Abstracts from the Tenth Annual National Association of Specialty Pharmacy (NASP) Annual Meeting & Expo

National Association of Specialty Pharmacy (NASP)

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Abstracts from the Tenth Annual National Association of Specialty Pharmacy (NASP) Annual Meeting & Expo

POSTER #1

Follow the script: MS DMT access time & adherence

Presenting author: Amanda Hickman
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Trellis Rx

Background: Multiple sclerosis (MS) is a complex disease state where it is vital that patients start treatment as early as possible and remain adherent for best clinical outcomes. However, medication access can be impacted by a variety of factors such as payor and limited distribution networks that restrict the pharmacies and associated services available to patients. Integrated health system specialty pharmacies (HSSP) embed pharmacists and pharmacy liaisons into the clinical team, creating a care model that materially improves patient outcomes. This is accomplished, in part, through reducing time to medication access and increasing adherence in patients with multiple sclerosis.

Objective: This study evaluated script-to-mouth time for disease modifying therapies (DMTs) used to treat MS and the rates of adherence for patients whose prescriptions were filled with an Integrated HSSP compared to those whose prescriptions were filled at external pharmacies not affiliated with the health systems.

Methods: National, multi-center, retrospective study where patients were included if they had a diagnosis of MS and were prescribed a self-administered DMT. Patients were excluded if their prescriptions were dispensed through a manufacturer patient assistance program pharmacy. Script-to-mouth time was defined as the date on which the prescription was written to the date of first dispense of that prescription, if such information was available. Adherence was defined as proportion of days covered (PDC).

Results: 183 patients were evaluated for script-to-mouth time, and 293 were evaluated for PDC. Patients filling with an Integrated HSSP had an average script-to-mouth time of 7 days (median of 5, upper quartile of 8), and patients filling with an external pharmacy had an average of 24 days (median of 14, upper quartile of 29). The average PDC for the script-to-mouth population when filling with an Integrated HSSP was 0.97 (median of 1, upper quartile of 0.96), compared to the PDC when filling with an external pharmacy of 0.89 (median of 1, upper quartile of 0.88). For the whole PDC population, the results were an Integrated HSSP PDC average of 0.96 (median of 0.98, upper quartile of 0.94) and external pharmacy PDC average of 0.93 (median of 0.99, upper quartile of 0.91).

Conclusion: Patients with MS enrolled in HSSP services had a script-to-mouth time more than three times faster. They also had higher adherence levels than those patients filling with external pharmacies, especially for those who were starting a new therapy where the PDC was nearly 10% higher.

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Category: Adherence.

POSTER #2

Adherence texting program in a specialty pharmacy

Presenting author: Kelly Mathews
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Optum

Background: Medication nonadherence is associated with high healthcare costs that may result in poor treatment outcomes, disease progression, and avoidable hospitalizations. Between $100 and $300 billion annually is spent on nonadherent patients. With the increasing utilization of biologic medications, the specialty pharmacy market is expected to reach $475–$596 billion by 2023, likely leading to even greater costs of medication nonadherence.

Objective: To assess if participation in an adherence texting program (ATP) will improve medication adherence and duration on therapy in patients serviced by a national specialty pharmacy.

Methods: This single-center, retrospective non-inferiority cohort study evaluated patients who received prescriptions for multiple sclerosis (MS), inflammatory diseases (INF) or oncology (ONC) from one national specialty pharmacy. Infused, provider administrated, specific Risk Evaluation and Mitigation Strategy (REMS) medications, patients who opt-out of the ATP and/or participated in other
adherence programs were excluded. The observation period was June 2021 through April 2022. The intervention group included participants who received medication dose reminders, personalized adherence reports, and motivational messages. Non-participants did not agree to enroll in the adherence texting program. Primary outcomes were the proportion of days covered (PDC) for those enrolled in ATP with MS, INF, ONC, and all cohorts combined. Secondary outcomes included days on therapy (DOT), additional fills, persistency, and therapy gap days for patients enrolled in the ATP. Propensity score matching and two-sided t-test were completed for data analysis, with a p-value of <.05 considered significant.

**Results:** A total of 8,048 patients were enrolled and included in the analysis. The PDC in all cohorts combined was 93.0% for participants and 90.8% for non-participants (p < .001). The PDC for the MS population was 93.2% for participants and 90.6% for non-participants (p < .002), for the INF cohort was 92.9% for participants and 90.6% for non-participants (p < .001), and for ONC population was 93.3% for participants and 91.7% for non-participants (p = .01). In the INF cohort, participants had fewer gap days than non-participants (9 vs. 12; p < .001) and more sustained persistency (p = .02). In the MS cohort, participants had fewer gap days than non-participants (11 vs. 16; p = .002). In the ONC cohort, participants had fewer gap days than non-participants (8 vs. 10; p < .01) and more sustained persistency (p = .001).

**Conclusion:** Study results indicate that participation in an adherence texting program improved medication adherence. This gives a promising outlook on technology utilization to aid patient adherence to therapy and possibly reduce negative health outcomes and total costs of care. Additional research and longer follow-ups are needed to establish the clinical significance of ATP in the studied population and in patients who suffer from other chronic disease states.

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The mean baseline FEV1 was 82.3 (SD 35.83%) and mean BMI was 19.71 kg/m² (SD 5.35 kg/m²).

**Conclusion:** CFTRm have a consistently level of adherence over inhaled therapies. Higher adherence to this therapy may have a larger impact towards clinical outcomes above adherence to other inhaled therapies. This study does not have the adequate power to show associations between risk factors and the level of adherence, however more research is needed with a larger sample size to draw more concrete conclusions.

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**Category:** Adherence.

**POSTER #5**

**HealthBeacon: smart reminders improve adherence**

Presenting author: Sharifah Sarhan
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**Background:** HealthBeacon’s Injection Care Management System (ICMS) includes a Smart Sharps Bin and SMS reminders to support patient adherence to self-administered injections. By monitoring used injections dropped into the bin (drops), the ICMS can detect if a patient is likely to miss their injection and provide dose reminders. The bin’s blue light illuminates when a dose is due and patients may opt to receive smart SMS reminders, including a Late SMS 24 hours after, if they have not dropped their scheduled dose.

**Objective:** To investigate the impact of the smart Late SMS on medication adherence.

**Methods:** HealthBeacon monitored 30,129 drops eligible for a Late SMS from 2514 patients using the ICMS between January 2018 and March 2022. These patients were on therapy for Gastroenterological, Dermatological and Rheumatological conditions. Each drop recorded by the ICMS contributes to a patient’s adherence score. In this analysis, patient data was organized into two groups. Eligible drops were those not disposed of 24 hours following their scheduled time. Patients in Group 1 received a smart Late SMS for these drops, whereas those in Group 2 did not. There were 19,726 eligible drops (from a total of 79,515) from 1807 patients in Group 1, and 10,403 eligible drops (total 26,122) from 707 patients in Group 2. Patients’ adherence to late drops in each Group was compared, to determine the impact of the Late SMS on compliance.

**Results:** Patients in Group 1 dropped 26% of their late doses whereas those in Group 2 dropped 11%. This difference of 15% was significant ($\chi^2 = 409.09, p < .001$), highlighting the impact of the Late SMS on patients’ drop behavior; those who receive the smart reminder appear to take more doses of medication than those who do not. Differences in adherence to late drops across the 3 therapeutic areas (Rheum 23%, Gastro 19%, Derm 20%) were also significant ($\chi^2 = 20.18, p < .001$), while controlling for age and gender. For patients in Group 2, 40% of their total drops were eligible for a Late SMS, compared to 25% of total drops in Group 1. Hence, patients were more likely not to drop their dose in the 24-hour period after its scheduled time without the additional reminder.

**Conclusion:** This analysis indicates that smart Late SMS reminders can have a significant impact on adherence to late doses of medication, which may otherwise be missed. Although additional factors may contribute, this smart intervention should be considered when offering adherence support to patients on injectable medication.

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**Category:** Adherence.

**POSTER #6**

**Machine learning for adverse events: PREDICT**

Presenting author: Kali Sassack
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**Background:** Adverse events during oral oncology treatment are a known driver for discontinuations and a barrier to adherence. Some patients may be at a higher risk for these adverse events, due to comorbidities and concomitant medication usage. Objective: To explore the application of machine learning within the specialty pharmacy to understand if adverse events can be identified and mitigated using a hybrid of artificial intelligence and direct clinician intervention.

**Methods:** Utilizing retrospective claims data focused on drug cohorts, risk stratification models were created to identify patients at risk of discontinuation due to adverse events within the first 90 days of treatment. Those patients identified as high risk were auto-enrolled into a targeted adverse event education program within the pharmacy. Those patients receiving intervention by an oncology-trained pharmacist were followed at 30 and 90-day intervals to assess whether the patient continued or discontinued therapy.

**Results:** In the first patient cohort, 65% of identified eligible patients received intervention by a pharmacist. Patients receiving targeted intervention showed a 15% decrease in discontinuation of therapy.

**Conclusion:** The marriage of clinical acumen with artificial intelligence provides real-world application of data and analytics to adherence management. This approach allows a targeted, clinician guided approach to side effect management and translates to improved patient adherence to therapies and potentially better overall outcomes.

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**Category:** Adherence.

**POSTER #7**

**Patient compliance with oral oncology therapies**

Presenting author: Dipti Shah

**Background:** Adherence to oral therapy is a key factor in overall outcomes. Some patients may be at a higher risk for these adverse events, due to concomitant medication usage and comorbidities. Objective: To investigate the impact of the smart Late SMS on patients receiving intervention by an oncology-trained pharmacist were followed at 30 and 90-day intervals to assess whether the patient continued or discontinued therapy.

**Results:** In the first patient cohort, 65% of identified eligible patients received intervention by a pharmacist. Patients receiving targeted intervention showed a 15% decrease in discontinuation of therapy.

**Conclusion:** The marriage of clinical acumen with artificial intelligence provides real-world application of data and analytics to adherence management. This approach allows a targeted, clinician guided approach to side effect management and translates to improved patient adherence to therapies and potentially better overall outcomes.

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**Category:** Adherence.
Background: The number of oral oncolytics being utilized to treat patients has substantially increased in the past several years. While these drugs may be more convenient for patients, the shift from intravenous (IV) to oral therapy has resulted in cancer patients having less in-person contact with nurses and fewer opportunities for treatment and symptom management education. Nurses are positioned to enhance care for cancer patients receiving oral oncolytic therapy due to their expertise in medication management, patient education, self-care management training and focus on quality of care.

Objective: This study aims to determine the impact a nurse-led compliance and persistence program has on adherence among patients on oral oncolytics.

Methods: From August 2013 to February 2022, we identified patients who initiated oral oncolytic therapy supported by a Compliance and Persistency (C&P) program. A C&P program is a nurse-led patient outreach comprised of a call cadence designed to support new patients on a treatment plan established by their oncologist. Patients in C&P programs (study group) were compared to those patients not supported by a nurse-led C&P program (control group) using pharmacy claims. Each patient was followed for 12 months. During the study period, we compared medication possession ratio (MPR), defined as the sum of the days’ supply of medication divided by the number of days between first fill and last fill exhaust date during the study. A logistic regression model examined demographic factors associated with adherence; p-values <.05 were significant.

Results: In total, 7300 patients were enrolled in the study, of which 5771 (79.1%) received therapy supported by a nurse-led program. There were significant differences in age (61.2 vs. 59.2; p < 0.01) and percent African American (12.6 vs. 13.6%; p = .02) in the study group compared to controls, respectively. Program impact results were adjusted for demographic differences between groups. After 12 months, patients in the study group reported 5.7% points higher MPR compared to those in the control group (90.9 vs. 85.2%; p < .01).

Conclusion: Our findings suggest that patients supported by a nurse-led program have better adherence to oral oncolytic therapy. The study group showed higher adherence to therapy, suggesting that the standard of care group may benefit from nurse-led outreach programs to manage their oral oncolytic therapy effectively. A multidisciplinary patient support approach contributed to improved patient outcomes, as demonstrated by a statistically significant improvement in MPR.

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Category: Adherence.

POSTER #8

Specialty PharmD intervention targeting adherence

Presenting author: Autumn Zuckerman
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Background: This study aimed to determine if a structured, patient-tailored program to address specialty medication nonadherence improves adherence compared to standard of care. Initiating and maintaining access to specialty medications is complicated by lengthy third-party coverage determinations, ongoing treatment monitoring and the required use of specialty pharmacies. Nonadherence to specialty medications can lead to increased healthcare utilization and poor health outcomes. Research is needed to better understand specialty medication adherence barriers and effective interventions.

Objective: The aim of this study was to evaluate the impact of patient-tailored complex interventions on adherence to specialty medications.

Methods: We performed a single-center, pragmatic, randomized controlled trial at an integrated health-system specialty pharmacy. Patients with the following criteria were included into a data warehouse for pharmacist review: (1) proportion of days covered (PDC) < 0.9 over the previous 4 and 12 months between 10 May 2019 and 10 August 2020, and (2) filled a specialty medication at least 4 times in the previous 12 months from select specialty clinics. Patients were excluded if their electronic health records indicated they were misidentified as nonadherent (i.e., medication filled externally, clinically appropriate treatment holds), expected to discontinue therapy within the next 8 months, had a prescription from an outside provider or were deceased. Eligible patients were randomized 1:1 to the control (i.e., standard of care) arm or intervention arm. Intervention patients were contacted for a baseline adherence assessment to determine reasons for nonadherence and subsequently receive patient-tailored interventions varying from addressing medication affordability and managing side effects to providing pillboxes and additional refill calls. Study methods were informed by focus groups with patients and specialty pharmacists. Interventions and 8 months of follow up were provided at the discretion of the intervening pharmacist. The primary outcome was PDC calculated at 8-months post-enrollment. An ordinal regression model was used to estimate the effect of interventions on 8-month post-enrollment PDC while controlling for baseline 12-month PDC, age, gender, race, insurance type, drug administration route, time on therapy, online patient portal status, and clinic type (as a surrogate for specialty conditions). Secondary outcomes were PDC calculated at 6 and 12-months post-enrollment, reasons for nonadherence, and number of pharmacist interventions. The sample size was calculated to provide 90% power to detect a difference in PDC of 5%.

Results: Of the 1300 patients reviewed, 861 were excluded, primarily for being misidentified as nonadherent (775, 90%). The remaining 439 patients were randomized. Baseline characteristics were similar between the groups, most patients being female (68%), white (82%), with a median age of 53 years (interquartile range [IQR] 40, 64). Patients were commonly from the adult rheumatology (35%) and multiple sclerosis (20%) clinics. Median baseline 12-month PDC was 0.87 (IQR 0.78, 0.90). Of the 219 patients in the intervention arm, 207 patients provided 299 reasons for nonadherence. The most common reasons were memory (40%) and being unreachable to schedule refills (29%). Pharmacists performed 355 interventions. A Wilcoxon test found a significant difference in PDC at 8-months between intervention and control patients (0.89 vs. 0.83, p = .001); additionally, there was a significant difference at 6-months and 12-months post-enrollment (0.92 vs. 0.87, p = .004; 0.85 vs. 0.78, p = .012). After controlling for other variables, patients in the intervention arm were 1.79 times more likely to have a higher PDC than control patients. Age, baseline 12-month PDC, and clinic type were also significantly associated with higher 8-month post-enrollment PDC (p = .020, p < .001 and p = .033, respectively).
Conclusion: Patient-tailored interventions to address poor adherence to specialty medications resulted in significant adherence improvement compared to standard of care. Specialty pharmacies should consider targeting nonadherent patients for adherence interventions.

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Category: Adherence.

POSTER #9
COVID-19 impact on multiple myeloma prescribing

Presenting author: Dipti Shah
CVS Health

Background: COVID-19 has impacted several areas of oncology patient care, most notably the reduction of patient visits for treatments. Standard treatment of multiple myeloma (MM) involves a combination of intravenous (IV) and oral therapies.

Objective: The purpose of this study is to assess the impact COVID-19 had on IV and oral medication prescribing patterns pre and during the COVID-19 pandemic among MM patients.

Methods: This is a retrospective review of adult MM patients insured by a large commercial and Medicare health plan in the United States who started a new IV or oral MM agent during the study period. To assess the impact of COVID-19 on IV and oral medication prescribing patterns, we compared a pre-COVID period (1 March–31 August 2019) to a COVID period (1 March–31 August 2020). We utilized medical and pharmacy claims to identify patients and calculated new therapy starts per newly diagnosed patient (defined as the number of patients starting a new IV or oral medication for MM divided by the total number of patients with a first indication date of MM within the study timeframe). We compared rates using a Chi-square test; p-values ≤.05 were considered statistically significant.

Results: 1754 patients were enrolled in the study; there were no significant differences in demographic characteristics pre and during COVID-19 between the two groups with respect to age (67.05 vs. 66.64; p = .45), gender (p = .80), insurance plan type (p = .17), geographical region (p = .26) and medication (p = .59). During COVID-19, the number of newly diagnosed MM patients decreased by 22% (9657–7560) and the total number of new therapy starts decreased by 11% (930–824). When looking at rates of new therapy starts per newly diagnosed patient, both IV (11%; p = .03) and oral (51%; p = .03) medication rates significantly increased. Additionally, there were significant increases in new therapy start rates by region in the Northeast for oral (157%; p = .08).

Conclusion: While the total count of new therapy starts, a proxy for new diagnoses, decreased during COVID-19, the rate of new starts for both IV and oral therapies for patients diagnosed with MM significantly increased. These increased start rates may be explained by a remarkable 22% drop in the total number of newly diagnosed MM patients during COVID-19. As the pandemic continues, further study is warranted to understand how COVID-19 may impact IV vs. oral usage in MM.

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Category: COVID-19 Products or Services.

POSTER #10
Impact of COVID-19 on oral oncolytic adherence

Presenting author: Kelly McAuliff
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Background: CVS Health recently developed a best-in-class mobile app and website that enables oncology patients to start and stay on therapy. While digital patient engagement is relatively new, identifying and estimating the frequency of its use and the impact of COVID-19 on adherence are critical for planning strategies to mitigate the effects of the pandemic on cancer patient outcomes.

Objective: This study examined the impact of COVID-19 on adherence to oral oncolytic agents in a large health plan with a significant digital health platform.

Methods: This retrospective cohort study included adult patients with chronic myelogenous leukemia (CML), ovarian cancer or prostate cancer initiating oral oncolytics between 3/1/19 and 3/1/2021. Patients were divided into two groups: pre-COVID oral oncolytic initiators before 3/1/20 and COVID initiators after 3/1/20 and were followed for 1 year after therapy initiation. The primary outcome was optimal adherence to oral oncolytic agents as defined by a medication possession ratio (MPR) ≥ 0.8. Percent of digital engagement, defined as the number of times a patient interacted with the CVS digital platform, was examined as a secondary endpoint and was considered as a binary and categorical endpoint (none, low (<28), moderate (28–105) and high (>105)). Descriptive statistics and logistic regression modeling were performed; p-values < .05 were considered significant.

Results: In total, 15,494 patients were included in the study, with 8,067 (52.0%) in the pre-COVID initiator group. Patient demographics were similar across study groups, with the exception of pre-COVID initiators who were less likely to be male (75.32 vs. 77.34%; p < .01) and receive copay assistance (38.37 vs. 41.70%; p < .01). No difference in digital engagement pre and during COVID was noted (74.55 vs. 73.60%; p = .18). Pre-COVID initiators were less likely to be optimally adherent than COVID initiators (84.75 vs. 85.96%; p = .04). Therapy persistence was more common among COVID initiators, with greater number of fills (Median [quartile (Q) Q1–Q3]: 10 [4–12] vs. 9[4–12]; p < .01) and less changes to therapy (8.87 vs. 9.95%; p = .02). After regression, COVID initiation of oral oncolytics was not associated with optimal adherence (odds ratio (OR) = 1.06 [95% confidence interval (CI) 0.96–1.16]). Adherence increased as digital engagement increased (low: OR 0.64 [95% CI 0.56–0.72]; moderate: OR 0.67 [95% CI 0.56–0.76]; high: OR 1.71 [95% CI 1.48–1.99]). Other
High engagement has been shown to improve employee satisfaction. A trend identified through an annual health system employee engagement survey was lack of career growth for specialty pharmacy technicians (SPTs). This gap complemented the growing volume and diversity of patients managed by the health system specialty pharmacy (HSSP) requiring SPTs with specialized skills. Our approach to increase satisfaction and compliance to complicated therapies.

Background: High engagement has been shown to improve employee satisfaction. A trend identified through an annual health system employee engagement survey was lack of career growth for specialty pharmacy technicians (SPTs). This gap complemented the growing volume and diversity of patients managed by the health system specialty pharmacy (HSSP) requiring SPTs with specialized skills. Our approach to increase satisfaction while meeting the expanding demand was to implement a career ladder and create new opportunities. Additionally, persistence and number of fills were slightly improved in COVID initiators, suggesting that the current pandemic may have influenced adherence behaviors.

Methods: New roles were introduced to support operations and infrastructure, including medication assistance (MAP), financial clearance (PA), billing (Med B), customer service, staff educator, regulatory, purchasing, and leadership. New non-SPT roles (shipping) were created for entry-level candidates.

SPT career ladder allowed for promotion within certain roles. Advancement as a SPT required competency in current role and regulatory, purchasing, and leadership. New non-SPT roles (shipping) were created for entry-level candidates.

SPT career ladder allowed for promotion within certain roles. Advancement as a SPT required competency in current role and personal growth projects to demonstrate leadership and expertise. Similar career ladders were created for Med B and MAP.

Evaluation of the career ladder spanned from implementation in November 2019–June 2022. The number of employees who transitioned/advanced into new roles were collected. Employee engagement scores were collected in 2020 and 2021 for comparison.

Results: The following specialty positions have been created since 2019: Technician Supervisor, Customer Service Analyst, MAP Supervisor, Education Coordinator, PA Specialist, business implementation liaison, Safety/regulatory liaison, Shipping Associate, Purchasing/Inventory Specialist, and Ambulatory care technician. These roles total 29 new positions to support specialty pharmacy growth.

Since implementation, 30 SPTs have advanced from SPT I to II, and two were promoted to III status. One shipping associate advanced to SPT I. Employee satisfaction scores increased from 68 to 83 in 2020 and 2021, respectively.

Conclusion: Expanding opportunities for pharmacy technicians can improve employee engagement while supporting specialty pharmacy growth.

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Category: Delivery of Specialty Pharmacy Products or Services.

POSTER #12

Specialty pharmacy enhances the patient experience

Presenting author: Douglas Braun
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Background: How a specialty pharmacy creates an environment where providing the highest level of care and service to our patients maximizes their experience, and improves adherence and compliance to complicated therapies.

Objective: To educate the audience on how a specialty pharmacy is designed to improve the patient experience with high financial and clinical toxicity management.

Methods: Data collected includes: Turnaround time; Time to PAP approval; Adherence % (MPR); Patient satisfaction.

Results: Turnaround time <3 days; Time to PAP approval <1.5 days; Time to PAP approval 3 days; Adherence >95%; Satisfaction >95%.

Conclusion: Specialty pharmacies are in the best position to maximize care while minimizing the time to get on therapy.

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Category: Delivery of Specialty Pharmacy Products or Services.

POSTER #13

Biosimilar benefit use, adoption, and conversions

Presenting author: Richard Brook
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Background: How a specialty pharmacy creates an environment where providing the highest level of care and service to our patients maximizes their experience, and improves adherence and compliance to complicated therapies.

Objective: To educate the audience on how a specialty pharmacy is designed to improve the patient experience with high financial and clinical toxicity management.

Methods: Data collected includes: Turnaround time; Time to PAP approval; Adherence % (MPR); Patient satisfaction.

Results: Turnaround time <3 days; Time to PAP approval <1.5 days; Time to PAP approval 3 days; Adherence >95%; Satisfaction >95%.

Conclusion: Specialty pharmacies are in the best position to maximize care while minimizing the time to get on therapy.

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Category: Delivery of Specialty Pharmacy Products or Services.
**Background:** Biosimilars may control costs and increase access to biologic specialty-drugs. Despite receiving FDA approval, some biosimilars are still not available in the United States. FDA Marketed US biosimilars include: infliximab, filgrastim, pegfilgrastim, bevacizumab, trastuzumab, rituximab, and epoetin alfa.

**Objective:** Use objective data to examine the growth of specialty-drugs, biosimilar use, and coverage benefits.

**Methods:** Retrospective analysis of the Workpartners Research Reference Database representing 3.6 million employees and 5.6 million total lives from multiple US private sector employers in the retail, service, manufacturing, transportation, energy, technology, financial, and utility industries. Data in the RRDb come from multiple US commercial insurance plans. Annual claims and dollars for specialty-agents were classified as innovator (reference) agents or biosimilars and benefit used (prescription or medical). Members who received a prescription for the innovator or biosimilar in the period following availability of the biosimilar were evaluated. The most recent product dispensed was compared with the initial product dispensed for the member.

**Results:** Overall, 49.3% of filgrastim, 75.5% of rituximab, and 81.1% of infliximab patients had their initial and most recent prescription filled for the innovator product. Furthermore, in 2021, patient starts for innovator products demonstrate significant erosion, with only 22.4% starts for filgrastim, 61.2% for infliximab, and 48.8% for rituximab. 2021 costs were substantially lower for generics as compared to the innovator product. Patients dispensed filgrastim-sndz and filgrastim-aafi paid 56.4 and 28.8% of innovator cost respectively and claims under the medical benefit were 83.8% for filgrastim, 86.5% for filgrastim-sndz and 65.2% for filgrastim-aafi. In 2021 patients dispensed a biosimilar for infliximab paid between 49.6 and 58.6% of the innovator cost, and those dispensed a biosimilar for rituximab paid 49.1–75.1% of innovator costs. The medical benefit was used for >98.5% of rituximab claims and about 92.5% of infliximab claims.

**Conclusion:** Health plans have recognized the value/savings and increased the use of biosimilars. Adoption of biosimilars is increasing and price for the biosimilars erodes as more options become available.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

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**POSTER #14**

**Meaningful patient outcomes for achondroplasia**

**Presenting author:** Jay Bryant-Wimp  
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Frontier Therapies Pharmacy

**Background:** After reviewing the clinical trial results for Achondroplasia treatment, vosoritide, the primary outcome measurement was growth velocity. The Federal Drug Administration (FDA) approved the medication based on the data provided, which informed stakeholders about the effectiveness of the drug, but not necessarily an endpoint that the community of patients nor all prescribers considered the primary concern. Although there are on-going clinical trials, to date there has not been data released on correlation between treatment and decreased surgical interventions for life-threatening complications of Achondroplasia. Thus, our team determined there is an opportunity to work with those impacted most by Achondroplasia, the patients and caregivers, as well as prescribers, to capture data prior to the release of additional clinical trials.

**Objective:** Our objectives of this case study were three-fold. First, review the gap between clinical trials data for drug approval and real-world outcomes patients, caregivers and prescribers desire. Second, design a novel approach to soliciting meaningful outcomes from key stakeholders that impact patient care planning and decision making. Third, collect the most meaningful patient outcomes post-launch for first-in-class therapy for Achondroplasia.

**Methods:** Using a simple randomization method, 10% of the prescribers from the pivotal phase 3 clinical trial, Once-daily, subcutaneous voosoitide therapy in children with achondroplasia: a randomised, double-blind, phase 3, placebo-controlled, multicentre trial, were selected to be interviewed. Additionally, patient advocacy groups were screened by using the National Center for Advancing Translational Sciences approved advocacy groups and Little People of America fit the criteria. The key question, “what outcome is most important to collect for patients considering treatment for Achondroplasia,” was chosen for the key stakeholders. Our team conducted interviews with the groups listed below: Key Opinion Leader (KOL) interviews: Geneticist, pediatricians and an orthopedic surgeon; Patient support group/biotech council interviews: Little People of America Biotech Committee

**Results:** Our team captured the following outcomes that could be collected: prevalence of sleep apnea, number of ear infections, surgeries related to Achondroplasia, pain scale, PHQ2, PHQ9 depression scales and growth velocity. All outcomes, except for the depression scales, were important to all stakeholders.

**Conclusion:** By partnering and collaborating with the real experts — patients, caregivers and KOL prescribers — Optum Frontier Therapies created a patient-first outcomes model. We continue to conduct extensive research with patient advocacy groups, payers, prescribers and manufacturers to continue to inform our approach. Our team will continue to aspire to include the voice of the patient and strive to never forget their mantra “nothing about me, without me.” The data that we are collecting now will help patients, their families, and prescribers make decisions regarding treatment. We look forward to presenting our data within the next 12 months.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

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**POSTER #15**

**Leveraging technology for specialty refills**

**Presenting author:** Danielle Burkhart  
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aHospital of the University of Pennsylvania; bUniversity of Pennsylvania; cPenn Presbyterian Medical Center; dPenn Medicine; ePennsylvania Hospital
Background: In 2020, the Penn Medicine Specialty Pharmacy Refill program grew 85% over the previous 24 months with approximately 7000 specialty refills per month, but faced challenges meeting the growth demands due to a high number of technician vacancies. The specialty refill coordination was primarily conducted telephonically with outbound calls from technicians to patients. This process had inherent delays in reaching patients and the majority of outreach required two separate attempts, spanning over three business days, to reach patients and coordinate refills. Lastly, the information gathered during the telephone exchange expanded beyond refill coordination in order to meet accreditation requirements, such as medication adherence assessment and triaging clinical questions or concerns related to possible adverse drug effects or goals of therapy. This additional information collected increased communication time with each patient and led to extensive manual documentation of each encounter in electronic health record (EHR) by the technician.

Objective: Our team wanted to improve upon our current Specialty Pharmacy Refill model to enhance efficiency of the refill process, minimize administrative burden for the technician role, and continue to provide an excellent patient experience. We wanted to learn if leveraging texting functionality for specialty refills would positively impact our program, staff, and patients.

Methods: Program impact was measured through percentage of successful completions defined as check-ins that did not require telephonic intervention from staff. Patient impact was measured through Net Promotor Score (NPS) surveys sent to patients. Rolling NPS surveys were implemented in November 2021 via the texting platform to any patient that completed at least three refills. The system continues to send NPS surveys to any patient that meets this criteria, with plans to survey each patient annually. The data analytics for program and patient impact were collected through the texting data analytics dashboard and aggregated into real-time data. The staff impact was collected through a time analysis study conducted in February 2021 with 670 patient enrolled in the texting program. Objective of the study was to define texting process versus non-texting process time spent during each workflow step.

Results: In May 2020, we partnered with Penn Innovations Way to Health (W2H) team to design a texting platform for the Specialty Refill program that was easy-to-use, seamlessly integrated with pharmacy systems and workflows, and addressed all regulatory needs. The chatbot functionality was scripted and pre-programmed based on the parameters specified by pharmacy team. The program was able to integrate with EHR system and allow for information collected during texting to be auto-populated in a designated EHR refill note compared to the manual input of this information by technicians during telephone outreach. The initial pilot launched July 2020 at 1 Penn pharmacy location, 1 service line, 4 specialty medications, and 42 patients enrolled. Currently, the Specialty Pharmacy texting program has expanded to 7 Penn pharmacies, 8 service lines, 189 medications, and 3593 patients enrolled. Program impact is continuously assessed through our analytics dashboard and the percentage of successful completions remains high at 80%, with minority of patients requesting to speak with pharmacy staff or not responding within 48-hour timeframe. Staff impact analysis of 25 non-W2H and 25 W2H refill patients showed average total time spent for each patient was approximately 7 minutes for non-W2H and 3.5 minutes for W2H, with less time spent communicating with the patient and documenting in the EHR for W2H process. The majority of patients were reached on Day 1 with W2H compared to Day 3 for non-W2H. The NPS surveys were utilized to determine patient satisfaction. To date, 1352 survey responses obtained with overall pharmacy program NPS of 91, NPS for W2H texting program of 85.

Conclusion: The successful implementation of the W2H texting platform to our Penn Medicine Specialty Pharmacy Refill program has positively impacted program, staff, and patient outcomes. Over the past 2 years, the W2H texting platform has been widely expanded to many Penn pharmacies, service lines, and specialty medications. The W2H texting platform has increased program capacity through shortened time to reach patients by 2 days and 50% reduction in time spent for the W2H process. The W2H process reduced administrative burden on pharmacy technicians through decreased number of patient outreach and the W2H auto-populated EHR notes. Lastly, our promoter NPS score for the texting program demonstrates a high level of patient satisfaction with the service while also being consistent with the NPS score for the overall pharmacy program.

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Category: Delivery of Specialty Pharmacy Products or Services.

POSTER #16
Best practices for improving program performance

Presenting author: Kevin Cast
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Archbow Consulting

Background: In the specialty pharmaceutical space, there may not be a relationship more important that that between the manufacturer and their specialty pharmacy network. Through a carefully crafted approach, manufacturers and SPs can build mutually beneficial relationships that not only drive program success but also ultimately benefit patients through improved access and adherence. In this presentation, we’ll share best practices, lessons learned, and real-world insights gained from assisting multiple manufacturers repair their relationships with their SP partners in order to successfully rescue underperforming programs.

Objective: Attendees of this presentation can expect to learn:

- How much time to allow when building and/or repairing Manufacturer/SP relationships
- How to create a viable, mutually beneficial Manufacturer/SP contract
- Best practices for establishing KPIs that drive program performance
- How proactive planning can limit change orders and other potential areas of conflict
- Practical do’s and don’ts for program communication and QBRs
- When and why to encourage proactive solutions from SP account management teams
- Why it’s important to separate personal relationships from professional deliverables
- How one manufacturer successfully improved vendor relationships across their SP network through a series of organized, well-orchestrated tactics (real-world case study)
**Methods:** No trials or research are affiliated with this presentation.

**Results:** No trials or research are affiliated with this presentation.

**Conclusion:** No trials or research are affiliated with this presentation.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

**POSTER #17**

**AI chatbot provides efficiency and convenience**

Presenting author: Robin Coulter
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UPMC Enterprises

**Background:** UPMC Enterprises, in collaboration with UPMC Community Provider Services’ Retail Pharmacy Network, conducted a pilot program utilizing an AI-driven chatbot to provide automated follow-up clinical screenings to patients receiving certain specialty medications from TJC-accredited, health-system owned retail pharmacies. In order to meet accreditation and payer requirements, the retail pharmacies were responsible for providing regular patient outreach to patients on Hepatitis C treatment and post-transplant immunosuppressants. The follow-up assessments, prior to the pilot, were completed telephonically by pharmacy staff members. The patients receiving the qualifying medications were tracked, manually, on a spreadsheet and/or paper calendar.

**Objective:** The goal of the study was to show how the use of chatbot technology could offload manual phone calls from retail pharmacy staff for specialty patients.

**Methods:** By integrating with the pharmacy dispensing software, fills for a list of Hepatitis C and transplant GCNs were queried daily. Based on the sold date of the specified medications from participating pharmacies, tickets were automatically created in the Pharmacy CRM (customer relationship management) system and set to be due every 7 days after the sold date. When tickets were due, SMS messages were automatically sent to patients and prompted them to answer specific questions about side effects and medication adherence. The patient responses were logged, and, based on the patient data, the tickets would behave in various ways. If the patients were experiencing side effects, the tickets would change to “Pharmacist Requested” and a manual outreach call would be prompted. If the patients were not experiencing side effects, no call was warranted. If the patients responded that their dosing regimen had changed, the tickets would change to “Pharmacist Requested” and a manual outreach call would be prompted. If the patients’ regimen had not changed, no call was warranted. The patients were also prompted to self-report the number of doses they had on hand. If a patient reported less than a 10 days’ supply, then the tickets would change to “Refill Requested” and a manual outreach call would be prompted. If the patients reported greater than 10 days’ supply, no call was warranted.

**Results:** For the Hepatitis C population, 191 dialogs were started, patients responded to 76 dialogs, and completed 66. 18 patients identified side effects while 58 identified having no side effects. 67 patients self reported doses on hand.

For the Transplant population, 823 dialogs were started, patients responded to 356 dialogs, and completed 218. 22 patients identified side effects while 333 identified having no side effects. 49 patients said they did experience a regimen change. 2357 said they did not experience a regimen change. 217 patients self reported doses on hand.

**Conclusion:** By integrating with the dispensing software and deploying the AI-driven chatbot, UPMC retail pharmacies dispensing specialty medications for Hepatitis C and transplant were able to offload roughly 300 manual phone calls from pharmacy staff over a four month period of time and automatically track patient reported data. Clinical efforts could be reserved for those patients who specifically identified experience side effects, had a regimen change, or were nearing the end of their medication supply.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

**POSTER #18**

**Harnessing the EHR to improve workflow & reporting**

Presenting author: Cori Edmonds
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Vanderbilt Specialty Pharmacy

**Background:** Multi-user availability and immediate accessibility features of electronic health record (EHR) entries have been positive patient care benefits for those practicing in health system specialty pharmacy settings. Both medical and pharmacy providers can easily and quickly communicate, staying up to date in real-time, to see and monitor patient specialty medications from the approval process through ongoing follow-up. However, gathering and managing clinical data for outcomes reporting and patient management in a health-system often requires the use of multiple systems and is easily susceptible to being outdated by the time it is prepared and presented. Additionally, workflow associated with gathering this data is time intensive, often involving duplicative documentation and post-hoc chart review for pharmacy staff; which can negatively impact employee morale and increase the risk of burn-out of even the most highly motivated and performing pharmacy team members.

**Objective:** We sought to streamline specialty pharmacy documentation by harnessing untapped EHR functionality by the pharmacy department to gain real-time data reporting, save staff time and improve staff morale.

**Methods:** We conducted a quality improvement project in the Vanderbilt Specialty Pharmacy Hepatitis C (Hep-C) Clinic where current workflow was assessed for clinical content and duplicative documentation practices. A new workflow was designed to incorporate the use of the EHR SmartForm tool for collecting discrete data during routine specialty pharmacist patient care documentation. A dashboard was then created to aggregate, tabulate and graph data collected using the EHR tool to enable the specialty pharmacist to monitor patients based on clinical characteristics and access near real-time data for reporting.

**Results:** Prior to implementing the new workflow, pharmacists would enter patient care notes as narrative-based communications in the EHR and then re-enter it as discrete data for reporting into a separate HIPPA approved database. Implementing SmartForm tool documentation within the EHR has resulted in
the discontinuation of gathering discrete data in a separate database for reporting, decreased duplicative documentation, and decreased need for post-hoc chart review and report preparation. Additionally, the SmartForm documentation is viewable similarly to medical provider documentation, thus visibility of specialty pharmacy clinical documentation within the EHR was improved. The dashboard powered by the data collected in the EHR now provides operational and clinical support to pharmacists in the Hep-C clinic while eliminating the time spent on report creation by this team and is available in near real-time (weekly).

**Conclusion:** Implementing the EHR SmartForm tool for patient care documentation in the specialty pharmacy Hep-C clinic was effective in streamlining workflow, decreasing duplicate documentation, simplifying and eliminating reporting delays while improving team morale by allowing members more time to focus on clinical tasks.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

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**POSTER #20**

**Specialty pharmacy continuity optimization**

Presenting author: Vinay Sawant
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**Atrium Health Wake Forest Baptist**

**Background:** Specialty clinical continuity, whereby clinical care and specialty drug fulfillment is provided in an unfragmented manner, can improve access to therapy and improve adherence. Optimization of clinical continuity has been established as a key goal for Yale New Haven Health (YNHH). One proxy for specialty clinical continuity is the percent of written specialty drug orders retained within the health system (also known as prescription capture). Variation in clinical continuity across YNHH’s approximately 800 clinics results in fractured prescription fulfillment and clinical pharmacy services. As such, establishment of a team at the YNHH specialty pharmacy, Outpatient Pharmacy Services (OPS), to promote specialty clinical continuity and support clinics is key to patient care.

**Objective:** To develop, implement, and evaluate a multidisciplinary outreach team based out of the OPS specialty group.

**Methods:** In early 2021 clinics were evaluated and were prioritized for outreach if capture rate was below 90 percent for prescribed specialty medications. The clinical continuity team, comprising a nurse, pharmacists, and technician, engaged key stakeholders within these clinics. Tailored materials were developed to describe the benefits of OPS towards supporting specialty drug clinical continuity to improve the patient’s overall treatment experience and reduce barriers to care. In addition, an electronic health record Best Practice Advisory (BPA) offering was developed to reinforce the opportunity for utilization of OPS. The primary outcome of this initiative was improvement in specialty prescription capture from targeted clinics compared with baseline. Barriers to clinical continuity were also assessed.

**Results:** We initially identified 343 clinics with a continuity rate of less than 90 percent, and upon further refinement of the list based on potential specialty prescription opportunity the initial targeted list was reduced to 118 clinics. Outreach to 66 clinics were conducted in which clinical continuity opportunities were presented and activation of the BPA was offered. Twenty-seven clinics opted for the BPA. Overall, clinical continuity team outreach and BPA usage resulted in a 31% increase in capture rate over one year. Barriers to clinical continuity include slow adoption of prescribing pattern changes, insurance lockout, and patient preference.

**Conclusion:** Implementation of a clinic outreach team to promote and support targeted clinics, resulted in an increase in clinical continuity.

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**Category:** Delivery of Specialty Pharmacy Products or Services.
Specialty technician training program development

Presenting author: Vinay Sawant
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Abstract:

Background: The COVID-19 pandemic worsened a nationwide technician shortage with negative impacts on pharmacy workflow and patient care. Barriers to entering the pharmacy field as a technician included lack of years of experience and training, specifically in specialty pharmacy technician (SPT) roles that require one year of experience and advanced certification. With our growing business, the ability to hire SPT’s has been a challenge. Currently, Yale New Haven Health (YNHH) offers an ASHP/ACPE accredited Pharmacy Technician Training Program that prepares individuals for a pharmacy career in all practice settings, the Pharmacy Technician Certification Board (PTCB) exam, as well as the opportunity for practical experience in multiple practice settings and areas, including specialty pharmacy. The twenty-three week long program (we have removed the PTCB requirement to align with the changes in job description across the system that requires PTCB within 1 year of hire) is equivalent to one year of pharmacy experience. The YNHH health system specialty pharmacy (HSSP) collaborated with the YNHH Pharmacy Technician Training Program to create a specialty pharmacy focused track.

Objective: To increase the HSSP SPT candidate pool through the creation of a HSSP focused pharmacy technician training program rotation tract.

Methods: Rotation objectives were created to ensure compliance with American Society of Health-System Pharmacists (ASHP) accreditation standards, in addition to training objective that include exposure to all technician based positions within the specialty pharmacy realm. The traditional nine-week experiential rotation tract was adapted to allow seven weeks of specialty pharmacy focused rotations. Enrollment into the specialty pharmacy focused track was limited to one student per cohort for the first three rotation cycles. The number of students who completed the rotation and were retained as HSSP SPT’s was tracked. Specialty technician content experts within the HSSP were identified to serve as program preceptors. Specialty Pharmacy Supervisors also serve as rotation site coordinators for this tract.

Results: The development of the specialty pharmacy focused track of the YNHH Pharmacy Technician Training Program took five months. The specialty pharmacy focused track was first available to students on 28 March, 2022. Of the two students that entered the program, both students have completed the program and are being retained as SPT’s.

Conclusion: A specialty focused pharmacy technician training program can be a novel strategy to address HSSP pharmacy technician staffing shortage.

Category: Delivery of Specialty Pharmacy Products or Services.
Conclusion: An interdisciplinary nutrition referral program for oral chemotherapy patients can empower HSSPs to identify and refer SDoH issues for specialty patients.

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Category: Delivery of Specialty Pharmacy Products or Services.

POSTER #25

Appeal approval rating of specialty pharmacists

Presenting author: Alexis Mod Full author: Alexis Moda, Emily Achesona, Karen Houserb, Lisa Kenneya, Svetlana Lyamkinab and Allene Naplesb

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Background: University Hospitals Specialty Pharmacy (UHSP) is an integrated specialty pharmacy model and employs both centralized and decentralized clinical pharmacists. After prior authorization (PA) denial, these clinical pharmacists with subject matter expertise complete an appeal letter to the insurance company with the goal of obtaining medication authorization. Currently, no data exist to show the impact of a pharmacist-lead appeal initiative within a health-system specialty pharmacy.

Objective: This study aimed to determine the appeal approval rating of UHSP clinical pharmacists and the direct impact on medication access and patient outcomes.

Methods: This study was an IRB-approved retrospective chart review from January 1st to December 31st, 2021. Monthly reports for completed tasks related to appeals or letters of medical necessity were collected. Exclusion criteria included duplicate tasks referencing the same appeal, PA resubmissions, appeals submitted by other health-care providers, inability to obtain patient consent and appeals canceled by the third party payer. The primary endpoint evaluated overall appeal approval rating. Secondary endpoints included evaluation of common PA denial reasons, median time in business days from PA denial to appeal approval, and the overall impact on medication access and patient outcomes.

Results: A total of 423 appeals were included. The overall appeal approval rate was 70.7% (n = 299), with a majority approved after 1st level appeal (n = 286, 67.6%). The most common PA denial reasons included non-preferred/non-formulary drug (n = 106, 25%) and off-label use (n = 77, 18%). The median time from PA denial to appeal approval was 8.5 days (interquartile range: 4–15 days). Overall, 92% of included patients obtained access to a new medication through their insurance or other sources.

Conclusion: In 2021, the vast majority of appeals written by UHSP clinical pharmacists were approved with quick turn-around time from denial to approval, resulting in high medication access rates and allowing patients to proceed with important disease directed therapy.

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Category: Delivery of Specialty Pharmacy Products or Services.


POSTER #26

Group purchasing organization 505(b)(2) case study

Presenting author: Stacey Ness Full author: Stacey Ness, Brandon Wilkins and Jack Donahue Managed Health Care Associates (MHA)

Background: In 2019, the United States healthcare system saved an estimated $313 billion from generics and biosimilar drugs. However, the adoption of specialty generics has been slower, in part because specialty generics are more difficult to develop, obtain approval for, and manufacture. One pathway that manufacturers of specialty generics can use to streamline the approval process is the 505(b)(2) new drug application. This pathway allows some of the information required for approval of the specialty generic to come from studies that have already been conducted on the reference product, resulting in a less costly and faster route to approval. Given that specialty generics have faced obstacles in uptake, this nationwide home infusion and specialty pharmacy (SP) group purchasing organization (GPO) offered a pharmaceutical manufacturer agreement for participating pharmacies to access competitive 505(b)(2) product pricing along with clinical education and support.

Objective: The purpose of this case study is to understand changes in purchasing patterns by analyzing purchasing data from participating home infusion and specialty pharmacies for a 505(b)(2) product to treat osteoporosis before and after it was added to this home infusion and SP GPO contract portfolio and to compare its market share to the non-contracted reference product.

Methods: A retrospective analysis of purchasing data from this home infusion and SP GPO was conducted to determine sales growth for the 505(b)(2) product. The baseline for the pre-contracted measurement was average units from July 2020 through November 2020 and sales growth was analyzed quarterly in the post-contracting period from Q1 2021 through Q1 2022 and compared to baseline. Market share from November 2020 through March 2022 of the 505(b)(2) product compared to the reference product was also calculated.

Results: Compared to baseline, contracted 505(b)(2) product purchases grew 68% in Q1 2021, 134% in Q2 2021, 294% in Q3 2021, 335% in Q4 2021, and 307% in Q1 2022. Market share for the 505(b)(2) product as compared to the reference product stood at 0.05% in November 2020 and grew after contract initiation to 14.03% in March 2022.

Conclusion: Although unable to control for confounding factors, this case study suggests that pharmaceutical manufacturer agreements designed for participating pharmacies to access competitive 505(b)(2) product pricing along with clinical education and support through this home infusion and SP GPO could be one way to help drive adoption.

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Category: Delivery of Specialty Pharmacy Products or Services.
Background: Specialty disease modifying anti-rheumatic drugs (DMARDs) used to treat rheumatologic conditions result in immunosuppression. The American College of Rheumatology and the European League Against Rheumatism recommend vaccination in patients initiating specialty DMARDs to prevent infections, including influenza, pneumonia, and herpes zoster. At an integrated health-system specialty pharmacy, clinical rheumatology pharmacists identified an opportunity to improve vaccine screening during the pre-treatment counseling process. Prior to screening protocol implementation, specialty pharmacists provided general vaccine counseling to all patients initiating specialty DMARD therapy and documented counseling completion in the electronic health record (EHR) with no standard format.

Objective: This quality improvement project aimed to standardize and expand the vaccine screening process in patients initiating specialty DMARDs at an outpatient rheumatology clinic.

Methods: A specialty resident pharmacist developed a vaccine screening protocol for patients initiating new specialty DMARDs at an outpatient rheumatology clinic serviced by a health-system specialty pharmacy. Screening was completed in clinic by specialty pharmacists and individualized vaccination recommendations were provided during each new drug counseling. Patient vaccine eligibility criteria from package inserts and guideline recommendations were summarized and provided to pharmacists as a counseling reference. An EHR form was created and embedded in standardized counseling notes for specialty pharmacists to document specific vaccine recommendations. Mixed methods were used to assess the impact of implementing the standardized vaccine screening tool from 9/1/2021 through 10/19/2021. The primary outcome was the percentage of eligible patients with documented vaccination screening under the new protocol. Eligible patients prescribed a new specialty DMARD were identified through the specialty pharmacy management system, Atlas, and patients who received vaccine screening were identified by completion of the screening form in Epic. Secondary outcomes included the number and type of vaccines recommended and efficiency of the vaccine screening protocol as reported by specialty pharmacists. Specialty pharmacists provided feedback through surveys completed before and after vaccine screening protocol implementation and rated screening efficiency on a scale of 0 (not efficient) to 10 (highly efficient).

Results: During the evaluation period, 108 patients initiated specialty DMARDs and were identified for vaccine screening. Of those, 76 patients (71.7%) had a vaccine screening form completed in Epic within the initial counseling note. Specific vaccine recommendations were provided to 72 patients (94.7%) during initial counseling. Recommended vaccines included influenza ($n = 59; 49\%$), zoster ($n = 33; 28\%$), and pneumonia ($n = 28; 23\%$). In the pre-implementation survey, specialty pharmacists rated the existing vaccine screening process efficiency as a 4.2 out of 10. In the post-implementation survey, specialty pharmacists rated the new vaccine screening process efficiency as an 8 out of 10.

Conclusion: Implementation of a vaccine screening protocol led to successful screening in most eligible patients and encouraged specialty pharmacists to provide patient-specific vaccine recommendations. The new screening protocol created a more efficient vaccine screening process. Future directions include implementing the screening protocol in other clinics that use specialty DMARDs, creating vaccine handouts for patients, adding COVID-19 vaccines into the screening form, and following up with patients to verify vaccine receipt.

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Category: Delivery of Specialty Pharmacy Products or Services.
Data & analytics reduces medication delivery delay

Presenting author: Sebastian Pistritto  
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ParcelShield

Background: Specialty Pharmacies’ ability to predict patient medication delivery obstacles before shipping and prevent package delays is critical to supporting patients’ needs for on-time medication delivery, reducing operational costs, improving patient engagement and adhering to specialty pharmacy compliance. Unexpected weather events, compromised carrier routes, inconsistent service level delivery and carrier-specific logistical challenges contribute to the increasing U.S. carrier industry’s resend rate.

One large specialty pharmacy spends millions of dollars each year for carrier-related resends of medications. Shipping an average of 40,000 packages per month with a resend value per package of $6000, this pharmacy’s resend costs on average totaled over $6M per year. They partnered with ParcelShield to help reduce the number of reships, resends and overall product revenue losses.

Objective: The objectives were to

- identify disruptions, delays and inconsistencies across the parcel delivery journey,
- find ways to optimize supply chain efficiencies and route parameters against proactive disruption models and daily back-end fulfillment capacity, and then
- recommend the optimal date and carrier service level to maximize successful delivery times and minimize medication and fulfillment costs.

Methods: Using artificial intelligence, machine learning, and predictive analytics, we deconstructed years of data analytics and delivery patterns across multiple carriers, predicted areas of distress so the specialty pharmacy could avoid distress zones and hold or reroute packages, prevented or solved expensive medication losses and recoveries, and proactively kept patients informed of package delays.

Results: In five months, the pharmacy decreased its resend rate by 36.5%. In the process, three secondary benefits also were uncovered:

1. Increased overall profitability by avoiding $2.4M in product loss.
2. Overall improvement in shipping efficacy with improved planning across multiple origin sites
3. Improved patient satisfaction and Net Promoter Score

Conclusion: Use parcel tracking technology with predictive analytics to gain visibility into carrier schedules, real-time parcel tracking across the delivery journey, analytics to manage risks, and insights to ensure packages arrive on time regardless of the weather or carrier logistical delivery conditions.

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Specialty pharmacy call center metric optimization

Presenting author: Vinay Sawant
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\(^a\)Yale New Haven Health; \(^b\)Yale New Haven Health System

Background: Specialty pharmacy call centers are required to meet specific thresholds for speed of answer and abandonment rate to maintain accreditation. Historically at Outpatient Pharmacy Services at Yale-New Haven Health (OPS), incoming calls were triaged to a pool of specialty pharmacy staff who were also assigned other tasks including performing refill outreach. Due to staffing disruptions related to the COVID-19 pandemic, our health system specialty pharmacy call center metrics were highly variable. We evaluated various staffing solutions and, based on ease of implementation with current staffing levels and employee feedback, undertook a dedicated staffing model whereby pharmacy staff was assigned to two teams dedicated to managing inbound or outbound calls.

Objective: To improve pharmacy call center metrics by implementing a dedicated staffing model for managing inbound and outbound calls

Methods: We employed a Plan-Do-Study-Act (PDSA) approach to implement a staffing model with dedicated teams for triaging inbound and outbound calls. The initial pilot phase was for 5 days in December 2021, with subsequent PDSA cycles of one month. The Erlang calculator was utilized to determine the number of staff members assigned to the teams based on anticipated inbound call volume and the number of patients due for refill coordination. A combination of specialty pharmacy liaisons and pharmacists was utilized for the inbound team.

Assessment: On a daily basis, we reviewed the total calls presented and handled, the number of abandoned calls, and the percentage of calls abandoned. These metrics were also reviewed monthly at the end of each PDSA cycle, along with the results of a monthly staff satisfaction survey. Adjustments were made to the staffing model at the end of every PDSA cycle based on performance metrics and staff satisfaction.

Results: During the pilot phase, the call center’s average speed of answer and abandonment rate was 19.75 seconds and 1.75%, respectively. The average speed of answer for all PDSA cycles ranged from 25 to 26 seconds, and the abandonment rate ranged from 1.91 through 2.02%. Employee survey results from May 2022 were largely positive. As the COVID-19 pandemic progresses, the new model allows us to weather staffing variations while addressing accreditation standards.

Conclusion: Implementation of separate inbound and outbound teams increased operational efficiency, with increased employee engagement within health system specialty pharmacy

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POSTER #31

Compassionate care in a specialty pharmacy

Presenting author: Vinay Sawant
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\textsuperscript{a}Yale New Haven Health; \textsuperscript{b}Yale New Haven Health System

**Background:** Outpatient Pharmacy Services (OPS), a specialty pharmacy, at Yale New Haven Health provides disease management for more than 40 disease states. Specialty pharmacists and liaisons providing care to patients in various stages of chronic progressive diseases often interact with patients who have poor prognoses or are at the end-of-life. There is variation in staffs’ expertise in counseling these patients and providing compassionate care. Compassionate care is to suffer with deep awareness of someone else’s suffering and the wish to relieve it.

**Objective:** To evaluate OPS staffs’ knowledge and explore perceptions on providing compassionate care. Results will guide the development of an educational program.

**Methods:** We created an anonymous 14-item electronic compassionate care survey composed of 3 knowledge, 8 perception, and 3 demographic items using best evidence and content expert feedback. The survey link/QR codes were disseminated via email and in-person to OPS staff.

**Results:** Forty-nine staff completed the survey (26 pharmacists, 23 liaisons) yielding a 32% response rate. The percentage of participants who were able to correctly define: empathy 57%; compassion 6%; and 5 elements of active listening 10%. With regard to the perception items, 53% reported being confident/very confident communicating with patients having a poor prognosis. Most (82%) of respondents experienced sadness/grief after a patient died. Of the respondents, 68% perceived gaps in education for their role in relation to compassion, therapeutic communication, active listening, and personal coping skills.

**Conclusion:** Despite the fact that only 6% of respondents were able to define compassion, 71% of respondents found it not difficult to demonstrate compassion when communicating with patients with a poor prognosis. The survey results showed knowledge gaps in compassion, empathy, and active listening. As well as gaps in staff’s education for their role in relation to compassion, therapeutic communication, active listening and coping. The survey indicated that formal training was necessary to address these gaps and align their knowledge and perceptions on compassionate care.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

POSTER #32

Specialty pharmacist led nursing education series

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\textsuperscript{a}Yale New Haven Health; \textsuperscript{b}Yale New Haven Hospital-Smilow Cancer Hospital

**Background:** Outpatient Pharmacy Services (OPS) is a specialty pharmacy at Yale New Haven Health which includes a health system cancer center. The tremendous growth in targeted oral oncolytic agents has presented unique challenges in education and training. Upon identifying an educational gap on new oral oncology medications among oncology nurses an educational series was created.

**Objective:** To create, implement, and evaluate a pilot education series for the outpatient oncology practice nurses on oral oncology medications.

**Methods:** A multidisciplinary team, consisting of specialty pharmacists and a nurse manager from a health system cancer center convened, discussed and charted expectations for the educational series. A lead specialty pharmacist coordinated the educational series by developing a tentative list of oncology topics and recruited pharmacy residents and specialty pharmacists as potential speakers. Attendance of participants was taken with each session, which included pharmacists. At 10 months, an electronic survey was developed to assess both nurse and pharmacist satisfaction with the series, the likelihood of using the information in practice, and future topic opportunities.

**Results:** The initial education session was given on August 2021 and subsequent education sessions were carried out monthly to May 2022 with the exception of January 2022. There was an increase in attendance from 20 attendees in August 2021 to 44 attendees in May 2022. Topics presented included an overview of the oral oncolytic fulfillment process and education on new oncolytic medications. An electronic survey was sent out to the attendees (both nurses and pharmacists) on May 2022 and had 32 respondents. Approximately, 62.5% of participants were very satisfied and 37.5% were somewhat satisfied with the educational series. None of the survey participants were dissatisfied with the series. Approximately 62.5% of survey participants replied that they were likely to use the information “very often” in their practice. For future educational topics, the majority of participants preferred education on oncolytic medications with 50% preferring a review of oral oncology therapeutic classes and 38% preferring education on new oral oncolytics.

**Conclusion:** A successful pilot nursing educational series was created and implemented at a large health system with an integrated specialty pharmacy. Specialty pharmacists are uniquely positioned to close the educational gap among nursing and pharmacy staff.

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**Category:** Delivery of Specialty Pharmacy Products or Services.
POSTER #33

**Antipsychotics and GSKIP to against neurotoxicant**

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**Background:** GSK3 plays a crucial role in involving several physiological events at the cellular level and regulating numeral enzyme activities. It is reported to be one of the members of the AKT1/GSK3 signaling pathway, which is involved in psychopathological alterations of many psychiatric disorders. GSK3 is a naturally occurring negative regulator of GK3, it retains both PKA RI1 and GSK3 binding subunit and plays a role in PKA/GSKIP/GSK3/Drp1 signaling axis.

**Objective:** This type of autophagy event protects the cell from apoptotic damage and has been suspected due to, in part, the anti-oxidant signaling of nitro oxide.

**Methods:** GSKIP and antipsychotics can induce cytoprotective autophagy and protect neuronal cells from oxidative stress-induced damages. EGFP/sh-sy5y, EGFP-GSKIP wt/sh-sy5y, EGFP-L130P/sh-sy5y, were continuously screened for more than G418, and it took more than a month until more than 80% of the cells could observe the performance of GFP, and then collected cells or successors for drug treatment or attack and acidic and autophagy inhibitor treatment experiments.

**Results:** Olanzapine, paliperidone, or haloperidol all-cause autophagic marker-LC3 performance, and three drugs treat sh-sy5y cells for 6h at 10μM, which can already be seen to stimulate the performance of p62 and LC3. Three antipsychotics, at EGFP/sh-sy5y, whether at 10μM or 50μM concentrations, processing 6 or 12h stimulates autophagy and protect neuronal cells from oxidative stress-anti-oxidant signaling of nitro oxide.

**Conclusion:** Difference between olanzapine, serindole, and paliperidone-induced autophagy. The different autophagy inhibitors will be applied to figure out which step of the autophagy signaling pathway is crucial. We may further identify whether GSKIP has its application in psychiatric disorders through this study. Our achievements may benefit molecular drug development in Psychopharmacology.

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POSTER #35

**Pharmacy liaison-managed care model in diabetes**

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**Background:** Diabetes is a growing chronic health problem that can contribute to poor health outcomes and increased total medical expenditures. Patients with diabetes face numerous challenges, including medication affordability, barriers to adherence, and the complexity of managing their disease. The impact of pharmacist-led services on diabetes outcomes is well documented, however limited evidence supports the effect of pharmacy liaisons on challenges faced by patients with diabetes.

**Objective:** To describe an observational analysis of a pharmacy liaison-managed care model for patients with diabetes and to...
measure its impact on medication access, adherence, and changes in hemoglobin A1C (HbA1c).

Methods: An integrated model for the medication management of patients with diabetes was implemented within an adult and pediatric endocrinology clinic at a health-system specialty pharmacy (HSSP). To minimize common barriers to timely therapy, liaisons investigated patient pharmacy and medical benefits, completed prior authorizations (PAs), and identified financial assistance. Liaisons coordinated medication and durable medical equipment (DME) fulfillment while ensuring medication adherence during monthly refill calls and served as a bridge to prescribers to escalate clinical issues. Changes in HbA1c were measured starting up to 60 days prior to the patient's onboarding date, through the following 6 months after enrollment.

Results: The diabetes care model was integrated in two clinics in March 2019, with 548 total enrollees to date. From October 2020 to September 2021, liaisons completed over 2,000 medication PAs for enrolled patients, resulting in an average time to therapy of less than three days. Financial assistance secured through the care model resulted in medication copays with an 85th percentile of $8. Patients achieved high levels of medication adherence, as indicated by an average Proportion of Days Covered (PDC) of 97%. An average 1% reduction in HbA1c was observed in a sample of 82 patients after a minimum of 6 months on service.

Conclusion: Implementation of a pharmacy liaison-led diabetes care model was associated with positive outcomes for patients as demonstrated by high PDC, HbA1c reductions, time to therapy initiation, and medication copays. The 1% reduction in HbA1c in the study cohort has implications on total medical expenditures. This model can be adapted to other health systems to simplify care and improve health outcomes for patients with diabetes.

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POSTER #36

Comparing approaches to drive clinical continuity

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Background: Health system specialty pharmacies (HSSP) are integrated into institutional infrastructure, which facilitates the coordinated provision of clinical, financial, and operational services to patients on specialty medications. Despite these advantages, not all specialty medications remain within the health system (HS). On 1 May 2021, the Yale New Haven Health HSSP launched an initiative to improve clinical continuity, defined as the provision of specialty drug orders from HS clinics to the HSSP. This initiative employed an interdisciplinary outreach team complemented by electronic health record (EHR) messaging for clinics that opt into a Best Practice Advisory (BPA). The BPA is designed to recommend to clinicians ordering a specialty medication to an external pharmacy to consider selecting the HSSP.

Objective: To determine whether the implementation of a clinical continuity outreach team with or without the BPA improves clinical continuity.

Methods: This is a retrospective review of specialty medication orders placed within the EHR between 1 October 2020 and 31 May 2022. Orders were cohorted by origin from clinic with no HSSP outreach, HSSP outreach, or HSSP outreach with BPA messaging. Orders from non-HS clinics, acute care sites, and clinics referring patients to ambulatory pharmacy for specialty medication management were excluded. Volume of retained specialty orders were calculated as proportions and compared pre- and post- project implementation or clinic-specific outreach date. Statistical significance was tested using Chi-squared test, with alpha set at 0.05.

Results: Of 626 clinics evaluated for clinical continuity opportunity, 66 sites received tailored clinic outreach. Of these sites, 27 consented to BPA messaging. Overall, clinical continuity improved from baseline by approximately 30% for clinics with any outreach. This was significantly higher than the 3% organic growth from sites that did not receive any clinic outreach. Although the BPA resulted in 16% of orders initially placed to external pharmacies to remain within the HS, there were no significant continuity differences in clinics receiving the complementary BPA enhancement compared to clinic outreach alone. Non-hospital clinics seem to respond more favorably to clinic outreach with or without BPA (33 and 79% increase from baseline, respectively) in comparison to hospital clinics (14.6 and 5.4% increase from baseline, respectively).

Conclusion: HSSP outreach to clinics, with or without enhanced electronic tools, can improve clinical continuity within a health-care system.

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Category: Delivery of Specialty Pharmacy Products or Services.

POSTER #37

Patient satisfaction of delivery methods at one health system SP

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Background: Specialty pharmacy strives to provide comprehensive therapy management for complex disease states, many of which involve high-cost medications that require refrigeration. Ensuring
proper temperature of these medications from pharmacy to patient is vital for patient safety and medication efficacy. Various delivery methods are currently utilized to guarantee this storage. Conventional methods utilize resources such as cardboard boxes, insulation, and ice packs. This results in increased waste for patient and environment with increased costs to the pharmacy. The purpose of this study is to assess patient satisfaction regarding different delivery methods in a cost-saving and eco-friendly initiative.

**Objective:** At one health system specialty pharmacy located in West Virginia, delivery of medications is through health system owned couriers and United Parcel Service (UPS). To guarantee proper storage temperature, two delivery methods are utilized which include: conventional cold chain packaging consisting of an individual box with insulation and ice packs and eco-friendly cold chain packaging which includes a reusable, insulated container that stores multiple individually wrapped patient packages. Patients were considered eligible in the study if they received a delivery of specialty medication(s) from the sponsoring pharmacy site with conventional cold chain and eco-friendly cold chain packaging.

**Methods:** Patients were further categorized on the delivery method: couriers and UPS. A survey was conducted via telephone to assess patient satisfaction with eco-friendly cold chain packaging delivered by the couriers. The survey questions included demographic information and Likert scale questions regarding patients’ preferred delivery methods. The research team recorded answers in a secure electronic survey system. The primary endpoint was to determine if patients were more satisfied with the eco-friendly cold chain packaging compared to the conventional cold chain packaging. Secondary endpoints were to determine if patients were more satisfied with health system owned couriers or UPS deliveries and to determine if the eco-friendly cold chain packaging is more cost effective than the conventional cold chain packaging.

**Results:** Surveyors interviewed 101 patients. Baseline characteristics included: 61 patients were female and 84 patients received a medication that belonged to the specialty pharmacy’s inflammatory disease state team. Health system owned courier deliveries were categorized to 9 different pre-designed routes within a 3-hour radius of Morgantown, West Virginia. There were 60 patients that preferred the eco-friendly cold chain delivery method, 16 that preferred the conventional cold chain packaging, and 25 patients did not have a preference. There were 81 patients that rated their satisfaction at 5/5 of “very satisfied” with no patients rating their satisfaction below 3/5 of “neutral.” Of the 38 patients that had received a delivery from UPS and a courier, 17 patients preferred a courier, 17 did not have a preference, and 4 preferred UPS.

**Conclusion:** There is higher patient satisfaction and preference with the eco-friendly cold chain packaging compared to common conventional delivery methods at a West Virginia health system specialty pharmacy. This is attributed to ease of use and less bulk waste. The initiative is supported by pharmacy cost-savings and environmentally friendly practices. Additionally, patients have an increased preference of the use of health system owned couriers compared to UPS. This is attributed to maintained courier relationships and trust in ensuring timely delivery with proper temperature. Overall, increased adoption of similar eco-friendly delivery methods and/or in-house couriers across specialty pharmacies may increase patient satisfaction.

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**Category:** Delivery of Specialty Pharmacy Products or Services.

**Work submitted elsewhere:** ASHP Summer Meeting 2022.
Real-world survival in edaravone-treated ALS

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Background: Intravenous (IV) edaravone received approval from the US Food and Drug Administration in May 2017 based on a 33% (p = 0.0013) slowing of functional loss, as measured by the amyotrophic lateral sclerosis (ALS) Functional Rating Scale-Revised compared with placebo at 24 weeks.

Objective: To evaluate overall survival in patients with ALS treated with IV edaravone compared with those who were not treated with IV edaravone.

Methods: This retrospective observational analysis included patients with ALS who were continuously enrolled in Optum’s de-identified Clininformatics Data Mart database between 8 August 2017 and 31 March 2020. Propensity score matching (1:1) identified IV edaravone-treated patients (cases) and non–edaravone-treated patients (controls) matched for covariates potentially affecting survival: age, race, geographic region, gender, pre-index disease duration (defined as the period between the date of first claim for ALS diagnosis and the first claim for IV edaravone), insurance, history of cardiovascular disease, riluzole prescription, gastrostomy tube placement, artificial nutrition, non-invasive ventilation, and all-cause hospitalization. For cases, the index date was the date of the first claim for IV edaravone. For controls, the index date was the date IV edaravone was available on the market (August 2017). Shared frailty Cox regression analysis was performed to estimate the benefit of IV edaravone.

Results: In total, 318 cases were matched to 318 controls. In both groups, 208 patients (65.4%) had a history of riluzole prescription. As of 03/31/2021, there were 155 deaths (48.7%) among the cases and 196 among the controls (61.6%). Median overall survival time was 29.5 months with edaravone and 23.5 months without edaravone, respectively, and the risk of death was 27% lower among patients treated with IV edaravone compared with those who were not treated with IV edaravone.

Conclusion: This real-world analysis demonstrated that continuation of IV edaravone treatment, in a large predominantly riluzole-treated US cohort, is associated with improved overall survival compared with not using IV edaravone.

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Category: Outcomes (Cost or Other).
Work submitted elsewhere: This abstract was previously presented at the 2022 Academy of Managed Care Pharmacy (AMCP) meeting held on March 29–April 1, 2022 in Chicago, Illinois.

Patient-reported outcomes and interventions in MS

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Background: Patient-reported outcomes (PROs) can be used to measure patient health status, functioning, quality of life, and therapeutic response.

Objective: The objective of this study was to assess PROs and pharmacist interventions in patients prescribed specialty multiple sclerosis (MS) medications at a health system with an integrated specialty pharmacy.

Methods: We conducted a single-center retrospective analysis of patients taking specialty MS medications who completed ≥2 monthly refill questionnaires (MRQs) wherein PROs were collected between 1/1/2020 and 3/31/2020. MRQs are administered by a pharmacy technician when a medication refill is due and patient responses trigger pharmacist interventions if needed. The primary outcomes were MRQs regarding perceived medication effectiveness, adverse effects, and missed doses. The secondary outcome was frequency and type of pharmacist interventions prompted by MRQ responses. MRQ and intervention data were collected from the specialty pharmacy patient management database. Patient demographics and prescribed medications were collected from electronic health records. We calculated medians and interquartile ranges (IQR) for continuous variables and percentages for categorical variables.

Results: We included 335 patients: 24% male, 81% White, with median age of 52 years (IQR 45, 60). Patients filled 335 medications: fingolimod (n = 74, 22%), dimethyl fumarate (n = 63, 19%), interferon beta-1a (n = 56, 17%), glatiramer acetate (n = 56, 17%), dalfampridine (n = 33, 10%), teriflunomide (n = 32, 10%), interferon beta-1b (n = 13, 4%), peginterferon beta-1a (n = 7, 2%), and siponimod (n = 1, <1%). Patients completed a median of 3 MRQs (IQR 3, 3) over three months, for a total of 1,017 total MRQs in the sample. Most MRQ responses rated medication effectiveness as excellent (n = 331, 33%) or good (n = 468, 66%). One percent (n = 6) reported experiencing any adverse event. Ten percent (n = 34) reported missing ≥1 medication dose(s). Specialty pharmacists performed 136 interventions involving 95 patients, most often related to adherence or missed dose (n = 39, 29%), safety therapeutic monitoring (n = 36, 26%), and common side effect (n = 20, 15%).

Conclusion: Patients filling medication from our integrated health system specialty pharmacy model reported low rates of missed doses and side effects, and most rated high perceived effectiveness of their medication. Specialty pharmacists integrated in the MS clinic performed targeted interventions that ensured safe and effective medication use.

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Category: Outcomes (Cost or Other).
Patient-reported outcomes in an IBD clinic

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**Background:** Inflammatory bowel disease (IBD) can impact a patient’s quality of life by decreasing mood and routine functioning. Patient-reported outcomes (PROs) can be used to assess disease status and response to therapy. PRO instruments can also identify potential treatment barriers including medication adherence or adverse effects that may require interventions to initiate or adjust therapy.

**Objective:** This study assessed PROs in patients prescribed specialty medications by an IBD clinic at a health system and dispensed by an integrated specialty pharmacy.

**Methods:** We performed a single-center retrospective study of patients who received ≥2 fills of a specialty medication prescribed by the center’s outpatient IBD clinic and completed ≥2 corresponding monthly refill questionnaires (MRQs) from January to March 2020. A pharmacy technician conducts the MRQ that gathers PROs and prompts interventions if needed. The primary outcome was PROs including adverse effects, missed doses, and perceived medication effectiveness. Secondary outcomes were disease-specific PROs that measure quality of life, including the patient health questionnaire depression scale (PHQ) and short inflammatory bowel disease questionnaire (SIBDQ), as well as CRP values, an inflammatory biomarker. Demographics, medications and PHQ, SIBDQ, and CRP values were collected from EHRs. MRQ data was extracted from the specialty pharmacy patient management database. Interquartile ranges (IQR) or means with standard deviations (SD) were calculated for continuous variables, and frequencies and percentages were presented for categorical variables.

**Results:** We included 181 patients: 52% female, 92% white, median age of 42 years. The majority of patients (87%, n = 158) were diagnosed with Crohn’s disease. The most prescribed specialty medications were adalimumab (58%, n = 104) and ustekinumab (32%, n = 57). 515 MRQs were completed (median of 3 MRQs; [IQR 3, 4]) during the study. There were 2 reports of adverse effects and 11 reports of missing ≥1 medication dose. Medication effectiveness was rated as excellent (n = 69, 13%) and good (n = 433, 84%) in most responses. SIBDQ, PHQ, and CRP values remained relatively stable over time.

**Conclusion:** IBD patients receiving care from providers and specialty pharmacists within an integrated care model that includes a specialty pharmacy reported high medication effectiveness and low rates of adverse effects and missed doses. Additional research is needed to evaluate the relationship between PROs and long-term clinical outcomes.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** ASHP Midyear Clinical Meeting and Exhibition, December 2021.

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PROs in dermatology, asthma and allergy patients

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**Background:** Specialty medications are used to manage symptoms, prevent exacerbations, and slow disease progression for patients with inflammatory conditions including dermatology, asthma and allergy. Patient-reported outcomes (PROs) can be used to measure therapeutic response, as well as health status, functioning, quality of life, and disease management.

**Objective:** The objective of this study was to assess PROs and pharmacist interventions in patients prescribed specialty medications for dermatology, asthma and allergy at a health system specialty pharmacy.

**Methods:** This was a single-center retrospective analysis of patients prescribed specialty medications for dermatology, asthma or allergy disease states who completed 2+ monthly refill questionnaires (MRQs) from 1/1/2020 through 3/31/2020. MRQs administered by a CPhT when a medication is refilled, collect PRO data, and responses may trigger pharmacist interventions. Primary outcomes were adverse effects, missed doses, and perceived medication effectiveness. Secondary outcomes were specialty pharmacist interventions. Demographics and medication data were collected from the EHR. MRQ and intervention data were collected from the pharmacy patient management database. Means and interquartile ranges (IQR) were calculated for continuous variables, frequencies and percentages for categorical variables.

**Results:** We included 144 dermatology patients: 42% male, 79% White, median age 53 years and 46 asthma or allergy patients: 41% male, 67% White, median age 50 years. Most common dermatology medications were adalimumab (24%), dupilumab (22%), and apremilast (17%). Most asthma or allergy patients were prescribed dupilumab (82%). Dermatology patients completed 456 MRQs (median of 3 MRQs; [IQR 3, 4]) and asthma or allergy patients completed 146 MRQs (median of 3 MRQs; [IQR 3, 4]) over 3 months. Of 602 total MRQs, most responses rated medication effectiveness as excellent (8%) or good (91%). Adverse events were reported in 5 (<1%) MRQs. 6 (3%) patients reported missing ≥1 dose. Pharmacists performed 22 interventions for 19 dermatology patients and 7 interventions for 6 asthma or allergy patients.

**Conclusion:** Patients with inflammatory conditions who fill medication within an integrated health system specialty pharmacy reported low rates of missed doses and side effects, and rated high perceived medication effectiveness. Integrated specialty pharmacists in dermatology, asthma and allergy clinics perform targeted interventions to ensure safe and effective medication use.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** ASHP Midyear Clinical Meeting and Exhibition, December 2021.
Patient-reported outcomes in rheumatology

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Background: For patients with rheumatologic conditions, biologic and targeted synthetic disease modifying antirheumatic drugs (bDMARDs, tsDMARDs) reduce symptoms, improve function, and slow disease progression. However, patients may miss doses due to low perceived efficacy or side effects. Patient-reported outcomes (PROs) can assess health status and barriers to adherence, which help guide therapy and dictate further intervention.

Objective: The objective of this study was to evaluate PROs from patients prescribed a rheumatologic specialty medication and identify subsequent pharmacist interventions.

Methods: This study was conducted at a health system with an integrated pharmacy. Technicians complete a monthly refill questionnaire (MRQ) with each refill for patients filling with the pharmacy. It includes PROs that assess side effects, perceived medication effectiveness, exacerbations and missed doses. Responses trigger pharmacist interventions if necessary. This was a retrospective review of patients prescribed a bDMARD or tsDMARD by an outpatient rheumatology clinic, filled by the integrated specialty pharmacy and completed ≥2 MRQs between January and March 2020. Primary outcomes were PROs collected via MRQs. The secondary outcome was the frequencies and types of pharmacist interventions precipitated by PROs. PROs and intervention data were collected from the pharmacy patient management database. Demographics and medications were collected from EHRs. Medians with interquartile ranges (IQR) or means with standard deviations were calculated for continuous variables, and frequencies and percentages were used to summarize categorical variables.

Results: We included 809 patients: 69% female, 90% white, median age of 57 years. Most patients were prescribed adalimumab (32%), etanercept (27%) or tocilizumab IR/XR (13%). 2,306 MRQs were completed; patients completed a median of 3 MRQs (IQR 2, 3). Most MRQs rated medication effectiveness as excellent (29%) or good (67%). 109 MRQs (13%) reported missing ≥1 doses. Specialty pharmacists performed 304 interventions, mostly concerning adherence (41%), exacerbations (18%), or side effects (11%). Of the 31% that did require intervention, the median completed per patient was 1 (IQR 1, 1).

Conclusion: Patients on bDMARDs and tsDMARDs through an integrated specialty pharmacy reported high rates of perceived effectiveness and low rates of missed doses, side effects, and exacerbations. Specialty pharmacists performed targeted interventions to ensure safe and effective medication use.

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Category: Outcomes (Cost or Other).

Patient-reported outcomes in specialty pharmacy

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Background: Specialty medications are used to manage symptoms, minimize relapses or exacerbations, and slow disease progression. Patient-reported outcomes (PROs) can be used to assess therapeutic response to medications. Perceived effectiveness or side effect occurrence can affect patient willingness to take medication, which can subsequently impact treatment outcomes.

Objective: The purpose of this study was to determine if there is an association among PROs (missed doses, side effects, perceived medication effectiveness) in patients prescribed specialty medications at an integrated health system specialty pharmacy.

Methods: We conducted a single-center retrospective analysis of patients prescribed specialty medications from rheumatology, MS, neurology, dermatology, and asthma and allergy clinics. PROs were assessed when patients completed ≥2 monthly refill questionnaires (MRQs) from January to March 2020; MRQs collect PROs including missed doses, side effects, and medication effectiveness. The primary outcomes were frequency of PROs related to missed doses, side effects, and perceived medication effectiveness. We fit a cumulative link mixed effects model with medication effectiveness as the response to explore the associations between efficacy, missed doses, and side effects. Electronic health records were used to collect demographics and PROs were collected from the pharmacy patient management database. We summarized data using descriptive statistics such as median and interquartile ranges for continuous variables, and frequencies and percentages for categorical variables.

Results: We included 1398 patients from six specialty clinics. Most patients were female (66%) and white (87%) with a median age of 56. Of 4125 MRQs completed, missed doses were reported 172 times (4%), most often due to intentional holding for illness/procedure. Side effects were reported 41 times (1%), and most reported effectiveness as good (72%) or excellent (25%). For patients who did not report side effects, the odds of reporting higher effectiveness were 7.49 (95% CI: 3.31, 16.95) times that of patients who did report side effects. For patients who did not report a missed dose, the odds of reporting higher effectiveness were 2.13 (95% CI: 1.42, 3.19) times that of patients who did report a missed dose.

Conclusion: Patients filling medications with an integrated health system specialty pharmacy reported low rates of missed doses and side effects. Also, patients who did not report missed doses or side effects were significantly more likely to have higher perceived effectiveness of treatment.

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Category: Outcomes (Cost or Other).
Work submitted elsewhere: ASHP Summer Meeting & Exhibition, June 2022.
Factors influencing CDK4/6 inhibitor adherence

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Background: The National Comprehensive Cancer Network recognizes CDK4/6 inhibitors palbociclib, abemaciclib, and ribociclib in combination with aromatase inhibitors or fulvestrant as first-line therapy regimens in the treatment of HR-positive/HER2-negative advanced or metastatic breast cancer. Several reports describe adherence and persistence with oral oncolytics and with CDK4/6 inhibitors specifically. However, to our knowledge no reports describe factors associated with adherence for this drug class.

Objective: The primary objective is to understand factors impacting a patient’s adherence to CDK4/6 inhibitors.

Methods: This was a multicenter, retrospective observational analysis of adult patients new to a CDK4/6 inhibitor from 35 U.S. health systems working with ShieldsRx with integrated specialty pharmacies (HSSPs). Inclusion criteria was treatment initiation within the last four years, at least 3 prescriptions filled for a CDK4/6 inhibitor, and currently on therapy or discontinued. Patients with <3 fills during the study period and an invalid zip code were excluded. Data evaluated included age, drug, number of prescription fills, insurance type, average PDC, zip code, and health system geographic region (Midwest, Northeast, South, West). Descriptive statistics were used to analyze the groups and stratified by drug, age, insurance type, median household income, and geographic region.

Results: Data from 4245 patients on CDK4/6 inhibitors during this time period were identified, with an average PDC of 88% (SD ±11%; median PDC 91%). Adherence was consistently 86-89% across all ages, region, and drug. Average PDC was consistently 86-89% across all regions, drugs, and insurance type, except for ribociclib in the South region (PDC 82%). Stratification of PDC by U.S. state based on patient’s zip code and median household income showed a general trend among U.S. states with lowest median household income corresponding with a lower PDC; those in the highest income group (≥$68,428) had an average PDC of 89.1% and those in lowest median income group (≤$59,324) had an average PDC of 86.9%.

Conclusion: Analysis of a large cohort of CDK4/6 inhibitor patients at HSSPs demonstrated high and consistent adherence across drug, age group, insurance type, and geographic location, highlighting the impact of the HSSP care model. Observations between U.S. state income level and adherence underscore the need to direct additional support to vulnerable populations.

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Category: Outcomes (Cost or Other).

CF refill utilization trends with CFTR modulators

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Background: The past decade has revolutionized cystic fibrosis (CF) care with the development of disease-modifying therapies. Anecdotally, clinicians and pharmacists have observed a down-trend in the refilling of guideline-recommended CF supportive therapies since the introduction of CF transmembrane conductance regulator (CFTR) modulator therapies most notably elexacaftor/tezacaftor/ivacaftor (Trikafta) in 2019.

Objective: The aim of this study is to conduct a comparative analysis of the trend in utilization of CF supportive therapies in patients with CF six months before and after initiation of Trikafta and determine the impact of Trikafta on those refill trends.

Methods: This study is a retrospective, observational study. A collaborative specialty pharmacy reviewing dispense data for the study and a review of claims data pre- and post- initiation of treatment with Tricafta in CF patients will be conducted. Patients that began taking Trikafta between October 2019 and June 2020, that are six years of age or older with a diagnosis of CF, and have a minimum of three documented refills of at least three CF guideline recommended supportive therapies e.g. inhaled antibiotics, mucolytics, and pancreatic enzyme replacement therapy (PERT) will be included in the study. The following data will be collected: patient demographics, claims data, and CF specialty medication history six months pre- and post-treatment with Trikafta. The main outcome will be to compare refill trends of CF guideline-recommended supportive therapies before and after the initiation of treatment with Trikafta.

Results: The data consisted of claims processed between November 2019 and December 2020 and included thirty-nine patients ranging in age from 14 to 80 years old with at least three fills of each class of supportive therapies, within 6 months of Trikafta initiation in the study cohort. A 14.79% decrease in refills of inhaled antibiotics after Trikafta initiation, no change in mucolytic agents and a 5.61% increase in claims for PERT was observed.

Conclusion: Based on the observed results, patients taking Trikafta appeared less likely to refill inhaled antibiotics. It’s possible that patients may have experienced a reduction in pulmonary symptoms related to decreased microbial colonization which contributed to the decrease in refilling inhaled antibiotics. While no change in refill patterns for mucolytic agents was noted and there was a slight increase in claims for PERT, the reduction in refills for inhaled antibiotics may represent improved patient-reported outcomes while also generating cost savings for both patients and payors. Limits of this study include small sample size and that PERT claims are not restricted to specialty pharmacy which makes it more difficult to draw appropriate conclusions. Although these results are preliminary, monitoring trends in refills of supportive therapies in a larger population sample and for a longer period of time may provide a broader picture of real-world evidence of the effects of next-generation CFTR agents.

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Category: Outcomes (Cost or Other).
Background: Health system specialty pharmacies (HSSPs) deliver coordinated quality care for patients. Their integrated care model is uniquely positioned to improve patient outcomes for complex disease states. Currently, there is a lack of standardized clinical outcomes (CO) benchmarks within specialty pharmacy (SP) to measure performance. To evaluate COs across multiple HSSPs, we established a systematic approach to defining and reporting COs for multiple disease states.

Objective: To describe the process of reporting COs across HSSPs with the goal of creating standard benchmarks to compare performance.

Methods: COs were identified through a literature search for hepatitis C virus (HCV), human immunodeficiency virus (HIV), rheumatoid arthritis (RA) and oncology (ONC), then deployed into the patient management platform (PMP) used for multiple HSSPs using discrete data fields. Pharmacists completed a standardized clinical training program to ensure consistent documentation of COs within the PMP. Patient time on service requirements and limits on historical data were established for each disease state. To standardize the data extraction process for COs from the PMP, inclusion and exclusion criteria were applied to each disease state to establish a reproducible framework for evaluating results across multiple HSSPs. Data extractions for each disease state went through a quality assurance process to validate the results in a de-identified fashion prior to internal publication. Sustained virologic response (SVR), viral suppression, Routine Assessment of Patient Index Data 3 (RAPID3) and hospitalization were selected for quarterly reporting for HCV, HIV, RA, and ONC respectively.

Results: From Jan 2021 to Dec 2021, COs were analyzed for 15 HSSPs. Patients enrolled in the integrated care model and followed by clinical pharmacists were included for analysis. The percentage (n/N) of patients that achieved SVR, viral suppression, RAPID3 improvement, and were hospitalized were as follows: 94.8% (346/365), 92.2% (3819/4144), 43.6% (167/383), 6.9% (878/12,635).

Conclusion: A framework to develop and report COs was implemented for a network of HSSPs. Standardized criteria to uniformly evaluate COs allowed each SP to compare their performance and validate quality clinical care for patients.

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Category: Outcomes (Cost or Other).
**MR fast: helping patients get migraine relief fast**

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**Background:** Migraine creates a significant economic burden for patients and society through direct healthcare costs as well as disability and lost productivity. Trellis Rx partners with health systems to offer high-touch pharmacy services to migraine patients. Working onsite at health systems, specialty pharmacists use an efficacy protocol to proactively assess if patients are on an effective medication for their migraines and to intervene when therapy is determined to be sub-optimal or ineffective.

**Objective:** Assess the impact of implementing Health System Specialty Pharmacy (HSSP) services in a neurology clinic by measuring the time until effective migraine control and outcome of pharmacist interventions.

**Methods:** A multicenter, retrospective study of enrolled adult migraine patients initiating treatment with erenumab, fremanezumab, or galcanezumab between October 2020 and October 2021. Patients starting a CGRP modulator were offered enrollment into HSSP services, which included assessing effectiveness with scheduled headache data collection. Data was documented in Arbor, Trellis Rx’s proprietary specialty pharmacy technology platform, and reports were generated to assess clinical outcomes.

**Results:** 500 patients were evaluated. The average time to effective migraine control after therapy initiation was 73 days (SD 36.5). After enrollment in HSSP services, the average number of migraine days/month was reduced by 8 days (SD 8.7). 24 patients were determined to have ineffective or sub-optimally effective therapies during the 8–12 week efficacy check-in, and 71% of these patients became controlled. Pharmacists made recommendations for 22 of the 24 patients (92%), and 95% of the recommendations were accepted by patients and providers. The average conversion time from ineffective or sub-optimal effectiveness to effective migraine control was 85 days (SD 51.4).

**Conclusion:** HSSP services can improve outcomes in patients receiving prophylaxis for migraines as demonstrated by the results. Pharmacist therapy efficacy assessments and interventions were shown to be impactful as they directly corresponded with an increase in patients on effective migraine regimens.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** JAPhA, 2022 Pharmacy Quality Alliance (PQA) Annual Meeting Abstracts. 62 (2022) 897-901.

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**VMAT2i therapy for chronic Tic disorders**

Presenting author: Kayla Johnson
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**Background:** Tourette’s Syndrome and other chronic tic disorders are debilitating conditions that can impact an individual’s quality of life. Traditional pharmacotherapy, including antipsychotics and alpha agonists, have side effects that can limit their tolerability. Vesicular monoamine transporter 2 inhibitors (VMAT2i) are approved for movement disorders such as tardive dyskinesia and their use is being explored for other conditions. However, tolerability data for VMAT2i in adult tic disorders is insufficient.

**Objective:** This study will examine VMAT2i persistence rates in naive patients with a chronic tic disorder.

**Methods:** A single-center, retrospective cohort study was conducted including adult patients diagnosed with a chronic tic disorder newly initiated on VMAT2i between 1 January 2018 and 31 December 2020. Data were collected from electronic health records. The primary outcome was VMAT2i persistence rate at 12-months post-initiation. Secondary outcomes included the time to and reason for treatment discontinuation and rate of adverse effects experienced while on treatment. Descriptive statistics were used to summarize the data; categorical variables were presented as frequencies and percentages, and continuous variables as medians and interquartile ranges (IQR).

**Results:** Of the 25 patients screened, 11 were excluded (prior VMAT2i use: 8, VMAT2i started after study period: 2, no tic disorder diagnosis: 1). Of the 14 patients included, baseline characteristics were 57% male, 100% white, median age 37 years (IQR 32, 44), and median failure of 3 (IQR 2, 4) prior medications for tics. Half (50%; n = 7) of patients were persistent through the 12-month follow-up period. Patients who discontinued treatment were on therapy for a median of 54 days (IQR 26, 94). Patients discontinued due to lack of efficacy and adverse effects (n = 3) or adverse effects alone (n = 4). The most common adverse effects reported across all patients were drowsiness (21%), musculoskeletal effects (14%), and fatigue (14%).

**Conclusion:** In the first 12 months of VMAT2i therapy, 50% of patients discontinued treatment. The high rate of discontinuation suggests that the impact of adverse effects or lack of efficacy may outweigh potential benefits provided by VMAT2i therapy in this medication-refractory patient population. However, further studies are needed with larger sample sizes to further research these outcomes.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** College of Psychiatric and Neurologic Pharmacists (CPNP) Poster Presentation, April 2022
**POSTER #52**

**Pharmacist impact on coverage outcomes in oncology**

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Shields Health Solutions

**Background:** Many third-party insurance plans have implemented prior authorization (PA) requirements on specialty oncology medications due to the increasing cost and complexity of treatment. These PAs, coverage denials, and appeals are the most cited sources of administrative burden faced by oncologists. An integrated Health-System Specialty Pharmacy (HSSP) clinical program provided ambulatory clinical pharmacist support within oncology clinics at a large New York based integrated health-system to address these strains.

**Objective:** To evaluate the impact of an ambulatory clinical pharmacist program on third party coverage determination outcomes for specialty oncology medications in cancer patients managed by a HSSP.

**Methods:** This retrospective observational study compared PA outcomes (Cost or Other) for specialty oncology medications due to the increasing cost and complexity of treatment. These PAs, coverage denials, and appeals are the most cited sources of administrative burden faced by oncologists. An integrated Health-System Specialty Pharmacy (HSSP) clinical program provided ambulatory clinical pharmacist support within oncology clinics at a large New York based integrated health-system to address these strains.

**Results:** Out of the 1685 total PA and appeal requests, 961 (57%) requests were submitted with ambulatory clinical pharmacist support (comparator) and without ambulatory clinical pharmacist support (intervention) from September 2020 to May 2021 and June 2021 to February 2022, respectively, at oncology clinics located within a large New York based integrated health-system. Primary outcomes included the PA and appeal approval rates in the comparator and intervention groups, and secondary outcomes were the number of PAs and appeals completed and percentage of requests submitted with the ambulatory clinical pharmacist program.

**Conclusion:** Ambulatory clinical pharmacist support improved the approval rates of both PAs and appeals for specialty oncology medications. The program was associated with a positive impact on approvals even with a greater number of PA and appeal requests submitted. These programs may benefit various other healthcare clinics and sites that prescribe a high volume of specialty medications that require PAs.

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**Category:** Outcomes (Cost or Other).

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**POSTER #53**

**Impact of an embedded rheumatology pharmacist**

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Shields Health Solutions

**Background:** In the ambulatory care setting, rheumatologists are often limited in employing potentially effective treatments for their patients due to insurance coverage restrictions and delays in medication approvals. Studies suggest a pharmacist’s involvement can improve the insurance authorization process for specialty medications, but there is limited evidence to support a pharmacist’s role for rheumatologic disorders.

**Objective:** The aim of this project is to evaluate the impact of a pharmacist’s involvement on coverage determination outcomes, medication access, and provider satisfaction for a rheumatology practice affiliated with an integrated Health-System Specialty Pharmacy.

**Methods:** This was a single-center retrospective cohort analysis of prescriptions for specialty and non-specialty oral or injectable disease modifying anti-rheumatologic and supportive care agents prescribed by providers from a rheumatology clinic at a New York based integrated health-system. A clinical pharmacist was incorporated into an integrated care workflow within the clinic where liaisons investigated patient pharmacy and medical benefits and completed medication prior authorizations (PAs). The pharmacist provided clinical support for PAs, appeals and peer-to-peer reviews. Changes in PA turnaround time, PA approval rate, and appeal approval rate were measured six months post-implementation, 1 October 2021–31 March 2022, and compared to six months pre-implementation, 1 April 2021–30 September 2021. The clinic providers were also surveyed to determine satisfaction with pharmacist services.

**Results:** The addition of a pharmacist to the clinic’s workflow for insurance authorizations resulted in a 14% increase in prior authorization approval rate and a 15% increase in appeals approval rate as compared to baseline rates. In addition, PA turnaround time was reduced from 3.4 to 1.5 days after incorporation of the ambulatory clinical pharmacist in the workflow. Provider satisfaction surveys revealed that 100% of participants found the integration of a clinical pharmacist to be beneficial and 90% identified that assistance with insurance authorizations was one of the most impactful services provided to the clinic.

**Conclusion:** The addition of an ambulatory care pharmacist to the multidisciplinary team in a rheumatology practice can improve provider satisfaction and the quality of patient care, specifically related to medication access and timeliness of medication approvals.

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**Category:** Outcomes (Cost or Other).
Pharmacist management of prescription cannabidiol

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Background: There is limited data on real-world outcomes and management of prescription cannabidiol (CBD) therapy.

Objective: This study describes adverse effects (AEs) and drug-drug interactions (DDIs) reported during the first 12 months of prescription CBD therapy as well as their management by integrated specialty pharmacists (SPs).

Methods: This was a single-center, retrospective cohort study of patients prescribed CBD by a neurology provider and fulfilled through the center’s specialty pharmacy from January 2019 through April 2020. Patients enrolled in a clinical trial for CBD or for whom the insurance approval process was not completed by the center’s specialty pharmacy were excluded. Patients were followed for a period of 12 months following treatment initiation to collect information on AEs and DDIs. Baseline demographics, medication use patterns, AEs, and DDIs were collected from electronic health records while specialty pharmacist interventions were collected from a specialty pharmacy patient management database via a retrospective chart review. Descriptive statistics were used to summarize the data; categorical variables are presented as frequencies and percentages. This study was reviewed and approved by the institutional review board.

Results: Of 160 patients screened, 136 patients met inclusion criteria. They were 85% white, 50% female, and 68% pediatric. The most common route of administration was oral (n=113, 83%); about 15% of patients (n=20) administered prescription CBD via g-tube. Of 138 AEs reported, the most common was sedation/drowsiness (n=44, 32%), followed by gastrointestinal upset (n=20, 15%), psychiatric changes (n=17, 12%), and lethargy/fatigue (n=11, 8%). About 30% of hepatic function tests reported liver enzyme elevations. Sixty-five DDIs were reported during the initial 12 months of therapy with the majority being pharmacokinetic in nature (n=58, 89%) due to co-administration with clozapine (n=58, 89%). SPs performed 73 interventions to help mitigate AEs and DDIs including: provision of patient counseling (n=16, 22%), making a recommendation to the provider (n=11, 15%), reviewing the medical chart (n=10, 14%), notifying the provider (n=2, 3%), and performing a DDI check (n=34, 47%).

Conclusion: This study provides real-world data on AEs and DDIs encountered during the first 12 months of prescription CBD therapy. SPs play a vital role in appropriate medication management by mitigating AEs and DDIs to ensure patients can safely continue therapy.

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Category: Outcomes (Cost or Other).

Work submitted elsewhere: College of Psychiatric and Neurologic Pharmacists; April, 2021; Virtual Meeting.

Patient AEs starting enco/bini combination therapy

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Background: Encorafenib, a protein kinase B-raf (BRAF) inhibitor, and binimetinib, a mitogen-activated extracellular kinase (MEK) inhibitor, are a Food and Drug Administration approved combination therapy for the treatment of BRAF V600E or V600K unrespectable or metastatic melanoma. However, combination therapy is associated with adverse events (AEs) that may lead to dose reduction or discontinuation within the first several months of initiating therapy.

Objective: To assess the type and frequency of AEs and AE-associated medical actions (i.e., treatment holds, dose reduction and treatment discontinuation due to AEs) in patients initiating encorafenib and binimetinib combination therapy. The secondary objective was to measure medication adherence.

Methods: We performed a retrospective cohort analysis of patients initiating encorafenib and binimetinib combination therapy at Vanderbilt University Medical Center outpatient oncology clinic from July 2018 through December 2019 for unresectable or metastatic melanoma harboring a BRAF V600E or V600K mutation. Patients were excluded if they were enrolled in a clinical trial. Patient demographics, disease characteristics, and AEs-associated medical actions were collected from the electronic health record. Prescription claims data were extracted from specialty pharmacy databases and used to assess medication adherence using proportion of days covered (PDC). PDC was calculated from first fill of encorafenib and binimetinib therapy through the last fill during study period. To account for medically advised dose interruptions, PDC was adjusted by subtracting interrupted days from the denominator of the PDC calculation.

Results: Eighteen patients were included, 50% female and 100% white. Median age at start of therapy was 59 years (interquartile range [IQR] 43–65). About half of the patients (56%) had stage IV disease and most patients (72%) had a baseline Eastern Cooperative Oncology Group performance status of 1, indicating most patients had some restrictions in performing strenuous physical activity but remained ambulatory and able to carry out light activity. Median disease duration was 1.6 (IQR 0.77–3.0) years with common sites of metastasis including lymph nodes (n=8, 44%), brain (n=4, 22%) and liver (n=4, 22%). Patients commonly experienced the following AEs: fatigue (n=10, 56%), nausea (n=8, 44%), vomiting (n=5, 28%) abdominal pain (n=4, 22%), joint pain (n=4, 22%), and liver enzyme elevation (n=4, 22%). In this cohort, 44% of patients required one or more treatment holds with median time to hold being 26 (IQR 12–44) days and 38 (IQR 14–45) days for encorafenib and binimetinib, respectively. Additionally, 39% of patients required at least one dose reduction with median time to dose reduction being 22 (IQR 18–62) days and 50 (IQR 22–66) days for encorafenib and binimetinib, respectively. Two patients discontinued treatment, one due to disease progression and the other due to clinical decline. The median number of fills per patient was 8 (IQR 4–20) for both medications. A high rate of adherence was
observed with a median PDC of 0.96 (IQR 0.78–1.0) for both medications. **Conclusion:** Although patients achieved high medication adherence, treatment modifications due to AEs occurred commonly in patients initiating encorafenib and binimetinib combination therapy. Further research is needed to evaluate the role of an integrated specialty pharmacist in AE mitigation in an effort to maintain patients on the optimal dosing regimen.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** ASHP Summer Meeting June 2022.

**POSTER #56**

**Clinical interventions: cost savings impact**

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**Background:** Specialty pharmacies dispense high cost, high complexity medications for a variety of conditions including autoimmune diseases, hematologic and solid tumor cancers, hepatitis C, and some rare diseases. While the impact of clinical pharmacy interventions has been described in other settings, there is little data quantifying the impact of clinicians on specialty pharmacy patients.

**Objective:** To determine the frequency and extent of cost savings or avoidance associated with clinician interventions via a specialty pharmacy reporting tool.

**Methods:** This is a retrospective case series utilizing intervention data collected via a specialty pharmacy reporting system from 1 August 2020 to 31 July 2021. Patients included in initial data collection were required to have a completed, documented intervention during the study period in one of the following categories: prescription changes, adverse drug event management, dose verification, interaction management, financial assistance, prevention of hospitalization or emergency room visit, and other interventions associated with potential cost savings as identified by the performing clinician. Raw data from each intervention category was reviewed to identify trends and cost saving or avoidance associated with clinician interventions via a specialty pharmacy reporting tool.

**Results:** A total of 21,061 potentially cost saving or avoiding interventions were completed by specialty pharmacy clinicians over the study period. Clinicians reported between 1453 and 1883 interventions in the categories of interest per month over the study period. Included in the final analysis were 5 cost saving categories: quantity decreased, DAW change and/or lower cost alternative, dose change, dose verification resulting in a prescription change, and other clinician identified cost saving interventions. A total of 920 of these interventions were reviewed yielding an average cost savings of $6099 per intervention with a total cost savings over the study period of $5.61 million. The estimated cost avoidance over the study period was $4.05 million from 1948 interventions in the following categories: adverse drug event management, interaction management, and hospitalization or emergency department visit prevention. The total combined cost savings and avoidance estimated over the study period for the 2868 interventions reviewed was $9.66 million.

**Conclusion:** Based on clinician reporting, some specialty pharmacy clinical interventions are associated with cost savings and cost avoidance. Future studies are needed to assess true frequency, cost savings or cost avoidance, and clinical impact of these interventions on a wider scale.

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**Category:** Outcomes (Cost or Other).

**Work submitted elsewhere:** ASHP Midyear Clinical Meeting 2021.

**POSTER #57**

**Dashboards for clinical outcome measure reporting**

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**Background:** The need to create standardized collection methods for defined clinical outcomes measures (COMs) is an identified requirement and developing area in health system specialty pharmacy (HSSP). As we begin to understand which key COMs demonstrate positive patient impact across various disease states and the value they hold to key stakeholders, it becomes imperative that there is a method to standardize the reporting of this data in a consistent and actionable way. To accomplish this, Trellis Rx has implemented clinical dashboards that reflect key identified COMs defined in disease state-specific protocols at our partner health systems.

**Objective:** Illustrate the importance of how HSSP services incorporate clinical dashboards into the workflow optimizes patient care and outcomes measures reportability.

**Methods:** Disease state-specific clinical protocols defining key COMs were put in place between 2019 and 2021 across Trellis Rx’s partnering health systems. These COMs were defined and identified through literature review, specialty pharmacy organization recommendations, and internal development within clinical subcommittees. Once defined, dashboards were created that could measure appropriate collection, patient improvement, out-of-range values, patient-reported outcomes, and patients requiring intervention.

**Results:** Across all disease states, the dashboards resulted in consistent tracking of patient outcomes data. They allowed us to target patients that did not meet the goal for extra follow-up and investigation. A few key results included: Oncology-87% rate of 14-day post-therapy initiation, HCV-80% SVR12 return rate, HIV-96% undetectable viral loads, Inflammatory Bowel Diseases-95% quality of life measure collection, Multiple Sclerosis-97% of
patients in controlled status, Rheumatoid Arthritis, Ankylosing spondylitis, and Psoriatic Arthritis- 99% RAPID3 collection, Diabetes Mellitus- >2 point decrease in A1C, and Migraine- >3-day reduction in migraine days/month.

Conclusion: This project describes the importance of reporting and monitoring COMs using disease state-specific dashboards. This data reporting framework is critical to optimizing patient care, confirming clinical goals and metrics are achieved, and ensuring the accurate reporting of outcomes data. It provides meaningful information to share with key stakeholders and is essential to accurately track benchmark data to further standardize care in the specialty pharmacy space.

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Category: Outcomes (Cost or Other).

POSTER #58

Specialty pharmacy integration impact on fill time

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Background: The time from ordering an oral oncolytic to patient receipt of product can be a source of angst for both patient and prescriber hoping to avoid delays in treatment. Previous studies report a median time to access oral oncolytics ranging between four to twelve days. The factors that contribute to the lag between prescription writing and patient access include prior authorizations, financial toxicity, pharmacy review, and delivery time. Health System Specialty Pharmacies (HSSPs) are uniquely positioned to overcome these barriers. Parkview Health established an integrated specialty pharmacy model to streamline and improve the process for patients in need of oral oncolytics.

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

Methods: This retrospective comparative time-series analysis measures the access time of oral oncolytics for patients, before and after the integration of a health system specialty pharmacy at a genitourinary oncology clinic. Access time being defined as the difference in business days between a new order and patient receipt of the ordered product. The integrated specialty pharmacy completed prior authorizations, addressed financial barriers, completed chemotherapy education, and either dispensed the therapy or triaged to the in-network specialty pharmacy. A secondary endpoint compared the access time of patients filling an oral oncolytic at the HSSP versus an outside pharmacy.

Results: 80 were identified who had started an oral oncolytic prior to the health-system specialty pharmacy integration. Their median access time was 7 business days. 82 patients were identified who had started therapy after integration. Their median access time was 5 versus 9 business days for outside specialty pharmacies, resulting in a 43% reduction in access time post HSSP integration. The median access time when dispensing through the HSSP was 5 versus 9 business days for outside specialty pharmacies, resulting in a 43% reduction.

Conclusion: The integration of a HSSP resulted in a 15% reduction in patient access time, demonstrating the enormous impact HSSP can play in avoiding delays to therapy. Furthermore, this study demonstrates the importance of filling with the integrated HSSP as demonstrated by the 43% reduction in access time in patients filling internally.

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Category: Outcomes (Cost or Other).

POSTER #59

Pharmacist impact in a multiple sclerosis clinic

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Shields Health Solutions

Background: Multiple sclerosis (MS) is a complex, neurodegenerative disease affecting the central nervous system. To delay disease progression in MS, patients are treated with disease modifying therapies (DMT). Prompt treatment initiation is essential as therapy delays can lead to poor patient outcomes. Ambulatory care pharmacists (ACP) are equipped to support intricate medication management for MS patients.

Objective: The objective was to demonstrate the ACP impact in facilitating MS medication access on prior authorization (PA) turn-around-times (TAT), medication appeal and PA approval rates, and clinic satisfaction scores.

Methods: A retrospective observational study compared PA TAT and appeal/PA approval rates in NY health system-based (HSB) MS patients from 10/1/2021 to 3/31/22 to those rates six months prior to implementation of an ACP (4/1/2021–9/31/2021). Only patients on a DMT or the following medications were evaluated: dextroamphetamine þ amphetamine, modafinil, Emmgality, lisdexamfetamine, and methylphenidate. PA requests were placed into the Shields database where timely status updates were recorded. For denied PAs, the ACP formulated an appeal or performed peer-to-peer review. The following data was analyzed for pre and post implementation periods: percentage of PAs/appeals approved and PA TAT, medication appeal and PA approval rates, and clinic satisfaction scores.

Results: A retrospective observational study compared PA TAT and appeal/PA approval rates in NY health system-based (HSB) MS patients from 10/1/2021 to 3/31/22 to those rates six months prior to implementation of an ACP (4/1/2021–9/31/2021). Only patients on a DMT or the following medications were evaluated: dextroamphetamine þ amphetamine, modafinil, Emmgality, lisdexamfetamine, and methylphenidate. PA requests were placed into the Shields database where timely status updates were recorded. For denied PAs, the ACP formulated an appeal or performed peer-to-peer review. The following data was analyzed for pre and post implementation periods: percentage of PAs/appeals approved and PA TAT, medication appeal and PA approval rates, and clinic satisfaction scores.

Results: Since the incorporation of an ACP within a NY HSB MS center, total PA TAT decreased by 1 day and both PA and appeal approval rates increased by 23 and 12.5%, respectively. Results of the clinic survey, to which 11/14 individuals responded, demonstrated overwhelmingly positive feedback to the ACP service. Specifically, 100% of respondents found PA and appeal assistance the most impactful, followed by patient counseling and drug information resource (90%), and assistance in pharmacy prescription clarification (63.6%). All staff members who completed the survey would enhance ACP integration with 70% specifically requesting more teach appointments and incorporation into clinical initiatives.

Conclusion: The incorporation of an ACP into a NY HSB MS center has shown to increase PA and appeal approval rates, improve PA TAT, and increase clinic satisfaction.
Category: Outcomes (Cost or Other).

POSTER #60

Hepatitis C linkage to care initiative

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Background: In 2019, the American Association for the Study of Liver Diseases (AASLD) – Infectious Diseases Society of America (ISDA) updated their guideline recommendations advocating for a multidisciplinary team of providers involved in the treatment of Hepatitis C virus (HCV), to increase access to care. This reframing of the HCV care continuum has compelled innovative practice models for clinical pharmacists. The current wait time for HCV treatment can take 6–12 weeks or longer from the time of provider referral to a gastroenterology appointment for HCV treatment consideration, resulting in delayed labs and therapy starts. Health system specialty pharmacies (HSSP) can bridge this gap by prescribing HCV treatment through collaborative practice agreements (CPAs).

Objective: Evaluate the impact of a HSSP CPA by decreasing the time to the start of treatment for HCV access to care.

Methods: This is a single-center, retrospective chart review from January 2021 to December 2021, comparing the average time from referral to treatment start date of patients that did or did not receive pharmacist-prescribed treatment from the HSSP.

Results: Forty-five patients were identified as receiving HCV treatment services at the specialty pharmacy for assessment. All patients had labs ordered and screened prior to therapy start. A total of 12 patients that received a referral to the HSSP-managed CPA program were assessed and received prescribing, monitoring, and dispensing services for Hepatitis C medication by our HSSP pharmacists. In comparison, 33 patients only received monitoring and dispensing services at the HSSP. The referral to start date decreased by 30% for HCV treatment for HSSP CPA patients versus non-CPA prescribed patients.

Conclusion: HSSP CPA patients receiving HCV treatment had a referral to start date more than 28 days faster than non-CPA prescribed patients. HSSP CPAs play a pivotal role in decreasing the treatment start times for HVC access to care, closing a current gap in the care of HVC patients who otherwise have to wait longer for treatment.

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Category: Outcomes (Cost or Other).

POSTER #61

Oral oncolytics: adherence, cost and utilization.

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Background: Usage of cycled oral oncolytics (COO), where dosages vary per monthly supply, warrant a discontinuation approach to measuring adherence.

Objective: To identify significant associations between COO discontinuation and total medical cost and hospitalizations.

Methods: We used a retrospective cohort design with commercially insured patients from the MarketScan Commercial Claims and Encounters database from 2017 to 2019. Discontinuation was defined as a gap in medication supply greater than 1.5 times the last days’ supply in the last 6 months of 2018 or 2019. The measure was generated among patients using 8 generic products in 6 therapy classes as a single therapy. Patient had to be at least 18 years; with cancer diagnosis and continuous enrollment and initiating COO prior to last 45 days of year; and excluded for indications of death, hospice care, or transplants. Repeated measures were used to model differences in year-over-year total medical costs, or in 2019 to model odds of hospitalization. Discontinuation was treated as binary or continuous (covered days until first discontinuation), along with ten model covariates.

Results: A total of 4872 patients in 2018 met sample criteria, and 1534 of these patients also met criteria for 2018–2019. In 2018, 25.6% of patients had a discontinuation, and in 2018–2019, 23.3% of patients had a discontinuation in either year. Discontinuation in 2018 was significantly lower in the northeast region of the United States, with mail order pharmacy and with higher provider ratios; but significantly increased with new to therapy and hospitalization events. For 2018–2019, total medical costs significantly decreased across years ($12,757, p < .0006); but significantly increased for discontinued patients in 2018 compared to others (p < .0001, $50,558) and over time (p < .0002, $12,289); patients who discontinued in 2019 had higher estimated costs (p < .002, $23,080). Odds of hospitalization in 2019 were significantly associated with high discontinuation in 2019 (OR = 2.32, p < .0001) and inversely associated with longer medication coverage in 2018 (OR = 0.66 at <61 days compared to OR = 0.51 at 150+ days, p < .02). Other significant covariates are presented in poster per model.

Conclusion: Fewer gaps in medication coverage on COO can lead to lower short-term and longer-term mean medical costs and odds of hospitalization.

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Category: Outcomes (Cost or Other).
Integrated specialty model lowers pharmacy expense

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Background: Specialty drugs contribute disproportionately to costs, representing greater than 50% of pharmacy spend. Integrated Health-System Specialty Pharmacies (HSSPs) have shown improved outcomes and lower medical expenses yet are largely excluded from restricted drug and payer networks. A group of HSSPs implemented a comprehensive patient care model for several specialty disease states. A previous analysis of a national health insurer’s de-identified claims database demonstrated that the HSSP group was associated with significantly less total medical expense among the population of patients filling self-administered oncology drugs.

Objective: To evaluate pharmacy and medical expenses among non-oncology specialty pharmacy patients in a HSSP group care model versus a national Network.

Methods: A national health insurer de-identified database of 36 million Medicare Advantage members was used to identify patients filling self-administered specialty medications for HIV, cardiovascular conditions, multiple sclerosis (MS), inflammatory conditions, and transplant from 2018 to 2019. The HSSP group included members enrolled in the specialty care model who filled at the participating HSSP group pharmacies with prescribers integrated into the care model and was compared to Network members using pharmacies in the same geographic area. The primary outcome was mean per member per month (PMPM) total medical and pharmacy costs, and secondary outcome was mean healthcare utilization per member per year (PMPY).

Results: The 76 HSSP group members had a $903 PMPM reduction in pharmacy expense compared to the 6,136 Network members ($3,875 vs. $4,778, respectively; p = .05). Total medical expense was greater with the HSSP group than the Network ($4,345 vs. $3,908, respectively; p = .38). The number of ER visits PMPY was significantly lower with the HSSP group than the Network (0.3 vs 0.6, respectively; p < .01), while the number of outpatient and physician office visits PMPY were not significant between groups.

Conclusion: The HSSP care model within a population of HIV, cardiovascular, MS, inflammatory, and transplant patients was associated with significantly less pharmacy expense with a small but non-significant increase in total medical cost. By contrast, the previous analysis of oncology patients managed within a HSSP group demonstrated significantly lower total medical expense with a slight increase in pharmacy expense when compared to the network group. Future research is needed to gain insight into these differences.

Pharmacy model impact on HIV PrEP persistence

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Background: Persistence to HIV pre-exposure prophylaxis (PrEP) during times of increased HIV acquisition risk is integral to preventing new HIV infections. Previous studies have shown real-world PrEP persistence is low and additional insight is needed into PrEP delivery strategies that improve persistence.

Objective: The objective of this study is to measure persistence to HIV PrEP in patients filling through an integrated health-system specialty pharmacy (HSSP) compared to those filling at an external pharmacy.

Methods: We conducted a single-center, retrospective, cohort study comparing HIV PrEP persistence in patients with prescriptions filled by an integrated HSSP to those with prescriptions filled by an external pharmacy. Adult patients initiating tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) in the Vanderbilt PrEP Clinic between 9/1/2016 and 3/31/2019 were included. Data were gathered from the electronic health record. Persistence at 6, 12 and 18 months was reported using time from first prescription sent to last prescription sent plus prescription days’ supply or date of reported medication discontinuation. Reasons for non-persistence were categorized as lost to follow up, medication discontinuation, and transfer of care. The Kaplan-Meier estimation method was used to estimate the probability of remaining persistent, stratified by whether the patient filled with the HSSP. Difference in Kaplan-Meier curves was tested using the log-rank test. The primary outcome was time to non-persistence, which was modeled using the Cox proportional hazards (PH) regression method with the following covariates: pharmacy used, age, reported condom use, and reported number of sexual partners in the past 6 months.

Results: Patient characteristics were similar between the groups. Patients with prescriptions filled by the HSSP had a significantly higher probability of remaining persistent to therapy when compared to patients filling at an external pharmacy. Persistence probability at 6, 12, and 18 months for patient filling with the HSSP was 0.87 (95% CI 0.79–0.95), 0.75 (95% CI 0.66–0.86), and 0.64 (95% CI 0.53–0.76) compared to 0.65 (95% CI 0.51–0.83), 0.41 (95% CI 0.28–0.62), and 0.32 (95% CI 0.2–0.53), respectively, for those filling with an external pharmacy. The Cox PH model showed that patients using an external pharmacy were 2.7 times more likely to be non-persistent than HSSP patients (HR 2.7, 95% CI 1.6–4.7, p < .001). We observed a nonlinear association between age and the outcome, with younger patients being more likely to discontinue than older patients, with the trend leveling off at roughly 40 years of age (2 degree of freedom test of association p < 0.001). No association was observed between either patient-reported condom use or patient-reported number of sexual partners in the last 6 months and likelihood of non-persistence. Rate of discontinuation was higher in patients using an external pharmacy (50 vs 39%); however, reasons for discontinuation were similar in the two groups with perceived lack of risk being reported most often (50% non-HSSP and 73% HSSP).

Conclusion: Patients receiving PrEP treatment in a multidisciplinary clinic with prescriptions filled by the integrated HSSP had...
significantly higher rates of persistence and fewer discontinuations. These findings demonstrate that patients were better maintained on PreEP therapy when their prescriptions were filled with the HSSP compared to external pharmacies, thus highlighting the role HSSPs can have in ending the HIV epidemic.

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Category: Outcomes (Cost or Other).
Work submitted elsewhere: Persistence to hiv pre-exposure prophylaxis filled through an integrated health-system specialty pharmacy compared with external pharmacies, APhA, March 2022

POSTER #65
AEs and modifications in patients starting a PARPi

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Background: Poly (ADP-ribose) polymerase inhibitor (PARPi) therapy is used to treat various cancers, but patients often encounter frequent and challenging adverse events (AEs) in the first several months after initiating therapy that may lead to treatment modifications.

Objective: The primary objectives of this study were to identify the type and frequency of AEs in patients initiating PARPi therapy for cancer treatment and the corresponding rate of treatment modifications (hold, dose reduction and discontinuation) related to an AE. The secondary objective was to measure adherence to PARPi therapy.

Methods: This was a single-center, retrospective analysis of adult patients initiating PARPi therapy from November 2017 through October 2019 and receiving medication from the center’s specialty pharmacy or the PARPi manufacturer. Patients receiving PARPi therapy for a non-Food and Drug Administration approved use or participating in a clinical trial were excluded. Data was collected from the time of PARPi initiation through first 90 days of treatment. Patient demographics, clinical disease characteristics, AEs, and treatment modifications (hold, dose reduction, and discontinuation) were collected from the electronic health record. Prescription, insurance, and financial data were extracted from the specialty pharmacy databases. Proportion of days covered (PDC) was used to calculate medication adherence. To account for medically advised dose interruptions, PDC was adjusted by subtracting interrupted days from the denominator of the PDC calculation.

Results: We included 28 patients, 96% female and 82% white with median age of 62 years (interquartile range [IQR] 53–72). Median disease duration was 1.8 years (IQR 1.4–3.6) and median number of previous chemotherapy regimens was 2 (IQR 2–3.5).

Olaparib was the most commonly prescribed PARPi therapy (n = 25, 89%), most frequently for ovarian cancer (n = 21, 84%). Among all PARPi therapies during the first 90 days of treatment, most patients experienced at least one AE (all grades), most commonly fatigue (n = 13, 46%), nausea (n = 10, 36%), arthralgia/myalgia (n = 8, 29%), anemia (n = 8, 29%), and vomiting (n = 6, 21%). Due to an AE, 54% of patients had 1+ treatment holds and 43% required 1+ dose modifications. Five patients (18%) discontinued treatment due to either disease progression (n = 4) or AE (n = 1). Median time to discontinuation was 75 days (IQR 36–79). After adjusting for medically advised treatment holds, median PDC was 1 (IQR 0.96–1), indicating a high median medication adherence of 100%.

Conclusion: In patients initiating PARPi therapy, rates of AEs were similar to previous literature. Subsequent treatment modifications were common in the first 90 days; however, adherence to PARPi therapy was high. More research is needed to understand differences in safety profiles and AEs experienced across different PARPi therapies, indications, or lines of therapy and if improved AE management or prevention can reduce the need for treatment modifications. The subsequent prospective phase of this study will evaluate the integrated specialty pharmacist role in AE mitigation including patient education and providing supportive therapy.

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POSTER #66
RAPID-3 metrics for RA patients in specialty TM

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Background: Quality of life assessments are important tools for therapy management (TM) pharmacists to support Rheumatoid Arthritis (RA) patients taking specialty disease modifying antirheumatic drugs (sDMARDs) in determining therapy effectiveness. The Routine Assessment of Patient Index Data (RAPID-3) is validated for RA and consists of function, pain, and global domains. While the total score is often utilized, it is unknown whether domain scores may better inform TM pharmacist in understanding patient needs.

Objective: This study examined total RAPID-3 and domain-specific changes among RA patients by baseline disease severity classes (near remission, low, moderate, high severity).

Methods: This was a retrospective cohort of RA patients presenting to a specialty pharmacy for sDMARD therapy from 8/2018 to 7/2021. Patients were included if they were new to the pharmacy or sDMARD, had ≥1 RAPID-3 measured within the first 30-days and ≥1 RAPID-3 recorded within 3-12 months following TM
Patients receiving biologic therapy for the management of inflammatory bowel disease (IBD) often require dose escalation to counteract loss of response and/or low drug levels. However, dose escalation usually requires completing a complex insurance approval pathway, including prior authorization. Previous research has demonstrated that the insurance pathway can delay time to biologic initiation.

**Objective:** The objective of this study was to evaluate the impact of time to insurance approval on disease activity.

**Methods:** We performed a retrospective cohort analysis of patients prescribed biologic therapy from the Vanderbilt University Medical Center outpatient Inflammatory Bowel Disease (IBD) clinic from 1 January 2018 through 31 December 2018. Adult patients were included if they were prescribed a higher dose of self-injectable biologic therapy than was approved for labeling by the Food and Drug Administration (FDA) at the time. Patient and clinical data was collected from the electronic health record and prescription insurance pathway and dispensing data were collected from pharmacy software (AtlasRx and EnterpriseRx). The primary outcome was C-reactive protein (CRP) at follow-up, defined as the first measurement after 45 days following a decision to escalate dosing. The secondary outcome was patient-reported disease activity evaluated using Harvey Bradshaw Index (HBI).

**Results:** Of 227 patients reviewed, 114 patients with relevant outcome data were included. Half of patients were female (53%), most were white (96%), with an average age of 40 years (standard deviation = 14). Adalimumab 40 mg weekly (37%) and ustekinumab 90 mg every 6 weeks (44%) were the most commonly prescribed biologic dosing regimens. Mean time from decision to escalate dose to insurance approval was 11.1 days (SD = 20.9). Median CRP prior to dose escalation was 4.2 mg/dL (interquartile range [IQR] 1.3–9.7). Follow-up median CRP, evaluated at a median of 92 days (IQR 72–119) after dosing regimen change, was 4.5 mg/dL (IQR 1.4–9.8). Using multiple linear regression, a longer time to insurance approval significantly decreased the likelihood of CRP improvement (p = .019). Median HBI prior to requested dose change was 3 (IQR 1–7, n = 62). Follow-up median HBI, evaluated at a median of 95 days (IQR 89–118) after dose escalation, was 4 (IQR 2–6). Time to insurance approval did not have a significant impact on HBI.

**Conclusion:** Longer time to insurance approval of a higher biologic dosing regimen was associated with an increase in CRP in at least 45 days after the decision to escalate dose, suggesting the longer time to approval, the less likely to see an improvement in CRP. This highlights that the complex dose escalation process of biologic therapy can negatively impact clinical outcomes.

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