

members to choose either retail or mail pharmacy as their preferred distribution channel. **METHODS:** Claims (n = 168,381) submitted between April 1, 2008 and December 31, 2008 for an employer after it began offering the same price on 90-day retail and mail maintenance prescriptions were used to calculate Medication Possession Ratio (MPR), Generic Dispensing Rate (GDR), Generic Substitution Rate (GSR), and Preferred Brand Dispensing (PBDR) for patients impacted by the benefit. GDR, GSR, and PBDR were calculated for all claims with a 90-day supply. MPR was calculated for all patients who were eligible 180 days before and after their first 90-day prescription between April 1 and June 30, 2008 for each maintenance class, using that first prescription and any within the subsequent 180 days. Overall metrics and those for select classes with sufficient sample size are presented. **RESULTS:** The average MPR, across all classes, was 80% for retail dispensed prescriptions and 78% for mail. Among six high-volume classes, the average MPR was 82% at retail and 81% at mail, with MPRs for individual classes ranging from 75% (PPIs) to 89% (ACEs and Anti-convulsants) for retail-dispensed and 74% (SSRIs) to 85% (ACEs) for mail-dispensed. When comparing retail and mail dispensed prescriptions, GDR (57% vs. 56%), GSR (99% vs. 99%), and PBDR (86% vs. 86%) were nearly identical. **CONCLUSIONS:** When out-of-pocket costs and days supply per prescription are identical, adherence rates and related formulary performance metrics for mail and retail-dispensed maintenance medications appear essentially similar in early results. These pilot results will need to be confirmed as more payers adopt this benefit design and longer follow-up periods improve adherence measurement precision.

PIH28

#### THE IMPACT OF MEDICARE SUPPLEMENT INSURANCE ON ACCESS, UTILIZATION, AND COST OF HEALTH CARE AND ON COMPLIANCE WITH RECOMMENDED PHARMACEUTICAL TREATMENT

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**OBJECTIVES:** The literature was reviewed to determine the impact of Medicare supplement insurance (i.e. Medigap) on the Medicare program with respect to access, utilization, outcomes, costs, and drug compliance. Additionally, we discuss a new program to improve pharmaceutical utilization for Medigap enrollees. **METHODS:** We conducted a literature search using PubMed, looking for peer-reviewed articles that compared access, utilization, outcomes and costs between enrollees with Medicare fee-for-service coverage alone to those with Medigap. Additional searches focused on differences in pharmacological compliance, for those with and without drug coverage, among the two groups. Finally, we searched for pharmacy compliance programs offered through supplement insurance plans. **RESULTS:** Twenty-seven articles met our search criteria. The literature suggests Medicare Supplement Insurance can be cost-effective, that it is correlated with better access to health care services, and may result in higher utilization of preventive services than would be the case without such coverage. Also, the type of supplement insurance did not significantly influence prescription drugs utilization among Medicare enrollees. No articles found discussed any current efforts to manage the pharmaceutical treatment of Medicare Supplement Insurance enrollees. **CONCLUSIONS:** Medigap programs have not historically managed their enrollees like Medicare Advantage plans have done. In particular, the literature suggests there is much room for improvement in pharmacy management for all Medicare populations, including those enrolled in Medigap plans. This has led AARP and UnitedHealth Group to offer a pharmacological compliance program, with disease management and case management programs, for their AARP Medicare Supplement Insurance enrollees, beginning in 2009. Results from this care management effort will help tailor models for more ways to better manage the care for fee-for-service Medicare enrollees with supplement coverage.

PIH29

#### COMPARISON OF ADHERENCE, PERSISTENCE AND MEDICATION WASTAGE IN 30-DAY VERSUS 90-DAY REFILL CHANNELS

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**OBJECTIVES:** To compare medication possession ratio (MPR), medication persistence & pill wastage in 90-day versus 30-day refill channel among 5 different drug classes. **METHODS:** We conducted a retrospective study using pharmacy claim database. The cohorts were classified based on the type of refill duration (30-day or 90-day). Patients included in the study were continuously eligible in the insurance plan for the study duration and were new to therapy during the identification period (January 1, 2006 to June 30, 2006) and were followed for 21 months after their index date. Claims in the first 3-months after the index date were excluded from the analysis to avoid immortality bias. Outcomes included MPR, persistence to therapy, and pill wastage. Pill wastage was calculated only among those who switched therapy within a pharmacological class of drugs (i.e. diuretics). Therapeutic drug classes included in the study were antihypertensives (AH), anti-depressants (AD), antihyperlipidemics (AL), anti-asthmatics (AA) and anti-diabetics (AD). **RESULTS:** A total of 8403, 6296, 7197, 5383 and 2722 subjects in AH, AD, AL, AA and AD drug classes were included. MPR and persistency were consistently and statistically higher in the 90-day versus the 30-day group at 9-months and 18-months post index among all the 5 drug classes studied. There was a consistent trend of decrease in MPR and persistency at 18-months in comparison to 9-months follow up in all the 5 therapeutic drug classes studied. The higher trend in pill wastage in the 90-day versus 30-day refill channel was not consistent across all therapeutic categories. **CONCLUSIONS:** Members who refilled 90-day

versus 30-day were associated with a significant higher MPRs and persistency. Efforts to increase medication adherence should be continued steadily along the course of therapy as a medication adherence with chronic medications continues to decrease over time.

PIH30

#### PATTERNS OF UTILIZATION AND DISCONTINUATION OF MEDICATION IN A RETIREE POPULATION

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**OBJECTIVES:** To describe the patterns of medication discontinuation in a retiree population. Premature discontinuation of medications adversely affects patients' outcomes and may require use of additional health care resources. **METHODS:** The study included pharmacy claims from a retirement system for the period January 2000-September 2005. The unit of analysis was the course of drug therapy (CDT), representing a unique combination of a patient and a drug product (i.e. generic name, formulation and strength). CDTs initiated between August 1, 2000 and July 31, 2001 and discontinued before March 1, 2005 were included in the analysis. Days in therapy for each CDT were calculated as the difference between the date of the first and last prescription of the CDT. **RESULTS:** The study included 1.1 million CDTs representing 5.9 million claims. 37.0% of CDTs were discontinued with less than a month in therapy, 50.0% with less than 6 months, and 76.0% within one year. Maintenance therapy comprised 740,788 CDTs (70.30%) of which 27.0% had a single claim. Maintenance therapies had the following cumulative utilization patterns: 36.7% CDTs discontinued in less than 3 months of therapy, 45.0% in less than 6 months, 74.7% within one year, and 87.2% within two years. 21.6% of non-maintenance CDTs were continued for more than a year and 11.8% for more than 2 years. **CONCLUSIONS:** Premature discontinuation of therapy intended for long-term use is highly prevalent with more than one-fourth of all maintenance therapies discontinued at the first prescription, and nearly three-fourths discontinued within the first year of therapy. In the other hand, over one-fifth of non-maintenance therapies were used for over a year. The assessment of compliance using claims data should account for discontinuation of therapy prior to the potential manifestation of positive patient outcomes and for the short-term usage of maintenance therapies and prolonged use of non-maintenance therapies.

PIH31

#### ASSESSING THE VALUE OF LESS FREQUENT MEDICATION DOSING ON ADHERENCE AND OUTCOMES

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**OBJECTIVES:** To systematically evaluate studies assessing the outcomes and economic value of decreased medication dosing frequency. **METHODS:** We searched the literature from 1998 to 2008 using the MEDLINE database for articles that evaluated the cost-effectiveness of dosing frequency changes and adherence. Only non-English articles were initially excluded; from the identified citations, all abstracts were reviewed; those lacking a clear link between dosing frequency changes, adherence, and costs or cost-effectiveness analysis (CEA) were excluded. The selected articles were thoroughly reviewed and summarized. **RESULTS:** A total of 168 citations were identified: after exclusions by reviewing the abstracts, 21 were selected and reviewed—18 original studies and three systematic reviews. The articles encompassed several chronic pathologies, e.g., osteoporosis (seven) and hepatitis C (two). Seven of the ten economic studies utilized decision modeling frameworks (usually one-year horizon), where the effect of dosing frequency changes on adherence was not the primary outcome. In most cases, assumptions on adherence changes were used as part of the sensitivity analysis, but lacked support from strong evidence. Only two randomized clinical trials where adherence was not the primary outcome reported the effect of dosing changes, but focused, as did cross-sectional surveys, on patient preferences instead of cost-effectiveness. Observational studies and retrospective claims database reviews used different measures, definitions, and methodologies, making it difficult to summarize their results. Overall, the studies suggested that less frequent dosing leads to improved outcomes, although direct evidence of economic benefit was often lacking. **CONCLUSIONS:** Due to the lack of direct evidence, head-to-head direct comparisons of dosing regimens and long-term prospective studies are ideally needed to evaluate the cost-effectiveness of less frequent dosing that may improve outcomes through improved adherence or improved pharmacokinetic/pharmacodynamic effects.

PIH32

#### THE BRAZILIAN PORTUGUESE VALIDATION OF THE PROLAPSE – QUALITY OF LIFE QUESTIONNAIRE – P-QOL

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**OBJECTIVES:** The aim of this study was to translate and validate a Brazilian version of the “Prolapse – Quality Of Life Questionnaire” (P-QOL) as a specific instrument to assess the severity of symptoms and their impact in the quality of life of Brazilian women with genital prolapse. **METHODS:** Sixty-five patients (45 with symptomatic and 20 with asymptomatic pelvic organ prolapse), were enrolled from the outpatient clinic of the Urogynecology and Vaginal Surgery Section of the Gynecology Department of the Federal University of São Paulo (UNIFESP). At first, we translated the P-QOL

into Brazilian Portuguese language following international methodological recommendations. Because of language and cultural differences we performed cultural, structural, conceptual, and semantic adaptation on the P-QOL, so that patients were capable to completely understand the questions. All patients answered P-QOL twice on the same day with an interval of 30 minutes, applied in face-to-face interviews by two different interviewers. After 7 to 15 days, by phone interview, P-QOL was applied again. The reliability assessed using Cronbach's alpha and validity was assessed comparing symptom scores between affected and asymptomatic women and comparing symptom scores with objective prolapse stages. **RESULTS:** The results showed that the Brazilian Portuguese version of P-QOL has very good psychometrics properties. The total scores for each P-QOL domain were significantly different between symptomatic and asymptomatic women ( $p < 0.05$ ). All items achieved a Cronbach's alpha greater than 0.70 showing moderate to good inter-observer reliability. The test-retest reliability confirmed a highly significant correlation between the total scores for each domain. **CONCLUSIONS:** P-QOL was cross-culturally adapted and validated for Brazilian women with genital prolapse, showing good reliability and validity. The Brazilian Portuguese version of P-QOL is a good option for Brazilian researchers to evaluate the quality of life in women with pelvic organ prolapse.

PIH33

#### LONGITUDINAL VALIDATION OF THE PREMENSTRUAL SYMPTOMS IMPACT SURVEY (PMSIS)

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**OBJECTIVES:** To validate the Premenstrual Symptom Impact Survey (PMSIS), a six-item self-assessment patient-reported outcomes instrument designed to evaluate impact of premenstrual symptoms on a woman's health-related quality of life. **METHODS:** The PMSIS and SF-12v2 Health Survey were administered in two waves to females (18–45 Yrs) with premenstrual complaints (e.g., irritability, depression, headache and abdominal bloating). Retrospective criteria from the American College of Obstetricians and Gynecologists and the DSM-IV-TR were used to categorize women into either Premenstrual Syndrome (PMS) or Premenstrual Dysphoric Disorder (PMDD) groups respectively. PMSIS responses were analyzed for internal consistency, reliability, convergent and discriminant/known-group validity, at each time point. Responses across times were analyzed for test-retest reliability. **RESULTS:** At Wave1 (N = 1100) and Wave2 (N = 770), 34.2% and 32.6% of participants were identified in the PMS group while 14.9% and 14.2% were identified in the PMDD group, respectively. The mean PMSIS scores at each wave were as follows: PMS groups (54.3, 52.0), Non-PMS groups (32.4, 28.3), PMDD groups (59.0, 55.0) and Non-PMDD groups (36.5, 32.8). The PMSIS showed good internal consistency at each time ( $\alpha \geq 0.88$ ), and adequate test-retest reliability across times (intra-class correlation: 0.74). PMSIS scores correlated significantly ( $p < 0.001$ ) with SF-12 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores. At each time, PMSIS scores discriminated well across presence/absence of PMS and PMDD (all F's > 100, all ps < 0.001), and between low/medium/high PCS and MCS groups (all F's > 24, ps < 0.001), indicating known-group discriminant validity. Receiver operating characteristics analyses showed satisfactory values for areas under the curve ( $\geq 0.78$ ) in detecting women with PMS and/or PMDD at each time. **CONCLUSIONS:** This study demonstrates that the PMSIS has good internal consistency, test-retest reliability, and convergent and discriminant validity, making the PMSIS a viable option for identifying and assessing premenstrual problems.

PIH35

#### DEVELOPMENT OF THE INJECTION PEN ASSESSMENT QUESTIONNAIRE (IPAQ) TO EVALUATE A NEW DEVICE TO ADMINISTER HUMAN GROWTH HORMONE (HGH)

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**OBJECTIVES:** To develop a questionnaire that evaluates parent and child perception of attributes of injection devices (pens) used to administer hGH, particularly ease of use, convenience, and preference. **METHODS:** Parent-child dyads with current experience using the Genotropin Pen® participated in focus groups (N = 8 dyads) and cognitive debriefing interviews (N = 8 dyads) to develop the IPAQ. Four focus groups identified attributes of injection devices relevant to children and/or parents of children being treated with hGH. The IPAQ was cognitively debriefed to assess the instrument's face validity, ease of administration, and item understandability. Focus group and debriefing transcripts were analyzed using ATLAS.ti. A translation assessment was performed and revisions were made to improve the usefulness of the IPAQ. **RESULTS:** Ease of use and convenience regarding preparing the device, setting the dose, injecting the medicine, and maintaining the device were identified as major attributes influencing preference. Findings from the debriefings suggest that ease of use and convenience were considered similar concepts when evaluating device attributes. Equivalent terms describing the concept of convenience are difficult to find in languages other than English, where the term "convenient" is most often translated as "easy." Revisions based on debriefings, translation assessment, and internal discussions resulted in a 29-item questionnaire: 14 items assessing ease of use for each device (5-point response scale ranging from "very easy" to "very difficult"), 14 items comparing ease of use for the two devices ("Genotropin Pen® easier to use," "new injection pen easier to use," and "no difference"), and 1 item assessing preference ("prefer Genotropin Pen®," "prefer new injection pen," and "no preference"). **CONCLUSIONS:** The IPAQ, which assesses convenience/ease of use and preference for injection device

attributes, can be used to evaluate and compare current and newly developed devices from the perspective of the parent-child dyad.

PIH36

#### DEVELOPMENT OF A SPECIFIC QUESTIONNAIRE ASSESSING THE IMPACT ON PARENTS OF AN INFANT'S BRONCHIOLITIS HOSPITALIZATION

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**OBJECTIVES:** To develop a questionnaire assessing the impact on parents of an infant's hospitalization for bronchiolitis. Bronchiolitis is a viral respiratory infection of the bronchioles most commonly caused by the respiratory syncytial virus. It usually affects infants of less than 2 years, particularly following premature delivery, bronchopulmonary dysplasia or congenital heart disease. Although generic questionnaires about the impact of a child's disease on family are available, no specific questionnaire linked to bronchiolitis hospitalization exists. **METHODS:** A multidisciplinary scientific committee was set up and included in the whole process of questionnaire development. A literature review, 3 clinician interviews and 18 exploratory interviews with parents of children hospitalized for bronchiolitis were conducted in parallel. The concepts identified were organized into a model. Items were generated for each concept using parents' words. The Impact of Bronchiolitis Hospitalization Questionnaire (IBHQ®) was developed in French to be completed by the parent who was the most often present at the hospital, within the seven days after bronchiolitis hospitalization, and again three months after hospitalization. The IBHQ® was tested for relevance and comprehension with nine new parents, and revised accordingly. **RESULTS:** Items generated for each concept identified were organized into eight sections: parents' emotional impact, infant's reactions, parents' physical impact, impact on daily organization, siblings' reactions, parents' behaviour with infant and siblings, impact on couple, and financial consequences. Except a few items that were modified or deleted following parents' suggestions, most of the items were well understood, and considered relevant and adequate by parents during comprehension tests. The revised IBHQ® contains 65 items. **CONCLUSIONS:** The IBHQ® is a unique and promising tool that provides a comprehensive evaluation of the impact of a child's bronchiolitis hospitalization on parents. An observational study is currently under way to validate psychometric properties and scoring of the questionnaire.

PIH37

#### URINARY URGENCY INTENSITY RATING IN RELATION TO SYMPTOM FREQUENCY, BOTHER, AND TREATMENT SEEKING: RESULTS FROM EPILEPTICS IN THE US, UK, AND SWEDEN (SE)

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**OBJECTIVES:** Overactive bladder (OAB) is characterized by urinary urgency (UU), with or without urgency incontinence (UUI), typically with frequency and nocturia. As urinary urgency is highly subjective and difficult to assess, we examined the relationship of urgency intensity with symptom frequency, symptom-specific bother, and treatment seeking to better understand urinary urgency. **METHODS:** This cross-sectional, population representative survey of men and women age 40 and older was conducted via the Internet in the US, UK, and SE. Participants were asked to rate how often they experienced urinary symptoms during the past four weeks on a 5-point Likert scale. Urgency intensity was rated using a 10-point numerical rating scale. ANOVA was used to assess urgency intensity by frequency and bother levels. Logistic regression was used to assess treatment seeking and urgency intensity while controlling for demographics and medical comorbidities. **RESULTS:** Overall response rate was 59.2%; of the 30,000 who participated, about half of men (n = 7172) and 65% of women (n = 9887) reported UU at least "rarely" or more often. Mean ages were 58.4 (men) and 57.3 (women), and about 80% were white. Urgency intensity increased in relation to symptom frequency and symptom-specific bother for both men and women. Even after controlling for covariates, intensity of UU was significantly ( $p < 0.0001$ ) associated with treatment seeking. **CONCLUSIONS:** Urgency rating increases with both UU frequency and bother for both men and women. Higher levels of urgency intensity increase the likelihood of seeking treatment.

PIH38

#### STATISTICAL ANALYSES OF FACTORS AFFECTING LENGTH OF STAY AND TOTAL CHARGES FOR PEDIATRIC PATIENTS AFFLICTED WITH PERINATAL INFECTION

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**OBJECTIVES:** Infants are vulnerable to sexually transmitted diseases due to the major long-term health problems infected mothers can transmit to newborns, i.e. perinatal infection. Some experts say there is insufficient or unreliable data regarding the treatment for infants diagnosed with perinatal infection. Therefore, this study aims to explore a national data set of perinatal infection inpatients for trends that may be useful towards improving the efficiency and quality of prenatal treatment and management. **METHODS:** Provided by the National Inpatient Sample, the study's data consisted of 30,000 infants with and without perinatal infection. It was released in 2007 and reflects a 2005 sample collected from more than 100 hospitals and