



RESEARCH PRESENTATION ABSTRACTS

September 14-18, 2020

Published as a supplement to the Journal of Drug Assessment
An Official Journal of the National Association of Specialty Pharmacy

Journal of Drug Assessment

2020 National Association of Specialty Pharmacy Annual Meeting & Expo: Research Presentation Abstracts

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Special Issue: Abstracts from the Eighth Annual National Association of Specialty Pharmacy (NASP) Meeting

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INTRODUCTION



2020 National Association of Specialty Pharmacy Annual Meeting & Expo: research presentation abstracts

Richard A. Brook^{a,b} and Sheila Arquette^b

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The National Association of Specialty Pharmacy (NASP) is hosting its 2020 Annual Meeting & Expo September 14–18, 2020. Due to the COVID-19 pandemic and concern for the health and well-being of conference attendees, NASP made the decision to pivot from hosting the conference as a live event to presenting it as a virtual experience. Utilizing innovation and cutting-edge technology, NASP promises a full-scale virtual experience that is the next best thing to being there.

The virtual experience conference agenda includes five pre-conference workshops and 26 unique educational sessions organized into four dynamic **CORE** tracks: **C** – Clinical; **O** – Operational; **R** – Regulatory; and, **E** – Specialty Experience. The conference also features keynote speakers, an interactive virtual exhibit hall, continuing education satellite symposia, industry awards and recognition, and poster presentations.

The poster presentation program provides an interactive forum to showcase research related to specialty pharmacy products and services. NASP has partnered with the *Journal of Drug Assessment*, an official journal of NASP, to publish the accepted abstracts as a journal supplement, further demonstrating NASP's commitment to academic literature and the value of complex research. Abstracts are subject to a blinded review by NASP volunteers. This year, 33 abstracts were accepted for presentation, with 45% showcasing research related to the delivery of specialty pharmacy products or services, 24% on adherence, 21% on outcomes studies, and the final posters focusing on COVID-19 products or services. Research on multiple sclerosis, hemophilia, hepatitis C, HIV, hyperkalemia, osteoporosis, post-transplant immunosuppression, rheumatologic conditions, and conditions treated with oral oncolytics were represented. In addition to the information published in this supplement, which is available at www.tandfonline.com/toc/ijda20/current, the NASP website hosts copies of abstracts and posters from prior years. To access, please visit www.naspnet.org/abstractsposters.

NASP is a 501(c)(6) nonprofit trade organization and the only nonprofit national association representing all stakeholders in the specialty pharmacy industry. The mission of NASP is to elevate the practice of specialty pharmacy by

developing, delivering, and promoting continuing professional education and specialty certification while advocating for public policies that ensure patients have appropriate access to specialty medications in tandem with critical services.

NASP provides an online education center offering 50+ accredited continuing pharmacy education programs, hosts an annual meeting that offers education sessions and continuing education credits, actively engages in federal and grassroots advocacy efforts on behalf of its multi-stakeholder membership, and is the only organization that offers a certification program for specialty pharmacists.

NASP members include the nation's leading independent specialty pharmacies, pharmaceutical and biotechnology manufacturers, group purchasing organizations, patient advocacy groups, integrated delivery systems and health plans, technology and data management vendors, wholesalers/distributors, and practicing pharmacists, nurses, technicians, and students. With over 125 corporate members and 1,800 individual members, NASP is the unified voice of specialty pharmacy in the United States. To learn more, please visit www.naspnet.org.

Specialty Pharmacy's comprehensive, coordinated, and patient centric model is integral to patients achieving a successful treatment outcome. Specialty pharmacies connect patients who are severely ill with the medications prescribed for their conditions. However, the provision of the drug itself is simply transactional. The value of a specialty pharmacy is directly related to the patient management and product support services provided and patient interaction necessary to maximize the patient's chances of achieving a successful outcome. Specialty pharmacy was perfectly positioned to respond to the challenges posed by the COVID-19 pandemic, able to support shelter in place requirements, and effectively manage patients remotely due to their established business model, technological infrastructure, and patient management and fulfillment capabilities. As we learn more about this novel coronavirus and new formulations of specialty drugs are explored as potential treatment options, NASP members will continue to play a vital role in the management of our most vulnerable patients.

Access to direct acting antiviral therapy for recipients of solid organs from hepatitis C-viremic donors

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ABSTRACT

Background: Emerging data supports the transplantation of organs from hepatitis C-positive (HCV) donors into HCV negative recipients to expand the donor pool. Access to HCV direct-acting antivirals (DAAs) has been cumbersome and expensive for use in patients seeking approval for on-label indications through insurance and assistance programs. Access has not been well described in the donor derived-HCV (dd-HCV) solid organ transplant (SOT) population where off label use has been more common.

Objectives: Evaluate HCV DAA prescription access, cost, timing, and barriers to the first dose (FD) in patients with dd-HCV infection post heart, kidney, lung, or liver SOT in the real-world, standard practice.

Methods: We conducted a retrospective review of all patients prescribed DAAs at our center following dd-HCV SOT between October 2016 and July 2019. Our on-site specialty pharmacy (SP) managed the DAA access process for all patients. We collected dates of transplant, DAA request, approval, and FD. Univariate proportional odds logistic regression assessed whether the length of time from DAA request to FD was associated with insurance type, insurance appeal, pharmacy location, transplant type, or off-label use.

Results: There were 91 patients in the study period (54% private insurance; 46% ledipasvir/sofosbuvir, 41% glecaprevir/pibrentasvir, 13% velpatasvir/sofosbuvir; transplant types: 52% heart, 30% kidney, 11% liver, 2% lung, 5% dual organ). All accessed DAA therapy: 97% insurance, 3% assistance programs. Among 88 insured patients, 65% had DAAs approved on initial prior authorization (PA) while 35% required an appeal. Common PA denials were the absence of chronic HCV diagnosis (42%) and request for more than 8 weeks of therapy (36%). Median time from SOT to DAA request was 28 days [IQR 18.5–41.5], DAA request to approval was 6 days [IQR 4–12] and approval to FD was 8 days [IQR 6–12.5]. Private insurance, first fill at an off-site SP, non-kidney transplant, and need for insurance appeal were all associated with significantly longer time from DAA request to FD, but off-label use was not. Of the 63 patients who filled DAA therapy at our center's on-site SP, 49% used copay assistance, reducing average monthly out-of-pocket costs from \$2003 [range \$7–7536] to \$2 [range \$0–5].

Conclusions: Access to outpatient DAA therapy in dd-HCV post-solid-organ transplant patients is achievable and affordable. The use of an on-site specialty pharmacy is associated with a significantly shorter time to the first dose.

Previous presentation: American Transplant Congress Annual Meeting, May 2020

POSTER #2

Assessing interventions to improve patient care conducted by pharmacists at an outpatient renal transplant clinic within a collaborative pharmacy practice agreement

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ABSTRACT

Background: A collaborative pharmacy practice agreement (CPPA) permits pharmacists to perform clinical services under the guidance of a supervising physician without direct physician intervention. A CPPA has been in use within the Vanderbilt Renal Transplant Clinic since March 2017.

Objective: We aimed to quantify and categorize interventions performed by two clinical pharmacists with a CPPA at an academic renal transplant clinic and determine the impact of interventions on patient care.

Methods: Clinic notes were reviewed to collect pharmacist interventions (defined as an encounter with one or more actions to improve patient outcomes), performed between 1 January 2019 and 30 June 2019, for adult patients prescribed immunosuppressant or non-immunosuppressant medication. Interventions were categorized by type (medical record assessments, medication counseling, or the resolution of barriers to medication continuation), then further classified into subcategories. The number and type of interventions performed were summarized with frequency distributions. We also calculated the number of prescription orders entered by the clinical pharmacists during this time.

Results: During the 6-month window, clinical pharmacists under a CPPA placed 5793 prescription orders and performed 1821 clinical chart reviews for 1233 patients. Five percent of all orders were audited by the attending physician with a zero percent error rate. Within all clinical chart reviews, 3852 interventions were performed: 2695 medical record assessments, 734 medication counseling, and 423 resolutions of barriers to medication continuation.

Conclusions: Pharmacists practicing under a CPPA were able to reduce provider burden and improve patient care by managing the prescribing of transplant medications. The most common intervention performed was medical record assessment, which facilitates the prescribing of appropriate medication and dosage. Pharmacist interventions ensured treatment adherence and persistence in patients that were evaluated.

Previous presentation: Virtual Presentation at AMCP 2020 – Assessing Interventions to Improve Patient Care Conducted by Pharmacists at an Outpatient Renal Transplant Clinic within a Collaborative Pharmacy Practice Agreement

POSTER #3

Assessing rates and reasons for treatment lapses in patients treated with denosumab

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ABSTRACT

Background: Denosumab is a subcutaneous injection administered in the clinic every six months for patients with osteoporosis at high risk of bone fracture. Reasonable interruptions to therapy include dental procedures, fractures from trauma, infections, and certain adverse effects. Little research has explored rates and reasons for lapses in denosumab therapy in real-world settings.

Objectives: To assess the reasons for treatment lapses in patients taking denosumab and discuss potential interventions to aid in adherence.

Methods: At a large academic medical center in the United States, we conducted a retrospective review of adult patients who received ≥ 2 denosumab injections between January 2010 and December 2018. Patient demographics and treatment dates were collected from electronic medical records. We calculated how many patients had a lapse in therapy defined as 240 or more days between injections (excluding lapses due to death, transfer of care, temporary medication change, or patient discontinuation of therapy). Reasons for lapses were collected and categorized. Logistic regression was used to test whether the occurrence of lapse was associated with patient race, smoking status, sex, BMI, or age.

Results: We included 534 patients: 86% female, 95% White, mean age 69 years. After starting denosumab, 152 patients incurred a lapse, and 45 patients incurred multiple lapses, resulting in 252 treatment lapses. Reasons for lapses were: Adverse reactions, infections, illnesses, low calcium or vitamin D (42, 17%); Dental problems or procedures (40, 16%); Care coordination delays or logistical barriers (36, 14%); Appointment cancelation or no-show without reason (29, 12%); Fractures, surgeries, research enrollment, or hospital admission (13, 5%); Financial, billing, or insurance problems (12, 5%); Patient decision (6, 2%); or Other reasons (16, 6%). No reason was documented for the remaining 58 lapses (23%). In logistic regression, no characteristics were associated with lapse occurrence (p-values >0.05).

Conclusions: Treatment lapses were common, often for medically minded reasons to reduce the risk of adverse effects or increase the likelihood of successful outcomes. Some lapses could be prevented by pharmacist intervention or care coordination to help patients navigate logistical or financial barriers. More work is needed to identify patients at risk for treatment lapses and to develop patient-centered interventions to promote higher adherence to osteoporosis therapy.

Previous presentation: Gipson HM, Gregory WT, Chakrabarti A, DeClercq J, Choi L, Peter M. Assessing rates and reasons for treatment lapses in patients treated with denosumab. Poster presented to the American Society of Health-Systems Pharmacists Midyear Clinical Meeting and Exhibition, Las Vegas, NV. December, 2019

POSTER #4

Assessing reasons for primary medication non-adherence in oncology specialty medications

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ABSTRACT

Background: Primary medication non-adherence (PMN), the rate at which a prescription is written, but never obtained by the patient, is an increasingly common metric to assess quality for specialty pharmacies. However, reasons for PMN are complex and may not be captured to accurately calculate PMN based on pharmacy claims.

Objectives: Identify the rates and reasons for PMN in patients prescribed specialty oral oncolytics.

Methods: Single-center, retrospective cohort analysis of patients prescribed a specialty oral oncolytic agent by a Vanderbilt University Medical Center provider and whose prescription was sent to Vanderbilt Specialty Pharmacy from January to December 2018. Data for all oncolytic agents within the index period were extracted from the electronic medical record and pharmacy claims database and assessed for PMN eligibility. Prescriptions were eligible for PMN if the following criteria were met: no fill of any oncology medication within a 180-day lookback period and no duplicate prescription sent within 2 days of the original. If a prescription was rerouted to a different pharmacy within a 2-day window, the prescription was not considered to be an instance of PMN. PMN was then calculated by dividing eligible prescriptions not filled after 30 days (numerator) by all eligible prescriptions (denominator). Next, a chart review of identified patients with PMN was performed to differentiate true PMN from misidentified PMN.

Results: 197 prescriptions were identified as potential cases of PMN. After chart review, 37 (19%) prescriptions met the criteria for true PMN. Rerouting a prescription to a different pharmacy (26.4%) and filling the medication through a patient assistance program (21.3%) were the most common reasons a prescription was falsely classified as PMN. The most frequent reason for true PMN was the patient's decision to not start therapy (32.4%), followed by the medication being changed (21.6%), patient clinically declining (16.2%), and the patient dying before fulfillment (10.8%).

Conclusions: Using a common PMN definition and clinical chart review, only a small portion of prescriptions represented true cases of PMN and most were due to external fills of the prescription. This finding highlights the importance of researching the cause of a prescription deemed as PMN and the limitation of using raw PMN as a quality metric for specialty pharmacies.

Previous presentation: ASHP Annual Meeting 2019

POSTER #5

Cost effectiveness study of hyperkalemia management

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ABSTRACT

Background: Patiromer (PAT) is a sodium-free, non-absorbed potassium (K+) binder approved for the treatment of hyperkalemia (HK). There is limited real-world evidence on the cost implications associated with the PAT treatment of HK.

Objectives: To assess the cost-effectiveness of treating HK with PAT vs. no K+ binder in a Medicare Advantage population.

Methods: This retrospective, matched cohort study was conducted using the de-identified Optum Clinformatics[®] Data Mart Database from 1 January 16 to 31 December 2018. Two HK cohorts were identified: PAT exposed and unexposed (NoPAT). Patient inclusion criteria: pre-index serum K+ ≥ 5.0 mEq/L and HK diagnosis (ICD-10 code) and ≥ 6 months insurance enrollment post-index. Propensity score matching and coarsened exact matching with baseline variables were used to identify the complete set of matching unexposed and exposed HK episodes. Follow-up began on index date and ended at the first censoring event (insurance disenrollment, death, 31 December 2018, sodium polystyrene sulfonate [SPS], or sodium zirconium cyclosilicate [SZC] initiation, PAT discontinuation [exposed only], PAT initiation [unexposed only]). Cost outcomes measured at 6 months post-index: total, inpatient, emergency department (ED), outpatient services, and outpatient pharmacy (mean US\$[CI 95%]).

Results: The study population was 2004 patients (1002 matched pairs). Overall, the mean age was 74 years and 60% were male. Patients had a mean of 5 comorbidities. Comorbidities included: diabetes mellitus (73%), chronic heart failure (35%), and end-stage renal disease (10%). At 6 months post-index, 300 (150 matched pairs) PAT and NoPAT patients remained uncensored. Total PAT mean cost difference (savings) of \$7220 (\$2211, \$9584) was observed at 6 months post-index ($p < 0.01$). This cost difference included a pharmacy increase of \$3094 (\$3964, \$2224) and a decrease in medical costs, specifically, inpatient \$4718 (\$2222, \$7215), outpatient \$4781 (\$2274, \$7288), and ED \$815 (\$488, \$1142).

Conclusions: At 6 months post-index, patiromer cohort observed a 27% reduction in cost compared with the unexposed cohort for HK management. Further study is warranted to replicate these findings in a large cohort.

Previous presentation: ACCP 2020 Virtual Poster Symposium

POSTER #6

Development of a rheumatoid arthritis patient management program

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ABSTRACT

Background: Routine disease activity assessment can improve the care of patients with rheumatoid arthritis (RA) and is recommended every 6 months to guide therapy. The RAPID 3 (R3) is a validated measure of RA disease severity recommended by the American College of Rheumatology and uses patient-reported outcomes allowing assessments to be completed remotely, which is ideal since Intermountain Specialty Pharmacy (ISP) is a closed-door pharmacy.

Objectives: Our objective was to develop and implement a disease activity management program for RA patients, run by a Specialty Pharmacy Service. This program would assess and evaluate disease activity over time using the R3.

Methods: This study used a prospective cohort design. Patients were identified through Enterprise Rx with a diagnosis code of RA, active RA medication within the previous 3 months, and ≥ 2 assessments. Patients were sent a letter along with their RA medication, informing them an ISP clinical staff member would be contacting them to complete a baseline R3 assessment. Follow-up assessment frequency and timing was based on disease severity. ISP collected R3 disease severity, resources shared referral to the provider, time spent counseling, and provider recommendations, and acceptance rate. Information on patient satisfaction with the program was also collected. Descriptive continuous variables were reported using average and standard deviation with the categorical variables reported as counts and percentages. Changes in continuous variables were measured with a paired student *t*-test with categorical measures using a McNemar's test, using Stata v14, and alpha =0.05.

Results: A total of 375 enrolled in the program, with 480 assessments completed and 214 patients having at least 2 assessments. The average age was 50 years, 60% female, duration of follow-up 214 days, and duration of disease 10.8 years. R3 score improved by 1.7 points ($p = 0.0014$). From baseline to follow-up there was an 8% improvement for near remission, 10% for low severity, 3% for moderate severity, and 2% for high severity categories ($p < 0.001$).

Conclusions: This program shows RA disease activity scores can be improved through the use of routine disease activity evaluation. The program was successfully developed and implemented by a Specialty Pharmacy, adding value to the patients as well as the Integrated delivery system. Limitations include data recording timing, the capture of information for patients unwilling to participate, and accounting for disease flares.

POSTER #7

Utilization of a network adherence dashboard and subsequent quality initiative to enhance adherence

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ABSTRACT

Background: Non-adherence and side effects challenges to specialty treatments can have an impact on morbidity, quality of life, and cost of care. A data reporting platform was created through which members of a national network of health system specialty pharmacies submitted data used for calculations such as adherence via the proportion of days covered (PDC). This systematic process of reporting PDC on a scheduled cadence allows specialty pharmacists to assess adherence dashboards on a regular basis and to make appropriate therapy changes such as addressing patient side effects challenges to therapy. One specialty pharmacy network member-reviewed PDC performance and found although the PDC was within a therapeutic goal, there was a trend toward decreased rates in the oncology and transplant therapeutic areas.

Objectives: Reviewer specialty pharmacists set out to understand the reasons for the declining PDC rates in oncology and transplant in order to inform the implementation of a quality improvement initiative to reverse the downward trend in PDC.

Methods: Investigation-Reviewed clinical pharmacist workflow and documentation around interventions in the oncology and transplant population to assess potential effects on adherence. Quality initiative-Results of investigation found that standardized workflows, systematic, and consistent documentation practices around interventions and ongoing education focusing on adherence was needed.

Results: After the implementation of the quality initiative we found an increase in the systematic documentation of interventions related to adherence factors. There were 92 total transplant clinical interventions completed in 12 months and 39% of those were associated with improving PDC mostly due to outcomes such as potentially improved therapy adherence and resolved side effect challenges. There were 613 total transplant clinical interventions completed in 12 months and 35% of those were associated with improving PDC mostly due to outcomes such as potentially improved therapy adherence and resolved side effects challenges.

Conclusions: A systematic process for reporting adherence led to a quality initiative that improved the understanding of prescribing practices, clinical pharmacist intervention documentation, development of a strategic side effect management process, education, and improved PDC reporting.

POSTER #8

Digital technology as a communication tool with pharmacy staff during COVID-19 pandemic

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ABSTRACT

Background: The COVID-19 Pandemic has resulted in rewriting the proverbial 'playbook' for all organizations. The information has been in a constant state of fluidity since the pandemic began and employees had to depend on a myriad of sources to keep themselves updated. At Yale-New Haven Health, an Incident Command System for Pharmacy was quickly established and the communication action team was tasked with consolidating messaging, providing frequent updates, and developing effective ways of reaching out to its nearly 900 pharmacy employees.

Objectives: The team adapted a multichannel approach to ensure employees are connected on and off the health system network. Email, manager communication, and weekly updates were established means of communication. Remote work/Work from home posed challenges with the current process. A new digital messaging tool was introduced as a solution.

Methods: Yale New Haven Health partnered with a mobile engagement firm that had the ability to proactively deliver 1:1 member experience. It works on the basic concept of clicking into a hyperlink in a text message which then takes the user to a customized, PHI enabled web message. Requirements for this program were phone master list and training on the software platform. An initial message was released with an address from the Chief Pharmacy Officer to all employees about COVID-19 response in an embedded video format. The subsequent weekly message included update communication, FAQs, and suggestions from employees regarding Employee Safety, Clinical and Drug Use Policy, Operations, Specialty & Retail, and staffing. Post message analysis conducted by the communication team was disseminated to section chiefs and then to all employees.

Results: Metrics and click percent for each section in the text were gathered as a means to identify the most relevant information for employees. The initial message had 914 successful deliveries with 63.35% click percent. Subsequent messages had lower click% as the multichannel communication strategy provided multiple avenues for information. Areas of improvement include communicating at the initial launch about the message not being spam and an updated master phone list.

Conclusions: Utilization of digital technology in the form of a text messaging tool during the Covid-19 pandemic was a pharmacy system effort to communicate important messages to all employees in a new interactive format. A transformation survey showed this method to be 3rd in the overall communication strategy for COVID-19. It was deemed successful as part of YNHHS Pharmacy Incident Command System's communication strategy and will continue to be utilized with refinements in content and cadence.

POSTER #9

Disease activity scores and medication adherence in university hospitals rheumatoid arthritis patients

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ABSTRACT

Background: Lack of objective metrics quantifying disease activity documented in the electronic medical record, thus not meeting clinical practice guidelines and recommendations from American College of Rheumatology for patient care, as well as CMS Criteria for reimbursement.

Objectives: The purpose of this study was to gain insight into the current level of disease activity in patients with Rheumatoid Arthritis (RA) seen in a University Hospitals Rheumatology Clinic. Routine Assessment of Patient Index Data (RAPID3) scoring was implemented within the clinic for capturing an objective disease activity score. The primary objective was to describe the level of patient's RA disease activity based on RAPID3 scores. Secondary objectives included: medication adherence, as measured by the proportion of days covered (PDC) for patients filling with University Hospitals Specialty Pharmacy (UHSP), determination if a correlation existed between adherence calculation and level of disease activity for patients filling with UHSP; and comparing the RAPID3 score of patients who filled their medication with UHSP compared to with RAPID3 scores of patients who filled elsewhere.

Methods: This was a retrospective chart review of adult patients with an ICD-10 code reflecting a diagnosis of rheumatoid arthritis. Inclusion criteria: treated with a disease-modifying anti-rheumatic drug (DMARD) and had a RAPID3 result recorded in the electronic medical record (EMR) between 1 March 2019 and 29 February 2020.

Results: A total of 203 RAPID3 scores met the inclusion criteria. Of those 203, 30 belonged to patients who filled their DMARD medication with UHSP. The majority of RAPID3 scores placed patients in high disease severity (60%). Only 17% of scores met the treat to a target goal of low disease activity or remission. With only 30 patients filling their DMARD medication with UHSP, it was hard to come to any conclusions, however, there was no correlation between PDC and disease activity in the patients we were able to capture.

Conclusions: Only 17% of RAPID-3 scores achieved the target of low disease activity or remission indicating a need for stronger clinical implementation of the treat-to-target approach for RA. Low overall number of patients filling with UHSP make it difficult to make any firm conclusions from the secondary objectives. Overall there was a low capture rate of RAPID3 scores within the RA population, indicating an increased RAPID3 capture rate is needed.

Previous presentation: Ohio Pharmacy Residency Conference (May 2020)

POSTER #10

Dose optimization strategies for two specialty infusion medications lead to significant cost savings

Poster withdrawn by the authors

POSTER #11

Evaluating prescription outcomes for specialty agents used to treat dermatologic conditions: a quality improvement initiative

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ABSTRACT

Background: Patient access to high-cost specialty dermatology medications depends on the successful navigation of a cumbersome insurance approval process. Integrated specialty pharmacists are uniquely positioned to improve the efficiency and outcomes of this process.

Objectives: Evaluate specialty prescription outcomes, current time to specialty medication access, and pharmacist role in the insurance approval process.

Methods: This was a single-center, retrospective cohort study of treatment-naïve patients at least 18 years of age prescribed specialty therapy by the outpatient dermatology clinic serviced by the center's specialty pharmacy from 1 January to 30 June 2019. The primary aim was to evaluate prescription outcomes following provider decision to treat. Other data points included: time from decision to treat to insurance approval, treatment history, adequacy of objective clinical assessment documentation, and the need for additional pharmacist clarifications. Data was gathered from the electronic health record and pharmacy database.

Results: Of 78 prescriptions reviewed, 28 were included for the following medications: adalimumab ($n = 13$), apremilast ($n = 3$), dupilumab ($n = 5$), secukinumab ($n = 2$), and ustekinumab ($n = 5$). Reasons for exclusion were treatment-experienced ($n = 42$) and non-dermatology clinic prescriptions ($n = 8$). The mean age was 55 years, with 57% female and 86% Caucasian. Most patients had commercial insurance (64%). Treatment indications included atopic dermatitis ($n = 5$), psoriasis ($n = 18$), and hidradenitis suppurativa ($n = 5$). Of the 26 prescriptions requiring prior authorization, 96% were approved; median time from decision to treat to approval was 9 days (IQR 3 to 14 days). For 2 prescriptions, prior authorization wasn't pursued after the pharmacist identified that step therapy requirement had not been met. For 86% of prescriptions, the medication initiated was the provider's first choice. Fifteen prescriptions required additional clarification from the prescriber.

Conclusions: Pharmacist-driven management of the prior authorization process for dermatologic specialty medications can achieve a high rate of access; however, variability in clinical documentation necessitates further provider clarifications, which can increase time to medication approval.

Previous presentation: American Society of Health-System Pharmacists

POSTER #12

Evaluating reasons for medication discontinuations across specialty pharmacy therapeutic areas

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ABSTRACT

Background: Medically-integrated health system specialty pharmacies are uniquely positioned to track the reason for a patient's discontinuation of therapy. It is understood that common reasons patients discontinue therapy include ineffectiveness, adverse events, and managed care formulary restrictions. This real-world data can be used to better predict which therapies are likely to result in better adherence for individual patients.

Objectives: Because discontinuation rates vary by disease state, the primary objective of this study is to analyze the reasons for these discontinuations and develop targeted interventions that are specific to their respective drug and disease state to avoid unwarranted discontinuation.

Methods: This is a multi-center, retrospective, observational study across Trellis Rx partner health systems reviewing adult patients who received a specialty medication. Therapy discontinuations were assessed by stratifying reasons for discontinuation, medication, and patient diagnosis. Embedded pharmacists document therapy discontinuations in Trellis Rx's ArborTMspecialty pharmacy technology platform.

Results: Of 14,904 patients reviewed, 2,903 patients had a documented therapy discontinuation. Of the 19 discontinuation reasons identified, the most common reason was "therapy completion," and was primarily seen in Hep C patients. "Therapy change; ineffective" was the most common reason for discontinuation for patients on an oncology therapy, with a significant amount also due to "intolerable side effects." Patients with neurological disease were most likely to change therapy due to "ineffectiveness" or to change from the current regimen to a "newly approved drug."

Conclusions: We identified that therapy ineffectiveness and drug intolerance are disproportionately higher in patients receiving an oral oncology specialty medication. We believe that embedded health system specialty pharmacists can play a pivotal role in reducing discontinuation rates in this patient population through targeted patient outreach. Further interventional studies will be needed to assess how targeted pharmacist interventions can be incorporated into the medically-integrated health system specialty pharmacy model to lead to a reduction of discontinuation rates in patients on oral oncolytics.

POSTER #13

Evaluating the benefit of a medically integrated health system specialty pharmacy care model in treating rheumatologic diseases

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ABSTRACT

Background: Trellis Rx partners with health systems to offer medically integrated health system specialty pharmacy (HSSP) care to their patients. Our approach embeds pharmacists and liaisons alongside other providers, under the health system's brand, ensuring patients receive coordinated, high-touch support to improve outcomes. Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of three patient-reported measures the American College of Rheumatology (ACR) accepts as core data set measures in Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA): function, pain, and a patient global estimate of status.

Objectives: There are two different paths a patient can take under our care: clinical services only or clinical and dispensing services. The primary objective of this study is to compare the benefit of utilizing dispensing services alongside clinical services by measuring the overall disease severity of patients with RA or PsA. The data will also be analyzed to determine if any drug class, payor, demographic, or monetary trends correlated with disease severity in the population.

Methods: This will be a multi-center, retrospective, case-control study of adult patients with a diagnosis of RA receiving care from the HSSP from August 2018 to May 2020. We will administer RAPID3 tests to all adult patients with RA and PsA seen by rheumatology providers and assess that data, alongside demographic and medication administration data collected from the electronic health record (EHR).

Results: 1320 patient cases were reviewed, resulting in 198 patients with three or more data points. The change of RAPID3 from baseline to the first data point collected was 1.4 in patients who dispensed opt-in ($n = 38$) versus 0.8 in patients who dispensed opt-out ($n = 160$). Change in RAPID3 from baseline to most recent RAPID3 collected for patients who dispensed opt-in were 1.6 versus dispense opt-out of 1.2. After performing an analysis of the demographic, drug class, payor, and monetary trends the results were similar in that there was no one agent or class that showed a better cost or efficacy profile than any other.

Conclusions: When comparing outcomes of patients who opted to dispense through their HSSP versus an outside pharmacy, the HSSP produced 1.75 times better results in a change from baseline to the first collection of RAPID3 scores and 1.33 times better results in change overall. There is no evidence of superiority when comparing the medications head to head in this subset of data.

POSTER #14

Evaluation of an integrated health-system specialty pharmacy technician-driven 7 day post-transplant discharge telephonic follow-up

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ABSTRACT

Background: Patients discharged after organ or stem cell transplant are often naïve to specialty pharmacy utilization. As they are on multifaceted medication regimens with frequent changes based on lab monitoring and complex payer requirements, an explanation of services is paramount at discharge and follow up. The Wake Forest Baptist Health Specialty Pharmacy identified an opportunity for a technician-driven post-transplant call to review Welcome Packet contents, medication billing, and refills. This point of contact allows for addressing early dose changes, patient concerns, and offering pharmacist counseling.

Objectives: To evaluate the impact of a technician-driven 7 day post-transplant discharge call, focused on patient retention after initial dispense, assessment of the number of dose changes, and pharmacist interventions at the time of outreach.

Methods: A retrospective review was completed for all new kidney, pancreas, heart, and bone marrow transplant patients with documented 7 day post-transplant call between November 2019 and June 2020. Descriptive statistics were used to evaluate the retention rate, medication changes, and pharmacist interventions.

Results: During the study period 168 patients were identified and 157 were included in the analysis. On average patients were reached at 9.7 days post-transplant discharge. Kidney transplant patients comprised 85% of completed calls. The retention rate was positive with 85% of patients continuing to use the in-house specialty pharmacy. Payer restrictions were the main reason for the pharmacy change. Patients reported medication changes included 30% immunosuppression, 33% infection prophylaxis, and 33% other therapies. There were 3% of patients requiring pharmacist intervention which consisted of 50% general concerns, 25% billing questions, and 25% adverse events.

Conclusions: Post-transplant discharge follow-up calls, conducted 7 days post-discharge by a pharmacy technician offered the opportunity to confer important pharmacy information and process specific medication-related changes. On average patients were reached 9.7 days post-transplant discharge and few required pharmacist interventions. Medication changes noted at this call enabled the advance opportunity to appropriately request new prescriptions. The majority of patients were able and willing to continue filling with the in-house specialty pharmacy.

POSTER #15

Evaluation of an integrated health-system's approach in facilitating at-home use of granulocyte colony-stimulating factors in the face of the COVID 19 pandemic

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ABSTRACT

Background: Studies have demonstrated high incidences of adverse events and death in cancer patients who are infected with COVID 19.^{1,2} Myelosuppressive chemotherapy regimens require patients to return to the clinic 24 h after chemotherapy to receive granulocyte colony-stimulating factors (GCSF), increasing viral exposure risk. At-home GCSF administration decreases healthcare interactions but challenges include high copays and potential delays in therapy due to outpatient pharmacy coordination.

Objectives: To describe a specialty pharmacy service (SPS) care coordination program designed to transition patients from medically billed on-site GCSF use to pharmacy billed at-home GCSF use during the COVID 19 pandemic and evaluate associated outcomes.

Methods: To decrease the number of face-to-face healthcare interactions related to on-site GCSF administration, the SPS and Levine Cancer Institute designed a process to complete pharmacy benefit investigations and prior authorizations (PAs), obtain financial assistance, and coordinate delivery to patients in a timely manner if filling internally. A quality review included patients prescribed GCSF between 23 March 2020 and 23 April 2020. Data was collected from the EMR and dispensing software. The rate of successful care transitions was calculated. Turn-around-time (TAT) was defined as the average number of business days between the written date of prescriptions to date of the outcome documentation (same day =0, next day =1). Finally, we assessed the values of copay cards and grants, as well as average copays of prescriptions filled through our service.

Results: 141 investigations and 115 PAs were completed. The average TAT for PA determination was 0.97 days. Of 137, 67% transitioned to SP dispense of GCSF through their pharmacy benefit. The remaining 33% were ineligible for copay cards and elected to receive GCSF on-site, to be billed through their medical benefit. The SPS average TAT for patient outreach was 0.78 days. Copay assistance was obtained for 34 patients for a combined value of \$470,000.00. The SPS average copay was \$4.67, 60% ($n = 30$) paid \$0.00, median copay = \$0.00.

Conclusions: Health-system SP services can deliver efficient benefit investigation and care coordination services when transitioning from on-site to at-home administration of GCSF. SPs can ensure low out-of-pocket expenses through the appropriate use of available financial assistance.

POSTER #16

Expansion of outpatient pharmacy services through initiation of a rapid-start antiretroviral therapy program

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ABSTRACT

Background: In 2017, the World Health Organization recommended to initiate antiretroviral therapy (ART) on the same day as HIV diagnosis based on emerging evidence that demonstrates benefit in long-term clinical outcomes. In randomized controlled trials, immediate ART initiation has been found to improve retention in care and achieve faster virologic suppression. Additional benefits associated with rapid-initiation of ART include reduced community transmission and reducing the size of the latent HIV reservoirs in those with acute HIV infections. Currently, Yale New Haven Hospital (YNHH) does not have a program in place to facilitate rapid-start antiretroviral therapy (RSAT) in patients who are newly diagnosed with HIV or are reentering into care after prolonged durations without ART. In order to initiate ART on the same day as an HIV diagnosis is made, a comprehensive RSAT program was developed that required modifications to current operating procedures within the YNHH infectious disease clinics.

Methods: Current workflow processes of the infectious disease clinics, Yale New Haven Hospital retail pharmacy locations, and various financial resources for prescription coverage were identified. Major barriers to successful program implementation involved identifying prescription coverage for those without insurance and facilitating timely medication delivery. A protocol was developed to outline inclusion and exclusion criteria for the RSAT program, baseline laboratory testing, and recommended initial pharmacotherapy agents in accordance with guideline recommendations. A proposed new workflow process was developed and education was provided to the involved staff.

Results: This project demonstrated the clinical redesign processes and collaboration efforts of our health-system specialty and retail pharmacies and infectious disease clinics to successfully implement a RSAT program. Future studies will assess the impact on clinical outcomes from implementing this program, which will include time to viral suppression and rates of retention in care analyzed pre-and post-program implementation.

Conclusions: It is anticipated that this project will enhance the health system's comprehensive care for patients with HIV by providing enhanced access to vital ART.

POSTER #17

Healthcare resource utilization and cost burden of hemophilia B in the US

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ABSTRACT

Background: Prior studies have investigated the economic burden of hemophilia B, but focused on outcomes within the overall study sample without stratifying by disease severity or clinical profile.

Objectives: To quantify the healthcare resource utilization and costs associated with hemophilia B, both overall and by clinical profile, in the United States.

Methods: Adult male patients were selected from the MarketScan Commercial and Medicare Supplemental database (June 2011–February 2019) if they had ≥ 2 diagnoses of hemophilia B and continuous enrollment during the 1-year baseline before and 1-year follow-up period after a randomly selected hemophilia B diagnosis date (index date). Patients were matched 1:1 to a control group without bleeding disorders based on birth year, region, insurance plan type, and index year. Clinical profile was categorized as severe, moderate-severe, moderate, or mild using a claims-based algorithm that incorporated frequencies of factor IX therapy claims and hemorrhage events during baseline. Resource use and cost outcomes during follow-up were compared between patients with hemophilia B versus matched controls using McNemar's tests for categorical variables and Wilcoxon signed-rank tests for continuous variables.

Results: Patients with hemophilia B ($n=454$) and matched controls ($n=454$) were 46 years old on average. Resource use was significantly higher among patients with hemophilia B than controls in terms of inpatient, outpatient, emergency department, and specialist visits and prescribed opioid use (all $p < 0.05$). The average annual total costs were \$205,783 among patients with hemophilia B (vs. \$8052 for controls; $p < 0.001$) and increased by clinical profile, ranging from \$83,291 (mild) to \$643,979 (severe). Across all clinical profiles, patients with hemophilia B had a significantly higher medical, pharmacy, and total costs than controls (all $p < 0.001$).

Conclusions: Hemophilia B is associated with substantial healthcare resource use and costs in the US. Such a significant burden highlights that unmet needs remain in hemophilia B.

Previous presentation: ISTH 2020 Virtual Congress: 12–14 July 2020

POSTER #18

Impact of an integrated specialty pharmacy model on patient access to dalfampridine

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ABSTRACT

Background: Dalfampridine is a specialty medication to improve walking speed in patients with multiple sclerosis (MS). Access to specialty medications can be hindered by insurance restrictions, high costs, challenges navigating specialty pharmacies (SP), and limited distribution networks (LDNs) imposed by manufacturers. Integrated specialty pharmacies often embed pharmacists in clinics while dispensing medications from their internal pharmacy. Vanderbilt Specialty Pharmacy (VSP) is an integrated SP at Vanderbilt University Medical Center (VUMC) with two clinical pharmacists embedded in the MS Center. VSP gained access to the dalfampridine LDN on 1 May 2018, at which time the embedded pharmacists began to manage the comprehensive therapy initiation process.

Objectives: To assess the impact of an integrated SP model on access to dalfampridine by comparing access to therapy before and after the SP gained admission to the limited distribution network.

Methods: The study was conducted at VUMC, an academic medical center, with an integrated specialty pharmacy, VSP. We performed a retrospective review of adult patients with MS who were prescribed dalfampridine from March 2010 to December 2018. Eligible prescriptions were new starts (no prior use) or restarts (after prior use and discontinuation). Prescriptions were classified as pre-VSP and post-VSP, which differentiates the time-frame before and after VSP gained access to dispense dalfampridine and the embedded pharmacists began to manage the initiation of therapy process. Study outcomes were insurance approval (yes/no), successful initiation of therapy (yes/no), and time from treatment decision to medication access.

Results: We included 258 patients and 285 total prescriptions, as 26 patients had more than one prescription. Most prescriptions (84%) were initial starts and 16% were restarts. Of the 260 pre-VSP prescriptions, 97% were approved by insurance and 93% of patients started therapy with an average access time of 34.3 days (SD =33.3). Of the 25 post-VSP prescriptions, 100% were approved by insurance and 100% of patients started therapy with an average access time of 4.4 days (SD =12.0).

Conclusions: After an integrated specialty pharmacy obtained access to dispense dalfampridine, all patients who were prescribed medication successfully initiated therapy and the time to access therapy was reduced, suggesting that limited distribution networks (LDNs) delay patient access to therapy.

Previous presentation: Poster presentation at ASHP Dec 2019

POSTER #19

Impact of specialty pharmacies on stomatitis prophylaxis with dexamethasone at everolimus therapy initiation

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ABSTRACT

Background: 2017 SWISH trial concluded that prophylactic use of dexamethasone mouthwash reduced the incidence and severity of stomatitis of patients on Everolimus (Afinitor®). Thereafter everolimus prescribing information was updated to include use of dexamethasone at everolimus initiation. Specialty pharmacies (SPs) are in a unique position to ensure patients start therapy appropriately to reduce adverse events, increase adherence, and improve outcomes.

Objectives: Observe the impact of specialty pharmacies on improving outcomes and quality of care for patients via access to dexamethasone upon initiating everolimus.

Methods: Retrospective observation of data within TherigySTM® clinical management platform between July 2018 to April 2020 of selected SPs where patients ($n=206$) were screened for mouthwash prescription at everolimus initiation. TherigySTM® prompted users to screen for mouthwash upon patient onboarding and clinical assessments. If mouthwash script is negative, resources on the benefits and a link to a free voucher for dexamethasone was provided. Negative statuses were compared upon subsequent clinical follow-ups to track change. Data was collected via TherigyInsights™ and odds ratio (OR) analysis performed using Microsoft Excel.

Results: A total of 102(49.5%) patients reported “yes” to script versus 117(56.8%) on the last observable follow-up. In pts with ≥ 2 responses ($n=22$), 15(68.2%) reported a positive change of “no” to “yes” for script. In pts with discontinuations ($n=90$), 11/28 (39.3%) with no dexamethasone ended ≤ 30 days versus 7/62 (11.3%) with dexamethasone; OR: 5.1 (95% CI 4.9–5.3; $p=0.003$).

Conclusions: Patients starting everolimus without dexamethasone showed a significantly higher chance of early therapy discontinuation and patients that initially did not have dexamethasone script had a 68.2% positive status change. The limitations of the study include data gaps such as incidence and severity, resolution of stomatitis, and valid reasons to a negative dexamethasone script. It is unclear that dexamethasone is solely responsible if a patient is likely to discontinue early. However, patients who ultimately reported access to dexamethasone can be viewed as a surrogate marker of success from services performed by SPs. SPs who are ensuring patients having a proper start of therapy are more likely to perform other services in maximizing patient’s outcomes. Future prospective studies would be needed to address the data gaps mentioned.

POSTER #20

**Advanced innovations in telehealth to deliver cancer therapy during
COVID-19 & beyond**

Poster withdrawn by the authors

POSTER #21

Improving patient experience by identifying and addressing injection training gaps via a novel clinical product: a test and learn specialty pharmacy program

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ABSTRACT

Background: The incidence of chronic autoimmune conditions are rising significantly. Many patients require costly self-injectable, specialty medications to be administered at home. Studies have shown that only 61% of patients read the instructions for use and 84% make errors when using autoinjectors. These errors can be mitigated through proper training and onboarding.

Objectives: This study measures patient satisfaction and addresses training injection gaps *via* a live, interactive, face-to-face injection training call with a specialty pharmacy clinician.

Methods: A retrospective analysis was performed from a single-center specialty pharmacy. The criteria for inclusion involved treatment naïve and treatment-experienced patients receiving a self-administered, injectable medication. Patients received pharmacist counseling. At the professional judgment of the pharmacist, they offered live, video chat. If the patient accepted (opted-in), their acceptance was recorded and an appointment was made at a time convenient to the patient. Real-time feedback on the injection technique was provided to the patient, including instilling confidence in injecting the medication, medication device education, and side-effect management. Motivational Interviewing was used to help the patients make sense of their condition or therapy, address knowledge gaps, and overcome barriers to reach their desired outcomes. Clinical call documentation was analyzed over a two-month time period. The analysis included answers to closed-ended yes/no questions: Was the patient trained on how to correctly administer the medication prior to this call? Would the patient recommend this training to someone else who may be starting this medication? and open-ended question: Of the patients that were trained previously, what was their goal of the call?

Results: Of the nineteen opted-in patients, 68% of the patients were not previously trained on how to administer the medication and closed a knowledge gap through the injection training. Of the patients that were previously trained, their goals were: reassurance of injection technique, education of all resources available for their condition, confidence for their caregiver, and overcoming barriers: the fear of self-injecting the medication and anticipating painful injections because “the needle would be large since the pen is large.” Patients were highly satisfied, overwhelmingly recommending this service 100% of the time answering yes to: Would the patient recommend this training to someone else who may be starting this medication?

Conclusions: A live injection training call with a specialty pharmacy clinician delivered high patient satisfaction in patients that had not received injection training. Additional analysis would be required to determine if training call closed the knowledge gap or resolved specific patient and caregiver barriers.

POSTER #22

Modeling rates of primary medication nonadherence with specialty oncolytic agents

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ABSTRACT

Background: Understanding primary medication non-adherence (PMN), the rate at which a new medication is prescribed but not obtained within a defined time period, can help identify adherence barriers. Specialty pharmacies utilize variable PMN calculations, with little known on the impact of adjusting these variables.

Objectives: Evaluate the impact of PMN methodological differences on resulting rates; Define a range of probable rates of PMN among patients prescribed specialty oncolytic agents.

Methods: A single-center, retrospective study was performed using specialty oncolytic prescriptions by a tertiary health system oncology provider and sent to an integrated specialty pharmacy between January-December 2018. Data were collected from the electronic medical record and pharmacy dispensing system. Twenty-four methods were used to calculate PMN based on the following parameters: (i) absence of prior oral oncolytic prescription within lookback window (LBW) (90, 180 days); (ii) absence of a duplicate prescription within duplicate window (DW) (2, 7, 30 days); and (iii) prescription claim within fill window (FW) (14, 30, 60, 90 days). Parameters were applied in a step-wise fashion: LBW, then DW, then FW. For each method, rate of PMN was computed as the number of prescriptions not dispensed within the FW divided by all eligible prescriptions.

Results: We evaluated 4482 prescriptions from 1422 patients (53% male, median age 64 years). PMN ranged from 16 to 23%. Increasing the LBW added 72 (2%) additional prescriptions, but had little impact on PMN with only 1 method (DW 7, FW 14) not producing the same result at LBW 90 vs. 180 days. Most duplicates (87%) were recorded within 2 days of prescription date. PMN rates were slightly affected by DW adjustments. Using LBW 180 and FW 30, PMN rates were 20, 18, and 16% at FW 2, 7, and 30, respectively. Most prescriptions with a fill were filled within 30 days, 98% in the LBW 180, DW 2, FW 30 method. Adjusting the FW impacted PMN in each model, with the largest difference occurring between FW 14 vs. 30 days. Using the PQA-endorsed PMN calculation LBW 180, DW 30, and FW 30 resulted in the lowest rate of PMN from any method (16%).

Conclusions: PMN methodological variations can impact outcomes, particularly DW and FW variability. When reporting PMN, pharmacies should include comprehensive methodology. Reasonable PMN rates for specialty oncology agents may range from 16 to 23% based on these findings.

Previous presentation: ASHP Annual Meeting 2019

POSTER #23

Multiple sclerosis disease modifying therapies' adherence and hospital costs using pharmacy quality alliance guidelines and MarketScan commercial claims and encounters database

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ABSTRACT

Background: The Pharmacy Quality Alliance (PQA) approved a quality metric for monitoring adherence to disease-modifying therapies (DMT) used to treat multiple sclerosis (MS) in 2017. Research is needed to demonstrate that adherence to DMT medications can reduce both hospitalization events and related costs, by use of PQA-approved measure methods.

Objectives: To identify significant associations between PQA DMT medication adherence and health-care cost and utilization over a 2-year period.

Methods: We used a retrospective cohort design with commercially-insured patients from the MarketScan Commercial Claims and Encounters database from 2015–2017. DMT adherence was calculated with PQA criteria: age (≥ 18 years), continuous enrollment, 365 day follow-up from index date for proportion of days covered (PDC), and non-infused DMT list (i.e. interferon beta 1a, interferon beta 1b, peginterferon beta-1a, glatiramer, fingolimod, teriflunomide, and dimethyl fumarate). Selected patients had at least two DMT fills (56 plus day supply) starting 1 January 2015 (with 2-year follow-up through Dec 2017 from index), and no indication of death or hospice stay. MS diagnosed patients were categorized as consistently adherent (PDC $\geq 80\%$) in both years, adherent only in one year, or adherent in neither year. Outcomes were combined 2-year total hospital costs, count of hospital admissions, bed days for those hospitalized, DMT pharmacy costs, and associated medication pharmacy costs. Model covariates included gender, age, census region, metropolitan location, count of associated MS medication therapy groups, DMT switching, mail order, and changed insurance type.

Results: Of the 18,519 patients: 60.6% were adherent in both years, 26.5% were adherent in 1 of 2 years, and 12.9% of patients were non-adherent in both years. Overall adherence was significantly lower in the second year compared to the first. Adjusted costs for DMT pharmacy or associated therapy prescriptions were significantly higher for those consistently adherent vs never adherent (a 1.7–2.1 multiple, respectively). Compared to patients who were not adherent in either year, consistently adherent patients had significantly lower hospital costs ($-\$1213$, $p < 0.0001$), significantly fewer admissions (odd ratio of 0.65, $p < 0.0001$) and significantly fewer bed days (1.95 less days, $p < 0.04$).

Conclusions: DMT medication adherence (PDC ≥ 0.80) can lead to lower hospitalization costs and fewer such events or length of stay over a 2-year period, compared to non-adherent cohorts.

POSTER #24

Persistence on droxidopa for the management of orthostatic hypotension at an integrated care center

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ABSTRACT

Background: Droxidopa has demonstrated an improvement in blood pressure and reduction in falls for patients with orthostatic hypotension (OH). However, high rates of discontinuation at 6 months are reported, most commonly due to adverse events (AEs). Specialty pharmacists closely monitor therapeutic response and AEs to reduce inappropriate discontinuation.

Objectives: Measure persistence and outcomes in adults with OH using an integrated specialty pharmacy for medication fulfillment.

Methods: This was a single-center, retrospective analysis of adult patients prescribed droxidopa through the center's neurology and cardiology departments with at least 3 medication fills by the center's specialty pharmacy from May 2017 through Sept 2019. Demographics, indication, insurance type, reported AEs and falls, emergency room visits and hospitalizations were collected from the electronic medical record. Medication fill dates were collected from the center's pharmacy database and used to calculate persistence and adherence. Persistence was measured as time to first non-persistent event, defined as a coverage lapse exceeding 60 days. Time to non-persistence was calculated for all patients. Restricted mean survival time was defined as the average time a patient remains persistent, accounting for patient censoring. Adherence was calculated using proportion of days covered (PDC).

Results: 89 patients were included. Median age was 73 years, majority male (64%), Caucasian (85%), and receiving Medicare (75%). Indications included: primary autonomic failure (89%), dopamine beta-hydroxylase deficiency (1%), non-diabetic autonomic neuropathy (5%) and other (5%; amyloidosis, diabetic autonomic neuropathy, OH exacerbated by dialysis, and postural orthostatic tachycardia syndrome). Twenty-three patients discontinued treatment. Restricted mean survival time for persistence was 1.5 years out of the 2-year study duration. Median PDC was 0.97; 12 patients had PDC below the industry threshold of 0.8. Twenty-eight patients reported an AE, most commonly hypertension (31%). Half of patients reported a fall, 11 patients had at least one emergency room visit and 9 patients had at least 1 hospitalization.

Conclusions: Our findings demonstrate that high levels of droxidopa persistence and adherence are achieved within an integrated care model.

Previous presentation: Presented at College of Psychiatric and Neurologic Pharmacists Annual meeting (virtual conference) on 27 April 20

POSTER #25

Rates, reasons, and timing for treatment discontinuation in patients prescribed denosumab

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ABSTRACT

Background: Denosumab, a clinic-administered subcutaneous injection given to treat osteoporosis, increases bone density and decreases fracture risk. Patients who discontinue without transitioning to an alternative therapy have increased fracture risk. Understanding when and why patients discontinue denosumab may prepare clinicians to address common barriers to treatment adherence and persistence.

Objectives: The primary objective was to assess discontinuation rates and reasons in patients treated with denosumab. Secondary objectives were to assess how many patients transitioned to alternative therapy after denosumab discontinuation and to describe the frequency and timing of fractures relative to discontinuation.

Methods: This retrospective cohort study was conducted at an academic health center in the Southeast United States. Eligible study participants were adult patients who received two or more doses of denosumab from 2010 to 2018. The following data were collected from August to December 2018 from electronic medical records: patient demographics, treatment dates, dates of fractures incurred after initiating denosumab, and whether the patient discontinued therapy. In patients who discontinued therapy, the number of treatments before discontinuation, reason for discontinuation, transition to alternative therapy, and fracture incurred before and/or after discontinuation were collected. Reasons for treatment discontinuation were categorized and summarized.

Results: We included 534 patients in this study. Fifty-three (10%) patients discontinued denosumab. Adverse effects were the most common reason for discontinuation ($n = 37$, 61.7%). Additional reasons cited were cost or insurance problems ($n = 5$, 8.3%), patient decision or preference ($n = 5$, 8.3%), and transportation or scheduling problems ($n = 2$, 3.3%). After discontinuing denosumab, fewer than one third of patients ($n = 16$, 30.2%) transitioned to alternative osteoporosis treatment. Fractures occurred in 30.2% ($n = 16$) of patients who discontinued denosumab, with 3.8% and 26.4% experiencing fracture before and after discontinuation, respectively.

Conclusions: Denosumab discontinuation was most often due to adverse effects, though cost and logistic factors were also common reasons. However, most patients did not transition to alternative therapy after discontinuation. Additional research is needed to design and test how clinician interventions can promote high patient adherence and persistence to osteoporosis treatment.

Previous presentation: Gregory WT, Gipson HM, Chakrabarti A, Peter M. Rates, reasons, and timing for treatment discontinuation in patients prescribed denosumab. Poster presented to the American Society of Health Systems Pharmacists Midyear Clinical Meeting and Exhibition, Las Vegas, NV. December, 2019.

POSTER #26

The economic burden of hemophilia B – a lifetime decision analytic model

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ABSTRACT

Background: Hemophilia B (HB) presently requires lifetime treatment to prevent or manage bleeding and associated morbidity. The current standard of care (SOC) for patients with severe and moderately-severe HB is prophylactic factor IX (FIX) replacement therapy with an extended half-life (EHL) or standard half-life (SHL) products. Frequent intravenous administration of FIX can be burdensome to people with HB and is costly to the healthcare system.

Objectives: The objective is to develop a decision-analytic model and report estimated lifetime costs of HB management under two scenarios: EHL and SHL product usage.

Methods: An expert panel consisting of clinicians, Health Technology Assessment (HTA) specialists and patient advocacy representatives evaluated and reached consensus on the model framework. A Markov model was constructed allowing the estimation of costs associated with health states: “no bleed,” “bleed into joint,” “bleed not into joint,” and dead, across sub-models of joint damage status: 0, 1, and 2+ areas of joint damage. Treatments consisted of a prophylaxis regimen with EHL or SHL FIX products. The model quantified lifetime costs, including costs for FIX prophylaxis and costs related to bleeding episodes and joint destruction from a US payer perspective. Sensitivity analyses were conducted for shorter time horizons of 3, 5, and 10 years.

Results: We estimated that in adult patients with severe and moderately severe HB, the estimated lifetime cost per patient from onset of adulthood with EHL FIX prophylaxis treatment was \$22,987,000. FIX cost constituted >95% of the total medical cost. The costs at shorter time horizons were \$2,424,000, \$3,920,000, and \$7,278,000 for 3, 5, and 10 years, respectively. The costs of SHL FIX prophylaxis were slightly lower than those of EHL FIX prophylaxis.

Conclusions: This decision-analytic model demonstrated significant economic burden across multiple time horizons associated with the current SOC for HB in the US.

Sponsor: uniQure Inc.

Previous presentation: WFH Virtual Summit 2020

POSTER #27

The impact of initiating specialty pharmacy services in outpatient health system clinics: a provider satisfaction analysis

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ABSTRACT

Background: With the growing rate of patients being managed in the outpatient setting, there has become an apparent need for specialty pharmacies to exist within health systems. This clinic-based team has an opportunity to provide patients with the highest level of care while also making it more affordable to gain access to specialty medications. Understanding the benefits of what these services provide for patients, the question arises on the benefits providers also receive from these services.

Objectives: The purpose of this study is to assess overall provider satisfaction at baseline, 6 months, and 1 year after implementation of Specialty Pharmacy Services (SPS).

Methods: An anonymous provider satisfaction survey was developed by Trellis Rx and offered to various healthcare providers as specialty pharmacy services were being implemented into their clinics. Providers were given a survey at baseline (before the implementation of SPS), 6 months, and 1 year after implementation of SPS. Survey results were compared to assess the impact of SPS services to evaluate whether provider satisfaction scores improved. Survey results were collected in a numerical format and assessed as using Net Promoter Scores (NPS).

Results: Overall, provider satisfaction scores improved from baseline to 1 year with the implementation of SPS services. At baseline, 67% of healthcare providers reported a lack of visibility into a patient's adherence rate, and 58% stated that the entire referral process itself was overly complicated for them. Additionally, 63% reported that patients have barriers to access due to affordability. The NPS score for providers recommending their patient's current specialty pharmacy to their friends or colleagues was -40. After the implementation of SPS, 81 and 91% of providers at baseline and 1 year respectively expressed that the SPS team helped manage patients' drug therapy with them for better outcomes. 82 and 89% of providers reported that SPS has improved the overall ease of the specialty medication referral process. The affordability of medications for patients also increased to 81 and 90%. Finally, the NPS score for providers recommending their own health system specialty pharmacy versus the patient's previous specialty pharmacy also increased to 57 and 87.

Conclusions: This study proves that the implementation of SPS dramatically improved provider satisfaction from baseline and that these services are essential to optimizing patient care.

POSTER #28

The impact of university hospitals specialty pharmacy hepatitis C patient management program on patient and pharmacy outcomes

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ABSTRACT

Background: Treating Hepatitis C patients can be a challenge due to several factors including access to care, high cost of medications, insurance difficulties, and patient compliance. University Hospitals Specialty Pharmacy is designed as an integrated healthcare delivery model that focuses on helping with patient access, clinical disease management, and patient support with the goal of successfully treating Hepatitis C. This study focused on the impact and overall success of having a specialty pharmacy integrated with a major hospital system in managing a complex patient disease state such as Hepatitis C.

Objectives: The impact and success of University Hospitals Specialty Pharmacy (UHSP) in managing patients with Hepatitis C measured by the incidence of documented sustained virological response (SVR) after therapy completion and documented patient monitoring and adherence compared with documented SVR after therapy completion, documented patient monitoring and adherence of patients who filled through outside specialty pharmacies.

Methods: A retrospective analysis of adult patients in the University Hospitals Health System (UHHS) electronically prescribed Hepatitis C treatment between 1 January 2018 and 30 June 2018. UHSP patients were managed by both the UHSP team and a clinical pharmacist working in the hepatology clinic. The primary outcome measured the rate of documentation of the SVR, monitoring, and adherence. Secondary outcomes focused on the time to prior authorization approvals, financial assistance implementation, and the total out-of-pocket treatment costs.

Results: A total of 147 patients were e-prescribed hepatitis C treatment during the study period; 63 patients were started on therapy and were managed by UHSP. Of the 63 patients started, 55 (87%) completed therapy with 55/55 (100%) achieving a documented SVR compared to 29/44 (66%) of patients who filled their prescriptions through outside pharmacies and had a documented SVR rate reported upon completion of therapy. Documented patient monitoring and follow-up were compared with those who filled with UHSP versus outside pharmacies as well as patient adherence to therapy and the percentage of patients lost in follow up between UHSP and outside specialty pharmacies. The average turnaround time for prescriptions was 18 days and included prior authorization approval time and financial assistance implementation.

Conclusions: UHSP comprehensively manages patients and supports the integrated specialty pharmacy model. The SVR rate of UHSP patients was 100% with a 91.6% documented adherence. This study shows the success of integrating a specialty pharmacy into a health system in managing patients in a complicated disease state.

POSTER #29

Tools for improving delivery of pharmacy services and driving compliance in specialty pharmacy

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ABSTRACT

Background: Specialty pharmacy has witnessed substantial growth over the last decade and will continue to grow for the foreseeable future. With this expanding opportunity come the growing pains. The global pandemic, changes to affordability, payer networks, margins, accreditation, and access to limited distribution drugs continue to be top-of-mind factors across the specialty spectrum. Keeping up with these changes, present, and future, is the key challenge that the industry stakeholders are facing.

Objectives: (1) To gain clearer insights into the specialty niche within the pharmacy industry to better understand the specialty pharmacy's current operating environment, its' most prominent needs, biggest challenges, and the opportunities within this space. (2) To help retail specialty pharmacy drive growth and profitability by eliminating inefficiencies and addressing its current weaknesses.

Methods: We partnered with Specialty Pharmacy Times and launched a comprehensive survey to the retail and health system specialty pharmacies sending it out to 5100 contacts in the HS specialty pharmacy space and 6500 contacts in the retail specialty pharmacy space. The survey was open from late February 2020 to early May 2020. The survey questionnaire had 22 questions including logic advancing respondents down a predefined path based on previous answers. It included 6 yes/no questions, 10 multiple choice questions and 6 choose all that apply questions. Survey results were reported at 90% confidence level with a 10% margin of error with the sample size being statistically significant based on the market size of 2000 specialty pharmacies (health system and retail). Market size estimate was obtained *via* our proprietary data and secondary data sources.

Results: Top 4 issues (1) Shrinking margins: The majority of the survey respondents named margins as their biggest business challenge. (2) Compliance issues: 50% of respondents had experienced reimbursement or government fine issues. (3) Patient record management: 80% of respondents admitted to having issues with duplicate patient records. (4) Inefficient marketing outreach and market development abilities. 44% expressed interest in improving their market development via market data insights.

Conclusions:To address its current weaknesses, in 2020 specialty pharmacy needs to focus on: (a) Eliminating inefficiencies and hedging the risk of exposure via robust compliance solutions; (b) Implement patient record management solution - to keep patient data clean, updated for accurate identification at the point of care; (c) Drive market development efforts by identifying high-value prescribers, their affiliations, and referral patterns for targeted marketing and sales outreach.

POSTER #30

Understanding biosimilar purchasing patterns within a home infusion and specialty pharmacy group purchasing organization: an inflammatory conditions case study

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ABSTRACT

Background: Biosimilars have long been anticipated to result in significant savings as compared to innovator biologic drugs. However, recent analyses suggest that biosimilars have only achieved 9% of the \$1B in cost savings estimated by the Congressional Budget Office. Given that biosimilars have faced significant obstacles in uptake, this nationwide home infusion and specialty pharmacy group purchasing organization (GPO) offered a pharmaceutical manufacturer agreement for participating pharmacies to access competitive biosimilar purchase pricing along with clinical education and support.

Objectives: 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 the non-contracted innovator biologic and a contracted biosimilar to treat inflammatory conditions.

Methods: A retrospective analysis of purchasing data from this home infusion and specialty pharmacy GPO was conducted to determine sales growth for the non-contracted innovator biologic and the contracted biosimilar. The baseline for measurement was 4Q17 and sales growth was analyzed quarterly through 4Q19 and compared to baseline. Pharmacies that had at least one purchase of the contracted biosimilar within the study time frame were included in the analysis. Clinical education, communication, and support were provided at intervals throughout the study time period.

Results: When compared to baseline, contracted biosimilar purchases grew 52% in 1Q18, 104% in 2Q18, 165% in 3Q18, 209% in 4Q18, 213% in 1Q19, 386% in 2Q19, 529% in 3Q19, and 1047% in 4Q19. When compared to baseline, non-contracted innovator biologic purchases grew 2% in 1Q18, 12% in 2Q18, 9% in 3Q18, 18% in 4Q18, 14% in 1Q19, 34% in 2Q19, 27% in 3Q19, and 31% in 4Q19.

Conclusions: Although unable to control for confounding factors such as regulatory issues related to biosimilars, payer formulary, payer reimbursement, and provider adoption, this case study shows the contracted biosimilar grew at a significantly higher rate than the non-contracted innovator biologic during the study time period. Given that biosimilars have faced significant obstacles in uptake, pharmaceutical manufacturer agreements designed for participating pharmacies to access competitive biosimilar purchase pricing along with clinical education and support through this home infusion and specialty pharmacy GPO could be one way to help drive adoption.

Previous presentation: National Home Infusion Association 2020 Meeting (Cancelled due to COVID-19)

POSTER #31

University hospitals specialty pharmacy event reporting

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ABSTRACT

Background: University Hospitals Specialty Pharmacy (UHSP) is a part of an integrated health-system delivery network model with the University Hospitals Health System (UHHS) in Cleveland, Ohio. UHSP is committed to continuous quality improvement and is dually accredited by the Utilization Review Accreditation Commission (URAC) and the Accreditation Commission for Health Care (ACHC). Compliance with accreditation measures is necessary in order to optimize patient care, to improve patient outcomes, and to reduce overall healthcare burden and costs. The previous tracking mechanism was identified to be under-reporting errors, adverse events, and near misses both within our specialty pharmacy team and at our dispensing site. This quality improvement project was born out of the necessity for increasing the probability of an accurate event reporting method.

Objectives: The primary objective is to determine the dispensing and distribution accuracy of University Hospitals Specialty Pharmacy by the percentage of different types of errors being reported. The secondary objectives include identifying the percentage of each type of event that occurs and determining the percentage of errors by service line.

Methods: The number of items documented on the Event Log within Sharepoint between 7 October 19 and 31 March 2020 were collected. Patient demographic information, prescription information, provider information, and event type was collected to track, notify, and follow up on pharmacy events for accreditation and internal quality improvement purposes.

Results: Total number of prescriptions during this time period was 15,524 prescriptions. 707 of these 15,524 prescriptions were reported to contain an error. The error rate during this time period was 4.5%. Out of 707 total errors that were reported within this time frame, 53% of these errors reported were external prescriber errors. There were a total of 264 external prescriber errors, the majority (51%) of these errors were from the oncology service line.

Conclusions: In conclusion, the implementation of this event reporting system within Sharepoint has enabled errors to now be captured and reported within UHSP and the production site team. Future steps for UHSP's reporting structure includes adding additional fields to the event log for the "severity of error" and the "prescriber of the prescription" to provide further insight into new opportunities to optimize patient safety and to extrapolate the magnitude of these interventions on overall patient safety. In addition, the creation of ambulatory clinical interventions and medication safety subcommittee will be formed to identify providers, medications, or workflow processes that require intervention as evidenced by trends in the event reporting data.

POSTER #32

Development of an evidence-based, outcome driven specialty pharmacy program for hemophilia

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ABSTRACT

Background: Hemophilia patients have complex treatment regimens requiring enhanced specialized care and expertise. It is essential for specialty pharmacies to develop and support a comprehensive care model to manage hemophilia patients. In January 2020, an academic medical center specialty pharmacy launched a pharmacist-nurse hemophilia program to deliver customized care.

Objectives: To describe the process of designing and implementing an evidence-based hemophilia program that uses a pharmacist-nurse clinical model to deliver comprehensive patient care.

Methods: A literature search was conducted to identify clinically meaningful hemophilia outcomes. Data elements required by commercial payors in the hemophilia market, and accreditation standards pertaining to the management of a specialty pharmacy, were compiled. Clinical outcomes, payor requirements, and accreditation standards were built into an internal patient management platform (PMP) utilized by a hemophilia nurse and specialty pharmacists to track patient outcomes and to perform patient outreach while implementing customized care plans.

Results: A total of 11 commercial payors with 25 unique reporting requirements specific to hemophilia, 58 patient documentation accreditation standards, and 9 clinically meaningful hemophilia outcomes identified through the Medical and Scientific Advisory Council of the National Hemophilia Foundation and clinical trials, were captured. All were organized into a question-answer format and built into the PMP. The workflow was delineated between the hemophilia nurse and specialty pharmacists to identify unique patient care responsibilities. The hemophilia nurse operationalized the management of infusion-related supplies for the specialty pharmacy, and in-home nursing services were established. As the hemophilia nurse and specialty pharmacists performed patient outreach, adherence checks, prescription management, and coordination of care, patient data were collected and entered into the PMP. Patient care onboarding, initial, and follow-up plans were implemented to enhance patient outcomes.

Conclusions: A systematic approach to gathering requirements from payors, accreditation organizations, and clinical best practices served as a foundation to build a hemophilia program. On-going evaluation of patient care outcomes will serve to validate the quality care provided by the hemophilia nurse and specialty pharmacists.

POSTER #33

Implementation of an enhanced oral chemotherapy care model to prevent medication errors

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ABSTRACT

Background: Oral chemotherapy (OC) is associated with significant medication errors, with previous studies reporting an error rate of up to 10%. These errors can occur at any phase of the medication-use process, including dosing, prescribing, dispensing, and administration. Reviewing laboratory values prior to a patient receiving chemotherapy is commonplace in the infusion or inpatient setting, but this important safety check does not always occur with OC in the outpatient setting. Patients on OC self-administer their chemotherapy at home and may request refills that can be inappropriately dispensed due to a lack of insight into the patient's current clinical status.

Objectives: To reduce medication errors with OC via the implementation of a system of increased safeguards around OC refills in a hospital-owned specialty pharmacy.

Methods: In response to a medication error, a workgroup was convened with the specific goal of eliminating the risks of patients possessing their chemotherapy. A literature search and review of national organization guidance was conducted to identify components of an OC care model that modeled best practice.

Results: A workflow was established that flagged all patients starting on cyclic therapy as "High-Risk." These patients underwent enhanced laboratory screening during their initial fill, where the pharmacist will double-check all available laboratory values in the electronic medical record against reference values or contact the provider if there are none available. Prior to any refills, the pharmacist was required to complete a scheduled prescreen activity where the same process is repeated before any subsequent dispensations. During the first four months of the program, the enhanced care model was utilized on 32 unique patients. Of these 32 patients, there were seven interventions related to increased laboratory monitoring (22%).

Conclusions: Specialty pharmacy access to the electronic medical record is paramount to providing the highest quality care for patients prescribed specialty medications. Integrating laboratory review prior to oral chemotherapy dispensations caught errors in one-fifth of cases. Further enhancements to the workflow, including the automatic categorization of "High-risk" is ongoing.