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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.

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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

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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.

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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.

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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.

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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-