of Rochester Wilmot Cancer Institute between July 20, 2020, and July 20, 2021, and filled at our specialty pharmacy. The data were analyzed using descriptive statistics.

**RESULTS:** Over a 1-year period, a total of 12,310 prescription claims were reviewed for 1746 patients who filled an oral oncolytic through our specialty pharmacy. Of these patients, 932 (53.4%) patients received financial assistance, including 25% of patients who used copay assistance from independent foundation grants, 11.2% who used manufacturer copay cards/vouchers, and 17.2% who received financial support through internal social work funding. After optimizing New York State Epic enrollment, our specialty pharmacy patients received $4,403,513.73 in financial assistance, including $2,704,845.41 that was obtained either from independent grants (38.5%), manufacturer copay card/vouchers (41.8%), or the University of Rochester internal social work funding (19.7%). Before financial assistance was obtained, the average patient copay for foundation/grant, copay card, and social work was $328.65, $1730.70, and $807.05, respectively. After financial assistance was obtained through this project, the average patient copay was $0.80, $46.48, and $96.23, respectively.

**CONCLUSION:** These relatively low copays with our financial assistance program for high-cost oral anticancer therapy highlight the value that an integrated health-system specialty pharmacy has in the care of patients with cancer when financial assistance is obtained.

1. Zullig LL, Wolf S, Vlastelica L, et al. The role of patient financial assistance programs in reducing costs for cancer patients. *J Manag Care Spec Pharm*. 2017;23:407-411.
2. Niccolai JL, Roman DL, Julius JM, Nadour RW. Potential obstacles in the acquisition of oral anticancer medications. *J Oncol Pract*. 2017;13:e29-e36.
3. Farano JL, Kandah HM. Targeting financial toxicity in oncology specialty pharmacy at a large tertiary academic medical center. *J Manag Care Spec Pharm*. 2019;25:765-769.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR08**

# Perceptions of PGY2 Oncology Programs on Financial Toxicity Education and Preparedness

**Presenter:** Nicholas K. Chow, PharmD, BCOP, Clinical Pharmacy Supervisor, Clinical Trials, Miami Cancer Institute, Baptist Health South Florida

**Co-Authors:** Gaines Kyna Gania, PharmD, Ochsner Medical Center; Monica Tadros, PharmD, Miami Cancer Institute, Baptist Health South Florida; Benito Fernandez, PharmD, Nova Southeastern University College of Pharmacy; Aisha Shokoya, PharmD, Baptist Health South Florida; Nicholas Chow, PharmD, Miami Cancer Institute, Baptist Health South Florida

**BACKGROUND:** Patients with cancer face a rising financial burden resulting from increased direct and indirect costs associated with cancer treatment.[1] This has an overall negative impact on the financial well-being of a patient,[1-11] which is known as financial toxicity.[5] There is a lack of literature about the implementation of financial toxicity education in postgraduate oncology residency training for pharmacists. In addition, the current American Society of Health-System Pharmacists (ASHP) resident standards for postgraduate year 1 (PGY1) and PGY2 residency programs do not address financial toxicity.

**OBJECTIVE:** To describe the perceptions of PGY2 oncology pharmacy residents and residency program directors about the incorporation of financial toxicity as an area of their training programs and the self-perceptions of their ability and experience in managing financial toxicity for patients.

**METHOD:** In December 2020, we e-mailed a qualitative, voluntary, and anonymous RedCap electronic survey to directors and residents of PGY2 oncology programs who were identified from a convenience sample using the ASHP residency program database. Separate surveys were used for directors and for residents.[12,13] The questions aimed to assess the directors' or residents' familiarity with the concept of financial toxicity, potential training incorporated into the residency program, and the experience with managing financial toxicity. Descriptive statistics were used to analyze the survey data.

**RESULTS:** Overall, 64% of residency program directors were familiar and comfortable with the concept of financial toxicity, whereas 73% of pharmacy residents were less than familiar with the concept of financial toxicity within their program. Only 44% of residency program directors thought that their programs provided sufficient opportunities to master financial toxicity. Furthermore, only 40% of residency program directors were comfortable assisting patients with their financial toxicity, whereas a majority of residents were either uncomfortable or highly uncomfortable managing financial toxicity for patients. In addition, the most frequently used methods of incorporating the concept of financial toxicity in all programs were through specialty pharmacy and patient assistance programs; residents preferred these educational methods, along with guest speakers to provide such training.

**CONCLUSION:** These data indicate that there is a need to improve financial toxicity training in PGY2 oncology residency programs, and this training should be considered as an educational standard. We suggest introducing the concept through guest speakers, followed by practical applications integrated in specialty pharmacies and patient assistance programs. Further research should be considered to assess different pharmacists and/or pharmacy technicians' roles and methods that may help to alleviate the financial toxicity of patients with cancer.

1. McGuire A, Drummond M, Martin M, Justo N. End of life or end of the road? Are rising cancer costs sustainable? Is it time to consider alternative incentive and funding schemes? *Expert Rev Pharmacoecon Outcomes Res*. 2015;15:599-605.
2. Soni A. Top 10 most costly conditions among men and women, 2008: estimates for the U.S. civilian noninstitutionalized adult population, age 18 and older. Medical Expenditure Panel Survey Statistical Brief #331. July 2011. Rockville, MD: Agency for Healthcare Research and Quality. http://meps.ahrq.gov/mepsweb/data_files/publications/st331/stat331.shtml. Accessed November 13, 2021.
3. Mariotto AB, Robin Yabroff K, Shao Y, et al. Projections of the cost of cancer care in the United States: 2010-2020. *J Natl Cancer Inst*. 2011;103:117-128. Erratum in: *J Natl Cancer Inst*. 2011;103:699.
4. Mailankody S, Prasad V. Five years of cancer drug approvals: innovation, efficacy, and costs. *JAMA Oncol*. 2015;1:539-540. Erratum in: *JAMA Oncol*. 2015;1:544.
5. Tran G, Zafar SY. Financial toxicity and implications for cancer care in the era of molecular and immune therapies. *Ann Transl Med*. 2018;6:166. doi: 10.21037/atm.2018.03.28.

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**Abstract #CR08** *(Continued)*

6. Bestvina CM, Zullig LL, Zafar SY. The implications of out-of-pocket cost of cancer treatment in the USA: a critical appraisal of the literature. *Future Oncol.* 2014;10:2189-2199. Erratum in: *Future Oncol.* 2015;11:544.
7. Yabroff KR, Dowling EC, Guy GP Jr, et al. Financial hardship associated with cancer in the United States: findings from a population-based sample of adult cancer survivors. *J Clin Oncol.* 2016;34:259-267.
8. Ramsey S, Blough D, Kirchhoff A, et al. Washington State cancer patients found to be at greater risk for bankruptcy than people without a cancer diagnosis. *Health Aff (Millwood).* 2013;32:1143-1152.
9. Witte J, Mehlis K, Surmann B, et al. Methods for measuring financial toxicity after cancer diagnosis and treatment: a systematic review and its implications. *Ann Oncol.* 2019;30:1061-1070.
10. Meeker CR, Geynisman DM, Egleston BL, et al. Relationships among financial distress, emotional distress, and overall distress in insured patients with cancer. *J Oncol Pract.* 2016;12:e755-e764.
11. Zafar SY, Newcomer LN, McCarthy J, et al. How should we intervene on the financial toxicity of cancer care? One shot, four perspectives. *Am Soc Clin Oncol Educ Book.* 2017;37:35-39.
12. Jones TL, Baxter MAJ, Khanduja V. A quick guide to survey research. *Ann R Coll Surg Engl.* 2013;95:5-7.
13. Choi BCK, Pak AWP. A catalog of biases in questionnaires. *Prev Chronic Dis.* Jan 2005;2:A13.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR09**

# Pharmacist-Led Oral Chemotherapy Monitoring Pilot Study and Assessment of Patient-Reported Outcomes and Adherence

**Presenter:** Jessie Signorelli, PharmD, BCOP, Clinical Pharmacist–Hematology/Oncology, Massachusetts General Hospital, Boston

**Co-Authors:** Christopher Bell, PharmD, BCOP, Clinical Pharmacist–Hematology/Oncology, Pharmacy, Massachusetts General Hospital; Stephanie Monaco, PharmD, BCOP, Clinical Pharmacist–Hematology/Oncology, Pharmacy, Memorial Sloan Kettering Cancer Center

**BACKGROUND:** With the shift from intravenous to oral chemotherapy, patients are more responsible for self-monitoring medication adherence and adverse events (AEs).[1-6] Specialty pharmacies may assess for adherence or AEs; however, no standard model is currently available for patient assessment.[6-12] Oncology pharmacists are in a unique position to focus on the quality and safety of care for patients with cancer using oral chemotherapy, while providing communication between the patient, the physician, and specialty pharmacies. This pilot study aimed to monitor patients with leukemia who started treatment with oral chemotherapy.

**OBJECTIVES:** To characterize an oral chemotherapy monitoring program for patients with leukemia, and to quantify and describe the types of patient-centered activities performed.

**METHOD:** Patients with leukemia who started oral chemotherapy between July 2020 and February 2021 were included in this pilot study. Pharmacists performed education, medication reconciliation, and drug interaction screening at the initiation of oral chemotherapy. Pharmacists followed up with patients every 2 weeks, up to 2 months, and monthly thereafter. Follow-up included telephone calls and in-person visits. Adherence was assessed using the Morisky Medication Adherence Scale-8, and patient-reported outcomes were assessed using the revised Edmonton Symptom Assessment Scale (ESAS).[7,8,11,12] AEs specific to each oral chemotherapy were also assessed. After each follow-up, providers were contacted, which was documented with assessment scores and recommendations.

**RESULTS:** Of the 32 patients who were screened, 19 patients were included in this pilot study. The oral chemotherapy used by patients included imatinib (N = 4), dasatinib (N = 5), ponatinib (N = 1), gilteritinib (N = 2), enasidenib (N = 1), and venetoclax (N = 6). All 19 patients received oral chemotherapy education, with 79% of the education sessions performed inpatient. In addition, 14 medication reconciliations were performed at oral chemotherapy initiation, and 53 reconciliations were performed at follow-up. We identified 14 drug interactions, 11 medications were discontinued, 9 medications were added, and 2 doses were changed. Pharmacists performed 62 follow-up encounters. A total of 26 adherence assessments demonstrated adherence (N = 21), medium adherence (N = 4), and low adherence (N = 1). Furthermore, 62 revised ESAS assessments were performed, with 64% reporting no symptoms, 17% mild, 13% moderate, and 5% severe symptoms. A total of 20 laboratory tests were ordered based on pharmacist recommendation at oral chemotherapy initiation and follow-up. The median follow-up time spent with patients was 10 minutes (IQR 10-15), and the overall median time spent on follow-up was 25 minutes (IQR 15-29).

*Continued*

**Abstract #CR09** *(Continued)*

**CONCLUSION:** During this pilot study, pharmacists identified drug interactions, recommended monitoring, and provided symptom assessment and recommendations for patients with leukemia who started oral chemotherapy. The results demonstrated that pharmacists have a role in oral chemotherapy monitoring and symptom management.

1. Bedell CH. A changing paradigm for cancer treatment: the advent of new oral chemotherapy agents. *Clin J Oncol Nurs*. 2003;7(6 suppl):5-9.
2. DeCardenas R, Helfrich JS. Oral therapies and safety issues for oncology practices: patient support is key to delivering safe oral chemotherapy. *Oncol Issues*. 2010;25:40-42.
3. Muluneh B, Deal A, Alexander MD, et al. Patient perspectives on the barriers associated with medication adherence to oral chemotherapy. *J Oncol Pharm Pract*. 2018;24:98-109.
4. Krikorian S, Pories S, Tataronis G, et al. Adherence to oral chemotherapy: challenges and opportunities. *J Oncol Pharm Pract*. 2019;25:1590-1598.
5. Partridge AH, Avorn J, Wang PS, Winer EP. Adherence to therapy with oral antineoplastic agents. *J Natl Cancer Inst*. 2002;94:652-661.
6. Noens L, van Lierde MA, De Bock R, et al. Prevalence, determinants, and outcomes of nonadherence to imatinib therapy in patients with chronic myeloid leukemia: the ADAGIO study. *Blood*. 2009;113:5401-5411.
7. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. *J Clin Hypertens (Greenwich)*. 2008;10:348-354.
8. De Las Cuevas C, Peñate W. Psychometric properties of the eight-item Morisky Medication Adherence Scale (MMAS-8) in a psychiatric outpatient setting. *Int J Clin Health Psychol*. 2015;15:121-129.
9. Fromme EK, Eilers KM, Mori M, et al. How accurate is clinician reporting of chemotherapy adverse effects? A comparison with patient-reported symptoms from the Quality-of-Life Questionnaire C30. *J Clin Oncol*. 2004;22:3485-3490.
10. Basch E, Deal AM, Kris MG, et al. Symptom monitoring with patient-reported outcomes during routine cancer treatment: a randomized controlled trial. *J Clin Oncol*. 2016;34:557-565. Errata in: *J Clin Oncol*. 2016;34:2198; *J Clin Oncol*. 2019;37:528.
11. Hannon B, Dyck M, Pope A, et al. Modified Edmonton Symptom Assessment System including constipation and sleep: validation in outpatients with cancer. *J Pain Symptom Manage*. 2015;49:945-952.
12. Chang VT, Hwang SS, Feuerman M. Validation of the Edmonton Symptom Assessment Scale. *Cancer*. 2000;88:2164-2171.

## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR10**

# The Impact of a Comprehensive Immunotherapy Continuing Education Curriculum on Pharmacists' Knowledge, Competence, and Confidence

**Presenter:** Michelle A. Worst, PharmD, BCOP, MBA, Director of Clinical Strategy, Hematology/Oncology, Medscape Oncology

**Co-Authors:** Haleh Kadkhoda, MS, Executive Director, Strategic Accounts, Medscape Oncology; Jacob Cohen, Manager, Outcomes, Medscape Oncology

**BACKGROUND:** Ten years after their introduction, immune checkpoint inhibitors are widely used across a variety of tumor types, including melanoma, lung cancer, head and neck cancers, bladder cancer, hepatocellular carcinoma, and renal-cell carcinoma. Within these tumor types, immune checkpoint inhibitors have demonstrated an extension of patient survival. The success of these agents also introduces significant challenges in terms of the role of biomarkers, integration of emerging data into clinical practice, and the identification and management of immune-related adverse events.

**OBJECTIVE:** To determine if an online continuing education (CE) curriculum consisting of a series of online, video-recorded discussions, developed through the collaboration between Medscape Oncology and the Society for Immunotherapy of Cancer (SITC), could improve pharmacists' ability in managing patients with solid tumors who are receiving immune checkpoint inhibitors.

**METHOD:** The analysis used a repeated pairs pre-/post-test study design, in which each individual served as his or her own control. Overall improved learner was assessed from December 2020 to August 2021, by calculating the percentage of learners who gained knowledge or competence, as demonstrated by answering at least 1 more question correctly after CE participation than before. We compared pre- and postassessment scores to determine relative changes in the proportion of correct responses to knowledge or competence questions. McNemar's chi-square test was used to assess the significance of improvements in knowledge, competence, and confidence.

**Abstract #CR10** *(Continued)*

**RESULTS:** Statistically significant improvements in knowledge, competence, and confidence were seen after education consumption among participating pharmacists. Pharmacists (N = 22 to 1632) improved their knowledge of immune checkpoint inhibitor mechanisms ($P$ <.001) and clinical trial data ($P$ <.001). The skills to identify patients eligible for immune checkpoint inhibitors also improved ($P$ <.001). Finally, the confidence in using immune checkpoint inhibitors for the treatment of cancer improved ($P$ <.001), as well as coordinating with the interprofessional team ($P$ <.001). This education also resulted in 80% of the pharmacists experiencing an increase in or reinforcement of knowledge or competence from this CE.

**CONCLUSION:** The use of a series of online, video-recorded discussions was successful in improving the knowledge, competence, and confidence of pharmacists regarding the management of patients who are receiving immune checkpoint inhibitors across solid tumors. These results can translate to improvements in clinical care. We also identified the need for additional educational activities to address residual gaps and further increase pharmacists' ability in this clinical setting.

## LATE-BREAKING RESEARCH: Clinical/Translational Research

**Abstract #LB01**

# Effect of Concomitant Azole Antifungals on Duration of Myelosuppression in Newly Diagnosed Patients with AML Receiving Venetoclax in Combination with Cladribine and Low-Dose Cytarabine

**Presenter:** Caitlin R. Rausch, PharmD, BCOP, Clinical Pharmacy Specialist, Leukemia, University of Texas M.D. Anderson Cancer Center, Houston

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**BACKGROUND:** The addition of venetoclax to cladribine and low-dose cytarabine (Clad/LDAC) alternating with azacitidine is being investigated for the treatment of patients with newly diagnosed acute myeloid leukemia (AML).[1] Prophylaxis with mold-active antifungals is recommended for patients with AML undergoing induction therapy associated with prolonged and profound neutropenia.[2] The triazole antifungals (azoles) inhibit CYP3A4, the enzyme responsible for venetoclax metabolism. With the combination of venetoclax and hypomethylating agents, concomitant azoles increase the duration of thrombocytopenia.[3] The impact of concomitant azoles on the duration of myelosuppression with Clad/LDAC and venetoclax has not been previously described.

**OBJECTIVE:** To describe the duration of neutropenia and thrombocytopenia in patients receiving Clad/LDAC and venetoclax with concomitant azoles.

**METHOD:** We evaluated newly diagnosed patients with AML treated with intravenous cladribine 5 mg/m$^2$ on days 1 to 5, subcutaneous cytarabine 20 mg twice a day on days 1 to 10, and venetoclax 400 mg, or equivalent, on days 1 to 21 as part of a clinical trial.[1] Venetoclax 100 mg with posaconazole or with voriconazole (strong CYP3A4 inhibitor); 200 mg with isavuconazole (moderate CYP3A4 inhibitor) were considered equivalent. Time to absolute neutrophil count (ANC) and platelet count was counted from day 1 of each course of therapy.

**RESULTS:** A total of 50 patients who achieved complete remission with or without complete blood count recovery after induction were included in the study. During induction, 8 (16%) patients received venetoclax 400 mg without an azole. The remaining 42 received either posaconazole (N = 26; 52%), voriconazole (N = 14; 28%), or isavuconazole (N = 2; 4%). The median time to ANC >1000 μL$^{-1}$ was 27 days for patients receiving no azole or moderate CYP3A4 inhibitor, and 26 days for those receiving a strong CYP3A4 inhibitor. The median time to platelet count >100,000 μL$^{-1}$ was 27, 18, and 22 days for patients receiving no azole, a moderate CYP3A4 inhibitor, or a strong CYP3A4 inhibitor, respectively. One patient did not

**Abstract #LB01** *(Continued)*

achieve ANC >1000 cells/μL, and 4 patients did not achieve platelet count >100,000 $\mu L^{-1}$ after induction; 4 of them were receiving posaconazole and 1 received voriconazole. All patients received a concomitant CYP3A4 inhibitor during consolidation. Patients receiving posaconazole had prolonged median time to ANC >500 $\mu L^{-1}$ of 49 days (95% confidence interval [CI], 35.43-62.57) and platelet count >50,000 $\mu L^{-1}$ of 74 days (95% CI, 24.25-123.75).

**CONCLUSION:** Concomitant azoles did not significantly affect the duration of myelosuppression during induction; however, the only 4 patients who did not achieve platelet count recovery were receiving a strong CYP3A4 inhibitor. Patients receiving posaconazole had prolonged count recovery during consolidation. Pharmacokinetic analysis of serum venetoclax concentrations when combined with azoles is ongoing. Given the need for concomitant azoles in this patient population, therapeutic drug monitoring may be necessary to optimize venetoclax-based therapies.

1. ClinicalTrials.gov. Identifier: NCT03586609. Venetoclax, cladribine, low dose cytarabine, and azacitidine in treating patients with previously untreated acute myeloid leukemia. https://clinicaltrials.gov/ct2/show/NCT03586609?term=NCT03586609&draw=2&rank=1.
2. Maertens JA, Girmenia C, Brüggemann RJ, et al. European guidelines for primary antifungal prophylaxis in adult haematology patients: summary of the updated recommendations from the European Conference on Infections in Leukaemia. *J Antimicrob Chemother*. 2018;73:3221-3230.
3. Rausch CR, DiNardo CD, Maiti A, et al. Duration of cytopenias with concomitant venetoclax and azole antifungals in acute myeloid leukemia. *Cancer*. 2021;127:2489-2499.

## LATE-BREAKING RESEARCH: Clinical/Translational Research

**Abstract #LB02**

# The Safety of FOLFIRINOX Regimen: Oxaliplatin and Irinotecan Sequence of Administration

**Presenter:** Kara Kubli, PharmD, BCOP, Clinical Pharmacy Specialist–Bone Marrow Transplant, University of Rochester Medical Center, NY

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**BACKGROUND:** The chemotherapy regimen FOLFIRINOX (5-fluorouracil, leucovorin, oxaliplatin, irinotecan) is used in the treatment of pancreatic cancer and colorectal cancer. There is conflicting evidence in the literature regarding the sequencing of irinotecan and oxaliplatin. Historically, oxaliplatin has been administered first, followed by irinotecan. One review suggested that sequencing had no impact on efficacy or safety outcomes, whereas another recommended that irinotecan be given first to reduce cholinergic effects. An in-vitro study showed that oxaliplatin exerts maximal cytotoxicity when administered before SN-38, irinotecan's active metabolite, suggesting giving irinotecan first only in cases of dysarthria. The FOLFOXIRI regimen contains the same medications; however, irinotecan is historically administered first. At our institution, we updated the sequencing of FOLFIRINOX to administer oxaliplatin first. Since that change, providers have noticed adverse effects, including dysarthria and dysphagia.

**OBJECTIVES:** The primary objective was to determine if the sequencing of oxaliplatin and irinotecan has an impact on the incidence of adverse reactions, including dysarthria, dysphagia, numbness, and gastrointestinal discomfort. The secondary objectives were to determine if age, gender, or presence of atropine had an impact on adverse reactions.

**METHOD:** This retrospective study included 84 adults receiving FOLFIRINOX, modified FOLFIRINOX, or FOLFOXIRI plus bevacizumab, from July 2017 to August 2020. We used mixed logistic regression models,

**Abstract #LB02** *(Continued)*

including a fixed effect for regimen sequence, to estimate the infusion adverse reaction rate, while accounting for correlations in the data from multiple infusions on the same patient via a random intercept. Using these models, odds ratios were estimated to compare the risk of infusions between the 2 regimen sequences, while adjusting for other covariates, including age, gender, and use of atropine.

**RESULTS:** When oxaliplatin was administered first, the infusion reaction rate was 18.4% (95% confidence interval [CI], 10.7%-29.7%). When oxaliplatin was administered second, the infusion reaction rate was 2.8% (95% CI, 0.9%-8.0%). The odds ratio of infusion reactions when oxaliplatin was administered first was 7.94 (95% CI, 2.82-22.4; $P$ <.0001). After adjusting for age, gender, and atropine, the effect of sequencing still holds (odds ratio = 7.62; 95% CI, 2.77-21.0; $P$ <.0001).

**CONCLUSION:** These data suggest that there is a correlation between infusion reactions and administration sequence. These data may be beneficial in patients who have reactions; however, more data are needed to evaluate the efficacy of sequencing of irinotecan and oxaliplatin.

1. da Silva AA, Carlotto J, Rotta I. Standardization of the infusion sequence of antineoplastic drugs used in the treatment of breast and colorectal cancers. *Einstein (Sao Paulo)*. 2018;16:eRW4074. doi: 10.1590/S1679-45082018RW4074.
2. Conroy T, Desseigne F, Ychou M, et al; for the Groupe Tumeurs Digestives of Unicancer and the PRODIGE Intergroup. FOLFIRINOX versus gemcitabine for metastatic pancreatic cancer. *N Engl J Med*. 2011;364:1817-1825.
3. Gil-Delgado MA, Bastian G, Guinet F, et al. Oxaliplatin plus irinotecan and FU-FOL combination and pharmacokinetic analysis in advanced colorectal cancer patients. *Am J Clin Oncol*. 2004;27:294-298.
4. Lambert A, Gavoille C, Conroy T. Current status on the place of FOLFIRINOX in metastatic pancreatic cancer and future directions. *Therap Adv Gastroenterol*. 2017;10:631-645.
5. Mancini R, Modlin J. Chemotherapy administration sequence: a review of the literature and creation of a sequencing chart. *J Hematol Oncol Pharm*. 2011;1(1):17-25.
6. Masi G, Vasile E, Loupakis F, et al. Randomized trial of two induction chemotherapy regimens in metastatic colorectal cancer: an updated analysis. *J Natl Cancer Inst*. 2011;103:21-30.
7. Matsuoka A, Maeda O, Inada-Inoue M, et al. FOLFIRINOX-induced reversible dysarthria: a case report and review of previous cases. *Oncol Lett*. 2015;10:2662-2664.
8. Valencak J, Raderer M, Kornek GV, et al. Irinotecan-related cholinergic syndrome induced by coadministration of oxaliplatin. *J Natl Cancer Inst*. 1998;90:160.
9. Zeghari-Squalli N, Raymond E, Cvitkovic E, Goldwasser F. Cellular pharmacology of the combination of the DNA topoisomerase I inhibitor SN-38 and the diaminocyclohexane platinum derivative oxaliplatin. *Clin Cancer Res*. 1999;5:1189-1196.

## LATE-BREAKING RESEARCH: Practice Management Research

**Abstract #LB03**

# Evaluation of the Reliability of 5-FU Elastomeric Pump in an Ambulatory Infusion Center

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

**Co-Author:** Alice Beers, BSN, OCN, NPD-BC, MedStar Washington Hospital Center, Washington, DC

**BACKGROUND:** Continuous infusion of fluorouracil (5-FU) is often used in the treatment of gastrointestinal (GI) malignancies through an ambulatory infusion pump.[1,2] However, the infusion rate of elastomeric pumps is affected by environmental and patient factors.[3,4] Monitoring drug delivery by the pump is essential to treatment efficiency and drug safety.[5] Visual inspection, as recommended in the package insert, is not reliable. A quantitative method to assess the delivery of 5-FU via an elastomeric pump is in great need. Recently, Cusano and colleagues showed the feasibility to monitor 5-FU delivery via Baxter elastomeric pump by comparing pump weights before and after infusion.[6] However, more than 24% of the pumps had remaining fluid of >10%, suggesting insufficient delivery of the elastomeric pumps.[6,7]

**OBJECTIVE:** To evaluate the reliability of SMARTeZ elastomeric pump to deliver 5-FU, by measuring the percentage of pumps that deliver >90% of expected 5-FU dose at the end of 46 hours of infusion.

**METHOD:** This retrospective chart-review study included patients who were at least 18 years old, diagnosed with GI cancer and treated with intravenous 5-FU continuous infusion over 46 hours through elastomeric pump between April 1, 2021, and September 30, 2021. Pregnant females or patients younger than 18 years

**Abstract #LB03** *(Continued)*

old were excluded. The primary end point was the reliability of the 5-FU elastomeric pump, measured by the percentage of elastomeric pumps delivering >90% of expected 5-FU doses. Secondary end points included the average percentage of 5-FU delivery of each pump, the average weight of empty, and full and returned empty pump.

**RESULTS:** A total of 24 patients and 117 pumps were included in the analysis. Overall, 95.7% of the patients received >90% of expected 5-FU dose. The average percentage of 5-FU delivery was 94.9% ± 7.3%. The average weight of empty, full, and returned pumps was 92.9 g ± 1.3 g, 335.1 g ± 1.5 g, and 105.4 g ± 17.7 g, respectively.

**CONCLUSION:** SMARTeZ elastomeric pumps were reliable to deliver 5-FU continuous infusion over 46 hours for patients with cancer.

1. Sabbagh Dit Hawasli R, Barton S, Nabhani-Gebara S. Ambulatory chemotherapy: past, present, and future. *J Oncol Pharm Pract*. 2021;27:962-973.
2. Backler C. Which ambulatory infusion pump is best for 5-FU? April 18, 2019. *ONS Voice*. https://voice.ons.org/news-and-views/which-ambulatory-infusion-pump-is-best-for-5-fu. Accessed July 31, 2021.
3. Salman D, Biliune J, Kayyali R, et al. Evaluation of the performance of elastomeric pumps in practice: are we under-delivering on chemotherapy treatments? *Curr Med Res Opin*. 2017;33:2153-2159.
4. Abe T, Matsuzaka K, Nakayama T, et al. Impact of air temperature and drug concentration on liquid emission from elastomeric pumps. *J Pharm Health Care Sci*. 2021;7:1. doi: 10.1186/s40780-020-00185-5.
5. Institute for Safe Medication Practices. Accidental overdoses involving fluorouracil infusions. June 18, 2015. www.ismp.org/resources/accidental-overdoses-involving-fluorouracil-infusions. Accessed August 31, 2021.
6. Cusano EL, Ali R, Sawyer MB, et al. Baxter elastomeric pumps: weighing as an alternative to visual inspection. *J Oncol Pharm Pract*. 2018;24:163-169.
7. Chambers CR, Pabia M, Sawyer M, Tang PA. Baxter elastomeric pumps: feasibility of weight estimates. *J Oncol Pharm Pract*. 2017;23:429-435.

## LATE-BREAKING RESEARCH: Practice Management Research

**Abstract #LB04**

# Time to Treatment Initiation and Outcomes for Patients with Nonmetastatic Breast Cancer Before and During the COVID-19 Pandemic at Community Cancer Centers

**Presenter:** Fangzheng Yuan, PharmD, BCPS, Clinical Pharmacy Specialist, Baptist Hospitals of Southeast Texas

**Co-Authors:** Ahmed Abdelhakeem, MD, Baptist Hospitals of Southeast Texas; Samantha Blevins, RN, Baptist Hospitals of Southeast Texas; Chelsey Peters, RN, OSN, Baptist Hospitals of Southeast Texas; Susan Whalen, BSN, CTR, Baptist Hospitals of Southeast Texas; Ernest Hymel, MD, PhD, Baptist Regional Cancer Network

**BACKGROUND:** Delays in breast cancer treatment have been associated with increased mortality.[1] The COVID-19 pandemic has posed prolonged and significant stress on healthcare resources, which may have affected the quality and outcomes of breast cancer care.[2]

**OBJECTIVE:** To compare the time to treatment initiation (TTI) and outcomes in patients with nonmetastatic breast cancer before and during the COVID-19 pandemic.

**METHOD:** This retrospective study included adult patients with newly diagnosed nonmetastatic breast cancer at 2 community cancer centers of the Baptist Regional Cancer Network (BRCN) in Southeast Texas. Patients diagnosed between January 2018 and June 2019 were included in the control group. Patients diagnosed between April 2020 and September 2021 were included in the COVID-19 group. Patients were excluded if they received initial treatment outside of the BRCN network or for palliative intent. The primary outcome was TTI, defined as time from histologic diagnosis to treatment initiation. The primary analysis was done by *t*-test. The study had 80% power to detect an absolute increase of 10 days in TTI using a 2-sided alpha of 0.05.

**RESULTS:** The study included 156 patients—87 patients in the control group and 69 in the COVID-19 group. The median follow-up periods were 37 months (IQR, 32-40 months) in the control group and

**Abstract #LB04** *(Continued)*

8 months (IQR, 6-14 months) in the COVID-19 group. No significant difference in TTI was observed between the control (48.3 days) and the COVID-19 (47.7 days) groups (absolute difference, 0.7; 95% confidence interval, 8.6-10.0; *P* = .88). After adjusting for initial treatment modality, histology, and clinical stage, the TTI remained similar between the control group and the COVID-19 group (*P* = .92). No association was noted between the TTI and the number of new COVID-19 cases in the county in the COVID-19 group (*P* = .85). The proportion of patients diagnosed at disease stage II or III was higher in the COVID-19 group (52.2%) compared with the control group (42.3%), although this was not statistically significant (*P* = .23). Breast-conserving surgery was done in 26.5% (9/34) of the control group and 55% (11/20) of the COVID-19 group among patients who completed neoadjuvant systemic therapy and surgeries (*P* = .04). Pathologic complete response was achieved in 58.3% (7/12) of the control group and 14% (1/7) of the COVID-19 group among patients with triple-negative or HER2-positive breast cancer who completed neoadjuvant systemic therapy and surgeries. Overall survival rates at 1 year were 89.7% (78/87) in the control group and 100% (25/25) in the COVID-19 group among patients who reached 1 year after diagnosis (*P* = .09).

**DISCUSSION:** No significant delay in breast cancer treatment initiation was observed during the COVID-19 pandemic. Although preliminary outcomes were similar before and during the COVID-19 pandemic, further assessment of the long-term impact of COVID-19 on breast cancer outcomes is needed.

1. Cone EB, Marchese M, Paciotti M, et al. Assessment of time-to-treatment initiation and survival in a cohort of patients with common cancers. *JAMA Netw Open*. 2020;3:e2030072. doi: 10.1001/jamanetworkopen.2020.30072.
2. Bartlett DL, Howe JR, Chang G, et al. Management of cancer surgery cases during the COVID-19 pandemic: considerations. *Ann Surg Oncol*. 2020;27:1717-1720.