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and most important step that causes properly usage of such products as well as preventing the side effects from abuse of such products and for highly consumed products such as sunscreen cares and depilatories.

PHP50

IMPLEMENTATION AND ASSESSMENT OF PERIODIC SAFETY UPDATE REPORTING SYSTEM AT TERTIARY CARE TEACHING HOSPITAL, KARNATAKA, INDIA: A DRUG CONTROLLER GENERAL OF INDIA INITIATIVE

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OBJECTIVES: To implement the PSUR system in all wards of hospital. Reporting of PSURs for all the running newly launched drugs since 2011 in hospital periodically to DCG (I), New Delhi and assessment of the PSUR system functioning in the hospital. **METHODS:** Prospective observational study. Drug safety reporting either manual or through online portal. Preparation and submission of PSURs as per Schedule Y of drugs and Cosmetics act, India. **RESULTS:** To implement the DCG (I) initiative PSUR program, one PSUR committee, one drug safety review panel and one Delphi panel for PSUR system assessment has been constituted. Drug safety reporting and assessment tools are prepared and validated. A manual reporting system of drug safety has been set up and one link on hospital intranet website will be very soon available for online drug safety reporting through each ward and departments of hospital. Necessary training on drug safety reporting is provided to all health care professionals. Online hospital information services are in use to track the prescription of these drugs to the in-patients and then, these patients are extensively followed for any drug related problem during their hospital stay. All the associated drug safety reports routed through wards to PSUR work station. The collected reports are assessed and coded using various scales, tools and softwares, e. g. Naranjo Scale, Hartwig severity scale and MedDRA coding software etc. PSUR system functioning in the hospital is assessed at regular time intervals through tool which is prepared and validated using Delphi technique. So far, since its inception two PSURs has been successfully submitted to DCG (I) at six months regular interval and third one is ready to report for next phase. **CONCLUSIONS:** The present pioneering hospital based PSUR setup will create an environment for healthy safety reporting and helps the regulatory authorities for safety related decisions.

PHP52

STUDY ON AUDIT AND CONTROL SYSTEM AND ITS CURRENT SITUATION

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OBJECTIVES: To study assessment and control the quality and the safety of hospitals in Mongolia. **METHODS:** The research has been conducted by cross-sectional study by collecting information according to the quantitative and qualitative method. **RESULTS:** In order to increase the quality and safety at the primary level hospitals the activity of special supporting (80.6%) and quality team control (66.7%) has been implemented, though, insufficient financing (33.3%) and professionals in quality control (19.4%) as well as special supporting activity has not been implemented (91.7%). The special supporting activity (87.0%) has been implemented ($p<0.05$) in the secondary level hospitals to increase the quality and safety, though, financing is insufficient (39.1%). The quality is conceptual idea, even though, this is a value that always could be felt and existed. The supporting activity (87.0%) and quality team (68.4%) are implemented ($p<0.05$) to develop the quality in the tertiary level hospitals, however, other activities that develop quality are not implemented. The participants in the study answered about the challenging issues are high at all hospital levels, such as long queue to receive health service (54.5%-76.5%), overload in the hospital (67.6%-81.8%) and referral between hospitals (45.5% -72.2%) as well as hospital professionals are susceptible to illness (31.3%-52.2%). **CONCLUSIONS:** Policy on quality and other related strategic documents are established 60-70% in the hospitals. Determination of health care and "determination of specialized health care standard through the diagnosis of the care" are insufficient at all level.

PHP53

ORGANIZATION POTENCY AND HUMAN RESOURCE

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OBJECTIVES: The purpose of the study was identifying the main problems of improving health care quality, organizational safety and human resource. **METHODS:** Questionnaire with 15 questions to study human resource potency. Financial statement balance of 2007 and 2012. Questionnaire with 12 questions to study medical equipments potency Observational lists of internal and external environment safety of the hospitals **RESULTS:** Totally 214 medical professionals were participated in the research: medical doctors 85 (39%), nurses 73 (34%), administration staff 16 (7%), and other staff 40 (19%). In 2007-2012 hospitals' funding were increased up to 80%, whereas the number of birth increased up to 121%, number of surgeries increased up to 26% and number of inpatient clients up to 19%. It's important to confirm the work position for medical equipment specialists and engineers according to the demands of medical equipment. **CONCLUSIONS:** It is concluded that there is increasing need of consideration on the number of nurses, doctors and other health professionals. The result showed that it is urgent to run policy to assess the employees' skills and supporting, appraising system should be open for everybody. Therefore 25% of the employees don't recognize the organization mission, security policy and the decision making system is highly relevant to money. Amount of funding has improved but it still inadequate. Funding is still inadequate even it has improved between 2007-2012. Domestic and foreign training is not enough for medical equipment specialists and engineers. Medical equipment technician's skills are not adequate. Medical professionals' knowledge about external and internal environment security are ineffective. Hospitals external conditions got worse to 27% and internal safety conditions worsen to 20%. Therefore there is a need to organize trainings for administrative staffs and workers.

PHP54

PHARMACOECONOMIC RESEARCH AND APPLICATION IN 10 ASIAN COUNTRIES BETWEEN 2003 AND 2013: A SYSTEMATIC REVIEW

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OBJECTIVES: To describe and analyze specific aspects of pharmacoeconomic research and application in 10 Asian countries in recent years from 2003 to 2013. **METHODS:** Our study concentrated on 10 Asian countries, including China, Indonesia, Japan, Malaysia, Philippines, Singapore, South Korea, Taiwan, Thailand and Vietnam. Literature was collected and reviewed systematically from United States National Library of Medicine- PubMed. Grey literature was also taken into account. After screening, a total of 268 pharmacoeconomic research articles and 38 pharmacoeconomic application studies were included. This review followed the Cochrane systematic review guidelines and PRISMA flow diagram. Publication was analyzed by regions, economic evaluation techniques used, drug groups analyzed. The status of these pharmacoeconomic studies was identified with options being: for scientific interest, undertaken to support reimbursement issues directly or performed in the framework of clinical guidelines or formularies. **RESULTS:** There is an increasing in the number of pharmacoeconomic studies in Asian countries in the later period (2008-2013) compared with the first five years considered (2003-2007). Most pharmacoeconomic studies were carried out in Japan (26%), China (22%), Thailand (15%), Taiwan (12%) and South Korea (10%). Cost-effectiveness analysis and cost-utility analysis were the most popular economic evaluation techniques used in 84% of total studies published. Antiinfectives for systemic use, antineoplastic and immunomodulating agents, nervous system and cardiovascular system drug groups were mostly researched and accounted for 41.79%, 19.78%, 10.45% and 8.21%, respectively. Status of pharmacoeconomics applications varied among countries. **CONCLUSIONS:** The number of pharmacoeconomic studies in Asia increased from 2008 onwards. The studies were mostly carried out in 5 specific countries (85% total) and concentrated to 4 specific drug groups. Types of pharmacoeconomics applications and research foci differ considerably amongst Asian countries.

PHP55

AN ANALYSIS OF PRICING PREMIUMS GRANTED THROUGH SUBMITTING LOCAL RCT AND PHARMACOECONOMICS DATA IN TAIWAN

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OBJECTIVES: The purpose of this study was to understand the drivers of the pricing premiums granted for submitting local RCT and / or local pharmacoeconomics (PE) data during the Taiwanese reimbursement assessment process. **METHODS:** The 11 products that submitted local RCT and / or local PE data in their reimbursement submission to the NHIA between January 2012 and March 2014 were analysed in this study. **RESULTS:** Of the 6 products that submitted local RCT data, 3 received the maximum 10% pricing premium for submitting these data. Abatacept was not granted any premium for not being a new molecule and benidipine hydrochloride was not granted any premium since its price comparator was an existing product that was already priced based on local data. Sorafenib has yet to receive a decision for the premium granted. Of the 7 products that submitted local PE data, 5 received a premium. 2 received a 1% and 2% premium respectively for submitting data with high uncertainty, 1 received a 2% premium for using inappropriate comparator dosage in the analysis, and 2 received a 5% premium for submitting data that were well accepted by the NHIA. 2 products did not receive any premium, as their data were considered to be incomplete or inappropriate. All of the submissions highlighted the product's cost-effectiveness against the comparator. **CONCLUSIONS:** A 10% pricing premium through local RCT data is likely achievable as long as the product with local RCT data is a new molecule whose comparator has not been priced based on its local data. On the other hand, achieving the maximum 10% pricing premium for submitting local PE data seems difficult to achieve; as of now, a 5% premium seems to be the maximum achievable. A premium as low as 1-2% is likely if there is any uncertainty in the data.

PHP56

REVIEW OF TAIWAN NHIA'S TWO-STAGE NEW DRUGS LISTING AND REIMBURSEMENT ASSESSMENTS (2013-FEB. 2014)

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OBJECTIVES: In Taiwan, the Second-Generation National Health Insurance (2G-NHI) Act was implemented since Jan. 1st, 2013. Thereafter, listing and reimbursement of new products are 2-stage assessments performed by the Expert Advisory Committee (EAC) and Pharmaceutical Benefits Reimbursement Scheme (PBRS) of National Health Insurance Administration (NHIA). EAC primarily evaluates clinical comparative effectiveness and safety of new products, and assessments are rated as Category 1 (substantial improvement), 2A (moderate improvement) or 2B (similar) compared to current standard therapy which are also used for pricing comparators. PBRS further appraises the EAC's suggestions and make final reimbursement recommendations. The objective of this study was to analyze the trends of the PBRS appraisals from Jan. 2013 to Feb. 2014 since implementation of the 2G-NHI Act. **METHODS:** A total of 33 new drugs underwent EAC assessments and PBRS appraisals were reviewed for their Categories. Further analysis was conducted to understand the trends based on the therapeutic indications and comparators. **RESULTS:** There were 21 new drugs granted reimbursement recommendations from PBRS joint meeting. Approximately 57% of them were rated as Category 2B, 38% as Category 2A, and only 5% as Category 1. A new trend revealed that Category 2B new drugs were easier to be listed and reimbursed. The only Category 1 new product is an orphan drug in western countries used to mobilize haematopoietic stem cells for autologous trans-