## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR01**

# Assessing Student Pharmacists' Knowledge and Perceptions of Financial Toxicity Concepts Introduced in an Oncology Pharmacotherapy Course

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**BACKGROUND:** Current, standard pharmacy school oncology curricula thoroughly discuss treatment toxicities and patient education. As cancer treatment costs continue to rise, financial toxicity is an increasingly important component of patient education. A national survey of how pharmacy schools incorporate concepts of affordable medication options revealed that the concept of financial toxicity was not described within the context of oncology care. There is no current literature evaluating financial toxicity education within pharmacy oncology courses nor student pharmacists' knowledge of the concept.

**OBJECTIVE:** This survey-based study is designed to assess the impact of assigned reading material and lecture-based practice discussions on pharmacy students' knowledge and perceptions of the concept of financial toxicity in cancer care during an oncology pharmacotherapeutics course.

**METHODS:** During an oncology pharmacotherapeutics course, a pre-lecture questionnaire was disseminated to students which assessed baseline student knowledge and perceptions of financial toxicity in cancer care. Students were assigned reading materials and participated in a formal lecture-based in-class discussion on the concept of financial toxicity and its implications in pharmacy practice. Students then completed a post-lecture questionnaire designed to assess changes in student knowledge and perceptions of financial toxicity as it relates to cancer care and treatment. The questionnaire consisted of Likert scale, multiple choice, and free response prompts to evaluate defining the concept, its role in cancer care, the resources available for patients, and the pharmacist's role. All questionnaires were completed within 1 week surrounding the lecture discussions.

**RESULTS:** A total of 78 pharmacy students participated in the survey. Prior to instruction, 23 (29.5%) students agreed/strongly agreed that they could clearly define the term financial toxicity compared with 73 (93.6%) students post-instruction. In terms of being able to clearly define the role that financial toxicity plays in overall cancer and patient outcomes, 31 (39.7%) students agreed/strongly agreed pre-instruction compared with 71 (91.02%) students post-instruction. Regarding the knowledge of patient resources, 10 (12.8%) students agreed/strongly agreed pre-instruction compared with 55 (70.5%) students post-instruction. Regarding their opinion on the importance of the pharmacist's role in managing financial toxicity, 65 (83.3%) students agreed/strongly agreed pre-instruction compared with 71 (91%) students post-instruction.

**CONCLUSION:** This study demonstrates the need for increased education on the concept of financial toxicity in oncology pharmacy curricula. It is important that pharmacy students are exposed to this during their coursework and have a basic understanding of financial toxicity on graduation. Based on this study, further financial concepts will be evaluated in this pharmacy school's oncology curriculum.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR02**

# Biodistribution and Shedding Analysis Following RP1 Oncolytic Immunotherapy Dosing in Patients From the IGNYTE Clinical Trial: Implications for Oncology Pharmacists

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**BACKGROUND:** RP1 is an HSV-1–based tumor-directed oncolytic immunotherapy modified to enhance safety and increase oncolytic potential that is administered via intratumoral injection. To date, RP1 plus nivolumab has demonstrated clinical activity with an acceptable safety profile in a variety of cancers.

**OBJECTIVE:** To assess biodistribution and shedding data from 87 patients enrolled in the phase 1 dose expansion (n=14) and phase 2 (n=73) cohorts from the ongoing IGNYTE clinical trial (NCT03767348).

**METHODS:** In an open-label, multicenter phase 1/2 study, patients with advanced cancers received the combination of RP1 and nivolumab. RP1 was injected into both superficial and deep lesions; the 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 for RP1 DNA by quantitative polymerase chain reaction assay. Positive RP1 DNA samples were further assessed for infectious virus by 50% tissue culture infectious dose (TCID50) assay.

**RESULTS:** This analysis included 791 blood, 894 urine, 931 oral mucosa, 525 dressings, and 914 injection-site swab samples collected from 87 patients. RP1 DNA was detected in 16.9% of blood, 0.9% of urine, and 28.1% of injection-site swab samples, suggesting the local presence of RP1. The incidence of RP1 on injection-site dressings (8.2% of 525 samples) was lower than that from the injection site (28.1% of 914 samples), suggesting that dressings act as an effective barrier. RP1 DNA was present at low levels on oral mucosa (1.9% of 931 samples). At follow-up, RP1 DNA was only found on the injected lesion surface (5.4%/2.4% of patients at 30/60 days, respectively, after last dose). All but 1 swab that was positive for RP1 DNA (indicating the presence of a therapeutic agent at the sample site) tested negative for infectious virus by TCID50; all follow-up samples were negative. No RP1 DNA was found on swabs tested from potential herpetic lesions, with no reports of herpetic infection in caregivers.

**CONCLUSION:** RP1 DNA was primarily detected on the surface of injected lesions, with dressings appearing to serve as a protective barrier against RP1 DNA dissemination. These findings suggest that the risk of infection and transmission of RP1 is minimal. As the use of viral oncolytic immunotherapies is incorporated more into patient care, pharmacy staff and caregiver understanding of the biodistribution and shedding potential will be critical for the proper handling of and education surrounding these agents.

*These data were previously submitted to and accepted for presentation at the Society for Immunotherapy of Cancer 2023 annual meeting.*

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR03**

# Characterizing Second-Line and Beyond Treatments for Primary Central Nervous System Lymphomas

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**BACKGROUND:** Primary central nervous system lymphoma (PCNSL) is a rare and aggressive lymphoma that affects the CNS in the absence of other systemic involvement. High-dose methotrexate (HD-MTX)–based regimens are recommended as frontline treatment, followed by consolidation with high-dose chemotherapy regimens, whole brain radiation therapy (WBRT) with or without temozolomide (TMZ), or autologous stem-cell transplant (autoSCT). Despite treatment advancements with the introduction of HD-MTX and rituximab, up to half of patients will have disease relapse, 10% to 15% may have primary refractory disease, and the median survival is approximately 2 months without additional intervention. Treatment for relapsed or refractory disease can widely vary because preferred regimens in this setting are not well-established.
**OBJECTIVES:** The primary objective was to characterize the therapies used in relapsed or refractory PCNSL. The secondary objective was to characterize the consolidation methods used after frontline treatment.
**METHODS:** This retrospective, descriptive analysis included adult patients with PCNSL who received an HD-MTX–based frontline regimen between April 1, 2016, and July 1, 2022. Patients who received HD-MTX for the treatment of secondary CNS lymphoma, PCNSL arising from non–B cell origin, and intraocular lymphoma were excluded.
**RESULTS:** A total of 54 patients were included in this study, with a median age of 67 years. Thirty-one (57%) patients received consolidation therapy with rituximab and high-dose cytarabine (R-HDAC), WBRT, or both. Thirteen (24%) patients proceeded with autoSCT. Twenty-five patients had disease progression, with 17 patients opting for second-line treatment. The second-line treatments were WBRT (24%), clinical trial (18%), rituximab with lenalidomide (18%), re-induction with HD-MTX–based regimens (18%), ibrutinib plus rituximab (12%), and R-HDAC (12%). Seven patients had disease progression, and all received third-line treatment. The treatments varied, including rituximab with lenalidomide; ibrutinib with or without HD-MTX; rituximab, methotrexate, and cytarabine; R-HDAC; rituximab plus nivolumab; and WBRT. Five patients received a fourth-line regimen, including rituximab with or without lenalidomide, rituximab plus HD-MTX, and nivolumab monotherapy. The regimens for the 3 patients who received fifth-line treatment and beyond included rituximab plus TMZ and pembrolizumab monotherapy in addition to the previously mentioned regimens.
**CONCLUSION:** To our knowledge, this is the first real-world, retrospective descriptive analysis of regimen utilization for relapsed or refractory PCNSL. As evidenced by this analysis, regimen selection varies and is highly dependent on physician preference and patient factors, including clinical trial eligibility, previous therapies, performance status, organ function, and treatment intent. Prospective clinical trials are desperately needed to guide the management of this disease in patients with a poor prognosis.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR04**

# Coordinating Better Outcomes in Multiple Myeloma: An Educational Initiative to Elevate Pharmacist Leadership in Novel Antibodies and CAR-T Therapy

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**BACKGROUND:** As the role of the clinical pharmacist evolves, it is crucial that hematology-oncology pharmacists, as experts in drug information, develop knowledge and clinical skills to guide safe and effective delivery of modern antibody and cellular therapies to patients with multiple myeloma (MM).
**OBJECTIVES:** To improve pharmacists' knowledge and ability regarding integration of these platforms into MM care, PeerView designed an educational initiative that provided guidance on navigating real-world challenges in using CD38- and BCMA-directed antibody and CAR-T therapy across various MM treatment settings and insights into how pharmacists can modernize MM treatment protocols by ensuring appropriate care coordination, addressing safety and dosing considerations, and optimizing therapy delivery.
**METHODS:** A live and enduring educational initiative was launched in conjunction with the 2023 HOPA annual meeting. Expert faculty used a linked case-based approach to enhance the understanding and application of antibody and cellular therapies in MM, providing insights on appropriate care coordination, safety and dosing considerations, and optimal therapy delivery. To measure the effects of the education, PeerView assessed learners before and after participation. Enduring participant responses were compared with a demographically matched nonparticipant sample.
**RESULTS:** The participants (N=1256; 140 live and 1116 enduring) had a substantial increase in knowledge and competence regarding BCMA CAR-T constructs and neurotoxicity management, including the understanding of the efficacy and safety profiles of subcutaneous versus intravenous isatuximab, with a 57% increase after the live event and a 42% improvement over nonparticipants with the enduring activity; proficiency in developing step-up dosing schedules for teclistamab in patients with relapsed or refractory MM, with 83% of live and 88% of enduring learners responding correctly; and the ability to develop modernized protocols to address practical aspects of care when using antibody and cellular therapy platforms, with 94% versus 49% of nonparticipants answering related questions correctly. The participants indicated a strong intent to implement learned strategies, counsel patients on treatment, and integrate novel approaches into practice, and 92% versus 38% of nonparticipants planned to always or frequently coordinate care for patients with MM receiving CAR-T therapy during intake, preinfusion, infusion, and the early and late-care continuum.
**CONCLUSION:** The findings demonstrate the efficacy of this initiative in enhancing pharmacist preparedness through a greater understanding of medication information and ability to manage practical aspects of care. By addressing these gaps, this initiative will improve the integration of antibody and cellular therapies into patient care to ultimately enhance patient outcomes and quality of life.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR05**

# Darolutamide, Enzalutamide, and Apalutamide for Nonmetastatic Castration-Resistant Prostate Cancer Patients in the United States (DEAR): Comparative Real-World Evidence

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**BACKGROUND:** Androgen receptor inhibitors (ARIs) are recommended for patients with nonmetastatic, castration-resistant prostate cancer (nmCRPC). Darolutamide, a novel ARI, has a distinct structure with low blood-brain barrier penetration which may confer a lower risk for central nervous system–related adverse events (AEs), and a lower risk for the AEs that are frequently associated with ARIs.

**OBJECTIVE:** DEAR (NCT05362149) is the first study comparing the real-world utilization, outcomes, and AEs of darolutamide versus enzalutamide and apalutamide in patients with nmCRPC.

**METHODS:** DEAR was a retrospective chart review cohort study that used electronic medical records from the Precision Point Specialty network of US urology practices. Eligible patients had nmCRPC, no previous novel hormonal therapy, and had initiated their first ARI treatment (index date) between August 2019 and March 2022. The outcomes analyzed included the proportion of patients who discontinued initial ARI treatment and the reasons for ARI discontinuation, the proportion whose disease progressed to metastatic CRPC (mCRPC), and the incidence of AEs. A comparative analysis was performed of the patients who received darolutamide versus those who received enzalutamide and those who received apalutamide using the Cox proportional hazards model for the time to discontinuation and time to mCRPC, adjusting for observed baseline factors.

**RESULTS:** In total, 870 patients were included (darolutamide n=362; enzalutamide n=382; apalutamide n=126). The median ages were 80, 79, and 80 years; the median baseline prostate-specific antigen doubling times were 6.8 months, 6.4, months, and 7.4 months; and the median follow-up times were 22.2 months, 22.7 months, and 23.3 months for darolutamide, enzalutamide, and apalutamide, respectively. Other baseline characteristics were similar across all groups. A lower proportion of patients discontinued darolutamide versus enzalutamide or apalutamide (30.4% vs 40.8% and 46%) or an mCRPC event (17.7% vs 28.3% and 27.8%) during the study period. The most common reason for treatment discontinuation was for AEs (darolutamide, 10.2%; enzalutamide, 14.4%; apalutamide, 15.1%). Multivariate analyses adjusting for baseline factors showed that patients who received darolutamide had a lower risk for ARI discontinuation (hazard ratio [HR], 0.73; 95% confidence interval [CI], 0.56-0.94 vs HR, 0.61; 95% CI, 0.44-0.85;) and mCRPC (HR, 0.59; 95% CI, 0.43-0.82 vs HR, 0.65; 95% CI, 0.42-0.99) over time versus enzalutamide and apalutamide. A lower proportion of patients receiving darolutamide had AEs versus enzalutamide and apalutamide (24.9% vs 29.3% and 30.2%).

**CONCLUSION:** Overall, a lower proportion of patients discontinued their initial ARI treatment, had disease progression to mCRPC, or had AEs after receiving darolutamide versus enzalutamide or apalutamide. In analyses adjusting for observed baseline factors, the patients who received darolutamide had a considerably lower risks for ARI discontinuation and mCRPC than the patients who received enzalutamide or apalutamide. This study confirms the efficacy and favorable tolerability profile of darolutamide in a real-world setting.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR06**

# Dosing, Safety, and Pharmacokinetics of Combination Therapy With Darolutamide, Androgen-Deprivation Therapy, and Docetaxel for Metastatic Hormone-Sensitive Prostate Cancer in the ARASENS Study

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**BACKGROUND:** In the ARASENS study (NCT02799602), darolutamide (DARO) plus androgen-deprivation therapy (ADT) and docetaxel (DOC) significantly reduced the risk for death by 32.5% (hazard ratio, 0.68; 95% confidence interval, 0.57-0.80; *P*<.001) versus placebo (PBO) plus ADT and DOC in patients with metastatic hormone-sensitive prostate cancer (mHSPC). The incidences of treatment-emergent adverse events (TEAEs) were similar between the treatment groups. We report the dosing, safety, and pharmacokinetics (PK) of the coadministration of DARO plus ADT and DOC.

**METHODS:** Patients with mHSPC were randomized 1:1 to DARO 600 mg twice daily or PBO, plus ADT and DOC (75 mg/m$^2$ every 21 days for 6 cycles). The effect of DARO on DOC PK was assessed by noncompartmental analysis from the first 25 patients with dense PK data and by population PK for all patients. DARO PK from ARASENS were compared with PK data from ARAMIS (NCT02200614; without DOC) to evaluate the impact of DOC on DARO PK.

**RESULTS:** The full analysis set included 1305 patients (DARO, n=651; PBO, n=654). The median treatment duration was longer with DARO than with PBO (41 months vs 16.7 months, respectively), and more DARO-treated patients (45.9% vs 19.1%, respectively) were receiving treatment at the data cutoff (October 25, 2021). Most patients completed 6 cycles of DOC (DARO, 87.6%; PBO, 85.5%), and a similar proportion of patients required DOC dose modification (interrupted/delayed or reduced; DARO, 60% vs PBO, 62.9%). TEAEs led to DOC discontinuation or reduction in 8% versus 19.9% and 10.3% versus 19.5% of patients who received DARO and PBO, respectively. Population PK analysis indicated that DOC PK in ARASENS was generally consistent with the existing literature. A slight numeric increase in DOC exposure was observed in the DARO plus ADT and DOC arm, with 15% higher maximum plasma concentration (geometric mean, 1.93 vs 1.68 µg/mL) and 6% higher area under the concentration-time curve ($AUC_{0\text{-}tlast}$ within an 8-hour sampling interval, 2.10 vs 1.99 µg·h/mL) versus PBO plus ADT and DOC. This small increase is likely not clinically relevant given the variability in DOC exposure (coefficient of variation, 23%-54%). PK meta-analysis of ARASENS and ARAMIS, including the patients' intrinsic characteristics as covariates (eg, age, body weight, region), indicated a 10% lower $AUC_{0\text{-}12ss}$ of DARO in patients receiving DOC versus not receiving DOC, which is not considered clinically relevant.

**CONCLUSION:** DARO plus ADT and DOC increases overall survival with a similar overall incidence of TEAEs and no observed drug-drug interactions between DARO and DOC. DARO can be effectively and safely administered with DOC in patients with mHSPC without clinically relevant changes in the PK of either agent.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR07**

# Evaluating Patient Hesitancy in Receiving a Second Dose of Evusheld (Tixagevimab and Cilgavimab) for COVID-19 Prevention After a Food and Drug Administration Dosing Recommendation Update

**Presenting Authors:** Fouad Boulbol, PharmD, Community Cancer Institute, Clovis, CA; Mohamed Karah Ali, PharmD, BCOP, Community Medical Centers, Clovis, CA

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**BACKGROUND:** Tixagevimab in combination with cilgavimab (Evusheld) was granted Emergency Use Authorization (EUA) by the FDA on December 8, 2021, to reduce the incidence of SARS-CoV-2 RT-PCR–positive symptomatic illness (COVID-19) in select patients. It was initially recommended for patients to receive tixagevimab 150 mg concurrently with cilgavimab 150 mg. On February 24, 2022, the FDA updated the EUA to increase the dose to tixagevimab 300 mg concurrently with cilgavimab 300 mg.

**OBJECTIVE:** This dose increase required patients to receive the updated dose. Despite this, many patients in our clinic did not receive their second dose, and this study will seek to evaluate why.

**METHODS:** In this institutional review board–approved retrospective, single-center study, we examined 25 patients who received a single dose of Evusheld from December 8, 2021, through February 24, 2022. It was later discovered that there were patients who did not receive their second dose. These patients were contacted to evaluate the reason why they did not receive their updated dose. Assessments on the patient's education level, concerns of side effects, concerns of efficacy, concerns of lack of full FDA approval, transportation issues, as well as if the updated dose were explained appropriately.

**RESULTS:** Of the 19 evaluable patients, 74% were not at all concerned about the potential side effects, 63% were not concerned about efficacy, 68% were not concerned that the medication was not fully approved by the FDA, and 89% had no transportation issues to come to the clinic. In all, 63% of the patients stated that the necessity of the second dose was explained well or very well, whereas 32% of patients stated that it was not explained at all. Almost 90% of the patients who did not receive their second dose stated that lack of communication was the primary reason.

**CONCLUSION:** The majority of patients were interested in receiving the second dose of Evusheld. Although communications were sent out to providers and their team, only 42% of the patients received their second dose of Evusheld. During the COVID-19 pandemic, managing oncology patients presented unique challenges, and providing additional immune support was a significant concern. Our clinic is looking at improving its communication methods to ensure that such treatments reach patients effectively, and to also ensure that such omissions are not repeated in the future.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR08**

# First-Line Nivolumab + Ipilimumab + Chemotherapy Versus Chemotherapy Alone in Metastatic Non–Small Cell Lung Cancer: CheckMate 9LA 4-Year Clinical Update

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**BACKGROUND:** In CheckMate 9LA (NCT03215706), first-line nivolumab + ipilimumab + chemotherapy (N+I+C) demonstrated durable survival benefit in patients with metastatic non–small cell lung cancer (NSCLC) versus chemotherapy alone.

**OBJECTIVE:** To report updated efficacy and safety with a 4-year minimum follow-up.

**METHODS:** Adults with stage IV/recurrent NSCLC (no known sensitizing *EGFR/ALK* alterations) and Eastern Cooperative Oncology Group performance score ≤1 were randomized 1:1 to nivolumab 360 mg every 3 weeks plus ipilimumab 1 mg/kg every 6 weeks and 2 cycles of chemotherapy (n=361) or 4 cycles of chemotherapy alone (n=358). Patients were stratified by sex, tumor PD-L1 (<1% vs ≥1%), and histology (squamous vs nonsquamous). Maintenance pemetrexed was allowed in the chemotherapy arm (nonsquamous NSCLC). Assessments included overall survival (OS), progression-free survival, objective response rate, safety, and treatment-free interval (TFI; time from last study dose to start of first subsequent systemic treatment or death).

**RESULTS:** At 47.9 months of minimum follow-up (database lock, February 2023; median follow-up, 54.5 months), N+I+C continued to provide long-term, durable OS benefit versus chemotherapy in all randomized patients (hazard ratio [HR], 0.74; 95% confidence interval [CI], 0.63-0.87; 4-year OS rate, 21% vs 16%, respectively). Similar clinical benefit was seen with N+I+C versus chemotherapy by PD-L1 status (PD-L1 <1%: HR, 0.66; 95% CI, 0.50-0.86; 4-year OS rate 23% vs 13%, respectively; PD-L1 ≥1%: HR, 0.74; 95% CI, 0.60-0.92; 4-year OS rate 21% vs 16%, respectively) and by histology (squamous: HR, 0.64; 95% CI, 0.48-0.84; 4-year OS rate 20% vs 10%, respectively; nonsquamous: HR, 0.80; 95% CI, 0.66-0.97; 4-year OS rate 22% vs 19%, respectively). The proportions of responders with ongoing response at 4 years were 25% versus 12% (all randomized), 29% versus 0% (PD-L1 <1%), 24% versus 15% (PD-L1 ≥1%), 17% versus 6% (squamous), and 30% versus 16% (nonsquamous). In all patients who received N+I+C (n=358), the median TFI was 2.2 months, and 11% of the patients remained treatment-free and alive at 4 years. In patients who discontinued all components of N+I+C as a result of treatment-related adverse events (n=61), the 4-year OS rate was 41%, the median TFI was 10.6 months, and the 4-year TFI rate was 27%. No new safety signals were identified with longer follow-up.

**CONCLUSION:** With a 4-year minimum follow-up, patients who received N+I+C continued to derive long-term, durable efficacy benefit versus chemotherapy, regardless of PD-L1 expression or histology, with greater magnitude of benefit in patients with PD-L1 <1% or squamous histology. Together, these data further reinforce the use of N+I+C as an efficacious first-line treatment option for patients with metastatic NSCLC.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR09**

# Impact of Frailty on Outcomes After CAR T-Cell Therapy for Patients with Relapsed/Refractory Multiple Myeloma

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**BACKGROUND:** With a median age at diagnosis of 69 years, multiple myeloma (MM) primarily affects elderly patients, of whom many have been excluded from clinical trials evaluating CAR T-cell therapy. It has been shown that chronologic age alone should not be a barrier towards effective treatments including stem cell transplant and CAR T cells, and that instead of age, frailty scores should be incorporated into screening assessments.
**OBJECTIVE:** Because there is limited literature on the safety and efficacy of CAR T-cell therapy in frail patients, we retrospectively evaluated the clinical characteristics and outcomes of frail patients with MM who received CAR T-cell therapy.
**METHODS:** Three academic medical centers contributed data that included patients who had received BCMA-directed CAR T-cell therapy. Frailty was defined using the simplified frailty index (score based on age + ECOG performance status + comorbidity index; frail = score ≥2). The outcomes included the incidence and severity of cytokine release syndrome (CRS), immune effector cell–associated neurotoxicity syndrome (ICANS), infections, treatment-related mortality, overall response rates (ORRs), progression-free survival (PFS), and overall survival (OS).
**RESULTS:** Of the 136 patients analyzed (age, 41-81 years), 83 (61%) were considered frail at the time of CAR T cell infusion. The frail group had a significantly higher proportion of renal insufficiency (18% vs 6%), performance status ≥2 (18% vs 2%), triple-class refractoriness, and worse comorbidity burden than the nonfrail group. Although the frail group had less CRS (76% vs 79%) and more ICANS (39% vs 17%) than the nonfrail group, the incidences of grade ≥3 CRS and ICANS were similar. The rates of infection were similar between the groups, with nearly one third of the patients having an infection within 6 months of receiving CAR T cell infusion. With a median follow-up of 7 months, the best ORR was 81% in the frail group versus 96% in the nonfrail group. The median PFS was 6.9 months in the frail group versus 11.1 months in nonfrail group ($P$=.028). The median OS was 14 months in the frail group and was not reached in the nonfrail group ($P$=.025). Treatment-related mortality was observed in 7 (8%) patients in the frail group and in 1 patient in the nonfrail group.
**CONCLUSION:** Most patients in this real-world study were frail by simplified frailty index. Although frail patients had worse performance status and higher comorbidity burden at the time of infusion, the incidence of high-grade toxicities was similar. When compared with the nonfrail group, frail patients had statistically inferior survival outcomes. This study highlights the need for fitness-based assessments to personalize care for patients with MM.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR10**

# Improving Post-Transplant Vaccination Compliance via Implementation of a Clinical Pharmacist–Managed Service

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**BACKGROUND:** Post-transplant vaccination plays a key role in restoring immunocompetence after hematopoietic stem cell transplant (HSCT) and chimeric antigen receptor T cell therapy (CAR-T), a population at increased risk for preventable infections because of the loss of humoral immunity and long-term immunosuppression. In 2020, our vaccine protocol and procedures were updated to delegate post-transplant vaccination management to the HSCT pharmacists. This included electronic immunization plan generation, scheduling coordination with clinic staff, and quarterly compliance tracking. Vaccination compliance was added as an internal quality measure, with an overall aim of >90% inactive vaccine receipt.

**OBJECTIVES:** The primary objective was to evaluate the incidence of vaccine administration in baseline and pharmacist-managed groups at each due time. The secondary objectives were to measure if administrations were on time (within 1 month of due date) as well as the utilization of optional vaccines (meningococcal, hepatitis B, varicella-zoster) among the baseline population.

**METHODS:** This retrospective, single-center review obtained data via the electronic medical record and state immunization registry for all patients who received an autologous or allogeneic HSCT, or CAR-T within our institution between December 1, 2017, and September 1, 2021, which allowed for all patients to be at least 24 months post-transplant. Those patients who received more than 1 HSCT or cellular therapy during the study time were excluded. COVID-19 and influenza vaccines were not included. The patients were divided into 2 groups: baseline and pharmacist managed. If death occurred during the revaccination period, the patient was deemed ineligible for remaining vaccines due. Live vaccines were evaluated separately because of the potential variations in clinical eligibility.

**RESULTS:** Overall, 125 patients were included for evaluation: 50 baseline and 75 pharmacist managed. The baseline cohort consisted of 100% autologous HSCT and the intervention group consisted of 67% autologous, 28% allogeneic, and 5% CAR-T. Inactive vaccine compliance was increased on average from a baseline 88.3% to 95.4%; 80% of the time points were above goal. Nearly 25% more patients in the intervention group were on time. Live vaccine administration was higher in the baseline population than in the pharmacist-managed population (71% vs 44%, respectively). Optional vaccines were received 64% of the time.

**CONCLUSION:** HSCT pharmacist intervention improved inactive vaccine compliance and timeliness under a revised schedule that contained historically optional vaccines as standard. Discrepancy in live vaccine administration may result from the study cutoff soon after the 24-month eligibility date for some patients, as well as a clinically heterogenous patient population. Based on these findings, we will continue the pharmacist-managed revaccination service at our site.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR11**

# Incidence and Outcomes of Pneumonitis/Interstitial Lung Disease in Patients Receiving Trastuzumab Deruxtecan

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**BACKGROUND:** Trastuzumab deruxtecan (T-DXd) is a HER2-targeted antibody-drug conjugate currently approved for metastatic HER2+ and HER2-low breast cancer, HER2-mutant non–small cell lung cancer, and HER2+ gastric cancer. Although the adverse events of T-DXd are generally manageable, clinical trials showed increased rates of interstitial lung disease (ILD), with an overall incidence up to 15.4% across all disease states, 3.5% of which were grade ≥3. Given its novel mechanism of action and expanding use in practice, a better understanding of ILD monitoring and management is necessary to ensure patients fully benefit from T-DXd.

**OBJECTIVE:** To examine the incidence, severity, and management of ILD in patients receiving T-DXd compared with clinical trials.

**METHODS:** This study was a retrospective chart review of patients who have received ≥1 dose of T-DXd at Massachusetts General Hospital or Beth Israel Deaconess Medical Center between December 2019 and February 2023. Patients aged ≥18 years with a diagnosis of breast, gastric, or lung cancer were included. The primary outcome was the incidence of ILD. The secondary outcomes included the timing and severity of ILD based on the Common Terminology Criteria for Adverse Events and management strategies for confirmed ILD.

**RESULTS:** A total of 126 patients (breast cancer, 80%; gastric cancer, 11%; lung cancer, 9%) were included in this multicenter, retrospective review. The median number of T-DXd doses received was 6 (range, 1-50 doses), with a median treatment duration of 126 days (range, 0-1085; interquartile range [IQR], 46-193). The overall incidence of confirmed ILD was 5.6%, with 1 patient (4%) having a grade ≥3 event. The median time to the first incidence of ILD was 81 days (range, 1-273; IQR, 52-148), with a median time to resolution of 44 days (range, 8-258; IQR, 28-95). ILD was primarily managed with observation (71%), steroids (25%), and supportive care (8%). All 24 patients who had confirmed or possible ILD had ≥1 risk factor; 95.8% had ≥1 previous anticancer therapies with a notable risk for ILD, 79% had previous chest radiation, 29% had a history of smoking, and 25% had a history of lung disease (including ILD).

**CONCLUSION:** The incidence of T-DXd–associated ILD in this study was less than that reported in clinical trials; however, the severity remained similar. Patients with risk factors for ILD were more likely to have ILD. This study demonstrates the need for increased awareness and monitoring of ILD, particularly in patients with preexisting risk factors for ILD.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR13**

# Number-Needed-to-Treat Analyses of Zanubrutinib in Relapsed/Refractory Chronic Lymphocytic Leukemia

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**BACKGROUND:** Chronic lymphocytic leukemia (CLL) is the most common leukemia type, with an annual incidence of 4.9 per 100,000 people in the United States. In 2020, an estimated 207,463 people were living with CLL. Zanubrutinib is a Bruton tyrosine kinase inhibitor that is FDA approved for CLL. In the phase 3 ALPINE trial (NCT03734016), zanubrutinib elicited a significantly higher overall response rate and significantly longer progression-free survival (PFS) than ibrutinib.

**OBJECTIVE:** This study aimed to compare zanubrutinib versus ibrutinib in relapsed/refractory (R/R) CLL by calculating the number needed to treat (NNT) to avoid 1 event of disease progression or death and the associated incremental costs.

**METHODS:** A health-economic model was developed to evaluate the number of patients with R/R CLL who needed treatment to avoid progression or death from the US payer perspective. The payer blend was assumed to be 40% commercial and 60% Medicare. Clinical efficacy data were extracted from the ALPINE trial. The 24-month PFS from the final study analysis (zanubrutinib, 79.5%; ibrutinib, 67.3%) was used for the model base-case analysis. The model considered the costs of treatment, adverse-event management, medical resource utilization, and subsequent treatment. The model captured the NNT, incremental cost per treated patient, and incremental cost per additional patient who had disease progression or died. Deterministic sensitivity analyses were conducted to assess the parameter uncertainties and key model drivers. The impact of different PFS estimates was tested in scenario analyses.

**RESULTS:** The base-case results from the NNT model showed that for every 8 patients treated, 1 event of disease progression or death would be avoided with zanubrutinib compared with ibrutinib. The total costs per patient treated with zanubrutinib and ibrutinib were $370,558 and $430,150, respectively, with a cost-savings of $59,593 per zanubrutinib-treated patient in a 24-month time frame. Drug costs and PFS had major impacts on the incremental cost per patient. Varying the PFS scenarios (including adjustment for drug interruption, COVID-19–related death, or treatment discontinuation) changed the NNT from 8 to 12 patients and was associated with a cost-savings of $58,179 to $67,153 per patient treated with zanubrutinib. Applying the model results to a hypothetical clinical practice of 100 patients treated with zanubrutinib versus ibrutinib suggested that approximately 13 patients would avoid events of disease progression or death.

**CONCLUSION:** This NNT model suggests that treating patients who have R/R CLL with zanubrutinib versus ibrutinib results in more favorable clinical and economic outcomes in the United States.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR15**

# Patient Perspective: Logistics of Intravenous Iron Administration and Adherence to Therapy

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**BACKGROUND:** Iron deficiency anemia (IDA) affects approximately 5 million people in the United States and has a substantial effect on health and quality of life (QoL). Intravenous iron (IVI) is indicated for the treatment of IDA when oral iron is not effective or tolerated. Although IVI treatments are effective, some patients miss or delay their appointments, potentially leading to incomplete IVI treatment response.
**OBJECTIVE:** To identify the barriers to treatment with IVI from the patient perspective.
**METHODS:** In early 2023, patients aged >18 years in the United States with a confirmed diagnosis of IDA who recently received IVI therapy were asked to respond to an online survey conducted by The Harris Poll. The questions queried patient demographics, appointment logistics, IVI infusion experience, the impact of infusion on daily activities, the reason(s) for missed doses, and ways to improve adherence.
**RESULTS:** A total of 323 patients completed the survey, of whom 193 reported being prescribed ≥2 IVI infusions per month; 71 of the 193 (36.8%) patients reported having missed at least 1 dose. These 71 patients had an average age of 34.9 years and were mostly female (76.1%) and Caucasian (64.8%). The patients resided in urban areas (45.1%), near a city (38.0%), or in rural areas (16.9%). The leading causes of IDA were heavy menstrual bleeding (36.6%) and inflammatory bowel disease (18.3%). Respondents received an average of 2.62 IVI infusions monthly. The average reported time (minutes) spent on IVI appointment logistics included scheduling the infusions (46), traveling to the infusion center (76), the arrival to the start time of the infusion (51), and infusion chair time (89). Patients reported that IVI treatment negatively impacted their productivity (63.4%) and their attendance at important events (64.8%), and they schedule their life around treatment (80.3%). The most common reasons for missing a dose were "due to a conflict," "fitting the scheduled appointment," and "transportation difficulties." Most patients (84.5%) agreed that fewer IVI infusions would improve adherence to the full prescribed course of therapy. Overall, 38% of patients were not satisfied with the infusion frequency, 84.5% preferred fewer trips, and 85.9% would favor a single-dose option.
**CONCLUSION:** Despite the therapeutic benefits of IVI treatment, more than one-third of patients prescribed ≥2 IVI infusions monthly reported missing an infusion. The time spent on arranging and receiving IVI treatment negatively impacted patients' perspectives on their treatment. From these variables, the patients' preference for a single-dose treatment option may improve adherence and QoL. Based on the responses, convenience should be included and discussed when determining an IVI treatment choice, because it plays an important role in patient adherence.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR16**

# Pharmacist-Led Monitoring for Patients Initiating PARP Inhibitor Therapy

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**BACKGROUND:** Patients taking poly (ADP-ribose) polymerase inhibitors (PARPi) often encounter adverse events (AEs) soon after initiation that may lead to treatment interruptions, dose reductions, and discontinuations. Research is needed to understand if increased treatment monitoring early in therapy impacts outcomes.
**OBJECTIVE:** This study assessed the impact of pharmacist-led tailored monitoring on medication interruptions, dose reductions, discontinuations, and emergency department visits/hospitalizations over the first 90 days of treatment in patients initiating PARPi therapy.
**METHODS:** This was a single-center, pre- and postintervention study of adults initiating PARPi therapy between November 2017 and October 2019 or July 2021 and October 2022 with medication filled by the center's specialty pharmacy or the manufacturer assistance program. Clinical trial participants and patients without an FDA-approved use for PARPi therapy were excluded. A tailored early treatment monitoring intervention program was implemented in July 2021. Patients initiating PARPi therapy received counseling and a welcome kit at therapy initiation, followed by 7 monitoring calls over 90 days aligned with the expected onset of AEs. Pharmacists documented patient-reported AEs, pharmacist interventions, and outcomes in the specialty pharmacy database. Descriptive statistics were used to compare data between the study arms. Specific AEs and pharmacist intervention frequency were also described.
**RESULTS:** Preintervention (n=28; data reported first throughout) and postintervention (n=29; data reported second throughout) populations were similar, mostly white (82%, 90%), female (96%, 90%), had median ages of 62 years (interquartile range [IQR] 53-72) and 63 years (IQR 56-69), and had median disease durations of 1.8 years (IQR 1.4-3.6) and 1.1 years (IQR, 0.6-3.3). Olaparib was the most frequently prescribed PARPi (89%, 90%), and ovarian cancer was the most common cancer type (82%, 69%). Postintervention patients had fewer interruptions in treatment (54% vs 31%) with a shorter treatment duration (median days, 17 [IQR 7-24] vs 7 [IQR 6-21]). Dose reductions were similar between the arms (36% vs 34%). Discontinuations occurred more in the postintervention population (18% vs 31%); however, disease progression drove treatment discontinuation in both arms (80% vs 89%). Fewer hospitalizations occurred in the postintervention population (25% vs 7%) although emergency department visits were similar in both groups (7% vs 10%). Fatigue (46%, 76%) and nausea (36%, 72%) were reported most often in both arms. The most common interventions were supportive therapy (43%) and treatment interruption (39%) in the preintervention group and patient education (93%), and supportive therapy (62%) was the most common in the postintervention group.
**CONCLUSION:** Patients receiving pharmacist-led tailored monitoring during the first 90 days of PARPi therapy had fewer hospitalizations and fewer and shorter dose treatment interruptions. Larger studies are needed to verify the impact of pharmacist-led interventions.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR17**

# Predictive Factors of Dose Reduction Among Patients Treated With Palbociclib for Advanced or Metastatic Breast Cancer in a Real-World Setting

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**BACKGROUND:** The Canadian palbociclib monograph recommends a starting dose of 125 mg/day and subsequent dose reductions during treatment if adverse events occur. However, in practice, clinicians sometimes choose to initiate palbociclib at a lower dose to prevent the occurrence of adverse events in patients who are considered more likely to have them.

**OBJECTIVES:** This study aimed to identify baseline patient characteristics that may predict the need for palbociclib dose reduction during treatment. The secondary objectives were to describe treatment patterns and clinical outcomes, including progression-free survival (PFS), in patients treated with palbociclib at the Centre hospitalier de l'Université de Montréal (CHUM). The study also aimed to identify the frequency and type of interventions carried out by oncology pharmacists for these patients.

**METHODS:** This single-center, retrospective medical chart review study included adults diagnosed with hormone receptor–positive, human epidermal growth factor 2–negative, advanced or metastatic breast cancer treated with palbociclib in combination with letrozole or fulvestrant between April 2019 and June 2022 at CHUM. Logistic regression was performed to identify the factors predicting dose reduction during treatment. The Kaplan-Meier method was used to estimate PFS. Log-rank tests were performed for comparison.

**RESULTS:** A total of 149 patients were included: 59.7% were treated with palbociclib plus letrozole, and 40.3% were treated with palbociclib plus fulvestrant. Most patients (65.1%) received palbociclib as first-line therapy. The median age was 66 years, and 1.3% of patients were men. Palbociclib was initiated at 125 mg/day and 75 mg/day or 100 mg/day in 90.6% and 9.4% of patients, respectively. Palbociclib dose reductions occurred in 37.6% of all patients, mostly as a result of neutropenia. Only 2 factors were predictive of dose reduction: age ≥70 years (odds ratio [OR], 2.1; 95% confidence interval [CI], 1.063-4.148; *P*=.033) and absolute neutrophil count (ANC) $<3.5 \times 10^9$/L before initiating treatment (OR, 3.120; 95% CI, 1.516-6.422; *P*=.002). Exploratory analyses showed that the median PFS was 17.3 months; patients with dose reduction had a better median PFS (20.4 vs 14.1 months; *P*=.112). Pharmacists carried out on average 14.4 interventions per patient, mainly to answer questions from oncology nurses (17.5%).

**CONCLUSION:** These real-world data suggest that patients aged ≥70 years and those whose ANC before initiating treatment is $<3.5 \times 10^9$/L may benefit from an up-front dose reduction because they are at higher risk for a dose reduction of palbociclib during treatment.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR18**

# Real-Life Study: Evaluation of the Safety of PARP Inhibitors in Ovarian Cancer at the Centre Hospitalier de l'Université de Montréal (CHUM)

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**BACKGROUND:** Poly (ADP-ribose) polymerase inhibitors (PARPi) significantly improve progression-free survival in ovarian cancer. However, these oral treatments have a safety profile that requires close monitoring. In a real-life setting, it is important to be aware of adverse events and their impact on treatment, such as treatment interruption, dose reduction or permanent discontinuation. Management of toxicities results in a significant burden for the treating team, including oncology nurse navigators and oncology pharmacists.

**OBJECTIVE:** To describe the tolerance of PARPi in a population of patients with ovarian cancer in real-life settings and the impact on the workload of oncology nurses and pharmacists.

**METHODS:** This is a retrospective, observational study including women with ovarian cancer treated with olaparib or niraparib as maintenance therapy between April 1, 2019, and March 31, 2022, at Centre hospitalier de l'Université de Montréal (CHUM). The primary end point was to compare the incidence of adverse events between patients treated at CHUM and phase 3 trials. The secondary end points included analyzing the incidence of dose reduction or dose interruption and the interventions performed by oncology nurses and pharmacists.

**RESULTS:** A total of 65 patients were included in this study, of whom 42 patients received olaparib and 23 received niraparib. Although 58% of patients required a dose reduction, 61% of them required at least 1 dose interruption. The majority of patients receiving niraparib initiated their treatment at a reduced dose of 200 mg once daily, regardless of weight, platelet count, and indication. Thrombocytopenia and fatigue were the most common hematologic and nonhematologic adverse events, leading to a dose interruption in 23% and 9% of patients, respectively. The most common adverse events leading to dose modifications were nonhematologic adverse events (41%), thrombocytopenia (15%), and anemia (14%). Oncology pharmacists and nurses provided a median of 7 (2.5-70) interventions per patient monthly, with the most frequent interventions focusing on care coordination and laboratory monitoring. The median follow-up duration of patients was 8.3 months.

**CONCLUSION:** Our study shows that in real-world settings, PARPi use leads to a higher frequency of dose reductions. In addition, the monitoring of patients undergoing PARPi treatment places a substantial workload on the healthcare team. As the indication for these medications continues to broaden, workload is a factor to be considered, and a thoughtful approach is necessary to optimize the management of patients on PARPi treatment.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR19**

# Remote Outpatient Temperature Monitoring for Early Detection of Febrile Neutropenia After High-Dose Cytarabine Consolidation Chemotherapy (the REMEDY Trial)

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**BACKGROUND:** Febrile neutropenia (FN) is a common and potentially life-threatening complication of high-dose cytarabine (HiDAC) consolidation for patients with acute myeloid leukemia (AML). Early detection may limit negative sequelae. Although continuous temperature monitoring via commercially available remote temperature monitoring transdermal patch (RTM-patch) is reported to detect FN earlier than intermittent manual monitoring in hospitalized patients, evaluation in the outpatient oncology setting is lacking.

**OBJECTIVE:** To examine the feasibility and effectiveness of a remote continuous temperature monitoring device for early detection of FN after HiDAC.

**METHODS:** This institutional review board–approved pilot study compared a prospective cohort (July 2021-May 2023) of patients utilizing RTM-patch for 15 days after HiDAC or until hospitalization for FN, with a historical cohort (January 2015-July 2021) who used manual intermittent monitoring with a thermometer. The subjects included were aged ≥18 years and received HiDAC consolidation monotherapy for AML. The subjects in the prospective cohort signed informed consent and were provided transdermal patches, a phone if needed, instruction on patch placement and smartphone application, and an end-of-study satisfaction survey. The outcomes measured included the incidence of FN, hospital and intensive care unit (ICU) admission and length of stay, and death. The descriptive statistics are reported.

**RESULTS:** Most subjects in the retrospective and prospective cohorts received HiDAC 3 gm/m$^2$ (68% vs 50%) with growth factor (95% vs 100%) and antibiotic prophylaxis (83% vs 79%). The retrospective cohort included 41 cycles for 21 patients. In the retrospective cohort, admission for FN occurred after 13 cycles (32%), 4 (9.8%) patients required transfer to the ICU, 28 (68%) had microbiologically defined infection, and none died. In the prospective cohort, 17 subjects over 22 cycles were screened, resulting in 12 subjects and 14 cycles enrolled. Two (14%) subjects self-discontinued early for technical difficulties. Eight patients had fever, but 2 (25%) refused to go to the hospital. Admission for FN occurred after 6 cycles (43%), and 1 (7%) subject had documentation of sepsis per an outside hospital. None of the patients in the prospective cohort required ICU transfer, had microbiologically defined infection, or died. Of the 9 surveys completed, all reported ease of use of patches and application; however, 1 of the 9 subjects reported skin irritation, and 8 cycles had at least 1 technical difficulty (patch misplacement or malfunction, distance from smartphone app, etc).

**CONCLUSION:** Limited data from this pilot study suggest a remote temperature monitoring device is feasible and potentially beneficial in mitigating the negative outcomes of FN in the outpatient setting; however, various technology issues should be considered when devising further studies and evaluating the clinical benefit of these devices in the ambulatory cancer population.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR20**

# Survey of PGY-2 Oncology Residency Program Directors to Assess Current Resources and Effects on Burnout

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**BACKGROUND:** Many hematology-oncology pharmacists have reported high burnout levels for reasons including increased hours worked and administrative requirements in a recently completed survey. This has resulted in challenges in recruiting and retaining hematology-oncology pharmacists in addition to already demanding clinical responsibilities. Oncology PGY-2 residency program directors (OPGY-2 RPDs) are particularly vulnerable with voluminous regulations and administrative requirements to conduct a residency program in addition to clinical responsibilities. Neither the well-being of OPGY-2 RPDs nor the implementation and impact of additional resources have been described.

**OBJECTIVES:** The goal is to describe the status, structure, support for RPDs, and time requirements of OPGY-2 across the country and to provide a well-being assessment of these RPDs to capture the level of burnout.

**METHODS:** A 22-question survey was sent to 124 OPGY-2 RPDs from the American Society of Health-System Pharmacists (ASHP) residency program directory. OPGY-2 RPDs were asked about their programs, perceptions on workload, time requirements, and a one-time Stanford Professional Fulfillment Index (PFI). Descriptive statistics were used for demographic questions, resources, incentives, time requirements, and basic assessment of the PFI. Where appropriate, nonparametric tests were used to assess the differences. To identify the program structure factors that promote OPGY-2 RPD professional fulfillment, linear regression was used to predict the Professional Fulfillment Scale measure.

**RESULTS:** The overall response rate was 45.9%. Most respondents had ≤3 years of experience (61.4%), ≤15 preceptors (66.7%), and ≤2 residents (70.1%). In all, 61.5% of OPGY-2 RPDs had no title-related incentives, but 17.5% had budgeted protected time, 15.7% had financial incentives, and 12.2% had incentives not listed. A total of 73.6% of RPDs felt that they spent ≥5 hours weekly on RPD responsibilities, and 68.4% felt this was not enough time to manage them. Clinically, 43.8% felt they managed responsibilities effectively. In all, 50.8% felt that the ASHP standards did not provide enough time to cover responsibilities, and 70% of OPGY-2 RPDs have considered stepping down within the past 12 months. The mean (standard deviation [SD]) PFI score was 2.6 (SD±0.6), and 35.09% of RPDs reported high professional fulfillment. The mean burnout score was 1.5 (SD±0.7), and 47.37% of RPDs reported high burnout. No specific variable was significantly associated with burnout. Spearman's rank correlation coefficient is –0.4995 ($P$<.001), suggesting a moderately strong negative correlation between burnout and PFI.

**CONCLUSION:** Based on self-reporting and PFI scores, there are high levels of burnout among RPDs and a high risk for attrition. OPGY-2 RPDs need more support to run residency programs including ≥5 hours of protected time.

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## Completed Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #CR21**

# Taxane Titration: To Prime or Not to Prime?

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**BACKGROUND:** Patients exposed to paclitaxel and docetaxel (taxanes) have an increased rate of hypersensitivity reaction (HSR), especially during the first and second exposures (21% to upward of 41%). Most symptoms are mild that involve skin reactions, to more severe, including anaphylaxis and death. Taxane administration varies in practice settings, including the rate of infusion during titration and priming intravenous lines with drug versus diluent because of a lack of supporting evidence in the literature.
**OBJECTIVES:** To determine the impact of titrating taxanes on HSR incidence rates and severity in patients receiving first or second taxane doses, and to identify if there is a difference between HSR incidence rates and severity in the first 2 exposures when priming the taxane lines with drug compared with priming with diluent.
**METHODS:** A total of 99 taxane patient infusions (first and second doses) were titrated using lines primed with drug and were prospectively monitored and compared for HSR incidence and severity with a retrospective cohort of taxane infusions (n=123) without titration. A follow-up monitoring of 999 taxanes with a modified titrated rate and lines primed with diluent were then compared with the original cohort (n=99, titrated infusions using lines primed with drug) and (n=123, nontitrated infusions) to evaluate the differences in HSR rate and severity.
**RESULTS:** There was a significant decrease ($P$<.001; 6% vs 18.7%) in the incidence rates of HSRs when titrating taxanes using a line primed with drug compared with taxane patients exposed without titration. In addition, there was no significant difference ($P$=.659) between HSR rates and severity when taxane patients were titrated with lines primed with diluent compared with lines primed with drug.
**CONCLUSION:** These comparisons showed a significant reduction in HSRs when patients received a slow rate of infusion during the initial exposures to taxanes. There was no statistical difference between priming with diluent versus with drug when both groups were titrated, proving a slower rate of administration is crucial. In both analyses, there was no significant difference in severity based on the grade of reaction; however, the use of epinephrine and the incidence of hospitalizations and treatment interruptions were reduced in the titration arms.

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## Completed Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #CR22**

# Treatment and Outcomes Associated With Caplacizumab in the Management of Acquired Thrombotic Thrombocytopenic Purpura

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**BACKGROUND:** Despite standard-of-care treatments, mortality rates for acquired thrombotic thrombocytopenic purpura (aTTP) of as high as 20% continue to be reported, identifying a need for improved treatment strategies. Caplacizumab, a humanized monoclonal antibody that targets von Willebrand factor, has shown faster platelet normalization and lower aTTP recurrence rates. Despite its approval based on phase 3 clinical trial results, many

questions remain regarding the practical applicability and clinical value of caplacizumab.

**OBJECTIVES:** The primary objective of this study was to compare aTTP exacerbation or refractory disease between patients with aTTP who received caplacizumab versus those who did not. The secondary objectives include exacerbation, relapse, refractory aTTP, time to platelet normalization, time to recurrence, duration of therapeutic plasma exchange (PEX), and duration of hospitalization.

**METHODS:** A single-center, retrospective chart review was conducted to evaluate the effectiveness of caplacizumab in patients diagnosed with aTTP between January 1, 2012, and October 31, 2021. Patients meeting the inclusion criteria were stratified by exposure to caplacizumab (largely before and after the drug's market approval). Patient, disease, and treatment characteristics were analyzed via descriptive statistics. Categorical and continuous outcomes were analyzed using Fisher's exact test and Wilcoxon rank-sum test, respectively. All statistical tests were 2-sided, and $P<.05$ was considered statistically significant.

**RESULTS:** A total of 48 patients (n=16 caplacizumab, n=32 non-caplacizumab) were included in this study. The caplacizumab group was more likely to be African American (75% vs 21%, respectively) and receive rituximab (93.4% vs 34.4%, respectively) compared with the non-caplacizumab group. Other characteristics were similar between the groups. Although not statistically significant, patients in the caplacizumab group were less likely to have aTTP exacerbation or refractory disease compared with the non-caplacizumab group (6% vs 22%, respectively; $P=.24$). The caplacizumab group had a similar safety profile to the non-caplacizumab group, including all-cause mortality (6% vs 22%, respectively; $P=.24$). One major bleeding event was reported among the patients who received caplacizumab (not requiring factor support).

**CONCLUSION:** The study's findings were consistent with the results reported in previous clinical trials. Based on our findings and previous literature, patients with aTTP may see benefit in the initiation of caplacizumab. We identified a trend in effectiveness outcomes that may suggest a clinical benefit with the addition of caplacizumab. A similar duration of hospitalization between the caplacizumab and non-caplacizumab groups (14 days vs 12 days, respectively) is likely accounted for by the institutional standard of care to taper PEX. These data may be useful in continuing to optimize the role of caplacizumab in the management of aTTP.

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## Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #LB01**

# Comparison of the Efficacy of Generic Plerixafor Versus Mozobil as Adjunct Peripheral Blood Stem-Cell Mobilization Agents in Patients With Multiple Myeloma

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**BACKGROUND:** Plerixafor is an adjunct agent for peripheral blood stem cell (PBSC) mobilization with well-demonstrated safety and efficacy since its FDA approval in 2009. Until recently, plerixafor was solely available in the United States under the brand name of Mozobil (Sanofi-Aventis; France), and its widespread use has been limited by cost. Our institution recently switched from using Mozobil to generic plerixafor (Meitheal Pharmaceuticals; Chicago, IL) with a much lower cost.

**OBJECTIVE:** This retrospective, observational study was conducted to compare the mobilization efficacy of generic and brand-name plerixafor in patients with multiple myeloma (MM).

**METHODS:** Two cohorts of consecutive patients with MM who underwent PBSC mobilization immediately before (n=64) and after (n=61) the switch from brand-name to generic plerixafor were identified. All were mobilized with filgrastim at 10 µg/kg/day for 4 days, with plerixafor given subcutaneously either upfront in the evening of day 4 prior to starting collection on day 5 or added just in time on day 5 following low peripheral blood CD34 counts or collection yields. Injections and apheresis collections continued until 2-3 × 10e6 or 4-6 × 10e6 CD34+ cells/kg for single and double transplant candidates, respectively, were collected.

**RESULTS:** The 2 cohorts had no significant difference in sex (brand-name, 65.5% male; generic, 60.7% male; *P*=.70), median age (brand-name, 61.5; generic, 64; *P*=.30), and mean weight (brand-name, 82 kg; generic, 86.86 kg; *P*=.20), previous radiation therapy (brand-name, 14.1%; generic 9.84%; *P*=.59), previous number of therapy lines (brand-name: 70% 1 line, 28.1% 2 lines, 1.56% 3 lines; generic: 67.2% 1 line, 32.8% 2 lines, 0% 3 lines; *P*=.70), upfront (vs just-in-time), or plerixafor use (brand-name, 62.5%; generic, 73.8%; *P*=.250). Patients required a lower median number of plerixafor doses and collection days in the generic arm (1; interquartile range [IQR], 1-2) versus brand arm (2; IQR, 1-2; *P*<.05). Only 31% of patients in the generic arm required more than 1 dose versus 59% of patients in the brand-name arm (*P*<.05). There is a significantly higher post-plerixafor day-1 yield (10e6 CD34+ cells/kg) in the generic versus brand-name cohorts (4.79 vs 3.78, respectively; *P*<.05). There were no significant differences in the median total yield after treatment with plerixafor (brand-name, 5.38; generic 5.47; *P*=.441) and the median overall cumulative total yield (brand-name, 5.91; generic, 5.80; *P*=.505). Only 4.69% and 3.28% in the brand-name and generic cohorts did not collect 2 × 10e6 CD34+ cells/kg (*P*=1).

**CONCLUSION:** Generic plerixafor produced similar cumulative collection yields with fewer doses and collection days compared to brand-name plerixafor.

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## Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #LB02**

# Pharmacist Interventions Resulting From a Health System Specialty Pharmacy 14-Day Oncology Check-In Protocol

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**BACKGROUND:** Several studies have illustrated value in early patient contact following oral anticancer medication (OAM) initiation, particularly within the first 14 days of therapy, as adverse effects may inspire early discontinuation and poor adherence. Health system specialty pharmacies (HSSPs) are optimally positioned for pharmacists to adopt this best practice for early contact and formalize protocols to identify and mitigate issues. Despite clear advantages of early OAM patient contact, evaluating pharmacist-generated interventions resulting from this check-in is needed to understand the impact of early patient-pharmacist contact following the initiation of OAM.

**OBJECTIVE:** To describe the interventions created following a HSSP pharmacist-led 14-day check-in protocol in patients receiving OAM.

**METHODS:** CPS client HSSPs enacted a protocol in January 2022 requiring embedded oncology clinic pharmacists to contact patients within 14 days of OAM initiation, aiming to optimize adverse-effect management, offer needed supportive care, address adherence, and provide education. This retrospective, multicenter, descriptive study reviewed intervention data linked to this protocol across CPS client health systems from January 2022 to November 2023. The interventions included were for patients with cancer aged ≥18 years who were prescribed OAM and were clinically managed by HSSP pharmacists. Interventions were excluded if they were canceled or if there were incomplete or missing details. The intervention types included adherence, adverse drug reaction (ADR), laboratory, drug information/education, vaccine, and regimen appropriateness. Intervention types were further categorized for reason, recommendation, and acceptance. Data analysis evaluated the intervention count, type, category, and acceptance rate.

**RESULTS:** In total, HSSP pharmacists created 1698 interventions from the 14-day check-in call. The average patient age was 66.3 ± 13.5 years (range, 22-95 years). The most frequently cited cancer diagnoses were breast (25.4%), gastrointestinal (14.4%), and prostate (12.1%). The medications that most frequently required interventions were capecitabine (12.9%) and abemaciclib (8.5%). The most frequent intervention types were ADR (91.2%), followed by adherence (3.2%) and regimen appropriateness (2.9%). HSSP pharmacist recommendations included counseling on mitigation strategies (53.6%), recommending a new therapy (20.1%), recommending an office visit (10.2%), recommending a therapy change (8.9%), and providing disease/drug education (4.7%). Overall, 95.5% of pharmacist recommendations were accepted, 2.6% required a follow-up, and 1.8% were declined.

**CONCLUSION:** Implementing a 14-day check-in protocol allows HSSP pharmacists to mitigate barriers to OAM adherence and promote persistence. This study validates the importance of early check-in and illustrates the scope of the oncology pharmacist's role by evaluating critically meaningful interventions and quantifying pharmacist recommendations and acceptance.

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## Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #LB03**

# Post-Transplant Cyclophosphamide, Tacrolimus, and Mycophenolate vs Tacrolimus and Methotrexate as GVHD Prevention Following Allogeneic Stem Cell Transplant With Myeloablative Conditioning

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**BACKGROUND:** The use of post-transplant cyclophosphamide, tacrolimus, and mycophenolate (PTCy-Tac-MMF) has gained popularity for the prevention of graft-versus-host disease (GVHD) following hematopoietic stem cell transplant (HSCT) with an HLA-matched related donor (MRD) or an HLA-matched unrelated donor (MUD) donor. Although the results of BMT-CTN 1703 solidified the role of PTCy-Tac-MMF as standard of care following reduced-intensity conditioning, limited data exist evaluating its use following myeloablative conditioning.

**OBJECTIVE:** The purpose of this study is to compare the efficacy and safety of PTCy-Tac-MMF and tacrolimus and methotrexate (Tac-MTX) as GVHD prevention among patients who underwent HSCT from a MRD or MUD following myeloablative conditioning.

**METHODS:** This single center, retrospective cohort study included patients who received an HSCT from an MRD or MUD following myeloablative conditioning from January 2019 to August 2022. The primary outcome, 1-year GVHD-free, relapse-free survival (GRFS), was estimated by Kaplan Meier method and compared between the groups using a log-rank test. The secondary outcomes included the incidence of GVHD, time to engraftment, time of relapse, overall survival (OS), and incidence of adverse events.

**RESULTS:** The study included 90 patients, of whom 77 (85.6%) received Tac-MTX and 13 (14.4%) received PTCy-Tac-MMF. The 1-year GRFS rate was 21% (95% confidence interval [CI], 0%-44%) for PTCy-Tac-MMF and 6.5% (95% CI, 1%-12%) for Tac-MTX ($P$=.066). The rate of acute GVHD (aGVHD) was 30.8% versus 68.8%, and the rate of chronic GVHD (cGVHD) was 38.5% versus 54.5% in the PTCy-Tac-MMF and Tac-MTX groups, respectively. Grade 3 or 4 aGVHD and moderate-to-severe cGVHD were less frequent among those who received PTCy-Tac-MMF. Neutrophil engraftment was achieved in 92.3% of those receiving PTCy-Tac-MMF (median time to engraftment, 17.5 days; interquartile range [IQR], 15.8-20.2) compared with 97.4% of those receiving Tac-MTX (median, 18 days; IQR, 16-20). The 1-year cumulative incidence of relapse was 15% (95% CI, 2.2%-40%) and 13% (95% CI, 6.6%-22%) for PTCy-Tac-MMF and Tac-MTX, respectively. The 1-year OS was 68% (95% CI, 43%-94%) among those receiving PTCy-Tac-MTX and 70% (95% CI, 60%-80%) among those receiving Tac-MTX.

**CONCLUSION:** Tac-MTX did not have statistically different 1-year GRFS versus PTCy-Tac-MMF. Lower rates of GVHD, including grade 3 or 4 aGVHD and moderate-to-severe cGVHD, were observed among the PTCy-Tac-MMF cohort. The 1-year relapse rates and 1-year OS were similar between the 2 groups. Limitations include the small sample size of the PTCy-Tac-MMF cohort and a short time of follow-up. Future directions include extending the study time period to include additional patients in the PTCy-Tac-MMF cohort and adjusting for prognostic factors.

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## Late-Breaking Research: CLINICAL/TRANSLATIONAL RESEARCH

**Abstract #LB04**

# Real-World Clinical Outcomes With Fostamatinib for the Treatment of Refractory Chronic Immune Thrombocytopenia

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**BACKGROUND:** Fostamatinib is a spleen tyrosine kinase inhibitor indicated for the treatment of chronic immune thrombocytopenia (ITP) that is unresponsive to at least 1 previous treatment. However, fostamatinib is often reserved for later lines of therapy after prior treatment with corticosteroids, rituximab, and a thrombopoietin receptor agonist. Real-world studies evaluating the utilization and effectiveness of fostamatinib outside the context of a clinical trial are lacking.

**OBJECTIVE:** To evaluate the effectiveness of fostamatinib for the treatment of ITP in a real-world cohort.

**METHODS:** We conducted a single-center, retrospective, observational study to evaluate the effectiveness of fostamatinib for the treatment of ITP. Eligible patients included adults aged >18 years who received fostamatinib for previously treated ITP. The primary end point was durable response as defined by the American Society of Hematology ITP response criteria. The secondary end points included overall response rate, time to response, and safety. Subgroup analysis was performed to assess the frequency of durable response in key subgroups of patients based on prior therapies. This study was approved by the institutional review board.

**RESULTS:** A total of 31 patients treated with fostamatinib for ITP were included in our analysis. Patients had received a median of 4 prior lines of therapy. Most patients had been previously treated with corticosteroids (100%), a thrombopoietin receptor agonist (93%), IVIG (74%), and rituximab (71%). A total of 10 (32%) patients achieved a durable response. Most patients who had a durable response maintained their response at 24 months (n=7; 70%). The median time to response was 9 days. Most patients (n=24; 77%) required a dose adjustment from 100 mg twice daily to 150 mg twice daily. In all, 4 (13%) patients discontinued fostamatinib as a result of an adverse event. The subgroups that had higher rates of durable responses included those who had received 2 or 3 prior lines of therapy (40%), splenectomized patients (50%), and those who had not received prior rituximab (55%).

**CONCLUSION:** Fostamatinib therapy in a real-world population of patients with heavily pretreated ITP led to the achievement of a durable response in one-third of patients, which was maintained for most responders. There may be specific patient populations and treatment histories for which fostamatinib may elicit the most clinical benefit. In addition, because most patients' doses were escalated to 150 mg twice daily, this should be evaluated as a potential starting dose for fostamatinib in ITP in the future.

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## Late-Breaking Research: PRACTICE MANAGEMENT RESEARCH

**Abstract #LB05**

# Unlocking Geographic Disparities in Lung Cancer Incidence Calls for Tailored Interventions and Pharmacist Partnerships

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**BACKGROUND:** Pharmacists play a crucial role in various aspects of healthcare, yet their potential impact in promoting lung cancer screening remains largely untapped within the United States. Lung cancer screening promotion is a critical need, because less than 10% of high-risk populations undergo lung cancer screening, whereas rates exceed 60% for breast, prostate, and colorectal cancer screenings. Addressing this disparity is imperative, because early detection can increase overall survival.

**OBJECTIVE:** This study aims to identify counties with significant disparities in lung cancer incidence based on race and sex. The findings will identify high-priority areas where partnerships with pharmacists can be established to develop effective strategies for increasing lung cancer screening rates.

**METHODS:** Data from the 2015-2019 Centers for Disease Control and Prevention's United States Cancer Statistics were used to identify counties with age-adjusted lung cancer incidence rates for non-Hispanic black (NHB) and non-Hispanic white (NHW) males and females. The comparator groups included the NHB versus NHW overall population, NHB versus NHW females, and NHB versus NHW males. Relative risk (RR) was used to determine lung cancer incidence disparity rates between the comparator groups and a chi-square test was used to determine *P* values.

**RESULTS:** A total of 459 counties in the United States were identified across 40 states; Washington, DC, had the highest disparity in lung cancer incidence for NHBs compared with NHWs (RR, 2.37; *P*=.0002). When stratified by sex, Richmond County, Virginia had the highest disparity in lung cancer incidence for NHB females (RR, 3.3; *P*<.0001). The top 5 states with the highest number of counties with disparities for NHB females were Texas (N=11), Virginia (N=11), California (N=10), Pennsylvania (N=10), and Illinois (N=8). For NHB males, Washington, DC, had the highest disparity in lung cancer incidence (RR, 2.88; *P*<.0001). The states with the highest number of county-level disparities for NHB males were North Carolina (N=31), Louisiana (N=20), Mississippi (N=19), Texas (N=19), and Virginia (N=18).

**CONCLUSIONS:** Washington, DC, exhibits the highest disparities in lung cancer incidence rates for NHBs. However, the concentration of disparities between NHBs and NHWs is notable in North Carolina, Texas, and Virginia for both males and females. This underscores the importance of partnering with pharmacists in these areas to customize screening interventions and address the specific challenges faced by these communities.

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