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The National Association of Specialty Pharmacy Abstract Program

Richard A. Brook and Sheila Arquette

The National Association of Specialty Pharmacy (NASP) Annual Meeting & Expo is being held from September 9–12 at the Marriott Wardman in Washington, DC. More than 1,200 specialty pharmacy stakeholders are expected to attend. The agenda includes 36 educational sessions organized into four CORE tracks: C = Clinical; O = Operational; R = Regulatory; and E = Experience. The conference also includes keynote speakers, a large exhibit hall, post-conference workshops, continuing education satellite symposia, and poster presentations.

The poster presentations allow NASP members to showcase the results of their research. Blinded abstracts were reviewed by NASP members and over 40 abstracts were accepted for presentation at the conference. The abstracts represent a diverse array of topics, including specialty pharmacy management, interventions, medication adherence, and access. Many of the abstracts focus on specialty conditions, including oncology, transplant therapy, hepatitis C virus, multiple sclerosis, and autoimmune conditions.

During the conference, authors will present their posters that further demonstrate their innovation, commitment to quality care, and service excellence, as well as specialty pharmacy’s positive impact on the patient journey and the total cost of care. Conference attendees will vote to select the top poster(s), and the author(s) will be presented with an award on Wednesday morning at 8 AM.

NASP has partnered with the Journal of Drug Assessment to make the abstracts available to a larger worldwide audience in this open-access supplement. Copies of abstracts and posters from 2019 and prior years can be accessed at www.naspnet.org/abstractsposters. Additionally, as of September, the Journal of Drug Assessment will serve as an official journal of NASP.

As a 501(c)(6) non-profit trade organization, NASP is the only non-profit national association representing all stakeholders in the specialty pharmacy industry. The mission of NASP is to elevate the practice of specialty pharmacy by developing and promoting continuing professional education and certification of specialty pharmacists, while advocating for public policies that ensure patients have appropriate access to specialty medications in tandem with critical services.

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. With over 110 corporate members and 1,600 individual members, NASP is the unified voice of specialty pharmacy in the United States.

The association was founded in 2013 and hosts this annual meeting each September that offers education sessions, continuing education credits, and a certification program for specialty pharmacists. The NASP website is located at www.naspnet.org.
**Patiromer and maintenance of RAASI therapy in hyperkalemic medicare patients**

Nihar R. Desai, Christopher G. Rowan, Paula J. Alvarez, Jeanene Fogli and Robert D. Toto

**ABSTRACT**

**Background:** Renin angiotensin aldosterone system inhibitor (RAASI) therapy is part of the cornerstone of therapy for patients (pts) with cardiovascular disease including hypertension, CHF, and/or CAD, but use is often limited by the development of hyperkalemia. Patiromer (PAT) is a sodium (Na)-free non-absorbed potassium (K⁺) binder approved for hyperkalemia (HK) treatment. Patiromer has been shown to reduce recurrent HK and allow pts to maintain RAASI.

**Aims:** This retrospective cohort study evaluated RAASI utilization among Medicare Advantage pts with HK.

**Methods:** RAASI utilization was evaluated from a large, de-identified national health insurance claims database, Optum Clininformatics Datamart, from January 1, 2016 to December 31, 2017. Three HK cohorts were identified: (1) patiromer (PAT cohort) or (2) sodium polystyrene sulfonate (SPS cohort), or (3) HK diagnosis code without K⁺-binder prescription (NoKb cohort). Pts were included who had a pre-index serum K⁺ ≥5.0 mEq/L and were continuously exposed to RAASI for ≥6 months pre-index (i.e. index date is date of first K⁺ binder dispensing or HK diagnosis). Exposure during follow-up was classified as intent to treat (ITT) and continuous exposure (CE). ITT follow-up began on the index date and ended at the first censoring event (i.e. plan disenrollment, death, December 31, 2017) or 6 months post-index while CE also included censoring for discontinuation or switching of binder therapy (i.e. PAT or SPS). RAASI continuation and down-titration (the latter assessed for lisinopril, losartan, and valsartan) were assessed at 6 months post-index.

**Results:** The study population included: 214 PAT pts, 2371 SPS pts, and 8531 NoKb pts. Overall, the mean age was 75 years and 50% were male. Pt comorbidities (all cohorts): CKD (48%), ESRD (1%), CHF (23%), and DM (54%). At 6 months post-index, 102 (ITT)/36 (CE) PAT pts, 1,627 (ITT)/35 (CE) SPS pts, 5,543 (ITT)/5,127 (CE) NoKb pts were evaluated. RAASI continuation rates for CE were 78%, 57%, and 57% and for ITT were 63%, 52%, and 56% in the PAT, SPS, and NoKb cohorts, respectively. Down-titration rates for the CE/ITT groups were 13%/9%, 6%/7%, and 7%/8% in the PAT, SPS, and NoKb cohorts, respectively.

**Conclusions:** At 6 months post-index, among continuously exposed patiromer pts, a high RAASI continuation of ~80% was observed. RAASI continuation for pts in the SPS and NoKb cohorts was <60%. Down-titration rates of RAASI in all three cohorts were low (~10%). Further study is warranted to fully elucidate these findings.

**KEYWORDS**
Congestive heart failure; chronic kidney disease; hyperkalemia; RAASI therapy; Medicare

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**Sponsor:** Funded by Relypsa, Inc., a Vifor Pharma Group Company

**Previous presentations:** American Society of Nephrology Kidney Week 2018, October 23, 2018, San Diego, CA. Poster #SA-P0712. Academy of Managed Care Pharmacy Managed Care & Specialty Pharmacy Annual Meeting 2019, March 25, 2019, San Diego, CA.

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Psoriasis patients utilizing secukinumab, ixekizumab, or brodalumab – comparisons to prior biologic medication adherence levels, reasons for switching, and reported changes in disease symptoms

Renee Baiano, Francis Staskon and Rick Miller

ABSTRACT

Background: Since the approval of interleukin-17 (IL-17) inhibitors to treat psoriasis progression, an increasing number of patients have switched to these third-generation biologics (i.e. secukinumab, ixekizumab, or brodalumab). Little is known about the impact of the new therapy choices upon patient adherence, reasons for switching, or patient reported impacts.

Aims: Describe pharmacy utilization for IL-17 inhibitors, and investigate differences from prior biologic treatments (i.e. adalimumab, ustekinumab, or etanercept) on associated medication adherence levels, or patient reported reasons for switching and current disease symptoms after switching.

Methods: Pharmacy records from a national specialty pharmacy were examined retrospectively for patients starting an IL-17 inhibitor from January 2016–December 2017, as well as their biologic treatment in the prior 12-months (i.e. adalimumab, ustekinumab, or etanercept). In addition, patient reported information from the clinical management platform was included for those switching from a prior therapy. A 180 day follow-up period was used after starting the IL-17 inhibitor (till May 31, 2018). The medication adherence outcome was the proportion of days covered (PDC) in the observation period (180 days). Excluded patients were under the age of 18 at the start of the new IL-17 inhibitor, or those residing in a US territory.

Results: The study sample of 5,215 consisted of 2,218 (42.5%) switching from a prior treatment. The most frequent IL-17 inhibitor dispensed was secukinumab (76.1%), followed by ixekizumab (23.7%), and the more frequent prior treatments were etanercept (37%) and adalimumab (35.8%). Gender and age distributions were similar across the IL-17 inhibitors. Medication adherence significantly increased after switching 6.4% on average PDC, and patients were 1.56-times more likely to be adherent (PDC ≥ 80%); after adjusting for age, gender, census location, and provider specialty. In these multivariate models, the only covariate significantly associated to higher adherence was if the provider specialty was in rheumatology. The most common reason reported for switching was “ineffective treatment” (64.7%). After switching to an IL-17 inhibitor, 45.7% of patients report symptoms as “better”, 26.5% the “same”, and only 5.3% state “worse” symptoms.

Conclusions: Specialty pharmacies offering the recent IL-17 inhibitors allow for additional treatment options for patients needing alternative therapies.

KEYWORDS
Psoriasis; outcomes; specialty pharmacy; interleukin inhibitors

PRESENTER
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The impact of an integrated health-system specialty pharmacy on HIV antiretroviral therapy adherence, viral suppression and CD4 count in an outpatient ID clinic

Elizabeth Barnes, Adam Giumenta, Marc Johnson and Jing Zhao

ABSTRACT

Background: Atrium Health (AH) is a Charlotte-based not for profit hospital network that currently cares for HIV-infected patients through three outpatient ID clinics. AH recognized that novel approaches to patient care which incorporate clinical pharmacists and health-system specialty pharmacy into the practice model can help improve the HIV continuum. As a result, AH created an HIV specialty pharmacy service line that embedded an HIV-trained clinical pharmacist and pharmacy technician within one of three health-system outpatient ID clinics.

Aims: This study aimed to evaluate the antiretroviral medication adherence rate, viral load, and CD4 count among patients utilizing Atrium Health Specialty Pharmacy Service (AH SPS) compared to patients that opted out of the program.

Methods: This was a single-center, retrospective cohort study conducted from 7 August 2017 to 30 June 2018. All patients were already on HIV therapy at either entry or declination to the AH SPS program. The intervention group was defined as HIV patient care that incorporated AH SPS into the practice model. The control group was defined as HIV patient care that did not involve our health-system specialty pharmacy. The primary endpoints were medication adherence, viral suppression, and CD4 counts. Adherence was measured using pharmacy claims data and the Medication Possession Ratio (MPR) calculation. Baseline viral load and CD4 count at the time of entry or declination to the program was recorded as well as at the end of the observation period. Comparisons between the opt-in and opt-out groups were made.

Results: For those patients using AH SPS, the overall average adherence rate was 100% versus only 89% for those patients that opted out of the service ($p < 0.01$). Furthermore, all but 3 patients using AH SPS reached viral suppression ($p = 0.03$) and all but one had improved immunefunction with a CD4 count 200 or greater by the end of the observation period ($p = 0.03$). The change in viral suppression and CD4 count of 200 or greater was not statistically improved between baseline and follow up in those opting out of using AH SPS.

Conclusions: The AH SPS utilized an innovative practice model that fully integrated a specialty pharmacy team within an outpatient ID clinic. This novel approach to patient care significantly improved adherence which in turn lead to improved viral suppression and immune markers in patients enrolled within the program compared to those opting out.

KEYWORDS

HIV; adherence; specialty pharmacy; viral load

PRESENTER

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Work submitted elsewhere: Manuscript has been submitted for review by the Journal of Managed Care and Specialty Pharmacy.
Assessment of integrated specialty pharmacy services as a medication optimization strategy for rifaximin in hepatic encephalopathy patients

Elezabeth Mac, Alicia Battershell, Haitam Buaisha and Kami Nolan

ABSTRACT

Background: Lactulose non-adherence has been identified as a factor for recurrent episodes of hepatic encephalopathy (HE). Treatment guidelines recommend adding rifaximin (Xifaxan) to lactulose for ongoing management after an overt HE recurrence on lactulose alone to reduce the risk of further episodes and HE-related hospitalizations. Clinical observations suggested that rifaximin therapy is not initiated in patients upon HE-related hospital discharge where indicated.

Aims: Integrate the CHI Health Specialty Pharmacy medication access coordinator (MAC) into the cascade of care of patients during an HE-related hospitalization to optimize access to and initiation of rifaximin upon discharge.

Methods: Retrospective assessment of integrated MAC assistance in the CHI Health gastroenterology clinic from 26 September 2018 to 31 March 2019. Hospitalized patients were identified using TheraDoc reporting. Inclusion criteria: rifaximin ordered during an HE-related hospital admission at CHI Health. Exclusion criteria: discharge care assignment to an alternative physician group or facility. Primary outcome: the percentage of patients initiated on rifaximin upon hospital discharge via the integrated MAC. Secondary outcomes: cases requiring benefits verification and financial assistance, and number of rifaximin prescriptions acquired by the CHI Health Specialty Pharmacy.

Results: A total of 40 patients met the inclusion criteria during the assessed timeframe. Thirty-one patients were excluded, 27 to other groups and 4 to facilities. Integrated MAC assistance was utilized for the remaining 9 patients and 100% were initiated on rifaximin upon discharge. Of those, 4 required benefits prior authorizations, 2 qualified for manufacturer patient assistance and 3 received sample medication. CHI Health Specialty Pharmacy acquired 2 rifaximin prescriptions.

Conclusions: Integrated MAC assistance in a health-system gastroenterology clinic optimizes rifaximin access and initiation in patients following an HE-related hospitalization. It is anticipated that more patients going forward will qualify for MAC assistance due to a reduction in the community physician groups providing care at CHI Health. Further evaluation is warranted to determine whether medication optimization results in improved adherence and reduced readmissions in this population.

KEYWORDS
Rifaximin; hepatic encephalopathy; medication optimization; medication access coordinator

PRESENTER
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Notes
1. Xifaxan is a registered trademark of Salix Pharmaceuticals
2. TheraDoc is a registered trademark of Premier Inc.
Medication adherence and graft survival among kidney transplant recipients

Safia Boghani, Heather Kirkham, Edward A. Witt, Nishita Hira, Wida S. Cherikh, Amber R. Wilk, Jude Maghirang and Glen Pietradoni

ABSTRACT

Background: Though medication adherence is essential for graft survival, non-adherence to immunosuppressants post kidney transplant is common (30–35%), potentially leading to poor quality of life and increased healthcare costs.

Aims: The objective of this study was to examine the association between graft survival and adherence in kidney transplant recipients.

Methods: This retrospective, observational cohort study used claims data from a single, large national pharmacy chain and post-transplant follow-up data from the OPTN Network database. The sample included adult deceased donor kidney transplant recipients (most recent transplant if more than one) who had: >2 pharmacy claims for any immunosuppressant >150 days apart in the 12 months after their first fill in the study period (2013–2016). Proportion of days covered (PDC) by any immunosuppressant for 12 months after first fill was calculated as a measure of adherence (defined as PDC >80%). Graft survival was defined as having a surviving graft at the end of the study period. Logistic regression was used to estimate the association between adherence and graft survival controlling for covariates (age at transplant, time since transplant, gender, race/ethnicity, copay, number of prescriptions for chronic conditions, pharmacy insurance plan, brand medication usage, digital fills, filling at a transplant specialized pharmacy, receiving financial assistance, the interaction between brand medication usage and receiving financial assistance, and the interaction between age and adherence).

Results: Of the 14,703 kidney transplant recipients eligible for the study, 73% were adherent and 85% had a surviving graft (1 to 9780 post-transplant). After adjusting for covariates, the odds of having a surviving graft were higher for adherent patients than for non-adherent patients (OR = 2.75, [1.95, 3.87]; p < .001). Other notable factors associated with graft survival included having no post-index prescriptions for chronic conditions (OR = 3.48, [2.95, 4.11]; p < .001) and commercial insurance (vs. Medicare Part B) (OR = 1.35, [1.16, 1.56]; p < .001).

Conclusions: This analysis suggests adherent patients were more likely to have a surviving graft than those who were not adherent to immunosuppressants. As medication adherence behaviors may vary across patient populations, future studies should aim to show which patient behaviors contribute to medication adherence.

KEYWORDS
Transplant; adherence; graft survival; immunosuppressant; graft failure

PRESENTER
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ABSTRACT

Background: Though medication adherence is essential for graft survival, little is known about the impact of non-adherence on heart transplant survival.

Aims: The objective of this study was to examine the association between graft survival and adherence in heart transplant recipients.

Methods: This retrospective, observational cohort study used claims data from a single, large national pharmacy chain (claims data from 2013-2016) and post-transplant follow-up data from the OPTN database (data from post-transplant to 2016). The sample included adult, deceased-donor heart transplant recipients (most recent if more than one) who had >2 pharmacy claims for any immunosuppressant >150 days apart in the 12-months after their first fill in the study period (2013–2016). Proportion of days covered (PDC) by any immunosuppressant for 12-months after first fill was calculated as a measure of adherence (defined as PDC >80%). Graft survival was defined as having a surviving graft at the end of the study period. Logistic regression was used to estimate the association between adherence and graft survival controlling for covariates (age at transplant, time since transplant, gender, race/ethnicity, copay, number of prescriptions for chronic conditions, pharmacy insurance plan, brand medication usage, digital fills, filling at a transplant specialized pharmacy, and receiving financial assistance).

Results: Of the 3,435 heart transplant recipients who were eligible for the study, 75% were adherent and 81% had a surviving graft (range = 6–10,012 days post-transplant; median = 1,409 days). After adjusting for covariates, the odds of having a surviving graft were almost double for adherent patients than for non-adherent patients (OR = 1.94 [95% CI = 1.58–2.37]; p < 0.001). Other notable factors associated with graft survival included having three or fewer post-index prescriptions for chronic conditions (OR = 4.33 [3.55–5.27]; p < 0.001) and filling immunosuppressants digitally (OR = 2.25 [1.13–4.48]; p < 0.001). A sensitivity analysis using a PDC >90% as the definition for adherence showed that the odds of having a surviving graft were 2.01 (95% CI [1.67–2.43]) times more likely for adherent patients.

Conclusions: This analysis suggests adherent patients had greater odds of having a surviving graft than those who were not adherent to immunosuppressants. Future studies should aim to show which patient behaviors contribute to medication adherence and what PDC threshold should be used for transplant research.

KEYWORDS
Heart transplant; adherence; acute rejection; graft survival

PRESENTER
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ABSTRACT

Background: Cancer care is shifting from chemotherapy to more effective targeted immunotherapies. New therapies, some with expanded indications (including maintenance) and many with price increases require re-evaluation. Many agents are handled through specialty pharmacies (SPs).

Aims: The onslaught of newer oncology therapies have increased economic concerns. Coinsurance and benefit limitations can leave patients “financially toxic” but produce outcomes that justify coverage. Efforts utilizing immuno-oncology (chimeric antigen receptor [CAR]-T therapy and tumor-agnostic treatments) directed at molecular signatures are revolutionizing chemotherapy. There are ≥165 CAR-T therapies in trials, three marketed tumor-agnostic drugs used in combination with other oncology agents. The objective was to determine oncology areas of most concern to managed care plans.

Methods: An online survey invitation was sent to officers of US healthplans and PBMs covering: officer and plan information, cancer ranking (lowest = 1 to 13 = highest), copays, benefit design, cancer management, and concerns today and in 5 years from budgetary and medical points of view (POVs). The results were compared with prior surveys.

Results: Eighty-five respondents completed the survey. Respondents served on a variety of committees from plans covering multiple member types including Commercial FFS = 41%, Medicaid = 70%, IDN = 57%, HMO/PPO = 22% and Employer self-funded = 22%. Oncology was the third highest ranked SP – condition covered 85.3%; 13.5% and 51.2% of respondents reported they participated in oncology accountable care/disease management organizations; 88.5% covered oncology genomic tests; 13.8% used value-based contracting for oncology. The cancers most concerning were: lung = 11.1, breast = 10.8, colon and rectal = 9.7, prostate = 8, melanoma = 7.6, leukemia = 7.4, myeloma = 7.4, non-Hodgkin’s lymphoma (NHL) = 7.3, pancreatic = 5.7, kidney = 5.1, endometrial = 4.9, bladder = 4.7 and thyroid = 2.9. Cancer management is: 61.2% 7.7% sometimes leave specialists alone, always follow NCCN guidelines 67.4%; 6% sometimes follow other guidelines or pathways 81.3% and 53.1% sometimes follow internal protocols. Oncology outranked other newer expensive therapies as a financial concern – combination oncology therapy was ranked first = 68%, CAR-T second 35.3%. Cancer was consistently a top concern from medical care (47.2% today, 50% in 5 years) and budgetary (50% today, 60.9% in 5 years) POVs.

Conclusions: Improvements in oncology agents and the growth of immuno-oncology have implications that require plans to focus on benefit design, adopt newer agents and utilize pathways.

KEYWORDS

cancer; immuno-oncology; guidelines; pathways

PRESENTER

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Sponsor: TPG-National Payor Roundtable

Previous presentation: ISPOR
Management of specialty drugs, specialty pharmacies and biosimilars in the United States

Richard A. Brook, Michael J. Sax, Jeffrey A. Carlisle and Jim E. Smeeding

ABSTRACT

Background: Specialty medicines continue to increase as a percentage of spending with biologics representing a large portion of specialty spending. Health plans expect to adjust their formularies to maximize expected savings from biosimilars.

Objectives: A better understanding of health plan management of specialty pharmacy (SP), SP products and biosimilars.

Methods: Online survey of health plan executives on: roles and plan information, specialty pharmacies and specialty pharmaceuticals, expected biosimilar coverage/restrictions/copays. Results were compared with prior surveys (changes >2% reported).

Results: Survey completed by 85 respondents: 42.9% were senior officers, 13.1% regional, 8.3% payor specific, 1.2% therapeutic area specific; 36.9% worked for healthplans, 13.1% PBMs, 9.5% IDNs, 2.4% PPOs/IPAs, 1.2% Government. Plans were national = 29.9%, regional = 24.7% or local = 22.1% and cover multiple member types: commercial (58.6% = FFS, 77.8% = HMO/PPO), Medicaid (Traditional = 27.8%, HMO/PPO = 72.3%), Medicare (71%, PDP-only = 51%), Employer/Self-funded = 79% and IDN (43.6%, 340B Qualified = 43.8%); 45.6% reported the plan’s PBM as their SP provider and providers were restricted by 58% #23% with plans restricting products: 58% to those under contract, 11.6% for those available through multiple SPs, 10.1% allow any SP handling a product and 4.4% carving out their SPs. Compared with last year, providers shifted approximately 6% from independents to internally provided and currently 45.6% are PBM owned, 38.2% health plan owned, 25% independent and 13.2% hospital/IDN owned. SP products continue to move from fixed to percentage copays with more plans determining by group and benefit design. Plans covered clinician-administered products under the medical benefit (36.8% #7.3%), 2.9% under the pharmacy benefit; the remainder used price and plan design. Biosimilar use expected for all reference product indications 58.8% #5.7%, 31.4% #13.5% will restrict to approved indications and 9.8% will use indication as the basis for copay. 10% #15% expect the biosimilar to be the only product available, copays are expected to be discounted off the innovator 58% #10.1% and 32% #4.9% to vary based on approval timing. Biosimilar education provided through: different copays = 64.7%, prescriber and patient mailings (76.5% #4.2% + 58.8%), prescriber and patient calls (51% #10.6% + 27.5% #4.1%). Biosimilar savings are expected to be 63.5% this year; in 5 years, 66% of savings are expected to be greater than 20%.

Conclusions: Costs associated with specialty pharmacies and specialty pharmacy products have shifted and are expected to grow with some relief coming from biosimilars.

KEYWORDS
Specialty pharmacy; biosimilars; copays

PRESENTER
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Sponsor: TPG-National Payor Roundtable

Previous presentations: ISPOR, AMCP
**Adherence of patients to oral oncolytic and neurologic specialty medications provided by a specialty pharmacy**

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**ABSTRACT**

**Background:** Specialty medications (SP-D) are high cost prescription medications designed for the treatment of complex chronic conditions, i.e. cancer and neurological diseases. Such medications require special handling and shipping, administration, and patient education. To achieve the desired treatment outcomes, including minimizing adverse events, medication adherence is key. There are barriers to poor medication adherence, some of which include high cost, poor understanding of disease and associated therapy, psychological status, forgetfulness, complex dosing regimens, and side-effects. The consequences of non-adherence include increased healthcare resource consumption and poor disease treatment outcomes, e.g. increased relapse, decreased survival time, and/or lack of patient satisfaction. Specialty pharmacy provided medication therapy management (SPMTM) can be important to achieving acceptable medication adherence and, therefore, better treatment outcomes. The specialty pharmacy is a community pharmacy focused on dispensing and providing clinical services pertaining to SP-D. It has pharmacy permits in 50 states as well as in Washington DC, Puerto Rico, and the US Virgin Islands. It is accredited by URAC and ACHC as a specialty pharmacy. Some of the key services provided by specialty pharmacy are: oncology, neurology, autoimmune disease, analgesia (non-controlled drug), investigational drugs, and other SP-D to treat rare/ultra-rare conditions.

**Aims:** The primary objective of the study was to measure the adherence rate to the oncology and neurology SP-D dispensed by the specialty pharmacy. The secondary objective of this study is to compare the quality-of-life (QoL) of patients who voluntarily participated in the SPMTM program at the program’s start of care (SOC) assessment (before the SP-D had been started) and at the follow-up (F-U) assessment (after SP-D had been started).

**Methods:** A retrospective, observational study of patient reported outcomes (PRO) was conducted at a specialty pharmacy among patients diagnosed with various forms of cancers and neurological issues who had prescriptions filled for SP-D from January 1, 2018 to December 31, 2018. Patient education by the pharmacist was offered as part of the SPMTM program throughout patient participation in the program. Each patient was offered medication therapy assessment at SOC and 7 days prior to each refill dispense, using a proprietary clinical assessment instrument designed to capture patient reported data via telephonic interview with patients or their caregivers. Embedded in the assessment instruments were two QoL PRO metrics: (1) Number of days work/school missed; and (2) How have you been feeling? (1–10 scale, where 1 was feeling terrible and 10 was feeling wonderful). The means of the SOC (BEFORE SP drug state) and the F-U (AFTER SP drug state) data were captured monthly and annualized. The annualized means were compared, using the Mann-Whitney U-value (M-WU) two-tailed statistic to test for a statistically significant difference between the annualized means of the respective QoL measures at the p < 0.05 level of significance. In addition, the overall mean of the Proportion of Days Covered (PDC) was calculated, using the URAC PDC formula.

**Results:** The total number of unique patients was 39,567, and the average number of dispenses per unique patient was two. The number of unique patients who voluntarily participated in the SPMTM program and received clinical assessments was 33,243 (84%); 6,331 (16%) patients declined to participate in the SPMTM program. The number of patients who completed only the SOC assessment was 19,946 (60%); the number of patients who participated in only F-U assessment was 3,324 (10%); and the number of patients who participated in both assessments was 4,322 (13%). The overall mean annual Proportion of Days Covered (PDC) was 0.962 (96.2%). The medication adherence rate is 20.25% higher as compared to the industry standard adherence rate of ~80%. The mean Days of work/school missed QoL metric at SOC was 0.16 days and it was 0.02 days after F-U assessment. The annualized mean difference in work/school days missed demonstrated an improvement between before and after receiving SP-D, and SPMTM was 0.14 days. The Mann-Whitney U-value (M-WU) was determined to be 4, which had a calculated $p = 0.0001$, and the M-WU value at the $p < 0.05$ level was 37. The How have you been feeling QoL metric annualized mean at SOC assessment was 7, and the annualized mean at...
refill assessment was 7.46. The total improvement in feeling is 0.46 higher on the 10-point scale. Therefore, patients reported improvement in how they felt after taking SP-D and participating in the SPMTM program. The M-WU value is 4, and calculated $p = 0.0001$. The critical value of M-WU at $p < 0.05$ is 37.

**Conclusions:** From this 1-year study it was determined that: (1) the annualized PDC adherence rate of 0.96 was 20.25% higher than the industry standard of 0.8; (2) the Number of days work missed QoL was less after starting on a SP-D with SPMTM; and (3) the How patients feel QoL metric demonstrated that patients felt better after starting SP-D with SPMTM. The improved adherence rate was associated with taking the SP-D while participating in the SPMTM. The encouraging findings of this study suggest that additional larger studies should be conducted.

**KEYWORDS**
Adherence; MTM; PRO; QoL; assessments

**PRESENTER**
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Appropriate prescribing of antiemetics with oral oncolytic therapy: a single center experience


ABSTRACT

Background: Chemotherapy-induced nausea and vomiting (CINV) is a common and significant side-effect of chemotherapy that can impact a patient's quality-of-life (QoL). As oral oncolytic therapies (OOT) become a common treatment option, they pose unique challenges for providers and patients. Unlike infusion therapies, a single-day administration, OOT may require daily dosing during a treatment cycle and, therefore, require patients to be proactive in terms of supportive care monitoring and prevention. The American Society of Clinical Oncology provides recommendations for appropriate emetic prophylaxis, however, due to limited data for OOT, only offer recommendations for single-day IV chemotherapy.

Aims: The objective of this quality improvement study was to review the appropriate prescribing of antiemetics with OOT, in the specialty and ambulatory setting, and evaluate the opportunity to enhance medication safety and improve vigilance of concurrent prescribing with pharmacist involvement.

Methods: All patients ordered for OOT between January and December 2018 to the Hospital of the University of Pennsylvania specialty pharmacy were reviewed for concurrent antiemetic prescriptions. Patients were excluded if prescriptions were sent to a satellite or outside institution pharmacy. Patients who were identified to have a discordant antiemetic:OOT prescribing ratio were evaluated for adverse events such as CINC-related office visits or hospitalization; as documented in the electronic medical record.

Results: A total of 1,630 OOT prescriptions were written for 354 patients. Two hundred and sixty-eight patients were excluded for the following reasons; 117 (33.0%) were prescribed to a satellite or outside pharmacy and 151 (42%) had concordant antiemetics. Eighty-six patients were included based on initial discordance given that OOT and antiemetics were not ordered within the same office visit. Upon further evaluation, 60 were found to have active antiemetics ordered as part of a previous line of therapy and, therefore, had an adequate supply. Of the n = 26 without antiemetics, n = 4 were deemed to not require antiemetics, while n = 22 were confirmed to lack prescriptions. There were no reports of CINV that required urgent care or hospitalizations.

Conclusions: OOT is becoming increasingly common, with unique risks such as CINV. The authors plan to increase the pharmacist involvement with the prescribing and counseling of new OOT to promote improved supportive care measures, communication between patients and providers, and potential avoidance of patient harm and improved QoL.

KEYWORDS
Antiemetics; oral chemotherapy; CINV; oral oncolytic

PRESENTER
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Variation in health plan specialty drug coverage: an empirical analysis

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ABSTRACT

Background: Patients’ access to specialty drugs is determined in part by their health plan. Because health plans develop their own coverage policies, coverage of specialty drugs can vary, which in turn may affect their members’ access to care.

Aims: Our objective was to examine variation in how commercial health plans cover specialty drugs.

Methods: We used the Specialty Drug Evidence and Coverage (SPEC) Database for this research. SPEC contains 6,139 specialty drug coverage decisions current as of December 2018 issued by 17 of the largest US commercial health plans. SPEC includes 239 drugs and 484 drug-indication pairs (when a drug is approved for multiple indications, each drug-indication pair is represented separately in the database). We compared each plan’s publicly available coverage policies with the drugs’ FDA labels and categorized coverage as follows: (i) broader coverage than the FDA label (the plan provided coverage for populations not included in the FDA label indication), (ii) coverage with no restrictions, (iii) coverage with restrictions (the plan applies restrictions beyond the FDA label to their coverage decision, e.g., step edits or patient subgroup restrictions), (iv) mixed restrictiveness (coverage was more restrictive than the FDA label in one way but broader in another) (v), or not covered. We examined the consistency in coverage of the drug-indication pairs across the included health plans.

Results: Overall, 10% of coverage decisions were broader than the FDA label, 43% covered with no restrictions, 40% covered with restrictions, 5% “mixed” restrictiveness, and 3% not covered. We found substantial variation between health plans, with the proportion of the included plans’ coverage decisions including restrictions ranging from 14% to 85%. We also found notable variation in how the included health plans covered the included drug-indication pairs, with only 5% of drug-indication pairs covered the same way by all included plans.

Conclusions: Health plans applied restrictions in roughly half of their coverage policies. We found notable inconsistency between plans, with the proportion of restricted coverage decisions varying widely. All plans covered few drug-indication pairs the same way, indicating that a patient’s plan may have a large influence on their access to specialty medications.

KEYWORDS
Patient access; specialty drug; variation

PRESENTER
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Development of a collaborative pharmacy practice agreement to improve efficiency and management of prescribing in a renal transplant clinic

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ABSTRACT

Background: Post-transplant patients require complex medication regimens to ensure the survival of the transplanted organ and patient overall well-being. These regimens are frequently adjusted, initiated, or discontinued after transplantation. Pharmacist (PharmD) expertise can be utilized to optimize post-transplant medication use.

Aims: This study describes the creation and corresponding outcomes of a Collaborative Pharmacy Practice Agreements (CPPA) between PharmDs and physicians within a renal transplant clinic.

Methods: After the Tennessee (TN) Pharmacist Association and TN Medical Association finalized legislation approving CPPAs for licensed PharmDs in TN (effective July 1, 2014), the Vanderbilt Renal Transplant Clinic and integrated health system pharmacy (IHSP) developed a CPPA, which was approved by the Vanderbilt University Medical Center (VUMC) Pharmaceutical, Diagnostics, and Therapeutics Committee and VUMC Medical Board. To evaluate the outcomes of the CPPA, we assessed the type of authorizer for immunosuppressant (IS) prescriptions (nurse, physician, or PharmD; measured as % of IS prescriptions) and the volume of IS prescriptions across three 7-month intervals: 1) before PharmD clinic integration (11/1/14–5/31/15), 2) with PharmD integration without a CPPA (12/1/15–6/30/16), and 3) with PharmD integration and a CPPA (4/1/17–10/31/17). Adult patients with at least one IS prescription generated in each time interval were included. Frequency of safety concerns and staffing requirements resulting from the CPPA were collected. Finally, we assessed the total volume of prescriptions filled by the IHSP.

Results: Following PharmD prescription management under a CPPA, physician and nurse refill workload for IS prescriptions reduced from 42.7% and 57.3% to 8.7% and 5.9%, respectively. Overall prescription generation to the IHSP increased from 13,523 prior to PharmD integration to 45,320 after integration with a CPPA. No safety concerns were reported in any of seven quarterly reviews, and the IHSP has grown from a team of eight in 2015 to 23 team members in 2018.

Conclusions: After implementing a CPPA, more IS and non-IS prescriptions were generated by pharmacists, which reduced physician and nurse burden and allowed pharmacy staff growth. Pharmacists in collaborative practice agreements are uniquely suited to closely monitor patients’ post-transplant medication regimens, ensuring safety and effectiveness of therapy.

KEYWORDS
Transplant; renal; collaborative; clinic; pharmacy

PRESENTER
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Previous presentations: AMCP, ATC (American Transplant Congress)
Hereditary angioedema C1-inhibitor replacement therapy and coexisting autoimmune disorders: findings from a claims database

Henriette Farkas, Moshe Fridman, Dylan Supina, Joseph Chiao, Subhransu Prusty and Melvin Berger

ABSTRACT

Background: Autoimmune diseases are a leading cause of morbidity and mortality in the US (estimated prevalence: 4.5%) and often associated with dysregulation of the complement system (innate and adaptive immune response). The classic complement pathway is regulated by the C1-inhibitor (C1-INH), which binds to C1 to prevent its activation. Hereditary angioedema with C1-INH deficiency (C1-INH-HAE) may be linked to increased autoimmunity due to secondary deficiency of C1r, C1s, and other components.

Aims: It was hypothesized that increased regulation of the complement system via C1-INH replacement therapy may reduce autoimmunity in patients with C1-INH-HAE. The coexisting autoimmune disease claims frequency was compared between C1-INH-HAE patients treated with plasma-derived (pd) C1-INH vs “other (non-C1-INH)” treatments.

Methods: C1-INH-HAE patients were identified in the IMS Health PharMetrics Plus claims database between January 2012 and December 2015 by International Classification of Diseases 9/10 diagnosis code, and classified based on the use of pdC1-INH or “other (non-C1-INH)” treatments for HAE. Index date was the first claim for HAE treatment. For patients using pdC1-INH, the first fill was the index date, even if other HAE medications were used previously. Frequency of visit claims for autoimmune conditions was identified by diagnostic codes (primary or secondary). Mean visits per patient per year by treatment group, gender, and age (<50 vs ≥50 years) were summarized for autoimmune conditions.

Results: Of 589 patients with HAE identified (69% female, 38% aged ≥50 years), 276 (729 patient-years) received pdC1-INH and 313 (860 patient-years) received “other (non-C1-INH)” treatments. In this cohort, 12.9% of patients had ≥1 visit associated with a coexisting autoimmune disorder – the most common were lupus, alopecia, rheumatoid arthritis, sicca (Sjogren) syndrome, and connective tissue disorders. The mean (95% CI) number of visits for autoimmune diagnoses per patient per year was numerically lower for patients treated with pdC1-INH compared to those receiving “other (non-C1-INH)” treatments (1.37 [0.56–2.19] vs 2.28 [0.83–3.73]).

Conclusions: Based on these findings, it is concluded that treatment of C1-INH-HAE with pdC1-INH may have a positive impact on coexisting autoimmune conditions by normalizing complement. Further research is needed on this important issue. There may be implications for healthcare resource utilization among patients with HAE and coexisting autoimmune disorders.

KEYWORDS
Angioedema; C1-inhibitor; autoimmune; complement

PRESENTER
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Sponsor: CSL Behring

Coupling patient care management operations with technology and data platform to optimize hepatitis C therapy outcomes

Lily Duong, Matthew Malachowski and Khang Tran

ABSTRACT

Background: Over the past 20 years there have been major improvements in the treatment and outcomes of hepatitis C pharmacotherapy. While the HCV treatment regimen is much simpler, safer, and more effective, there is an opportunity to improve the overall patient journey.

Aims: The objective of this observational study is to demonstrate the cure rate measurement possible with standardized pharmacy clinical operations supported by a technology platform.

Methods: The study period covered January 1 to September 30, 2018. In the patient care process, the pharmacist collaborates with the clinic staff to select the best treatment regimen based on clinical guidelines. The pharmacist also selects the treatment regimen to satisfy coverage policy. In this way, patient onboarding is streamlined and therapy initiation is expedited. Patient evaluation is performed in the clinic, and initial patient education is provided and documented. The data necessary for outcomes measures such as genotype, viral load, and past medical history is documented during the care process. The monthly monitoring plan is established for adherence and side-effect management. The entire care process is facilitated by a technology platform where documentation is completed.

Results: In the study cohort, 209 patients were onboarded to the technology platform through the clinic process. Of the 209 patients, 183 were provided an initial clinical assessment. The appropriate end points for this study were: documentation of therapy completion using dispensing and adherence data, lab data at the end of treatment, and SVR12 value. A total of 150 patients had all three of the end point measures documented. Of the 28 patients who did not have the end points documented, seven had a discontinuation survey completed and 21 were lost to follow-up for unknown reasons. In this study cohort, 99% of patients completed therapy and had SVR12 confirmed by lab data, yielding a cure rate of 98%.

Conclusions: In this observational study of standardized clinical pharmacy operations provided in a medical clinic supported by a pharmacy technology platform it was demonstrated that the pharmacy care process can be streamlined between the numerous steps and become a dynamic patient management operation. In addition, the study demonstrated that an intuitive and robust data platform can greatly improve longitudinal follow-up and HCV cure rate measurement.

KEYWORDS
Hepatitis C; outcomes; SVR12; pharmacy technology; adherence

PRESENTER
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Clinical impact of pharmacist interventions on improving outcomes in patients receiving immune globulin therapy in a home setting

Joseph DiStefano and Leslie Vaughan

ABSTRACT

Background: Immune globulin (IG) therapy is considered a safe and frequently used treatment in a wide range of disease states but has well known associated adverse drug reactions (ADRs) that may be problematic. Patients that receive IG in the home setting may be at higher risk for undertreated ADRs due to the limited number of immediate interventions in the home. Published literature indicate minor reactions are reported in up to 20% of IG infusions and serious ADRs in 2–6%. A pro-active approach to the prevention or reduction of known IG ADRs is critical for these patients. Pharmacists can have the greatest impact on ADRs due to their on-going and regular communication with the patients.

Aims: To determine the frequency, type, and severity of ADRs associated with IG infusions and the impact of pharmacist intervention on reducing or eliminating the ADRs.

Methods: An ADR Assessment tool was developed to track ADRs reported by patients during or after IG infusions, the severity of the ADR, interventions made by the pharmacist, acceptance of those interventions by the IG prescriber and the outcome of those interventions on reducing or preventing recurrence of the same ADRs.

Results: ADRs tracked over a 2-year period show 98% of reported ADRs were mild or moderate in severity having limited impact on the patient’s normal activities. These were all able to be managed at home with simple and readily available therapeutic treatments. After the occurrence of an ADR, pharmacist interventions made to the IG prescriber on future IG infusions had an acceptance of 93%. Pharmacists suggested ADR interventions had a 90% success rate in the total or partial prevention of the same ADR during the next infusion cycle. During this same 2-year period, of the ADRs reported, 0.35% were categorized as serious. Review of these patients and reported serious ADRs showed events that were consistent with the FDA box warnings required on all IG products but did not result in discontinuation of IG therapy in half of these patients.

Conclusions: Pharmacists can have a significant impact on preventing or reducing ADRs associated with IG therapy. In addition, the interventions suggested by the pharmacist have a high acceptance rate by prescribers and a positive effect on preventing recurrence of ADRs.

KEYWORDS
Adverse drug reactions; immune globulin therapy

PRESENTER
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Determining specialty pharmacy FTEs (full-time equivalents) needed in a clinical practice

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ABSTRACT

Background: The Hospital of the University of Pennsylvania (HUP) created the Penn Specialty Pharmacy Program in 2014 to establish a pharmacy presence in clinics, with a patient focus on specialty medication access and adherence. The program utilizes both pharmacists and technicians to assist the clinics with medication counseling, prior authorizations, and copay assistance. As the program expands to more clinics throughout Penn, there is a growing need to employ more pharmacists and technicians, without a method in place to determine exactly how many FTEs are needed in clinic.

Aims: To determine the number of clinical pharmacist and technician FTEs required in a clinical practice for maximum efficacy and patient care.

Methods: Calculations were obtained by recording duties handled by the pharmacist (including those for which time does not allow), and determining if the task requires handling by a pharmacist, or if it could be delegated to a tech. This pilot program was first tested in the Dermatology Clinic at HUP, with the intent of launching throughout Penn, if successful. Once assignments were determined as either pharmacist or tech-appropriate, the recommended number of FTEs needed in the practice was calculated based on data obtained during an average 8-h work day: Duration of all tasks (in hours) \( \div 5 \text{ days} = \frac{\text{RPh/Tech Hours}}{40} = \frac{\text{RPh/Tech FTE}}{} \).

Results: The Dermatology pharmacist was observed over the course of 4 h as they completed several tasks, such as sending electronic rxs, patient calls, filling out paperwork for drug manufacturer programs, and responding to patient and provider cost-related concerns. Using the formula, and including roughly 7 h of assistance a pharmacist cannot currently provide (clinic/photopheresis rounds, appeals, etc.), this study was able to determine that the clinic would require ~1.5 Pharmacist FTE and 0.39 Tech FTE.

Conclusions: Many of the duties categorized as tech-specific were clerical or cost-related issues that did not require clinical intervention from a pharmacist. Addition of the 0.39 Tech FTEs would provide the RPh with additional resources to delegate duties to a tech, maximizing focus on patient care. This would also give the clinic an opportunity to include the pharmacist in other areas of the practice. More data may be needed to make a final decision on the needs of the clinic; however, this will be a helpful tool in validating departmental needs in other clinical settings for broad use in FTE determinations.

KEYWORDS

FTE; full-time; pharmacist; clinic; pharmacy

PRESENTER

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ABSTRACT

Background: The area and population served by the Southern Ohio Medical Center (SOMC) is one that has been hit hard by the opioid epidemic, resulting in a very high incidence of Hepatitis C virus infected individuals. In this rural area, many patients have struggled with access to specialty healthcare. In January 2018, specialty pharmacy services were started. The main goals were to provide a valuable and personalized service to patients and increase access to specialty medications. When taken as prescribed, HCV therapies can lead to high cure rates (>95%). The program integrated a clinical pharmacist and pharmacy liaison in the infectious disease clinic to begin providing in-clinic education, 24/7 support, prior authorization assistance, financial aid assistance, refill reminders, and other services to patients. The specialty pharmacy service has assisted many local patients to obtain treatment for HCV. The following data analysis details the study design and results.

Aims: The study was completed to assess the impact of the clinic-based specialty pharmacy program on medication access, affordability, and clinical outcomes for patients with HCV.

Methods: The study was IRB-approved. Endpoints measured were SVR12 rates, rates of patient return for SVR12 labs, and out-of-pocket costs for patients using the SOMC Specialty Pharmacy. To be eligible for the study, patients must have started an HCV regimen written by an SOMC provider after January 1, 2018. Data was collected by reviewing patient electronic medical records and pharmacy dispensing records.

Results: The study included 67 HCV patients who utilized the SOMC specialty pharmacy program to obtain treatment. Thirty-seven of the patients were male, none had liver decompensation, and 65 were treatment-naïve. By offering in-clinic specialty pharmacy services to patients, SOMC was able to remove barriers, such as cost, to improve specialty medication access and adherence. This resulted in 100% medication access and therapy completion rates for participating patients. SVR12 rates were higher than clinical trials. Finally, the average out of pocket cost to patients was found to be $0.75, with 90% of patients having zero copay. Clinical pharmacists and pharmacy liaisons played a key role in achieving this result by providing in-person education to patients, securing financial assistance for patients, and regularly following-up with patients regarding their therapy.

Conclusions: Clinic-based health system specialty pharmacy programs can play a vital role in improving medication access and adherence, leading to better clinical outcomes. By offering on-site specialty pharmacy services, SOMC provides a personalized patient experience and affordable access to specialty prescriptions. These elements help ensure patients adhere to their treatment regimens over time and fully realize the benefits of their specialty medications.

KEYWORDS
Hepatitis C; integrated; SVR12; medication; access

PRESENTER
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Impact of ambulatory clinical pharmacist interventions on outcomes in the HIV population

Lindsey Foltanski

ABSTRACT

Background: Previous studies have demonstrated the benefit of clinical pharmacist intervention in the care of patients with human immunodeficiency virus (HIV) in an ambulatory care setting. Patients who receive interprofessional care that includes a clinical pharmacist are more likely to see clinical benefit including improved adherence and reduced HIV viral load. With recent improvements in virologic testing and HIV medications, it is useful to identify which types of pharmacist interventions are significantly improving clinical outcomes in the most difficult-to-treat patients.

Aims: Determine the impact of clinical pharmacy interventions and specialty pharmacy involvement in an uncontrolled HIV population.

Methods: HIV patients with a detectable HIV viral load (>20 copies/mL) were retrospectively included in the study if they had at least one visit with a clinical pharmacist and at least one follow-up HIV viral load documented after the visit between January 1, 2017 and March 1, 2019. Patient charts were reviewed to obtain information regarding HIV history, relevant interventions made by the clinical pharmacist, and adherence rates. The primary outcome was the proportion of patients who achieved an undetectable viral load (<20 copies/mL) after seeing a pharmacist in clinic. Secondary outcomes included types of pharmacist interventions, and specialty pharmacy capture rate.

Results: Fifty-one patients were included in the primary analysis. The median baseline viral load was 22,900 copies/mL and 68.6% of patients were able to achieve an undetectable HIV viral load after meeting with a pharmacist. The most common pharmacist intervention was compliance counseling, followed by medication change and medication initiation. In this cohort where 30% of patients were uninsured and unable to fill medications at the associated specialty pharmacy, the specialty pharmacy capture rate was 39%.

Conclusions: The clinical pharmacists within the Regional Center for Infectious Disease care for a large proportion of the clinic’s difficult-to-treat HIV patients with uncontrolled viral loads. Within this population, patients whose care included clinical pharmacist interventions were able to achieve an undetectable viral load more than two-thirds of the time. Clinical pharmacists are also uniquely positioned to encourage utilization of specialty pharmacies to improve delivery and adherence. Utilization of skilled pharmacists will be vitally important in achieving new viral suppression rate targets, particularly within difficult-to-treat patient populations.

KEYWORDS
HIV; viral load; ambulatory; infectious disease

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Previous presentation: UNC Research in Education and Practice Symposium (May 2019)
Development of a palivizumab specialty pharmacy management program

Lana Harlan, Katlyn Benskin, Carolin Gatzke and Alexandra Majors

ABSTRACT

Background: Palivizumab is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in high risk pediatric patients. Due to the high cost, handling requirements, administration route, and importance of adherence, palivizumab is best managed by specialty pharmacies able to provide robust clinical services. In collaboration with the health system and surrounding pediatric clinics, a specialty pharmacy management program was established to serve patients receiving palivizumab.

Aims: To develop a relationship with local pediatric clinics to provide specialty pharmacy services for patients receiving palivizumab.

Methods: The patient medication liaison (PML) completed a query of the internal electronic medical record based on diagnosis code to target high risk infants and newborns meeting approval criteria for palivizumab. Providers were notified and palivizumab was prescribed if warranted. During RSV season, internal referrals were also received from the transition of care team directly from the neonatal intensive care unit. An intake form was created for outside clinic/institutions referring pediatrics meeting criteria. The form included: patient, insurance, prescriber, clinical, and prescription information. The PML initiated contact with the parent/guardian and proceeded with benefits investigation. The PML coordinated refills, clinic visits, and nurse visits. The clinical pharmacist provided education on dosing, administration, side-effects, warnings/precautions, importance of adherence, goals of therapy, and RSV prevention strategies. The outcomes of the project include: number of approved prior authorizations, number of prescription fills for Mizzou Specialty Pharmacy, and the number of patients enrolled in patient assistance.

Results: From October 2016 through April 2019, the specialty pharmacy worked with two local pediatric clinics. Two hundred and thirty-nine patients were referred to the pharmacy for benefits investigation; 172 prior authorizations (PAs) were approved: 34 triaged to an outside specialty pharmacy, 129 managed by Mizzou Specialty Pharmacy, 18 chose not to pursue. Finally, 48 PAs were denied and 19 patients were approved for patient assistance.

Conclusions: Mizzou Specialty Pharmacy successfully developed relationships with local pediatric clinics to serve their patients receiving palivizumab.

KEYWORDS
Palivizumab; respiratory; pediatric; liaison; Mizzou

PRESENTER
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Cost-effectiveness model for on-demand treatment of hereditary angioedema (HAE) attacks

Christopher Tyson, Anurag Relan, Phillipe Adams, Angela Haynes and Raf Magar

ABSTRACT

Background: Hereditary angioedema (HAE) is a rare C1-inhibitor (C1-INH) deficiency disease involving recurrent painful episodes of severe swelling that should be promptly treated.

Aims: To determine cost and utility estimates for on-demand treatment of HAE attacks in order to better clarify and control expenses related to disease management.

Methods: A decision-tree model included four comparators (ecallantide, icatibant, plasma-derived [pd] C1-INH, and recombinant human C1-INH [rhC1-INH]) and incorporated probabilities for self-administration vs healthcare provider administration, re-dosing, and hospitalization risk. Modeled costs comprised HAE therapies and healthcare system expenses. Effectiveness considered utility during attacks (0.51), no-attack baseline (0.83), and time to attack resolution. Overall drug cost and effectiveness per attack were used to estimate cost per quality-adjusted life year (QALY). Sensitivity analyses were performed to establish cost-effectiveness ranges. A budget impact model was developed for a health plan of 1 million (M) covered lives.

Results: Costs and utility per attack were, respectively, $12,342 and 0.804 for rhC1-INH, $14,369 and 0.749 for icatibant, $13,993 and 0.759 for pdC1-INH, and $20,315 and 0.786 for ecallantide. At a mean annual attack rate of 26.9, cost per QALY was $402,769 for rhC1-INH, $475,942 for icatibant, $462,275 for pdC1-INH, and $666,153 for ecallantide. Re-dose rate was identified as a primary driver of cost-effectiveness variability. Estimated annual cost to the plan was $6.64 M for rhC1-INH, $7.73 M for icatibant, $7.53 M for pdC1-INH, and $10.93 M for ecallantide. A 5000-trial probabilistic sensitivity analysis (PSA) indicated that rhC1-INH was the most cost-effective in many scenarios, while ecallantide was the least cost-effective: mean costs (effectiveness) from PSA were $12,390 (0.786) for rhC1-INH, $14,132 (0.738) for icatibant, $13,050 (0.746) for pdC1-INH, and $20,286 (0.785) for ecallantide.

Conclusions: This model demonstrated that rhC1-INH was the most cost-effective and ecallantide the least cost-effective on-demand HAE treatment and, overall, cost-effectiveness was substantially impacted by re-dosing rates. For icatibant, re-dosing rates of up to 44% to treat an HAE attack have been reported, and prescribing information allows up to three doses per 24-h period to treat a single attack. Driven by higher re-dosing rates, icatibant suffers from a higher per-attack drug cost and comparatively poor effectiveness.

KEYWORDS

C1 inhibitor; cost; hereditary angioedema; recombinant; ruconest

PRESENTER

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Previous presentation: Academy of Managed Care Pharmacy Annual Meeting 2019, March 25–28, 2019, San Diego, CA; reprinted with permission from Journal of Managed Care Pharmacy.
Cost of leukopenia and neutropenia in metastatic breast cancer within last 12, 36, and 60 months using a curated disease model

Sharon Hensley Alford, Marie Ng and Denise Meade

ABSTRACT

Background: Evaluating changes to historical treatment costs is critical for healthcare professionals to make informed business decisions. However, real-world clinical and cost outcome data is challenging to use regularly without significant data science knowledge or resources.

Aims: This study sought to demonstrate the potential value in user-friendly analytics tools to identify drivers of costs and outcomes.

Methods: The IBM Access and Value Connect solution was used to analyze a patient cohort of metastatic breast cancer (mBC) patients treated in the most recent 12, 36, and 60 months in the IBM MarketScan; Commercial and Medicare Supplement Database. We used the interactive visual explorer tool to quickly (<15 min) determine the mean total per-patient-per-month (PPPM) cost associated with mBC overall and for select side-effects by age group (45–54, 55–64, 65–74, and 75+), and generated histograms for mean total PPPM overall and for leukopenia and neutropenia by age group for each study period.

Results: The mean total PPPM across all mBC patients ranged from $6,562 for the 75+ age group at 60 months to $14,201 for the 45–54 age group at 12 months. For those who experienced leukopenia, the mean total PPPM ranged from $10,319 for the 75+ age group at 60 months to $19,598 for the 45–55 age group at 60 months. Similarly, for those who experienced neutropenia, the mean total PPPM ranged from $10,593 for the 65–74 age group at 60 months to $21,784 for the 45–54 age group at 12 months.

Conclusions: These methods show that it is possible to make PPPM costs easily available without data science, clinical, or programming knowledge with interactive, visual analytics. The results showed that in general PPPM costs are higher for younger patients overall and among those who experience leukopenia or neutropenia. This is likely due to the practice to aggressively treat younger patients.

KEYWORDS
Cost; real-world data; analytics; tools

PRESENTER
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Previous presentation: ISPOR
Integrating high touch specialty pharmacy services within a neurology clinic to improve medication access and affordability

Brandon Newman, Amanda Hickman and Kathryn Edwards

ABSTRACT

Background: The cost of medications has been an upfront topic in the public, with 24% of patients reporting difficulty with affordable access, and specialty medications contribute to those concerns through an increase in price by 57% since 2014. Specialty pharmacy services (SPS) were implemented into a neurology clinic to assist with medication coverage and affordability.

Aims: To assess the impact of integrating high touch SPS within a neurology clinic by measuring migraine medication affordability.

Methods: The dispensing data for patients (1) filling a Calcitonin Gene-Related Peptide (CGRP) receptor antagonist (CGRPra) and/or onabotulinumtoxin A (Ona A) for migraine through the onsite specialty pharmacy, and (2) being treated through the SPS-affiliated neurology clinic was gathered and analyzed for medication cost coverage and patient financial responsibility. The study endpoints were to observe a minimized patient copay and assess the amount of $0 copays after the initiation of the clinic-based SPS.

Results: For the CGRPra group, the SPS were able to reduce the patient responsibility to 2% of the medication cost, and more than 25% of the CGRPra dispenses had a $0 copay. For the Ona A group, comparing January 2018 to January 2019 showed a 185% increase in vials dispensed on pharmacy benefits and a patient responsibility of < 1% medication cost in January 2019 vs 19% in January 2018. The median copay went from $150 in January 2018 to $0 in January 2019. No vials in January 2018 had $0 copays, 20 did in January 2019. Measuring 6 months before SPS were started and 6 months after, the Ona A had similar results as the January comparison, with an increase of 188% dispensed through the pharmacy and the same median copays, $150 vs $0. The number of vials with $0 copay increased from four before SPS to 112 6 months after SPS was integrated. In addition, through the SPS reimbursement audits and benefit verification for Ona A billing, the Ona A reimbursement is projected to increase by $325,000 over 3 years due to switching Medicaid Ona A patients to bill through pharmacy benefits.

Conclusions: The implementation of high touch SPS in a clinic can benefit patients through prescription coordination and price mitigation. Through the SPS, patients were responsible for only 2% of the CGRPra cost and < 1% of the Ona A cost. The SPS were able to verify which insurance branch was preferred for Ona A, which helped mitigate patient copays and improved facility financials for Ona A through upfront reimbursement through the preferred method of pharmacy benefits.

KEYWORDS
Integrated specialty pharmacy services; cost mitigation; reducing medication cost; clinical pharmacy services; migraine

PRESENTER
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Implementation of an internal check of oral oncolytics: a single-center, specialty pharmacy safety initiative

Mitchell Hughes, Richard Kriska, Gregory Strong, Jennifer Chung, Lily Nguyen, Daniel Rubin, Melissa Murphy, Joseph Favatella and Donna Capozzi

ABSTRACT

Background: Oral oncolytic therapies (OOT) for patients with cancer continue to pose unique safety challenges. Unlike infusion therapies, there are few best practice recommendations for checking OOT. A multicenter review of four oncology clinics in the United States, estimated 8.1 errors in medications per 100 clinic visit identified. 1 The American Society of Health-System Pharmacists identify administration and ordering were the most common phases of the medication-use process where errors occur. 2 Despite the high-risk nature of OOT and high error-rate in these particular phases, with pharmacist surveillance, there continues to be little consensus for oral oncolytic safety to guide specialty pharmacists (SPs).

Aims: The objectives of this single-center, quality improvement study was to review the quality metrics of the implementation of an oral oncolytic check process, in the specialty and ambulatory setting as a method to enhance medication safety and improve vigilance.

Methods: The study was approved by the Institutional Review Board at the Hospital of the University of Pennsylvania. A standardized check process and documentation of capecitabine and temozolomide was implemented beginning in December 2016 for an adult oncology population. SPs have direct communication to pharmacy specialists and provider teams through the electronic medical record via Epic. Upon receipt of a new prescription, the SP reviews the prescription for: prescriber, chemotherapy regimen, indication, body surface area, dose verification, appropriate day supply/refills, laboratory values, allergy evaluation, drug interactions, and pre-medications. The SP documents this review as an intervention in Epic for every capecitabine and temozolomide prescriptions before processing. Intervention data between December 2016 and September 2018 was queried and quantified.

Results: Over 22 months, a total of 1,619 intervention documents were reviewed with 551 intervention documents requiring intervention (34%). A total of 639 actionable interventions were identified. The top three categories were missing pre-medications (54.1%), missing/abnormal laboratory results (19.6%), and drug-drug interactions (13.6%). Rare interventions included dose clarification requests (3.6%), dose change requests (1.4%), and quantity supply requests (2.7%). A SP referred to a pharmacy specialist or provider outside of Epic communication in 21.2% of cases and 3.7% of cases respectively. The average time by the SP per intervention was 12.1 minutes (Range: 10-45 minutes).

Conclusions: OOT is exponentially growing with unique risks associated when prescribing, with the SP being the last line of defense. Implementing an internal checking tool of oral oncolytics creates a standardized safety check and promotes active communication with oncology care teams. Addition of all OOT to incorporate mandatory documentation is ongoing.

KEYWORDS
Oncology; oral oncolytics; temozolomide; capecitabine; oncolytic safety

PRESENTER
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Previous presentation: HOPA Annual Conference 2019
Impact of specialty pharmacy taking ownership of the prior authorization process of multiple sclerosis specialty medications to increase access to infusible disease-modifying therapy (DMT)

Miranda Whetstone, Jeffrey Reichard and Shelley Sigmon

ABSTRACT

Background: Multiple sclerosis (MS) is an autoimmune inflammatory demyelinating disease of the central nervous system (CNS) that is a leading cause of disability. Many disease-modifying therapies (DMT) with different routes of administration have been approved and introduced to the market to treat MS. These DMT are often costly and require Prior Authorizations (PA) which can lead to barriers in accessing DMT. This project was a response to the need for timely PA approval for patients needing infusible DMT. A previous project reviewed the impact of the specialty pharmacy taking ownership of all DMTs in regards to approved authorizations and timeliness of the approval. After this project highlighting the need and cost savings to the institution, an additional staff member was added to focus on infusible DMT PA.

Aims: To increase the number of approved authorizations of infusible DMT and increase the timeliness of authorizations in order for patients to receive appropriate and timely DMT.

Methods: The program was developed by a specialty pharmacy team and neurology team. The target audience were patients being initiated on a DMT for MS from September 2018–April 2019. A note was sent in the electronic medical record (EMR) to the pharmacy team to initiate the PA process when the neurologist prescribed a new DMT. Communication was made to the neurology team regarding the status of the DMT PA before scheduling a patient for their infusion.

Results: A total of 92 patients had a new PA completed. Eighty-three (90%) authorizations were approved and three (3%) were denied. Of the three denials, additional appeals were done either by completing appeal letters or scheduling peer-to-peers. Two of the three patients then qualified to receive free medication through the manufacturer due to having two denials in place. One has applied for free medication and is currently pending. A total of 10 appeal letters were written, and seven peer-to-peers were set up for the attending physician. Five PAs were cancelled. Three of these required authorization through pharmacy benefits vs medical benefits, one received free medication through the manufacturer, thus the PA was cancelled, and one did not have a referral from the Veteran’s Association (VA) to be seen outside of the VA. One authorization was not covered due to the plan only covering preventative care. Overall, 89 (96.7%) patients received their DMT infusion.

Conclusions: This program provides a new service to increase the number of approved infusible DMT to improve access and outcomes for MS patients.

KEYWORDS
Multiple sclerosis; disease modifying therapy (DMT); authorization; infusible; access

PRESENTER
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Impact of a specialty pharmacy benefit on rheumatoid arthritis medication adherence and functional status: a continuation study

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ABSTRACT

Background: Patients with rheumatoid arthritis (RA) have benefited from the introduction of tumor necrosis factor (TNF) inhibitors; however, multiple studies have reported that rates of medication adherence are sub-optimal. Specialty pharmacies offer various management strategies to improve adherence in patients with RA to help improve disease status.

Aims: To expand the initial analysis results by gathering adherence data between 6 and 12 months and HAQ-II scores at 12 months after transitioning members to the specialty pharmacy to determine the impact of a specialty pharmacy benefit on RA medication adherence and functional status.

Methods: A retrospective analysis was conducted using an internal pharmacoadherence application. Members with claims for TNF-inhibitors were included, provided they received at least two fills within the study time periods of May 1, 2017 – December 31, 2017 (pre-transition), January 1, 2018 – August 31, 2018 (post-transition), and September 1, 2018 – April 30, 2019 (extension). Pharmacy claims were analyzed to measure adherence by calculating the proportion of days covered (PDC) in each time period. Members with a baseline HAQ-II score after transition were compared to 6-month post-transition and 12-month extension HAQ-II scores for a correlation to adherence.

Results: A total of 101 members with RA were included. Prior to transition, 34% of members were filling at non-specialty pharmacies and 66% of members were filling at specialty pharmacies. PDC values for baseline, post-transition, and extension time periods were 0.848, 0.907, and 0.819, respectively, for members filling at non-specialty pharmacies prior to transition and 0.904, 0.889, and 0.818, respectively, for members filling at a specialty pharmacy prior to transition. The percentage of patients achieving a desired adherence level (PDC>0.8) increased post-transition for members previously filling at non-specialty pharmacies (65.2% vs 84.8%). A statistically significant inverse relationship was found between baseline HAQ-II score and pre-transition PDC value ($r = -0.200, p = .035$) for 112 members with completed functional assessments.

Conclusions: PDC is significantly correlated to HAQ-II scores at baseline, and adherence is also shown to increase for members transitioning from a non-specialty to specialty pharmacy. More analysis is needed to determine if the HAQ-II is an appropriate functionality questionnaire to assess RA disease status.

KEYWORDS

Rheumatoid arthritis; adherence; Health Assessment Questionnaire II; patient-reported outcomes; TNF-inhibitors

PRESENTER

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Sponsor: Navitus Health Solutions

Previous presentations: 2019 Annual Academy of Managed Care Conference in San Diego, CA (poster presentation); 2019 Great Lakes Pharmacy Residency Conference in West Lafayette, IN (PowerPoint presentation).
Economic burden of hemophilia B in the US: a systematic literature review

Nanxin (Nick) Li, Eileen K. Sawyer, Konrad Maruszczyk, Marta Slomka, Tom Burke, Antony P. Martin and Jamie O’Hara

ABSTRACT

Background: Hemophilia B (HB) is a rare disease caused by congenital Factor IX (FIX) deficiency. HB requires life-long management to prevent or manage bleeding and associated morbidity. Although HB affects only a small portion of the population, it is associated with high overall cost and imposes a significant financial burden on individuals, payers, and society in general. Due to variation in patient clinical characteristics and treatment choice, cost and healthcare resource utilization associated with disease management can vary significantly from patient to patient.

Aims: To review published direct costs and healthcare resource utilization associated with the management of HB in the US.

Methods: A systematic literature review was conducted by searching electronic databases (e.g. MEDLINE, Tufts CEA registry) to identify full-text studies (March 2009–March 2019). Additionally, a manual search for abstracts from relevant conferences was performed (from 2016). Studies were included in the review using pre-defined inclusion/exclusion criteria for population, study type, language (English), and location (US). Publications consisting of budget impact analysis, cost, burden of disease, healthcare resource utilization, and economics evaluations were included.

Results: Of 693 titles and abstracts screened, a total of 17 studies evaluating cost and resource utilization in patients with HB in the US were included. Data sources for these studies included: medical records ($n=5$), insurance claims databases ($n=10$), and surveys ($n=2$). Reported cost and resource use varied across studies depending on severity of the disease, treatment regimen, and product type: extended (EHL) or standard half-life (SHL). The cost of FIX replacement therapy constitutes the majority of costs in HB management. Among patients with severe or moderate HB, reported mean annual cost of FIX ranged from $187,070 to $925,864 with an average of $560,801. Annual cost of EHLs could exceed more than twice the cost of SHLs. For example, mean annual cost of EHL FIX was $921,291 vs $478,096 for SHL FIX. Rates of healthcare resource utilization were also substantial for patients with HB and include hospitalizations, emergency room visits, and physician visits.

Conclusions: This systematic literature review found significant economic burden associated with HB in the US. The substantial costs and health resources utilized by patients highlight unmet needs remaining in HB.

KEYWORDS
Hemophilia; haemophilia; burden; cost; resource

PRESENTER
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Sponsor: uniQure Inc.

Previous presentation: The abstract was submitted to AMCP Nexus 2019 conference.
Impact of specialty pharmacist integration on time to medication access for pimavanserin

Sabrina Livezey, Robert McCormick, Nisha B. Shah, Leena Choi, Joshua DeClercq and Autumn D. Zuckerman

ABSTRACT

Background: Patient access to pimavanserin treatment, an antipsychotic agent used to treat Parkinson's disease-related psychosis, is limited by insurance approval and navigating a limited distribution network. Once initiated, safety and efficacy monitoring is needed to ensure adherence and clinical benefit.

Aims: To determine the impact of specialty pharmacist integration on time to pimavanserin access. A secondary objective is to describe pharmacist interventions related to pimavanserin.

Methods: This was a single-center, retrospective cohort study with a pre–post design. Patients prescribed pimavanserin through the center's neurology clinic during May 2016 through July 2018 were included. An electronic chart review was performed to collect data for patient demographics (age, race, gender), insurance information (type, prior authorization process), and pharmacist interventions. The primary outcome was defined as time to medication access (in days) between the initial intent to treat and insurance approval. Univariate analysis and multiple logistic regression were performed to assess the associations between medication access time and pharmacist integration.

Results: Ninety-four patients met inclusion criteria. Patients were mostly male (80%) and Caucasian (96%). Median age was 74 years. Baseline demographics between the pre- and post-integration cohorts were similar. Pre-integration, 33 patients were prescribed pimavanserin, with 82% attaining insurance approval and 79% starting therapy. Post-integration, 61 patients were prescribed pimavanserin, with 95% attaining insurance approval and 93% starting therapy. Median time to access decreased following integration (3 days compared to 24.5 days). Patients prescribed pimavanserin pre-integration had a 23-fold increase in odds of experiencing a longer time to access compared to post-integration (OR = 23; 95% CI = 8–69; p < 0.001). In addition, patients with non-commercial insurance were more likely to have a shorter medication access time compared to patients with commercial insurance. The pharmacist performed at least one intervention for 85% of patients, including medication counseling (n = 58) and interventions to improve clinical care (n = 120) and medication access (n = 135).

Conclusions: Integration of a specialty pharmacist decreased time to pimavanserin access and facilitated pharmacy interventions to ensure safety and efficacy of use. Additional research is needed to evaluate the impact of faster medication access on clinical outcomes.

KEYWORDS
Pimavanserin; psychosis; Parkinson's disease; access

PRESENTER
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Previous presentation: Poster presentation at CPNP annual meeting in Salt Lake City, UT (April 8, 2019)
A targeted approach to reducing rates of discontinuation and dose reduction in patients receiving sorafenib or regorafenib

Ryan Nix, Brooke Looney, Carson Lamb, Megan Peter and Autumn Zuckerman

**ABSTRACT**

**Background:** Sorafenib and regorafenib are oral multikinase inhibitors used to treat some cancers, but adverse events for both drugs are common and often cause patients to discontinue therapy or reduce their dose within several months of initiating therapy. Pharmacists have the potential to prevent discontinuation by closely monitoring and addressing patients’ adverse reactions.

**Aims:** To assess whether a pharmacist-initiated tailored intervention reduced patient discontinuations and dose reductions due to adverse reactions from sorafenib and regorafenib.

**Methods:** We conducted a historically controlled intervention (initiated Aug 2017) to detect and address adverse events in patients prescribed sorafenib and regorafenib. All patients who initiated therapy after August 2017 were in the intervention group (IG); at treatment initiation, IG patients received initial pharmacist counseling and a welcome kit containing educational materials, urea based creams, therapeutic socks and pill container (sorafenib only). During the 90 days after initiating treatment, pharmacists called IG patients six times to conduct assessment questionnaires, designed to detect common adverse reactions at each interval. Pharmacists addressed adverse events by providing additional counseling, referring patients for clinic appointment or requesting ancillary medications. The comparison group (CG) patients initiated therapy between September 2016 and August 2017. CG patients only received pharmacist counseling at treatment initiation. We collected patient demographics and treatment indication, and compared how many patients discontinued or reduced dose in the IG vs the CG.

**Results:** We assessed 33 patients (16 IG vs 17 CG). Most were female (61%) and White (88%); median age 53 years. Common indications were hepatocellular carcinoma (36%), acute myeloid leukemia (30%) and desmoid tumor (21%). In the 90 day follow-up, IG had lower rates of treatment discontinuation (13% vs 29%) and dose reduction due to side effects (13% vs 18%) than CG. Combined events of either discontinuation or dose reduction due to side effects were less frequent in the patients in the IG than the CG (25% vs 65%).

**Conclusions:** Patients treated with sorafenib or regorafenib were less likely to discontinue therapy or reduce doses due to adverse reactions after receiving a pharmacist-led phone intervention. Findings suggest tailored phone assessments are effective in detecting and treating adverse reactions, thus enabling patients to remain on therapy longer and without dose modification.

**KEYWORDS**
Sorafenib; regorafenib; pharmacist; adverse events

**PRESENTER**
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**Previous presentation:** AMCP Annual Meeting 2019, San Diego, CA
Measuring the impact of integrating post-graduate year two ambulatory care pharmacy residents into specialty clinics

Cathy Spencer, Michelle Woosley, Amanda Brenske and Emily O’Reilly

ABSTRACT

Background: It is well established that integration of a pharmacist into specialty clinics increases access to medication, improves patient adherence and decreases financial burden on patients. As specialty clinics and the prescribing of specialty medications continues to exponentially grow, it is critical for pharmacy residents to be provided learning opportunities within these settings to maximize pharmacy services as well as to educate future pharmacists in this field. The University of Louisville Hospital is an academic medical center that currently trains two post-graduate year two (PGY-2) ambulatory care pharmacy residents annually.

Aims: To measure the impact of utilizing PGY-2 ambulatory care pharmacy residents on increasing coverage and provider satisfaction in specialty clinics. Additionally, to evaluate the ability of the learning experience in meeting the residents’ educational objectives.

Methods: PGY-2 residents were trained to provide ambulatory care pharmacy services in the Hepatitis C and Multiple Sclerosis (MS) Clinics. They then provided those services with peripheral support from a preceptor over a 6 month period. Outcomes collected to determine the impact of PGY-2 residents included hours of clinic coverage provided, number of patients served, number of patients that discontinued treatment and provider satisfaction with pharmacy services. To demonstrate the meaningfulness of this learning experience, the educational objectives met as defined by the American Society of Health System Pharmacists (ASHP) residency standards will be reported.

Results: Over 6 months, pharmacist coverage was expanded by 104 hours in the Hepatitis C Clinic and 84 hours in the MS Clinic through utilization of PGY-2 residents. The total number of patients served during those hours was 114 in Hepatitis C and 102 in MS. During this 6 month period, only three patients discontinued hepatitis C treatment before completing therapy and two patients discontinued therapy in the MS clinic due to medication related issues. Of the providers surveyed, 100% were satisfied with the pharmacy services provided and agreed that the pharmacist took prompt action to resolve their needs and/or concerns. ASHP educational objectives met through this learning experience include R1.1.3, R1.1.4, R1.1.6, R1.1.7, R2.1.2, R3.3.1 and R3.3.2.

Conclusions: These results and observations show that patients, providers and PGY-2 ambulatory care residents all benefit from integration of PGY-2 residents into the specialty clinic setting.

KEYWORDS
Resident; satisfaction; academic; integration; clinic

PRESENTER
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Impact of using real-world outcomes versus clinical evidence and list prices on value assessments

Denise Meade, Marie Ng and Sharon Hensley Alford

ABSTRACT

Background: To assess value, industry organizations often use list or net prices to calculate average prices per patient or price per QALY. However, this methodology requires numerous assumptions which need to be validated and can be challenging to ascertain. A better approach is to use fully adjudicated net prices and real-world clinical outcomes data for value assessments.

Aims: We sought to demonstrate the impact on value analyses of using list vs. net prices.

Methods: Using the IBM Access and Value Connect solution, patients in the IBM MarketScan Commercial Database between 1 October 2016 and 30 September 2017 with a psoriasis diagnosis were identified. To demonstrate an example of impact on value assessments, we calculated the mean per-patient-per-month (PPPM) cost associated with apremilast and compared that to the net price calculation reported in the 2018 Plaque Psoriasis Condition Update by the Institute for Clinical and Economic Review (ICER), based on per-unit dosing and discount assumptions.

Results: We identified 4169 patients with a psoriasis diagnosis during the study period. The adjudicated claims PPPM cost for US health plans was $20,821 with a mean duration of exposure to apremilast of 243 days and including concomitant psoriasis medications. This is approximately $10,000 less than the net price presented in the 2018 ICER report ($30,807 Year 1, $31,018 Year 2). Numerous additional differences between the real-world performance data and ICER evidence report were identified.

Conclusions: Our analysis found that using a fully adjudicated net price: (1) allowed direct comparison of prices amongst therapies quickly and easily; and (2) facilitated a more accurate reflection of price versus value when used alongside analysis of the real-world clinical outcomes data. We recommend that net prices and real-world data be used for value assessments whenever possible. Value assessment organizations should incorporate the numerous data sets and tools available to improve transparency, accuracy and ease of analysis.

KEYWORDS
Costs; real-world data; analytics; tool

PRESENTER
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Previous presentation: ISPOR
Understanding purchasing patterns and product access of newly launched specialty generics

Stacey Ness and Ron Lucas

ABSTRACT

Background: Many specialty drugs have lost patent exclusivity and more specialty generics (SGs) are expected in the future. Payers continue to look for ways to manage health care costs in the specialty pharmacy space and SG products offer the opportunity for savings. Given increasing interest in SGs, manufacturers are expected to invest more than $100 billion in the development of SGs over the next five years. To remain competitive, pharmacies must have access to SG products and access to competitive pricing for SGs, which can be obtained by accessing pharmaceutical manufacturer agreements through MHA Specialty Pharmacy Solutions.

Aims: Understand purchase patterns of newly launched SGs and see if increased access to product was facilitated by the entrance of a SG.

Methods: To determine purchase patterns of newly launched SGs, the rate of change of both the brand and generic products were measured for five specialty drugs across MHA pharmacy members. When possible, the brand rate was measured by the units of brand product purchased the quarter prior to the generic launch compared to the number of units in first quarter 2019 (1Q19). The generic product rate was measured by the units of generic product in the quarter it launched compared to units in 1Q19. To detect changes in product access to SGs, the number of corporations dispensing the brand was measured in the quarter prior to the generic launch compared with the number of corporations dispensing the generic in 1Q19.

Results: Brand imatinib (Gleevec) number of units decreased 80% while generic imatinib units grew by 134%. The number of corporations dispensing generic imatinib increased 34%. Brand hydroxyprogesterone caproate (OHPC) (Makena) number of units decreased 67% while generic OHPC units grew by 641%. The number of corporations dispensing generic OHPC increased 38%. Brand abiraterone acetate (Zytiga) number of units decreased 63% while generic abiraterone units grew by 289%. The number of corporations dispensing generic abiraterone increased 60%. Brand tetrabenazine (Xenazine) and brand dalfampridine ER (Ampyra) could not be measured due to limited distribution. Generic tetrabenazine units increased 2967% and the number of corporations dispensing increased 2114%. Generic dalfampridine ER units increased 1451% and the number of corporations dispensing increased 463%.

Conclusions: Pharmacies purchasing through MHA Specialty Pharmacy Solutions are able to expand their access to products and quickly adopt SGs in order to grow their businesses and serve patients.

KEYWORDS
Specialty; generic; access; GPO; distribution

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Sponsor: Managed Health Care Associates Inc. (MHA)

Notes
1. Gleevec is a registered trademark of Novartis
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Development of a specialty pharmacy productivity benchmarking model

Thom Platt and Rushabh Shah

ABSTRACT

Background: Benchmarking in healthcare is used to evaluate productivity on the basis of workflows, policies and performance in hopes of optimizing current practices and improving patient outcomes. Benchmarking has long been used in pharmacy practice, whether in tracking dispensing activities or optimizing clinical workflows. Internal benchmarking allows organizations to examine internal processes to determine allocation of institutional resources. Currently there is no validated model to evaluate productivity in specialty pharmacy workflows.

Aims: To develop and validate a specialty pharmacy productivity benchmarking tool.

Methods: A timer tool was developed to allow pharmacists to track the time spent performing activities which we identified as key performance indicators. Key performance indicators were identified as: prior authorizations, appeals of coverage denial, financial assistance activities, clinical onboarding activities, care plan activities and clinical assessments. These times were utilized to establish benchmarks for each key performance indicator. Raw activity number was tracked for each branch utilizing data from specialty management software database, Therigy. From these data, benchmark standards were derived, and all branches were evaluated.

Results: Benchmarking standardized to the inflammatory diseases branch showed a near 2.5 fold elevation in workload in the hematology and oncology branch. The pulmonary branch showed a decreased workload compared to inflammatory diseases by approximately 35%. Neurology and infectious diseases within the 20% relative workload range of inflammatory diseases and are considered to have an equal productivity level.

Conclusions: Results from this study provide a solid foundation for this benchmarking tool. Moving forward with this model the addition of technician metrics and a broader collection of performance indicators across a larger data collection period will be required to more fully develop the model.

KEYWORDS
Benchmarking; productivity; specialty pharmacy

PRESENTER
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Previous presentation: The Great Lakes Pharmacy Resident Conference
Estimating the value of pharmacist interventions in a specialty pharmacy setting

Grant Knowles

ABSTRACT

Background: As the pharmacist (RPh) role has evolved from a dispensing to a clinical focus, the need to demonstrate the value of routine RPh interventions is necessary to drive the profession forward. In 2018, Saulles and Chang reported an estimate of the financial impact of 716 RPh interventions in a regional health system specialty pharmacy to be $299,415. While RPh-led anticoagulation and medication therapy management (MTM) is well established with reducing medical costs, the value of daily specialty pharmacy care is not as well studied despite interventions being made frequently.

Aims: The objective of this study was to analyze the interventions in a specialty pharmacy and to provide an estimate of the economic value in terms of both RPh time and the potential adverse events (AEs) or unnecessary medical costs prevented had the intervention not taken place.

Methods: In this retrospective study, interventions documented at Ardon Health specialty pharmacy were categorized using a coding system. A way to identify certain interventions was developed to distinguish a subset of interventions (termed RPh impacts) that directly led to or had a high likelihood to prevent negative outcomes. Impacts documented in 2017 were reviewed by a RPh, and the actual or predicted outcome, such as avoidance of hospitalization or medication waste, was predicted. A financial value was then attributed to each impact. The 2006 Health Care Utilization Project report was used to estimate the costs of prevented hospitalizations. Other costs were estimated using emergency room (ER) visit costs available in the literature and actual costs of avoided medication waste. Two scenarios were completed: one in which all the prevented outcomes were predicted to occur, and one where 50% of the total cost of prevented outcomes would be incurred. Surveys were completed by the RPhs to estimate the average time per intervention to estimate the value of devoted RPh time.

Results: A total of 14,441 interventions were documented, of which 115 were identified as RPh impacts. The total estimated value of interventions ranged from $2,518,442 to $4,603,358, with an estimated value per intervention of $174 to $319. Most of the RPh impacts were predicted to have prevented an unnecessary hospitalization.

Conclusions: While the estimative nature of this analysis poses limitations, the analysis demonstrates the profound clinical and economical value of RPh care in a specialty pharmacy setting.

KEYWORDS
Specialty pharmacy; interventions; impacts; economic; value

PRESENTER
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Evaluation of a specialty pharmacy health coaching program

Dana Simonson, Marj Wittenborg, Mallory Snyder, Holly Wiest and Ann McNamara

ABSTRACT

Background: Fairview Specialty Pharmacy provides comprehensive therapy management (TM) for patients, yet some patients require additional social, physical, and psychological support that may be unmet by a pharmacist or nurse. To address complex patient needs and remotely improve social determinants of health, a health coach is employed. The projected benefits of a health coaching program for patients include providing holistic support for health and mental well-being, identifying and overcoming barriers to healthy coping, and identifying additional resources for support.

Aims: Goals of this study were to determine the impact of a health coach in patients who receive specialty pharmacy services as measured by number of referrals to this program, patient satisfaction and perceived impact on health, and impact on patient depression scores.

Methods: Health coaching services were offered to patients during initial TM call or when a trigger was identified, such as emotional distress, new chronic illness diagnosis, life transition, coping issues, stress management, end of life, advanced care planning, or family concerns. Initial outreach health coach call to the patient provided program overview, confirmed interest, determined focus area (emotional/spiritual needs, loss/grief, lifestyle changes, or stress management), encouraged goal setting, and documented baseline depression score using the Patient Health Questionnaire (PHQ-9). Follow-up calls between the patient and health coach were focused on patient goals; referrals to additional services were documented. At the end of the third call, the PHQ-9 was given and a satisfaction survey was mailed to the patient. Program impact was determined based on satisfaction surveys, referrals, and the change in PHQ-9 after the third call.

Results: 623 health coaching assessments were completed in 82 patients (April 2016-January 2019). The most common coaching focus (46% of patients) was combined emotional/spiritual and loss/grief. PHQ-9 was assessed in 54 patients at baseline and session 3; improvement occurred in 30 of the 54 patients (56%). In patients with baseline moderate to severe depression, 70% of patients experienced decreased depression. Anonymous patient experience survey (n = 21) revealed that 86% of patients in this program strongly agreed or agreed that their physical health and 95% strongly agreed or agreed that their mental health was positively impacted by working with the health coach. All patients (100%) strongly agreed or agreed that they were satisfied with the Fairview Specialty Pharmacy health coaching program. The health coach referred 37 patients to additional services, including support groups, social workers, case managers, physicians, psychiatrists, and hospice or advance care planning.

Conclusions: The specialty pharmacy health coaching program was impactful, as measured by high patient satisfaction, positive patient perception of program impact on physical and mental health, improved patient depression scores, and referrals to other resources.

KEYWORDS
Health coach; social determinants of health; complex patients; patient satisfaction; depression score

PRESENTER
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Impact of multidisciplinary patient education sessions on expectations and understanding of new calcitonin gene-related peptide treatments

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ABSTRACT

Background: The new calcitonin gene-related peptide (CGRP) medications offer an exciting alternative to daily preventative migraine treatments. Finding effective and efficient ways to educate patients can be challenging for providers and pharmacists alike given the treatments are subcutaneous injections with extended half-lives and data is limited on long-term efficacy and adverse effects.

Aims: We aimed to develop and evaluate a patient-oriented, multidisciplinary presentation to inform patients about the new CGRP drug class to decrease provider and pharmacist education burden while increasing patient understanding.

Methods: Three live, one-hour CGRP informational sessions were conducted jointly by a headache medicine neurologist and clinical pharmacist from the institution’s specialty pharmacy. Prior to medication initiation, patients were educated about CGRP pathophysiology, benefits, risks, injection technique, and logistics of cost and medication access. The third presentation was video recorded and transitioned to an online platform. Participants completed surveys before and after watching the in-person or online session. Patients had the ability to fill these self-injectable therapies at the institution’s specialty pharmacy, who assisted with benefits investigation and prior authorization. If within payor network, the patient was offered specialty pharmacy services.

Results: A total of 84 patients participated in the session (41 in-person; 43 online). Patients had frequent headaches (mean = 18/month; SD = 9.2) with severe (MIDAS >21) headache-related disability (mean MIDAS score = 63.1). Participants reporting confidence in understanding CGRP significantly increased from 68% to 97% following the informational session (p < .001) for those completing both the pre- and post-survey question (n = 69). There was also a significant increase from 84% to 97% in participants reporting comfort with injection technique (p = .008, n = 70). For both measures, there was no statistically significant difference between the in-person and online sessions. Nearly all participants (97%) would recommend the session to family or friends with migraine.

Conclusions: The multidisciplinary informational session was an effective and efficient method of educating patients about these new treatments while concurrently decreasing provider and pharmacist education burden. The online video was as effective as the in-person session in educating patients, but improved access and availability.

KEYWORDS
CGRP; migraine; multidisciplinary

PRESENTER
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Previous presentation: American Headache Society Annual Scientific Meeting
A novel tool to monitor adherence to oral oncolytics: a pilot study

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ABSTRACT

Background: Non-adherence is an important issue in cancer care as more oral cytotoxic and targeted agents become available. Although oral therapies may be more convenient for patients, measuring and optimizing adherence is challenging. The Nomi system records real-time medication taking behavior from a “smart” prescription bottle and displays the data on a web-based interface. Nomi can also communicate with patients via text message to intervene in cases of non-adherence.

Aims: The objective is to report the results of a 28-patient pilot study aiming to assess Nomi’s ability to assist patients taking capecitabine, an oral chemotherapy agent with a complex, cyclical regimen.

Methods: Eligible patients were prescribed capecitabine for breast, colorectal, pancreatic, or biliary cancer. The study had a pre-intervention stage, during which patients were monitored, and an intervention stage, in which the text messaging feature was enabled. Adherence was defined as the number of correct doses (both timing and quantity) over the total number of prescribed doses. Conversions were events in which patients took a dose after receiving a text intervention (from Nomi). Adherence throughout the study was calculated from the data that the bottles collected – we calculated adherence scores for each patient, during each cycle and study period (pre vs. post-intervention), defined as the number of correct doses (both timing and quantity) over the total number of prescribed doses. We defined three categories of patients by percent change in adherence: category 1 (>8%), category 2 (8% to 8%), and category 3 (<8%).

Results: We collected data from 28 patients (24 pre/post and 4 pre-only). On average, patients were 84% adherent (N = 28; SD = 11%). During pre-intervention, patients had a self-adherence of 89% (SD = 12%), and afterwards, they had an average adherence of 90% (SD = 6%). Most of the patients in category 1 demonstrated a substantial conversion rate (>35%). Patients in category 1 tended to live in regions with lower average household income (Mean = $58,937) than those in category 2 (Mean = $77,482) and category 3 (Mean = $90,972). Of survey respondents, 56% indicated that they would want to continue using Nomi, while 67% indicated that they would recommend it to others.

Conclusions: This innovative technology is able to monitor, measure and intervene for patients taking capecitabine in real-time. Adherence overall was high, and some patients appeared to benefit more from text message interventions. Future work should focus on patients deemed high risk for non-adherence.

KEYWORDS
Adherence; technology; NOMI; bottle; capecitabine

PRESENTER
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Sponsor: SMRxT

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Correlates and barriers to medication adherence in multiple sclerosis patients and their impact on clinical outcomes

Jenna Lee, Danielle McPherson, Mark D’Ambrosi and Martha Stutsky

ABSTRACT

Background: Multiple sclerosis (MS), a debilitating, chronic disease of the central nervous system, is the most common cause of neurological defects in young adults. There are currently over a dozen disease-modifying therapies (DMTs) that reduce relapse rates and slow disease progression. Despite positive efficacy studies, there are many barriers to medication adherence, which may impact patient outcomes.

Aims: The purpose of this study is to evaluate the correlation between medication adherence and clinical outcomes and to identify barriers to adherence in the MS patients filling DMT prescriptions at Yale New Haven Health Outpatient Pharmacy Services (OPS).

Methods: This retrospective study was conducted with 138 adult patients filling MS medications at OPS between 1 January 2018 and 31 July 2018. Subjective adherence and outcomes data were obtained through semi-annual MS patient assessments. The following data were evaluated for correlation with medication adherence: age, gender, ethnicity, language, smoking status, alcohol dependency, PMH of depression, Charlson comorbidity index, medication frequency and route, insurance provider, and medication co-pay. Retrospective medication possession ratio (MPR) data were collected from the pharmacy dispensing system, and hospital admissions obtained through the electronic health record (EHR).

Results: Adherence data demonstrated that 3.6% of patients had an MPR <80% and 15.2% had an MPR <90%. A statistically significant correlation (p < .05) was identified between patients with a diagnosis of depression and patients with an MPR <80%, suggesting a correlation between worsening adherence and increasing depressive symptoms. A statistically significant correlation (p < .05) was identified between patients with hospital admissions or ED visits due to MS symptoms and patients with an MPR <80% as well as the cumulative MPR results, suggesting a correlation between worsening adherence and increasing hospital admission or ED visits due to MS.

Conclusions: Patients with lower adherence to DMTs were associated with a higher rate of hospital admissions or ED visits due to MS symptoms documented in the EHR indicating the importance of medication adherence for this patient population. The importance of mental health for patients should be emphasized in this population as increasing depression symptoms were correlated with decreasing medication adherence.

KEYWORDS
Multiple sclerosis; DMT; disease modifying therapy; adherence

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Impact of health-system specialty pharmacy services on medication adherence in pediatric patients with cystic fibrosis

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ABSTRACT

Background: Specialty medications represent a growing part of the pharmacological management of chronic disease states such as cystic fibrosis (CF). The management of CF in the pediatric population is complex, as it involves multiple medications and treatment success is largely determined by adherence to the care plan. There is often a delay between prescribing of specialty medications and initiation of therapy in the pediatric CF population. Health-system specialty pharmacy services provide significant benefits when compared to external specialty pharmacies, including direct access to the medical record, collaboration with the healthcare team, continuous patient education and continuity of care.

Aims: The objective of this initiative was to assess the impact of Outpatient Pharmacy Services at Yale New Haven Health (OPS), a health system specialty pharmacy, on medication adherence in pediatric patients with CF.

Methods: A prospective review of 65 pediatric patients with CF seen by the pharmacist in a health-system CF clinic over 6 months was conducted for medication adherence and compared to a retrospective cohort. Education about the health-system specialty pharmacy services was provided to patients through the following methods: invitation letter, informational pamphlets distributed in clinic and direct education by the clinic pharmacist. A clinic workflow was implemented to streamline the referral process. Primary endpoints include: medication possession ratio (MPR), proportion of days covered (PDC), and percentage of prescriptions sent to and filled by the OPS.

Results: A total of 65 pediatric CF prescriptions were written from September 2017 to February 2018, with only 7.7% of the prescriptions sent to OPS prior to implementation of the clinic workflow. The MPR and PDC in this retrospective cohort were 0.85 and 0.75 respectively. From September 2018 to February 2019 the number of prescriptions for all medications written was 304, with 32.9% sent to OPS and a fill rate of 89%. The MPR and PDC for that year were 0.86 and 0.80 respectively.

Conclusions: This single-center review that assessed the impact of specialty pharmacy services on pediatric patients with CF in a large health system demonstrated improved and sustained patient medication adherence. The increase in utilization of OPS led to an increase in prescriptions received and filled by the health-system specialty pharmacy.

KEYWORDS
Pediatric; cystic fibrosis; MPR; PDC

PRESENTER
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Impact of outpatient specialty pharmacy on medication adherence in post-kidney transplant patients

Adina Petrosan, Kristen Belfield, Elizabeth Cohen, Mitchell DelVecchio and Martha Stutsky

ABSTRACT

Background: Post-kidney transplant patients are initiated on a complicated medication therapy regimen including 6-7 new medications, with each consisting of multiple tablets or capsules. Medication adherence may be difficult due to the complexity of the regimen and non-adherence can lead to an increased risk of rejection. At Yale New Haven Transplant Center (YNHTC), patients are presented with the option to receive their medications through Outpatient Pharmacy Services (OPS), a Yale New Haven Health specialty pharmacy.

Aims: The objective of this study is to determine the impact of OPS on patients’ medication adherence.

Methods: A retrospective, single center, chart review was conducted of 50 patients who received a kidney transplant at YNHTC between January 2017 and June 2017. Exclusion criteria included patients who were actively enrolled in a research study, deceased within one year of transplant, or had incomplete medical records. Refill data of patients’ prescribed doses of anti-rejection medications (tacrolimus, cyclosporine, mycophenolate and azathioprine) was manually retrieved from pharmacies. Adherence was assessed by calculating the proportion of days covered (PDC) in a 365-day time period. The adherence rate between each drug class was then averaged. The primary outcome was the relationship between the patient’s pharmacy and the adherence rate (PDC). Patients were divided into three groups; patients who use OPS (n = 26), patients who use both OPS and another pharmacy (n = 8), and patients who use another pharmacy only (n = 16). Secondary outcomes included pre-transplant adherence survey, MediSetGo score, and number of post-transplant readmissions (hospital stay greater than 24 hours).

Results: PDC ranged between 65.5-100% for OPS (average = 94.8%), 56.5–98.5% for OPS and another pharmacy (average = 83.2%), and 53.5–100% for another pharmacy only (average = 91.8%). The PDC was significantly lower for patients who used OPS and another pharmacy compared to either OPS alone or another pharmacy alone (p = .045). Secondary endpoints studied, such as third-party payer, pre-transplant adherence survey and MediSetGo score, were not found to be related to the PDC.

Conclusions: Use of OPS alone did not impact the one-year medication adherence rate of post kidney transplant patients. However, a patient’s medication adherence rate may be related to the use of multiple pharmacies versus one single pharmacy. Further studies to investigate this relationship should be conducted.

KEYWORDS
Transplant; kidney transplant; PDC

PRESENTER
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Patterns of on-demand medication use in patients with hereditary angioedema treated long-term with prophylactic subcutaneous C1-inhibitor

Donald S. Levy, Joseph Chiao, John Dang, Christopher Hood, Dylan Supina and Henrike Feuersenger

ABSTRACT

Background: Hereditary angioedema (HAE) is characterized by recurrent, debilitating attacks of angioedema that may require immediate (on-demand) treatment. HAE prophylactic therapy may reduce the need for on-demand treatment by decreasing the frequency and severity of attacks, which may in turn impact treatment costs. Subcutaneous C1-inhibitor (C1-INH [SC], HAEGARDA®, CSL Behring) at the FDA-approved dose of 60 IU/kg is indicated as routine prophylaxis to prevent attacks in patients with HAE. In the pivotal phase III COMPACT trial, the median reduction in attack rate relative to placebo was 95% with twice-weekly C1-INH (SC) 60 IU/kg, and the median reduction in on-demand medication use was >99%.

Aims: We examined patterns of on-demand medication use in patients treated with C1-INH (SC) 60 IU/kg in a long-term, open-label extension (OLE) of the COMPACT trial.

Methods: The OLE of the COMPACT trial was a multicenter, international, randomized, parallel-arm study that evaluated patients aged ≥6 years with ≥4 attacks over 2 consecutive months before enrollment. The trial included patients from the COMPACT trial and C1-INH (SC)-naïve patients. Patients were randomized to receive C1-INH (SC) 40 IU/kg or 60 IU/kg twice weekly for 52 weeks or up to 140 weeks (US patients only). The time-normalized number of uses of medication for treatment of HAE attacks was an exploratory endpoint.

Results: Of the 63 patients in the 60 IU/kg group, 35 had a total of 371 attacks, of which 229 (61.7%) were treated with on-demand medication: 84% (192/229) were treated with 1 medication, 62% with C1-INH (IV), and 38% with icatibant. The majority of treated attacks (113/229) were severe. A total of 28 patients (44.4%) had no attacks; 11 (17.5%) had no treated attacks, and 24 (38.1%) had ≥1 treated attack. Post-hoc analysis of annualized on-demand medication use showed that 39 patients (61.9%) treated with C1-INH (SC) 60 IU/kg did not use any on-demand medication; 66.7% used it less than once per year (mean (SD): 3.8 (9.6) uses/year; median: 0.0 uses/year). Between months 25 and 30, 87% of patients (20/23) did not use any on-demand medication (mean: 0.08/month, or ~1 use/year).

Conclusions: On-demand medication use remained consistently low during prophylactic therapy with C1-INH (SC) in the OLE study, with two-thirds of patients using medication less than once per year. Reduction in on-demand medication use over time should be considered in cost-effectiveness analyses of HAE prophylactic therapies.

KEYWORDS
Angioedema; prophylaxis; C1-inhibitor

PRESENTER
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Sponsor: CSL Behring

Comparison of healthcare utilization among managed Medicaid individuals diagnosed with multiple sclerosis treated with emergent versus established disease modifying therapy

Alexis Parente, Bryce Sutton, Allison Petrilla and Christie Teigland

ABSTRACT

Background: Emerging disease-modifying therapies (DMTs) have evolved as an alternative treatment for patients with multiple sclerosis (MS). The efficacy and safety of established DMTs (interferons, glatiramer acetate, natalizumab, fingolimod and mitoxantrone) have been well studied and clinical trials with small sample sizes have suggested that emerging DMTs (iteriflunomide, dimethyl fumarate/BG-12, alemtuzumab and pegylated IFN) may have distinct advantages relative to established DMTs including better outcomes and reduced healthcare resource utilization. However, there is limited real-world information regarding which DMTs (established vs. emerging) provide the best clinical response and outcomes in managed care populations of patients with MS.

Aims: To compare MS related healthcare use within one year of initiating emergent and established DMTs among Managed Medicaid individuals diagnosed with MS in the US.

Methods: A large national sample of patient-level administrative healthcare claims data was used for this analysis. MS patients aged 18 years and over with a new prescription fill for an established or emergent DMT between 2013 and 2016 were evaluated. Patients were eligible if they were continuously enrolled in a health plan with pharmacy and medical coverage for at least 6 months before and 1 year after initiation of therapy. Four types of healthcare use were examined: MS-related hospitalizations, emergency room (ER) visits and relapse events (inpatient and outpatient). Multivariate negative binomial models with robust standard errors were used to estimate the association between MS related healthcare use and type of DMT. All models adjusted for age, gender, Charlson index and geographic region.

Results: During the study period, 6981 Managed Medicaid individuals with a MS diagnosis initiated a DMT. Of those, 79.8% were female, 50.4% were aged 40–64 years and 21.5% were on emergent DMTs. Emergent DMT users had fewer hospitalizations compared to first generation DMT users within one year of initiating therapy (adjusted risk ratio [ARR] = 0.64, 95% confidence interval [CI]: 0.46–0.88) and fewer outpatient relapses (ARR = 0.86%, CI: 0.79–0.95). Differences in inpatient relapses and ER visits were not observed by DMT type.

Conclusions: This study suggests emergent DMTs are associated with reduced MS-related hospitalizations and outpatient relapses within one year of initiating therapy. Studies examining a longer treatment time frame and additional outcomes are warranted to confirm these findings.

KEYWORDS
Multiple sclerosis; disease modifying therapy; Managed Medicaid; healthcare utilization

PRESENTER
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ABSTRACT

Background: Hepatitis C (Hep C) is a liver infection caused by the Hep C virus. It is the most common, chronic, blood-borne infection in the US. It is estimated to affect as many as 3 million Americans and is the leading cause of liver transplants in the US. Hep C is often curable with newer antiviral therapy that is short in duration of treatment and more tolerable than traditional therapies.

Aims: To measure the impact of a high-touch, specialty clinical program on driving therapy completion of glecaprevir/pibrentasvir in Hep C patients.

Methods: This study was performed from a single center specialty pharmacy (SP). We evaluated patients initiating glecaprevir/pibrentasvir from February to March 2019. The outreach strategy included onboarding new-to-therapy patients by pharmacy technician specialists through the completion of a "Welcome Call". The technician specialists determined the best time with every patient’s input for the pharmacist to follow up with a "New Start Pharmacist Initial Counseling Call". A clinical pharmacist completed the Hep C counseling call. Afterward, a nursing refill reminder call was completed. Also, a “Patient Care Coordinator Refill Reminder Call” was coordinated to set up the shipment of the medication. After the patient completed their final refill, a nurse generated an “End of Therapy Call” to determine whether completion of therapy occurred.

Results: Of the 46 patients managed by the SP, 44 patients received the cumulative days’ supply required to complete therapy. The SP had a 100% completion rate of therapy for the patients that were eligible to continue therapy. Two patients, due to allergic reactions, were not eligible to complete therapy. As such, this resulted in an overall completion rate of 96%. All patients received an initial counseling call. Thirty of the 46 patients received refill reminder calls from a nurse; 16 patients were not eligible for this call due to the patient reaching out to the pharmacy prior to the refill reminder call for their shipment, refill not applicable or allergies to the medication. Forty-four patients had end-of-therapy calls completed.

Conclusions: A collaborative, high-touch SP, managing Hep C patients, drove a high rate of completion of glecaprevir/pibrentasvir Hep C therapy (100% of patients eligible). Specialty pharmacies that demonstrate improved Hep C completion rate outcomes with robust, coordinated care processes can be more confident in building future value-based reimbursement models with payers and pharmaceutical manufacturers.

KEYWORDS
Hepatitis C; value-based care; high-touch; outcomes; completion rate

PRESENTER
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Predicting time to medication access for hematologic malignancies: the impact of an integrated specialty pharmacy and limited distribution drug networks

Autumn D. Zuckerman, Megan E. Peter, Samuel Starks, Matthew Maulis, Josh Declerq, Leena Choi and Madan Jagasia

ABSTRACT

Background: Barriers to accessing oral oncolytic therapy include insurance authorization, high copays and limited distribution drug (LDD) networks. In September 2015, a pharmacist joined an outpatient hematology clinic to facilitate timeliness of medications (for which the pharmacy has access) dispensed by Vanderbilt Specialty Pharmacy (VSP). The scope expanded to manage non-VSP medications (LDD) in June 2016.

Aims: Compare access time to oral oncolytic therapy between drugs to which VSP has access vs. non-VSP medications, and to test whether patient access time to non-VSP agents reduced after integrating a pharmacist.

Methods: We reviewed medical records of adult patients prescribed oral oncolytic therapy by a hematology provider. The primary outcome was the time (in days) from treatment decision to medication shipment, stratified by drug access (VSP vs. non-VSP) and time (Time 1: September 2015–May 2016; Time 2: June 2016–September 2017). Using proportional odds logistic regression, we compared time to medication shipment between VSP and non-VSP drugs, and tested whether time to shipment decreased for non-VSP drugs from Time 1 to Time 2.

Results: A total of 367 patients with 410 prescriptions were included: 285 VSP drugs and 125 non-VSP drugs. Median time from treatment decision to shipment was 6 days (IQR: 3–9) for non-VSP and 3 days (IQR: 1–6) for VSP drugs. In Time 1, time from treatment decision to shipment was significantly longer for non-VSP vs. VSP drugs (OR = 6.5, p < .001). For non-VSP drugs, time to shipment reduced from Time 1 to Time 2 (OR = 0.41, p = .04).

Conclusions: Integrating a pharmacist into clinic significantly shortened time from treatment decision to shipment for non-VSP drugs. However, access to these drugs is still slower than VSP medications as they cannot be fully integrated into clinic workflow. The integrated pharmacist at VSP adds value to patient access and outperforms LDD medications, challenging the value of LDD networks beyond medical economics.

KEYWORDS
Oral oncolitics; limited distribution; medication access; specialty pharmacy; integrated pharmacist

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Previous presentation: AMCP Nexus conference, Orlando, FL 10/2018
Comparison of extended to standard half-life recombinant factor VIII therapy in patients with hemophilia A on prophylactic therapy

Michael McCall, Pamela Koerner, Rick Miller and Melanie Radi

ABSTRACT

Background: Hemophilia A is a genetic bleeding disorder caused by a deficiency in factor VIII (FVIII). FVIII maintains bleeding homeostasis within the body through its downstream effects on the intrinsic clotting cascade. The extent of the disease – mild, moderate or severe – depends on the amount of available FVIII in the blood. Patients with severe disease (FVIII levels <1%) experience spontaneous bleeds into the joints or muscles causing pain, inflammation and discomfort. Left untreated, this may lead to long-term complications such as joint damage, chronic pain or joint replacements.

Treatment of hemophilia A involves replacing FVIII through either on-demand or prophylactic infusion of antihemophilic FVIII products. On-demand treatment involves infusing the FVIII product at the time of a bleed to stop the event. Prophylactic therapy is the routine replacement of FVIII to prevent bleeds from occurring. The Medical and Scientific Advisory Council recommends the use of a prophylactic regimen, particularly in patients with severe disease, to maintain FVIII levels above 1%. This has been shown to reduce bleeds and joint damage over on-demand treatment, and may have the potential to improve health outcomes.

Prophylactic treatment with standard half-life (SHL) rFVIII products are typically infused three to four times a week due to an approximate half-life of 8-12 hours. This can have a great impact on patient quality of life, adherence to therapy and treatment outcomes. Improved technology such as PEGylation and fragment-cristallization (Fc) immunoglobulin protein fusion introduced rFVIII products with a half-life of 1.5 to 1.8 times that of standard therapies. These extended half-life (EHL) rFVIII products maintain FVIII levels similar to SHL rFVIII products with an infusion frequency of once to twice weekly. This may present an opportunity for patients to achieve the clinical benefit of prophylactic treatment without the potential limitations and burden of treatment with SHL rFVIII products.

EHL rFVIII products have demonstrated efficacy for prophylactic therapy by reducing bleed rates in patients with hemophilia A, particularly in many clinical trials. However, the benefit of using EHL over SHL rFVIII products for prophylactic therapy has not been universally established, and there is no recommendation for one product over the other. A few studies have indirectly compared EHL and SHL rFVIII products or have looked at patient outcomes and bleed rates after switching from SHL to EHL rFVIII products. Limited studies currently exist that directly compare treatment outcomes between EHL and SHL rFVIII products in a real-world patient population.

Aims: The primary objective of this study was to compare annualized bleed rates (ABRs) of hemophilia A patients on prophylactic therapy prescribed either EHL or SHL antihemophilic rFVIII products. Secondary objectives were to compare quality of life outcomes (pain, missed school or work, use of mobility accessories, and hospitalizations), monthly factor utilization, cost, monthly insurance coverage amounts and monthly patient copays.

Methods: Specialty pharmacy records of patients taking an FDA approved SHL or EHL rFVIII product for the prophylactic treatment of hemophilia A were retrospectively reviewed from 1 January 2017 to 31 December 2018. Data was collected from pharmacy dispensing software, therapy management programs, and chart notes provided from Hemophilia Treatment Centers (HTCs), doctors’ offices and/or home infusion nurses. Data included demographic information, patient reported bleed history, missed work or school, pain, hospitalizations, factor utilization and cost of treatment. Patients were excluded if they were being treated for an inhibitor with immune tolerance therapy (ITT), coagulation factor VIIa (recombinant) (NovoSeven®), anti-inhibitor coagulant complex (Feiba®) or emicizumab-kxwh (Hemlibra®). A secondary analysis was also done to compare the individual EHL rFVIII products to the SHL group. Mann–Whitney and independent t-test statistical data analysis was completed utilizing SPSS software®. Study approval was obtained from the Duquesne University Institutional Review Board.
Results: Patients prescribed EHL rFVIII products had a statistically significant lower ABR than those prescribed SHL rFVIII products ($p = .005$). No statistically significant difference was found in monthly factor utilization ($p = .824$) or quality of life outcomes between products. EHL rFVIII products were significantly more costly than SHL rFVIII products ($p = .035$). Monthly insurance coverage amounts and patient copays were similar between the groups.

Conclusion: Patients prescribed EHL rFVIII products had a statistically significant lower ABR than those prescribed SHL rFVIII products ($p = .005$). No statistically significant difference was found in monthly factor utilization ($p = .824$) or quality of life outcomes between products. EHL rFVIII products were significantly more costly than SHL rFVIII products ($p = .035$). Monthly insurance coverage amounts and patient copays were similar between the groups.

KEYWORDS
Hemophilia; extended half-life; recombinant; factor VIII; prophylaxis

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Notes
1. NovoSeven is a registered trade name of Novo Nordisk
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3. Hemlibra is a registered trade name of Genentech
4. SPSS is a registered trademark of IBM