2016 NASP Annual Meeting & Expo
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Annual Meeting Abstracts

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#1: Improvements Following Clinical Pharmacist Integration in the Management of Hepatitis C

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Objective: The objective of this pilot program was to assess the benefit of integrating a clinical pharmacist (CP) in an existing infectious diseases (ID) clinic to manage patients with hepatitis C virus (HCV) infection.

Method: This was a single-center, retrospective and prospective cohort pilot performed at Vanderbilt University Medical Center (VUMC). Patients were included if they received care at the VUMC Infectious Diseases (ID) Clinic and were evaluated and/or treated for HCV during the study period. Following an initial clinical evaluation by a prescribing provider, patients were referred to the CP for pre-treatment evaluation and counseling. The CP provided patient-specific medication education and action plans following treatment approval. A prescribing provider evaluated patients at approximately week 4 of treatment and 12 weeks after treatment completion. The CP assessed patients in clinic and by phone at these and other scheduled and as needed intervals. The primary endpoint of this evaluation was the change in time to HCV treatment initiation from the initial clinic visit. Secondary endpoints include: change in time to HCV treatment approval from the initial clinic visit; change in the number of prescriptions written for HCV therapy; change in number of visits with a prescribing provider prior to initiating HCV therapy.

Results: The study was performed from July 2015 to June 2016. Three months prior to CP integration was examined as the baseline period and assessed retrospectively. The CP pilot was started in October 2015. The three quarters following CP integration was the intervention period, assessed prospectively. The median time to HCV treatment approval from initial visit decreased by 78% and the time to treatment initiation decreased by 68%. Pre-treatment appointments decreased by 35%. Additionally, there was a 32% increase in number of prescriptions generated per clinic day.

Conclusion: CP integration in the ID clinic resulted in decreased time to medication approval and initiation, decreased pre-treatment appointments, and an increase in the number of prescriptions generated. With a greater number of patients eligible for HCV treatment, stressing a limited number of clinical providers, pharmacists are in an ideal position to mitigate this disparity and ensure patients are supported to facilitate treatment completion.

Encore presentation Information:
Data from this research has also been submitted for presentation as a Clinical Pharmacy Forum abstract for the American College of Clinical Pharmacy (ACCP) Annual Meeting held October 23rd through 26th, 2016. While similar data will be presented, the foci of the two presentations will be unique.

#2: **Development of the First FDA-Approved MS Generic Disease-Modifying Therapy: Glatopa® (glatiramer acetate injection)**

Christine Bell, PhD[1]*; James Anderson, PhD*[1]*; Tanmoy Ganguly, PhD*[1]*; Jim Prescott, PhD*[1]*; Ishan Capila, PhD*[1]*; Jon Lansing, PhD*[1]*; Richard Sachleben, PhD*[1]*; Mani Iyer, PhD*[1]*; Ian Fier, BS, MBA*[1]*; James Roach, MD*[1]*; Kristina Storey, BA*[1]*; Paul Miller, MS*[1]*; Steven Hall, PharmD*[2]*; Daniel Kantor, MD*[3]*; Benjamin M. Greenberg, MD*[4]*; Kavita Nair, PhD*[5]*; Joseph Glajch, PhD*[1]

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Objective: Last year, the US Food and Drug Administration (FDA) approved the first generic disease-modifying therapy for MS: Glatopa® (glatiramer acetate [GA] injection; "generic GA") 20 mg/mL, as fully substitutable for Copaxone® (GA injection; "originator GA") 20 mg/mL for relapsing-forms of MS. This poster summarizes the development of the FDA-approved generic 20 mg/mL formulation.

Method: GA is a complex mixture of polypeptides (not a biologic) and, consequently, its characterization presented challenges not generally encountered in generic drug development. Multiple samples of originator and generic GA 20 mg/mL were used for analyses. Utilizing the Abbreviated New Drug Application (ANDA) regulatory pathway, equivalence of generic to originator GA 20 mg/mL was evaluated based on starting materials and basic chemistry; structural signatures associated with the process used to manufacture GA; structural (physicochemical) properties; and biological and immunological properties.

Results: No differences were observed in the structure and function of originator and generic GA 20 mg/mL following a comprehensive, high resolution scientific evaluation. Structural properties were equivalent across more than 45 tests and biological properties were equivalent across more than 15 assays including gene expression studies and in three versions of an animal model of MS. The content of generic 20 mg/mL prescribing information (PI) is the same as the originator GA 20 mg/mL PI, and the adverse events received from launch until June 30, 2016 for generic GA are consistent with what is described in the generic GA PI.

Conclusion: Glatopa 20 mg/mL is the sole FDA-approved generic GA to date. Cost implications of these agents along with information regarding a 3-times-a-week GA 40 mg formulation (currently under FDA review) will also be provided at the time of the poster.

Disclosure: Sponsored by Momenta and Sandoz.

#3: **Medication and Therapy Management for Cholesterol in the United States (US)**

Richard A. Brook, MS, MBA[1]*; Sarah H. McManama, BS*[2]*; Michael J. Sax, PharmD*[2]*; Jim E. Smeeding, RPh, MBA*[3]
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Objective: Cholesterol management begins with dietary and lifestyle modifications, and may progress to one or more pharmaceutical therapies. Cholesterol management treatments have varying rates of prior authorization (PA), tier classifications and patient cost-shares within different managed care (MC) plans. Several agents have become generically available. In recent years, newer therapies with different targets, higher prices and requiring injectable self-administration have become available. This study sought to understand how United States MC plans manage cholesterol medications on their formularies.

Methods: Two hundred twelve managed care Medical and Pharmacy Directors who have participated in prior National Payor Roundtable programs were sent invitations to complete an online survey. Topics included: advisor and plan information, copays and drug/treatment usage of different classes for cholesterol management (classifying as: Unrestricted, 1st tier, 2nd tier, 3rd tier, or requiring PA).

Results: There were 61 responses (29%) between February and March 2016. Fifty-nine percent of respondents were Medical Directors, with the remainder comprised mostly of pharmacists who mostly worked for a health plan (62.3%). The health plans were 41.1% national, 30.4% regional, and 28.6% local. Plans could cover multiple types of members and 79.6% covered commercial lives, 61.1% Medicaid; 68.5% Medicare. Responses identified the highest PA rates were for: Proprotein Convertase Subtilisin/Kexin type 9 (PSCK9s) inhibitors (alirocumab and evolocumab)=84.62%, lomitapide=71.1%. The PSCK9s are injected, require self-administration training, and will likely be subject to a specialty copay. Classes with generic options were often first tier and included statins=47.2%, triglycerides management products=33.3%; and fibrates=29.4%. Combination cholesterol agents=44.2% and cholesterol/cardiovascular combinations=43.1% and were mostly in tier 2. While over the counter fish-oil products and supplements were generally unrestricted in Medicaid plans, not covered by Commercial or Medicare plans; the prescription therapy icosapent was PA restricted by 17.3% of plans. The most common tier 2 products included ezetimibe (40.4%) followed by the bile-acid sequestrants (32.7%).

Conclusions: As new products enter the cholesterol management market, health plans will likely impose restrictions and plan designs on new classes favoring less expensive, generically available agents until real world effectiveness data becomes available.

Sponsorship: TPG-National Payor Roundtable

#4: **Specialty Pharmacy, Diagnostic and Genetic Testing Coverage in the United States (US)**

Richard A. Brook, MS, MBA[1]*; Sarah H. McManama, BS*[2]*; Michael J. Sax, PharmD*[2]*; Jim E. Smeeding, RPh, MBA*[3]
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Objective: Specialty pharmacy (SP) products treat specific, complex chronic diseases and are costly; require reimbursement and handling assistance/training, have unique/limited distribution processes. According to IMS Health, specialty medicine spending increased 21.5% in 2015. Diagnostic/genetic tests identify/predict diseases and treatment response. A survey was fielded to gain a better understanding of health-plan management of Specialty Pharmacies, SP-products and diagnostic/genetic testing.

Methods: Online survey of US Medical and Pharmacy Directors from public/private plans with multiple member-types on: advisor and plan information; specialty pharmacies pharmaceuticals, copays, and genetic/diagnostic test coverage and restrictions. Two hundred twelve directors were sent electronic survey invitations.

Results: There were 61 responses (29%). 51.7% of plans restricted SP providers and 40.3% used their PBM as their SP, 46.1% of the Specialty Pharmacies were privately-owned, 46.1% PBM-owned, and 7.7% hospital-Integrated Delivery Network-owned. Top SP-conditions covered by the plans included: HCV=90.4%; Oncology=88.5%; HIV=73.1%. The majority (68.1%) restricted SP services to a small set under contract, 14.9% allow any SP; 14.9% only restricted products available by multiple specialty-pharmacies, 2.1% carved them out. Plans covered clinician-administered products under the medical-benefit (MB=64.3%); under the pharmacy-benefit (PB=5.4%); 30.4% were product-specific; 70.9% expect no change; and 29.1% expect to complete changes before 12-18. Oral Biologics (OBs) were managed under the PB=78.9%; the MB=7.0%; 14.0% based on plan-design/product. Expectations for OB benefits: no change (78.6% of plans), currently changing (7.1%); before 12-17 (12.5%) and before 12-19 (1.8%). SP+OB copays vary by group/benefit design and are shifting from fixed to %-copays with Multiple-Sclerosis agents maintaining more fixed copays. Most (82.5%) of plans do not require AMCP-dossiers for testing. In 2016, genetic tests (GTs) were covered in all cases (63.5% of plans); not covered (15.4%) and threshold-based (21.1%) with minimal expected changes. GT coverage was highest for oncology (92.4%); OB/GYN (66.0%); cardiovascular (52.8%). Disease marker tests help predict the effectiveness of therapies and covered in all cases (79.6%), not covered (5.6%), and 14.8% threshold-based. Coverage for therapy-response tests (HCV, RA, etc): all cases (68.5%), no cases (20.4%); and 11.1% threshold-based.

Conclusions: Specialty pharmacy/pharmaceutical expenditures are expected to grow and require appropriate coverage. Testing can reduce expenditures by focusing treatments that are effective against disease markers and stopping therapies do not demonstrate a therapeutic response.

#5: **Cancer Concerns from United States Managed Care Medical and Pharmacy Directors 2016**

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Objective: Cancer is costly, managed by a variety of treatments that include traditional and robotic surgery, radiation, chemotherapy, and immunotherapy. Pharmaceutical treatments are shifting from chemotherapy to effective targeted immunotherapies. Chemotherapy has limited effectiveness and multiple side-effects. Targeted immunotherapies have fewer side effects, multiple treatment pathways and are receiving fast track approvals. To determine the types of cancers most concerning to United States Managed Care plans, a survey invitation was sent to Medical and Pharmacy Directors of United States health plans, insurers, and pharmacy benefit managers.

Methods: Managed Care Medical and Pharmacy Directors completed an online interactive survey. Topics included: advisor and plan information; Ranking (highest=12-to-1=lowest) of cancer-types; Copays; benefit-design; and top concerns today and in 5 years from budgetary and medical points of view.

Results: Fifty-four percent of respondents were MDs. Most worked for a health plan (83.6%) and 39.6% of the plans were local; 35.4% national; and 25.0% regional. Plans could cover multiple types of members and 91.3% covered commercial lives, 89.1% Medicaid; 91.3% Medicare MA-PDP and 76.1% Medicare PDP-only lives. Average ranking (out of 12): Breast Cancer=10.6; Lung Cancer=10.0; Colon and Rectal Cancer=9.1; Prostate Cancer=7.9; Melanoma=7.5; Leukemia=7.2; Non-Hodgkins Lymphoma=6.5; Pancreatic Cancer=5.2; Kidney Cancer=4.7; Endometrial Cancer=3.8; Bladder Cancer=3.6; Thyroid Cancer=2.7. Cancer/oncology was consistently reported the top concern from medical (38.9% today, 51% in 5 years) and budgetary (52% today, 71.1% in 5 years) points of view. Oncology was the 2nd highest ranked Specialty-Pharmacy (SP) condition with 64.3% of plans always managing under the medical-benefit, 5.4% always under the pharmacy-benefit. SP copays are decreasing in fixed (2015=15.8%; 2017=13.0%) and percentage-bases (2015=42.1%; 2017=37.0%) with the rest varied by group and benefit-design.

Conclusions: The environment for cancer treatment is undergoing a series of changes. The shift from traditional chemotherapies toward targeted immunotherapies and the potential cost implications requires payor medical and pharmacy directors to adapt and evaluate these newer agents and pathways along the same rapid timelines as they become available.

Sponsorship: The TPG-National Payor Roundtable

#6: **Ledipasvir/Sofosbuvir (LDV/SOF) for 8 Weeks in Genotype 1 (GT1) Treatment-Naïve (TN) Noncirrhotic (NC) Patients with HCV Viral Load (VL) <6 Million IU/ML (6M): A Comparative Analysis of the Phase-3 ION-3 Data to Real World Effectiveness (RWE)**

Peter Buggisch, MD[1]*; Jorg Peterson, MD*[1]*; Stefan Mauss, MD*[2]*; Kris Kowdley, MD*[3]*; Michael Curry, MD*[4]*; Peter Ruane, MD*[5]*; Dani Ain, BS*[5]*; Naoky Tsai, MD*[6]*; Yoori Lee, BS*[7]*; Edward Eggleton*[8]*; Macky Natha, MB*[8]*; Bruce Kreter, PharmD*[8]*; Diana Brainard, MD*[8]*; Patrick Ingiliz, MD*[9]*; Michele Puyear, PharmD*[8]

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Objective: The optimal duration of therapy to achieve sustained virologic response (SVR) depends on multiple factors. Patients treated with LDV/SOF for 8-24 weeks achieved SVR12 from 94-100% in the ION Phase 3 studies. A decision to shorten therapy to 8 weeks is based on treatment history, cirrhosis status and baseline VL. In a post-hoc analysis of the ION-3 (TN, NC patients) 8 week data, a VL<6M was shown to be the best predictor of SVR. RWE is often different from Phase III trials and there is a need to understand real-world 8 week regimens in a broader spectrum of patients.

Methods: RWE 8 week LDV/SOF data is emerging from multiple single-center and multicenter retrospective and prospective cohorts. In this analysis, the phase-3 ION-3 data is compared with data from several diverse real world populations and one post-marketing investigator sponsored HIV/HCV trial. Patient demographics, characteristics, SVR12 and discontinuation data has been collated and compared.

Results: The ION-3 post-hoc analysis reported 123 patients who were TN, NC and VL<6M and treated with 8 weeks of LDV/SOF. Mean age was 52, 22% black, 72% GT1a; the SVR12 was 97% (119/123). The overall SVR12 rate from six diverse real world and post marketing cohorts was also 97% (638/658). There was no significant impact of HCV genotypes or subtypes (GT1a, 1b versus GT4), prior treatment history, presence or absence of cirrhosis, high viral load (HCV VL>6M), or HIV/HCV co-infection.

Conclusions: LDV/SOF for 8 weeks yielded high SVR rates in ION-3. Analysis of RWE data from several diverse and heterogeneous cohorts from the United States and European Union show SVR outcomes that were consistent with the Phase-3 ION-3 results and supports the use of 8 weeks LDV/SOF in treatment-naive, non-cirrhotic GT1 patients with a baseline HCV VL <6M and possibly in other populations including HIV/HCV co-infected patients. Discontinuation rates were low despite diverse patients and clinical settings.

This research was funded by Gilead Sciences, Inc.

#7: Abstract Withdrawn by authors

#8: **Clinic Staff Perspectives on Obstacles to Specialty Medicine Access and Adherence: A Qualitative Study**

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Objective: Specialty medications are expensive and require special handling. The purpose of this study is to map the medication access process from the specialty clinic perspective and identify obstacles to treatment adherence. This is part of a larger study that investigates access from patient, specialty, and community pharmacist perspectives.

Method: Qualitative semi-structured telephone interviews are being conducted with clinic staff from a tertiary, quaternary health care system. Demographic information is collected and the interviews are audio-recorded and transcribed. Transcripts are analyzed using inductive and deductive thematic approaches to map the access process and understand stakeholder perspectives. A $50 gift card is provided to participants. Data collection is ongoing.

Results: Eighteen (of an expected 20) clinic staff have been interviewed, representing cystic fibrosis (2), rheumatoid arthritis (3), multiple sclerosis (6), cancer (3), and hepatitis C (4). Their roles included physician (4), nurse practitioner (3), nurse (5), clinic pharmacist (3), medical assistant (1), social worker (1), and administrative assistant (1). The average time in practice was 13.3 years, (range 3-35).

Preliminary analysis suggests respondents share a broad consensus that insurance authorizations and re-authorizations are frequent obstacles to specialty medication access. Despite working closely with specialty pharmacies, clinics continue to develop systems to facilitate medication access that often involve multiple staff members in order to respond to delays associated with insurer denials, formulate appeals, and make therapeutic changes to accommodate insurance policy. The wide variety of insurance plans, formularies, and policies combined with changes in disease severity and insurance coverage for patients necessitate flexible and evolving strategies for clinics striving to assist patients. Medication cost is an additional area of concern. Clinics assist patients in accessing support programs to help with payments and copayments. Cost is perceived to be a strong obstacle to adherence.

Conclusion: Clinics shoulder significant burdens associated with access to specialty medications. Given that specialty pharmacies also create systems devoted to authorization processes, these data suggest that there may be added efficiencies for clinics through increased coordination with specialty pharmacy staff to improve patient experiences.

Disclosures: Cara Joyce, Heather Kirkham, and Kara Clark are currently employed by Walgreen Co.

#9: **Impact of Increasing Infusion Rates in Patients Currently Receiving Immunoglobulin Therapy**

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Objective: Intravenous immunoglobulin (IVIG) formulations were approved in the 1980s to treat immune deficiencies. Excipients and impurities then present in immunoglobulin formulations negatively impacted infusion rates causing numerous side effects. Over the past 3 decades, improved production and filtering processes for immunoglobulins have reduced these impurities. Despite these improvements and studies demonstrating that faster infusion rates are safe, protocols at many institutions still limit infusion rates. We implemented a protocol change (PC) in an outpatient infusion clinic to assess how increasing infusion rates might impact costs, satisfaction, and tolerability.

Methods: Patients over 18 with diagnoses including neurologic conditions and immuno-deficiency disorders who had received at least 2 infusions of Gamunex and reported no previous infusion reactions, met inclusion criteria for the protocol change. Infusion rates in these patients were increased with titrations starting at 0.02 ml/kg/min x 15 min, then 0.04 ml/kg/min x 15 min. Infusion rates were increased to max of 0.06 ml/kg/min.

Results: Twenty-one patients were included in the study resulting in mean infusion time savings of nearly 2 hours per patient. Patient-defined mild and moderate side effects increased in 3 of 8 reported measures however, patient satisfaction levels were high. The reduc-tion in infusion time resulted in improved chair efficiencies cost savings for the clinic.

Conclusion: The results of this study demonstrate that faster infusion rates with Gamunex can be safe in stable, previously treated IVIG patient populations. These faster rates can result in lower infusion costs for the healthcare system as well as improved clinic efficiencies and high patient satisfaction. Further research is needed to elucidate these findings and determine patient characteristics associated with faster infusion rates.

Research sponsored by Grifols SSNA

#10: **Retrospective Evaluation of Disease Modifying Therapy Utilization Patterns and Healthcare Resource Utilization in a Commercially Insured Multiple Sclerosis Population**

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Objective: Prior healthcare resource utilization (HCRU) research in multiple sclerosis (MS) patients receiving disease modifying therapies (DMTs) has found that non-pharmacy HCRU is increased in patients who switch or discontinue therapy. This research has been limited to select DMTs and does not include information on relapse episodes or pharmacy provider type. The primary objective of this study assessed the relationship between HCRU and DMT utilization patterns, including non-persistence and adherence, encompassing all available DMTs dispensed from a specialty pharmacy. Secondary analysis explored relationships between HCRU and relapse rates, available DMTs, and DMT formulations.

Methods: Using administrative claims data from January 2014 to December 2015, HCRU was assessed among the variables of non-persistence and adherence patterns in patients with MS. For each variable, patients were assigned to a descriptive cohort. Non-persistence was defined as a DMT switch or gap in DMT greater than 30 days, regardless if prior DMT is restarted. Sensitivity analyses were conducted to justify the 30-day definition. Patients were grouped based on the number of non-persistent episodes. Adherence was assessed using proportion of days covered (PDC), defined as the sum of days covered on therapy divided by the number of days in the period. Patients were categorized into three descriptive groups based on PDC adherence rates. Relapses were measured within each cohort, defined as any inpatient visit with primary ICD-9 diagnosis code of 340.xx, or any outpatient visit with the aforementioned diagnosis code and a claim for corticosteroid use up to seven days after the visit. Additionally, the study investigated relationships between HCRU and relapses across available DMTs. Trends in HCRU, relapses and DMT formulations were also assessed.

Results: The analysis included 75 patients with a mean age of 50 years old and a total of 87.6 patient-years. The overall adherence rate was 0.93 (range 0.33-1.00) and the average number of non-persistent episodes was 4.28 (range 0-12). There were 28 relapses that occurred in 13 (17.8%) of all patients, indicating an annualized relapse rate of 0.63.

Conclusion: Overall, no differences were shown when assessing relationships between utilization patterns, non-pharmacy HCRU, and annualized relapses. Trends in decreased switching or discontinuation, annualized relapses, and non-pharmacy HCRU were identified when evaluating oral versus injectable DMTs. Results may guide future research to help improve clinical management programs within the specialty pharmacy setting.

#11: **Mitigating Changes in Immunosuppressant Therapies of Post-Transplant Patients Within an Integrated Delivery Network Specialty Pharmacy**

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Objective: Solid organ transplant patients are subject to regular evaluation of laboratory values in order to determine safe and efficacious dosing of tacrolimus post-transplant. After being discharged from a medical facility post-transplant, laboratory values determine if/when changes are required to a patient's initial therapy. Patients may be discharged with a particular dosage of tacrolimus that may later warrant adjustment and new outpatient prescriptions. The likelihood of a potential adverse event is high if this change is only communicated verbally to the patient and pharmacies do not have accurate prescription orders reflecting updates. An evaluation of mitigating tacrolimus therapy changes was conducted in order to reduce the probability of adverse events.

Method: Post-transplant outpatient prescription orders for tacrolimus were identified within an integrated delivery network (IDN). A clinical pharmacist accessed patients' electronic health records (EHR) in order to evaluate current laboratory values and compared them to the most recent prescription orders for patients within the IDN's specialty pharmacy. Potential discrepancies were identified and reported to the IDN's error reporting system.

Results: Statistical analysis of the error reporting system is pending. Post-evaluation, tracking denotes a significant increase in compliance with updated prescription orders for post-transplant tacrolimus.

Conclusion: The clinical pharmacist's role in proactively evaluating patients' laboratory values for post-transplant tacrolimus therapy is critical. Clinical pharmacists can review an IDN's EHR for laboratory values and request new orders from providers that accurately reflect the patients' current needs. Clinical pharmacists can also discontinue out-of-date orders within the pharmacy management software in order to reduce the likelihood of dispensing a less than therapeutic dosage to patients. If/when this is completed before every tacrolimus dispensation, post-transplant patients receive a safe and efficacious level of care.

Disclosures: None.

#12: **Immunoglobulin Utilization: An Assessment Using Infusion Pharmacy Data**

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Objective: The objectives of this study were to: 1) characterize patient, payer and treatment among those receiving Immunoglobulin, 2) assess differences in characteristics across type of administration, and 3) compare results to a recent survey of Immunoglobulin users.

Method: This study used a retrospective, cross-sectional design. The data source is pharmacies that are part of a national network of community pharmacies providing infusion services. Data were obtained through 2015 billing and reimbursement records. Data were analyzed using SAS (V9.4). Significance is reported at $p<0.05$.

Results: There were 108 patients in the sample, representing 1,183 drug administrations. The sample was predominantly female (69%), median age of 51, and median weight of 160 pounds. Ten percent of patients were 18 years and younger, while 64% were 45 years and older. Commercial insurers were the majority payer (56%), followed by Medicaid (30%) and Medicare (12%). The most frequently identified service lines were Allergy and Internal Medicine, both 7.4%. The percentage of administration types were IVIG (19%), SCIG (28%) and Both (53%). Comparison across the three administration types revealed significant differences in payer and service lines. Commercial payers paid for 62% of IVIG and 68% of both, but only 30% of SCIG. Medicaid paid for 57% of SCIG but less than 20% of the others. There were also significant differences in service lines across administration type. Comparison was made with the Immune Deficiency Foundation (IDF) Survey, a 2008 self-reported mailed survey of patients with primary immunodeficiency disease (n=1,030). The major difference between the two studies is the administration type. Percentage of administration type in the survey compared to the current study was: (IVIG: 75% vs. 19%; SCIG: 7% vs. 28%; Both: 18% vs 53%).

Conclusion: This study provides a current profile of patient, payer and provider associated with immunoglobulin use. Differences in payer and service lines were observed depending on the type of administration. When compared to the 2008 IDF survey, a difference was observed in administration type, where the IDF survey reported IVIG as the predominant administration type, while the current study reports Both as the predominant type. Differences could be reflecting changes in treatment patterns from 2008 to 2015, data collection methods (self-report survey vs. billing data), or difference in sample size (1,030 vs. 108).

#13: **Hospital Outcomes for Inpatients with COPD Treated with Nebulized Arformoterol or Nebulized Formoterol**

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Objective: Arformoterol is the (R,R)- enantiomer of formoterol and preclinical studies suggest this enantiomer has stronger bronchodilator and anti-inflammatory properties than racemic (R,R/S,S)-formoterol; however, potential clinical advantages have not been demonstrated (King P. Int J Chron Obstruct Pulmon Dis. 2008;3:385-392). Among inpatients with chronic obstructive pulmonary disease (COPD) who were treated with arformoterol or nebulized formoterol, this study compared length of stay (LOS), 30-day readmission (all-cause and COPD-related) rates, and doses of rescue medications.

Methods: This retrospective analysis utilized data from Premier Inc (Charlotte, NC), the largest nationwide hospital-based administrative database. COPD patients ≥40 years of age were included in the analysis if they were hospitalized between January 2011 and July 2014, had no diagnosis for asthma, and were treated with arformoterol or nebulized formoterol. LOS was measured from the day the patient initiated the study medication (the index day). Rescue medications were defined as short-acting bronchodilators used from the index day onward. Multivariate statistical models included a random effect for hospital and controlled for multiple background differences: patient demographics, hospital characteristics, admission characteristics, prior hospitalizations, comorbidities, pre-index service use, pre-index medication use, and index day.

Results: A total of 7,876 patients received arformoterol and 3,612 patients received nebulized formoterol. After adjusting for covariates, there was no significant difference in 30-day all-cause (arformoterol = 11.9%, formoterol = 12.1%, odds ratio [OR] = 0.981, p = 0.82) or COPD-related hospital readmission rates (arformoterol = 8.0%, formoterol = 8.0%, OR = 1.002, p = 0.98). The adjusted mean LOS was significantly shorter for arformoterol- than formoterol-treated patients (4.6 vs. 4.9 days, p = 0.039). Arformoterol patients used significantly fewer doses of rescue medications (5.9 vs. 6.6 doses, p = 0.006)

Conclusions: In this analysis, inpatients with COPD treated with arformoterol had a shorter LOS, used fewer rescue medications, but had similar 30-day readmission rates compared with those treated with nebulized formoterol. Treatment received upon discharge is unknown and this could have an impact on readmission rates. During inpatient stays, treating COPD with arformoterol instead of nebulized formoterol may lead to shorter LOS and lower rescue medication use.

Study sponsored by Sunovion Pharmaceuticals Inc.

#14: **Healthcare Resource Utilization of Patients with Pancreatic Cancer Compared to a General Managed Care Population in the United States**

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Objective: To describe differences in the healthcare resource utilization (HCRU) of patients diagnosed with pancreatic cancer (PaCa) compared to a non-PaCa population in the US.

Methods: In this observational, retrospective study, patients (age ≥ 18) with ≥2 PaCa (ICD9 157.xx) medical claims between 1/1/2007 and 6/30/2015 were identified using claims from the HealthCore Integrated Research Database. PaCa patients were matched to patients without a cancer diagnosis between 1/1/2006 and 6/30/2015 but similar in terms of age, gender, region, and plan type (non-PaCa patients). Patients with other cancer diagnoses during 60 days before the index date (first PaCa medical claim) were excluded. Patients were required to have ≥ 12 months of continuous health plan enrollment prior to index date. Claims data through 6/30/2015 or end of the patient's eligibility were analyzed. Results were annualized and reported in per patient per year (PPPY). Death was identified using the Social Security Death Index.

Results: 5,826 PaCa patients met the inclusion criteria and were matched (1:3) against 17,478 non-PaCa patients. Median follow up was 7.2 months for PaCa patients and 25.2 months for non-PaCa patients. 41.3% of PaCa patients (vs. 4.5% in non-PaCa) died during follow up

A higher proportion of PaCa patients had ≥ 1 hospitalization (78.4% vs. 9.2%) vs. non-PaCa patients. PaCa patients also had significantly more inpatient hospitalizations (mean: 7.7, SD:± 12.7) vs. (0.6 ± 8.1), p<.001, with a significantly higher length of stay (LOS) (52.9 ± 97.8) vs. (2.8 ± 34.5) days, p<.001. Average emergency room visits were almost three times for PaCa patients (0.9 ± 2.6) vs. (0.3 ± 4.4), p<.001. Average physician office visits were also higher for PaCa patients (26.7 ± 20.8) vs. (8.7 ± 13.6), p<.001. An even greater difference in average outpatient visits was observed between PaCa and non-PaCa patients (101.1 ± 79.0) vs. (26.5 ± 37.8), p<.001. Specifically outpatient visits related to drug administration represented the largest difference (73.6% vs. 37.4%), p<.001. The average number of pharmacy prescriptions fills per patient was significantly higher among PaCa patients (31.2 ± 24.4) vs. (18.1 ± 17.5), p<.001.

Conclusions: HCRU among PaCa patients was significantly higher than those without cancer. Hospitalizations were 12.8 times higher in the PaCa group with average LOS 18.9 times longer. More effective and less toxic treatments along with improved care coordination could reduce the overall HCRU of PaCa patients.

Disclosure: Study funded by EMD Serono

#15: **Journey to Accreditation Success – A Small Pharmacy Finds Its Path**

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Objective: Specialty pharmacy accreditation provides external validation that a pharmacy has well-defined policies and procedures, highly-trained and educated staff, and elevated practice standards for the delivery of quality patient care. Accreditation serves as proof to patients, prescribers, payers and pharmaceutical manufacturers of a pharmacy's commitment to excellence in patient care. Historically, accreditation was only achieved by larger pharmacies due to the corporate structure and support needed to meet the required standards. This case study describes the successful journey of a small specialty pharmacy in achieving dual accreditation.

Method: Dual accreditation through two separate entities was targeted. An examination of accreditation standards from both agencies served as the basis for a gap analysis of current operations. Pharmacy leadership collaborated with experienced consultants to develop an action plan based on the gap analysis results. A stepwise plan to successfully reach accreditation goals was implemented. Key pharmacy staff were identified to perform multiple roles in support of critical accreditation processes, while continuing to provide uninterrupted patient care. Pharmacy policies and procedures were reviewed and revised to guide new practices needed to bridge identified gaps. Prior quality improvement programs and review processes were formalized and documentation was improved to better guide practice. Employee records were reviewed and education on accreditation was provided to the staff to ensure operational and patient care activities were being documented properly. Internal competencies and audits were performed to validate excellent performance by staff.

Results: Accreditation through both agencies was obtained within the desired timeline. Accreditation has brought the desired benefits such as participation in limited distribution drug programs and additional payer relationships, and has opened doors for growth, expanding the national footprint of the organization. Based on the pharmacy's excellent performance during the accreditation survey, leadership from the pharmacy was invited to serve on an advisory panel for one of the accrediting agencies.

Conclusion: With a clear goal, committed and educated leaders, and a strong team, a small specialty pharmacy can exceed accreditation standards.

#16: **ASSIST (Adherence, Support, Solutions and Intervention for Successful Treatment) Pilot Program: A Collaboration of a Regional Health Plan and Community Pharmacy to Improve Outcomes and Contain Costs for Patients with the Hepatitis C Virus (HCV)**

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Objective: Determine that a collaboration between a regional health plan and a community pharmacy may improve overall patient adherence to therapy and contain payer costs for patients with HCV.

Method: The health plan identified eligible patients as those with HCV that were prescribed sofosbuvir or ledipasvir/sofosbuvir. The pharmacy developed and utilized a split-fill escalating day supply dispensing process that featured 2 initial 7 day supply fills followed by a 14 day supply fill to complete the first 28 days of therapy. After the first 28 days of treatment, the pharmacist, in collaboration with the health plan, would assess patient's eligibility to graduate to full 28 day fills or continue treatment utilizing a more frequent refill schedule. The split-fill process created more opportunities for pharmacist engagement with the patient including increased monitoring of and emphasis on patient adherence to and performance on the prescribed therapy. Prior to treatment initiation, in order to avoid treatment interruption, a pharmacist would assess the patient's insurance benefits along with their ability to afford co-payments for the length of the treatment. Upon receipt of the first fill, and 3-5 days after each fill, a pharmacist performed defined program interventions. For the second and third fills, the pharmacist would continue engagement and assessment of adherence. Graduation to full 28 day fills was then assessed based on a review of patient engagement and compliance to therapy. High adherence was considered a proportion of days covered (PDC) score of ≥ 95%. Data was collected over 647 days.

Results: 55 patients were enrolled in the ASSIST group compared to 46 patients not provided a formal program. The weighted average PDC for the ASSIST patients was 98.80%, with 94.55% of patients achieving high adherence. The weighted average PDC for the No-Program group was 94.16%, with 80.43% achieving high adherence ($P<0.05$). Additionally, interventions in the ASSIST group prevented the regional health plan from unnecessarily paying for 126 days of avoided therapy. This was calculated based on prevented treatment failures and avoided therapy restarts.

Conclusion: An increased emphasis on adherence to therapy and frequent engagement with a community pharmacist, resulted in an increase in patient compliance to therapy and positive cost-containment outcomes due to the ability to short fill prescriptions and avoid waste when preceding discontinuation.

#17: **Switching Patterns in Patients with ICD-9 Diagnosed Chronic Inflammatory Demyelinating Polyneuropathy Initiating Intravenous Immunoglobulin Treatment**

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Objective: Real-world data comparing the different product characteristics of the available intravenous immunoglobulin (IVIG) therapies are limited. This study describes switching patterns of IVIG products among commercially insured ICD-9 diagnosed Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) patients from two parallel cohorts from different claims databases in the United States.

Methods: The first study (cohort 1) was conducted in the 2010-2013 MarketScan Commercial Claims database and the second study (cohort 2) in the 2010-2012 PharMetrics Plus database. All patients were required to be ≥18 years of age at diagnosis and have continuous eligibility for medical and pharmacy benefits at least 1 year prior to and 2 years post their initial diagnosis of CIDP. Final sample included treatment naïve CIDP patients with at least one claim with ICD-9 diagnosis codes (357.81) for CIDP and evidence of IVIg treatment initiation. Patients were further stratified based on their index IVIG product.

Results: Cohort 1 included 151 CIDP patients initiating IVIG treatment with a mean age 49.2 years and 53% male, while cohort 2 had 326 patients with a mean age of 55.6 years and 62% were male. The most often initiated IVIG products in both studies were Gamunex, Gammagard, and Privigen. During the two-year follow-up period, 26% of cohort 1 and 23% of cohort 2 patients switched therapy. Product-specific switch rates showed Gamunex as having a significantly lower proportion ($p<0.001$) of switchers at 9% and 8% (cohort 1/2 respectively) when compared to Flebogamma (18%/22%), Privigen (24%/30%), and Gammagard (34%/25%). Among patients who switched their index product, the largest proportions (54%/41%) switched to Gamunex in both cohorts.

Conclusion: This study assessing switching patterns in naïve IVIG-treated CIDP patients from two separate US commercially-insured cohorts confirmed that Gamunex had a significantly lower switch rate than all other IVIG products. Further analyses need to be conducted to determine which factors might contribute to patients switching IVIG therapies.

Research sponsored by Grifols SSNA

#18: **The Financial Impact of Implementing Increased Utilization of Patient Assistance and Copay Assistance Programs in a Startup Specialty Pharmacy**

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Objective: To show the financial benefit brought into a specialty pharmacy through the use of Patient Assistance Programs (PAP) and Copay Assistance Programs (CoPAP).

Method: Pharmacy employees were encouraged to enroll patients in PAP and CoPAP and were asked to track the number of PAP and CoPAP they enrolled patients in at the end of each business day. Results were tallied and displayed to the pharmacy team in order to show the efforts put in by each workgroup. Monthly revenue was compared to amount of programs enrolled in order to show that these programs benefit not only the patient, but also the pharmacy utilizing them.

Results:

Number of patients with CoPAP Grants Awarded (January to May 2016): 64

Total dollar amount of CoPAP Grants Awarded (January to May 2016): $728,000

Number of patients with PAP Medications Received (January to May 2016): 14

Total cost savings from PAP Medications Received: $124,695

The implementation of PAP and CoPAP utilization allowed for $852,695 in savings over a 5 month period.

Conclusion: The utilization of PAP and CoPAP increases access of specialty medications to patients who otherwise would not be able to afford them. The implementation of PAP and CoPAP in the specialty pharmacy environment has shown to be financially beneficial to both the patients enrolled in them as well as the pharmacy that fills their prescriptions. Current tallies for the month of June show a total enrollment of 53 PAP applications and 76 CoPAP. Future financial reports should reflect even higher savings for the patient and the pharmacy due to increased enrollment. In the future, increased utilization of PAP and CoPAP can be used to justify adding on a full time employee designated to PAP and CoPAP enrollment. Staffing a full time employee that solely enrolls patients in these programs would allow for other pharmacy staff members to have more time to provide care to patients of the pharmacy.

Disclosures: The authors have no conflicts of interest or disclosures related to this publication.

#19: **Trends in Pregnancy Rates in Women with Multiple Sclerosis: A US Administrative Claims Database Analysis**

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Objective: To evaluate the rate of pregnancy in women with multiple sclerosis (MS) from 2006 to 2014, and to determine how these trends varied with age, region, and payer type.
Methods: A retrospective analysis of women with MS (International Classification of Diseases, Ninth Revision, Clinical Modification code: 340.xx) from the IMS Health Real World Data Adjudicated Claims – US database was conducted. Pregnancy rates were assessed by year (2006–2014), age, region, and payer type. Baseline demographic and clinical characteristics were evaluated for those with and without a pregnancy-related claim (diagnosis code or procedure) in the dataset for each year of data.

Results: The number of women with MS included in the annual study cohorts from 2006 to 2014 ranged from 39,801 to 59,622. The mean age of women with MS and a pregnancy-related claim ranged from 32.23 to 32.95 years, whereas the mean age of all women with MS ranged from 45.33 to 46.58 years. The proportion of women with MS who had a pregnancy-related claim fluctuated between 2.40% and 2.55% between 2006 and 2011, declined to 2.48% in 2012, and increased to 2.57% in 2014. The proportion of women with MS with a pregnancy-related claim was highest for those aged 25–29 years (range: 11.64–13.62%) and 30–34 years (9.66–11.77%), living in the Northeast (2.41–2.79%), and with Medicaid insurance (2.64–6.76%).

Conclusions: A numerical increase in pregnancy rates was observed in this US population of women with MS from 2006 to 2014. This is in contrast to pregnancy rates for all women in the US, which have steadily declined since 1990. This may reflect a change in perceptions regarding pregnancy risks in this patient population. More women with MS in the Northeast, aged 25–29 and 30–34 years, and with Medicaid health insurance had a pregnancy-related claim.

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Previous presentation: Data from this abstract have been accepted for presentation at ECTRIMS 2016 (September 14–17, 2016; London, UK).

#20: **Specialty Pharmacy and Specialty Clinical Collaboration Promotes Access to Direct Acting Antiviral Therapies for Hepatitis C**

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Objective: Direct acting antiviral (DAA) therapies are effective treatments for hepatitis C virus (HCV). Access to DAAs can be negatively impacted by high costs, insurance coverage and complex patient management. Walgreens Local Specialty Pharmacies (LSPs) coordinate with clinical practices to reduce access barriers to DAAs by facilitating prior authorization requests, appeals, copays and by providing refill reminders. This study describes the pharmacy workload and impact on DAA access and clinical outcomes as the result of a liver clinic utilizing the services of a LSP.

Method: This is a descriptive retrospective study using a joint clinical and pharmacy database for HCV patients prescribed DAAs at Piedmont Atlanta Hospital. Patients also received LSP services from 12/2013-12/2015.

Results: Of 388 patients prescribed DAAs, data on prescription fills and LSP facilitated financial assistance was available for 364 (94%) patients included. Though 225 (62%) patients were able to fill DAAs at the LSP, 139 patients (38%) were required to fill DAAs at a non LSP pharmacy due to insurance requirements. About half of patients had cirrhosis (n=211, 58%) or were treatment naïve (n=179; 49%); the majority had not received a liver transplant (307; 84%). Prescription coverage included commercial plans (n=249; 68%), Medicare (n=64; 18%), and Medicaid (n=32; 9%). Most patients (n=317; 87%) required prior authorization for DAAs. Insurance initially denied coverage to 79 (22%) patients. The LSP drafted appeal letters for 64 (81%) of the 79 patients and 5 (8%) were granted approval. Information on patient copays was available for 153 LSP patients; 56 (37%) had no copay, 31 (20%) had $1-20 copays, 41 (27%) had $21-1000 copays, and 25 (16%) had >$1000 copays. With LSP copay assistance requests, initial copays of >$20 declined to $5 or less for 63 (95%) of 66 patients. Full financial assistance was received for 20 patients with no insurance or no DAA coverage. Among 189 LSP patients with prescribed time to therapy information, most patients received medications in a week (n=119; 63%) and mean time to fill was 15 days (median: 5 days). In total, 331 (94%) patients completed their intended treatment duration (excluding deceased patients). Of those, sustained virologic response was achieved for 301 (91%) patients.

Conclusion: Collaboration between providers and LSP minimized delay in therapy, lowered rates of DAA denial, and maximized patient financial assistance.

Disclosures: Cara Joyce, Julia Zhu, Ron Hazen, Ambrose Delpino, Heather Kirkham, Shauna Markes-Wilson and Tomeka Kim are currently employed by the study sponsor, Walgreen Co.

#21: **Retrospective Analysis of the Medication Utilization and Clinical Outcomes of Patients Treated with Various Regimens for Hepatitis C (HCV) Infection**

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Objective: To evaluate medication utilization and clinical outcomes (sustained viral response (SVR), side effects, adherence rates, reasons for discontinuation, etc.) of patients being treated for HCV with any approved therapeutic combination.

Methods: The records of patients receiving their HCV medications, on FDA approved regimens, through Walgreens Specialty Pharmacy who started therapy for HCV and were eligible for SVR between January 1, 2014 and September 30, 2015 were retrospectively reviewed. Data was collected from Walgreens prescription processing and clinical assessment software. Patient responses in assessments were obtained and evaluated through Excel and Statistical Package for the Social Sciences (SPSS) software using descriptive statistics.

Results: Initially 3,609 patients were identified during that time period; however, only 1,805 were eligible for SVR during the study period and had SVR data captured. Of the 1,805 patients analyzed, 90.3% were between 46 and 65 years of age. The most common genotypes were genotype 1 (80.1%) and genotype 2 (9.6%). 56.7% of patients were treatment naïve and 34.7% had received previous treatment for HCV. The treatment history for 8.6% of patients was unknown. High initial viral loads (>800,000) were reported for 52.3% of the study population at start of therapy. Out of the original 3,609 patients identified, discontinuation of treatment occurred in 110 patients. The data showed that the largest reason for discontinuation was adverse events (26 patients). Discontinuation reasons were unknown for 40 patients.

Conclusion: SVR rates are high with currently approved agents. The average reported SVR is 92% in this study without regard to prior treatment status. Also, SVR rates observed in clinical trials are similar to what is being seen in real-world data. In addition to SVR rates, the adverse event profile of these medications is much more tolerable and discontinuations are lower than with previous therapies.

#22: **Long-Term Follow-Up of Patients with Chronic Hepatitis C Infection Following Treatment with Direct Acting Antiviral Regimens: Maintenance of SVR, Persistence of Resistance Mutations and Clinical Outcomes**

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Objective: Significant advances in the treatment of chronic hepatitis C (CHC) have been made with the introduction of direct acting antiviral (DAA) regimens. While sustained virologic response (SVR) rates may now be achieved in the majority of patients, data describing long term virologic and clinical outcomes with these regimens are needed.

Methods: Evaluation of interim data from two 3-year registry studies capturing long-term outcomes in CHC patients treated with DAAs. Subjects were enrolled into two registries according to SVR status: SVR versus non-SVR (Sequence registry). The durability of SVR, relapse rates, reinfection rates, and the persistence of resistance associated variants (RAVs) were assessed in addition to rates of hepatocellular carcinoma (HCC), changes in laboratory evaluations and liver disease assessments.

Results: 5433 patients enrolled in the SVR registry with a median (range) follow-up of 71 (0-156) weeks. 536 patients enrolled in the Sequence registry with a median (range) of follow-up of 44 (0-159) weeks. In the SVR registry, at the time of data analysis 99.7% (5414/5433) of patients have maintained SVR with 0.3% (19/5433) having emergent virus (6 relapses, 8 new infections, 5 to be confirmed). Viral emergence occurred by Week 96 in all patients. In the Sequence registry, of 89 patients who received an NS5A inhibitor and had baseline sequencing data 91.0% (81/89) had NS5A RAVs at Week 96. Hepatocellular carcinoma (HCC) was reported in 0.3% (16/5433) and 0.9% (5/536) of patients in the SVR and Sequence registries through Week 96 respectively. There were no significant changes in laboratory evaluations or liver disease assessments.

Conclusions: SVR achieved following treatment with direct-acting antiviral regimens is durable. In patients failing NS5A containing regimens, treatment-emergent NS5A RAVs persist. Rates of clinical disease progression and HCC are low. Ongoing reporting from the registry studies will be required to confirm the durability of these findings.

This research was funded by Gilead Sciences, Inc.

#23: **Evaluation of Newer Drug Therapies for Hepatitis C at a Specialty Pharmacy**

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Objective: To compare the sustained virological response at 12 weeks post therapy completion (SVR12) of newer hepatitis C therapies, approved between November 2013 and December 2014, in patients at a specialty pharmacy to SVR12 rates from published literature. Insurance coverage rates will be compared to determine a difference among insurances.

Method: Data were collected electronically from patient charts utilizing the existing computer system and manually through chart review. A complete data collection form in excel compiled the collected data and included the SVR12 rates by therapy, and sub-analysis data such as demographic and descriptive variables. Therapies included ledipasvir/sofsbuvir, simeprevir + sofosbuvir ± ribavirin (RBV), paritaprevir/ombitasvir/ritonavir/dasabuvir ± RBV, or sofosbuvir + RBV. Demographic and descriptive variables included gender, medical insurance, hepatitis C genotype, fibrosis score, treatment-experienced, treatment-naïve, and adverse effects. Insurance coverage rates were also collected through a separate electronic report.

Results: A total of 578 patients were included in the analysis of SVR12 (mean age = 59, 60% male). There were 50% of patients with genotype 1a, 18% had cirrhosis, and 60% were treatment-naïve. The overall SVR12 rate achieved by patients at the specialty pharmacy was not significantly different from published clinical trials (91% vs 91%, $p = 0.75$). A sub-group analysis of patients with cirrhosis demonstrated that patients at Avella achieved an overall higher SVR12 rate compared to published literature ($p < 0.05$). Data for coverage rates included a total of 6,284 patients and revealed that Medicare had the highest coverage rate (85%) while Medicaid had the lowest (30%).

Conclusion: Newer hepatitis C therapies used in a real world setting had similar SVR12 rates to published literature. Medicaid had a lower coverage rate compared to Medicare and commercial insurances while Medicare had the highest coverage rate.

Disclosures: There are no disclosures to report.

#24: **Impact of a Specialty Pharmacy-Based Oral Oncolytic Adherence Program on Patient Medication Adherence**

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Objective: Patient medication adherence is a basic requirement for treating chronic myelogenous leukemia (CML) with oral tyrosine kinase inhibitors (TKIs). When imatinib adherence rates are less than 80 or 90 percent, major and complete molecular responses, respectively, do not happen. The purpose of this study was to determine the effect of a real-time medication monitoring (RTMM) reminder system/ pharmacist support adherence program on the medication possession ratio (MPR) of 2 oral oncolytic medications, imatinib and nilotinib.

Method: A retrospective cohort study that extracted data from chart reviews for patients taking either imatinib or nilotinib who received services at a specialty pharmacy from 2011 to 2015. The study consisted of an intervention group utilizing the RTMM against a control group receiving no additional adherence support. MPRs, demographic, descriptive, and categorical variables were summarized using means, standard deviations (SD), and frequencies/percentages.

Results: The study population consisted of 100 adult patients, 50 in the intervention group and 50 in the control group, (mean age=62.2, SD=2.7, 50% male) who received imatinib or nilotinib as treatment for CML, gastrointestinal stromal tumors (GIST), or a similar positive Philadelphia chromosome cancer treated by a specialty pharmacy. A greater percentage of intervention group patients had a higher MPR than the control group (97% vs.81.0%, SD = 0.01 vs 0.04 respectively, $p < 0.29$). Only 4% of patients in the intervention group had an < 85% MPR, compared to 46% in the control group ($p < 0.001$).

Conclusion: Patients using an RTMM reminder system with additional pharmacist support had a mean increase of 16 percentage points for MPR. In those patients who had an MPR of ≥ 85%, the difference between groups was statistically significant. As past studies have shown, adherence rates greater than 90% have a higher likelihood of a major or complete molecular response and a greatly reduced risk of disease progression.

Disclosures: There are no disclosures to report.

#25: **Effect of a "Smart Pill-Bottle" on Medication Adherence in Patients Who Have Multiple Myeloma and Are New to Lenalidomide Therapy**

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Objective: According to the Network for Excellence in Health Innovation (NEHI), the United States spends $750 billion each year on wasted health care. Poor medication adherence alone accounts for $290 billion of the annual wasted healthcare spend. In many disease states, such as oncology, newer, targeted oral therapy has allowed patients to take their medication at home. However, medication non-adherence with these complex regimens can lead to ineffective treatments, hospitalizations, and unnecessary disease progression. The purpose of this study is to evaluate the effect of a "smart pill-bottle" on medication adherence in patients who have multiple myeloma and are new to lenalidomide therapy.

Method: In this prospective, randomized, single-blind, controlled study, 40 patients were provided with "smart pill-bottles". Available features of the bottle include reminder ringtones, lights, and text messages. Once patients were enrolled in the study they were randomized into one of two groups. The intervention group (N=20) received a pill bottle with activated lights, and noise alerts. On the other hand, the control group (N=20) received an identical pill bottle with all alerts deactivated. Using real-time data from individual pill bottles adherence rates between the intervention group and control group were compared.

Results: Between January 2016 and February 2016 we were able to enroll 40 new lenalidomide patients. After approximately 3 months of therapy we gathered preliminary data. We found adherence was significantly greater in intervention group when compared to the control group (median: 100% vs. 90.75%, p=0.001).

Conclusion: The present findings suggest that the "smart pill-bottle" device significantly improves patient adherence when compared to control group. However, further investigation with longer use of the device is needed to determine if "smart pill-bottles" lead to improved medication persistence and overall healthcare outcomes.

Disclosures: There are no disclosures to report.

#26: **An Evaluation of the Impact of Patient Out-of-Pocket Costs and Satisfaction with Therapy on Adherence to Disease-Modifying Drugs in Patients with Multiple Sclerosis**

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Objective: To evaluate the impact of patient out-of-pocket (OOP) costs and satisfaction with therapy on adherence to disease-modifying drugs (DMDs) in patients with multiple sclerosis (MS).

Methods: Patients with MS (n=1112) currently treated with a self-injectable or oral DMD from the US National Health and Wellness Survey or Lightspeed Research panel and its affiliates completed an internet survey between April and October 2015. The survey included questions about demographics, disease severity and symptoms, treatments, health behaviors, and comorbidities. MS-related OOP costs for doctor visits, medication, and other costs were reported as monthly estimates. DMD adherence was evaluated using the 4-item Morisky Medication Adherence Scale (MMAS-4). The Treatment Satisfaction Questionnaire for Medication (TSQM) assessed satisfaction (ie, effectiveness, convenience, and satisfaction) with current DMD.

Results: Of 805 survey respondents meeting study criteria, 429 reported high adherence (MMAS-4 = 0) and 376 reported low adherence (MMAS-4 = 1–4). Bivariate analyses showed no statistically significant differences in OOP costs between high and low adherers. TSQM scores for effectiveness, convenience, and satisfaction were significantly higher in high adherers vs low adherers (all $p<0.05$). The data were further delineated to elucidate if relationships could be uncovered with different adherence categories. Low adherers were re-categorized as either moderate (MMAS-4 = 1–2) or low (MMAS-4 = 3–4) adherers. New patterns emerged with the increased granularity. Compared with high adherers, (newly defined) low adherers had higher monthly MS-related OOP doctor visit costs ($42.60 vs $23.75 for moderate adherers and $24.07 for high adherers; $p<0.05$) and other OOP costs ($71.37 vs $42.34 for moderate adherers and $35.57 for high adherers; $p<0.05$). Compared with high adherers, (newly defined) low adherers had lower TSQM satisfaction scores (44.53 vs 56.51 for moderate adherers and 57.26 for high adherers; $p<0.05$).

Conclusions: In this real-world population, lower OOP costs and greater treatment satisfaction were associated with higher levels of DMD treatment adherence.

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Previous presentation: Data from this abstract have been accepted for presentation at ECTRIMS 2016 (September 14–17, 2016; London, UK).

#27: **The Development and Assessment of a Predictive Model for Dasatinib Persistency in a Specialty Pharmacy Setting**

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Objective: Persistency to oral oncolytic therapy has been shown to correlate with treatment effectiveness and healthcare resource utilization.[i,ii] We hypothesize that by using data points available upon patient intake, specialty pharmacies can potentially improve patient outcomes by tailoring clinical programs to better support patients at higher risk of non-persistence. Previous efforts have shown that predictive models can be designed using claim databases.[ii, iii, iv] The purpose of this study is to assess the applicability of implementing such a model for a dasatanib population within a specialty pharmacy setting.

Methods: A predictive mathematical model was created with the intent to predict a patient's persistence to dasatinib therapy. The model was assessed using retrospective claims data of a specialty pharmacy's dasatinib patient population (n=165; July 2014-July 2016). A backward stepwise logistic regression was performed to identify data variables that most impacted the model's efficacy[v].

Results: The predictive model developed for this study was able to predict persistence with a 64-66% accuracy rating for 3 and 6-month persistency, respectively. Variables found to be of most significance (P<.05) included prevalence of scheduled nursing calls and insurance type.

Conclusions: This study set out to investigate the design and application of a persistency model in a specialty pharmacy setting. The results of this study will be used to further improve our predictive modeling abilities across other therapeutic areas.

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#28: **Real World Assessment of All Oral, Sofosbuvir-Based, Hepatitis C Therapy at an Academic Medical Center with Integrated Specialty Pharmacy Services**

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Objective: Hepatitis C therapy has drastically changed over the last few years with the introduction of all-oral, direct acting antiviral (DAA) therapy. Clinical trials report sustained virologic response rates 12 weeks post therapy (SVR12) at over 90% with these new DAAs. Clinical trials have the benefit of strict inclusion and exclusion criteria and are able to provide full access to medications. The medical diversity and medication tolerance of patients outside of a clinical trial paired with financial barriers create a different environment for those patients being treated in the real world setting. The purpose of this study was to evaluate patient tolerance, response and medication access to all-oral, sofosbuvir (SOF)-based, hepatitis C therapies in a real world setting.

Methods: Retrospective chart review at Vanderbilt Digestive Disease Center of adult patients treated between December 1, 2013 and May 31, 2015. Rates of medication access, copay costs, appeals, therapy completion, clinical cures and adverse effects were evaluated based on treatment regimens of sofosbuvir/ribavirin (SOF/RBV), sofosbuvir/simeprevir (SOF/SIM) and sofsobuvir/ledipasvir +/- ribavirin (SOF/LDV+/-RBV).

Results: A total of 717 patients were included in the analysis (mean age= 56, 59% male, 61% genotype 1a, 56% cirrhotic). An SVR12 was available in 686 patients showing an overall 87% cure rate. The SVR12 rate of the SOF/LDV regimen was 91%, SOF/LDV+/-RBV resulted in a 100% SVR12 rate, while SOF/SIM and SOF/RBV trailed at 86% and 82%, respectively. The clinic integrated Vanderbilt Specialty Pharmacy (VSP) serviced 67% of the patients. The therapy completion rate was 97% in the VSP patients and 93% in the non-VSP patients (p=0.02). The average patient pay prescription cost at VSP was $20, mode=$0. Insurance appeals were required for 25% of the population with a 91% approval rate. Overall, 71% of patients experienced side effects while on therapy with <2% of those patients discontinuing early due to medication intolerance.

Conclusion: The SVR12 rate of SOF-based all-oral, antiviral therapy in a medically diverse and largely cirrhotic patient population was impressive. Adverse effects were common but rarely caused early discontinuation. Patient utilization of the clinic integrated Vanderbilt Specialty Pharmacy significantly increased the likelihood of completion of the full course of therapy and kept patient pay prescription cost low.

Disclosures: There are no disclosures to report.

#29: **Impact of the Clinical Therapy Management Program for Immune Globulin on Infection Rate for Immune Deficiency Patients at Barnes Precision Specialty Pharmacy**

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Objective: In order to meet the needs of all stakeholders in a complex therapeutic category, Barnes Precision Specialty Pharmacy implemented MHA's Clinical Therapy Management (CTM) program to track and monitor immune globulin (IG) patients. CTM allows clinicians to follow a clinical support pathway to help enhance their specialty patient care and to facilitate the collection of clinical and dispensing metrics for specialty reporting and evaluation of outcomes. It is known that implementation of CTM at this pharmacy positively impacted adherence for IG patients, but further study was needed to determine its impact on clinical outcomes.

Methods: This study included 111 patients with an immune deficiency diagnosis who received a prescription for IG from January 1, 2015 to December 31, 2015, and for whom a baseline clinical assessment was completed. Upon enrollment into the CTM program, the baseline clinical assessment documented the number of infections reported in the previous year. Patients were then clinically assessed at each refill throughout the study period, which included ongoing tracking of the number of infections and patient impression of change.

Results: Upon enrollment in the CTM program, 15 patients reported no infections in the previous year; 57 patients reported from 1-5 infections; 35 patients reported ≥ 6 infections; 4 were unknown. After enrollment in the CTM program, 75 patients reported no infections in 2015; 25 patients reported from 1-5 infections; 11 patients reported ≥ 6 infections ($p<0.001$). Furthermore, patients reported feeling that they were responding positively to their therapy 71% of the time, while reporting that they did not feel that they were responding positively to their therapy only 2% of the time.

Conclusions: Enrollment into the CTM program at this specialty pharmacy had a positive impact on clinical outcomes for immune deficiency patients as measured by the marked decrease in number of infections after enrollment in the clinical management program. There was clear separation in the number of infections prior to enrollment in the program and post enrollment in the program as well as statistical significance between the two groups. Further analysis will include prior treatment and other possible confounding factors. The CTM program is one strategy this specialty pharmacy uses to manage a complex therapeutic category and work towards visibility into actionable clinical data, optimal patient outcomes, and excellent customer service to all stakeholders.

This abstract includes data previously presented at the Immune Globulin National Society (IgNS) 5th National Conference, September 15-18, Miami, FL.

#30: **Impact of the Clinical Therapy Management Program for Immune Globulin on Adherence for Patients at Barnes Precision Specialty Pharmacy**

Stacey Ness, PharmD, CSP, MSCS, AAHIVP[1]*; Trey Bankson, RPh*[2]*; Chris Popun, PharmD*[2]
[1]Managed Health Care Associates (MHA), Florham Park, NJ; [2]Barnes Precision Specialty Pharmacy, Gainesville, FL

Objectives: Clinical product variations, administration considerations, patient monitoring, reimbursement challenges, and increasing data needs must be considered when managing Immune Globulin (IG) patients. In order to meet the needs of all stakeholders, Barnes Precision Specialty Pharmacy implemented MHA's Clinical Therapy Management (CTM) program to track and monitor IG patients. CTM allows clinicians to follow a clinical support pathway to help enhance their specialty patient care and to facilitate the collection of clinical and dispensing metrics for specialty reporting. The objective of this study was to look at adherence from 12 to 18 months post implementation of the CTM program.

Methods: This specialty pharmacy implemented the professionally peer reviewed CTM program in September 2014. 178 patients who had at least one prescription dispensed for IG therapy in either of the first two study periods were included. The first study period was from 3/1/2014 through 8/31/2014 (6 months pre-CTM implementation), the second study period was from 10/1/2014 through 3/31/2015 (6 months post- CTM implementation), and the third study period was from 10/1/2015 through 3/31/2016 (12 months post-CTM implementation). Adherence for IG therapy was measured by average number of fills per patient and total number of fills prior to CTM implementation and post-CTM implementation. The average number of grams per patient in each of the study periods were also analyzed and compared.

Results: The total number of fills prior to the CTM program was 696 compared to 943 six months post implementation and 848 twelve months post implementation. The average number of fills prior to the CTM program was 3.91 compared to 5.3 six months post implementation (p=0.001) and 4.76 twelve months post implementation (p=0.042). The average number of grams increased from 168.54 grams in the first study period to 246.29 grams per patient six months post CTM implementation (p=0.015) and 235.77 grams per patient twelve months post CTM implementation (p=0.032).

Conclusions: Implementation of the CTM program had a significant impact on adherence that was maintained one year post implementation as measured by the average number of fills per patient and the total number of fills in each study period. The CTM program is one strategy that this specialty pharmacy uses to manage a complex therapeutic category and work towards visibility into actionable clinical data, optimal patient outcomes, and excellent customer service to all stakeholders.

This abstract includes data previously presented at the Immune Globulin National Society (IgNS) 5th National Conference, September 15-18, Miami, FL.

#31: **Local Specialty Pharmacists' Role in Care Transitions for Transplant Patients on a Multidisciplinary Team**

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Objective: To describe a multidisciplinary transplant team model involving community pharmacists and evaluate patient satisfaction of the services provided by community pharmacists on the transplant team.

Methods: This prospective, descriptive study took place at a single-center local specialty pharmacy in collaboration with a large, urban hospital. New liver, kidney and pancreas transplant recipients at BIDMC were recruited from March 2016 to May 2016 to participate in an anonymous telephone satisfaction survey, which consisted of 10 mixed questions (short answer and 10-point Likert scale, 1= extremely dissatisfied; 10 = extremely satisfied). Additionally, the study described and quantified the extent of community pharmacist involvement in the transitional care of these transplant patients using descriptive statistics.

Results: The 15 new transplant patients (mean age = 57+/- 8.2 years) that participated in the satisfaction survey delivered a 100% net promoter score in 80% of the categories evaluated, including "Overall Satisfaction" of the pharmacist-driven transplant program. In addition to the survey, this study described the different phases of the medication use process, and revealed that the most time-intensive phase of the medication use process (mean time = 70 minutes per patient) was at the very beginning of the patient's care; this was when local specialty pharmacists collaborated with other providers on the transplant team to resolve prescription insurance issues and discuss affordable therapy alternatives.

Conclusions: Incorporation of local specialty pharmacist involvement earlier in the transplant process allowed for greater collaboration with the health-system and proactive resolution of barriers to therapy. Patients were overwhelmingly satisfied with the pharmacist-driven transplant program.

Disclosures: This research was funded by Walgreen Co., and the following authors, Darlene Nguyen, Karen Poliskey and Allison Loring, are employees of Walgreen Co. All other authors of this presentation have nothing to disclose.

#32: **Real World Experience with PCSK9 Inhibitors in a Health System Specialty Pharmacy**

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Background: Fairview Specialty Services Pharmacy (FSSP) implemented a centralized process for dispensing Proprotein Convertase Subtilisin Kexin Type 9 (PCSK9) Inhibitors to ensure safe and appropriate use, monitor effectiveness, and improve medication persistence and adherence. Five to seven days after the patient receives the medication our pharmacists will screen for potential adverse events, difficulty with self-injection, and potential adherence concerns. Cholesterol laboratory values, including Low-Density Lipoprotein (LDL) cholesterol, are recorded prior to the patient starting therapy and then again 100 days post-therapy initiation to assess treatment effectiveness.

Objective: The goal of this retrospective evaluation was to better understand trends and patterns of PCSK9 use and identify potential barriers to adherence that could help us improve our pharmacy service offerings.

Methods: We reviewed dispensing data and health records for all patients who received at least 84 days of PCSK9 inhibitor therapy from FSSP. Dispensing data was used to calculate individual Medication Possession Ratios (MPR) and Proportion of Days Covered (PDC) adherence metrics. Health records were reviewed for changes in LDL values and any documentation of barriers to medication adherence, such as adverse events. Both MPR and PDC values were then compared to LDL cholesterol laboratory value change from baseline to follow-up.

Results: Thirty patients were included in our evaluation of PCSK9 Inhibitor treatment; Average duration of PCSK9 inhibitor therapy was 179 days (range 84 to 336 days). The average MPR was 0.91 (range 0.67 to 1) and the average PDC was 0.87 (range 0.59 to 1). Patients with recorded LDL cholesterol values (N=25) experienced an average decrease of 100 mg/dL from baseline resulting in a 30%-80% individual reduction. Only two adverse events were reported. Due to small patient population and high level of adherence among patients with follow-up LDL values the impact of adherence on LDL lowering could not be assessed.

Conclusion: Our retrospective review of PCSK9 inhibitor users suggests that patients have a relatively high level of adherence and, thus far, have reported very few barriers to adherence. Continued monitoring and follow-up with our patients is important to further define the impact of our program and understand the implications of non-adherence.

Disclosures: None.

#33: **Feasibility Study to Evaluate the Utility and Usage Frequency of a Digital Health Coach for Multiple Sclerosis (MS) Patients**

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Objective: The primary objective of this study is to test acceptance and interaction with a digital health coach (DHC) on multiple sclerosis (MS) patients.

Methods: Built using artificial intelligence, a DHC is designed to emulate a human, build a relationship and ultimately help change behavior. The DHC was given a name, Sara. The DHC's primary goal was to track and confirm patient adherence to prescribed daily medication. The DHC also obtained patient-reported data—administering several common clinical assessments used in clinical practice to monitor MS progression including: bowel and bladder assessments, Timed Up and Go test (TUG test), the 25-foot timed walk, and the MS Quality of Life questionnaire (MS QOL 54). The DHC recorded symptoms and adverse events on the patients. The DHC also answered common questions concerning daily MS symptoms and problems.

This is a multicenter, open label, single cohort, observational study, involving 17 subjects over 90 days. Patients were eligible for participation if they had been taking a daily administered FDA approved disease modifying treatment (DMT) for at least three months and had demonstrated stability, tolerability and compliance consistent with the standard of care.

Results: There were approximately 5500 unique interactions with the DHC. Most users interacted with her on a daily basis. The preferred interaction method was to type questions or answers with 72% of all inputs typed. The second most common method was to click on a link or answer with 22% of all inputs using this method. Only 6% of all interactions were the result of people using their voice. Adherence was recorded by most participants during the study. Overall adherence was 83%, measured as logged doses of prescribed medication.

Conclusion: The use of the DHC to communicate with MS patients was accepted by trial participants. The DHC was beneficial in maintaining adherence and gathering data on various clinical assessments and adverse events. Patients were comfortable discussing intimate concerns and symptoms with the DHC. Study participants interacted with the DHC in a natural, personal manner which evolved over the course of the study, demonstrating patient acceptance of this technology. A larger, more extensive trial is justified to investigate ongoing compliance and adherence maintained by the use of this technology, and the potential for a DHC to demonstrate stability, worsening, or improvement in disease state metrics as measured by the clinical patient-reported outcomes.

#34: **Retrospective Analysis of the Clinical Outcomes, Medication Utilization, and Economic Impact of Patients Treated with Lumacaftor/Ivacaftor for Cystic Fibrosis**

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Objective: The purpose of the study is to evaluate clinical outcomes (side effects, adherence rates, discontinuation rates, and reasons for discontinuation), medication utilization (medication possession ratio/proportion of days covered), and the economic impact for patients that are using lumacaftor/ivacaftor for the treatment of cystic fibrosis.

Methods: Patients of Walgreens Specialty Pharmacy – Central Specialty locations who started therapy with lumacaftor/ivacaftor for cystic fibrosis between August 1, 2015 and January 31, 2016 were retrospectively reviewed. Data was collected from Walgreens prescription processing and clinical assessment software. Data included demographic information, genotypes, patient reported side effects, discontinuations, adherence markers, and therapy costs. Patient responses in assessments were obtained and evaluated through Excel and Statistical Package for the Social Sciences (SPSS) software using descriptive statistics. Patients were excluded if they were younger than 12 years of age, if they were not homozygous for the F508del mutation, or if the genotype was unknown.

Results: Of the 1,005 patients included in the study, 124 discontinued therapy for various reasons, representing 12.3% of the study population. The top reason for discontinuation (49 patients, 39%) was adverse events. The leading adverse event that resulted in therapy discontinuation was dyspnea, followed by chest tightness. The median medication possession ratio (MPR) was 97% and there was not a statistically significant correlation between the impact on MPR and patient-reported adverse events. From a financial standpoint, there were 772 patients who had commercially-funded primary insurance coverage and 416 of these patients had no secondary insurance, which resulted in an average monthly copay of $37.00.

Conclusions: Lumacaftor/ivacaftor is generally well-tolerated and out-of-pocket cost is not a barrier to access for the majority of patients. Also, after analyzing the MPR data, clinical programs and follow-up assessment, this study population was adherent to their medication regimen. This data in the real-world population is very promising for the treatment of CF.

This abstract includes data previously presented at the Academy of Managed Care & Specialty Pharmacy's Annual Meeting, April 19-22, 2016, San Francisco, CA.

#35: **Quality Indicators for a Pharmacy Fertility Medication Phone Consultation Program**

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Objective: Medications are a regular part of infertility treatments and the primary treatment for women with ovulation disorders. Gonadotropins are the most common type of medications used for ovarian stimulation when the first-line therapy, clomiphene citrate, is not successful. Gonadotropins are expensive and administered by injection. Walgreens Fertility Order Review (FOR) Program is designed to help reduce patient anxiety as they prepare to self-administer gonadotropins, as well as prevent wastage or loss due to incorrect storage of medication or missed doses, by offering a personalized phone consultation. The FOR program allows for patients to have direct access to fertility nurses who provide tailored support through a phone consultation to review: 1) the contents of the fertility medication order, 2) the purpose of each item, medication administration and correct storage, 3) the refill process and 4) any patient questions with escalations to a pharmacist as needed. This objective study assesses select quality indicators regarding the FOR program.

Method: This descriptive study was conducted among patients who received services from the FOR program from September, 2014 through June, 2016.

Results: Among 27,358 patients in the FOR program during the study period, the fertility nurses spent 1-10 minutes with 20,992 (76.7%) patients, 11-20 minutes with 6,187 (22.6%) patients, and more than 20 minutes with 151 (0.6%) patients. The estimated wastage or loss prevented was $40,098. The FOR program prevented a total of 1.42 missed doses/month for 15,283 patients from September, 2014 to August, 2015 and 0.7 missed doses for 12,075 patients from September, 2015 to June, 2016. The missed doses declined with the support of the program. 8,790 patients completed a survey, with a 97.0% satisfaction rating of their Walgreens Specialty experience.

Conclusion: This study demonstrated the FOR program prevented medication wastage and loss for patients who received expensive injectable fertility medication. The program also prevented missed or late doses of medications which could have resulted in total loss of their fertility cycle. These positive patient outcomes helped to validate the significance of the program. Surveys also indicated a high level of satisfaction and positive patient overall experience with the specialty pharmacy's service.

Disclosures: All authors are currently employed by the study sponsor, Walgreen Co.