

**OBJECTIVES:** To assess and obtain data on the proper use of drugs and present irrational drug use pattern by medical practitioners that weather the patients receive the medicines, weather these are appropriate for their clinical needs, in proper doses, for appropriate periods of time, weather cost effective and were dispensed properly. **METHODS:** This study was designed to assess' irrational drug use pattern which is a great concern of the entire world and WHO in general and in our country in particular. For this study we used the WHO indicators utilizing the services of trainee Pharmacists in two major city Hospitals. This study was conducted from April, 15th 2014 to May, 14th 2014. Data was collected using patient's prescriptions and direct patient communication using a structured check list for the prescribing indicators including number of drugs per prescription, number of antibiotics, number of injections, number of steroids and number of food supplements. The patient care data, including proper doses, proper timing, cost effectiveness and proper dispensing was directly interpreted and analyzed over the dispensing counters of Pharmacies by the trainee Pharmacists. **RESULTS:** The results showed that in both hospitals (860 prescriptions), the average number of drugs per prescription were 5, the patients were prescribed antibiotics at least two antibiotics per prescription (40%). The percentage of injections, steroids and food supplements were 20% each. The percentage of proper doses, proper timing, cost effectiveness and proper dispensing was 70%, 60%, 20% and 20% respectively. This irrational prescribing pattern/habit of the medical practitioners was observed in both the hospitals. **CONCLUSIONS:** This study indicates that this type of irrational practice is the reflection of state and regulatory affairs in the country and this is a warning for all developing countries which need strict regulations and strategies for drug prescriptions and dispensing including the utilization of services of more Pharmacists.

#### HEALTH CARE USE & POLICY STUDIES – Risk Sharing/Performance-Based Agreements

##### PHP173

#### FORMULARY MANAGEMENT OF BRANDED DRUGS WITH AND WITHOUT BOXED WARNINGS WITHIN THERAPEUTIC CATEGORIES

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**OBJECTIVES:** Step therapy is defined as the practice of beginning drug therapy for a medical condition with the safest and most cost-effective drug therapy and progressing to more risky or costly therapies. This analysis assessed the number of US health plans that require patients to step through a branded boxed warning product before initiating a branded non-boxed warning product. **METHODS:** This cross-sectional analysis was conducted using formulary data compiled by the MMIT Formulary Analytics Specialty Assessment database, which includes 2015 formulary status and policies for all US health plans. Of the 27 therapeutic classes that include products with a boxed warning, 9 therapeutic classes met all of the following criteria: (1) include currently marketed branded products, (2) include branded boxed warning products, (3) include branded non-boxed warning products, (4) include specialty or small-molecule products. Formulary requirements and restrictions for the 30 largest commercial US health plans were examined for cases in which patients are required by formulary design to step through a branded drug with a boxed warning before initiating a product without a boxed warning. **RESULTS:** The 30 commercial plans represented 121 million lives, or 56% of the 217 million commercial lives in the United States. The number of health plans requiring patients to step through a branded boxed warning drug before initiating a non-boxed warning product in the 9 therapeutic classes included were: anti-infectives (miscellaneous), 0; anticonvulsants, 0; antidiabetics, 0; gastrointestinal agents, 0; immunological agents and biologics, 18 (45% of covered lives); respiratory agents, 0; dermatologic agents, 0; central nervous system drugs (anti-Parkinson), 0; and renal agents, 0. **CONCLUSIONS:** The designs of US formularies generally do not require a step through products with a box warning prior to initiating a product without a boxed warning. The one notable exception is the class of immunological agents and biologics.

##### PHP174

#### KEY MILESTONES OF PUBLIC-PRIVATE PARTNERSHIPS FOR DRUGS IN BRAZIL

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**OBJECTIVES:** To identify the key milestones for the public-private partnerships in Brazil. **METHODS:** We conducted a literature review (2004–2014) on the legislation and local articles about public-private partnership (PPP) for drugs in Brazil. **RESULTS:** In 2004 the government issued law #11079 establishing general rules for PPPs in all sectors. The first specific mention to healthcare was done in the article 'Development, health-industrial complex and industrial policy' (Gadelha, 2006). In 2010 via the decree #1284 the government sets its list with the strategic products for the healthcare public system. Still in 2010 law #12349 creates the preference margin benefiting in bids/tenders products locally produced. In 2013 in "Brasil Maior" plan the government formalizes its aim to achieving autonomy in producing strategic drugs via partnerships for productive development (PDP). More recently, public consultation #8 was opened in August/2014 with the content of the bill which aims to set criteria and guidelines for the PDPs. **CONCLUSIONS:** For the last 10 years the Brazilian government has consistently put in place either legislation or initiatives to achieve autonomy in producing key products for the public healthcare system.

##### PHP175

#### OUTCOMES-BASED PRICING AND REIMBURSEMENT ARRANGEMENTS FOR PHARMACEUTICAL PRODUCTS IN THE US AND EU-5: PAYER AND MANUFACTURER EXPERIENCE AND OUTLOOK

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**OBJECTIVES:** Outcomes-based pricing and reimbursement arrangements (OPRAs), a type of performance-based risk-sharing (PBRS) arrangements, have emerged as a promising avenue for payers to share pharmaceutical risk and for manufacturers to improve access. The aim of this study was to explore the U.S. and EU-5 perspectives regarding historical and future activity for OPRAs as well as payers' and manufacturers' perceptions of OPRAs. **METHODS:** Our study combined 2 approaches: targeted literature review and primary research with U.S. and EU-5 stakeholders. The targeted literature review included the following sources: University of Washington's PBRS Database, payer and health technology assessment agencies' websites, Factiva, PubMed, and congress abstracts. Only schemes relating to pharmaceuticals were included. Twenty-seven experts were interviewed using a structured questionnaire: 14 US payers, 5 EU-5 national payers, 8 manufacturers' pricing/market access executives (4 US, 4 EU-5). **RESULTS:** A total of 117 arrangements were identified from 1994 to 2014. This understates the level of OPRAs activity as many schemes are confidential. U.S. and EU-5 interviewees expect that 2 to 10 times more OPRAs will be implemented in the next 5 years than in the previous 5 years. Historically, Italy has accounted for most OPRAs activity; however, other nations are expected to increase OPRAs activity. Key drivers include the introduction of a national OPRAs framework in Spain, potentially a similar framework in the United Kingdom, a growing sick-fund activity in Germany, and a US movement towards accountable care. Motivation for OPRAs varies markedly across markets and stakeholders, with operational feasibility a significant hurdle in the U.S. and France. Cost and risk reduction were the primary focus for payers, while improving access was key for manufacturers. **CONCLUSIONS:** This research suggests high OPRAs growth is expected in the EU-5 and, to a lesser extent in the U.S., particularly if clear, uncomplicated OPRAs frameworks can be developed.

##### PHP176

#### EVALUATION OF A PHARMACEUTICAL RISK-SHARING AGREEMENT WHEN PATIENTS ARE SCREENED FOR THE PROBABILITY OF SUCCESS

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**OBJECTIVES:** Pharmaceutical risk-sharing agreements are a type of contract between drug manufacturers and third party payers. These agreements are increasingly being used as part of formulary listing decisions due to uncertainties about price and performance of new drugs at the time of launch. We develop a game theoretic model of a pay-for-performance agreement. **METHODS:** We model interactions between the payer and manufacturer as a Stackelberg game. The pharmaceutical firm chooses the drug price and then the payer chooses which patients will be eligible for treatment. Following treatment the manufacturer pays a rebate to the payer for all patients who did not respond to the new drug. We solve for the optimal price and treatment decisions by both parties. We define the social welfare as the sum of the payer's and manufacturer's objective functions, and investigate whether a combination of taxes, subsidies and additional rebates can result in the optimal social welfare when the two parties act independently in a decentralized system. **RESULTS:** We examine how the rebate rate determines the payer's optimal treatment decisions. Specifically, we find a break-even threshold for the rebate rate for which the payer incurs neither a loss nor gain for patients not responding to the drug. We create several numerical examples to investigate how the distribution of the probability of success throughout the population influences the manufacturer's profits and the net health benefits purchased by the payer. We find that a single rebate based on performance does not, in general, lead to a socially optimal outcome, but that that socially optimal outcome can be achieved through additional rebates or by using appropriately designed taxes and subsidies. **CONCLUSIONS:** A pay-for-performance risk-sharing agreement may be welfare-improving for certain ranges of rebate rate. Formulary managers should be aware of the incentives created by different types of agreements when negotiating with drug manufacturers.

##### PHP177

#### CURRENT SITUATION OF THE PUBLIC-PRIVATE PARTNERSHIPS FOR DRUGS IN BRAZIL

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**OBJECTIVES:** In August/2014 the Brazilian government opened for public consultation its bill on public-private partnerships (PDPs). The aim of this study is to understand the current situation of the public-private partnership in Brazil. **METHODS:** We combined different database publicly available in the government website ([www.saude.gov.br](http://www.saude.gov.br)) encompassing: a) projects under analysis (submission period: March/2013–April/2014); b) products currently being purchased via PDPs; and c) projects rejected by the Ministry of Health. **RESULTS:** There are 43 projects under analysis by the Ministry of Health, oncology representing over 50% of the submissions. Government currently purchases 13 products from 7 official laboratories, vaccines being the main products. 151 projects were rejected by the Ministry of Health, participation of different therapeutic areas is fragmented. **CONCLUSIONS:** To this point, data shows that vaccines are the key products in the PDP arena. However, according to recent submissions, oncology seems also to be a field of interest.

#### HEALTH CARE USE & POLICY STUDIES – Conceptual Papers

##### PHP178

#### TWO-PART PRICING FOR PATENT PROTECTED MEDICINES â€“AN ECONOMIC ANALYSIS FROM A SWEDISH HEALTH CARE PERSPECTIVE

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Two-Part Pricing for Patent Protected Medicines – An Economic Analysis from a Swedish Health Care Perspective Holm, H J and Hertzman, **OBJECTIVES:** Many new medicines are targeting small patient populations. In order to recoup R&D costs the medicines are highly priced. A dilemma is that the price per patient (or pill or vial) can