PHP43

PREVALENCE OF PRESCRIPTION MEDICATION USE NOT CAPTURED BY PRESCRIPTION CLAIMS DATABASES

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OBJECTIVES: Prescription claims databases are commonly used for identifying patients for disease management programs, studying health outcomes and reporting on quality measures. A shortcoming of claims databases for these purposes is that they include only prescriptions that are adjudicated through insurance plans. Growth in the use of cash discount generic programs and the frequent use of drug samples suggests that an increasing number of prescriptions dispensed to insured consumers may not be captured on claims databases. We examined the extent to which prescription claims databases do not provide complete records of insured patients' prescription drug use. **METHODS:** We used the 2009 Medical Expenditure Panel Survey (MEPS) dataset. We included participants who purchased at least one prescription medication and who had prescription drug insurance for all of 2009. We quantified the extent to which insured patients used drug samples, drugs paid for by cash only, and/or discount generics. We measured the numbers of prescriptions in each of these categories and the numbers of consumers who had at least one prescription in each category. We reported descriptive statistics. **RESULTS:** A total of 75.1% of the U.S. non-institutionalized civilian population was insured for prescription drugs. Of the total number of prescriptions dispensed to insured consumers, at least 0.8% were drug samples and 23.3 % were paid for by cash, of which 11.3% were potentially discount generics. Additionally, 11.6 % of insured consumers received at least one sample medication, 68.0% paid for at least one of their prescribed medications by cash, of which 42.5% used at least one potential discount generic product. **CONCLUSIONS:** Our results indicate that drug samples do not contribute substantially to the problem of missing prescription data on claims databases. On the other hand, substantial number of prescriptions, paid for by cash and discount generics, may be missing from these databases.

PHP44

IMPACT OF DRUG REIMBURSEMENT MODALITIES ON TREATMENT ADHERENCE IN PATIENTS COVERED BY PRIVATE DRUG INSURANCE

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OBJECTIVES: To compare adherence to prescribed medications between patients with differed and those with immediate reimbursement at the point of service among Quebecers (Canada) with private drug insurance. **METHODS:** A retrospective cohort was constructed by selecting patients aged 18-64 years with private drug insurance from the reMed database between March 2008 and December 2012. An algorithm was developed to assess the patient's reimbursement modality, i.e. the drug cost covered by the insurance company is reimbursed immediately at the point of service (immediate reimbursement) or at a later time (differed reimbursement). Adherence was measured with the proportion of days covered (PDC) over one year for new users of the five most dispensed classes of medications, i.e. statins, proton pump inhibitors, thyroid hormones, antidepressants, and antihypertensive medications. Linear regression models were used to estimate the adjusted mean difference of the PDC between the two groups for each drug class. **RESULTS:** The cohort included 6,494 patients with immediate and 1,950 patients with differed drug reimbursement. More than 40% of patients were 35-49 years, 26% were men and 85% were past or non-smokers. The mean PDC was 79.9 % for patients with immediate reimbursement and 89.3 % for patients with differed reimbursement among new users of statins. Corresponding figures were 48.3% and 45.1% for new users of proton pump inhibitors, 84.7% and 84.8% for new users of thyroid hormones, 67.1% and 66.8% for new users of antidepressants, and 68.4% and 73.5% for new users of antihypertensive medications. The results of the linear regression analyses showed no significant differences between patients with immediate and differed drug reimbursement. **CONCLUSIONS:** Patient's adherence was low for several drug classes but appeared to be unaffected by differed reimbursement. The short period of time between the purchase of the medication and the reimbursement by the insurer might explain the results.

HEALTH CARE USE & POLICY STUDIES – Equity & Access

PHP45

DIFFERENCE BETWEEN UNITED STATES AND EU AUTHORISATION TIMELINES AND TIME TO REIMBURSEMENT IN THE EU5

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OBJECTIVES: The purpose of this study was to estimate the time difference between the FDA and EMA approvals, as well as time to reimbursement in the UK, GER, FRA, ESP and ITA after EMA approval. **METHODS:** 32 high-cost drugs that were approved by both the FDA and EMA in 2011-2013 were assessed. Two-thirds of the sample were oncology drugs; the remaining one third included drugs treating other specialty diseases. Out of 32 drugs, 17 have obtained reimbursement from all EU5 countries. Time of reimbursement was defined as the date of publication of SMC guidelines in SCT, NICE Final Appraisal Determination in ENG, CT decision in FRA, G-BA decision in GER, AIFA decision in ITA and AEMPS decision in ESP. **RESULTS:** The average time difference between the FDA and EMA approvals (USA-EU approval interval) was 5.9 months (standard deviation (SD) 5.2 months), similar to the median USA-EU approval interval (6 months). The average time to reimbursement after EMA approval varies from 211 days in SCT (SD 75.9 days) to 336 days in ESP (SD 203 days). On average, the USA-EU approval interval for oncology drugs was almost twice as long as for non-oncology drugs (7.0 vs. 3.8 months), but there was minimal difference in time to reimbursement for oncology versus non-oncology drugs in the EU5, except in ESP, where the reimbursement decision for non-oncology drugs was 112 days faster than for oncology drugs. **CONCLUSIONS:** There is still a long gap (5.9 months) between an innovative product's FDA and EMA approval. Average time to reimbursement in the EU5 after the EMA approval ranges from 7.0-11.2 months. Pharmaceutical companies need to plan ahead and submit the application dossier as early as possible to achieve faster access, especially for oncology products. Early access programmes, such as ATU in FRA and Cnn in ITA, may also be considered in certain countries.

PHP46

SOCIOECONOMIC AND HEALTH DETERMINANTS ASSOCIATED WITH THE USE OF THE AMBULATORY AND HOSPITAL CARE SERVICES AMONG THE MEXICAN POPULATION

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OBJECTIVES: Health care utilization is likely to be conditioned to socioeconomic factors. The aim of this study is to identify the impact of these determinants, as well as the health perception variables in the use of the health services in the Mexican population. **METHODS:** Data from the National Health Survey 2012 was used to identify social, economic and health perception variables among users of the ambulatory and hospital care services. Statistical analysis was performed to test significant differences among users in relation to gender, equivalent household income and age data. A Probit model was used to identify and measure the impact of these variables on the utilization of the ambulatory care services among patients and a Poisson model for modelling the number of hospitalizations. **RESULTS:** 8.48% of the population used ambulatory services during the last two weeks and 3.89% required hospitalization at least once during the last year. Significant statistical differences were observed between gender, income and age with the ambulatory and hospital care use. The results from the Probit model showed that men are less likely to use ambulatory services compared to women, as well as individuals at younger ages (0-9 years) (Z=7.95). Additionally, at higher income deciles, a positive significant impact was found for using this service. The Poisson model revealed that education, employment and medical insurance are statistically significant variables with positive impact on the times people are hospitalized. Finally, other variables with a positive impact on both types of care are morbidity and the illness perception mainly when this is severe. **CONCLUSIONS:** In addition to the influence of socioeconomic and demographic factors, health perceptions among patients are significant determinants that explain the decision and frequency of the health care utilization in the Mexican population.

PHP47

RAJASTHAN'S UNIVERSAL HEALTH CARE PLAN WITH FREE DISTRIBUTION OF QUALITY MEDICINES THROUGH COST MINIMIZATION

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OBJECTIVES: Public expenditure on health on India is around 1% of GDP and 79% expenditure in health of people is through out-of-pocket. Almost 30 % of the households slide into poverty due to high treatment costs and medicines. Though, India is considered as pharmacy for developing countries, yet due to poor regulatory control there is huge price variation in off-patent branded generics, even 50 times or more and leaving affordability at the mercy of prescribers/dispensers. **METHODS:** The Government of Rajasthan (a federal State in India with population about 70 million) has launched a scheme called Chief Minister's Free Drug Distribution Scheme (CMFDDS) for providing free essential medicines to all irrespective of their economic status through establishing an autonomous Rajasthan Medical Services Corporation (RMSC). By well-defined transparent prequalification measures for products and suppliers, RMSC procures quality medicines through cost-minimization. Educational, managerial and regulatory strategies have been used to promote compliance by stakeholders **RESULTS:** Quality essential medicines are procured at unbelievable low cost compared to market retail prices, e.g. procurement cost / market retail prices for strip of 10 tablets of DICLOFENAC 50 mg, ATORVASTATIN 10 mg, GLIMEPIRIDE 2 mg, and CLOPIDOGREL 75 mg are INR 1.24/31.73, 2.98/103.74, 1.95/125.00 and 8.54/147.44 respectively (1 USD=INR 63) resulting an increase in access and equity with monthly patient inflow increased from 44,000,00 to 66,000,000 and decrease/elimination in out of pocket expenditure, as amount spent on medicines in 2 years is around INR 5,070,000,000 whereas market price of these medicines would be. INR 30,000,000,000. **CONCLUSIONS:** Essential medicines are not costly but are being made expensive. By utilizing the pricing information of quality medicines along with transparent pooled procurement and proper distribution system can make free access to medicines, especially underserved population with a strong political commitment coupled with the proper strategies in low resource settings.

PHP48

REAL-WORLD CLINICAL EVIDENCE DEVELOPMENT: AN ANALYSIS OF RELEVANT INTERNATIONAL MODELS FOR THE POTENTIAL IMPLEMENTATION OF SUCH A PROGRAM IN QUEBEC

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OBJECTIVES: There is a growing need for the development of real-world clinical evidences, particularly in the field of health technology assessments. The objective of this analysis was to identify and describe the key elements for the implementation of a program aiming to develop real-world clinical evidences in Quebec. **METHODS:** A literature review was conducted to analyze the position, progress and development of strategies fostering risk management and development of real-world clinical evidences in different provinces and countries. A literature search was performed using electronic databases including Pubmed, Medline and Embase. Additional guidelines and government policies were retrieved using Google and Google Scholar. The following keywords, were used for search, alone or in combination: risk-sharing and product listing agreements, coverage with evidence devel-

opment, patient access scheme, drug reimbursement, risk management, clinical evidence development, real-world, real-life setting. **RESULTS:** A total of 15 programs of risk management and development of real-world clinical evidence were analyzed. Of these programs, 6 were selected as relevant models for the province of Quebec. For 4 of these programs, ongoing in Canada, Australia and Europe, it was the manufacturer's responsibility to develop and perform data collection. Otherwise, it was the responsibility of government agencies. For 100% of analyzed programs, a substantial financial participation from the manufacturer was required. Half of programs reported a direct participation of academic research institutions in the collection and processing of data while the other half did not mention their participation explicitly. Fifty percent of these programs were related to a reimbursement decision. **CONCLUSIONS:** This study indicated that the success of programs aiming to develop real-world clinical evidences involve active participation of academic research organizations as well as support from the manufacturers. These key elements should be considered in developing such a program in Quebec.

HEALTH CARE USE & POLICY STUDIES – Formulary Development

PHP49
USE OF ECONOMIC EVIDENCE TO INFORM DRUG REIMBURSEMENT DECISION MAKING: THE CASE FOR ONTARIO

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OBJECTIVES: The Ontario Drug Benefit (ODB) Formulary is the publicly funded provincial drug plan in Ontario. Drugs are included subsequent to a review of submitted clinical efficacy and pharmacoeconomic evidence by the Committee to Evaluate Drugs (CED). The objective of this analysis was to examine the degree to which economic evidence was utilized to inform drug reimbursement decision making in Ontario. **METHODS:** All publicly available CED "Recommendation and Rationale" documents were reviewed to classify type of economic evidence, CED recommendations and rationales. Descriptiveand logistic regression analyses were conducted to examine the extent that economic evaluation impacts CED recommendations among other potential predictor factors. **RESULTS:** A total of 123 separate recommendations were retrieved (July 2007 to November 2012). Forty –seven percent received a fund recommendation while 53% received a do not fund recommendation. Almost all recommendations included some discussion of economic evidence; however complexity was limited to a discussion of price of therapy only for the majority (70%). Regression analysis found that documents including a discussion of economic evidence beyond price and statement of a price of therapy less than or similar to alternatives were more likely to result in positive recommendations ($p < 0.05$). **CONCLUSIONS:** Although economic evidence was routinely reviewed, discussion was usually limited to price of therapy. However, when pharmacoeconomic evidence beyond price alone was discussed, a recommendation to fund by the CED was more likely.

PHP50
ACADEMY OF MANAGED CARE PHARMACY (AMCP) DOSSIERS: USE IN HEALTH CARE DECISION MAKING

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OBJECTIVES: The Academy of Managed Care Pharmacy (AMCP) dossier format was introduced in 2000 to guide manufacturers in presenting evidence for new pharmaceuticals, biologics, and vaccines to gain reimbursement and/or formulary placement in the United States (US) health care system. Limited information has been published on the role of these dossiers in health care decision making; therefore, this study aimed to characterize decision makers' use of AMCP dossiers in access and formulary placement for new health technologies. **METHODS:** We reviewed the published literature and third-party websites to identify how health care decision makers employ AMCP dossiers. We then developed a discussion guide for use in one-on-one interviews with medical and pharmacy directors involved in formulary decision making at a range of US health plans (national, regional, integrated). These interviews focused on how AMCP dossiers inform decision making and the usefulness of each dossier section. **RESULTS:** Decision makers' reports of the utility of AMCP dossiers varied greatly. Some decision makers use AMCP dossiers directly; others conduct research independent of the dossier. Pharmacy directors are more likely to use AMCP dossiers than medical directors, who typically are provided with briefs based partly on AMCP dossiers. Clinical study data, comparator information, and drug price are key in decision making. Decision makers are highly skeptical of AMCP dossier modeling sections and offered several suggestions to increase transparency and accountability. Great value is placed on succinctness and information relevant to the disease area (e.g., in less-prevalent diseases). **CONCLUSIONS:** Although there are formal guidelines for AMCP dossiers, health care decision makers seek information tailored to the disease and technology. Given the varied use of AMCP dossiers in practice and the reality of US health care reform, clearly understanding payer use and perspectives is important. Brevity and accuracy are crucial for health care decision making.

PHP51
IMPACT OF EARLY HEALTH TECHNOLOGY ADVICE ON CLINICAL DEVELOPMENT PROGRAMS

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OBJECTIVES: The research and development strategy for a new drug or device should be examined early in its clinical development to ensure that it ultimately delivers value for the patient, prescriber, and payer. The target product profile, clinical study program, and value proposition for investigational products at Sanofi are evaluated regularly by an external Health Technology Advisory Council (HTAC) empanelled with payers, clinicians, policy makers, health economists, and patient representatives. This study sought to identify trends in key advice and actionable information derived from HTAC meetings in North America, Europe, and Asia that influenced the development of pipeline products. **METHODS:** Between 2010 and 2013, 16 HTAC meetings were conducted for 14 Sanofi products in preclinical, Phase I and Phase II research. Six to 12 months after completion of each meeting, Clinical Development Leads completed a 15 question survey to identify the impact of HTAC on their projects. The results were collected and analyzed to determine the overall impact of the HTAC meetings. **RESULTS:** A total of 14 surveys were completed. Advice and actionable information consisted of suggestions on clinical study design (36%), need of additional Health Economics and Outcomes Research (HEOR) studies (20%), and insights regarding pricing & reimbursement (11%). Feedback from HTAC influenced leadership committee decision-making (14%). Respondents agreed that the HTAC enabled important interactions with global experts early in development; moreover, all suggested that additional time be allowed to prepare for HTAC meetings. All Clinical Development Leads indicated they would return to HTAC and recommend it to a colleague. **CONCLUSIONS:** The most frequent HTAC advice involved suggestions to improve clinical study design. HTAC also recommended performing additional HEOR studies. In many instances, feedback from HTAC influenced leadership committee decision-making, such as licensing agreements.

HEALTH CARE USE & POLICY STUDIES – Health Care Costs & Management

PHP52
SOURCES OF SPENDING VARIATION IN PROFESSIONAL SERVICES AMONG TEXAS HOSPITAL REFERRAL REGIONS: AN ANALYSIS OF PRIVATE INSURANCE POPULATION

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OBJECTIVES: Health care expenditure in the United States is expected to be 19.9% of GDP by 2022 and professional services account for a substantial portion of the total health care spending. The study aims to decompose the source of spending variation in professional services across Texas hospital referral regions (HRRs) due to quantity, price, health risk and cost of doing business. **METHODS:** The study used 2011 professional claims data for 3,829,083 members enrolled in Blue Cross Blue Shield (BCBS) of Texas, largest commercial insurance provider in Texas. Professional claims were classified into seven categories (i.e. evaluation and management, procedures, imaging, tests, durable medical equipment, other and exceptions/unclassified) using the Berenson-Eggers Type of Service (BETOS) code and Health Care Procedure Coding System (HCPCS) procedure codes. Geographic variation in spending per capita for each category was decomposed into quantity, price, cost of doing business and health risk. **RESULTS:** Overall, spending variation in professional services is mainly explained by quantity (68.5%), followed by price (19.0%), cost of doing business (8.4%) and health risk (4.1%). Across categories, variation due to price was observed to be the highest for procedures (28.2%) and evaluation and management (22.4%) categories. Quantity accounted for majority of variation for imaging (80.5%), tests (83.2%), durable medical equipment (80.9%) and other (78.6%) categories. Contribution of health risk in explaining variation was relatively small for all professional subcategories (range: 0.34% to 7.0%). **CONCLUSIONS:** Majority of the geographic variation in professional services spending was explained by quantity. However, contribution of quantity and price varied considerably in explaining geographic differences across different professional services. Further exploration is required in understanding factors that lead to such variations across service types.

PHP53
ANALYSIS OF AVERAGE MANUFACTURER PRICES OF NEW DRUGS APPROVED IN THE UNITED STATES (1990-2012)

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OBJECTIVES: Reimbursement of brand drugs is typically set as a percentage of manufacturers' listed prices. Thestudy evaluates trends the manufacturer listed prices at market entry of oral solid forms of new molecular entities (NMEs) approved by the US Food and Drug Administration (FDA) in the period 1990-2012. **METHODS:** Drug regulatory information derived from the FDA. Daily defined dosages (DDD) were collected from the World Health Organization. Average wholesaler prices (AWP) per unit at market entry derived from the RedBook. Prices were converted to 2013 dollars using the consumer price index. Descriptive statistics, 95% confidence intervals and t-tests were performed in the analysis. **RESULTS:** The FDA approved 576 NMEs during the study period; 505 were marketed as of Dec 31, 2013, and 339 had a solid oral form at approval. The analysis included 243 NMES withcomplete DDD and price information. There were 141 NMEs approved in the 1990s, 82 in the 2000s and 20 in the period 2000-2013. The average AWP per DDD was $13.81±$31.99 (95%CI:$8.53-$19.09) in the 1990s, $45.54±$92.44 (95%CI:$25.53-$65.55) in the 2000s, and $112.83±$175.27 (95%CI:$36.02-$189.64) in the period 2010-2013. The average AWP per DDD was significantly higher ($p=0.001$) for FDA priority review drugs ($59.01±$113.90, 95%CI:$34.80-$83.23, n=85) than for standard review drugs ($18.50±$52.38, 95%CI:$10.33 $26.66). It was also higher ($p=0.005$) for orphan drugs ($88.64± $112.85, 95%CI: $43.49-$133.79, n=24) than for non-orphan drugs ($26.54± $75.27, 95%CI: $16.57-$36.50). Last, the AWP was significantly higher ($p<0.001$) for drugs marketed as of December 2013 ($34.75±$84.66, 95%CI: $23.66-$45.84, n=224) than for discontinued drugs ($8.15±$5.30, 95%CI: $5.76-$10.53,