Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR01

Optimizing Iron Dextran Infusion Protocols to Enhance Efficiency and Patient Throughput in an Outpatient Infusion Center: A Process Improvement Initiative

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BACKGROUND: Iron dextran 1000 mg is frequently used in our outpatient infusion center to treat iron deficiency anemia,[1] requiring a lengthy 4-hour chair time, including a test dose followed by a 1-hour observation period before administering the full dose.[2] With increasing patient demand and limited space, reducing the total infusion time became critical to enhance efficiency and patient throughput without compromising safety. Wong and colleagues have demonstrated the safety and efficacy of administering 1000 mg of iron dextran over 1 hour, making it a viable option for streamlining administration.[3] A formal discussion of the proposal was presented to the infusion pharmacist, the nurse leader of the outpatient infusion center, and the medical director for our anemia management program. All agreed to our proposal.

OBJECTIVES: To reduce the observation period between the iron dextran test dose and full dose from 1 hour to 15 minutes, ultimately reducing overall chair time and improving workflow efficiency.

METHODS: A literature review of iron dextran protocols was conducted, and key stakeholders, including the infusion pharmacist, nurse leader, and medical director for the anemia management program, discussed and approved the proposal. The intervention, which began in May 2024, was implemented in 2 phases:

- Phase 1: 34 patients had a 30-minute observation period.
- Phase 2: 50 patients had the observation period reduced to 15 minutes.

Retrospective data on wait times, chair times, and adverse events were collected through the electronic health records for patients receiving iron dextran from October 2023 to September 2024 to assess pre- and postintervention outcomes.

RESULTS: A total of 119 doses were assessed preintervention, and 84 doses were assessed postintervention. The intervention resulted in a 22.6% reduction in wait time (from 95 to 73.5 min) and a 26.9% reduction in chair time (from 305 to 222.2 min). In all, 4 minor reactions were reported, with 2 patients discontinuing treatment. All reactions occurred within 10 minutes of the test dose.

The results were not as drastic as expected, primarily due to the need for additional preparation time for the full dose after communication between nurses and pharmacists.

CONCLUSIONS: Shortening the observation period between iron dextran doses improved infusion center efficiency by reducing chair time and increasing patient throughput, without compromising patient safety. However, further improvement is needed by streamlining the preparation process and enhancing communication between nurses and pharmacists to fully realize the potential of reduced wait times. Future steps include staff education, improving preparation times, and ongoing evaluation of outcomes to ensure sustained and further improvements over the next 6 months.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR02

Characteristics and Dosing Patterns of US Patients Diagnosed With HR-Positive/HER2-Negative Early Breast Cancer Initiating Abemaciclib at a Lower Dose Than the Approved 150 mg Twice Daily

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BACKGROUND: Abemaciclib in combination with endocrine therapy is approved for adjuvant treatment of adult patients with hormone receptor (HR)-positive/HER2-negative, node-positive early breast cancer at high risk of recurrence. Anecdotal insights indicate providers may initiate abemaciclib at a lower dose than the approved 150 mg twice daily to aid tolerability with the aim to increase to the approved dose. This real-world study describes demographic and clinical characteristics, dosing patterns, and incidence of prespecified adverse events (AEs) in patients with early breast cancer who were started on abemaciclib at a lower dose.

METHODS: This study used the nationwide Flatiron Health electronic health records–derived deidentified database. Patients started on abemaciclib October 2021 to November 2022 were included. All results were summarized descriptively. Additional analyses were conducted to compare characteristics of patients starting <150 mg twice daily versus 150 mg twice daily.

RESULTS: Among 453 patients, 65 started abemaciclib at <150 mg twice daily (median follow-up time, 7.1 months). Median age was 56 years, 33.8% had stage III disease, 49.2% had ECOG Performance Scale score of 0 and median Charlson Comorbidity Index score was 0. Abemaciclib was frequently combined with aromatase inhibitors (92.3%), and most patients (56.9%) had a dose modification. The most common starting doses were 100 mg twice daily (56.9%) and 150 mg daily (24.6%); the time to first dose increase was 71 and 15 days, respectively. At first dose modification, 32.3% of patients increased the dose to 150 mg twice daily. Common real-world AEs were diarrhea (58.5%), fatigue (52.3%), and nausea/vomiting (40.0%). In comparison to patients started on 150 mg twice daily (n=388), patients started on a lower dose were more likely to be aged ≥75 years (4.9% vs 13.8%; *P*=.022).

CONCLUSIONS: In the real world, patients with HR-positive/HER2-negative early breast cancer started on abemaciclib at <150 mg twice daily were started on different doses and titration intervals. One-third of patients received the dose increase to 150 mg twice daily. Real-world AEs were generally consistent with clinical trial results.

This abstract was previously presented at the 2024 European Society for Medical Oncology Breast Cancer Annual Meeting.

Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR03

Clinical Characteristics and Treatment Persistence in US Patients With HR-Positive/HER2-Negative, Node-Positive Early Breast Cancer Treated With Abemaciclib: Real-World Study From First Year After Approval

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BACKGROUND: Abemaciclib in combination with endocrine therapy is approved for adjuvant treatment of adult patients with hormone receptor (HR)-positive/HER2-negative, node-positive early breast cancer at high risk of recurrence. The monarchE trial established the efficacy of abemaciclib and endocrine therapy for early breast cancer, with the highest rates of early discontinuation observed in the first few months. The use of abemaciclib in the real-world early breast cancer setting can provide insight into treatment patterns and inform adverse event (AE) management strategies. This retrospective study describes clinical characteristics and treatment persistence in patients with HR-positive/HER2-negative, node-positive early breast cancer starting abemaciclib.

METHODS: Data were accessed from Flatiron Health electronic database. Adult patients with node-positive, stage I-III early breast cancer starting abemaciclib October 2021 (FDA approval) to November 2022 at 150 mg twice daily were analyzed. Persistence rate was defined as the percentage of patients remaining on abemaciclib at 3 months, allowing for ≤60-day medication gap.

RESULTS: A cohort of 354 patients with a median follow-up time from abemaciclib initiation of 8.8 months were selected. The median age was 56 years, 25.4% were aged ≥65 years, 12.7% were Black, 4.0% were Asian, and most patients (80.8%) received care in a community setting. More than half (55.4%) of patients were postmenopausal; 57.9% had an ECOG Performance Status 0; whereas 25.1% had ECOG Performance Status 1. Approximately 33.9% had ≥1 comorbidity, and 12.1% had ≥2 comorbidities, with diabetes (14.1%) being the most frequent. Most patients had stage II (41.8%) or III (38.4%) disease, nodal status N1 (45.2%) or N2 (35.3%), and tumor grade 2 (52.3%). Abemaciclib was initiated at a median of 11.1 months after early breast cancer diagnosis. Before abemaciclib initiation, most patients received radiotherapy (96.3%) and chemotherapy (83.1%), with 46.3% receiving neoadjuvant chemotherapy. Most patients (74.0%) initiated endocrine therapy 1.6 months before abemaciclib initiation. The median time to abemaciclib initiation from breast surgery was 6.7 months. The most frequent regimen was abemaciclib and aromatase inhibitors (91.0%). At 3 months, 81.6% of patients were persistent; 5.6% resumed abemaciclib after >60-day interruption and 11.3% discontinued due to AEs. Additional information on dose modifications will be presented.

CONCLUSION: In this real-world study of utilization of abemaciclib in the first year after approval for early breast cancer, an older, less fit, and more racially diverse population than participated in the monarchE trial, as well as a higher proportion of patients with lower nodal status, was observed. The high 3-month persistence rate suggests abemaciclib for early breast cancer is well-tolerated in routine clinical practice.

This abstract was previously presented at the 2024 San Antonio Breast Cancer Symposium.

Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR04

Clinical Outcomes of 2-Dose Tandem Influenza Vaccination Strategy in Patients With Plasma Cell Dyscrasias

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BACKGROUND: Patients with multiple myeloma and other plasma cell dyscrasias (PCD) are especially susceptible to infections, including influenza (flu). Multiple risk factors arise from disease-related immunoparesis, alteration in T-cell immunity, treatment-related immunosuppression, diminished protection from flu vaccines, and age-related decline in immune function. After the standard flu vaccine, these patients have shown to have low hemagglutination antibody inhibition titers, with decreased seroprotection rates of <20%. A booster dose could enhance immune efficacy. At Massachusetts General Hospital, we began implementing a 2-dose tandem flu vaccination strategy in patients with PCD in January 2021. Although it was previously reported that tandem flu vaccines can improve seroprotection rates, it has not yet been linked to better clinical outcomes.

OBJECTIVE: To compare flu-related clinical outcomes in patients with PCD who received 1 versus 2 flu vaccine doses.

METHODS: This study was a retrospective review of patients with PCD who received ≥1 flu vaccine over the past 4 flu seasons in 2020 to 2024. The primary outcomes were documented flu infections, level of clinical care required, and duration of hospitalization/PCD treatment interruptions. Secondary outcomes included flu treatment and time from most recent vaccine to flu infection.

RESULTS: A total of 100 randomly selected patients with PCD were included. The majority of patients had multiple myeloma (80%), and other PCDs included monoclonal gammopathy of undetermined significance, AL amyloidosis, and Waldenstrom macroglobulinemia. We identified 58 cases of documented flu infections (6 confirmed; 52 possible). In comparing flu rates, 84% of the flu cases occurred in patients who received 1 dose versus 16% in patients who received 2 doses of flu vaccine. The level of care required included phone call to the office (57% vs 5%), office visit (19% vs 7%), urgent care visit (7% vs 2%), and hospitalization (2%, 30-day vs 2%, 10-day) in the 1-dose versus 2-dose cohorts, respectively. PCD treatment interruption was required in 21% in the 1-dose cohort versus 2% in the 2-dose cohort. The mean duration of treatment interruption was 12 days (range, 1-30) and 10 days (range, not applicable; 1 instance) in 1-dose versus 2-dose cohorts, respectively. Oseltamivir was prescribed in 3.4% in the 1-dose cohort versus 1.7% in the 2-dose cohort. The time of flu from most recent vaccine was longer in the 1-dose cohort, with 237 days (range, 34-583), compared with 141 days (range, 52-420) in the 2-dose cohort.

CONCLUSIONS: The 2-dose tandem flu vaccines improve seroprotection and directly result in favorable flu-related clinical outcomes in patients with PCD. Other benefits include lower utilization of healthcare resources, decreased hospital stay, and decreased incidents of PCD treatment interruptions.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR05

Dexamethasone Versus Tocilizumab for Management of Cytokine Release Syndrome Related to Teclistamab in Patients With Relapsed/Refractory Multiple Myeloma

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BACKGROUND: Teclistamab is a B-cell maturation antigen-directed bispecific antibody approved for use in patients with relapsed/refractory multiple myeloma. In the MajesTEC-1 trial, cytokine release syndrome (CRS) occurred in 72.1% of patients and was primarily managed with tocilizumab.[1] Recently, the International Myeloma Working Group released guidelines supporting the use of tocilizumab for low-grade CRS.[2]

OBJECTIVE: To evaluate the safety and efficacy of CRS management with dexamethasone compared with tocilizumab.

METHODS: In all, 6 US academic medical centers contributed data on 243 patients who started teclistamab as of July 2024. All patients received teclistamab in a step-up dosing manner per the prescribing information. Patients received adverse event management based on institutional protocols. CRS was graded using the American Society for Transplantation and Cellular Therapy criteria.[3] Outcomes included incidence and severity of CRS, overall response rate (ORR), progression-free survival (PFS), and overall survival (OS).

RESULTS: Of the 243 patients included, 133 (55%) patients had CRS (41% grade 1; 13% grade 2). Three grade 3+ events resolved with intensive care. At a median follow-up of 8.7 months, the ORR, median PFS, and median OS were 66%, 6, and 14.3 months, respectively. Dexamethasone was used in 23% of patients, tocilizumab in 29%, and dexamethasone and tocilizumab were used in 23% of patients. Of the 30 patients in the dexamethasone and tocilizumab group, 11 received dexamethasone before tocilizumab. Of those 11, 6 received dexamethasone for immune effector cell-associated neurotoxicity syndrome and 2 of the remaining 5 received subsequent tocilizumab due to grade 2 CRS not resolved with dexamethasone.

Of the 31 patients who had CRS in the dexamethasone group, 87% had grade 1 events. Thirteen patients (42%) who received dexamethasone had recurrent CRS after a subsequent teclistamab dose; however, all subsequent events were of the same or lower grade and resolved with a median of 2 (range, 2-5) additional dexamethasone doses.

In the tocilizumab group, 68% and 32% of patients had grade 1 and 2 events, respectively. The majority (92%) of patients received 1 dose of tocilizumab, with 3 patients requiring multiple doses. Six patients (16%) had recurrent CRS after a subsequent dose.

Median duration of CRS was 1 day for both groups, and step-up doses were delayed a median of 1 day in approximately a quarter of patients in both groups (P=.78). ORR, PFS, and OS were similar between the groups.

CONCLUSIONS: Although more patients had subsequent CRS with dexamethasone, CRS was low grade and manageable with repeated dexamethasone. While considering advantages over tocilizumab in regard to availability, ease of use, and cost, this study highlights the feasibility of dexamethasone for the management of CRS in patients receiving teclistamab.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR06

Evaluating the Impact of Interactive Ambulatory Care Discussions at an Oncology Center

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BACKGROUND: An interactive Ambulatory Shared Pharmacy Student Instruction (ASPSI) program was developed to supplement ambulatory care clinic rotations at a large oncology academic medical center. However, traditional ambulatory care disease management is mostly absent due to the specialized nature of these oncology clinics. Pharmacy students completing advanced pharmacy practice experiences (APPE) primarily engage in specialized oncology-related patient care during their rotations, which limits their ability to fully apply didactic knowledge and gain practical application of common ambulatory care diseases such as diabetes mellitus or hypertension during their 6-week rotation.

OBJECTIVE: To evaluate the perceptions of 4th year APPE students on their ambulatory care disease expertise after participation in ASPSI.

METHODS: ASPSI is a series of case-based interactive topic discussions to enhance learning on designated topics for APPE students during their ambulatory care rotation(s) at MD Anderson Cancer Center. Four discussions are held during each 6-week rotation. The discussions are diabetes mellitus, hypertension, constipation/diarrhea, and anticoagulation. Discussions are intended to be interactive learning experiences while led and facilitated by ambulatory care oncology clinical pharmacy specialists. Over the past academic year, each student involved in these topic discussions was asked to voluntarily complete an anonymous survey at the end of the 6 weeks. Students were asked to rate their confidence level on a 5-point Likert-type scale for the ability to care for a patient on a scale of 1 to 5, with 1 being very low confidence and 5 being very high confidence. Survey results were compiled and described.

RESULTS: All students (N=11) completed the survey, with 100% reporting these discussions improved their confidence in managing patients with diabetes mellitus, hypertension, constipation/diarrhea, and anticoagulation. The mean confidence score for diabetes management increased from 2.36 to 3.55, for hypertension from 2.82 to 4.18, for anticoagulation from 2.82 to 4.09, and for constipation/diarrhea from 2.45 to 4.18. Median confidence scores across all conditions also showed a shift from 2 to 3 before the discussions to 4 after the discussions. These results indicate a marked increase in student confidence in managing these conditions after participating in the interactive discussions.

CONCLUSIONS: Student evaluations of the interactive ASPSI topic discussions were overwhelmingly positive in a nontraditional ambulatory care APPE setting. The results support the continued use of this instructional approach to reinforce core ambulatory care topics during specialized oncology APPE ambulatory care rotations. Ongoing use of student feedback through surveys will allow preceptors to improve the program and potentially expand the range of topics covered in future iterations.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR07

Evaluation of a Decentralized Infusion Pharmacist in an Oncology Infusion Clinic of an Academic Medical Center

Presenting Author: Sarah Castelo, PharmD, BCOP, Vanderbilt University Medical Center, Nashville, TN

Co-Author: Nick Hopkins, PharmD, BCSCP, Vanderbilt University Medical Center, Nashville, TN

BACKGROUND: Pharmacists trained in oncology oversee and manage the use of oncology medications from a core pharmacy within the oncology infusion center. There are limited data on the value of a decentralized infusion pharmacist in an oncology infusion center.

OBJECTIVES: To improve efficiency of infusion clinic workflow by integrating an oncology-trained infusion pharmacist with the nursing staff to assist with troubleshooting, problem-solving, and communication with the core pharmacy and the clinical pharmacy specialists. Also, to improve patient care by providing more direct access to a pharmacist.

METHODS: This quality improvement study was conducted at an oncology infusion center at Vanderbilt University Medical Center, Nashville, TN, an academic medical center. A pharmacist worked in the decentralized infusion pharmacist role during peak clinic hours when the operations of the pharmacy could be safely and efficiently managed without the pharmacist physically located inside the core pharmacy. The decentralized infusion pharmacist worked in the oncology infusion clinic, integrated with the nursing staff. Data collected included the number of bedside double-checks for chemotherapy conducted, the number of questions fielded from nursing and the core pharmacy, communication with clinical pharmacy specialists, and patient education. The authors conducted an online satisfaction questionnaire after the pilot program was complete.

RESULTS: A total of 1796 patient visits were completed on 20 separate days from January 2024 to August 2024, when decentralized infusion pharmacist coverage was provided. The most common tasks performed by the decentralized infusion pharmacist included fielding questions from nursing (n=209), bedside double-checks for chemotherapy (n=156), and fielding questions from the core pharmacy (n=86). Of the staff members who completed the satisfaction questionnaire, 60% of nurses reported feeling less busy with the integration of a decentralized infusion pharmacist; whereas 54% of pharmacists in the core pharmacy reported no significant difference in their workload.

DISCUSSION: Decentralization of pharmacy services includes moving the decision-making closer to users. By adapting departmental workflow, pharmacy services are better able to support nurses. There was continuous effort to refine processes to address nursing and pharmacy concerns.

CONCLUSIONS: The integration of a decentralized infusion pharmacist in the oncology infusion clinic improved accessibility to a pharmacist, improved clinic workflow for the nursing staff, and increased the ability to troubleshoot issues. Further studies are needed to fully evaluate the effects the decentralized infusion pharmacist role would have on patient-related outcomes.

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2. Chacko R, Worsham T, Gass J. Assessment of nursing satisfaction with pharmacy services. Poster presented at: ASHP 2019; December 8-12, 2019.
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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR08

Evaluation of Reduced Observation Times for Subcutaneous Administration of Daratumumab and Hyaluronidase in Patients With Multiple Myeloma

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BACKGROUND: Daratumumab is an anti-CD38 monoclonal antibody that can be given subcutaneously (SC) when formulated with hyaluronidase for previously untreated and relapsed/refractory multiple myeloma. Infusion-related reactions are often observed with daratumumab, and premedication is required before administration. However, the manufacturer provides little guidance on observation times and monitoring after daratumumab/hyaluronidase SC administration. Our institution originally adopted observation times similar to research protocols conducted within the institution of 6 hours for the first dose, 2 hours for the second dose, and 15 minutes for subsequent doses of daratumumab/hyaluronidase SC. Since then, publications have demonstrated the appropriateness of shorter monitoring periods of varying degrees. Due to these data, observation times after daratumumab/hyaluronidase SC administration were reduced to 2 hours for the first dose, 30 minutes for the second dose, and 15 minutes for subsequent doses.

OBJECTIVES: The primary objective was to determine if reduced observation times for daratumumab/hyaluronidase SC affected the rates of infusion reactions. The secondary objective was calculation of chair time saved.

METHODS: All daratumumab/hyaluronidase SC administrations during a 2-year time frame (February 4, 2021, to May 1, 2023) were collected via Pharmacy Analytics. Administrations were separated based on preintervention and postintervention. Preintervention was defined as SC daratumumab administrations with an observation time of 6 hours after the first dose and 2 hours after the second dose. Postintervention was defined as SC daratumumab administrations with an observation time of 2 hours after the first dose and 30 minutes after the second dose.

RESULTS: A total of 203 patients were included, with 87 in the preintervention group and 116 in the postintervention group. No clinically significant differences were found in rates of reaction with reduced observation time with daratumumab/hyaluronidase SC. Reactions were similar, with 6% for dose 1 and 1% for dose 2 for the preintervention group, and 4% for dose 1 and 3% for dose 2 in the postintervention group. The most common reactions were hypertension followed by shortness of breath. For the 116 patients in the postintervention group, reduced observation time saved nearly 27 days of chair time.

CONCLUSION: The results of this study show there was no clinically significant difference in infusion-related reactions when comparing longer observation times to shortened observation times. Shortened observation times resulted in a significant amount of chair time saved. Based on the results of this study, it is recommended to continue the shortened observation time after administering daratumumab/hyaluronidase SC.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR09

Evaluation of Services Provided by Pharmacists in Addition to Accredited Patient Management Program Responsibilities in a Health-System Specialty Pharmacy

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BACKGROUND: Health-system specialty pharmacies struggle to maintain adequate staffing with continuous growth. New positions are typically justified by increased prescription volume; however, pharmacists are frequently tasked with providing services for patients not directly falling under responsibilities of their accredited patient management program. Guidance on services and time spent may be a valuable tool for health-system specialty pharmacies to consider in requesting additional support.

OBJECTIVE: To approximate the quantity and type of pharmacist actions related to patients fulfilling their specialty prescriptions at external pharmacies or nonspecialty medications.

METHODS: Single-center, prospective quality improvement study to evaluate pharmacy services requested for patients either not actively enrolled in a University of Rochester Specialty Pharmacy (URSP) patient management program or related to medications fulfilled externally. URSP is accredited by the Utilization Review Accreditation Commission and the Accreditation Commission for Healthcare. External was defined as any pharmacy other than URSP, which included ambulatory, infusion, or inpatient pharmacy sites within the health system. Standardized actions performed by clinical pharmacists employed by the specialty pharmacy and with integrated workflows in the nononcology (cardiology, dermatology, gastroenterology, hepatology, infectious diseases, neurology, primary care, rheumatology) and oncology clinics were documented in the electronic medical record between September 1, 2023, and November 30, 2023. The primary outcome was quantity of pharmacist actions requested to intervene with medication therapy problems or to answer drug information questions. Secondary outcomes included source of the request for pharmacy services, drug category (specialty, nonspecialty, infusion), status of enrollment in the patient management program, urgency of request, and approximate time spent. All analysis was descriptive.

RESULTS: Pharmacists performed 926 actions, documenting 775 encounters involving 630 unique patients. The majority of pharmacy service requests were from the oncology clinic (76.3%), followed by rheumatology (11.2%) and neurology (5%). Among oncology clinic, providers most requested pharmacy services (57.5%), specifically advanced practice providers (39.6%) and physicians (17.9%). Most actions were nonurgent, representing 68.9% for oncology and 84.8% for nononcology clinics. Actions were most frequently categorized as drug information (68.9%) followed by medication therapy problems (16.5%). The most common pharmacy service requests from oncology clinics involved nonspecialty medications (47.8%) and infusions (30.7%), whereas nononcology clinics primarily received requests related to specialty medications fulfilled externally (61.6%). Pharmacists spent <15 minutes (68.8%) and 15 to 30 minutes (24.1%) per patient on most encounters.

CONCLUSION: This study highlights the significant contributions that URSP provides to patients in addition to their responsibilities within the scope of their specialty pharmacy–accredited patient management programs and supports the request for additional pharmacist support.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR10

Hematologic Oral Oncolytics: Adherence, Healthcare Cost, and Utilization

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BACKGROUND: Connected Care Oncology is a patient-centered clinical program that includes a set of 21 unique oral hematologic oncolytic agents for affected oncology patients.

OBJECTIVE: To identify significant associations between a discontinuation adherence metric for the set of Connected Care Oncology hematologic oral oncolytic agents and total medical costs, hospitalizations, and total length of stay (LOS) for inpatients. Research was deemed exempt from HIPAA (Health Insurance Portability and Accountability Act) by Walgreens Advarra Independent Review Board #39505.

METHODS: A retrospective cohort design of patients was used from the MarketScan Commercial Claims and Encounters for 2022. The sample selection required ≥2 fills of targeted medication from the 2022 files with a primary cancer diagnosis code in medical files for 2021 or 2022, and patients must have been continuously enrolled and aged 18 to 64 years. Exclusion criteria were presence of hospice care or organ transplants and those starting medication therapy in the last 45 days of 2022. Discontinuation was indicated by a gap exceeding 1.5 times (previous days' supply) on consecutive fills. General linear models predicted total medical costs, hospitalizations, and LOS (with gamma or logit links). Predictors included discontinuation, and 12 covariates (including COVID-19 indications, surgeries, Charlson Comorbidity Index comorbidities [less cancer], combination therapy, inpatient and outpatient utilization levels, demographics, and insurance type) and their interaction terms. The economic valuation compared the model predictions by discontinuation status.

RESULTS: A total of 4296 patients in 2022 met sample and model criteria, with 72.3% adherent. Predicted total medical costs significantly increased for nonadherent patients compared with adherent patients ($73,663 per member per year [PMPY]; $P<.0001$). When considering the additional costs associated with pharmacy adherence, the predicted total medical and pharmacy costs remained increased for nonadherent patients ($19,193 PMPY; $P<.46$). Compared with adherent patients, odds of hospitalization were significantly increased (odds ratio, 2.22; $P<.0001$) and LOS was significantly longer for nonadherent patients (4 days; $P<.0001$). When considering the difference in hospital admissions rate and LOS when admitted, the predicted inpatient medical spend was higher for the nonadherent patients ($22,691 PMPY). Details on all significant model covariates and outcomes as well as economic valuation comparisons are presented in the poster.

CONCLUSION: Being adherent to oral hematologic oncolytics can lead to lower medical costs, odds of hospitalization, and LOS after controlling for many other influences on these outcomes.

Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR11

High Antimicrobial Resistance in a Pediatric Oncology Unit in Malawi Underscores Relevance of Stronger Antimicrobial Stewardship in Sub-Saharan Africa

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BACKGROUND: Antimicrobial resistance (AMR) is a global threat contributing to significant deaths worldwide. Pediatric patients with cancer are prone to serious infections requiring antimicrobial treatment. There is paucity of data on AMR in pediatric oncology units in sub-Saharan Africa, where routine blood cultures are often unavailable.
OBJECTIVE: To describe the prevalence of AMR in a treatment center in Malawi to inform the need for stronger advocacy for antimicrobial stewardship in the region.
METHODS: This was a retrospective cross-sectional study of blood cultures obtained between January 2019 and August 2023 from pediatric oncology patients at Kamuzu Central Hospital in Lilongwe, Malawi. Multidrug resistance was defined as lack of susceptibility to ≥1 antimicrobial drugs in ≥3 antimicrobial categories. Association between categorical variables was measured with Pearson's chi-square test, and multivariate logistic regression was used to test for association between multiple variables.
RESULTS: We identified 447 blood culture results from 262 patients. Most were obtained from patients with leukemia (37.5%), lymphoma (28.6%), or solid tumors (21.4%). The blood culture positivity was 37.9% (169/447). Of these, 32.5% (55/169) were identified as contaminants. Of the remaining 114 true isolates, 70.2% were gram-negative (50% Enterobacteriaceae, with *Klebsiella* as the most common). The prevalence of multidrug resistance was 54.4% (95% confidence interval, 44.8%-63.7%), with rates of 68% versus 41% for gram-negative and -positive organisms, respectively (P=.04). Of the gram-negative isolates with sensitivity data, resistance was as follows: gentamicin (68%), ceftriaxone (67%), ciprofloxacin (59%), ceftazidime (52%), imipenem (47%), and piperacillin-tazobactam (38%). No significant associations were found between multidrug resistance rate and cancer diagnosis.
CONCLUSION: The prevalence of AMR in our population is higher than described in developed countries, emphasizing critical need for routine blood cultures in pediatric oncology units as a strategy for surveillance and to aid antimicrobial stewardship. High contamination rates denote the need for implementing proper blood culture collection techniques.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR12

Identifying Barriers to Expanded Access Program (EAP) Patient Enrollment in the Hematology/Oncology Community

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BACKGROUND: Expanded access programs (EAPs) provide a pathway for patients with serious or life-threatening conditions to obtain investigational treatments outside of clinical trials, when no satisfactory or comparable treatment options exist, or they do not qualify for a clinical trial. Use is limited by a number of challenges, including poor access to information, document burden, and lack of response from drug sponsors regarding the ability to supply drug.[1] This study aims to gauge the baseline knowledge gaps and barriers that may deter oncology/hematology pharmacists from enrolling patients into an EAP.

OBJECTIVES: To assess the knowledge of US academic and community oncology/hematology pharmacists regarding EAPs and identify barriers to patient access through these programs.

METHODS: Dissemination of a Rutgers electronic Institutional Review Board–approved protocol #Pro2024000713 voluntary Qualtrics survey through the Hematology/Oncology Pharmacy Association's email list. The research survey was sent only to US members who practice clinical oncology/hematology pharmacy in academic and/or community settings. Students, residents, fellows, technicians, and pharmaceutical industry members were excluded from the study. The survey was disseminated in June 2024 and was open until the end of July 2024.

RESULTS: After reviewing 38 survey responses, our findings suggest pharmacists working in an academic setting were more aware of EAPs than those working in a community setting. A total of 69% of participants requested use of a drug through an EAP. However, most (63%) participants were slightly knowledgeable or not knowledgeable at all when it comes to finding access to investigational drugs for patients via EAPs. The information sources varied among pharmacists, with the most common being the pharmaceutical manufacturer (59%). The top barriers included time to enroll patients (66%), documentation burden (59%), and lack of familiarity with EAP processes (56%).

CONCLUSIONS: Pharmacists, as part of the interprofessional care team, play a critical role in decision-making during a patient's treatment journey. EAPs are an option for patients who have limited or no treatment options remaining. This study identifies key knowledge gaps and barriers to treatment access via EAPs. These results provide an opportunity to close knowledge gaps and barriers related to EAPs by providing continuing education credits to pharmacists in the academic and community settings. Informing oncology/hematology pharmacists in academic and community centers regarding EAPs allows the opportunity to educate and offer alternative treatment options to patients, providing hope to patients and families. Further research will be needed to assess the unmet educational needs and the potential benefits of increased education on patient care and outcomes.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR13

Effect of Clinically Embedded Oncology Pharmacists on Immune Checkpoint Inhibitor Treatment Outcomes

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BACKGROUND: Multiple publications have highlighted the pharmacist's role in managing immune-related adverse events (AEs) from immune checkpoint inhibitor (ICI) therapy for patients with cancer.
OBJECTIVE: The purpose of this study was to compare outcomes in patients initiating ICI therapy for cancer before and after the integration of 2 clinically embedded clinical pharmacists in a large community oncology practice via the Pharmacists Optimizing Oncology Care Excellence in Michigan program.
METHODS: This single-center, retrospective analysis was conducted with data from March 2018 to March 2024. The intervention was clinically embedded pharmacist care, which was identified by a pharmacist education visit. Up to 134 patients in each of the pre- and postintervention groups were identified. Charts were eligible for abstraction if the patients were newly prescribed an ICI for cancer. The following data were abstracted: patient demographics, ICI medication, therapy intent (curative vs palliative), cancer diagnosis, start date, education date, corticosteroid use, follow-up visits, emergency department and hospitalizations, reason for emergency department/hospitalization, and reasons for ICI discontinuation. Chi-square analysis compared the pre- and postintervention time periods.
RESULTS: Abstraction was completed for 133 patients in the preintervention group and 134 patients in the postintervention group. The demographics in the preintervention group versus the postintervention group included a mean age of 67 years (standard deviation [SD], 12.3) versus 69 years (SD, 11.5), respectively; 64% female versus 70% female, respectively; 96% White versus 97% White, respectively; and 17% curative versus 34% curative, respectively. The most common cancer diagnoses were lung, endometrial, melanoma, kidney, breast, and bladder. Pembrolizumab was utilized most frequently in 43% of the preintervention patients and 52% of the postintervention patients. More patients in the postintervention group received education before starting ICI therapy (99% vs 86%; *P*=.002). The postintervention group had a 41% discontinuation rate due to AEs, progression, or hospice/death compared with 51% in the preintervention group (*P*=.098). Steroid use was similar between groups, with 27% of patients in the preintervention group requiring steroids and 25% in the postintervention group. There were no differences between the groups in the time to steroid initiation or the time receiving a steroid. The postintervention group had less hospitalizations (24% vs 41%; *P*=.009) and less emergency department visits (28% vs 46%; *P*=.005) within the first 6 months of therapy for cancer or treatment-related AEs compared with the preintervention group.
CONCLUSION: Embedded clinical pharmacist care improved the outcomes of patients receiving ICIs for the treatment of cancer, including improved rates of education and decreased incidence of unplanned healthcare utilization.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR14

Effect of Clinically Embedded Pharmacists on the Time of Other Oncology Clinicians

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BACKGROUND: Clinical pharmacists save physicians' time through interventions and clinical services offered in the emergency department, but studies evaluating time savings in oncology practice have not been done.[1] Clinical pharmacists embedded in ambulatory care practices provide a variety of services, such as selecting appropriate chemotherapy regimens and supportive care, reviewing medication lists and laboratory tests, managing adverse events, educating patients, and answering drug information questions. Administratively, they may also build order sets, provide staff education, and release orders. The purpose of this study was to describe the time spent by embedded clinical oncology pharmacists and whom that effort would be attributed to if they were not in the clinic.
METHODS: On 2 different weeks, 7 pharmacists from Pharmacists Optimizing Oncology Care Excellence in Michigan practices recorded their activities using a data collection form that included patient- and non–patient-focused activities.[2] The second data collection is the basis for this analysis, and data were collected in July 2024. The 7 pharmacists provided 922 entries grouped into administration, chart review/release orders, care coordination, clinical question, documentation, follow-up, order management, teach, staff education, and other. The number of minutes attributed to the activity and the professional who would do the activity if the clinical pharmacist was not present were recorded. Hours per activity and the substituted professional were determined.
RESULTS: Pharmacists recorded activities for an average of 42 hours per week, and 70% of activities were patient-focused. Among patient-focused activities, pharmacists' distribution of time was primarily focused on chart reviewing and releasing orders, teaching, and documentation. For patient-focused activities, pharmacists substituted a mean of 5 hours for advance practice practitioners, 3.3 hours for physicians, 1 hour for medical assistants, 11.8 hours for nurses, 4.1 hours for another pharmacist, and 3.7 hours for no one in the clinic on a per-pharmacist-per-week basis. For non–patient-focused activities, the clinical pharmacists substituted 7.3 hours for no one in the clinic and 4.1 hours for another pharmacist, per pharmacist per week.
CONCLUSION: Oncology pharmacists' time was 70% patient-focused, and they saved on average 20 hours per week per pharmacist for nurses, advance practice practitioners, and physicians.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR15

Effect of Embedded Clinical Pharmacists on Health Utilization Outcomes in a Large Community Oncology Practice

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BACKGROUND: Pharmacists play a critical role in team-based care, and this is well established in the primary care setting.

OBJECTIVE: To compare healthcare utilization outcomes before and after the integration of 2 embedded clinical pharmacists in a large community oncology practice via the program, Pharmacists Optimizing Oncology Care Excellence in Michigan.

METHODS: This single-center, retrospective analysis was conducted with data from January 2018 to March 2024. The intervention was clinically embedded pharmacist care, identified by a pharmacist education visit. Up to 400 patients in each of the pre- and postintervention groups were identified. Charts were eligible for abstraction if patients were newly prescribed anticancer therapy for any of the 3 following areas: gynecologic oncology diagnosis, the use of an immune checkpoint inhibitor(s), or the use of an oral anticancer agent(s). The following data were abstracted: patient demographics, medication, cancer diagnosis, emergency department visits and hospitalizations, and reason for emergency department/hospitalization. A chi-square analysis compared pre- and post-intervention time periods.

RESULTS: Abstraction was completed for 398 patients in the preintervention group and 350 patients in the postintervention group. No demographic differences were detected between groups. The preintervention group had a mean age of 67 years (standard deviation [SD], 11.5), 69% were female, and 96% were White. The postintervention group had a mean age of 68 years (SD, 12.5), 57% were female, and 97% were White. The majority of patients in both groups were diagnosed with either ovarian, endometrial, non–small cell lung, prostate, or breast cancer. At 6 months following treatment initiation, the preintervention group had a 24% incidence of hospitalization due to cancer symptoms, treatment-related adverse events, or unknown reason versus 19% in the postintervention group (P=.065). Emergency department visits at 6 months resulting from cancer symptoms, treatment-related adverse events, or unknown reason were 32% in the preintervention group versus 25% in the postintervention group (P=.035).

CONCLUSION: Embedded clinical pharmacist care reduced the incidence of emergency department visits in the first 6 months of anticancer treatment initiation.

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Completed Research: PRACTICE MANAGEMENT RESEARCH

Abstract #CR16

Improving Oral Anticancer Medication Adherence/Adverse Event Assessment Documentation

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BACKGROUND: To improve patient safety, most oral anticancer medication (OAM) programs monitor adverse events (AEs) and adherence within 7 to 14 days following OAM initiation. At our institution, we identified key tasks associated with documenting OAM adherence and AEs during cycle 1. However, only 50% of these tasks were appropriately documented.

OBJECTIVE: As part of the 2022-2023 Hematology/Oncology Pharmacy Association/American Society of Clinical Oncology quality training program, we conducted a quality improvement project aimed at improving our task documentation rate to >75%.

METHODS: We engaged a multidisciplinary team to assist in gathering and interpreting data. A process map was created and barriers were identified. A cause-and-effect diagram, Pareto chart, and action prioritization matrix were used to narrow the focus of improvement changes initially and after each cycle. Three plan-do-study-act (PDSA) cycles were conducted (January 2023 to January 2024). Outcome measure was documentation of AEs/adherence by day 10 of cycle. Our study included all patients with cancer initiating OAM and excluded those on intravenous/oral regimens and gynecology/oncology patients. Process measure was percentage of 9 crucial tasks identified as necessary to appropriately document AEs/adherence. Balance measures included provider visits, emergency department visits, and telephone/electronic medical record OAM-related messages.

RESULTS: PDSA cycle 1 (education on documenting patient education) was implemented in January 2023. PDSA cycle 2 (retraining nurses on OAM AEs/adherence documentation process) was implemented in March 2023. PDSA cycle 3 (standardized cycle 1 OAM process and created a tool to facilitate communication of OAM start date) was implemented in September 2023. Improvement in our outcome measure (percentage of 9 essential tasks for documenting OAM adherence/AEs in cycle 1) was improved following PDSA cycles 1, 2, and 3 (50%-67%; $P<.001$). This rate was sustainable in the 2 months following project completion. OAM-related patient provider visits, emergency department visits, and OAM-related telephone messages (ie, balance measures) were decreased ($P<.001$). An improvement in documentation of OAM treatment start date was observed with each additional cycle (10%, 23%, and 83%, respectively) and improvement in AE documentation was similarly observed (10%, 12%, and 83%, respectively).

CONCLUSION: Our results were likely affected by significant nursing turnover, lack of formal OAM process training, and institutional buy-in for OAM program/training. Our standardizing process initiative improved the percentage of AEs/adherence documentation tasks necessary to ensure completion of appropriate OAM monitoring by day 10 of cycle 1 following prescription. This also resulted in fewer OAM-related telephone messages, which not only decreased provider time but signified that fewer potential problems occurred with appropriate AEs/adherence checks.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR18

Managing Oral Anticancer Therapies in Patients With Early or Advanced HR-Positive, HER2-Negative Breast Cancer: A US-Based Community Healthcare Provider Survey

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BACKGROUND: In the past decade, the number of options and use of oral anticancer medications (OAMs) has grown among patients with hormone receptor–positive (HR-positive) and HER2-negative breast cancer. Adherence to OAMs is critical to ensure treatment effectiveness and long-term outcomes.[1] However, there is limited evidence on methods used by healthcare providers (HCPs) to support adherence to OAMs.

OBJECTIVE: To describe methods used by HCPs (pharmacists, oncologists, and advanced practice providers [APPs]) at individual and system levels to support adherence to OAMs for HR-positive, HER2-negative breast cancer.

METHODS: Between July 2023 and October 2023, a cross-sectional survey was conducted among HCPs with ≥12 months of experience in treating patients with HR-positive, HER2-negative breast cancer in community settings across the United States. A total of 282 HCPs (100 pharmacists, 91 oncologists, and 91 APPs) completed a one-time online questionnaire.

RESULTS: The majority of HCPs (87.0% pharmacists, 95.6% oncologists, and 71.4% APPs) had ≥5 years of experience treating patients with breast cancer. Half of HCPs (53.0% of pharmacists, 49.5% of oncologists, and 49.5% of APPs) were extremely or very satisfied with the methods they use in practice to support adherence to OAMs. The 3 most common patient-level methods to support adherence reported by HCPs included dose adjustments (pharmacists: 65.0%, oncologists: 50.5%, and APPs: 79.1%), use of prophylactic medications (pharmacists: 68.0%, oncologists: 39.6%, and APPs: 76.9%), and advising nonpharmacological interventions (pharmacists: 69.0%, oncologists: 35.2%, and APPs: 60.4%). Retail pharmacists reported higher use of nonpharmacological interventions and lower use of dose adjustments and prophylactic medications than pharmacists working in clinical or specialty settings. Overall, dose adjustment was reported to be most successful across HCPs, with 66.6% of users perceiving this approach as extremely or very successful in supporting adherence; 64.4% and 32.7% reported prophylactic medications and advising nonpharmacological interventions, respectively, to be similarly successful. The most common system-level methods include staff to help navigate insurance approvals (59.9%) and referral to patient assistance programs (59.2%).

CONCLUSION: Dose adjustments and use of prophylactic medications were considered the most successful patient-level methods to support adherence in patients with HR-positive, HER2-negative breast cancer and were reported as the most commonly used by HCPs. Notably, pharmacists and APPs appeared to use all methods more extensively than oncologists, highlighting their vital role in supporting adherence. Broader incorporation of pharmacists into the management of patients receiving OAMs will help enhance the implementation of these methods, with the goal of increasing patient adherence to OAMs.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR19

Safety and Cost Associated With Fixed-Dose Immunotherapy in Patients With Weight Extremes

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BACKGROUND: Nivolumab and pembrolizumab were initially approved with weight-based dosing of 3 mg/kg every 2 weeks and 2 mg/kg every 3 weeks, respectively. Later, the FDA approved fixed doses of 240 mg every 2 weeks or 480 mg every 4 weeks for nivolumab and 200 mg every 3 weeks or 400 mg every 6 weeks for pembrolizumab based on pharmacokinetic modeling showing similar areas under the curve compared with weight-based dosages.[1-3] However, patients of low and high weights represented a small percentage of the patients included in the simulations,[1,3] which led to questions regarding safety and cost implications in patients with weight extremes.[3]

OBJECTIVES: To compare the incidence of adverse events (AEs) in patients weighing ≤50 kg or ≥110 kg with the previously reported literature and to determine the cost implications of fixed dosing strategies.

METHODS: Retrospective review of adult patients receiving single-agent pembrolizumab or nivolumab for treatment of cutaneous malignancies within the UCHealth System between January 1, 2016, and May 30, 2024. Patients were included if they received ≥1 dose of nivolumab 240 mg or pembrolizumab 200 mg and weighed ≤50 kg or ≥110 kg. Data collection included baseline demographics, autoimmune disease, line of treatment, earlier treatments, immunotherapy received, dose administered, total number of doses administered per patient, and incidence of AEs. Treatment cost per patient was calculated using standard vial size and present-day vial cost provided from the internal purchasing department. Theoretical cost-savings using weight-based dosing instead of fixed-doses was calculated using the same vial sizes and cost.

RESULTS: A total of 95 patients were assessed, including 45 patients weighing ≤50 kg in the low-weight group (LWG) and 50 patients weighing ≥110 kg in the high-weight group (HWG). Nivolumab was administered to 67% in the LWG and 56% in the HWG. The mean number of fixed immunotherapy doses per patient was 10±12 for the LWG and 13±14 for the HWG. The observed incidence of AEs with immune checkpoint inhibitors was similar for each group when compared with the literature.[3-5] Fixed doses of nivolumab and pembrolizumab were associated with increased drug cost totaling $1.8 million when used for patients weighing ≤50 kg.

CONCLUSION: The implementation of weight-based nivolumab and pembrolizumab dosing for patients with low weight is a safe and efficient drug cost–saving strategy.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR20

Safety and Feasibility of Short-Duration Infusion Obinutuzumab With Venetoclax in Patients With Chronic Lymphocytic Leukemia: A Prospective Observational Study

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BACKGROUND: Obinutuzumab is approved in combination with venetoclax for chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) and with chemotherapy for classic follicular lymphoma (cFL). Infusion-related reactions (IRRs) occur in 60% (grade ≥3 IRRs: 10%) of patients with CLL/SLL receiving obinutuzumab. During cycles (C) 2 to 6 (C2-6), obinutuzumab was infused over ≥195 minutes. A 90-minute short-duration infusion (SDI) obinutuzumab starting with C2 is safe in patients with cFL without grade ≥3 IRR in C1. Data on SDI obinutuzumab in CLL/SLL are limited. We report a prospective observational study to evaluate the safety of SDI obinutuzumab in patients with CLL/SLL receiving treatment with venetoclax.

OBJECTIVES: To evaluate the proportion of patients with grade ≥3 IRR with 90-minute SDI obinutuzumab in patients with CLL/SLL receiving venetoclax.

METHODS: This prospective, exact single-stage, observational study included the first 28 consecutive patients with treatment-naïve or relapsed/refractory CLL/SLL and who received venetoclax identified via a lymphoid malignancy patient registry approved by the institutional review board. Dosing, schedule, premedications, and infusion rates were according to the obinutuzumab prescribing information. Starting with C2, absent grade ≥3 IRR in C1 and an absolute lymphocyte count of <5000/μL on day (D) of treatment, obinutuzumab was administered at 100 mg per hour for 30 minutes, then 900 mg per hour for approximately 60 minutes. The primary end point included the proportion of patients with grade ≥3 IRR defined per Common Terminology Criteria for Adverse Events v5.0. Response was evaluated per International Workshop on Chronic Lymphocytic Leukemia (iwCLL) 2018.

RESULTS: Between January 23, 2023, and April 11, 2024, 28 consecutive patients with CLL/SLL received venetoclax with SDI obinutuzumab. The median age was 65 years (range, 27-88), and 79% were treatment-naïve. Absolute lymphocyte count was ≥25,000/μL before C1D1 in 54% and ≥5000/μL before C2D1 in 0%. All patients received SDI obinutuzumab on C2D1. None discontinued obinutuzumab prematurely; the median number of obinutuzumab Cs was 6 (interquartile range, 6-6) and all completed ≥4 Cs. All patients achieved an iwCLL objective response. No patients had a grade ≥3 IRR. The incidence of grade 1 to 2 IRRs was 53.6%. All IRRs were grade 2 and occurred on C1D1, including 1 patient with recurrent grade 2 IRR on D2, and none occurred on days 8-15 of C1. One had an IRR after C1; this was a grade 2 IRR occurring on C3D1.

CONCLUSION: SDI obinutuzumab with venetoclax was safe in patients with CLL/SLL. This study met the primary end point and supports adoption of SDI obinutuzumab starting in C2 absent grade ≥3 IRR during C1 when absolute lymphocyte count <5000/μL.

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Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR21

Updated Biodistribution and Shedding Analysis of RP1 Oncolytic Immunotherapy From the IGNYTE Clinical Trial: Administration and Handling Implications for Oncology Pharmacists

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BACKGROUND: RP1 is a herpes simplex virus type 1–based oncolytic immunotherapy currently in clinical development that is administered via intratumoral injection. RP1 plus nivolumab has demonstrated deep and durable responses with a favorable safety profile in advanced melanoma.

OBJECTIVE: To assess the biodistribution and shedding profiles from the skin cancer cohorts of the ongoing IGNYTE clinical trial (NCT03767348), thus informing the administration and handling methodology for RP1.

METHODS: In this open-label, multicenter phase 1/2 study, patients with advanced cancers were treated with the combination RP1 plus nivolumab. After RP1 injections into superficial and deep lesions, injection sites were covered with occlusive dressings. Samples from blood, urine, dressing exteriors, injection sites, oral mucosa, and lesions of suspected herpetic origin were assessed during predose, treatment, and follow-up visits for RP1 DNA by quantitative polymerase chain reaction assay. Positive RP1 DNA swab samples were further assessed by 50% tissue culture infectious dose (TCID50) assay for the presence of live virus.

RESULTS: This analysis included 1573 blood, 1976 urine, 2052 oral mucosa, 1114 dressings, and 1947 injection-site swab samples collected from 278 patients with skin cancer. RP1 DNA was detected in 7.8% of blood, 0.2% of urine, and 18.4% of injection-site swab samples. The incidence of RP1 detection on injection-site dressing exteriors (9.5% of 1114 samples) was lower than that from the injection sites (18.4% of 1947 samples), demonstrating that dressings act as a barrier to RP1 dissemination. RP1 DNA was very rarely present on oral mucosa (0.9% of 2052 samples). At follow-up, RP1 DNA was detected only in injection-site swab samples. All available samples were confirmed to be negative for live virus by TCID50 assay. A total of 8 swab samples from 7 patients from different locations were collected from areas of suspected herpetic infection; none tested positive for infectious virus. No communal or secondary transmission was reported.

CONCLUSION: RP1 DNA was primarily detected on the immediate surface of injected lesions. Overlying occlusive dressings appear to serve as a protective barrier against RP1 DNA dissemination. No infectious live virus was detected

in samples from follow-up visits. These findings indicate that the risk of infection and transmission of RP1 is negligible. Oncolytic immunotherapy such as RP1 is emerging as an integral part of cancer therapeutics. Defining the biodistribution and shedding potential of these agents will be important for pharmacy staff and caregivers to develop the educational activities and best practices necessary to properly handle these agents.

Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #CR22

Venetoclax and Obinutuzumab in Relapsed/Refractory Patients With Chronic Lymphocytic Leukemia or Small Lymphocytic Lymphoma: A 3-Year Follow-Up

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BACKGROUND: In patients with previously untreated chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL), venetoclax and obinutuzumab resulted in higher complete response rates compared with chemoimmunotherapy[1,2] and is FDA approved as first-line therapy but not in relapsed/refractory (R/R) CLL/SLL, where venetoclax plus rituximab is approved despite studies indicating that obinutuzumab is the more effective monoclonal antibody in CLL.[1,2] Venetoclax and obinutuzumab incorporates an obinutuzumab lead-in phase, which allows for cytoreduction and reduces venetoclax-related tumor lysis syndrome (TLS) risk, whereas in venetoclax plus rituximab, venetoclax starts first, not allowing for cytoreduction. We report 3-year follow-up of our experience with safety and efficacy of venetoclax and obinutuzumab in R/R CLL/SLL.

METHODS: This retrospective study included patients aged ≥18 years with R/R CLL who received venetoclax and obinutuzumab at Massachusetts General Hospital locations between July 2019 and June 2022. Updated progression and survival data were collected through October 9, 2024. Safety end points included laboratory or clinical TLS per Howard criteria, infusion-related reactions (IRRs), and hematologic adverse events defined per Common Terminology Criteria for Adverse Events v5.0. Efficacy end points included progression-free survival (PFS) and overall survival (OS), which were estimated using Kaplan-Meier method.

RESULTS: We identified 40 consecutive R/R CLL patients treated with venetoclax and obinutuzumab. Median follow-up was 41 months (range, 2-64). Median age was 72 (range, 51-94) years, with 31 (78%) patients aged ≥65 years, 28% (n=11/39) with del(17p)/*TP53* alterations, and 66% (n=21/32) with unmutated *IGHV*. Median previous treatments was 1 (range, 1-6), with 55% (n=22) previously treated with Bruton tyrosine kinase inhibitor. Median creatinine clearance (CrCl) was 57 mL/min (range, 22-134), with CrCl <60 mL/min in 53% (n=21) of patients. Laboratory TLS occurred in 3% (n=1) of patients, arising during obinutuzumab initiation; no patients had clinical TLS. IRRs occurred in 30% (n=12), with 27% (n=11) having grades 1 or 2 and 3% (n=1) grade 3. Four of 11 (36%) patients who had grade 1 or 2 IRRs were treated as inpatients. Grade 3/4 hematologic adverse events occurred in 60% (n=24; neutropenia, 50%; anemia, 25%; thrombocytopenia, 45%). The 3-year PFS and OS rates were 65% (95% confidence interval [CI], 0.51-0.82) and 84% (95% CI, 0.73-0.97), respectively.

CONCLUSION: In 3-year follow-up, venetoclax and obinutuzumab continued to be safe and effective treatment for R/R CLL. Laboratory TLS occurred more frequently during obinutuzumab initiation (3%) than with venetoclax (0%), which may reflect obinutuzumab use over rituximab, or venetoclax and obinutuzumab use in real-world patients with comorbidities that may have excluded them from prospective trials. More intensive TLS mitigation and monitoring should be considered when starting the obinutuzumab phase of venetoclax and obinutuzumab in R/R CLL, including inpatient administration in patients with comorbidities or high tumor burden.

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Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

Abstract #LB01

Smart Solutions: Leveraging Artificial Intelligence in Investigational Drug Services

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BACKGROUND: Clinical research protocols are often complex, intricate, and lengthy documents and require the development of department-specific summaries to operationalize at the study site. Creating these summaries requires significant pharmacist time and effort. Incorporating artificial intelligence (AI) into this process may significantly decrease administrative burden and time while maintaining clinical accuracy.

OBJECTIVES: To assess the time required to complete pharmacy-specific study summaries manually versus AI-assisted and to assess the accuracy of documents created with AI assistance.

METHODS: As assessed by a scoring system, moderate- or high-complexity trials were eligible for inclusion. The time required for the manual preparation of pharmacy study summaries through usual workflow by the lead pharmacist for the study was recorded. Microsoft Copilot was prompted to complete a study summary template using the study protocol and pharmacy manual. The resulting AI-assisted summary was reviewed by an investigational drug service (IDS) pharmacist who was naïve to the study protocol. The time taken by an IDS pharmacist to complete the document was compared with the time taken by an IDS pharmacist assisted with AI. A mean difference of 20 minutes was defined as significant a priori. The number of corrections and grades of error were recorded for each study.

RESULTS: A total of 4 protocols were summarized manually and AI-assisted in parallel. The mean time to complete a study summary with AI assistance was significantly lower than manual summarization (35 minutes vs 167 minutes, respectively; P=.0296). There was an average 74% reduction in the time to complete the study summaries using AI-assisted workflow. Each initial prompt output required an average of 4.5 corrections.

DISCUSSION: In this case, the burden of time-consuming creation of documentation was mitigated by utilizing predesigned prompts to create standardized document output. Although manual reprompting and quality control were required to correct major errors, improvements in the prompt model and automation may further reduce manual effort.

CONCLUSION: The integration of AI into the clinical trial workflow significantly reduced the time to synthesize a study summary document when compared with traditional, manual processes.

Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

Abstract #LB02

Evaluating the Value of Clinical Oncology Pharmacists: Time-Savings for Healthcare Providers in The US Oncology Network

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BACKGROUND: Evaluating pharmacists' value through novel metrics is becoming increasingly important in the face of drug margin compression in the oncology space. Trinidad and Patel evaluated the impact of oncology pharmacists in the ambulatory setting, reporting that 545 interventions over the course of 2 years resulted in an estimated 140 hours of provider time saved.[1] This underscores the potential for pharmacists to optimize workflows while providing the same quality of care, potentially freeing clinician time for additional patient care.

OBJECTIVE: To determine the value of interventions made by remote-based clinical oncology pharmacists by quantifying the time saved for healthcare providers within The US Oncology Network (The Network).

METHODS: Clinical pharmacist intervention data were analyzed over a 2-week period to identify the intervention subtypes that saved provider time. A survey was developed with example patient scenarios for each intervention type and was sent to providers to validate the time, in minutes, that each type of task would take them. The median provider time spent by category was calculated. Standard criteria were used to prospectively document interventions as saving provider time. The data for 1 month were analyzed using descriptive statistics, and the provider time saved was calculated by multiplying the median minutes from the provider survey by the number of interventions categorized as saving provider time within that category.

RESULTS: Survey responses were received from 17 practices within The Network and included 61 physicians, 17 nurse practitioners, and 12 physician assistants. The median provider time saved for each intervention type resulted as follows: Business Office Support was 23 minutes, Drug-Drug Interaction was 8 minutes, Drug Dosing was 8 minutes, Drug Information was 23 minutes, and Supportive Care was 23 minutes. In October 2024, 667 interventions were recorded by 14 clinical pharmacists, with 353 (53%) of these interventions falling into categories with known provider time-savings based on survey data. These interventions resulted in a total time-savings of 4489 minutes (75 hours) for practice providers.

CONCLUSION: This analysis revealed that pharmacists' interventions save a substantial amount of provider time. This saved time allows providers to dedicate more attention to patient care. Future directions aim to further substantiate these advantages and explore additional ways in which clinical oncology pharmacists contribute to the value of the healthcare team. By reducing the time providers spend completing medication-related tasks, clinical pharmacists enhance the efficiency of oncology practices. These findings emphasize the critical role of remote clinical oncology pharmacists in optimizing resources within The Network.

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Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

Abstract #LB03

Incorporation of a Statewide Cancer Drug Repository Program Within an Integrated Specialty Pharmacy

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BACKGROUND: Medication access for patients with cancer has become increasingly challenging as oral anticancer agents have established a prominent position in cancer treatment. Medically integrated specialty pharmacies serve an important role in enhancing patient medication access and in navigating the multiple financial barriers and facilitators of medication access.

OBJECTIVE: To describe the impact that participation in a statewide cancer drug repository (CDR) program has on specialty pharmacy employees and the impact its use has on other medication access resources.

METHODS: This single-center, retrospective analysis was conducted with data from September 2023 to September 2024. In addition, an employee satisfaction survey was completed by specialty pharmacy staff in December 2024. The intervention was participation in a statewide CDR network, YesRx, beginning in September 2023. Our institution had a stand-alone CDR from January 2023 to September 2023 before joining the statewide network. Therein, we describe the utilization of medication access resources, workflow, and employee satisfaction related to YesRx participation.

RESULTS: A total of 19 of 21 (90%) specialty pharmacy employees completed the satisfaction survey. Of those 19, 9 were pharmacy technicians, 9 were pharmacists, and 1 was a pharmacy intern. In all, 12 of the participants reported working within the specialty pharmacy before CDR participation. Of the 12, 5 (42%) participants reported an increase in workload and the remaining 7 (58%) reported no change. In all, 8 of 12 (67%) participants reported an increase in work satisfaction as a result of YesRx participation, and the remaining 4 of the 12 participants reported no change in satisfaction. None of the respondents reported a decrease in satisfaction. All 19 participants recommend CDR participation to other integrated specialty pharmacies. From September 2023 to September 2024, we dispensed a total of 263 prescriptions from the statewide CDR. We found that the use of the CDR did not decrease our utilization of other medication access resources but rather supplemented it. The majority of patients receiving CDR medication did so in conjunction with another resource, and the CDR allowed us to begin therapy in a timelier fashion or allowed us to fill a gap in benefits coverage that would have otherwise resulted in nonadherence.

CONCLUSION: Participation in the statewide CDR network, YesRx, provided a high level of satisfaction for our team members and complemented the current medication access resources.

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Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #LB04

Choice of Antifungal Prophylaxis and Risk for Invasive Fungal Disease in Patients With Acute Leukemia Receiving Oral Anticancer Therapies With Significant CYP450 Drug Interactions

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BACKGROUND: Patients with acute leukemia have a high risk for invasive fungal disease (IFD). Per the NCCN guidelines, antifungal prophylaxis is recommended for patients with acute leukemia and neutropenia for the prevention of IFD. Triazoles are often employed for antifungal prophylaxis, but patients are prone to drug interactions with oral anticancer agents.

OBJECTIVE: To assess the prescribing patterns, efficacy, and safety of antifungal prophylaxis among patients with acute leukemia who received induction chemotherapy including an oral anticancer agent metabolized through CYP450.

METHODS: This was a single-center, retrospective-cohort analysis conducted from July 2020 to August 2024. The inclusion criteria were age >18 years, a diagnosis of acute leukemia, and receiving oral anticancer therapy with induction treatment. Patients were excluded from the study because of incomplete data. Patients were identified through the electronic health record, and the data that were extracted included demographics, laboratory values, vitals, acute leukemia subtype, new leukemia diagnosis or relapse, induction chemotherapy regimen, antifungal prophylaxis, previous antifungal use, previous fungal infection(s) and treatment, coinfections, response achieved after induction, and adverse events.

RESULTS: A total of 128 patients were included in the study. Most patients had acute myeloid leukemia (94%), with most being new diagnoses (68%). The median age was 69 years, and 59% of the patients were male. The leukemia prognostic risk categories were 55% poor risk, 39% intermediate risk, 4% favorable risk, and 2% unknown risk. Most patients were prescribed antifungal prophylaxis (87%), with 46% receiving micafungin, 7% triazoles, and 34% sequential therapy (micafungin or triazole followed by the other). The oral chemotherapy agents received included venetoclax (78%), midostaurin (14%), dasatinib (4%), ponatinib (2%), and ivosidenib (1%). In all, 3 patients had proven IFD (2 with micafungin and 1 with subsequent therapy) and 11 patients had possible IFD (6 with micafungin, 1 with voriconazole, 3 with subsequent therapy, 1 with no prophylaxis). Adverse events were observed across all of the groups, including micafungin (grade 1 or 2, 14.9%; grade 3 or 4, 11.2%), triazole (grade 1 or 2, 8.6%; grade 3 or 4, 8.9%), subsequent therapy (grade 1 or 2, 15.3%; grade 3 or 4, 14%), and no prophylaxis (grade 1 or 2, 6.4%; grade 3 or 4, 6.8%).

CONCLUSION: The prescribing patterns favored micafungin for antifungal prophylaxis. Patients who received micafungin alone had an increased incidence of IFD. The micafungin and subsequent therapy groups had the highest rates of adverse events. Because of the small sample size and low rates of IFD, a larger study is needed to evaluate the preferred antifungal prophylactic agent for patients with acute hematologic malignancies receiving induction therapy with oral anticancer agents that interact with azole antifungals.

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Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #LB05

Evaluation of Fam-Trastuzumab Deruxtecan Utilization Among Patients With Advanced or Metastatic Gastric/Gastroesophageal Junction Adenocarcinoma

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BACKGROUND: Fam-trastuzumab deruxtecan (TDxd) is approved for use in advanced gastric/gastroesophageal junction cancer (aGC) as well as any HER2-positive solid tumor. There are differences in dosing and in HER2 testing methodology in the studies used to support the aGC and solid tumor indications. It is hypothesized that the higher dose recommended for aGC may lead to greater adverse events, potentially negating benefit. Furthermore, not retesting for HER2 status after failure of previous anti-HER2 therapy in aGC could miss patients whose tumors no longer express HER2.

OBJECTIVES: To describe the efficacy and safety of TDxd in patients receiving treatment for aGC in a gastrointestinal medical oncology clinic at a large comprehensive cancer center. The secondary objectives include determining the median starting dose and relative dose intensity and describing the patterns of use in terms of line of therapy and HER2 testing before the initiation of TDxd.

METHODS: A retrospective chart review was conducted that included patients who initiated TDxd for the treatment of aGC at The James Cancer Hospital between January 1, 2021, and May 31, 2024. The coprimary end points were progression-free survival (PFS) and overall survival at 6 months and the incidence of select grade 3 or 4 adverse events (neutropenia, thrombocytopenia, diarrhea, pulmonary adverse events, or any hospitalization for a potentially drug-related adverse event).

RESULTS: A total of 14 patients met the study criteria, of whom 13 were evaluable for survival. TDxd was administered in the second-line setting in 5 patients, and the median number of previous therapies for the entire cohort was 2. The median average TDxd dose per patient was 6.4 mg/kg, and the median relative dose intensity was 89.9%. The 6-month PFS rate was 46.2% (n=6) and the 6-month overall survival rate was 61.5% (n=8). Of the 10 patients evaluable for disease response, 7 had at least a partial response according to their primary oncologist. Of the 14 total patients, 7 (50%) had a grade 3 or 4 adverse event that was considered potentially treatment-related, including 2 (14.3%) cases of fatal lung adverse events. A total of 6 patients discontinued TDxd because of adverse events without disease progression and an additional patient had radiographic progression but continued receiving TDxd treatment, which was later stopped because of worsening adverse events.

CONCLUSION: Despite use in a heavily pretreated sample, TDxd was administered with high relative dose intensity, and the efficacy outcomes were comparable with those in larger controlled clinical trials. The adverse events were worse in our cohort, however, compared with clinical trials. It is possible that use of a lower TDxd dose would improve tolerability without compromising efficacy.

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Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

Abstract #LB06

Role of CYP2D6 Phenotypes in Doxorubicin-Related Cardiotoxicity

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BACKGROUND: Cardiotoxicity is a major adverse event of doxorubicin.[1] Doxorubicin is metabolized by CYP2D6 to doxorubicinol,[2] which is more cardiotoxic than doxorubicin.[3,4]

OBJECTIVE: To determine if increased CYP2D6 function will have an impact on the composite rate of cardiotoxicity or cardiomyopathy in patients who received doxorubicin.

METHODS: All patients who received intravenous conventional or liposomal doxorubicin between January 1, 2009, and December 31, 2021; were aged >18 years at the time of first doxorubicin administration; and had CYP2D6 genetic testing were included in our cohort. Patients were excluded from the study if they had a liver transplant before the administration of doxorubicin. Cardiomyopathy was defined as receiving a diagnosis in the medical record after the last doxorubicin dose or cardiomyopathy that occurred before doxorubicin was started but worsened after doxorubicin was completed. Worsening cardiomyopathy was defined as the reduction in left ventricular ejection fraction (LVEF) by ≥5%[5] or a QTc increase of ≥30 msec from baseline after doxorubicin treatment.[6] Cardiotoxicity was defined as a decrease of LVEF by ≥10% to a value ≤50% or a decrease in LVEF by ≥20% and/or a QTc >500 msec after the treatment or an increase in QTc by ≥60 msec from baseline.[7] Increased CYP2D6 function included CYP2D6 ultrarapid or rapid metabolizers. CYP2D6 function that was not increased was defined as poor, intermediate, or normal metabolizers. Liposomal doxorubicin cumulative doses were converted to conventional doses. Cumulative dosing was categorized into ≤250 mg/m^2 or >250 mg/m^2.[7] Logistic regression models were used to measure the association between CYP2D6 function and cardiotoxicity.

RESULTS: A total of 238 patients met the study inclusion criteria. Of these patients, 8 (3.4%) had CYP2D6 increased function and 230 did not have CYP2D6 increased function. A total of 43 (18.1%) patients received a cumulative doxorubicin dose of >250 mg/m^2. There were 36 (15.1%) patients with cardiotoxicity and/or cardiomyopathy. In all, 3 (37.5%) patients among those with a CYP2D6 increased function had cardiotoxicity or cardiomyopathy, whereas 33 (14.3%) patients among those without a CYP2D6 increased function had cardiotoxicity or cardiomyopathy (unadjusted odds ratio [OR], 3.6; 95% confidence interval [CI], 0.7-15.3; *P*=.091). Adjusting for the cumulative doxorubicin dose, CYP2D6 function was not significantly associated with cardiotoxicity or cardiomyopathy (adjusted OR, 3.9; 95% CI, 0.8-17.1; *P*=.074).

CONCLUSION: This is the first study to analyze cardiotoxicity rates based on CYP2D6 function for patients who received doxorubicin. There were numerically increased rates of cardiotoxicity or cardiomyopathy in patients with increased CYP2D6 function; however, they were not statistically significant. This study was likely underpowered because of its small sample size.

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Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

Abstract #LB07

Implementation of an Oral Oncolytic Monitoring Pilot Program: A Specialty Pharmacist–Led Approach Using the Revised Edmonton Symptom Assessment System

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BACKGROUND: Oral oncolytic therapy offers benefits such as ease of administration, fewer clinic visits, and enhanced quality of life. However, the monitoring of adverse drug reactions largely relies on patient self-reporting, which may result in undetected issues. The revised Edmonton Symptom Assessment System (ESAS-r), a validated tool used in outpatient cancer care, serves as a patient-reported outcomes measure to assess symptoms and therapy-related side effects. The implementation of the tool at the health-system specialty pharmacy (HSSP) level has yet to be extensively explored. Given their frequent patient outreach, specialty pharmacists may be ideally positioned to complete the ESAS-r for patients to assist with bridging care, proactively monitor medication safety, and provide patient education.

OBJECTIVE: To evaluate the implementation of a specialty pharmacist–led oral oncolytic monitoring program in an HSSP. The program utilizes the ESAS-r to capture, assess, and prompt interventions by specialty pharmacists aimed at addressing gaps in current oral oncolytic monitoring practices.

METHODS: This quality improvement project is a prospective descriptive study designed to evaluate a specialty pharmacist–led oral oncolytic monitoring program within an HSSP. Patients receiving an oral oncolytic drug from September 24, 2024, to November 23, 2024, from the CHRISTUS Specialty Pharmacy (CSP) were included in the pilot study. To integrate the ESAS-r into the CSP workflow, a flowsheet was developed for use in conjunction with routine clinical assessments. Based on the ESAS-r score, the pharmacists' interventions were implemented, including patient counseling or provider outreach, as clinically appropriate. The primary end points used descriptive statistics to evaluate the type and quantity of the pharmacist interventions. The secondary end points examined the frequency of symptom severity, average symptom scores, and the average time spent by the specialty pharmacist completing the oral oncolytic monitoring program.

RESULTS: A total of 76 patients were enrolled in the oral oncolytic monitoring program. The most common cancer types were breast cancer (20%), followed by chronic lymphocytic leukemia (16%) and prostate cancer (14%). Palbociclib (10.5%) and venetoclax (10.5%) were the most frequently received treatments. Of the total patients, 72% required an intervention, with patient counseling (42%) being the most common type. Among all reported symptoms and side effects, tiredness was the most frequent and severe.

CONCLUSION: The high number of pharmacist interventions required highlights a potential unmet need in patients receiving oral oncolytics. Implementing an oral oncolytic monitoring program that incorporates the ESAS-r allows for the HSSP to capture and proactively address patient-reported side effects. This pilot study suggests that specialty pharmacists could be an optimal stakeholder to address the gaps in current oral oncolytic monitoring practices.

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Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

Abstract #LB08

Pressurized Intraperitoneal Aerosolized Chemotherapy: Operationalizing From a Pharmacy Perspective at a Large Academic Medical Center

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BACKGROUND: Intraperitoneal chemotherapy has been available for the treatment of peritoneal metastases and primary peritoneal cancers for almost 7 decades. Pressurized intraperitoneal aerosolized chemotherapy (PIPAC) was developed in Europe and has only recently been offered in the United States. PIPAC provides an alternative for patients who do not qualify for hyperthermic intraperitoneal chemotherapy (HIPEC) and cytoreductive surgery.
OBJECTIVE: To describe pharmacy involvement in the implementation of PIPAC at The University of Vermont Medical Center (UVMMC).
METHODS: The investigators describe the compounding procedures for chemotherapy, mechanics of instillation via a single-chamber power injector, supportive medications needed before and/or after cytoreductive surgery, and the safety protocols used for PIPAC in the operating room.
RESULTS: The first 2 patients at UVMMC received PIPAC with cisplatin and oxaliplatin in fall 2024. One patient subsequently qualified for HIPEC, and the other is continuing PIPAC and systemic chemotherapy.
CONCLUSION: The investigators developed compounding procedures and a line setup for loading the power injector, and collaborated on safety procedures in the operating room to successfully and safely implement PIPAC at UVMMC. With this, UVMMC became one of the first hospitals in the nation to implement this procedure.

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