painless or bleeding completed a pain history and five PRO instruments (EQ-5D-5L, Brief Pain Inventory, SF-36v2, International Physical Activity Questionnaire [IPAQ], and Hemophilia Activities List [HAL]) during routine clinic visits. To assess concordance of individual questionnaire items and correlation of domain/global scores using intraclass correlation coefficient (ICC), initial patients (target 125–150) were approached to fill out the PROs at their 3–4 hour visit in a similar non-blinding study. RESULTS: From October 2013–October 2014, 381 patients enrolled, 164 (88% of initial 187) completed the retest. Median age of retest cohort was 33.9 years (Q1, Q3: 26.8, 46.0). Median time for completion of the initial survey with five PROs was 36.0 minutes and for the retest was 21.0 minutes. Median/mean time between tests was 1.5/1.6 hours. The majority of subjects had hemophilia A (74.4%) and were white-non-Hispanic (72.6%); 48.7% were married, 62.6% had some college or graduate-level education, 80.7% were employed and 8% were overweight or obese. HCV was more common than HIV (49.4% vs 6.15%); 61% self-reported arthritis/bone/joint problems. Median/mean test-retest concordance was: EQ-5D-5L, 76/77% (6.4%, IPAQ, 100%/100% and HAL, 77%/74.5%. ICC for test-retest reliability were: EQ-5D-5L Health Index, 0.890; BPI–severity, 0.910; HAL total score, 0.970. CONCLUSIONS: All five PROs had excellent test-retest reliability. Further research or clinical care should be driven by instrument characteristics other than reliability.

PSY59 MEASUREMENT PROPERTIES OF WEB BASED LUPUSPRO, A DISEASE TARGETED OTCOME TOOL, AMONG ITALIAN PATIENTS WITH LUPUS

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OBJECTIVES: Patient reported outcomes provide important information on the comprehensive impact of Systemic Lupus Erythematosus (SLE) on daily lives of SLE patients. It also fosters patient physician communication, patient engagement and satisfaction with medical care. LupusPRO is a disease targeted patient reported outcomes measurement software that has been validated in several countries. Herein we report the measurement properties of the Italian translation of the LupusPRO that was administered using a web based format. METHODS: LupusPRO was translated using forwards and back translation methodology. It was pre-tested in 5 native Italian speaking subjects. As part of another study, 344 patients with SLE diagnoses were approached through the Patients organization network, asked to provide their demographics, medical history and responses to the online LupusPRO. We evaluated internal consistency reliability (ICR) of the LupusPRO domain items, floor-ceiling effects, known groups validity (KGV) and confirmatory factor analysis (CFA). ICR was tested using cronbach’s α. CFA was tested against current use of corticosteroids, with the hypothesis that SLE patients who were taking corticosteroids would have worse health status than without. Goodness of fit was evaluated in the CFA. RESULTS: Mean (SD) age and duration of disease were 39.7 (11.1) and 11.7 (9.3) years. Ninety percent were women/men. Sixty-four percent were generationalists and sixty-six percent were on hydroxychloroquine at the time of the study. ICR and Floor-ceiling effects were tested against current use of corticosteroids, with the hypothesis that SLE patients currently on corticosteroids would have worse health status than without. Goodness of fit was evaluated in the CFA. CONCLUSIONS: This study found an increase in the percentage of patients who were taking corticosteroids when compared to non-corticosteroid use in the same time frame. METHODS: The study used regulatory and prevalence data derived from the US FDA, the European Medicines Agency (EMA), and other publicly available sources. Descriptive statistics and the chi-square test were performed in the study. RESULTS: A total of 103 BLAs and 799 NMEs were approved by the FDA from 1983 to 2014. The percentage of new drugs with orphan designation at approval was 43.7% for BLAs and 20.7% for NMEs (p < 0.001). Orphan drugs represented 13.9% of the new drugs approved from 1983 to 1989, 21.2% in the 1990s, 25.5% in the 2000s, and 33.8% from 2010 to 2014. Information about the prevalence of disease was available for 73.7% of the orphan drugs. Indications approved for use in diseases with a prevalence of less than 1000 patients (i.e. ultrarare drugs) represented 8.4% of all new orphan drugs. Ultra-rare drugs represented 12.5%, 3.6%, 7.7%, and 15.8% of all orphan indications approved in 1983–1989, 1990s, 2000s, and 2010–2014, respectively. CONCLUSIONS: This study found an increase in the percentage of drugs approved by the FDA for orphan diseases and conditions. Ultra orphan drugs revealed a greater increase over time than other orphan drugs as a proportion of all orphan indications. The limited innovation in diseases with large prevalence, the incentives provided by the Orphan Drug Act of 1982 and favorable reimbursement for orphan drugs in the US health care system may explain the increase in the approval of orphan drugs in the US.

SYSTEMIC DISORDERS/CONDITIONS – Health Care Use & Policy Studies

PSY61 CHARACTERISTICS OF PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) CURRENTLY EXPERIENCING FLARES IN CLINICAL PRACTICE SETTINGS IN EUROPE (EU)

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OBJECTIVES: To assess the characteristics of SLE patients currently experiencing flares in Europe. METHODS: A multi-center retrospective medical chart review of adult (16–89 years) SLE patients was conducted in 1Q2014 among rheumatologists/internal medicine physicians in UK/France/Germany/Italy/Spain (SEU). Physicians were recruited from a geographically representative sample in each country. APPROX. 5 consecutive eligible persistent active or relapse remitting SLE patients currently managed as part of usual care were identified within the study observation period. A 24-item, self-administered disease characteristics, lab values and treatment patterns. Patient disease status and humanistic burden was assessed by physician by clinical judgment & patient interaction. RESULTS: Significant disease activity and humanistic burden was assessed by physician by clinical judgment & patient interaction. Patients experiencing a flare were identified for analysis. RESULTS: Significant disease activity and humanistic burden was assessed by physician by clinical judgment & patient interaction. Patients experiencing a flare were identified for analysis.

PSY62 TRENDS IN APPROVALS OF NEW DRUGS WITH ORPHAN DESIGNATION IN THE US (1983-2014)

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OBJECTIVES: Orphan drugs are indicated for rare diseases and conditions. We assessed trends in approvals of new drugs with orphan designations in the US over the past three decades. METHODS: We assessed trends of approvals of new drugs with orphan designation at approval in different time periods (1983-1989, 1990s, 2000s, 2010-2014). RESULTS: The percentage of new drugs with orphan designation at approval was 43.7% for BLAs and 20.7% for NMEs (p < 0.001). Orphan drugs represented 13.9% of the new drugs approved from 1983 to 1989, 21.2% in the 1990s, 25.5% in the 2000s, and 33.8% from 2010 to 2014. Information about the prevalence of disease was available for 73.7% of the orphan drugs. Indications approved for use in diseases with a prevalence of less than 1000 patients (i.e. ultrarare drugs) represented 8.4% of all new orphan drugs. Ultra-rare drugs represented 12.5%, 3.6%, 7.7%, and 15.8% of all orphan indications approved in 1983–1989, 1990s, 2000s, and 2010–2014, respectively. CONCLUSIONS: This study found an increase in the percentage of drugs approved by the FDA for orphan diseases and conditions. Ultra orphan drugs revealed a greater increase over time than other orphan drugs as a proportion of all orphan indications. The limited innovation in diseases with large prevalence, the incentives provided by the Orphan Drug Act of 1982 and favorable reimbursement for orphan drugs in the US health care system may explain the increase in the approval of orphan drugs in the US.

PSY63 DETERMINING PATTERNS OF OPIOID MISUSE AND MISPRESCRIBING IN SOUTH CAROLINA

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OBJECTIVES: Although opioids play a central role in the treatment, and palliation of many medical conditions, there is a large and growing problem of abuse nationally and in South Carolina particularly. According to the 2009 National Survey on Drug Use and Health, more than 5 million Americans abused prescription opioid painkillers in January 2011. Reports show an increase in cases of doctor shopping, prescription drug diversion, forgery, prescribing and dispensing, and other diversion activities. We determine patterns of opioid prescribing in South Carolina through an epidemiologic analysis and geo-spatial mapping of South Carolina prescription data for 2010-2011. Data are drawn from the Council on Medical Services, Reporting and Identification Prescription Tracking System (SCRIPTS), we conducted a state-wide epidemiologic analysis of patient and prescriber opioid prescribing patterns including distributions of number of prescriptions, number of prescribers and of pharmacies used by each patient. Additionally, we conducted county- and zip-code level analyses of opioid prescribing patterns. RESULTS: Prescriber deciles were created representing 10% groupings of prescribers based on controlled substances (CS) prescribing. The top 10% prescribers (N = 2,158,574) of the total CS II – IV prescriptions in 2010, and 58% of total opioid prescriptions. The top pharmacy decile dispensed about 44% of total prescriptions and about 37% of opioid prescriptions. Five Zip Code had the highest percentage of opioid prescriptions out of total prescriptions (Charleston, Richland, Greenville, Barnwell and Aiken). In 2010 counties with the highest percent of prescriptions (>61%) were Greenville, Richland, Barnwell and Charleston, whereas in 2011 the counties with the highest percent of prescriptions were Greenville, Chester, Richmond and Charleston. CONCLUSIONS: Our findings indicate a relatively small percentage of providers, concentrated in a few counties, account for most opioid prescriptions. This group represents a potential target for physician education and engagement in hard to treat pain management and appropriate use of opioids.

PSY65
TREATMENT PATTERNS AMONG CHRONIC USERS OF IMMEDIATE-RELEASE OXYCODONE INITIATING TREATMENT WITH EXTENDED-RELEASE OPIOIDS
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OBJECTIVES: Many chronic users of immediate-release opioids (IROs) initiating treatment with extended-release opioids (EROs) are shifted towards generic options, even if switching molecules is required. Switching may introduce uncertainty for patients regarding dosing, titration and efficacy. This study assessed treatment patterns among chronic users of immediate-release with EROs who were shifted towards generic options, due to the cross-sectional design, there might be some higher spending for opioid users who are more opioid-tolerant and have a higher number of opioid prescriptions. However, the effectiveness of opioids for CNCP is still controversy and associated medical expenditure is vague. We investigated the impact of opioid treatment on the total medical expenditures for U.S. citizens with CNCP. The average first year dose was higher than years 2 and 3, consistent with data for 2010-2011. Prescriber deciles were created representing 10% groupings of prescribers based on controlled substances (CS) prescribing. The top 10% prescribers of the total CS II – IV prescriptions in 2010, and 58% of total opioid prescriptions. The top pharmacy decile dispensed about 44% of total prescriptions and about 37% of opioid prescriptions. Five Zip Code had the highest percentage of opioid prescriptions out of total prescriptions (Charleston, Richland, Greenville, Barnwell and Aiken). In 2010 counties with the highest percent of prescriptions (>61%) were Greenville, Richland, Barnwell and Charleston, whereas in 2011 the counties with the highest percent of prescriptions were Greenville, Chester, Richmond and Charleston. CONCLUSIONS: Our findings indicate a relatively small percentage of providers, concentrated in a few counties, account for most opioid prescriptions. This group represents a potential target for physician education and engagement in hard to treat pain management and appropriate use of opioids.

PSY66
HYDROCODONE: A REVIEW OF THE LITERATURE
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OBJECTIVES: An estimated 100 million adults suffer from chronic pain in the US. The total cost of pain ranges from $560 to $635 billion in 2010, exceeding that of heart disease (213bn), cancer (243bn), and diabetes ($188 billion). The 2011 IOM report on pain states that effective pain management is "a moral imperative" for health care providers. Many pharmaceutical options are available to prescribers, however, the appropriate prescription of opioids poses a unique challenge. We assess the impact of rescheduling. Hydrocodone combination products are among the most commonly prescribed opioids in the US. The objective of this study was to perform a comprehensive literature review of the use and impact of hydrocodone in the US. METHODS: A comprehensive literature review was conducted regarding the use and impact of hydrocodone in the US. RESULTS: The US consumed 80% of global supply of opioids and 99% of the global hydrocodone supply. From 1997 to 2007, hydrocodone use increased 280%. Due to their potential for harm and abuse, hydrocodone combination products were recently rescheduled from Schedule III to Schedule II by the US Food and Drug Administration (FDA). Single entity hydrocodone extended release was recently released by the FDA, it has been met with much controversy due to its potential for abuse. CONCLUSIONS: Hydrocodone use is highly prevalent in the US. Long-term use of hydrocodone and single entity hydrocodone use need to be actively monitored for appropriateness. Future studies should assess the impact of rescheduling.

PSY67
ESTIMATION OF MEDICAL EXPENDITURE ASSOCIATED WITH OPIOIDS USAGE IN CHRONIC NON-CANCER PAIN: A CROSS-SECTIONAL STUDY BASED ON MEDICAL EXPENDITURE SURVEY AND PANEL DATA
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OBJECTIVES: Chronic or long-term pain disturbs numerous lives, which is one of the most burdensome problems for doctor visits and reduces people’s quality of life. Opioid treatment for long-term non-cancer pain (CNCP) is long-term opioid therapy. Very high and growing concerns over the increasing cost to the health care systems that are funding these treatments. Administrative databases can generate important information about the way these drugs are prescribed in a “real world” setting. The objective of the study was to determine the initial dosing and identify dose escalation patterns for biologicals in the treatment of psoriasis in Canada. METHODS: A sample of data from patients covered by the public (Quebec and Ontario) and private (McKesson) claims databases was used to identify patients with psoriasis in Canada. Dosing analysis was performed for four biologics approved for psoriasis in Canada: adalimumab, etanercept, infliximab and ustekinumab. Dose escalation was defined as a 20% dose increase above the previous dose, excluding induction. RESULTS: A total of 4,510 patients were identified and met inclusion criteria. The average first year dose was higher than years 2 and 3, consistent with

PSY68
DOSE PATTERN ANALYSIS FOR BIOLOGICS IN THE TREATMENT OF PSORIASIS IN CANADA: INDICATION-SPECIFIC INFORMATION RETRIEVED FROM ADMINISTRATIVE CLAIMS DATABASES
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OBJECTIVES: High cost biologic treatments for diseases such as plaque psoriasis, raise growing concerns over the increasing cost to the health care systems that are funding these treatments. Administrative databases can generate important information about the way these drugs are prescribed in a “real world” setting. The objective of the study was to determine the initial dosing and identify dose escalation patterns for biologicals in the treatment of psoriasis in Canada. METHODS: A sample of data from patients covered by the public (Quebec and Ontario) and private (McKesson) claims databases was used to identify patients with psoriasis in Canada. An estimated 100 million adults suffer from chronic pain in the US. The total cost of pain ranges from $560 to $635 billion in 2010, exceeding that of heart disease (213bn), cancer (243bn), and diabetes ($188 billion). The 2011 IOM report on pain states that effective pain management is “a moral imperative” for health care providers. Many pharmaceutical options are available to prescribers, however, the appropriate prescription of opioids poses a unique challenge. We assess the impact of rescheduling. Hydrocodone combination products are among the most commonly prescribed opioids in the US. The objective of this study was to perform a comprehensive literature review of the use and impact of hydrocodone in the US. METHODS: A comprehensive literature review was conducted regarding the use and impact of hydrocodone in the US. RESULTS: The US consumed 80% of global supply of opioids and 99% of the total medical expenditures for U.S. citizens with CNCP. The average first year dose was higher than years 2 and 3, consistent with data for 2010-2011. Prescriber deciles were created representing 10% groupings of prescribers based on controlled substances (CS) prescribing. The top 10% prescribers of the total CS II – IV prescriptions in 2010, and 58% of total opioid prescriptions. The top pharmacy decile dispensed about 44% of total prescriptions and about 37% of opioid prescriptions. Five Zip Code had the highest percentage of opioid prescriptions out of total prescriptions (Charleston, Richland, Greenville, Barnwell and Aiken). In 2010 counties with the highest percent of prescriptions (>61%) were Greenville, Richland, Barnwell and Charleston, whereas in 2011 the counties with the highest percent of prescriptions were Greenville, Chester, Richmond and Charleston. CONCLUSIONS: Our findings indicate a relatively small percentage of providers, concentrated in a few counties, account for most opioid prescriptions. This group represents a potential target for physician education and engagement in hard to treat pain management and appropriate use of opioids.