

assesses the clinical effectiveness of generic CD SMS. **METHODS:** An overview of reviews was deemed the most efficient approach to gather and summarise a large body of evidence, thereby efficiently informing clinical decision makers. Systematic reviews of RCTs and overviews of reviews assessing generic CD SMS interventions in adults were included. Assessment of included study quality was performed using the R-AMSTAR quality appraisal tool. **RESULTS:** Generic CD SMS interventions comprise a heterogeneous group that have been assessed for a diverse range of chronic diseases and for which there is limited evidence of clinical effectiveness. Small reductions in health care utilisation are reported in a limited number of RCTs for CD self-management programmes and in a review of a range of generic SMS interventions. While there is a large quantity of evidence, generally low or unreported quality of included studies with typically short term follow-up leads to a high degree of uncertainty around results. **CONCLUSIONS:** The optimal format of generic SMS, the diseases in which it is likely to provide benefit, and the duration of effectiveness, if any, remains unclear.

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DOES A SHORTER PROTOCOL TIME FOR CHEST PAIN PATIENTS IMPACT EMERGENCY DEPARTMENT FLOW? A QUEUING MODEL TO DISCUSS EMERGENCY DEPARTMENT MANAGEMENT METRICS

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OBJECTIVES: The Emergency Department (ED) represents the most important entry point to hospital services. Variability and unpredictability in demand, the heterogeneity of clinical paths combined with an ongoing pressure to optimize the use of scarce resources have led to increasing issues such as ED crowding. The goal of the current study is to assess the impact of shorter protocol times for the cluster of ED patients who present with chest pain on ED Key Performance Indicators (KPI). **METHODS:** A model based on a queuing theory has been developed and has been tested in a hypothetical ED with 20 chest pain patients (CPP) per day. The management of CPP mainly relies on serial measurements of troponin at defined time points. The model has been tested in two scenarios, one characterized by the use of a traditional troponin tests (6 hours protocol time), and one characterized by the use of high sensitivity troponin test (3 hours protocol time as recently recommended by clinical guidelines). In order to measure the impact of a shorter protocol time in the ED, we compare the ED KPIs resulting from the model in the two scenarios. **RESULTS:** The benchmark between the two scenarios shows an improvement of all ED KPIs for the scenario with a shorter protocol time: a reduction of (i) ED diversion rate (diff. 5.1%), (ii) ED waiting time (- 79%), (iii) ED length of stay (- 66%); a daily increase of (i) ED bed availability (+2.2 beds) and (ii) ED admission rate (+1 patient). **CONCLUSIONS:** A reduction in protocol time for chest pain patients would improve KPIs for this cluster of patients. As a subsequent impact other patients would benefit from released capacity which could alleviate ED flow issues in general. Future studies are going to validate the ED model.

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VALIDATION OF PERIODIC SAFETY UPDATE REPORTING SYSTEM IN A TERTIARY CARE TEACHING HOSPITAL USING ADVERSE DRUG REACTION MONITORING OF THREE COMMONLY PRESCRIBED DRUGS

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OBJECTIVES: A Periodic Safety Update Report (PSUR) is intended to provide an update of the worldwide safety experience of a medicinal product to competent regulatory authorities at defined time points post-authorization. Drug Controller General of India (DCGI) has taken initiatives for enforcing the submission of PSURs from hospitals throughout the country for drugs launched 2011 onwards. This data would be used to validate the accuracy/bias of the PSURs submitted by pharmaceutical companies. In this study the assessment and validation of the impact of PSUR system implementation and its functioning in the hospital was carried out. **METHODS:** Retrospective and prospective observational study for ADR reporting of three commonly prescribed drugs in the hospital for the period of 9 months before and 9 months after the PSUR system implementation in the hospital. **RESULTS:** Amlodipine, Furosemide and Risperidone are three commonly prescribed drugs in different wards of hospital. A total of 65 ADRs were reported for the period of March-November 2013, in which 10(2%), 40(5.69%) and 15(6.12%) ADRs were reported for Amlodipine, Furosemide and Risperidone respectively. There was a 60% rise in ADR reporting rate observed after implementation of PSUR system in the hospital. 107 ADRs were reported for the period of December-August 2014, out of which 20(4.62%), 62(9%) and 25(10%) ADRs were reported for Amlodipine, Furosemide and Risperidone respectively. **CONCLUSIONS:** This study showed that implementation of PSUR system for reporting of ADRs in the hospital works as a great tool for effective pharmacovigilance. PSUR reporting through hospital is a great initiative directed through DCGI, India. By following PSUR practice in a hospital, we can encourage more health care professionals to get involved in ADR reporting program for the safety and wellbeing of mankind.

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THE RELATIONSHIP BETWEEN KNOWLEDGE AND PERFORMANCE: THE CASE OF IRAN COMMUNITY PHARMACIES

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OBJECTIVES: This study tried to find out whether the level of knowledge and skills of people working in a community pharmacy and applying strategy planning in community pharmacies, in Iran, can affect their achievements, as small to medium sized enterprises working in a circumstance with little professionalization of community pharmacies activities. **METHODS:** In 2015, a cross-sectional survey was conducted using self-administered, anonymous questionnaires designed for man-

agers, pharmacy staff, and pharmacy clients. The target population of this study was community pharmacies settled in Tehran, the capital city of Iran. The managerial team of the invited pharmacies must remain unchanged for at least three years ending to the study. Manager's and staff questionnaires contained questions about their job satisfaction, self assessment of knowledge, skills, and performance. Staff was also asked about manager's behavior. Client's questionnaire evaluated client's satisfaction with the pharmacy. Confirmatory factor analysis and correlation test were performed using SPSS 16.0.0. **RESULTS:** Data from 187 pharmacies was gathered. Based on the results, applying strategy planning had significant relationship with financial (R=0.204, p-value<0.05) and societal results (R= 0.451, p-value < 0.01). Manager's behavior was significantly (p-value < 0.01) correlated with society, staff and client result (R= 0.234, 0.674 and 0.307, respectively). Staff's knowledge and skills was related with staff's satisfaction (R=0.211, p-value < 0.01), society (R=0.339, p-value < 0.01) and financial (R=172, p-value < 0.05) result, but client's satisfaction correlation was only significant with technical pharmacist's skills (R=0.275) and non-pharmaceutical knowledge (communication, information exchange, and ethics) (R=0.301). **CONCLUSIONS:** Although community pharmacies, in Iran, suffer from low professionalization and health policy makers' inattention, results of this study are promising, because show that manager's can still affect pharmacy achievements by improving their behavior, knowledge and skills.

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CHARACTER OF TOXIC DAMAGE OF LIVER IN INFLUENCES OF SUBSTANCES OF MEDIATOR TO FETAL CELLS ON HEPATOCYTES IN ACUTE LIVER FAILURE

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OBJECTIVES: In a comparative analysis of the hepatoprotective properties of mediator substances fetal cells were more expression than in essential and provided dose-dependent effect. The aim was to evaluate the effect of mediator substances of fetal cells to hepatocytes during acute liver failure. **METHODS:** For this experiment we used an experimental model of chronic hepatitis, where a carbon tetrachloride used as toxic agent, which were introduced into experimental rats at dose of 0,2ml / 100g. The experiment had been lasted 45 days. Thus, the level of alanine aminotransferase at the 2nd day of the experiment in the control group of untreated animals was 4.6 times higher than in intact rats. While the level of aspartate aminotransferase in blood serum of control animals receiving no hepatoprotective therapy increased 1.8 times to 10thday as compared to intact group. **RESULTS:** Experimental acute hepatitis accompanied by an increase in the values of thymol 1.5 times already on the 2nd day, on the 5th and 10th days of the experience were even more growth in this indicator when it exceeded the level of the intact group by 3.9 times and amounted to respectively p<0.05 and p<0.001. In the control group of animals exposed to the toxic effects of paracetamol and its metabolites to liver cells was observed marked change parameters of cholestasis. Thus, the content of bilirubin in the group of untreated animals on the 2nd and 5th day of the experiment exceeds the index of intact animals by 1.3 times, on the 10th day of the study, it decreased and was 1.2 lower than in the intact group (p<0.001). **CONCLUSIONS:** Morphological findings which were found in the experimental groups using the "mediator substances" of fetal cells in a dose of 0.1 ml/kg, showed that their hepatoprotective effect appears to 10th days.

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ITALIAN LAW 326/2003 FOR THE REIMBURSEMENT OF ORPHAN AND LIFE SAVING DRUGS AWAITING MARKET ENTRY: APPROVALS, REJECTIONS AND METHODS IN AIFA'S EVALUATION PROCESS BETWEEN JANUARY 2013 AND MAY 2015

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OBJECTIVES: Under Article 48 of Law 326/2003, AIFA has established an innovative funding scheme (Fondo AIFA 5%). Italian pharmaceutical companies are required to donate 5% of their promotional expenditure to an independent research fund. Half of this allowance is used for the reimbursement of orphan and life saving drugs awaiting market entry. This study is aimed to assess how many applications have been submitted to the Technical Committee of AIFA (CTS) and how they have been evaluated. **METHODS:** The reports of CTS meetings from January 2013 to May 2015 were reviewed, checking number and characteristics of drugs under evaluation, and analysing each single decision taken by CTS. **RESULTS:** Over the period under analysis, CTS evaluated 15 drugs, for the treatment of 61 patients. The therapeutic areas mainly represented were the respiratory system (cystic fibrosis), the onco-haematology (multiple myeloma and MCL) and other rare diseases (Duchenne muscular dystrophy, short-bowel syndrome, cystic fibrosis, inborn errors of primary bile acid synthesis). Out of 61 patient applications, 16 were approved, 26 rejected as the product obtained a full registration and reimbursement in the meantime, 8 rejected (expanded access program or drug already included in 648 List), 6 rejected due to the lack of data or waiting CHMP's decision, and 5 rejected due to technical reasons. **CONCLUSIONS:** AIFA has a very high engagement to assure patient access to orphan and life saving drugs. The 2014 fund amounted to 15.6 million Euro, half of it to be used for the reimbursement of orphan and life saving drugs awaiting market entry, whilst the other half aimed to support independent research, drug information programs and pharmacovigilance costs. However, having said this, the expenditure for the sole orphan and life saving drugs from the Fondo AIFA in 2014 amounted only to 239.895 Euro.

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WILLING TO PROVIDE MEDICATION ANALYSIS? PREDICTING PHARMACISTS' INTENTION TO PROVIDE MEDICATION ANALYSIS IN COMMUNITY PHARMACIES IN GERMANY

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