at the National Institute of Health, the FDA, and the Physician’s Desk Reference versions 1980-2012. Data were collected by 2 researchers and the MOAs classified as: known, unknown, or hypothesized. Another investigator resolved observed differences. Chi-square was used to assess differences in proportions. RESULTS: A total of 816 new drugs (79 BLA and 737 NMs) were approved by the FDA during the study period. The MOA was known for 95.7% of biologics and 64.4% of NMs. Of those, the approved was the Anti-Bacterial Therapeutic Class with the lowest proportion of known MOA (11.8% known MOA of all approved products). Blood and blood forming organs was the class with the highest proportion of known MOAs (92.7%; n=89). The proportion of products with known MOA increased overtime from 56.4% (n=202 approvals) in the 1980s to 71.7% (n=265) in the 2000s. No significant differences were observed in terms of known MOA between orphan/non-orphan drugs, marketed/respondent to data products, and subspecialty products. CONCLUSIONS: An important number of drugs did not have a known MOA. In addition, there was great variability in the wording of MOA, especially hypothetical ones. The lack of information on the mechanism of action make it difficult to consider standardizing the label with regard to MOA and encourage manufacturers to continue collecting evidence to verify a drug’s MOA after market approval.

PHP35 IMPROVING MEDICAL DEVICE REGULATION: EUROPE AND THE PERSPECTIVE IN THE UNITED STATES

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OBJECTIVES: Recent events in Europe and the US have brought into question the effectiveness of existing regulatory frameworks to ensure the performance, safety, and quality of new medical devices. Given that policymakers are currently exploring ways to reform medical device regulation to address these issues, this study aimed to examine current medical device regulation policies in both jurisdictions, understand outstanding regulatory challenges, and identify ways to improve regulatory practices. METHODS: The study examined the respective regulatory systems based on a critical review of available, relevant scientific and grey literature. In addition, the websites of national medical device regulatory authorities (e.g., FDA) were reviewed to identify key legislative and policy documents. RESULTS: The review highlighted a number of challenges for medical device regulation in both jurisdictions: 1) finding the right balance between centralized and decentralized regulation; 2) ensuring sufficient evidence for self-safety prior to market release; 3) providing safety, especially for high-risk devices; 3) implementing mechanisms and incentives for monitoring and evaluating post-market device safety and effectiveness; and, 4) providing adequate and transparent information exchange on the benefits and risks of new technologies. To address these issues, European and US policy makers and other stakeholders have implemented various initiatives or are considering their introduction. Specific policies include establishing a more centralized system of regulation in Europe, requiring uniform oversight and evidence requirements across and within European countries; and, use of national and European databases to track and monitor medical devices as well as regulators. CONCLUSIONS: Further research is needed to evaluate the effectiveness of regulatory policies. ADDITIONAL INFORMATION: This research was supported by the US National Science Foundation.

PHP36 PRIORITIZATION OF IN VITRO DIAGNOSTIC TESTS FOR UPDATING HEALTH COVERAGE IN COLOMBIA

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OBJECTIVES: In-vitro diagnostics (IVD) are essential for diagnosis, screening and monitoring diseases. IVD’s are emerging everyday but usually at a higher cost. Consequently, a formal health technology assessment (HTA) process to should determine its value. The prioritization to initiate this process is key given the limited resources for HTA in developing countries. Our aim was to identify the prioritization and ranking of IVD’s for assessment for inclusion or ratification in the Colombian health care system. METHODS: Using an adapted prioritization tool from the MoH which included 13 standardized criteria grouped into four domains: population needs, benefits and risks of testing, policy priorities and system costs; we performed two rounds of surveys using online Delphi panels with 64 clinician of the 12 medical specialties pertinent to the 87 IVD’s initially selected was independently submitted by the National manufacturers association (ANDI). Prioritization and ranking were determined by preference weights and Pareto diagram. RESULTS: From the 87 IVD’s tests evaluated, 47 were highly dependent and included in the ranking due to low favorability of lack of information. Highly specialized IVD tests with limited use in subspecialties or for rare conditions were often excluded. Tests evaluated with the highest favorability and ranked in the first 20 were driven by high performance, evidence, reputation, and the population which often coincides with policy priorities of the MOH. Costs and benefit-risk ratios seem less relevant. CONCLUSIONS: The use of this methodological, the first time in Latin American IVD’s, that integrates expert opinion and standardized criteria for prioritizing and ranking IVD’s to be considered for HTA is feasible and useful. Stakeholder involvement in prioritization and ranking technologies for HTA is particularly important in countries with limited resources to perform HTA for health care budget allocations.

PHP37 ARE THE RIGHT DIFFERENT WITH REGARD TO PRESCRIPTION DRUG UTILIZATION?

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METHODS: This research investigates the relationship between income, age, and the utilization of prescription drugs to determine variation by income levels and age group. METHODS: Data derived from a random sample of approximately one million commercially insured members whose pharmacy benefits are managed by a large pharmacy benefit manager were used. The sample included all adjudicated claims and basic demographic information for the period 2010-2012 combined with median income data at the Zip Code level based on Zip Code Tabulation Area data from the US Census Bureau. (Five Year Summary of the American Community Survey). The outcome measure was annual average days’ supply of prescription medications. Least Squares Means Estimates of annual days supply by income decile were adjusted by member age group. Median income ranged from about $32,000 to $104,000 and the age groups were defined as 0-19, 20-34, 35-49, 50-64 and 65+ (Non-Part D active or retired). RESULTS: The overall growth in average days’ supply of prescription medications varied considerably by income and age. Utilization growth was 1% or less for the top two income deciles and 2.3% and 6.6% for the bottom two deciles respectively in 2011 and 2012. However, utilization for patients under age 35 increased as income increased (34.9% increase) while the +65 group decreased as income increased (7.3% days in 2012). CONCLUSIONS: These results reinforce that for middle aged and older patients, lower income may be associated with poorer health habits and clinical outcomes. This is consistent with other published research indicating that health status is positively correlated with income.

PHP38 A COMPARISON OF PATIENTS WITH AND WITHOUT 90-DAY FILLS AT A RETAIL PHARMACY: OBSERVING MEDICATION CHANGES FROM SINGLE SOURCE BRAND TO GENERIC

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OBJECTIVES: This study compares the fill patterns among patients with and without 90-day fills at a single retail pharmacy. METHODS: The objective of this study is to determine whether 90-day supplies of Proton Pump Inhibitors (PPI) and Statins are associated with higher rates of patients changing from single source brand to generic alternatives, and to determine the cost implications to patients and their benefit plans. METHODS: This retrospective cohort study includes a random sample of patients with 1 or more fills for SSB PPIs (N=96,927) or Statins (N=26,057) at Walgreens pharmacy in the first quarter of 2011. Study patients are assigned to the 90-day group, if they had a 90-day fill of PPI or Statin within 270 days of their index fill of SSB PPI or Statin, otherwise they are assigned to the 30-day group. The primary outcome measure is change from single source brand (SSB) within 3 fills of the index date. RESULTS: The 90-day group has a significantly higher CR than the 30-day group: 9.3% versus 5.8% for PPI (p<0.0001) and 10.3% versus 7.5% for Statin (p<0.0001). Co-pay savings per drug change were considerably higher in the 90-day group (A13.6% and 19.9% for PPI and Statin). Savings per drug reduction were also higher for the 90-day group ($259 vs. $121 for PPI and $164 vs. $83 for Statin). CONCLUSIONS: Consistent with the 30-day group, patients in the 90-day group were observed to have a significantly higher rate of change from SSB drugs for generic drugs in both the PPI and Statin therapeutic classes. These physician approved medication changes translate into significant savings for both patients and their benefit plans.

PHP40 PREDICTORS OF DRUG THERAPY PROBLEMS AMONG HOME HEALTH PATIENTS RECEIVING PHARMACIST-PROVIDED TELEPHONIC MEDICATION THERAPY MANAGEMENT

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OBJECTIVES: To examine determinants of drug therapy problems (DTPs) among home health patients receiving telephonic medication therapy management (MTM) services. METHODS: Retrospective cohort data were used from patients (n=418) who participated in a randomized, controlled trial of telephonic MTM in a home health population. Data were extracted from two databases: 1) home health patients whose pharmacy benefit was in-home nursing assessments (OASIS-C), and 2) MTM records from pharmacists’ telephonic assessments. The primary dependent variable was the number of DTPs identified by the pharmacist during the initial MTM encounter. The independent variables included three subgroups of DTPs (medication discontinuation, hospitalization risk score, number of medications, Beers medications, narrow therapeutic index medications, self-reported adherence, and history of impaired medication management). RESULTS: Hospitalization risk score, number of medications, Beers medications, narrow therapeutic index medications, self-reported adherence, and history of impaired medication management were significantly associated with DTPs. These factors explained 26% of the variance in DTPs. CONCLUSIONS: Future research should consider these factors in their efforts to reduce DTPs among home health patients.