and pathologic findings per event. Draft questionnaires were developed with various subsections. Long versions of these questionnaires were analyzed by two experts in the area. Key questions were selected and presented to eight clinical experts in cardiovascular disease management and lipid-lowering medications (Face Validity). Questionnaires were also tested with six participants of clinical trials that had the event. Nine initial AE reports with insufficient information to assess causality were compared with follow-up reports for the same patients. The completeness and the ability to establish drug-event causality using a modified Naranjo algorithm were evaluated.

Results: In the face validity stage, initial follow-up questionnaires were reduced from an average of five pages to two pages. Only questions that had more than 70% expert consensus were included in the short version. Patients contributed to add more terms used to describe the events. Sixty-eight percent of follow-up reports contained information useful to assess causality. The topics with the lowest response rate were concomitant medications, dose-response and occurrence of a similar reaction with any previous exposure. All follow-up reports were returned with information on patient demographics and comorbidities.

Conclusions: Short follow-up questionnaires targeting specific events are useful tools to improve the quality of spontaneous adverse event reports.

798. Review of Stevens Johnson Syndrome and Toxic Epidermal Necrolysis Registered in an Established Pharmacovigilance Centre during a Twelve Years Period

Gloria Shalviri,[1] Kheirollah Gholami,[2] Marjan Karimi.[1] *[1]Iranian Pharmacovigilance Center, Ministry of Health, Tehran, Tehran, Islamic Republic of Iran; [2]Clinical Pharmacy, Tehran University of Medical Sciences, Tehran, Tehran, Islamic Republic of Iran.*

Background: Stevens Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN) are two rare and life threatening conditions. They often occur following medicines consumption and the treatment should be focused on eliminating the underlying cause, controlling symptoms and minimizing complications.

Objectives: To evaluate all registered cases of Stevens Johnson Syndrome and Toxic Epidermal Necrolysis in Iranian pharmacovigilance database. To detect preventive measures for reducing these adverse events and/or their complications.

Methods: All registered adverse drug events in Iranian pharmacovigilance database from 1998 through 2010 were screened for SJS and TEN. The extracted data were categorized based on factors related to patients, suspected medicines and adverse events. Assessment of system-organ classes, seriousness and causality of reactions was performed according to World Health Organization scale. Preventability of reported adverse events was analyzed based on Schumock questionnaire.

Results: In the study period, a total of 22826 reports were received by the Center in which 7442 ones were related to skin and appendages system. There were 212 cases of SJS and 42 cases of TEN registered in the database leading to 6 and 11 deaths, respectively. The highest number of SJS was occurred in the age group of children less than 10 years old (57 cases), whereas 21–30 group of age were the most frequent for TEN. Lamotrigine (45 cases) and carbamazepine (35 cases) were the most reported suspected drugs for SJS. TEN related reports were mostly suspected to trimethoprim/sulfamethoxazole (6 cases) and lamotrigine (6 cases). Inappropriate use of the drug and late discontinuance of suspected medicine were the most reasons involved in detected preventable complications.

Conclusions: SJS and TEN are two serious life threatening adverse events. The initial signs and symptoms of these reactions should be well known by health care professionals and must be included in the differential diagnosis. It is also important to inform health care professionals of the medicines with high potential of inducing such reactions.

799. Active Monitoring of Adverse Drug Reactions Due to Use Contrast Media - A 2000-Bed Medical Center Experience in Taiwan

Tan-Ping Shih,[1] Hsiang-Wen Lin,[1,2] Wen-Ling Lin,[2] Yow-Wen Hsieh,[1,2] Hsi-Chin Wu,[3] Yung-Jen Ho.[4] *[1]School of Pharmacy, China Medical University, Taichung, Taiwan; [2]Department of Pharmacy, China Medical University Hospital, Taichung, Taiwan; [3]Department of Urology, China Medical University Hospital, Taichung, Taiwan; [4]Department of Radiation, China Medical University Hospital, Taichung, Taiwan.*

Background: Although the contrast media agents seem relatively safer than some other medications, the adverse drug reactions (ADR) still occur among some patients (e.g., allergic-like effects, renal dysfunction). As for Taiwanese' population, it is unknown for what extent the ADR would occur.

Objectives: to describe the use patterns of contrast media (CM) and its occurrence of ADR in a medical center in Taiwan.

Methods: While the active ADR monitoring system specifically for CM agents was set up in 2008 in China Medical University Hospital (CMUH), a 2000-bed medical center, in Taiwan, the retrospective database analyses were conducted to examine the use patterns of CM and its occurrence of ADR. For those CMUH visitors, who were prescribed with CM during December 2008 to July 2009, their disease statuses, CM prescriptions and ADR symptoms reported to active monitoring system were evaluated using descriptive analyses.

Results: Of 2,121 patients being prescribed with CM (accounted for 2,477 total visits), male was predominated

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(59.87%), mean age was 55.9 ± 16.8 year-old. 7.92% of CM receivers were prescribed with CM more than once and 6.98% of them utilized different CMs. 50.98%, 8.24%, 5.23%, 0.57% of CM receivers had underline diseases of cancer, diabetes mellitus, renal dysfunction and asthma, respectively. 0.98% of CM receivers (42 patients) were reported to occur ADR. 41 patients occurred the documented ADR, which accounted for 0.61%, 1.05% and 0.04% of CM receivers for mild, moderate and severe ADR, respectively. The most frequent ADR symptom was skin reactions (1.08%). The creatinine level before and after using CM were1.80 ± 2.87 mg/dl and2.15 ± 3.33 mg/dl, respectively.

Conclusions: Although the occurrence of ADR among CM receivers were relative low, more aggressively monitor the skin reactions and deterioration of renal functions were needed, especially for patients with cancers, asthma, and renal dysfunction.

800. The Analysis of Drug Adverse Event using Association Rule Mining (ARM) in Regional Pharmacovigilance Center

Dong Hoon Shin,[1] Gyeong Im Yu,[1] Yoon Nyun Kim,[2] Chang Sik Son,[2] Suk Tae Seo,[2] Min Soo Kim,[2] Mi Young Lee,[1] Yeo Hyang Kim,[1] Sung Won Jung,[1] Hyeok Won Jang,[1] Hyeon Ah Lee,[1] Eun Young Bae,[1] Kyung Mi Seo,[1] Jae Wi Jo,[1] Sang Hyon Kim.[1] [1]*Regional Pharmacovigilance Center, Dongsan Medical Center of Keimyung University, Daegu, Republic of Korea;* [2]*Medical Informatics, School of Medicine, Keimyung University, Daegu, Republic of Korea.*

Background: In data mining, association rule learning is a popular and well researched method for discovering interesting relations between variables in large databases.

Objectives: The purpose of this study was to analyze the adverse event name with generic name using association rule mining (ARM).

Methods: [The subjects were extracted from DSMD Regional Pharmacovigilance Center. Apriori modeling of the ARM method was used to analyze subject data. Total subjects extracted 1,576 from DSMD Regional Pharmacovigilance Center.

Results: As a result of ARM, If adverse event is Vomiting then Oseltamivir phosphate(support, 12.37%; confidance, 65.13%) and If generic name is Oseltamivir phosphate then Vomiting (support, 24.87%; confidance, 32.40%), If adverse event is Nausea then Oseltamivir phosphate (support, 10.03%; confidance, 49.37%) and If generic name is Oseltamivir phosphate then Nausea (support, 24.87%; confidance, 19.99%) were determined to be important the adverse event name Vomiting and Nausea associated with generic name Oseltamivir phosphate.

Conclusions: In Conclusions, The adverse event name Vomiting was strongly associated with generic name Oseltamivir phosphate.

801. Withdrawn by Author

802. Development of a Signal Detection Process Using Multiple Data Sources Applicable to Innovative Therapies

Michael Taylor,[1] Wei Dong,[1] Dawn Flick,[1] Kim Alexander,[1] Laura Chu,[1] Katie Miller,[1] Bharat Thakrar,[2] Jamie Robinson,[2] Pavel Napalkov.[1] [1]*Genentech, A Member of the Roche Group, S San Francisco, United States;* [2]*Roche, Basel, Switzerland.*

Background: Implementation of meaningful signal detection processes for innovative therapies without appropriate (e.g., in-class) comparators is challenging.

Objectives: To develop a practical signal detection process with clinically acceptable sensitivity and specificity using both claims data and spontaneous adverse event reports that can be used for first-in-class therapies.

Methods: Development of the process required selection of appropriate data sources and analytic methods, creation of adequate but not burdensome documentation, pilot testing, and refinements. In the final process, disproportionate data mining events (DDME) for the drug of interest (DOI) are identified by analyzing claims data and spontaneous adverse event reports (FDA Adverse Event Reporting System [AERS]). An event is defined as a DDME based on either a statistically significant incidence rate ratio (IRR) > 2 or EBGM05$\geq$2. IRRs are calculated for every 3- and 4-digit ICD-9 diagnosis code in the claims analysis comparing a cohort treated with the DOI and a cohort receiving the standard of care (SOC). The EBGM05 is calculated for every MedDRA preferred term (PT) and select SMQs in the AERS analysis comparing the DOI to one or more backgrounds based on the SOC. Analyses are typically conducted every six months depending on how long the DOI has been marketed. Following identification of DDME, a multidisciplinary team evaluates the DDME to determine if the event is a potential safety signal that should be further evaluated.

Results: The process has been applied to multiple drugs across therapeutic areas. The sensitivity and specificity were deemed acceptable based on the confirmation of known safety signals and early identification of additional potential safety signals that required further evaluation. Moreover, the process has identified events that ultimately resulted in product labeling updates.

Conclusions: This practical signal detection process using both claims data and spontaneous adverse event reports is promising in terms of enhancing our ability to detect, review, and manage potential safety signals.

803. Prevalence of Adverse Drug Reactions in Hospitalized Elderly Patients in Short Stay Unit

Clarisse Joachim,[1] Géric Maura,[2] Moustapha Dramé,[1,3] Jean-Luc Novella,[1,3] Rachid Mahmoudi,[1,3] Thierry Trenque.[2,3] [1]*Department of Clinical Gerontology, University*

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