# ملخصات مشاركات المؤتمرات

| السنة Year | الحدث العلمي (Scientific Event) | اسم الباحث المشارك ( Presnting Author) | ملخص البحث ( abstact) | عنوان البحث (Title) | # |
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| 2024 | ISPE's 16th Asian Conference on Pharmacoepidemiology | (Solaiman Alhawas) سليمان الحواس | Background<br>Omeprazole ,a Proton Pump Inhibitor (PPI), is approved by Saudi Food & Drug Authority (SFDA) for the management of gastroesophageal disease, peptic ulcer disease, gastric ulcers, duodenal ulcers, reflux esophagitis, Zollinger-Ellison syndrome. Erectile dysfunction (ED) adverse event is already included in the product information of other PPIs such as esomeprazole, pantoprazole, lansoprazole, rabeprazole and dexlansoprazole.<br>Objectives<br>To evaluate the potential association between omeprazole and ED as a part of drug class effect project conducted by the SFDA.<br>Methods<br>We conducted a systematic literature search on January 2024, using several search engines, including PubMed, Embase, and Google Scholar, for English articles on human investigating the association between Omeprazole and the risk of ED. The search terms included 'omeprazole' OR 'Losec' AND 'erectile dysfunction' OR 'organic erectile dysfunction'. Moreover, we conducted a search in the World Health Organization (WHO) database "VigiBase" and in the local database of National Pharmacovigilance Center (NPC) to retrieve case reports up to March 2023. Then, the causality assessment of the cases was performed using the WHO-Uppsala Monitoring Center causality system.<br>Results<br>Six observational studies were identified. One observational study found a significant association between PPIs and ED (odds ratio: 1.81 [95% Confidence Interval (CI): 1.07-3.07]. A prospective observational study showed significant reduction in testosterone levels post omeprazole with one patient developing ED. Three pharmacovigilance database analysis studies identified several cases of ED. In 2 studies, ED related to Omeprazole had higher reporting compared to other medications within VigiBase [Reporting Odds Ratio (ROR): 2.13, 95% CI: 1.83-2.48] and Lareb (ROR: 2.54, 95% CI: 1.52-4.25). Forty cases were assessed; 1 probably related, 19 possibly related, 1 unlikely, and 19 un-assessable. In VigiBase, 288 global cases were reported and 13 cases with completeness score one were assessed; 2 probably related, 8 possibly related, and 3 were unlikely. No local cases were reported to the SFDA.<br>Conclusions<br>The available evidence suggests potential association between ED and Omeprazole. Further epidemiological studies are needed to investigate this potential association. | Potential Association of erectile dysfunction with omeprazole use | 1 |
| 2024 | المؤتمر الدولي لعلوم التغذية والأغذية International Conference on Nutrition and Food Sciences | ريوف النفيسة Ruyuf Alnafisah | Beverage choice can have implications for the risk of non-communicable diseases. However, there is a lack of knowledge in assessing the nutritional content of these beverages. This study aims to describe the nutrient content of pre-packaged beverages available in the Saudi market. Data were collected from the Saudi Branded Food Database (SBFD). Nutrient content was standardized in terms of units and reference volumes to ensure consistency in analysis. A total of 1490 beverages were analyzed. The highest median levels of the majority of nutrients were found among dairy products; energy (68.4 [43-188] kcal/100 ml in a milkshake); protein (8.2 [0.5-8.2] g/100 ml in yogurt drinks); total fat (2.1 [1.3-3.5] g/100 ml in milk); saturated fat (1.4 [0-1.4]g/100 ml in yogurt drinks); cholesterol (30 [0-30] mg/100 ml in yogurt drinks); sodium (65 [65-65] mg/100 ml in yogurt drinks); and total sugars (12.9 (7.5-27] g/100 ml in milkshake). Carbohydrate level was the highest in nectar (13 [11.8-14.2] g/100 ml); fruits drinks (12.9 [11.9-13.9] g/100 ml), and sparkling juices (12.9 [8.8-14] g/100 ml). The highest added sugar level was observed among regular soft drinks (12(10.8-14] g/100 ml). The average rate of nutrient declaration was 60.95%. Carbohydrate had the highest declaration rate among nutrients (99.1%), and yogurt drinks had the highest declaration rate among beverage categories (92.7%). The median content of vitamins A and D in dairy products met the mandatory addition levels. This study provides valuable insights into the nutrient content of pre-packaged beverages in the Saudi market. It serves as a foundation for future research and monitoring. The findings of the study support the idea of taxing sugary beverages and raise concerns about the health effects of high sugar in fruit juices. Despite the inclusion of vitamins D and A in dairy products, the study highlights the need for alternative strategies to address these deficiencies. | Nutrient Content and Labelling Status of Pre-Packaged Beverages in Saudi Arabia | 2 |

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| 3 | Uveitis Associated with Elasomeran Use: Adverse Events- Signal Review | Background:<br>Moderna COVID-19 vaccine is indicated for active immunization to prevent coronavirus disease 2019 COVID-19 in individuals 6 months of age and older. The vaccine enable the delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. Uveitis is a form of eye inflammation. It affects the middle layer of tissue in the eye wall (uvea). The symptoms include eye redness, pain and blurred vision. A signal of Elasomeran and uveitis was found in the medical literature. Saudi Food and Drug Authority (SFDA) has conducted this safety review based on that.<br>Aim: The purpose of this review is to evaluate the risk of uveitis in association with Elasomeran use.<br>Methods:<br>SFDA performed a search in the national ADRs database, World Health Organization (WHO) global ADRs database along with literature screening to retrieve all related information for the sake of investigating causality of drug-event combination.<br>Results: Cases Review: A search in the World Health Organization (WHO) database (Vigibase) was conducted to retrieve all reported cases via signal detection tool (Vigilyze). The search resulted in 230 Individualized Case Safety Reports (ICSRs). Authors applied WHO-UMC causality on 30 cases with highest completeness score. 28 cases resulted in possible association and two cases were unassessable. Data mining: Information Component (IC) value was measured using the method for disproportionality analysis developed by Uppsala Monitoring Center (UMC). (- 0.3) value for spontaneous reporting suggests that the reported cases of uveitis have been observed less with Elasomeran when compared to other medications in the WHO database. Literature: A case report entitled: (Anterior uveitis following COVID vaccination: a summary of cases from global reporting systems). It reported two cases of patients who developed anterior uveitis following the Moderna COVID-19 vaccine.<br>Conclusion: The weighted cumulative evidence identified from the causality assessment of the reported cases, and literature are sufficient to support a causal association between Elasomeran and the risk of uveitis. Health regulators and health care professionals must be aware of this potential risk and it is advisable to monitor any signs or symptoms in treated patients. | عبدالعزيز العقيل<br>(Abdulaziz alakeel) | 23nd ISoP Annual Meeting | 2024 |

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| 4 | Review of Camels Drugs Registered in SFDA and Their Administration in Practice | Background The dromedary camel (Camelus dromedarius) is a widely domesticated species in Gulf countries. Moreover, they are a source of a significant amount of meat, offal, and milk consumed by humans. Subsequently, mistreated camels' diseases could lead to undesired complications for the end consumer. Recently, there have been several conservation and breeding programs, as reported by the food and agriculture organization of the United Nations, that have improved the camels' health. However, international or regional programs still do not evaluate drug safety, efficacy, or the maximum residue limit (MRL).<br>Objective Reviewing the SFDA-registered drug for camels and their common practice of drug administration.<br>Method The search was conducted through SFDA registered vet drugs databases and electronic literature (PubMed and google scholar) with different combination of the following search terms: "camel", "diseases", "drug safety" and "drug efficacy" and applying inclusion and exclusion criteria to identify the publications of interest.<br>Result The scarcity of studies conducted on therapeutic drugs by the applicant targeting camels led to limited registration by SFDA. Compliance with such demand is challenging due to the value of the camel market globally. Currently, around 6% of total ruminant drugs registered at SFDA are for camels.<br>A pharmacological group of antibiotics is the focus of SFDA registered drugs, such as Albendazole, Chlortetracycline, and Ivermectin. Moreover, drugs approved for large ruminant species are administered in veterinary practice to camels despite the lack of clinical data on the latter's physiology. A prominent example of the risk associated with this practice is Ivermectin given as a subcutaneous injection being less effective in camels compared to other ruminants (Lanusse et al., 1997). Another case is that the benzylpenicillin injection site in camels will have residues of antibiotic compared to the other large ruminants, which has efficacy and safety concerns (Oukessou, 1995). In addition, this is evident across all practices involving antiparasitic, antibacterial, NSAIDs, and other drugs in camels. As suggested by Alquarawi et al., most of the undesired effects and variability are due to drug kinetics in camels varying from other ruminants.<br>Conclusion The registered camels drugs, mainly antibiotics, don't reflect demographic camel diseases and conditions. Moreover, drugs administration practices of camels as target species is highly questioned since most of the practice needs to be supported by studies. Subsequently, there is a lack of evidence based practices among veterinarians. The current drug administration practices need to be better understood; an evaluation of the safety and efficacy of current practices is encouraged, which can be timely and costly. We suggest conducting an evaluation based on a current veterinarian drug dosing and administration practices to provide evidence. Such an initiative could minimize the risk and create a more coherent practice, which would ensure public safety. | نورة بن يوسف (Nora M. Bin Yousef) | المؤتمر الدولي السادس للجمعية الدولية لأبحاث وتنمية الإبل "دور الإبل في الأمن الغذائي والنمو الاقتصادي" الأحساء The 6th Conference of the International Society of Camelid Research and Development | 2024 |
| 5 | Gas Chromatography-Tandem Mass Spectrometry Method for the Quantitative Determination of Ethylene Glycol and Diethylene Glycol in Paediatric Syrups | Ethylene glycol (EG) and diethylene glycol (DEG) are two contaminants that are known to be toxic to humans. These contaminants are mostly associated with glycerol, sorbitol, and polyethylene glycol-based drug syrups. In late 2022, World Health Organization issued a statement regarding cough and antihistaminic syrups that were found to contain toxic levels of EG and DEG in multiple countries, which resulted in serious injuries and fatalities among children. From an analytical standpoint, several methods of glycol analysis in pharmaceuticals have been reported in the literature, with the majority focusing on raw material analysis. We sought to develop and validate a selective method for evaluating a wide range of cough syrups in order to determine the safety of commercially available pediatric syrups on the local market. In this study, we present a method for determining EG and DEG using gas chromatography tandem mass spectrometry (GC-MS/MS), which has significantly higher selectivity than traditional single quadrupole gas chromatography mass spectrometry (GC-MS). The developed method complied with the current validation guidelines established by the International Council for Harmonisation. The method's selectivity was demonstrated by the absence of interfering peaks in both the unspiked cough syrup sample and the reference standard solutions. The calibration curves for EG and DEG were linear in the concentration range of 1-10 µg/mL. The detection limit for EG and DEG was 400 ng/mL, with a quantification limit of 1 µg/mL. The recovery values for both EG and DEG met the accuracy acceptance criteria. Furthermore, the developed method was successfully used to analyze pediatric syrups collected from the local market. | ( Yahya M. Alshehri) يحي الشهري | 34th International Symposium on Pharmaceutical and Biomedical Analysis (PBA 2024) | 2024 |

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| 2024 | 34th International Symposium on Chromatography – ISC 2024 | (Adnan AL-Mussallam) عدنان المسلم | In practice, ethanol-based perfumes consist of might contain 10 to more than 300 ingredients, which are known as a basic framework, fixatives, and solvents. So by conducting a non-routine testing of fragrance content in ethanol-based perfumes to evaluate their safety concerns by implementing Gulf standards GSO Safety Requirements for Cosmetics and Personal Care Products 1943/2016 and European regulations 1223/2009 as guidelines. Consequently, the safety risks associated with the fragrant ingredients utilized are questionable. Since perfumes are known to be skin sensitizers, but the frequency and concentration of ingredients may increase dermal sensitization. Exposure to perfume ingredients triggers sensitive skin, so assessing ingredients for skin penetration is crucial. Accordingly, a semi-quantitative approach is capable of providing a powerful tool to identify the volatile chemical constituents especially when coupled with mass spectrometry. Therefore, the GC-MS analysis was performed to identify a semi-quantitative approach in 140 ethanol-based perfumes in the Saudi market. The results demonstrate that the most common chemical constituents were volatile potentially allergenic substances, phthalates, synthetic musks, and other fixatives. To conclude, the results of tested 140 perfumes were the identification of more than 1400 volatile chemical constituents. Overall, the observation was that 95% of samples comply with the regulations under the prohibited fragrances annex. | The Role of Semi-Quantitative Approach in Identifying Fragrance Content in Perfumes | 6 |

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| 7 | Classification and Evaluation of Pre-Authorized Pharmacovigilance Agreements for Advanced Therapy Medicinal Products related Marketing Authorization Holders (MAHs): A Retrospective Observational Study | Classification and Evaluation of Pre-Authorized Pharmacovigilance Agreements for Advanced Therapy Medicinal Products related Marketing Authorization Holders (MAHs): A Retrospective Observational Study<br>Background:<br>The adoption of personalized therapies in medicinal production, as outlined by the SFDA, presents both opportunities and challenges in the realm of pharmacovigilance. The aim is to enhance patient safety and gain a better understanding of treatment outcomes. This involves various activities such as monitoring the safety and effectiveness of advanced therapy medicinal products, conducting long-term follow-up, conducting personalized risk-benefit assessments, generating real-world evidence, and ensuring compliance with regulatory standards. The most recent update to the Saudi GVP (Good Pharmacovigilance Practices) mandating Marketing Authorization Holders (MAHs) to establish pre-authorized pharmacovigilance agreements between relevant parties to ensure the proper implementation of pharmacovigilance activities.<br>Objective:<br>To classify the pre-authorized pharmacovigilance agreements according to the SFDA definition of advanced therapy medicinal products (ATMPs) and to evaluate the MAHs' response to the inspection team recommendation.<br>Method:<br>A retrospective observational study documenting various pre-authorized pharmacovigilance agreements was reviewed between March 2023 and March 2024. All submitted pharmacovigilance agreements were included to be classified into Advanced Therapy Medicinal Products related agreements where the Advanced Therapy defined as any of medicinal products for human use: Gene therapy, Cell-based medicinal product, and Combined ATMP products contain as an integral part of the product. The agreements were evaluated based on the approval status, the number of attempts, and the duration to approve the agreement.<br>Results:<br>A total of 75 pre-authorized pharmacovigilance agreements were examined; among them, 20% (15 agreements) were associated with Advanced Therapeutics-related Marketing Authorization Holders (MAHs). Of these 15 agreements, 53% (8) were successfully approved, with approval durations ranging from 1 to 137 days. The number of attempts this includes any revisions made in response to SFDA inquiries to secure approval for these agreements ranged from 0 to 4. The comments varied between there was no pharmacovigilance agreement submitted and no clarity on who will do the local pharmacovigilance activities to certain specifications like the accessibility to the global safety database and handling of local ICSR cases, the PSSF preparation and the accessibility to the global PSMF, signal screening, literature review, the external audit frequency.<br>Conclusion:<br>These findings emphasize the importance of addressing these concerns to strengthen pharmacovigilance practices. Clear guidelines and regulations are needed to ensure the submission and proper execution of pharmacovigilance agreements, the effective management of safety data, and compliance with international standards.<br>References:<br>1. Saudi Food and Drug Authority, V 3.1, January 2023. Guideline on Good Pharmacovigilance Practices (GVP). Riyadh: Saudi Food and Drug Authority: National Pharmacovigilance Center.<br>2. Saudi Food and Drug Authority, V 1, November 2023. SFDA Guideline on Classification of Advanced Therapy Medicinal Products. Riyadh: Saudi Food and Drug Authority: Drug sector. | (Amal Arafah)<br>امل عرفه | 23rd ISoP Annual Meeting | 2024 |

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| 8 | Potential Risk of Dry Mouth: Local Case Report Triggers Review of Levofloxacin Safety | Background:<br>The Saudi Food and Drug Authority (SFDA) plays a critical role in implementing Additional Risk Minimization Measures (aRMMs) for medicinal products in Saudi Arabia. To promote medication safety, the SFDA “Established 25 regional pharmacovigilance centers in different areas in Saudi Arabia. The purpose of establishing these centers is to improve the reporting culture of side effects, to reduce the risks associated with using medications and improve medication safety in Saudi Arabia.<br><br>Objectives:<br>Our initiative in cooperating with Regional Pharmacovigilance Officers (RPVOs) aims to improve the distribution and availability of aRMMs in local hospitals. Also, we aim to raise awareness about approved aRMMs, To improve the aRMMs implementation, and to communicate directly with Healthcare Professionals (HCPs).<br><br>Methods:<br>At the beginning of 2023, the SFDA conducted a meeting with RPVOs to explain to them the initiative's objectives. We have established three Key Performance Indicators: ensuring access to approved aRMMs by HCPs in the hospital, ensuring the availability of approved aRMMs in the hospital, and conducting one-to-one educational visits to HCPs to increase their knowledge and improve implementation of aRMMs. The Corrective actions were carried out in accordance with the desired outcomes.<br><br>Results:<br>The number of HCPs who received aRMMs experienced a significant rise, reaching 6,492 HCPs in 2023. This noteworthy increase can be attributed to the implementation of a monthly distribution system, wherein the approved aRMMs were transmitted electronically to the RPVOs via email.<br>Upon evaluation, it was determined that the availability of aRMMs in hospitals stood at about 70%. To enhance this figure in the future, we have initiated a corrective plan that involves redistributing aRMMs within hospitals and establishing direct communication channels between the Qualified Person Responsible for Pharmacovigilance in a pharmaceutical company and RPVOs to address any issues of missing aRMMs promptly.<br>Regarding educational visits, the RPVOs successfully conducted 100 visits to HCPs, surpassing the initial target by 100%. During these visits, HCPs found that aRMMs materials are useful and they expressed high satisfaction with the visits.<br><br>Conclusion:<br>Our project enhances HCP awareness of approved aRMMs at local hospitals as well as their accessibility and availability. Furthermore, Educational visits have been effective in enhancing healthcare professionals' understanding of aRMMs and they should be conducted more frequently. Further efforts are needed to improve the regular distribution of aRMMs by pharmaceutical companies. | (Aseel Alshayji)اسيل الشايجي | ISoP 2023 Annual Meeting | 2024 |

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| 9 | Visits to Healthcare Units to Raise Awareness and improve the Implementation of Additional Risk Minimization Measures (aRMMs) in Saudi Healthcare Settings | Introduction: The dissemination and implementation of aRMMs is crucial for enhancing medication safety.1 The Saudi Food and Drug Authority (SFDA), in collaboration with Regional Pharmacovigilance officers (RPVOs), initiated a project targeting healthcare providers (HCPs) across various governmental and private hospitals.<br><br>Objective: The project aimed to increase awareness and understanding of aRMMs, improve their implementation, promote adverse drug event reporting, and build communication channels with HCPs through educational visits.<br><br>Methods: The study employed a mixed-method approach, including pre- and post-educational visit surveys and discussions to evaluate HCPs recipients, knowledge and implementation of aRMMs. 28 RPVOs were trained in 2023 by SFDA to undertake the visits. HCPs completed the pre-visit surveys before the commencement of the sessions and the post-visit surveys immediately after. Knowledge was scored out of 5 and compared pre- and post-visit using Wilcoxon signed rank tests.<br><br>Results: RPVOs conducted 100 visits to the HCPs in 2023, the pre-visits surveys were filled by all HCP (100); however, only 79 responded to the post-visit surveys. The majority of HCPs were predominantly from pharmaceutical care (n=65), female and Saudi nationals (n=56 and n=80, respectively) with 5-10 years of experience (n=35). Prior to the visits, awareness of aRMMs was low, with only (36%) having heard of them and (35%) completely unaware. Few had visited the SFDA website for aRMMs (18%) or attended a lecture on aRMMs (17%). Though most prescribed/dispensed the relevant medications (78%), only (43%) knew they required aRMMs and (9%) provided patients with the materials. After the visits, 78 (98.7%) knew where to find approved aRMMs. Self-rated knowledge improved, with 54 (68.4%) rating understanding as greatly improved versus 20 (25.3%) rating it as adequate beforehand. A statistically significant increase in knowledge scores was observed between pre- and post-survey ($P < 0.001$). The median score increased from 4 (IQR: 3.5) to 5 (IQR: 4.5). 38 (48%) of participants demonstrated improved scores, 6 (8%) decreased, and 35 (44%) showed no change. The majority of HCP found the aRMMs materials very useful 48 (60.8%) and were highly satisfied with the awareness visit 40 (50.6%). Furthermore, 73 (92.4%) indicated willingness to accept future visits on aRMMs.<br><br>Conclusion: The educational visits significantly improved HCPs' understanding and use of aRMMs. The project identified areas for improvement, including more frequent visits, use of various educational and awareness methods, and technology integration (incorporating aRMMs into clinical systems). The findings support expanding such initiatives to ensure consistent aRMMs application in healthcare settings. | (Atheer Aldayel)<br>أثير الدايل | ISoP 2023 Annual Meeting | 2024 |

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| 10 | Immune Checkpoint Inhibitors and Overlap Syndrome of Myocarditis and Myositis or Myasthenia Gravis: Analysis of WHO VigiBase Database | Background<br>Immune checkpoint inhibitors (ICIs) have revolutionized the treatment of various malignancies. Despite their efficacy, ICIs may lead to the development of immune-related adverse events (irAEs). The overlap of irAEs, particularly the concurrence of dual conditions of myositis, myasthenia gravis, and myocarditis. Therefore, we used the WHO global database of individual case safety reports to understand clinical complexity of these cases.<br>Objectives<br>Describe concurrence of myocarditis and myositis or myasthenia Gravis associated with ICIs in VigiBase.<br>Methods<br>VigiBase was accessed on January 2023 and used to extract data for ICI-treated patients with myositis or myasthenia gravis reactions co-occurring with myocarditis. Patients were categorized into two groups: Single M (1M) of myositis or myasthenia gravis or myocarditis, and dual M (2M); which included patients with two adverse events of the three. The Pearson Chi-squared test, Wilcoxon rank-sum/ANOVA test, and log-rank test were used to compare categorical, continuous, and time-to-event data, respectively.<br>Results<br>A total of 1,623 patients with irAEs due to ICI therapy, 64% were male and 36% female, with a median age of 70. The majority fell into the age groups over 70 (628:50%). Most patients were on ICI monotherapy (74%). The most common cancers treated were lung cancer (471:33%). Myositis was the most prevalent condition (1199:74%), followed by myasthenia gravis at 589 (36%) and myocarditis at 255 (16%). Patients with only (1M) constituted (1,203:74%), while those with (2M) were (420:26%). Fatal outcomes were reported in (282:17.4%) of cases. The occurrence of myocarditis was exclusive to the 2M group, with a striking 61% prevalence, indicating a possible association between dual conditions and the development of myocarditis. Furthermore, there was a notable increase in myasthenia gravis cases in the 2M group (53%) compared to the 1M group (30%). While myositis was present in 86% of the 2M group, which was significantly higher than the 70% in the 1M group. Cases with 2M were more reported in renal cancer patients compared to those with 1M, at rates of 22% and 14% respectively. Conversely, lung cancer was less common in the 2M group (44%) compared to the 1M group (35%), with a statistically significant p-value of 0.005.<br>In 2M patients, there was a notable increase in fatal outcomes 56% of patients with a significant increase compared to 44% with 1M, p-value < 0.001.<br>Conclusions<br>This is the largest dataset demonstrating that duel M is associated with a significantly higher mortality than single M especially in cases with renal cancer. These data indicate the need to further study to identify temporal relationships, underlying risk factors, employ early immunosuppressive approaches to improve patient outcomes. | (Eman A. Alghamdi)<br>ايمان الغامدي | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

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| 11 | Pharmacogenomics-Pharmacovigilance Project: SFDA Experience | Background<br>Pharmacogenomics plays an important role in improving medication safety. The incorporation of pharmacogenomic data into pharmacovigilance activities has the potential to reduce the occurrence of adverse drug events (ADEs), thereby promoting patient safety.<br>Objectives<br>The Pharmacogenomics-Pharmacovigilance Project was conducted by Saudi food and Drug Authority (SFDA) to emphasizes the significance of pharmacovigilance in the identification of potential safety signals of pharmacogenomics related ADEs.<br>Methods<br>First, we have compiled a comprehensive list of products that are registered with the Saudi Food and Drug Authority (SFDA). These particular products contain CYP2C19*2 and CYP2D6 biomarkers, which have been determined to be the most prevalent among South Asians, including those in Saudi Arabia. 1 Second, we performed a drug labeling assessment regarding the effect of these biomarkers on risk of developing ADEs by cross-checking the product information approved by the U.S. Food and Drug Administration, European Medicines Agency, and the SFDA to exclude labeled ADEs related to the effect of pharmacogenetic markers on the safety of the products. Third, we conducted a comprehensive drug safety review of the unlabeled ADEs linked to the biomarkers of interest, utilizing various sources of evidence including unpublished clinical trials, literature, and local and global case reports and other relevant regulatory documents.<br>Results<br>A total of 36 registered medicinal products featuring CYP2C19*2 and CYP2D6 biomarkers were included in the project. Upon initial screening process, we reviewed all product information of these medicinal products and we found that the effect of pharmacogenetic markers were included in 21 local product information. However, we found lack of information in 11 local product information and as a result drug labeling update has been requested. Subsequently, 4 medicinal products in terms of the effect of pharmacogenetic markers underwent a comprehensive drug safety review. The outcome of these reviews yielded three recommendations for routine risk monitoring, However, for the last product, due to insufficient evidence, it was flagged for close signal without any regulatory actions.<br>Conclusion<br>The successful implementation of Pharmacogenomics-Pharmacovigilance Project by SFDA has led to enhanced identification and evaluation of potential safety signals/information related to biomarkers associated with medication use. | هدير (Hadir Aljohani) الجهني | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

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| 12 | Comprehensive Analysis of Pharmacovigilance Inspections Practices: Focus on QPPV Responsibilities in the Pharmaceutical Industry in Saudi Arabia. | Background: Pharmacovigilance is a critical component of pharmaceutical safety, it involves monitoring and assessing the safety of pharmaceutical products post-approval. The Saudi Food and Drug Authority (SFDA) regulates and ensures compliance with pharmacovigilance practices among Marketing Authorization Holders (MAHs) in Saudi Arabia. Objective: This study aimed to comprehensively analyze inspection findings among International MAHs, Regional MAHs, and Local MAHs and highlight areas of concern within the inspection topics of MAHs in Saudi Arabia.<br><br>Methods: A descriptive secondary data analysis was performed to examine inspection reports from the SFDA between January 2019 and December 2022. All MAHs submitted to regulatory inspections by the SFDA were included. The MAHs were categorized into three groups according to their countries of origin: International MAHs, Regional MAHs, and Local MAHs.<br><br>Results: The study analyzed 1122 inspection findings from 2019 to 2022, categorized based on severity and MAH type. International MAHs had the highest number [498, (46.7%)], with Major findings being the highest proportion in all [704, (62.7%)] MAH types. Additionally, management and signal management consistently emerged as a top inspection topic.<br><br>Conclusion: The analysis of MAHs and their inspection findings between 2019 and 2022 has revealed that international MAHs consistently reported higher inspection findings than regional and local MAHs. More inspection findings in regional MAHs than in local MAHs highlight the impact of regional guidelines, regulatory interpretations, resource constraints, and communication challenges on inspection outcomes. The lack of harmonization in pharmacovigilance systems between Saudi Arabia and neighboring countries further might contributed to major findings, emphasizing the need for alignment with global pharmacovigilance standards. Moreover, areas for improvement were identified, such as management and reporting adverse reactions. | (Hammad A. Al Dali) حماد الدالي | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepide miology (ISPE) Annual Meetings | 2024 |
| 13 | (CAR) T cell Immunotherapies and Potential association of Secondary T-Cell Malignancies | Background: Pharmacovigilance is a critical component of pharmaceutical safety, it involves monitoring and assessing the safety of pharmaceutical products post-approval. The Saudi Food and Drug Authority (SFDA) regulates and ensures compliance with pharmacovigilance practices among Marketing Authorization Holders (MAHs) in Saudi Arabia. Objective: This study aimed to comprehensively analyze inspection findings among International MAHs, Regional MAHs, and Local MAHs and highlight areas of concern within the inspection topics of MAHs in Saudi Arabia.<br><br>Methods: A descriptive secondary data analysis was performed to examine inspection reports from the SFDA between January 2019 and December 2022. All MAHs submitted to regulatory inspections by the SFDA were included. The MAHs were categorized into three groups according to their countries of origin: International MAHs, Regional MAHs, and Local MAHs.<br><br>Results: The study analyzed 1122 inspection findings from 2019 to 2022, categorized based on severity and MAH type. International MAHs had the highest number [498, (46.7%)], with Major findings being the highest proportion in all [704, (62.7%)] MAH types. Additionally, management and signal management consistently emerged as a top inspection topic.<br><br>Conclusion: The analysis of MAHs and their inspection findings between 2019 and 2022 has revealed that international MAHs consistently reported higher inspection findings than regional and local MAHs. More inspection findings in regional MAHs than in local MAHs highlight the impact of regional guidelines, regulatory interpretations, resource constraints, and communication challenges on inspection outcomes. The lack of harmonization in pharmacovigilance systems between Saudi Arabia and neighboring countries further might contributed to major findings, emphasizing the need for alignment with global pharmacovigilance standards. Moreover, areas for improvement were identified, such as management and reporting adverse reactions. | (Maha Alghamdi) مها الغامدي | المؤتمر الإقليمي - للجمعية الدولية لعلم الأوبئة الدوائية - الاسيوي Asian Conference on Pharmacoepid emiologys | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 14 | Proactive Safety Evaluation of antineoplastic Agents During Pregnancy: the SFDA Experience | Introduction<br>Chimeric Antigen Receptor (CAR) T- cell immunotherapies are approved by Saudi food and Drug authority (SFDA) for treatment of adult patients with refractory or relapsing large B-cell lymphoma, relapsed or refractory Follicular Lymphoma, adults with relapsed or refractory Multiple Myeloma, pediatric and young adult patients with B-cell Acute Lymphoblastic Leukemia.<br>Objectives<br>To evaluate the potential risk of secondary malignancies related to T-cells including T-cell lymphoma and leukemia, for the three SFDA approved CAR T-cell medicines: Ciltacabtagene Autoleucel (CARVYKTI®), Tisagenlecleucel (KYMRIAH®) and Axicabtagene Ciloleucel (YESCARTA®).<br>Methods<br>First, a systematic literature search was conducted from inception until January 2024, using PubMed, Google scholar, and Cochrane library and we also searched in Adis Insight database to include English publications and on humans that reported the targeted adverse event with the use of CAR T-cell medicines. In addition, searching the local adverse drug reactions database and World Health Organization (WHO) database was performed on January, 2024 via signal detection tool (Vigilyze) using the terms “Ciltacabtagene Autoleucel” OR “Tisagenlecleucel” OR “Axicabtagene Ciloleucel” (substance (WHO Drug) [AND] " T-cell lymphoma" OR “T-cell leukemia” (reaction preferred term (PT) (MedDRA). Then, the causality assessment of the cases was performed using the WHO-Uppsala Monitoring Center causality system.<br>Result<br>We found one case report of patient developed CAR T-Cell Lymphoma post CARVYKTI® therapy for relapsed refractory multiple myeloma. In addition, a phase I clinical trial was reported 2 cases of T-cell malignancies associated with use of CD19 CAR therapy. The search of WHO global database resulted in 12 cases as follows: T-cell lymphoma [(KYMRIAH® (n=5), YESCARTA® (n= 4), CARVYKTI® (n=2)], one case reported T- cell leukemia with YESCARTA®. Of them, 7 (58.3%) cases were females, 4(33.3%) males, and one with unreported gender. The patient’s age range in most cases was between 45 and 74 years old. All cases were classified as “serious”, most of them (60%) reported death outcome. Based on the WHO causality assessment of the included cases, 2(16.6%) cases were probably associated with medications use. However, the majority of cases (n=10, 83.3%) considered un-assessable due to lack of information such as time of onset, de challenge, and re challenge data. No local cases were reported to the SFDA.<br>Conclusion<br>The Available evidence suggests a potential association between secondary malignancies of T cell origin including T-cell lymphoma and leukemia with the use of CAR T cell immunotherapies. Further epidemiological studies are needed to assess this potential association. | (Manal Alruhami)<br>منال الرحيمي | ISPE's 16th Asian Conference on Pharmacoepidemiology | 2023 |

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| 15 | Standardized Approach to obtain Patients feedback on Risk Minimization Measures Shape and Content | Background:<br>Additional Risk Minimization Measures (aRMMs) are defined as interventions intended to prevent or reduce the occurrence of adverse reactions associated with the exposure to a medicine, or to reduce their severity or impact on the patient should adverse reactions occur. Saudi Food and Drug Authority has approved more than735 measures in Arabic and English languages directed to patients since 2015.<br>Objective:<br>To obtain patients' opinions and feedback about three aRMMs (patient guide) of semaglutide, ranibizumab and mycophenolate in regards to design, content and layout.<br>Methods:<br>A focus group discussion was conducted targeted patients who received patient guide of targeted medicines. These focus groups were conducted in collaboration with regional pharmacovigilance offices allocated in different hospital in Saudi Arabia. The focus group discussion was conducted by regional officers with help of SFDA staff. The questions were carefully designed to collect data on the effectiveness, clarity, design and content of the current aRMMs, as well as to gather suggestions for future improvement. Three medicines with patient guides were selected based on specific criteria, which is Seriousness of risk and the number of Generic products marketed in Saudi Arabia. After applying the criteria, the following products were chosen; semaglutide, ranibizumab and mycophenolate. Descriptive statistics were performed to represent demographic characteristics and patients' opinions using Microsoft Excel program.<br>Results:<br>A total of 60 patients participated in three focus group discussion conducted in three hospitals. The majority around 90% found that the Patient Guide is excellent, appropriate, and agreed that its appearance was clear and all instructions and medical terms are understandable, Also, the information provided can be followed obviously and easily. In addition, number of participants agreed that excess information is provided in the guide and briefing of information is preferable. However, 10% of participants stated that the medical terms were not clear. Also, more than 90% of participants agreed that the reporting of adverse drug reactions is clear and stated that the illustrations, size, font, and color were excellent, however, 7% of the participants stated that the font is small and reporting ADRs was not clear.<br>Conclusion:<br>Most pf patients are satisfied about design, content and layout of patients' aRMMs that approved by the SFDA. There are some suggestions should be considered such as simplifying the presenting of information, and preferably in short notes and use QR codes. Also, integrating electronic aRMMs through dispensing and prescribing hospital system is recommended. | (Naser Aljaser)<br>ناصر الجاسر | ISPE's 16th Asian Conference on Pharmacoepidemiology | 2024 |

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| 16 | Improving the Quality of Drug Safety Review Reports: the SFDA Experience | Background<br>Drug safety monitoring is essential for promoting patient safety in relation to medicine use and for safeguarding public health. However, one major challenge which was sometimes encountered is the substandard quality of drug safety review reports.<br>Objectives<br>Therefore, for the pharmacovigilance processes to be optimized, we developed a detailed checklist that guides drug safety assessors to seek and examine all available evidence and improve the quality of comprehensive drug safety review reports.<br>Methods<br>Using a combined approach, we utilized an introspective and expert-guided method to develop a new framework for developing drug safety review reports. We reviewed past drug safety review reports to identify quality issues as well as frameworks by other regulatory bodies. Input was also gathered from pharmacovigilance and pharmacoepidemiology experts regarding best practices in writing drug safety review reports. All these were carefully reviewed and used to draft checklist items for comprehensive drug safety review reports.<br>Results<br>The checklist outlines 10 required items for drug safety review reports as well as a detailed description of each item. Key quality items highlighted include Executive Summary, Background/Epidemiology, Methodology and Search Results (it should encompass an adequate description of the methodology, use of search keywords, adoption of Medical Dictionary for Regulatory Activities (MedDRA) terminology, comprehensive systematic search, and adherence to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines), Literature Evidence (should provide descriptions of study types ,objectives, methodology, and results interpretation, and identify major study limitations), Global and Local Cases Assessment (should cover the total number of cases retrieved and assessed with completeness score, patient demographics, assessment based on the World Health Organization (WHO) criteria, justification of chosen causality category, frequency of serious and fatal cases , and interpretation of the Information Component), comprehensive evaluation of Regulatory Submissions such as Periodic Safety Update Report , Screening of Other Regulatory Agencies' Action and proper interpretation of Bradford Hill Criteria for Causality Assessment. Language proficiency and proper use of citation engines should all be ensured.<br>Conclusions<br>The checklist is designed to mitigate inconsistencies and improve the quality of drug safety review reports, which will ultimately contribute to making the most informed regulatory decisions and optimize the regulatory decision-making process within the drug safety section | (Nouf Al-Fadel)<br>نوف الفاضل | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

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| 17 | Integrating Risk Minimization Measures of Medications into Hospital Information Systems: Insights from three Hospitals in Saudi Arabia | Background:<br>Additional risk minimization measures (aRMMs) are required for certain medications. These measures often consist of educational materials, such as printed brochures or alert cards, that inform healthcare professionals and patients on the key risks associated with the medication and actions necessary to minimize them. In Saudi Arabia, these materials are distributed through various channels, including printed dissemination or through e-mail. Here, we present an exploration of a regulatory initiative aimed at integrating medications' aRMMs into the Hospital Information System (HIS) in hospitals. The objective of this initiative is to enhance patient safety and improve the accessibility of aRMMs by directly incorporating them into Electronic Health Record (EHR) systems.<br><br>Objective:<br>To describe the collaborative initiative between the SFDA and three hospitals in Saudi Arabia to enhance awareness of risk minimization measures by integrating them into the HIS.<br><br>Methods:<br>We included all hospitals that participated in this regulatory initiative in Saudi Arabia and successfully integrated some or all of the approved additional risk minimization measures into their information systems.<br><br>Results:<br>Three hospitals have completed the incorporation of additional risk minimization measures into their internal HIS. In a tertiary care hospital in Riyadh, a dedicated portal has been developed to consolidate all aRMM information. This portal is seamlessly linked with the Electronic Healthcare Record (EHR) system, allowing prescribers to access aRMM details at the point of medication prescription. Upon prescribing a medication, an alert is generated and sent to the prescriber's email, notifying them that aRMM are applied to the prescribed medication. Simultaneously, a text message is sent to the patient, providing a direct link to educational material associated with the aRMM.<br><br>Furthermore, another tertiary care hospital in Riyadh incorporated aRMMs for Janus Kinase Inhibitors (Tofacitinib and Upadacitinib) into their EHR system. Instructions are displayed in the electronic system to the prescriber, along with the patients' materials. Additionally, a tertiary hospital located in Dhahran effectively integrated aRMMs by implementing prescribing alerts. Prescribers were required to acknowledge mandatory pop-up alerts when prescribing medications associated with aRMMs, ensuring their awareness and compliance with the risk minimization measures.<br><br>Conclusion:<br>The successful incorporation of aRMMs in the examined hospitals presents a promising framework that can be applied to other healthcare institutions, potentially yielding benefits in terms of patient safety and healthcare provider awareness. Nevertheless, the assessment of the impact of these digitalized measures on adverse reaction reduction and patient safety outcomes necessitates further research. | (Wed AlGhanna)<br>ود الغنام | ISoP Mid-Year Symposium 2024 | 2024 |

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| 18 | Potential Association of Syndrome of Inappropriate Antidiuretic Hormone Secretion with Olanzapine Use | Background<br>Olanzapine is an atypical Antipsychotic (AP) approved by Saudi Food & Drug Authority (SFDA) for the treatment of schizophrenia, moderate to severe manic episode, and for the prevention of recurrence of manic episode in patients with bipolar disorder.<br>Objectives<br>To evaluate the potential association of Olanzapine with the risk of Syndrome of Inappropriate Antidiuretic Hormone Secretion (SIADH) or hyponatremia as a part of class effect project conducted by SFDA.<br>Methods<br>We conducted a systematic literature search on January 2024, using several search engines, including PubMed, Embase, and Google Scholar for English studies on human investigating the association between Olanzapine and the risk of SIADH or hyponatremia. The search terms included ('atypical APs' OR 'Olanzapine' OR 'Zyprexa') AND ('hyponatremia' OR 'SIADH'). Moreover, a search was conducted in the World Health Organization (WHO) database "VigiBase" and in the local database of National Pharmacovigilance Center (NPC) to retrieve case reports up to March 2023. Then, the causality assessment of the cases was performed using the WHO-Uppsala Monitoring Center causality system.<br>Results<br>A total of 12 observational studies were identified. A significant association between atypical APs and hospitalization due to hyponatremia was reported in a case-control study (adjusted odds ratio: 1.32 [95% confidence interval (CI): 1.15–1.51]) and cohort (absolute risk increased by 0.06 % (95%CI: 0.02 to 0.10 %)) studies, one of which proposed SIADH effect. In addition, 9 published cases reported probable (N=1) and possible (N=8) association of Olanzapine with hyponatremia, 7 of which reported hyponatremia secondary to diagnosed SIADH. In VigiBase, 448 global cases were reported and 20 cases with the highest completeness score (CS) were assessed (CS=1); 6 were probably related, 7 possibly related, and 7 unlikely. No local cases were reported to the SFDA.<br>Conclusions<br>The available evidence suggests potential association of hyponatremia secondary to diagnosed SIADH with Olanzapine use. Further epidemiological studies are needed to investigate this potential association. | Shahad N. AlNasser<br>شهد الناصر | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

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| 19 | Determination of Sodium benzoate, Potassium sorbate, and Methylparaben in Herbal cough syrups by HPLC-UV | Herbal cough syrups have become increasingly popular natural alternatives to conventional over-the-counter medications, promising relief from cough and throat irritations with fewer synthetic components. Preserving these syrups is essential to guaranteeing their stability, safety, and effectiveness for the duration of their intended shelf life, just like with other liquid formulations. Preservatives are essential in reducing the possibility of microbial and bacterial growth contaminating these formulations and possibly endangering the consumer. However, their use is a double-edged sword: while essential for product safety, excessive or prolonged exposure to certain preservatives can pose health risks. Therefore, it is imperative to meticulously determine and keep the concentrations of these preservatives within permissible limits.<br>Sodium benzoate (NaB) is a food preservative, a stable, water-soluble sodium salt of benzene carboxylic acid (benzoic acid) with fungistatic and bacteriostatic effects. It has been used to preserve several foods and relative products, including flour, salad dressings, jams, carbonated drinks, fruit fillings and juices, cosmetics, and even pharmaceuticals. Although NaB has received GRAS (generally regarded as safe) status in many nations, the FAO/WHO expert committee on food additives has established acceptable limits of dietary intake of 0–5 mg/kg body weight. The consumption of beverages and/or carbonated drinks containing the preservative NaB has been linked with the development of behavioral deficits, including memory loss, motor impairment, and anxiety. Yetuk and his colleagues have followed an in vitro study in erythrocytes and reported evidence of oxidative stress with NaB.<br>Moreover, within the last decade, there have also been reports that the combination of benzoates and ascorbic acid (vitamin C), especially in drinks, was associated with the formation of benzene, a known carcinogen.<br>With its ability to effectively inhibit mold, yeast, and certain bacteria, potassium sorbate, the potassium salt of sorbic acid, is a widely used preservative in food, beverages, personal care products, and pharmaceuticals. It is considered safe and nontoxic at approved usage levels; as mentioned, it ensures product safety by extending shelf life and is generally recognized as safe for pharmaceutical use. However, while its preservative efficacy is well established, caution is advised in pharmaceutical applications due to potential concerns such as allergic reactions, drug interactions, and dose sensitivities that could arise with its use. The permitted dosage of potassium sorbate is 25 mg/kg body weight.<br>Methylparaben, also known as methyl parahydroxybenzoate, is a commonly used preservative in pharmaceutical preparations. Its use stems from its effective antimicrobial properties, particularly against fungi and some bacteria. Methylparaben is part of the paraben family, a group of chemicals widely used as preservatives in the cosmetic, food, and pharmaceutical industries. While methylparaben is considered safe at low concentrations, higher levels might increase the risk of toxicity. The latter can manifest as skin irritation or increased sensitivity, particularly in individuals predisposed to allergic reactions to parabens. Typically, the concentration of methylparaben in pharmaceutical preparations is limited to a maximum of 0.1-0.2%.<br>This study aimed to develop and optimize high-performance liquid chromatography (HPLC) methods for accurately analyzing and quantifying preserving agents in herbal pharmaceuticals. | (Thamer S. Alghamdi)<br>ثامر الغامدي | 34th International Symposium on Chromatography – ISC 2024 | 2024 |

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| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 20 | Detection of Gelatin Speciation, Heavy Metal Contamination and Fraudulent Labeling of Unregistered Dietary Supplements Available in Online Stores | Overview<br>Dietary supplements are widely used for filling nutritional gaps and promoting well-being, with gelatin from animal sources being a common capsule ingredient derived from collagen hydrolysis in slaughterhouses. This study focused on the detection of gelatin speciation, heavy metal contamination and labeling adulteration among unregistered vitamins and minerals sold directly to consumers online in Saudi Arabia. A descriptive cross-sectional study involved purchasing 84 vitamins and minerals samples. LC/MS-MS was employed for gelatin speciation analysis, with additional investigation into heavy metal contamination and label adulteration. 19 out of 66 gelatin-containing products were found to contain porcine gelatin. Some products lacked clear labeling for gelatin sources. Additionally, seven products showed elevated arsenic levels surpassing safety limits. The study underscores the importance of ongoing monitoring of online supplement sales to ensure consumer safety and product quality. Stronger regulations are necessary to ensure companies transparency regarding product labeling.<br>Introduction<br>Dietary supplements have become an indispensable aspect in modern life, offering a convenient and accessible way to fill nutritional gaps and promote overall well-being. The growing popularity of dietary supplements necessitates transparency and consumer awareness regarding their ingredients. Gelatin, a key capsule ingredient, is derived from animal sources, Pig skins and bovine hide and bones constitute the primary commercial sources of gelatin. In light of the religious dietary guidelines adhered by Muslims, Jews, Hindus, and other communities worldwide, it is essential to ensure that gelatin-derived food items are devoid of pork or beef components for some communities. The aim of this study is to detect gelatin speciation, heavy metal contamination and labeling adulteration in unregistered vitamins and minerals sold directly to consumers online in Saudi Arabia.<br>Methods<br>A descriptive cross-sectional study was conducted involving purchasing 84 products from a well-known website for healthy and natural products, these samples consisted of various vitamins and minerals in different forms. Liquid chromatography mass spectrometry (LC-MS/MS) was employed with Multiple Reaction Monitoring (MRM), for gelatin speciation. The method achieves detection of gelatin in mixtures with a validated Limit of Quantitation (LOQ) of 1% w/w. All samples underwent a heavy metals analysis for three toxic elements, Arsenic (As), Cadmium (Cd) and Lead (Pb) using ICP-MS. the safety limits were compared with established maximum limits set by GSO 193:2021 and USP 2016.<br>Results<br>The results indicate that among 66 gelatin-containing samples tested for porcine gelatin, 19 (28.8%) tested positive. Similarly, among the 66 samples tested for bovine gelatin, 24 (36.3%) were positive. Additionally, 6 (9%) of the samples were found to contain a mixture of both porcine and bovine gelatin. Regarding heavy metal analysis results indicated that all samples tested for Cd and Pb were within accepted limits, whereas seven products exceeded the maximum accepted levels for As (ranging from 1.6 to 23.24 mg/kg), surpassing safety limits set by USP 2016.<br>For labeling accuracy, the analysis revealed concerning inconsistencies. None of the 19 products containing porcine gelatin specified the source on the label, simply mentioning gelatin presence. Furthermore, two products labeled as "veggie capsules" were found to contain porcine gelatin.<br>Conclusion<br>These findings highlight the need for ongoing monitoring of online supplement sales to ensure consumer safety and product quality. Moreover, it is important to ensure companies to clearly disclose gelatin sources on product labels, particularly for consumers adhering to religious or dietary restrictions, thereby fostering transparency and facilitating informed purchasing decisions. | العنود الصقعبي<br>Alanoud Alsaqabi | التقدمات الأخيرة في تحليل الأغذية<br>Recent Advances in Food Analysis (RAFA) | 2024 |

# ملخصات مشاركات المؤتمرات

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| 21 | Treatment modification patterns of glucose-lowering agents in Saudi Arabia: A retrospective real-world data analysis | Aim: The growing number of antidiabetics has broadened therapeutic options, leading to heterogeneity in prescribing patterns. Studies identifying antidiabetics modification patterns are lacking in Saudi Arabia. Therefore, the aim of this study is to describe modification patterns in Saudi patients. Methods: Patients ≥ 18 years old with at least one antidiabetic between 2016 and 2022 were included. Follow-up started from the earliest to the last prescription. Two modification types were evaluated: “add-on,” prescribing new antidiabetics within a treatment episode, and “switching”, starting a new treatment episode after the preceding ends. Descriptive statistics were used to characterize patients and estimate events proportions. Results: Of 122,291 patients, 47.2 % had treatment interruption or modification, totaling 303,781 events. Interruptions accounted for 54 %, add-on for 11 %, and switching for 35 %. The median time to first event was 159 days. The most add-on included dipeptidyl peptidase-4 inhibitor (DPP-4) inhibitors to biguanide and sulfonylurea (8 %), and sulfonylurea to biguanide (8 %). Among 106,405 switching events, 23 % shifted from dual to monotherapy and 17 % from monotherapy to dual therapy. Conclusion: Nearly half of patients experienced modifications or interruptions, with notable shifts between monotherapies and dual therapies. These findings highlight the evolving landscape of treatment patterns in Saudi Arabia and guide future research and decision-making. | الها الفاخري Almaha Alfakhri | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |
| 22 | Hospitalization Endpoint in Clinical Trials of Outpatient Settings: using Anti-SARS-COV-2 Therapy as an Example | Abstract<br>Purpose<br>In response to the COVID-19 pandemic, the World Health Organization (WHO) developed a set of outcome measures for trials primarily aimed at hospitalised patients. However, a gap exists in defining outcome standards for non-hospitalised patients. Therefore, this study aims to discuss hospitalisation as a primary outcome in outpatient trials and its potential pitfalls, specifically focusing on trials related to anti-SARS-COV-2 therapy.<br>Methods<br>In this narrative review, researchers thoroughly searched MEDLINE and ClinicalTrials.gov from January 2020 to December 2022, targeting Phase III randomized controlled trials involving outpatients with mild-to-moderate COVID-19. The trials were specifically related to anti-SARS-COV-2 monoclonal antibodies or antiviral agents. The study collected essential data, including the type of intervention, comparator, primary objective, primary endpoint, and the use of estimands in the trial.<br>Results<br>The search identified 12 trials that evaluated the efficacy of anti-SARS COV-2 therapies in a predefined population. Three studies used hospitalisation and death as primary endpoints in high-risk patients receiving monoclonal antibodies. Nine studies assessed the efficacy of several antiviral agents: four trials used hospitalisation and death as the main endpoints, while others used different measures such as virologic measures using the Reverse Transcription-Polymerase Chain Reaction test (RT-PCR), the eight-point WHO ordinal scale, symptom alleviation by Day 7 and time to clinical response.<br>Conclusion<br>Choosing hospitalization as an endpoint may provide meaningful data such as the cost-effectiveness ratio of a drug. However, different hospital utilisation patterns and investigator decisions could bias clinical outcomes if no specific criteria are considered. Therefore, investigators should have clear criteria for determining variables that influence this measure. | الهنوف يوسف (Alhanouf Yousef) | The 2024 International Forum on Quality and Safety in Healthcare | 2024 |

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| 23 | Descriptive Analysis of Good Clinical Practice Inspection Findings from the Saudi Food and Drug Authority | Abstract<br>Introduction<br>Good clinical practice (GCP) inspections are carried at the Saudi Food and Drug Authority (SFDA) to ensure clinical trial integrity and to protect the rights, safety, and welfare of study participants, and to ensure trials are conducted in compliance with GCP and applicable laws. This study is the first report form the department of clinical trials at the SFDA.<br>Objectives<br>The aim is to describe GCP findings from inspected sites by the SFDA. And to discusses the results and their implications in comparison to international counterparts, and reflect on the results with recommendations for investigators to improve clinical trial conduction in Saudi.<br>Methods<br>Retrospective review of inspection information. Two senior independent inspectors reviewed, gathered and categorized the data. Categorical variables are summarized using descriptive statistics by frequency distributions.<br>Results<br>A total of 131 GCP inspections were performed between 2017 and 2023. There was a total of 722 observation from 116 (88.5%) inspection visits, and the remaining 15 (11.5%) inspection visits had no observation. The highest number of visits were conducted in contract research organization (CRO) (n=50; 38.2%) with 118 observations, followed by clinical investigator site (n=46; 35.1%) with 313observations, then bioequivalence center (BE) (n=33; 25.2%) with 256 observations, and the last 2 (1.5%) visits were conducted in phase I clinical trials units with 35 observations.<br>Conclusion<br>This study assesses GCP inspection reports and analyzes the type of deficiencies and grades in each area. There are noted differences between the respective conductor and related sited-observations. The recommendations given are guided by top most common findings to assist researchers and sponsors when conducting a clinical trial in Saudi Arabia.<br>Some of the recommendations include a) spread awareness among researchers and clinical trial teams, b) engage patients in clinical trials for increased awareness, c) to increase clinical research training courses for research members, d) advocate for collaboration between academic institutions and pharmaceutical industry and health institutions, e) quality improvement projects to enhance study site ecosystem, and f) engage or connect stakeholders in initiatives to improve research in Saudi.<br>Keywords: Clinical trial, regulatory, inspection, investigation, good clinical practice, Saudi Food and | أميمة عرب<br>(Omaima O. Arab) | Society of Clinical Research Associates | 2024 |
| 24 | Aflatoxins in food products consumed in the Kingdom of Saudi Arabia: A preliminary dietary risk assessment | Aflatoxins (AFs) are hepatotoxic, mutagenic, genotoxic, and immunosuppressive toxins. Several food commodities consumed in the Kingdom of Saudi Arabia (KSA) are susceptible to AF contamination because of improper storage practices and the warm and humid climate of the country. Therefore, the occurrence of AFs in 2388 food samples was measured and the estimated daily intake (EDI) of AFs in Saudi adults was assessed. The risks of AFB1 exposure were characterized using the margin of exposure (MoE) approach and by estimating the number of possible hepatocellular carcinoma (HCC) cases in the KSA. The results revealed that 12.1% of the analyzed samples were contaminated with AFs and the highest concentration of total AFs was observed in the nut and seed group. The mean EDI of AFB1 was estimated to be 0.21 and 0.55 ng/kg body weight (bw)/day for the lower bound (LB) and upper bound (UB) scenarios, respectively. The MoEs were estimated to be 1902.4 and 722.1, while the estimated liver cancer risk ranged from 0.002 to 0.008 cancer cases/year/100,000 persons. Based on the study's findings, contamination with AFs in the KSA is low; however, AFs are considered potent genotoxic contaminants, and therefore, exposure through food should be kept as low as possible. | الأمير جمانه<br>(Jumanah Alamir) | World Public Health Nutrition Congress 2024 | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 25 | NMR-based metabolomics study to validate fingerprint of different Saudi Honeys | Honey is a natural, agricultural product produced by bees from nectar of valuable nutritional and pharmacological value. Cultural and religious traditions value honey in Saudi Arabia for its exceptional health and medicinal benefits, making it an indispensable part of the main diet. In terms of fraud, it is one of the most vulnerable foods. Therefore, honey quality and authenticity are critical to address. The quality of the product depends on its purity, while authenticity depends on correctly labeling the botanical and geographical origin of the product. In literatures, metabolomics approach applied for the purpose of evaluation the quality, authenticity, adulteration, therapeutic nature, and nutritional levels of honey products as well as other agricultural products. The novelty of this work was conducted by performing metabolomics studies using NMR and chemometrics in Saudi honey. This has been established by applying both 1D and 2D NMR-based metabolomics to validate Saudi honey's botanical and geographical origin. The study revealed that 27 metabolites varied significantly across different honey species, while only five varied across regions. These results confirmed some of the quality, medicinal, and nutritional value of Saudi honey as well as validation of the botanical sources and geographical regions of the honey samples. Species classification is more informative than geographical location for identifying honey quality, indicating significant variation within species than across regions.<br>This discovery under SFDA is significant for honey consumers, as it indicates that honey quality is more variable within species than across locations. Our findings will help promote the production and marketing of local honey, which will encourage local beekeepers to increase their production of honey species that possess therapeutical and nutritional benefits. The primary results of this study will serve as the basis for guiding the methodology for future investigations of honey authenticity to build a robust Saudi Honey Database. | د. سمية المبيض (Somaiah Almubayedh) | RAFA 2024 11)th International Symposium on RECENT ADVANCES IN FOOD ANALYSIS) | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 26 | The Silent Threat Antimicrobial-Resistant Pathogens In Food Producing Animals And Their Impact On Public Health | The emergence of antimicrobial resistance (AMR) is a global health problem without geographic boundaries. This increases the risk of complications and, thus, makes it harder to treat infections, which can result in higher healthcare costs and a greater number of deaths. Antimicrobials are often used to treat infections from pathogens in food-producing animals, making them a potential source of AMR. Overuse and misuse of these drugs in animal agriculture can lead to the development of AMR bacteria, which can then be transmitted to humans through contaminated food or direct contact. It is therefore essential to take multifaceted, comprehensive, and integrated measures, following the One Health approach. To address this issue, many countries have implemented regulations to limit antimicrobial use. To our knowledge, there are previous studies based on AMR in food-producing animals; however, this paper adds novelty related to the AMR pathogens in livestock, as we include the recent publications of this field worldwide. In this work, we aim to describe the most critical and high-risk AMR pathogens among food-producing animals, as a worldwide health problem. We also focus on the dissemination of AMR genes in livestock, as well as its consequences in animals and humans, and future strategies to tackle this threat. | د. عايض المنصور (Ayidh ALMansour) | The 18th Congress of the International Union of Microbiological Societies (IUMS 2024) | 2024 |
| 27 | Reflections on the Saudi FDA Regulatory Experience With Smart GxP Inspections | Smart GxP inspections have gained increasing attention due to the COVID-19 pandemic, which, understandably, made it challenging for regulatory authorities to conduct on-site inspections. Smart GxP inspections are an oversight approach developed by the SFDA to enable remote compliance assessments of establishments. In this type of inspection, appropriate technical methods and tools (such as livestreaming video) are used without requiring the presence of inspectors onsite, ensuring efficient utilization of resources and the efficiency of inspection process. The objective of this research is to examine and document the shared encounters involving remote inspections and evaluations carried out by SFDA from 2020 to 2022. This will be achieved through the evaluation of the accuracy of document evaluation and the extent to which the objectives of smart GxP inspections were met. Data were collected from local and international smart inspections reports conducted by SFDA between 2020 and 2022, covering medical device manufacturers, pharmaceutical manufacturing sites, warehouses, accreditation offices, scientific offices, and food manufacturing facilities. The results indicate that smart GxP inspections were effective in achieving visit objectives, showing a high degree of document evaluation accuracy. The findings of this study support the use of smart GxP inspections as a valuable alternative to on-site inspections, offering a practical solution to regulatory compliance during the pandemic and beyond. Although the SFDA recognizes the usefulness of smart inspections in upholding regulatory oversight in the face of various challenges, it does not endorse the complete replacement of conventional on-site inspection methods. The SFDA acknowledges significant limitations associated with the current technological resources used in remote regulatory assessments, and these limitations will be explored in the relevant sections. | د. علي الحميدان Dr. Ali Alhomaidan | المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe | 2024 |
| 28 | Utilizing NMR and MS based Metabolomics Approaches for the Detection of Adulteration within the Tallow Product | Food adulteration is a practice that involves intentionally diminishing the quality of foods by substituting high-quality ingredients with cheaper alternatives for maximizing profits. There is an increased awareness of adulteration of tallow using vegetable oils whose detection requires precise analytical methods. In this study we have utilized nuclear magnetic resonance (NMR) and liquid chromatography-mass spectrometry approaches to establish the standardized spectra of pure tallow and pure samples of common adulterants such as coconut oil, palm oil, and lard, as well as tallow containing varied percentages of these adulterants, and have thus identified the unique fingerprint regions and lipid compounds of both pure and adulterated produce. In addition, we also provide PCA statistical analysis of the NMR data to clearly show similarities and differences between the studied samples. Thus, we have identified standard biochemical signatures of pure and spiked tallow providing benchmark data for identification of these adulterants. | د.هبة الحربي (Hibah S. Alharbi) | The 2024 AOAC INTERNATIONAL Annual Meeting & Exposition | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 29 | Determination of pesticide residues in leafy vegetables and dietary risk assessment | The consumption of leafy vegetables has increased worldwide due to increasing consumer awareness of their nutritional value. Consumers are likely at risk of consuming pesticides since leafy vegetables are often consumed raw. This research aimed was to assess the potential health risks using Saudi Food and Drug Authority (SFDA)inspection and monitoring program data. In this study the risks of pesticide residues from the consumption of leafy vegetables (watercress, spinach, mallow, vine leaves, and lettuce) by Saudi adults were assessed, these crops were selected based on data availability. The health risk was evaluated in both terms: the acute health risk was based on the estimated short-term intake (EST) assessment for a single commodity over 24 hours. Cancer and noncancer (long-term risk) calculations for hazard quotient (HQ) and incremental lifetime cancer (ILCR) depend on the estimated daily intake (EDI). The results showed that the acute risks related to consuming of lettuce, spinach, and watercress were within the safe limits for biphenyl, cypermethrin, linuron, methomyl, oxadiazon, and pendimethalin. Regarding the cancer risk, the ILCR was between 1.30E-06 and C 3.38E-04. For the noncancer risk, the HQ was ranged from 1.3E-2 to 6.76 E-4, and the hazard of cumulative risk was less than1. Based on the obtained results for chronic and nonchronic risk, values complied with acceptable limits, indicating that there is no hazard associated with the consumption of tested leafy vegetables for the Saudi population. | راكان العجمي (Rakan S. Al-Ajmi) | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

# ملخصات مشاركات المؤتمرات

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| 30 | Indapamide-Induced Rhabdomyolysis: A Retrospective Analysis of Electronic Health Records | Background:<br>Post-marketing reports have been generated suggesting a potential association between indapamide use and rhabdomyolysis in patients with hypertension or congestive heart failure; especially those with abnormal potassium blood levels. However, and to our knowledge, a study to assess this association has not been published yet.<br>Objectives:<br>To evaluate the association between indapamide and rhabdomyolysis in patients with hypertension and/or congestive heart failure.<br>Methods:<br>This was a case-control study conducted in patients with hypertension and/or congestive heart failure between July 1,2016, and December 31,2022. The study data were extracted from the Saudi National Pharmacoepidemiologic Database (NPED) at the Saudi Food and Drug Authority (SFDA). The NPED hosts the standard data of electronic health records from the three tertiary health care regional institutions. Patients who had a record of rhabdomyolysis (cases) were matched to four controls based on age, gender and date. Rhabdomyolysis was ascertained based on the recording of a creatinine kinase level > 1,000 U/L. The odds of exposure to indapamide within three months before the case/control identification, i.e., current users, was co compared between the case and control groups. The odds of the indapamide exposure were also compared between the two groups up to six months, i.e., recent users, and six months, i.e., former users, before the case/control identification date. The analyses were conducted using a multivariable conditional logistic regression models adjusting for the potential confounding variables. Sensitivity analyses were conducted to restrict the analysis on patients with only hypertension. All analyses were conducted using RStudio 1.2.5033.<br>Results:<br>A total of 2,965 cases and 11,860 controls. The odds of the current exposure to indapamide were comparable between the case and control groups (adjusted odds ratio [AOR]: 0.3; 95% confidence interval [CI] 0.11 - 0.20). The recent users showed AOR of 0.2 (95% CI: 0.11 - 1.00). Additionally, the former users demonstrated an AOR of 0.2 (95% CI: 0.06 - 0.44). In the sensitivity analysis, the current exposure to indapamide in patient with hypertension showed AOR of 0.04 (95% CI: 0.00 - 0.44). Lastly, for the former users with hypertension presented AOR of 0.11 (95% CI: 0.07 - 0.18). The various sensitivity analyses yielded similar results.<br>Conclusions:<br>In this study, we did not find association between indapamide use and rhabdomyolysis regardless timing of exposure. | رسيل الربع<br>Raseel A. Alroba | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 31 | Reviewing and Improving Legislations to tackle Antimicrobial Resistance | Introduction: Antimicrobial Resistance (AMR) is a global health threat caused by the widespread use of antimicrobials, which leads to microbes developing defense mechanisms against them. AMR emphasizes the need to implement a One Health approach to tackle AMR nationally and international. Action plans from drug regulatory agencies to tackle AMR have been implemented to minimize its spread, maintain the effectiveness of available antimicrobials, and support the development of new antimicrobials.<br>Aim: This study aims to review and improve the currently implemented national legislations to tackle AMR based on national data of antimicrobial use among food-producing animals and in alignment with international drug regulatory agencies in order to minimize global AMR spread.<br>Method: This is a literature review study of international drug regulatory agencies action plan to tackle AMR, taking into consideration, the national data of antimicrobial use among food-producing animals.<br>Result: The results showed that some antimicrobials classified as highly important with limited or no alternatives to treat serious infections in human are still being used in food- producing animals locally.<br>Discussion: To address the control use of antimicrobials, the study proposes a new classification system for veterinary antimicrobials as prohibited, restricted, and accessible. These classifications were based on the national data on antimicrobial use in food-producing animals and international categorization of antimicrobial importance for human and animal health.<br>Conclusion: Establishing a one health approach is needed to limit the spread of antimicrobials resistance among humans and animals. National and international actions need to be taken into consideration to maintain the effectiveness of currently available antimicrobials and develop new antimicrobials to tackle the antimicrobial resistance problem. | سارة التميمي (Sarah A. Altamimi) | المؤتمر الآسيوي السادس عشر لعلم الوبائيات الدوائية (ISPE's 16th Asian Conference on Pharmacoepidemiology (ACPE16) | 2024 |
| 32 | Titanium dioxide (TiO2) in herbal and health products registered by Saudi Food and Drug authority (SFDA: Descriptive study | Background: Titanium dioxide (TiO2) is a brightening compound used as an additive in food and pharmaceuticals. TiO2 safety has been debated since evidence of carcinogenicity and genotoxicity emerged. While TiO2 is provisionally used as food additive by North America, it is banned by European Union (EU) countries and Saudi Arabia. There are no international regulations regarding TiO2 as an additive in medicinal, herbal or health products. In this study, the primary objective is to identify the percentage of herbal and health products containing TiO2 among all Saudi Food and Drugs (SFDA) newly registered products during the period from 2018 to 2022. A secondary objective is to describe products containing TiO2 according to product type, pharmaceutical form, registration year and manufacturing country. Methods: This study is a retrospective secondary data analysis using data derived from SFDA electronic products registration records (EURS) and drug management system (DMS). Descriptive analysis is conducted to describe the percentage of herbal and health products containing TiO2 among all SFDA- newly registered products during the period from 1st, Jan 2018 to 31st, Dec 2022. Results: One third [N:115, (31%)] of herbal and health products contain TiO2. Most TiO2-containing products were found in capsule pharmaceutical form [97 out of 115 (84%)], with significant statistical correlation (P=0.02). TiO2-containing products registration has peaked in 2020, then declined afterwards. Most products are provided by USA manufacturing companies, Spain and local companies, collectively. Conclusion: One third of newly registered herbal and health products contain TiO2, of which market availability may be affected in case of restrictive regulatory actions. USA and local manufacturing companies are leading contributors to TiO2-containing herbal and health products registered by SFDA. Exploring alternatives for TiO2 and TiO2-free products is needed. | سلوى المؤمن Salwa Almomen | المؤتمر السادس والأربعون للجمعية الأوروبية للتغذية السريرية والأيض 46th ESPEN Congress | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 33 | Lower Limb Amputation association with SGLT-2 inhibitors: Systematic Review and meta-analysis | Introduction:<br>Sodium-Glucose Cotransporter-2 Inhibitors (SGLT-2i) were approved for management of type II Diabetes Mellitus (DM II), heart failure, and chronic kidney disease. In patients with DM II, positive association of Lower Limb Amputation (LLA) among diabetic patients was shown in many meta-analysis studies but were highly sensitive to the exclusion of CANVAS Program studies. In non-diabetic patients, there were few Randomized Controlled Trials (RCTs) that reported LLAs but did not indicate a significant association.<br>Objective:<br>To conduct a comprehensive systematic review and meta-analysis of RCTs to assess association of SGLT-2i and the risk of LLA regardless of the indications.<br>Methods:<br>We performed a systematic search within CENTRAL, PubMed, Embase, and Google scholar databases from inception to April 31st, 2024. RCTs comparing SGLT-2i to placebo or active control were included. The primary outcome was incidence of LLA. Two authors extracted the data independently from each eligible study then crosschecked. Any discrepancies were resolved by consensus. Publication bias was assessed using forest plot. Comprehensive Meta-Analysis software (version 3.0) was used for analysis.<br>Results:<br>A total of 20 studies reporting LLA were included. Most studies reported a follow-up period of 6 months to 4 years. Due to high heterogeneity (I2>50%), a random effect meta-analysis model was performed. No significant difference in incidence of LLA between SGLT-2i users compared to the control groups regardless of the indication (OR, 1.26 [95% CI, 0.98-1.6]). In addition, the stratification by diabetes status; diabetic (OR, 1.32 [95% CI, 0.99-1.79]) versus non-diabetic (OR, 1.07 [95% CI, 0.77-1.49]) yielded similar results.<br>Conclusion:<br>No significant difference in the incidence of LLA between SGLT-2i users and non-users was observed. The positive associations shown in previous studies were highly sensitive to the exclusion of CANVAS program studies that lack adjudication committee for LLA assessment. Due to limited studies included, results in non-diabetic patients should be interpreted with caution. | عبدالعالي المطيري<br>(Abdulaale Almutairi ) | ISPE's 16th Asian Conference on Pharmacoepidemiology | 2024 |
| 34 | Comprehensive Analysis of Pharmacovigilance Inspections Findings: Focus oninspection Topics in the Pharmaceutical Industry in Saudi Arabia | Introduction: Pharmacovigilance is a critical component of phar maceutical safety, it involves monitoring and assessing the safety of pharmaceutical products post-approval. The Saudi Food and Drug Authority (SFDA) regulates and ensures compliance with pharma covigilance practices among Marketing Authorization Holders (MAHs) in Saudi Arabia.<br>Aim/Objective: This study aimed to comprehensively analyze inspection findings among International MAHs, Regional MAHs, and Local MAHs and highlight areas of concern within the inspection topics of MAHs in Saudi Arabia.<br>Methods: A descriptive secondary data analysis was performed to examine inspection reports from the SFDA between January 2019 and December 2022. All MAHs submitted to regulatory inspections by the SFDA were included. The MAHs were categorized into three groups according to their countries of origin: International MAHs, Regional MAHs, and Local MAHs.<br>Results: The study analyzed 1122 inspection findings from 2019 to 2022, categorized based on severity and MAH type. International MAHs had the highest number [498, (46.7%)], with Major findings being the highest proportion in all [704, (62.7%)] MAH types. Additionally, management and signal management consistently emerged as a top inspection topic.<br>Conclusion: The analysis of MAHs and their inspection findings between 2019 and 2022 has revealed that international MAHs con sistently reported higher inspection findings than regional and local MAHs. More inspection findings in regional MAHs than in local MAHs highlight the impact of regional guidelines, regulatory inter pretations, resource constraints, and communication challenges on inspection outcomes. The lack of harmonization in pharmacovigi lance systems between Saudi Arabia and neighboring countries further might contributed to major findings, emphasizing the need for alignment with global pharmacovigilance standards. Moreover, areas for improvement were identified, such as management and reporting adverse reactions | عبداللطيف العتيبي<br>(Abdullatif alotaibi) | 23nd ISoP Annual Meeting | 2024 |

# ملخصات مشاركات المؤتمرات

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| 35 | Investigation of Suspected Cases of Food Poisoning In Riyadh Region Saudi Arabia between 2015 And 2018 | Objectives: This study aimed to analyze the presence of bacterial contamination in food samples in Riyadh region, Saudi Arabia, and to investigate the pattern of food poisoning outbreaks in the city. Materials and Methods: a total of 7897 food samples and swabs collected between 2015 and 2018, 1707 were analyzed for the presence of coliforms, Salmonella, S. aureus, and B. cereus. In addition, clinical data was collected from surveys of food poisoning case numbers and outbreaks in order to characterize the incidence rate and epidemiological characteristics of human food poisoning in Riyadh. The bacteria isolated from the food samples and swabs were initially identified according to the procedures described by ISO Standards and by AOAC Official Methods. Results: The data revealed that 7.4% of the analyzed samples were positive for the pathogens of interest in this study: Salmonella, B. cereus, and S. aureus (12.6%, 9.8%, and 3.4%), respectively. Overall, females were slightly more likely to experience food poisoning than males. There was a greater incidence of foodborne illness symptoms in the 20–49 age group, followed by the (1–4), (15–20), (more than 50) age groups. Additionally, food poisoning events were mostly caused by the following foods, poultry (n= 93), meat products (n= 45), rice (n= 38), vegetables (n= 36), and salads (n= 30) and unclassified food (n= 67). Most cases of food poisoning occurred in June, followed by April (n=24), August (19), September (17), October (17), July (15), March (14), November (14), December (14), May (13), Feb (12) and January (9).Conclusions: The study revealed a lack of published information on regional foodborne diseases and thus a need to review the systems used to investigate and monitor foodborne disease outbreaks so as to minimize gaps between surveillance systems and the follow-up of food poisoning cases. | عبدالله العجلان (Abdullah Alajlan) | IUMS2024 | 2024 |
| 36 | Retrospective Observational Study on Real-World Adult Patients with Bipolar Disorder: Demographic, Comorbidity and Drug Prescription Profiles | Importance: Bipolar disorder (BD) is a chronic mental disorder that affects both adults and children worldwide; however, limited information is available in Saudi Arabia. Consequently, the aims of this study are (1) to identify the characteristics of patients diagnosed with BD in Saudi Arabia and (2) to evaluate the prescribing of medication during the first year after the initial prescription. Methods: This multicentre, retrospective, observational study used de-identified electronic health records (EHRs) for all adults (≥18 years) with newly diagnosed BD from 1 January 2015 to 31 December 2023, in outpatient or inpatient settings. The data were extracted from the National Pharmacoepidemiologic Database (NPED). Patients were identified using relevant ICD-10-CM diagnostic codes (F31.0-F31.9). Baseline demographic and clinical data were collected. Medication utilisation included mood stabilisers, atypical antipsychotics, antidepressants and benzodiazepines. Findings: A total of 1,348 patients with BD were included in the study (mean age 42.3 ± 16.0 years; 60.3% women; 80.8% BD Type I). Those in the 25-34- and 35-44-year age groups were the most common identified patients (25.4% and 18.5%, respectively). Medical comorbidities were present in 21.3% of the patients, with psychiatric comorbidities in 9.4%. Within the first year of diagnosis, 77.6% of the patients-initiated BD treatment. The most used medication classes were antipsychotics (87.8%), antidepressants (35.0%), benzodiazepines (28.3%) and mood stabilisers (21.4%). The most frequent treatment regimen was antipsychotic monotherapy (36.4%). The most frequently prescribed classes of drugs to the same patients were antipsychotic plus antidepressant (28.4%), with a significant gender difference (females, 30.7%, vs. males, 24.7%, p = 0.035). Regulatory Implication: The findings highlighted that antipsychotics were the most used medication class. However, there was a relatively low use of mood stabilisers, which is the mainstay of BD management. This finding corroborates with other real-world studies and highlights the need for the potential optimisation of prescribing practices for BD. | عمر البلوي Omar Albalawi | المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe | 2024 |

# ملخصات مشاركات المؤتمرات

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| 37 | The Risk of Hypokalemia in Patients Treated with Levetiracetam: A Comparative Cohort Study | Background: Although levetiracetam is an effective anticonvulsant drug with a positive benefit-risk profile, multiple cases of hypokalemia have been reported, following levetiracetam use, which may lead to serious cardiovascular complications, muscle weakness, Ileus disease, or renal failure. However, establishing causal relationship between levetiracetam and hypokalemia based on case reports might confounded by other therapies or comorbidities.<br>Objectives: To investigate the possible causal association between the use of levetiracetam and the development of hypokalemia using an active comparator approach. Considering the potential influence of class effects and if patients with drugs or conditions commonly associated with levetiracetam developed hypokalemia.<br>Methods: This was a retrospective cohort study using Real-world Evidence Research Network at Saudi Food and Drug Authority (SFDA) between 2016 and 2022. The cohort comprised adults (≥ 18 years old) who initiated either levetiracetam or carbamazepine (active comparator) and had no history of hypokalemia during the six months prior to initiation of either drugs. The index date was the first levetiracetam or carbamazepine prescription's date. Patients were followed until end of 2022, end of follow-up period (i.e. 6-months), death, loss of follow-up, or occurrence of hypokalemia. Study outcome definition was as ascertained based on diagnostic code (E87.6) or by serum potassium level (levels below 3.5 mmol/L). To control the measurable confounding factors, we employed a stabilized inverse probability of treatment weighting (IPTW) estimation in a Cox proportional hazards model.<br>Results: A total of 8,982 patients entered the study cohort, and their baseline characteristics were comparable between the two groups after IPTW adjustment. The incidence rate of hypokalemia was 303 cases per 10,000 patient-years in levetiracetam-exposed cohort compared to 57 cases per 10,000 patient-years among carbamazepine users. Patients exposed to levetiracetam had a higher hazard of hypokalemia, with an adjusted hazard ratio (HR) of 1.99 (95% confidence interval [CI], 0.88-4.49). By restricting hypokalemia definition to cases of moderate to severe hypokalemia we observed an adjusted HR of 2.17 (95% CI, 0.93-5.03). The different modeling assumptions in the sensitivity analysis yielded comparable results to the main analysis.<br>Conclusions: Our study found that risk of hypokalemia with levetiracetam cannot be ruled given the wide confidence intervals. Further studies with a larger sample size and different data source are needed to confirm our findings. | عهود المدني<br>Ohoud Almadani | المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings | 2024 |

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| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 38 | Can the pathogen Escherichia coli O157 spread in consumed meals within foodlaw? | Introduction:<br>STEC causes hemolytic uremic syndrome (HUS) to human andnormally associated with consumed food, particularly undercooked meat. Manycountries established microbiological criteria applied by food law to test and controlthe consumption of food matix against foodborne pathogens specially the mostwell-known strain of STEC, E. coli O157. However, some other countries did notinclude E. coli O157 and other important pathogens in their microbiological criteriawhich may lead to serious outbreaks.<br>Purpose:<br>Identify a relationship between food outbreaks and lack in foodmicrobiological criteria.<br>Methods:<br>Twenty microbiological criteria were intensively investigated. Thosecriteria are currently applied in fifty-three county. According to this studyapproximately only one third of food worldwide is controlled by microbiologicalcriteria. A number of foodborne outbreaks worldwide were positively or negativelylinked to microbiological criteria.<br>Results:<br>Out of the microbiological criteria tested in this study, fifteen (75%) applied E. coli O157 test to at least one food matrix related to meat products but not therest. All the evaluated microbiological criteria (100%) accepted prevalence of E. coli in two out of five replicates of tested food samples with maximum of 5x10 colonyforming unit (CFU) (with not further serotype identification). For example, Brazil andIndia' microbiological criteria do not require testing E. coli O157 in food matrix.Brazil and India are one of the biggest meat importers to Saudi Arabia market.According to Saudi Food and Drug Authority (SFDA), at least 6% of tested meatimported from Brazil and India are infected with E. coli O157. This is probably dueto the lack of Brazil and India' microbiological criteria in testing E. coli O157 in foodmatrix before export.<br>Significance:<br>There is a possible link between absence of testing E. coli O157 inmicrobiological criteria and existence the same pathogen in food matrix that publiclyavailable for consuming. | مشاري الهدلق<br>(Meshari Al Hadlaq) | IAFP confex | 2024 |

# ملخصات مشاركات المؤتمرات

| # | عنوان البحث (Title) | ملخص البحث ( abstact) | اسم الباحث المشارك ( Presnting Author) | الحدث العلمي (Scientific Event) | السنة Year |
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| 39 | Comprehensive Analysis of Pharmacovigilance Inspection Practices in the Pharmaceutical Industry in Saudi Arabia | Background: Pharmacovigilance is a critical component of pharmaceutical safety; it involves monitoring and assessing the safety of pharmaceutical products post-approval. The Saudi Food and Drug Authority (SFDA) regulates and ensures compliance with pharmacovigilance practices among Marketing Authorization Holders (MAHs) in Saudi Arabia. Objective: This study aimed to comprehensively analyze inspection findings among International, Regional, and Local MAHs and highlight areas of concern regarding the inspection topics of MAHs in Saudi Arabia. Methods: A descriptive secondary data analysis of SFDA inspection reports was conducted from January 1st, 2019, to December 2022 31st. All MAHs subject to regulatory inspections by the SFDA were included, focusing on initial routine inspections conducted as part of the MAH's first regulatory review. A total of 80 inspection visits were analyzed. MAHs were categorized based on their countries of origin: International, Regional, and Local MAH. Results: The study identified 1,122 inspection findings from 2019 to 2022, categorized by severity and MAH type. The results indicated a strong dominance of international marketing authorization holders (MAHs) in the market, accounting for 60% of the total distribution, and were primarily classified as major [704, (62.7%)] findings. A decreasing trend in the findings was observed from 2020 to 2022. International MAHs consistently reported most major findings, peaking in 2021, whereas regional MAHs showed variability with a notable decrease in major findings over the years. Local MAHs have fewer major findings, with [104, (9.3%)] peaking in 2022. Regarding inspection topics, managing and reporting adverse reactions emerged as a critical area alongside significant findings related to the Pharmacovigilance System Master File and the Qualified Person Responsible for Pharmacovigilance (QPRP). Areas such as Clinical Trials and Archiving showed minimal findings during the inspection. Conclusion: This study highlights significant disparities in inspection findings among MAHs from 2019 to 2022, noting an initial rise in major findings, particularly among international MAHs, followed by a decline by 2022. Key inspection topics, like pharmacovigilance practices, emphasize the need for robust systems to manage adverse reactions, focusing on the Pharmacovigilance System Master File and the QPRP. While some areas, had minimal findings, the study stresses the importance of continuous improvement in pharmacovigilance systems for patient safety. It calls for enhanced training and compliance measures across all MAHs to address deficiencies and ensure regulatory adherence, providing insights for stakeholders to improve pharmacovigilance and overall regulatory standards in the pharmaceutical industry. | ملاك المطيري Malak Almutairi | جمعية معلومات الأدوية Drug Information Association (DIA) | 2024 |
| 40 | Characterization of engineered titanium dioxide nanoparticles (TiO2 -NP) in selected food products | Titanium dioxide (TiO2), an E171 manufacturer-made food additive,is extensively utilised as a colourant in drug and a food products. Some studies showed that most of confectionary and food items contain inexplicable particles. The aim of this study is to determine the size and structure of TiO2 nanoparticles in different food products. Ten food samples, including coffee cream, white chocolate concentrate, frosting, gum, yoghurt candy, hard candies and chewy candies, were investigated for this purpose. The crystalline structure and particle size of TiO2 were determined by Powder X-ray Diffraction (PXRD) and Transmission Electron Microscopy (TEM).TEM images revealed that a few of the extracted nanoparticles had a rodlike shape, but most were spherical. Also, the size of the TiO2 particle had a wide distribution between 12 and 450 nm. Thus, to avoid human health risk, crucial factors such as size, and shape should be considered and regulated by food authorities. | نورة بنت محمد بن سعيدان Norah Mohammed BinSaeedan | 6th Edition of Euro-Global Conference on Food Science and Technology (FAT 2024) | 2024 |