Information Network (DPIN), which captures all community prescriptions – dispensed in the province. Data captured by DPIN from April 1998 to March 2015 were used to determine rates of incident and prevalent bisphosphonate use, Pharmacare coverage by fiscal year, and to investigate the impact of formulary changes.

Results: The use of bisphosphonates rose substantially early in the study period, with a 40% increase in new starts per year, peaking in 2003. Prevalent use grew by 219% to a peak in 2006. Despite the introduction of lower cost generic medications, utilization declined steadily until the end of the study period, with rates of incident and prevalent use down 62% and 33% from peak levels. The formulary coverage changes had a differential effect ($p < 0.0001$), with government-covered users dropping by 54% by 2014, while non-covered use only dropped by 13%.

Conclusions: The introduction of lower cost generics did not appear to have resulted in increased utilization, while formulary restrictions were associated with dramatically reduced rates of bisphosphonate utilization.

1012. The Impact of FDA Risk-Communication on Health-Related Perceptions and Knowledge of Individuals in the United States

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Background: The evidence on the impact of Food and Drug Administration (FDA) risk-communication strategies on individual-level outcomes and safety perceptions of food and drugs is unclear and sparse. Recall and withdrawal queries account for fourth largest online searches among health-related searches

Objectives: The primary objective of this paper was to study the impact of FDA reports and warnings on individual perceptions and scenario-actions and identify vulnerable groups to target the dissemination of information by the FDA

Methods: We used data from the Health Information National Trends Survey 4 FDA 2015. Attentiveness to reports was our independent variable. Actions in case of drug and food recalls, market safety of drugs, medical devices and trust of health information sources were our broad dependent variables. Multinomial logistic regression was used to obtain odds ratio estimates. The models were adjusted for age, gender, race, education, occupation, marital status, household income, health insurance, smoking and vaping status. Chi-square test was used to compare demographics of the population by our independent variable. P-values and 95%CI were used to obtain significance estimates

Results: Individuals paying attention to FDA reports were significantly older, non-Hispanic Blacks or non-Hispanic Asians, completed college or graduation, unemployed or retired and having health insurance. Individuals attentive towards FDA reports showed a significantly higher likelihood of protective behavior in case drug recalls and significantly higher trust in government sources for medical information. Married individuals and non-Hispanic whites showed significantly lower protective behaviors, and significantly higher trust in religious organizations for obtaining health-related information

Conclusions: Overall, the risk-communication strategy implemented by the FDA, has resulted in positive outcomes among the attentive individuals. However, there is a need to exploit the FDA programs meant for the welfare of the population by targeting them to be able to reach the vulnerable groups like married individuals, non-Hispanic Whites, low education groups and the employed

1013. Pharmacovigilance of Drug Quality Deviation in the Public Health System

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Background: Drug quality deviation (DQD) is defined as the disagreement with the parameters established for a pharmaceutical preparation at the registration process. Pharmacovigilance programs should be notified of DQD to support patient safety.

Objectives: To describe DQD from public health system and its impact on the pharmaceutical care.

Methods: Descriptive analysis of DQD recorded in public health care facilities at primary and secondary

level in Belo Horizonte, Brazil. All notifications (n = 271) of quality deviations of drugs from the Municipal List of Essential Medicines recorded from April to September 2016 were analysed. Variables selected were type of DQD, pharmaceutical product, therapeutic class, notifying health unit, risk classification (potential consequences for drug, patient and pharmaceutical care), and reply of DQD notification by private and public drug suppliers and by Brazilian Health Surveillance Agency (ANVISA). Variables were described by estimating absolute and relative frequencies.

Results: A total of 329 DQD was recorded, which led to a loss of 9,311 preparations, representing on average 0.2% of the acquired lot. Most DQD came from the primary health care level. Drug-related problems included deviations in package content (47%), package integrity (26%), label (5%), and pharmaceutical product itself (e.g. change in colour) (22%). DQD involving solid preparations was the most recorded (68.3%). Anti-infectives for systemic use and nervous system drugs accounted for 21.0% and 20.3% of DQD, respectively. Approximately, 70% of the DQD could lead to transient and reversible harm to patients (intermediate risk). Drug suppliers replied 83.6% of notifications, being the pharmaceutical manufactures more effective and faster in solving the complaints. None notification has been completely analysed by ANVISA until the end of the study.

Conclusions: Pharmacovigilance is an important tool to minimize potential patient harm by managing DQD and improving the quality of dispensed drugs. The results highlight the need to strengthen this activity as well as extend it beyond the hospital settings where this practice is best established.

1014. Application of Risk Analysis Methodologies for Risk Management Planning

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Background: The prioritization of risks for inclusion in risk management plans, as well as the choice of the most meaningful risk management strategy are often performed in unstructured and non-reproducible ways. Some efforts have been made with Failure Modes and Effects Analysis (FMEA) to provide some more rationale guidance on the choice of risk management interventions, but this method is not routinely used nor are the results of such exercises usually communicated.

Objectives: To apply risk analysis methodologies for the development of meaningful drug safety risk management strategies.

Methods: A modified ZHA (Zurich Hazard Analysis) was used for the evaluation of risk profiles and risk acceptability criteria, including setting the threshold of the required effectiveness of risk minimization. FTA (Fault-Tree Analysis) was used to analyze the logical connections between individual risk factors and to identify the critical risk factor of complex risks. A modified FMEA was applied to the analysis of medication processes and to determine critical process steps.

Results: ZHA was used to identify and prioritize important identified and potential risks for products from different therapeutic areas, show the relative importance of different risks and establish levels of risk minimization to be achieved in order to maintain a favourable benefit-risk balance. This helped in prioritizing risks for inclusion in RMPs and creating team consensus on BR profiles. FTA was applied to determine the critical risk factors in the analysis of complex, ill-understood risks to establish the optimal risk management approach. FTA showed that a proposed risk management approach was not effective and suggested a different approach that was corroborated by experimental evidence later. We routinely applied FMEA to identify likely failure modes and to design the most meaningful improvements of medication processes. By identifying the critical stakeholders we were further able to aid in the design of optimized educational and training materials and to reduce the burden on stakeholders. Finally, the analyses provided us with a basis to objectively select the appropriate process parameter for the evaluation of RMin effectiveness.

Conclusions: Formal risk analysis methodologies can be applied to prioritize risks for RMP development, to determine critical risk factors and to develop meaningful and effective risk minimization measures. The results of risk analyses provide a transparent and comprehensible decision and communication basis for risk management.

1015. Development of a Prediction Model Including Modifiable Risk Factors for Uncontrolled Clostridium Difficile Infection Using Hospital Electronic Health Records

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