ملخصات مشاركات المؤتمرات

#	عنوان البحث (Title)	ملخص البحث (abstact)	إسم المؤتمر	سنـــــة المشـــاركة	إسم الباحث المشـــــارك
1	Smoking prevalence, nicotine dependence, and intention to quit among cigarettes smokers	Introduction: Tobacco consumption remains a challenging issue to the global and public health that requires close monitoring of the spread of this epidemic and its impact. This study aims to assess the national prevalence and determinates of cigarette smoking and nicotine dependence in Saudi Arabia Methods: A cross-sectional national survey of a sample of 5148 of Saudi residents' ages 18 years or older was conducted through web-based-computer assisted telephone interviews. The two main measurements were current cigarette smoking status and nicotine dependence assessed using the Fagerstrom Test for Nicotine Dependence. Data was weighted by age, gender, and region to account for the different probabilities of selection. Descriptive and logistic regression analyses were used to assess cigarette smoking and nicotine dependence determinants Results: The national prevalence of cigarette smoking was 16.18% (95% CI:14.59-17.77) with 14.12% (95% CI:12.64-15.59) current daily smoking prevalence. Almost 72% of smokers started smoking before the age of 22 and 27% of smokers were highly dependent on nicotine. Having a smoker parent (AOR=1.84[95%CI:1.31-2.58], P < 0.001) or a smoker close friend (AOR=6.49[95%CI:3.89-10.81], P < 0.001) were significantly associated with being a smoker. Higher nicotine dependence level was significantly associated with early onset of regular smoking (ages<18) (AOR=2.71 [95%CI:1.38-5.34],P<0.001) and lower attempting to quit (AOR=0.51[95% CI:0.32-0.83],P<0.01) Conclusions: Cigarettes smoking and nicotine dependence are prevalent in Saudi Arabia. The study found the majority of smokers started regular smoking before the age of 22 and the early onset of smoking was associated with a higher nicotine dependence level. Restrict access to tobacco products to those below the age of 22 will help reduce smoking prevalence and lifetime addiction to nicotine. Key messages: Majority of smokers initiated smoking by the age of 21 and early regular smoking initiation was associated with higher nicotine dependence. Strategies to prevent initiation before the age of 21 will help prevent addiction to nicotine.	المؤتمر العالمي السادس عشر للصحة العامة 16th World Congress on Public Health (virtual)	2020	الجوهرة القباني Aljoharah Algabbani
2	Consumers' Behaviour and Awareness of Food Labelling in Saudi Arabia: A National Observational Study	Aim This research attempts to gain insight into consumers' behavior during grocery shopping and evaluate the level of knowledge of some essential dietary information among Saudis. Methods Data were collected using observation and face-to-face interviews (cross-sectional study). A convenience sample of adults aged 16 years and older was observed and surveyed at supermarkets in the administrative regions of Saudi Arabia. The observational method was specifically designed to increase the accuracy of the participant's behavior and interest when choosing a product. Moreover, a self-developed questionnaire was used to assess how often participants look at food labels and investigate the specific nutrient information most commonly viewed on nutrition labels. Results We found that about 65% of consumers assessed food products before purchase, whereas 35% did not view the product at all. Nearly half (47.5%) of those who checked products looked at the expiry date, whereas 19.2% only reviewed nutrition facts. Furthermore, there was a moderate level of dietary knowledge among consumers; on average, participants reported the correct definition of product labels. In addition, those who checked nutrient facts were more likely to report the correct definition of the product labels than those who did not check the products at all. Furthermore, we found no significant differences in knowledge between sociodemographic groups. Conclusion Our results suggest that Saudis' understanding of food product information is limited. Health promoters should aim to increase consumers' use of nutritional labels.	الاجتماع السنوي لجمعية تعليم الصحة العامة Society for Public Health Education (SOPHE) Annual meeting	2020	لولو المطيري Lulu Al mutairi

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3	Diabetic Patients' Post-marketing Experience of Using Blood Glucose Monitoring Devices	Introduction: Diabetes technologies such as Self-monitoring of blood glucose devices and Continues Glucose Monitoring devices are essential tools in diabetes care. Up to date, only few studies assessed diabetic patients experience when using glucose monitoring devices in Saudi Arabia. Objectives: This study explores the practices, attitudes related to glucose monitoring devices, and any reported side effects of using those devices. Methods: A cross-sectional online survey was conducted from the 1st of July to the 25th of September 2020. The survey link was sent to diabetic individuals through; emails and text messages. We targeted a convenience sample of 747 participants. The inclusion criteria were to target patients who are 18 years and above, diagnosed with Diabetes Mellitus, and used glucose monitoring devices. The survey consists of multiple-choice questions about demographical characteristics, practice and attitude, and post-marketing experience during the use of glucose monitoring devices. Results: A total of 848 completed surveys were recieved. More than 70% of the participants are diagnosed with type 2 diabetes. The primary reason to monitor the glucose levels among the participants was to response to the physician's request (60.6%). The most critical factors participants assured when buying glucose monitoring devices, or related accessories, are the test strip quality (57.3%) and the test strip price (43.1%). Only three side effects were reported, including pain caused by needle prick (15.4%), skin infections (3.8%), and bleeding caused by needle prick (1.5%). Conclusion: The study findings reveal that different aspects to the use of glucose monitoring devices require improvements, especially the factors related to increase the awareness of diabetic patients in selecting the device type, and the recognision of the best practice to achieve the maximum monitoring benefits. Further research is needed to assess different groups experiences while using these devices, such as teenagers, children, and pregnant women.	المؤتمر الدولي الثالث عشر حول المعلوماتية الحيوية والتكنولوجيا الطبية الحيوية 13th International Conference on Bioinformatics and Biomedical Technology (ICBBT)	2021	تحرير الضرغام Tahrir Aldhirgham
4	The Impact of Using Menu's Calories Information among Restaurants' Customers in Saudi Arabia: Nine Months Post Calorie-Labelling	Background Obesity is associated with a wide array of chronic Non-Communicable Diseases, and dietary habits are among the main contributors to the obesity epidemic. Therefore, governments are trying to combat obesity by introducing new policies and intervention programs. This study aims to investigate the impact of calorie menu labeling on consumers' food choices and awareness, as well as determine whether noticing or using calorie information is associated with customers' demographic characteristics. Method A face-to-face survey was conducted among restaurant customers at food courts of four different malls in Riyadh, Saudi Arabia. Calorie menu labeling awareness and use were assessed. The total number of calories purchased was evaluated using participants' order receipts. The collected data were measured through descriptive analysis, regression, and chi-square tests. Results A total of 605 customers participated in the study, of which 59.2% were female. Over half of the participants (58.2%) noticed menus calorie information, of those, 30% reported using them for food or beverage purchases. Overall, 14.9% of participants correctly stated all calories-related terms including recommended daily allowance of calories, serving size, and recommended calorie intake for women and men. Participants younger than 27 years and participants with higher education were significantly more likely to use the calorie information ($p < 0.05$). Noticing calorie information was not associated with purchasing fewer calories; yet, those who reported using calorie information purchased fewer calories than those who did not (P=0.646). Conclusion Promoting the use of calorie information is necessary to increase the prevalence of using it in the Saudi community. Other controlled studies are needed to examine the long-term impact of calorie menu labeling.	المؤتمر الدولي الحادي عشر للصحة والعافية والمجتمع Eleventh International Conference on Health, Wellness, & Society	2021	لولو المطيري Lulu Al mutairi

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5	Practice assessment of users of intense pulsed light (IPL) home hair-removal devices in Saudi Arabia	Background: Intense Pulsed light (IPL) hair removal device is a rapidly growing technology with a market extending from clinics to homes where it is unrestrictedly used by the public. IPL safety has been well-established, however, it relies largely on users' adequacy level in understanding and applying use instructions. Complications were described especially in dark skin types. A few incidents form home use have been reported to Saudi Food and Drug Authority (SFDA). To our knowledge, self-reported home experience of IPL use is not described in the literature. This study aims to assess the prevalence of IPL home hair-removal female users in Saudi Arabia, their practice, perceptions and complications rate. Methods: This national cross-sectional survey was conducted among female residents in Saudi Arabia aged 16 years and above (N=1041). Data was collected using Computer-Assisted Telephone Interview (CATI). Descriptive and regression analysis was done using IBM SPSS Statistics version 26. Results: The prevalence of IPL home hair-removal female users in Saudi Arabia is 19.5%. Self-reported complications rate was 20.2%. Approximately 10% of the complications were described as severe, yet were not managed by a physician. Observed overall practice in using IPL home devices were scored 60-100% 'good to excellent'. Following instructions during the removal session was significantly associated with low complications incidence (OR=0.12, 95% CI= 0.01-0.98, P=0.047). Most common purchase venue was online 64%. More than half the users 54.7% expressed having no concerns regarding home IPL devices. Conclusion: There is no concern regarding complications and use adequacy level. Complications rate is significantly associated with proper use. Based on users' practice scores, use adequacy is considered 'good to excellent'. Evaluation of users' knowledge and practice in IPL home hair-removal may be valuable in device classification and regulations.	لمؤتمر الدولي الثالث عشر للمعلوماتية الحيوية والتكنولوجيا الطبية الحيوية 13th International Conference on Bioinformatics and Biomedical Technology (ICBBT)	2021	سلوى المؤمن Salwa Almomen
6	Analyzing the US Post-Marketing Safety Surveillance of COVID-19 Vaccines	Background/Introduction: Since December 2020, three COVID-19 vaccines have been authorized in the United States (U.S.) and were proceeded by large immunization programs. Objective/Aim: The aim of this study was to characterize the U.S. post-marketing safet (PMS) profiles of these vaccines with an indepth analysis of mortality data. Methods: This was a retrospective database analysis study. Details of the U.S. PMS reports (15 December 2020 to 19 March 2021) of the three vaccines (Pfizer-BioNTech, Moderna, and Janssen Ad26.COV2.S) were retrieved from the U.S. Vaccine Adverse Event Reporting System (VAERS). A descriptive analysis was conducted to characterize the reported adverse events (AEs). A comparative (Pfizer-BioNTech vs. Moderna) analysis of mortality was conducted. The mean count ratio of death between the two vaccines was estimated using a negative binomial regression model adjusting for the measured confounders. Results: A total of 44,451 AE reports were retrieved (corresponding to 0.05% of the U.S. population who received at least one dose). The most commonly reported AEs were injection site reactions (30.4% of the reports), pain (reported in 26.7% of the reports), and headache (18.6% of the reports). Serious AEs were reported in only 14.6% of the reports with 4,108 hospitalizations. The total number of deaths was 1,919 with a mean count ratio of Moderna (n = 997) vs. Pfizer-BioNTech (n = 899) of 1.07 (95% confidence interval 0.86 to 1.33). Conclusions: The vast majority of PMS AEs in the U.S. were non-serious, and the number of serious AEs is very low given the total number of vaccinated U.S. population.	الاجتماع السنوي العشرون للجمعية الدولية لليقظة الدوائية The 20th Annual Meeting of the International Society of Pharmacovigilance (ISoP)	2021	عمر البلوي Omar Albalawi

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7	Vaccine Adverse Event Reporting System (VAERS): Evaluation of 31 Years of Reports and Pandemics Impact	Background: Vaccine adverse event reporting system (VAERS) was established in the United States (U.S.) as an early warning system with a main purpose of collecting post-marketing Adverse events following immunizations (AEFIs) reports to monitor the vaccine safety and to mitigate the risks from vaccines. During the coronavirus diseases 2019 (COVID-19) pandemic, VAERS got more attention as its important role in monitoring the safety of the vaccines Objectives: The aim of this study was to investigate VAERS patterns, reported AEFI, vaccines, and impact of different pandemics since its inception. Methods: This was an observational study using VARES data from 2/7/1990 to 12/11/2021. Patterns of reports over years were first described, followed by a comparison of reports statistics per year. Furthermore, a comparison of incidents (death, ER visits, etc.) statistics over years, in addition to statistics of each vaccine were calculated. Moreover, each incident's statistics for each vaccine were calculated and top vaccines were reported. All analyses were conducted using R (Version 1.4.1717) and Excel for Microsoft 365 Results: There were 1,396,280 domestic and 346,210 non-domestic reports during 1990-2021, including 228 vaccines. For both domestic and non-domestic reports, year of 2021 had the highest reporting rate (48.52% and 70.33%), in addition a notable changes in AEFIs patterns were recorded during 1991, 1998, 2000, 2006, 2009, 2011, and 2017. AEFIs were as follow: deaths (1.00% and 4.08%), ER or doctor visits (13.37% and 2.27%), hospitalizations (5.84% and 27.78%), lethal threat (1.42% and 4.38%), and disabilities (1.4% and 7.96%). Pyrexia was the top reported symptom during the past 31 years, except for 2021 where headache was the top one. COVID-19 vaccines namely Moderna, Pfizer-Biontech, and Janssen were the top 3 reported vaccines with headache, pyrexia, and fatigue as the top associated AEFIs. Followed by Zoster, Seasonal Influenza, Pneumococcal, and Human papillomavirus vaccines. Conclusions: The large data available in VARES make it a useful tool for detecting and monitoring vaccine AEFIs. However, its usability relies on understating the limitations of this surveillance system, the impact of governmental regulations, availability of vaccines, and public health recommendations on the reporting rate. Promoting VARES effectiveness and highlighting the significance of accurate reporting could improve AEFIs post marketing monitoring processes.	الاجتماع السنوي الثامن والثلاثون للجمعية الدولية لعلم الأوبئة الدوائية The 38th annual meeting of the International Society for Pharmacoepide miology (ISPE)	2022	عهود المدني Ohoud Almadani
8	Development of the Saudi branded food database: branded beverage database chapter: aims, design and structure	A branded food composition database is essential for governmental and non-governmental nutrition-related actions. Although a few Gulf Cooperation Council countries had attempted to develop food composition tables, such tables have included outdated, impractical, unavailable, and limited data on food items and nutrients. This article introduces the Saudi Branded Food Database (SBFD) and describes its first-phase development (Branded Beverage Database), outcomes, uses, and challenges. The SBFD gathers data on food and beverage items available in Saudi Arabian markets and uses manufacturer-provided food label information to create a reference database for the nutritional content of pre-packaged food and beverages. Therefore, food label data for 1748 beverages over 12 categories were collected between June and October 2021. Label sources included the Saudi Food and Drug Authority (SFDA) Food Registration and Clearance System (FRCS) (84%) and local markets (16%). All entries had complete data with regard to general information, food composition, ingredient list and added sugars, on-pack communication claims and statements, and front-pack labelling. Various beverage database applications related to the regulatory roles of the SFDA are under assessment. Efforts have been expended to develop the SBFD and make it available to regulators, researchers, and the general community at the individual and institutional levels.	المؤتمر الوطني الثاني والأربعون لبنوك بيانات المغذيات 42nd National Nutrient Databank Conference	2022	تحرير الضرغام Tahrir Aldhirgham

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9	The impact of using pictorial aids in caregivers' understanding of patient information leaflets of pediatric pain medications: A quasi-experimental study	Introduction: Patient information leaflets (PILs) are one of the main sources of information for over-the-counter medications (OTCs). This study aimed to assess caregivers' understanding of instructions in PILs provided with paracetamol medications and the impact of pictograms use. Methods: A quasi-experimental study was conducted among caregivers of children aged < 13 years recruited in pediatric outpatient clinics at University Medical City in Riyadh. The calculated sample size was 128; at least 64 participants were needed in each group (the text-only group and the text-plus pictograms group). Caregivers' health literacy was assessed using a validated Arabic version of the Newest Vital Sign scale. Participants' understanding of PILs instructions was assessed using eight questions on the route of administration, minimal hours between doses, max daily dose, shake medication before use, storage, and reporting adverse events; and was rated based on the number of questions correctly understood. Characteristics of participants were compared by Pearson X2 and t-test was used to assess the significance of mean score differences between groups. Results: A total of 130 caregivers participated in the study; almost half of them were mothers (47%, [n = 61]) and 43% (n = 56) have "a possibility of limited health literacy". The mean number of correct answers to questions assessing the understanding of PILs instructions was significantly higher among the text-plus pictograms group compared to the text-only group (5.25 ± 1.85 vs. 4.38 ± 1.27; p < 0.001). When results were controlled for age and gender, better health literacy was found to be associated with a better understanding of instructions (B = 0.39, 95 %CI 0.23–0.54) Conclusion Limited comprehension of medications instructions was observed; adding pictorial aids to PILs might enhance the comprehension. Differences in health literacy levels of caregivers should be considered when designing PILs.	المؤتمر الدولي الثامن والثلاثون لهندسة الأداء 38th International Conference on Performance Engineering (ICPE)	2022	الجوهرة القباني Aljoharah Algabbani
10	Readability of information imprinted in patient information leaflets (PILs) in Saudi Arabia: The case of antihypertensive medications	Background: The Saudi Food and Drug Authority (SFDA) requires marketing authorization holders to submit a PIL in both Arabic and English language. However, the readability of imprinted and disseminated Patient information leaflets (PILs) was not assessed extensively in Saudi Arabia. This study aims to assess the readability of PIL of antihypertensive drugs in both Arabic and English languages. Method: This study was a descriptive quantitative analysis conducted in Saudi Arabia in August 2021. PILs of all oral antihypertensive medications in Saudi Arabia were included in the study. The Arabic and English PILs were extracted from the Saudi Drugs Information System (SDI) and pharmaceutical companies' registration documents. The study used Flesch-Kincaid grade level to assess the readability of English and sentence length to assess the Arabic texts. Descriptive analyses were used to assess the readability scores and the mean differences. Results: It was found that almost 88% of English PILs were above recommended readability level compared to 79% of Arabic PILs. About 89% of English PILs of generic and 86% of brand-name medications were above the readability cutoff point compared with 83% of Arabic PILs of generic and 68% of brand-name medications. The means of grade level for readability of PILs for the widely used antihypertensive medications including angiotensin II receptor blockers (ARBs), antiadrenergic, diuretics, Beta-blockers (BBs), calcium channel blockers (CCBs), and combination antihypertensive medications, and CCBs were higher than the recommended readability level (p < 0.05). The highest mean grade level for readability among English PILs was for combinations of antihypertensive agents (9.35 ± 1.38, p 0.01) and among Arabic PILs was for ARBs (6.15 ± 1.62, p < 0.01). Conclusions: The majority of PILs of antihypertensive medications were above the recommended readability level that can be understood by the majority of the public, especially among generic medications and the most widely used antihypertensive medications. The study findings highlight the need of implementing guidelines to improve the readability of information imprinted in PILs and adopt new regulations requiring readability assessment for manufactures before submitting the PILs to the SFDA.	المؤتمر الدولي الثامن والثلاثون للهندسة الكهربائية 38th International Conference on Power Engineering (ICPE)	2022	الجوهرة القباني Aljoharah Algabbani

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11	Drug Shortage Concepts among Stakeholders in Saudi Arabia	Introduction: The SFDA internal records showed that several pharmaceutical entities (National Unified Procurement Company (NUPCO) and Saudi Food and Drug Authority (SFDA) are overlapping in their tasks within the system of drug availability in the Saudi market. This may have led to difficulties in terms of contacting which entity when drug shortages occur. This study aimed to identify stakeholders' understanding of drug shortage, the internal process of reporting a drug shortage to the SFDA, and to evaluate the clarity of the communication channels and the stakeholder's satisfaction regarding drug shortage reporting system at SFDA. Method: A cross-sectional study conducted between December 2020 and August 2021. The study consisted of three separate surveys targeting the main stakeholders in cluding healthcare institution (hospitals and pharmacies), NUPCO, and registered pharmaceutical companies/storage) with a response rate of (68.07%). The survey consists of three main parts: knowledge, practice, and perception of drug shortage reporting system at SFDA. Results: Healthcare in stitution defined drug shortages as unavailability of the product after confirmation of unavailability by the agent by 65.3% and low stock generic product by 44.9%. Nonetheless, 67.3% of healthcare institutions planned for inventory stock based on several factors such as the need of the stock/prod uct and consumption of the products per different periods. Moreover, NUPCO identified the drug shortages by two fac tors when the stock of brand drug is zero and after pharma ceutical companies confirm the unavailability of the prod uct. Additionally, all of the stakeholders were aware of SFDA communication channels for drug shortages. Conclusion: Based on our results, the internal workflow of stakeholders on the issue of drug shortages was reviewed and most re sponses provided a general overview of the internal processes for handling drug shortages, reporting steps, and submit ting drug shortage reports. Nonetheless, when it comes to choosing the right provider for a healthcare facility, price and delivery time are major factors that influence their decision. In addition, it is recommended that further investigation of internal workflows be conducted to measure aspects that may affect the clarity and quality of services provided by the SFDA.	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2022	ملاك المطيري Malak Almutairi
12	Non-steroidal anti-inflammatory drugs use and micronutrient status	Background: Non-steroidal anti-inflammatory drugs (NSAIDs) are among the most used pharmaceuticals worldwide. Objectives: This study aimed to (i) assess the prevalence of regular NSAIDs use in Saudi adult population, and (ii) to identify whether regular use of NSAIDs is correlated with prevalence of clinically relevant micronutrient deficiencies.Methods: We used a dataset from a recent nationwide cross-sectional study conductedamong Saudi adults from September 2019 to June 2021. The study objective was to examine levels of micronutrients including vitamins (A, B1, B2, B6, B9, B12, D, and E) and minerals (copper, iron, manganese, mercury, and zinc) via laboratory tests. The recruitment began with data collected by means of a questionnaire for demographics, lifestyle behavior, dietary intake, diagnosis of chronic conditions, and medication use via random phone interviews. A descriptive analysis was conducted to characterize the prevalence of NSAIDs, and sociodemographic differences among regular NSAIDs users. Micronutrient deficiencies correlation with NSAID use were identified by logistic regression after adjustment of several covariates. Results: A total of 3448 adults were included for analysis, and 7.1% reported NSAIDs use at least once in a typical week. Females reported a higher prevalence of NSAIDs use than males (74.8% vs. 25.2%). The age groups of 24 to 34 and 35 to 44 years old had the highest prevalence (25.1% and 26.7%, respectively). NSAIDs use was correlated with presence of iron deficient (odd ratio [OR]=1.429; 95% confidence interval [CI], 1.08-1.89). This difference was not statistically significant after adjustment for confounders (OR= 1.04; 95% CI, 0.77-1.41). Regular use of NSAIDs was correlated with the presence of vitamin B2 deficiency (adjusted OR=1.38; 95% CI, 1.04–1.81). Conclusions: Our study identified that the prevalence of typical use of NSAIDs is correlated with prevalence of vitamin B2 deficiency. Further well controlled studies should examine this association.	الاجتماع السنوي الثامن والثلاثون للجمعية الدولية لعلم الأوبئة الدوائية The 38th annual meeting of the International Society for Pharmacoepidemiology (ISPE)	2022	عمر البلوي Omar Albalawi

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13	Validating the standardized and ICD-9 code of type 2 diabetes mellitus in a Saudi common data model	Background: Validating diagnostic codes of type 2 diabetes type 2 mellitus in the Saudi electronic health records (EHRs) is s a priority given its high prevalence. However, no studies hashave been published to assess the validity of recording diagnostic codes in general, and that of type 2 diabetes mellitus in particular, in the Saudi EHRs. Objectives: This study was conducted to assess the validity of the original, the extracted and the standardized diagnostic codes of type 2 diabetes mellitus of the EHRs that were imported from a hospital to a Saudi common data model (the centralized National Pharmacoepidemiologic Database [NPED]). Methods: This study was a retrospective validation study. It was carried out using the EHRs that were imported and mapped from a private hospital in Riyadh to the NPED (a standardization was performed for these EHRs using the Observational Health Data Sciences and Informatics common data model). A random sample of type 2 diabetic patients, who visited the hospital in the period between 01 January 2013 and 01 July 2018, was extracted from the standardized EHRs of the hospital and matched with a control group (non-diabetic patients) based on age and sex. The included participants were required to be ≥18 years and have at least one health record. The standardized coding of type 2 diabetes in the NPED was validated by comparing the presence of diabetes in the NPED vs. the original electronic records at the hospital, the recording in paper-based medical records, and the physician re-assessment of diabetes in the included cases and controls; respectively. Sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) values were estimated for each pairwise comparison using RStudio 1.4.1103. Results: A total of 437 random diabetic patients were identified and were matched with 437 controls. Only 190 of 437 (43.0 %) had paper-based medical records. PPVs of NPED vs. original EHRs, paper-based records and physician re-assessment were 1.0 (95% confidence interval [CI] 0.99 to 1.0), 0.54 (95%CI 0.47 to 0.61), and 1.0 (95%CI 0.99 to 1.0); respectively. Sensitivities were 0.95 (95%CI 0.93 to 0.97), 0.93 (95%CI 0.86 to 0.97), and 0.95 (95%CI 0.93 to 0.97); respectively. NPVs were 0.95 (95%CI 0.92 to 0.97), 0.96 (0.92 to 0.98), and 0.95 (0.92 to 0.97); respectively. Specificities were 1.0 (95%CI 0.99 to 1.0), 0.68 (95%CI 0.62 to 0.73), and 1.0 (95%CI 0.99 to 1.0); respectively. Conclusions: The results of our study substantiate the validity of coding, extracting, and standardizing type 2 diabetes mellitus in the NPED. A future multi-center study would help adding more emphasis to the study findings.	المؤتمر الدولي لوبائيات الأدوية 2022 International Conference of Pharmacoepidemiology (ICPE)	2022	د. تركي الثنيان Turki Althunian

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14	The Impact of Generic Drug Marketing on Drug Prices in Saudi Arabia	Purpose: The increased drug spending has been driven mainly by brand-name drugs. Introducing generic drugs, bioequivalent replicates of brand-name drugs, into the market has been associated with a reduction in the prices of brand-name drugs. Specifically, this study aims to assess the extent of the reduction in the baseline prices of brand-name drugs associated with the introduction of generic drugs. Additionally, the study will compare the average prices of generic drugs to those of brand-name drugs to determine the extent of the price difference between the two. Methods: In this retrospective study, the Saudi Food and Drug Authority (SFDA) pricing database was used to collect pricing information for brand-name and generic drugs in Saudi Arabia. The study included all drugs based on the Anatomical Therapeutic Chemical (ATC) classification system for cardiovascular disease, diabetes, antibiotics, antidepressants, antipsychotics, and antacids, with the exception of brand-name drugs that did not have a generic equivalent and vice versa. An analytical approach was used to analyze the collected data, in which product prices and registration data were tracked retrospectively based on decisions made by the MOH and the SFDA Registration Committee, with up to four cycles of pricing events analyzed. Results: The average percentage difference between generic and brand-name drugs across all therapeutic classes, according to the study, was 32%. The average percentage difference, however, varied across therapeutic classes, with antidiabetics, antidepressants, and antacids having lower differences of 21%, 18%, and 26%, respectively, whereas antibiotics, antipsychotics, and cardiovascular drugs had higher differences of 40%, 40%, and 28%, respectively. The study also discovered that drug production in the Gulf, the Middle East, and Europe has a lower price compared to that produced in Saudi Arabia. Furthermore, the current drug price was more sensitive to immediate price changes than previous price changes. Conclusions: The study's findings have significant implications for pricing policies aimed at promoting value-based healthcare and facilitating competition in the prescription drug market. Policymakers can use this information to inform legislation and enforcement efforts that align with market share by demonstrating the potential cost savings associated with the approval of lower-cost generic medicines. Furthermore, the study's findings emphasize the importance of promoting the availability of equally effective generic drugs in order to lower prices and improve consumer affordability. Overall, these findings can help inform efforts to ensure that pricing policies are aligned with market dynamics and promote value-based healthcare.	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2023	ملاك المطيري Malak Almutairi
15	Content Analysis of Drug Recall Announcements in Saudi Arabia: Between 2016 and 2022	Background: This study aims to explore the characteristics of drug recall announcements issued over six years by the SFDA in Saudi Arabia. Additionally, to examine the patterns of voluntary drug recall requests by pharmaceutical companies (both innovator and generic) in response to product defects. Methods: A retrospective data analysis was conducted on drug recall announcements issued by the SFDA between 2017 and December 2022. The study included recalls of registered and unregistered drugs posted on the SFDA Drugs Circulars and Withdrawal webpage. Descriptive analysis was performed on relevant variables: recall year, therapeutic class, recall type, pharmaceutical company type, recall reasons and voluntary or involuntary product defect reports. Results: During the study period, a total of 371 products were recalled, with the majority being involuntary recalls (82.4%). About two-thirds of the recalls (66.0%) were related to registered products. The most common reasons for recalls were non compliance with the manufacturer’s specifcations (33.2%), contamination (23.7%), and violations (20.5%). A total of 109 pharmaceutical companies were associated with the recalled products, with (85.3%) being generic pharmaceutical compa nies. The majority of innovator pharmaceutical companies (68.8%) requested voluntary drug recalls of defective products. Innovator pharmaceutical companies requested voluntary recalls more often than generic pharmaceutical companies. Conclusion: The study fndings highlight the most frequent causes of drug recalls and the patterns of voluntary recall requests by pharmaceutical companies. Non-compliance with manufacturer’s specifcations was the most common reason for recalls. Signifcantly, more innovative pharmaceutical companies request voluntary recalls for product defects compared to generic pharmaceutical companies.	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2023	ملاك المطيري Malak Almutairi

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16	Food and beverage placement in child-focused YouTube channels in Saudi Arabia: a content analysis study	Background High exposure to food content encourages unhealthy dietary practices among children. Nowadays, children are exposed to many food products through social media, which influences their eating behaviors. Due to the growing social media use, the number of food advertisements via YouTube has increased. Therefore, regulatory agencies worldwide are investigating social media content to implement appropriate restrictions on unhealthy food marketing. However, in Saudi Arabia, no existing studies investigated food placement and marketing on children's social media channels. Methods This quantitative content analysis study aims to analyze the food content in the child-centric channels of Arabic speakers' vloggers on YouTube in Saudi Arabia. The researchers developed a codebook to measure the food presentation and promotional techniques associated with food and/or beverage placements and determine the type of food product placement. The variables in this study were measured by quantifying the appearance of each variable in each video. Results Four of the top subscribed channels in Saudi Arabia were selected; 96 videos were analyzed by watching 17 hours. Food placements appeared in 65 videos (67.7%), and the duration of the food placement was cumulatively 304 minutes. Among videos that featured food and beverages, 87.7% of the vloggers consumed the food that appeared. The most commonly employed persuasive marketing techniques were emotional and taste appeals, with a percentage of 90%. Unhealthy foods comprised 66.8% of the total number of products that appeared in the analyzed videos. Conclusion The prevalence of food content in the analyzed videos is high, which increases the chances of its influence on children in Saudi Arabia. The study also found that the placed foods were associated with fun and taste appeals. Besides, most of the foods that appeared in the videos were low-nutrient food products, which may be threatening to the global efforts to combat obesity.	المؤتمر الأوروبي للصحة العامة EUROPEAN PUBLIC HEALTH CONFERENCE (EPH Conference)	2023	لولو المطيري Lulu Al mutairi
17	Food Safety Practices during Hajj: On-Site Inspections of Food-Serving Establishments	The presence of crowds during Hajj increases the risk of foodborne infection. Yet, research on the practices of food handlers during Hajj is limited. This study aimed to assess compliance with food safety practices and its associated factors during Hajj 2022. An observational cross-sectional study was conducted in Mecca and Madinah before and during Hajj 2022 and involved 195 food-serving establishments (FSEs) contracted for Hajj catering. Collected data included visit time, establishment location, licensure, whether food handlers had food safety training (professional training), and whether FSEs were under supervision from a consulting office (professional supervision). The included FSEs were 168/195 (86.2%). Two-thirds of FSEs surveyed (113, 67.3%) were under professional supervision, and 91 (54.2%) hired trained food safety workers. Compliance rates varied between outcomes (72.67 ± 17.21% to 88.3 ± 18.8%). Compared to Mecca, Madinah FSEs were more adherent to cleanliness (80.5 ± 27.9% vs. 91.5 ± 19.9%, respectively, p = 0.006). FSEs with trained workers were more likely to comply with proper food safety practices compared to those with untrained workers: cleanliness (OR: 7.2, 95% CI [2.6–20.23], p < 0.001); workers' commitment to health requirements (OR: 2.8, 95% CI [1.1–6.9], p = 0.025); handling of refrigerated and frozen food (OR: 5.27, 95% CI [1.83–15.20], p = 0.004); and food storage practices (OR: 12.5, 95% CI [2.0–12.5], p < 0.001). The role of professional training in increasing food safety practices compliance was highlighted. FSEs in Madinah were more compliant with food safety practices than those in Mecca. Therefore, Mecca FSEs may need stringent safety measures.	المؤتمر الخامس الدولي لطب الحشود The Fifth International Conference on Mass Gathering Medicine (ICMGM)	2023	ريوف النفيسة Ruyuf Alnafisah

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18	An Assessment of Validated Algorithms for Identifying Multiple Sclerosis Cases, Subtypes, and Relapses in Real-World Databases: A Systematic Review	Though real-world data (RWD) are increasingly used to study multiple sclerosis (MS), MS diagnostic codes vary across RWD datasets. In addition, no specific diagnosis codes exist for either MS subtypes or MS relapses. Using validated algorithms to identify and characterize specific diseases or conditions is thus a priority for reducing systematic RWD bias.This study aimed to (1) identify all original validation studies used algorithms to identify MS (e.g., cases, subtypes, and relapses) in RWD, (2) assess evidence for algorithm validity, and (3) identify knowledge gaps for future research.A systematic review was completed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Four key bibliographic databases were searched, and gray literature was included. The reporting of studies conducted using observational methods and routinely collected health data was used to assess the quality of the included studies. Data synthesis was qualitative (i.e., narrative).Of 5,056 identified articles, 48 underwent detailed review, and 21 met inclusion criteria. Most included studies (43%) aimed to identify MS cases; others focused on MS subtypes (28%), relapses (15%), diagnosis and severity (9%), or disability status (5%). Only eight (38%) reported all four algorithm validity metrics: sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Specificity was most frequently used (76 %), followed by sensitivity (71%), PPV (67 %), and NPV (52 %). Manual validation was the gold standard (76.1%) for sixteen studies, all of which found at least one algorithm with high sensitivity (77–99%), while specificity ranged from 88 to 99.9%, PPV from 38 to 95%, and NPV from 70 to 100%. All the studies aimed at identifying MS cases reported sensitivity (44%–100%) and specificity (87–100%), but only five reported PPV and NPV (38–99% and 17–100%, respectively). All three studies that identified MS relapses used administrative health databases with manual validation as the gold standard, finding sensitivity to range from 70 to 100%, specificity from 87 to 100%, PPV from 64 to 100%, and NPV from 53 to 100%. The best preformed algorithm for MS relapse identification included diagnoses, medications, hospitalization duration, or outpatient visits (sensitivity 70%, specificity 100%, PPV 100%, and NPV 96%).This study supports the current recommendation by combining the advantages of using different disproportionality statistics methods in SRS analysis. In the case of a low number of reports, the IC and the EBGM provide more accurate results. .	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – I الأوربي nternational Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2023	عمر البلوي Omar Albalawi
19	Evaluation of Semicarbazide levels in flour products	Background Azodicarbonamide (ADA) is an approved food additive in Saudi Arabia as a dough improver. During heating process, ADA undergoes chemical reactions that results in the formation of a byproduct called semicarbazide (SEM). There is a concern about the safety of SEM containment as in vitro studies report risk of endocrine disturbance as well as tumor synthesis in rats. Given that there are no studies investigating this issue in Saudi, our objective is to assess the presence of SEM in local bread products. Methods This is a cross sectional study for bakery products produced by factories in Saudi Arabia. SFDA food registration data base was used to determine the number of bread factories to be included. After verifying bread's country of origin, imported products as well as unavailable products in the market were excluded. The final estimate for the sample was 27. All samples were logged in the Laboratory Information Management System (LIMS) and analyzed directly after reception through Liquid Chromatography-Mass Spectrometry (LCMSMS), in order to avoid sample deterioration. Results A total of 27 bread samples were collected. 18 (66%) of them were from the central region, and 9 (33%) were from the western region. An equal number of white toast and flat bread were analysed (8, 29%) for each, and 2 (7%) were Sandwich rolls, and the remaining 6 (22%) were other types of bread. As a result, no value of SEM was detected in our samples.	المؤتمر الدولي التاسع للتفاعلات الكيميائية في الأغذية 9th International Conference for Chemical Reactions in Food	2023	فيصل الرويس Faisal Alruways

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20	Bioequivalence trials for the approval of generic drugs in Saudi Arabia: a descriptive analysis of design aspects	Background: This retrospective analysis aimed to comprehensively review the design and regulatory aspects of bioequivalence trials submitted to the Saudi Food and Drug Authority (SFDA) since 2017. Methods: This was a retrospective, comprehensive analysis study. The Data extracted from the SFDA bioequivalence assessment reports were analyzed for reviewing the overall design and regulatory aspects of the successful bioequivalence trials, exploring the impact of the coefficient of variation of within-subject variability (CVw) on some design aspects, and providing an in-depth assessment of bioequivalence trial submissions that were deemed insufficient in demonstrating bioequivalence. Results: A total of 590 bioequivalence trials were included of which 521 demonstrated bioequivalence (440 single active pharmaceutical ingredients [APIs] and 81 fixed combinations). Most of the successful trials were for cardiovascular drugs (84 out of 521 [16.1%]), and the 2 × 2 crossover design was used in 455 (87.3%) trials. The sample size tended to increase with the increase in the CVw in trials of single APIs. Biopharmaceutics Classification System Class II and IV drugs accounted for the majority of highly variable drugs (58 out of 82 [70.7%]) in the study. Most of the 51 rejected trials were rejected due to concerns related to the study center (n = 21 [41.2%]). Conclusion: This comprehensive analysis provides valuable insights into the regulatory and design aspects of bioequivalence trials and can inform future research and assist in identifying opportunities for improvement in conducting bioequivalence trials in Saudi Arabia.	الإتحاد الأوروبي للعلوم الصيدلانية European federation of pharmaceutical sciences (EUFEPS)	2023	د. تركي الثنيان Turki Althunian
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..	الاجتماع السنوي الأربعين للجمعية الدولية لعلم الأوبئة الدوائية The 40th annual meeting of the International Society for Pharmacoepidemiology (ISPE)	2024	للها الفاخري Almaha Alfakhri

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22	Indapamide-Induced Rhabdomyolysis: A Retrospective Analysis of Electronic Health Records	Background: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. Objectives: To evaluate the association between indapamide and rhabdomyolysis in patients with hypertension and/or congestive heart failure Methods: 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 Results: 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 Conclusions: In this study, we did not find association between indapamide use and rhabdomyolysis regardless timing of exposure.	الاجتماع السنوي الأربعين للجمعية الدولية لعلم الأوبئة الدوائية The 40th annual meeting of the International Society for Pharmacoepidemiology (ISPE)	2024	رسيل الربع Raseel A. Alroba

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23	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 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 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 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 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 finding.	الاجتماع السنوي الأربعين للجمعية الدولية لعلم الأوبئة الدوائية The 40th annual meeting of the International Society for Pharmacoepidemiology (ISPE)	2024	عهود المدني Ohoud Almadani
24	Nutrient Content and Labelling Status of Pre-Packaged Beverages in Saudi Arabia	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.	المؤتمر الدولي لعلوم التغذية والأغذية International Conference on Nutrition and Food Sciences	2024	ريوف النفيسة Ruyuf Alnafisah

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25	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.	المؤتمر السادس والأربعون للجمعية الأوروبية للتغذية السريرية والأيض 46th ESPEN Congress	2023	سلوى المؤمن Salwa Almomen
26	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.	الاجتماع السنوي العالي لجمعية معلومات الأدوية drug information association (DIA) Global Annual Meeting	2024	ملاك المطيري Malak Almutairi

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27	Detection of Gelatin Speciation, Heavy Metal Contamination and Fraudulent Labeling of Unregistered Dietary Supplements Available in Online Stores	Overview 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. Introduction 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. Methods 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. Results 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. 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. Conclusion 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.	الندوة الدولية الحادية عشرة حول أحدث التطورات في تحليل الأغذية 11th International Symposium on RECENT ADVANCES IN FOOD ANALYSIS (RAFA)	2024	العنود الصقعبي Alanoud Alsaqabi

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28	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.	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2024	عمر البلوي Omar Albalawi
29	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.	المؤتمر السنوي لاقتصاديات الصحة ونتائج الأبحاث – الأوربي International Society for Health and Outcomes Research (ISPOR) Annual Meeting - Europe	2024	د. علي الحميدان Dr. Ali Alhomaidan

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30	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.	6th Edition of Euro-Global Conference on Food Science and Technology (FAT 2024)	2024	نورة بنت محمد بن سعيدان Norah Mohammed BinSaeedan
31	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.	The 15 European Pesticide Residue Workshop (EPRW24)	2024	راكان العجمي
32	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. 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.	RAFA 11) 2024th International Symposium on RECENT ADVANCES IN FOOD ANALYSIS)	2024	د. سمية المبيض

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33	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.	The 2024 AOAC INTERNATIONAL Annual Meeting & Exposition	2024	د.هبة الحربي
34	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.	IUMS2024	2024	عبدالله العجلان
35	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.	IUMS2024	2024	د. عايض المنصور

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36	Prevalence, Serovars, and Antimicrobial Susceptibility of Salmonella Isolated from Eggs in Local Markets in Riyadh, Saudi Arabia	Salmonella is a globally prevalent foodborne pathogen that causes salmonellosis. Contaminated eggs are a significant source of various Salmonella serovars that can cause outbreaks and the spread of antimicrobial resistance. Information regarding Salmonella in eggs is limited in Saudi Arabia. Hence, this study aims to evaluate the occurrence of salmonella in both the shell and contents of eggs obtained from local markets in Riyadh, Saudi Arabia. Additionally, the study investigates the susceptibility of these Salmonella strains to various antibiotics. Over the course of 1 year (April 2021-April 2022), 260 egg samples were collected from different local markets. Salmonella was detected and isolated according to ISO 6579-1:2017. Positive Salmonella samples were identified and tested their susceptibility to 32 antibiotics from 12 classes. The prevalence of Salmonella in eggs in Saudi Arabia was (20/260, 8%). Among the samples, the prevalence of Salmonella in eggshells was (12/260. 5%), while that in the liquid was (8/260, 3%). The predominant serovar was S. Enteritidis, accounting for (21%, 4/20) of positive samples, followed by S. Heidelberg, S. Bareilly, and S. Typhimurium at (15%, 3/20). S. Minnesota, and S. Blijdorp, were identified in (10%, 2/20) of the positive samples, and S. Infantis was isolated in (4%, 1/23) of the positive samples. The antibiotics sensitivity results show that 7 isolates exhibited resistance to 3 or more of the 32 antibiotics. One of the most resistant isolates was S. Infantis, which is resistant to 13 antibiotics. All isolates were intermediate to colistin except for S. Blijdorp. This study provides new information on the prevalence and antimicrobial resistance of Salmonella in eggs available in the local markets in Riyadh, Saudi Arabia. Investigation of Salmonella in eggs can help fill knowledge gaps and facilitate enhanced surveillance of the emergence and prevalence of diverse Salmonella serovars. Ultimately, this has led to the advancement of salmonellosis control caused by eggs and improved management of antimicrobial resistance.	The Federation of Infection Societies conference (FIS)	2023	أماني تركي السفياني
37	Can the pathogen Escherichia coli O157 spread in consumed meals within foodlaw?	Introduction: 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. Purpose: Identify a relationship between food outbreaks and lack in foodmicrobiological criteria. Methods: 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. Results: 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. Significance: 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.	IAFP confex	2024	مشاري الهدلق

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38	The Role of Semi-Quantitative Approach in Identifying Fragrance Content in Perfumes	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.	34th International Symposium on Chromatography – 2024 ISC	2024	Adnan AL-Mussallam
39	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.	34th International Symposium on Pharmaceutical and Biomedical Analysis (2024 PBA)	2024	Yahya M. Alshehri

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40	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. 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. 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. 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. 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%. This study aimed to develop and optimize high-performance liquid chromatography (HPLC) methods for accurately analyzing and quantifying preserving agents in herbal pharmaceuticals.	34th International Symposium on Chromatography – 2024 ISC	2024	Thamer S. Alghamdi

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41	Occurrence and dietary exposure assessment of heavy metals in baby foods in the Kingdom of Saudi Arabia	Early childhood exposure to heavy metals like arsenic (As), cadmium (Cd), and lead (Pb) through baby foods unfolds many concerns about their toxic effects on growth and health. In this study, occurrence and dietary intake of As, Cd, and Pb in stage 1 infant formula (0–6 months), stage 2 infant formula (7–12 months), cereal-based meals, and biscuits were estimated. First, the levels of As, Cd, and Pb were determined with ICP-MS, followed by the calculation of estimated daily intake (EDI), target hazard quotient (THQ), and hazard index (HI) for As and Cd, and margin of exposure (MoE) for Pb. Mean levels of As, Cd, and Pb were the highest in cereal-based meals and biscuits as 15.5–11.1, 5.18–8.76, and 35.2–53.8 µg/kg, respectively. Newborns to 6 months old infants were estimated to be the highest exposed population to Cd and Pb (0.08 and 0.36 µg/kg bw/day), while infants aged 7–12 months old were exposed the highest to As. Based on the THQ, HI, and MoE findings, the current exposure levels from the selected baby foods to As, Cd, and Pb pose low potential chronic risks to both infant age groups. This research provides a roadmap for future investigations in chemical contaminants often detected in baby foods consumed regularly by Saudi infants.	The 4th International Conference on Food Bioactives & Health (FBHC2023)	2023	نجلاء الحربي
42	Preliminary Risk Assessment of 3-monochloropropanediol and Glycidyl Fatty Acid Esters from Infant Formula & Baby Food Products in the Saudi market	3-Monochloropropanediol fatty acid esters (3-MCPDE) and glycidyl esters (GE) are well-identified processing-induced chemical toxicants detected in infant formula and baby foods worldwide. We analysed the levels of 3-MCPDE and GE in infant formula and baby food products available in Saudi Arabia, followed by a dietary risk assessment for exposure to these contaminants in infants and young children from birth to 3 years. Eighty-five commercial infant formulas (n = 35) and baby foods (n = 50) available for consumption by infants and babies purchased from the Saudi market during 2022 were analysed for these contaminants using gas chromatography-tandem mass spectrometry. 3-MCPDE and GE were detected in 100 and 80% of the samples, with a mean concentration of 57 µg/kg (range: 2–285 µg/kg) and 30 µg/kg (range: not detected–217 µg/kg), respectively. The highest concentration was found in milk-based formula for infants 0–6 months (285 µg/kg) and the lowest was found in fruit purees (2 µg/kg). Preliminary exposure and risk assessment showed increased exposure to 3-MCPDE for infants exclusively fed infant formula with exposure declining with age due to the introduction of solid foods. GE exposure levels reached 0.8 µg/kg body weight per day, which declined over time with margin of exposure values below 25,000. These results indicate that the levels of 3-MCPDE and GE in infant formula may pose potential risks to infants exclusively fed formula; therefore, adopting EU regulations should reduce the presence of these processing contaminants in essential infant foods.	The 4th International Conference on Food Bioactives & Health (FBHC2023)	2023	لى الميمان

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43	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.	World Public Health Nutrition Congress 2024	2024	جمانه الأمير
44	Detection and Assessment of Herbal- Drug Interaction Project: SFDA Experience	OBJECTIVES: There is a general perception of safety and efficacy of herbal medicine compared to conventionalmedicine. However, limited studies addressed herbal-drug interaction (HDI) in the literature. The SaudiFood and Drug Authority (SFDA) established the HDI Project to detect safety signals related to HDI andassess these signals based on available scientific evidence. METHODS: First, a list of SFDA registered herbal products (N=30) were selected and prioritized based on commonlyused herbs in Saudi Arabia. Second, reported HDIs were retrieved from the World Health Organization(WHO) global database of individual case safety reports (VigiBase), AdisInsight® and Natural Medicinesdatabase. We excluded the interactions of non-registered drugs in Saudi Arabia and labeled interactions indrug and herbal product information, using SFDA, the U.S. Food and Drug Administration and Europeanmedicines agency product information. Finally, comprehensive safety evaluation of potential interactionsignals were conducted using several evidence sources including literature, results of causalityassessment of global cases retrieved from VigiBase and local cases retrieved from the nationalpharmacovigilance database and other relevant documents. The Drug Interaction Probability Scale (DIPS)was used to assess the probability of a causal relationship between the potential HDI and the events. RESULTS: The project yielded 566 potential HDI signals, and 41 interactions had published evidence and referred forextensive evaluation. The assessment results based on DIPS and available evidence were; 24 possiblyrelated (85.5%), 5 probably related (12.1%) and 12 doubtful (29.2%) interactions. The recommendation wasto include the probable HDI in the local product information of herbal products and medications includeTurmeric-Tacrolimus, Etoposide-Echinacea, Ginkgo Biloba-Ibuprofen, Green Tea-warfarin and Licorice-thiazides interactions. CONCLUSIONS: The HDI project in SFDA successfully improved screening and identification of potential drug-herbalinteractions. The action plan of this project can be used in post-marketing activities worldwide to identifypotential drug interactions.	ISoP Advances in Pharmacovigilance for Herbal Medicines Conference	2023	Waad Alghamdi, Nouf Al-Fadel, Eman Alghamdi, Maha Alghamdi, Fawaz Alharbi

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45	Safety Monitoring of Orphan Drugs Project: SFDA Experience	OBJECTIVES: Orphan drugs are developed to treat rare diseases. Some regulatory bodies established orphan drugdesignation with incentives to help pharmaceutical companies to develop orphan drugs. However, there isa lack of pre-marketing safety data for orphan drugs because limited number of patients involved, due tothe rarity of the diseases. Considering that post-marketing long-term safety of orphan drugs still uncertainand the low utilization profile which make it challenging to monitor the safety of orphan drugs.The SaudiFood and Drug Authority (SFDA) initiated a project to monitor the safety of orphan drugs registered. METHODS: First, a list of SFDA registered orphan drugs from 2016 to 2022 were selected. Second, published reportedadverse events retrieved from AdisInsight database. Third, labelness assessment was performed on theretrieved adverse drug event (ADEs) lists by crosschecking the label of U.S. Food and Drug Administration,European Medicines Agency label and local label information to exclude labeled ADEs. Fourth, acomprehensive drug safety review for the unlabeled ADEs was conducted using different evidence sourcesincluding unpublished clinical trials, literature, local and global spontaneous reports and Periodic Benefit-Risk Evaluation Reports. RESULTS: From 2016 to 2022, 35 orphan medications registered by SFDA, with a total of 1403 reported events onAdisInsight. The crosschecking resulted in requesting of local label update for 13 orphan drugs. Projectyielded a total of 18 comprehensive drug safety reviews were performed for 22 potential safety signals.The safety review recommendations were requesting additional safety data from pharmaceuticalcompanies (n=6 signals), routine monitoring of the risk (n=11 signals) and closing the signal (n=5 signals). CONCLUSIONS: Safety Monitoring of Orphan Drugs Project in SFDA successfully improved the identification andassessment of new potential signals with medications use. It is important raise the ADEs reportingawareness associated with medicines especially orphan drugs.	ISPOR 2023	2023	Waad Altayyar, Hadir Aljohani, Nouf Al-Fadel, Fawaz Alharbi
46	Traceability of Infliximab Reference Medicinal Product and Its Biosimilar Products Adverse Drug Events Reports in Saudi Arabia	OBJECTIVES: Infliximab reference product and two biosimilar products were approved by the Saudi Food & DrugAuthority (SFDA) for the treatment of a wide variety of inflammatory conditions such as rheumatoidarthritis, Crohn's disease, and ankylosing spondylitis. Recording both the product trade name and thebatch number are essential in the spontaneous reporting of adverse drug events (ADEs) of biologicalmedicines due to the variability of the bio-manufacturing process that may cause safety risks such asimmunogenicity. This study aims to assess the availability of batch number and trade name in the ADEreports of Infliximab (reference product) and biosimilar products in the National PharmacovigilanceCenter (NPC) database at SFDA. METHODS: We performed a descriptive analysis of spontaneous ADE reports of Infliximab (reference and biosimilarproducts) in Saudi Arabia reported to the NPC from December 1, 2017, to January 03, 2023. The analysisexamined the reporting frequency of batch number, and trade name. RESULTS: Overall, a total of 731 cases were retrieved from the NPC database. We found reported trade names in626 (85.6%) cases [150 (23.9%) for the reference product and 476 (76%) reports for biosimilar products].However, the batch number identifier was only included in 39 (5.3%) out of 731 cases [7 (17.95%) inreference product and 32 (85.05%) in biosimilar products). 479 (89%) of case reports were received fromhealthcare professionals (pharmacists), whereas 146 (19.9%) cases have been reported from marketingauthorization holder. CONCLUSIONS: Our study showed a lack of reporting batch number with Infliximab reference and biosimilar products inthe NPC database. It is essential to raise awareness of the importance to report trade name and batchnumber of reference and biosimilar products among healthcare providers and the public to improve thedata quality of biologic and biosimilar products' ADE reports.	ISPOR 2023	2023	Sara Almishari, Fares Alrubaish, Nouf S. Al-Fadel, Fawaz Alharbi

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47	Proactive Drug Safety Monitoring of Adverse Drug Events in Saudi Arabia: 2022 Experience	OBJECTIVES: Saudi Food and Drug Authority (SFDA) established the Proactive Drug Safety Monitoring Program tomonitor the safety of registered medicinal products in Saudi Arabia more proactively and efficiently. TheProactive Drug Safety Monitoring Program evaluated the relatedness of adverse drug event (ADE) casereports exported from VigiBase, the World Health Organization global database of individual case safetyreports, with a group of medications approved by SFDA. METHODS: At the beginning, a list of medications was selected for all registered products by SFDA in 2021. Then, theADE case reports of the selected medicines were retrieved from VigiBase. After that, a crosschecking ofthe U.S. Food and Drug Administration, European Medicines Agency and local label information waspreformed to exclude the labeled ADEs using the list of retrieved ADEs lists for each medicine. Finally, acomprehensive drug safety review for the unlabeled ADEs was performed using different evidencesources including unpublished clinical trials, literature, local and global spontaneous reports and PeriodicBenefit-Risk Evaluation Reports. RESULTS: A total of 44 medicines were selected with 4762 reported ADE case reports retrieved from VigiBase. Thelabelness assessment resulted in requesting of label update for 30 medicines (68.18%). A total of 22comprehensive drug safety reviews were performed for 40 potential safety signals. The safety reviewrecommendations were requesting additional safety data from pharmaceutical companies (n=5 signals),keeping routine monitoring of the risk (n=21 signals) and closing the signal (n=14 signals). CONCLUSIONS: The Proactive Drug Safety Monitoring Program in SFDA successfully improved the identification of newsafety information for medicinal products.	ISPOR 2023	2023	Lama Alhusayni , Nora Alorf, Solaiman Alhawas ,Nouf S. Al-Fadel, Fawaz Alharbi
48	Active Surveillance for Safety monitoring of COVID-19 vaccines in Saudi Arabia	Objective: It is generally accepted that the world will not return to the pre-pandemic normally situation until safe and effective vaccines become available. However, the rare and unknown adverse events following immunization (AEFIs) are not usually detected in the clinical trials. Thus, monitoring the safety of coronavirus disease of 2019 (COVID-19) vaccines in real-world population is essential. Therefore, the Saudi Food and Drug Authority (SFDA) performed a post-marketing safety surveillance of AEFIs following administration of COVID-19 vaccines. Methods: A prospective cohort study conducted and followed subjects who received COVID-19 vaccines from the first day of vaccination for seven days after the first and second doses, then biweekly for three months. All information from the vaccinee (demographic information, vaccine type and AEFIs) were collected by phone through a standardized online questionnaire. Baseline characteristics and AEFIs were analyzed descriptively by SPSS software. AEFIs were classified according to medical Dictionary for Regulatory Activities (MedDRA). Results: 544 subjects of 8867 agreed to be part of the study. Among them, 218 subjects completed the study. Out of 218, 87 (39.91%) individual received Pfizer-BioNTech vaccine, 45(20.64%) received Oxford/AstraZeneca vaccine, 5(2.3%) individual received Moderna vaccine, and 81 (37.2%) received two different COVID-19 vaccines. The reported events were categorized to system organ class (SOC) according to MedDRA. The most reported SOCs were skin and subcutaneous tissue disorders (n=66 with Pfizer-BioNTech vaccine, n=34 with Oxford/AstraZeneca vaccine, n=5 with Moderna vaccine), infections and infestations (n=23 with Pfizer-BioNTech vaccine, n=33 with Oxford/AstraZeneca vaccine, n=4 with Moderna vaccine), musculoskeletal and connective tissue disorders (n=53with Pfizer-BioNTech vaccine, n=46 with Oxford/AstraZeneca vaccine, n=7 with Moderna vaccine). Only 10 (4.6%) cases were serious and required medical intervention. Conclusion: The preliminary results shows the short-term safety profiles of included COVID-19 vaccines are acceptable in Saudi Arabia.	ISPOR 2023	2023	Saja Alhabardi, Lama Alhusayni, Maram Aljebreen, Asma Alzamil, Mayada AlSwead, Manal Alrohaimi, Fawaz Alharbi

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49	Identification and Evaluation of Congenital Anomaly Safety Signals: SFDA Experience	OBJECTIVES: This project aims to identify signals of congenital anomaly (CA) related to potentially teratogenicmedications use and evaluate these signals based on the available evidence. METHODS: Individual case safety reports (ICSRs) of CA were retrieved from the World Health Organization (WHO)global database of individual case safety reports (VigiBase) using specific keywords, in February 2022.Then, the following exclusion criteria were applied; ICSRs with chromosomal anomaly, skeletal dysplasia,or genetic syndrome were excluded since aetiology is assumed not to be teratogenic; ICSRs with onlyexposed to (folic acid, minerals and/or vitamins); ICSRs with only exposed to topical medications, or non-locally registered drugs. Following, included drug-CA events ICSRs were crosschecked in the local product'sinformation comparing to U.S. Food and Drug Administration and European Medicines label information,then, identified signals underwent in-depth assessment by conducting a comprehensive safety evaluationusing several different evidence sources including literature, global cases retrieved from VigiBase and localcases retrieved from the national pharmacovigilance database of the national pharmacovigilance center atSaudi Food and Drug authority (SFDA) and Periodic Benefit-Risk Evaluation Reports. RESULTS: A total of 181 drug-CA pairs were subjected to initial assessment. Of these, 151 drug-CA events werelabeled in the Saudi product's leaflet; 18 drug-CA events were labeled in other stringent regulatoryauthorities; and 12 drug-CA events were referred to in-depth assessment. The assessment results wereone-drug-CA event was probably related, 11 were possibly related, and one was excluded due to off-labeluse in pregnancy. CONCLUSIONS: Post marketing data from VigiBase has successfully improved signal detection of CA related to potentiallyteratogenic medications use. Further epidemiological studies are needed to quantify the CA risks to helphealth care professionals to make risk versus benefit decision for using medicines in pregnancy.	ISPOR 2023	2023	Eman Alghamdi, Manal Alruhami, Nouf Al-Fadel, Fawaz Alharbi
50	Post-marketing Safety Assessment of Tisagenlecleucel: Analysis of Individual Case Safety Reports in VigiBase	Background:Tisagenlecleucel is the first Chimeric Antigen Receptor(CAR)-T cell therapy approved by Saudi Food&Drug Authority(SFDA)for B-cell lymphomas and leukemia treatment. Objective: To describe the individual case safety reports (ICSRs) associated with tisagenlecleucel use reported to the World Health Organization (WHO) Global Database of ICSRs (VigiBase) and identifying potential safety signals. Methods: A descriptive analysis of ICSRs associated with tisagenlecleucel use. A search has been conducted in VigiBase in December 2022 to retrieve all reported cases with use of tisagenlecleucel from inception to 31 December, 2022 via signal detection tool "Vigilyze". Then, labelness assessment was performed on retrieved ICSRs lists by crosschecking the label of United States Food and Drug Administration, European Medicines Agency and SFDA to exclude labeled ADEs. Results: A total of 2,660 ADEs associated with use of tisagenlecleucel were reported in VigiBase. The United States was the most reported country (63.7%). The ADEs occurred more frequently in males (60.4%) and the mean age was 38 years. Majority of ICSRs were serious (91.2%) and 22.3% of ICSRs reported fatal outcome. Approximately 93% of ICSRs were reported between 2019 to 2022. After removal of vague and duplicate events, 938 ADEs were identified. We excluded 915 ADEs had missing information, labeled in product information, or confounded by indication. The remaining 23 signals were referred for ICSRs causality assessment utilizing the WHO- Uppsala Monitoring Centre (UMC) causality assessment system. The majority of the signals were refuted due to un-assessable cases with limited information provided. We identified a single probable case of intracranial hypertension and bradycardia, 6 possible cases of shock and unlikely association with bradycardia (n=3), shock (n=2), myocarditis, pericardia effusion cerebellar syndrome, mydriasis and lymphadenopathy (n=1, each). Conclusion: Based on the analysis performed, the retrieved data from ADE reports reveals no new or unexpected safety information. However, it highlights considerable variability in the quality and completeness of ADE reports. Incomplete data is a known limitation of drug safety surveillance based on ADE reporting after marketing authorization and our evaluation indicates this is also true for CAR-T-cell products.	ISoP 2023 Annual Meeting	2023	Nora S. Alorf, Solaiman Alhawas, Nouf Alfadel, Fawaz Alharbi

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Waad Altayyar, Solaiman Alhawas, Hadir Aljohani, Nouf Al-Fadel, Fawaz Alharbi	2023	ISoP 2023 Annual Meeting	Introduction Medications are classified as hazardous when they exhibit one or more of the six toxicity criteria in humans, animal models, or in vitro systems including: carcinogenicity, developmental toxicity (including teratogenicity), reproductive toxicity, genotoxicity, organ toxicity at low doses, and chemical structure or toxicity profile that mimic existing drugs determined to be hazardous. These medications include chemotherapy, antiviral drugs, hormonal replacement medications, and immunosuppressive agents.1 Objectives To assess the safety measures related to safe handling and disposal of hazardous oral medications in the current local product information of hazardous oral medications Methodology First, we identified a list of oral hazardous medications that are registered in Saudi Arabia and listed as hazardous drugs in Healthcare Settings in the National Institute for Occupational Safety and Health (NIOSH). Then, we assessed the current safety measures (instructions and precautions) that available in product leaflets of all targeted registered hazardous medications. After that, the safety measures were classified as complete or incomplete based on whether (or not) the provided information was sufficient regarding safe handling and disposal of hazardous oral medication. We requested labeling update from pharmaceutical companies for oral hazardous medications that classified their content of safety measures as incomplete. Result A total of 84 out of 139 NIOSH oral hazardous medications were registered in Saudi Arabia. Carcinogenic medications account for 26.2% (n=22) of oral hazardous medications. After our assessment of safety measures, we have requested an update for 77 (90.6%) out of 84 oral hazardous products from pharmaceutical companies to add new safety measures in related sections to safe handling and disposal of hazardous medications to minimize the risk of exposure to healthcare personnel, patients and the environment. These new safety measures was adopted from the United States Pharmacopeia (USP) General Chapter <800> for safe handling of hazardous drugs in healthcare settings and American Society of Health-System Pharmacists (ASHP) guidelines on handling hazardous drugs. Conclusion Important safety measures for safe handling and disposal of hazardous medications was lacking in the local product information of oral hazardous medications. Further efforts are required to improve awareness among healthcare professionals and patients regarding safe handling and disposal of hazardous medications.	New safety measures to minimize exposure risk of oral Hazardous medications: SFDA experience	51

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52	Citalopram and Fluconazole Drug Interaction and Potential Risk of Serotonin Toxicity	Background Fluconazole, a triazole antifungal agent, is a potent inhibitor of cytochrome P450 (CYP) isoenzyme 2C9 and a moderate inhibitor of CYP3A4. It is also an inhibitor of the isozyme CYP2C19. Fluconazole has been associated with QT interval prolongation, hence the co-administration of drugs known to prolong the QT and metabolized via CYP3A4 are contraindicated. Citalopram is indicated for the treatment of depression, and it is mainly metabolized by CYP3A4 and CYP 2C19 which are substrates influenced by fluconazole administration. Citalopram as well known to cause QT prolongation Objectives This review aims to assess the potential risk of QT prolongation due to the drug-drug interaction between fluconazole and citalopram, as part of drug interactions' assessment project initiated by the Saudi Food and Drug Authority (SFDA). Methods The safety review utilized several sources. First, conduct causality assessment of the global cases of interacting drugs retrieved from the World Health Organization (WHO) database (VigiBase) and local adverse drug reactions database at the SFDA from inception to May 2023. Second, a systematic literature search was conducted in Cochrane, Embase and PubMed. In addition, the Google Scholar and Drug Interactions Checker Databases such as (Micromedex®, Lexicopm®, medicine's complete®) were also searched. The search included published studies from inception to May 2023, for eligible English publications with the appropriate keywords. Third, an overall assessment of the drug interaction using the Drug Interaction Probability Scale (DIPS) to assess drug interaction relation to adverse event was performed. Results The literature search yielded one case series, which discussed two cases of life threatening serotonin toxicity due to a drug interaction between citalopram and fluconazole. Using the DIPS scale, the assessment of the interaction is probable in both cases. In addition, 51 cases were identified in WHO global database that reported fluconazole interaction with citalopram. Out of that, 17 cases reported Serotonin Syndrome while five cases reported QT prolongation as drug-drug interaction outcome. The time to onset and dechallenge / rechallenge information were not provided to assess the causality. Out of the 5 QT prolongation cases, three cases were confounded by other medications known to cause QT prolongation (azithromycin, erythromycin). No local cases were found. Conclusion The available evidence shows a probable pharmacokinetics/ pharmacodynamics interaction between fluconazole and citalopram. The cumulative effect of decreased citalopram metabolism and pharmacodynamics interaction with fluconazole could lead to serotonergic effect and /or QT prolongation. Further assessment by epidemiological studies is needed.	ISoP 2023 Annual Meeting	2023	Maha Alghamdi, Waad Alghamdi, Nouf S. Al-Fadel, Fawaz Alharbi

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53	Pharmacogenomics-Pharmacovigilance Project: SFDA Experience	Background 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. Objectives 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. Methods 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. Results 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. Conclusion 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.	2024 ISPE Annual Meeting	2024	Hadir Aljohani, Maha H. Alghamdi, Manal H. Alrohaimi, Shahad N. Alnasser, Nouf S. Al-Fadel, Fawaz. Al-Harbi

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54	Potential Association of Syndrome of Inappropriate Antidiuretic Hormone Secretion with Olanzapine Use	Background 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. Objectives 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. Methods 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. Results 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. Conclusions 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.	2024 ISPE Annual Meeting	2024	Shahad N. AlNasser, Solaiman M. AlHawas, Nouf S. Al-Fadel, Fawaz F. AlHarbi

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55	Immune Checkpoint Inhibitors and Overlap Syndrome of Myocarditis and Myositis or Myasthenia Gravis: Analysis of WHO VigiBase Database	Background 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. Objectives Describe concurrence of myocarditis and myositis or myasthenia Gravis associated with ICIs in VigiBase. Methods 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. Results 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. 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. Conclusions 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.	2024 ISPE Annual Meeting	2024	Eman A. Alghamdi, Hassan Abushukair, Abdul Rafeh Naqash,Fawaz Alharbi

#	عنوان البحث (Title)	ملخص البحث (abstact)	إسم المؤتمر	سنـــــة المشـــاركة	إسم الباحث المشـــــارك
56	Lower Limb Amputation association with SGLT-2 inhibitors: Systematic Review and meta-analysis	Introduction: 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. Objective: 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. Methods: 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. Results: 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. Conclusion: 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.	ISPE's 16th Asian Conference on Pharmacoepidemiology	2024	Abdulaale Almutairi

#	عنوان البحث (Title)	ملخص البحث (abstact)	إسم المؤتمر	سنـــــة المشـــاركة	إسم الباحث المشـــــارك
57	Potential Association of erectile dysfunction with omeprazole use	Background 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. Objectives To evaluate the potential association between omeprazole and ED as a part of drug class effect project conducted by the SFDA. Methods 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. Results 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. Conclusions The available evidence suggests potential association between ED and Omeprazole. Further epidemiological studies are needed to investigate this potential association.	ISPE's 16th Asian Conference on Pharmacoepidemiology	2024	Solaiman M. AlHawas, Shahad N. AlNasser, Nouf S. Al-Fadel, Fawaz F. AlHarbi

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58	(CAR) T cell Immunotherapies and Potential association of Secondary T-Cell Malignancies	Introduction 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. Objectives 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®). Methods 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. Result 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. Conclusion 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.	ISPE's 16th Asian Conference on Pharmacoepidemiology	2024	Maha Alghamdi, Nouf Alfadel, Fawaz Alharbi

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59	Improving the Quality of Drug Safety Review Reports: the SFDA Experience	Background 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. Objectives 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. Methods 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. Results 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. Conclusions 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	2024 ISPE Annual Meeting	2024	Nouf S. Al-Fadel, Nora Alorf, Fares Alrubaish, Shahad N. AlNasser, Fawaz Al-Harbi

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60	Proactive Safety Evaluation of antineoplastic Agents During Pregnancy: the SFDA Experience	Background Safety of antineoplastic agents is one of the most crucial issues faced the cancer patients during their treatment, especially for pregnant women and women of childbearing age since pregnant women are usually excluded from clinical trials during the drug development process. In addition, some antineoplastic drugs might remain in the blood for up to 6 months at least after the completion of the therapy. Objectives The aim of this project is to assess the safety of antineoplastic agent use during pregnancy. Methods First, we identified a list of antineoplastic agents that are registered by the Saudi Food & Drug Authority (SFDA) . Second, we assessed the current information regarding 'Fertility, Pregnancy, and Lactation ' in relevant sections of product information (PI) by crosschecking the local PI with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) label information. We conducted a comprehensive safety assessment of the antineoplastic drugs that classified of their content of 'Fertility, Pregnancy, and Lactation "information as incomplete using various databases, literature review, global cases, and regulatory documents provided by the companies. Results A total of 53 SFDA-registered antineoplastic agents were retrieved based on drug classes (alkylating agents, antimetabolites, and hormones antagonists) which was subjected to an initial review of Fertility, Pregnancy, and Lactation information in their PI. Of these, a total of 26 (49%) antineoplastic agents underwent label update and 3 (5.6%) were referred to in-depth assessment through comprehensive safety evaluation. The comprehensive safety evaluation was closed with no further regulatory action due to limited evidence to draw a conclusion. Lastly, to communicate our findings, we released an infographic directed to the public to educate them about precautions related to the use of chemotherapy before and during pregnancy, the risk of associated infertility, contraception utilization, and the planning of pregnancy post-chemotherapy treatment. Conclusion This project shows the importance of the ongoing monitoring safety profile of antineoplastic agents among pregnant population. Further epidemiological studies are needed to quantify the risks associated with antineoplastic agents to help healthcare professionals to make risk versus benefit decision for using medicines in pregnancy.	ISPE's 16th Asian Conference on Pharmacoepidemiology	2024	Manal H. Alrohaimi, Eman A. Alghamdi, Maha H. Alghamdi, Nouf S. Al-Fadel, Fawaz. Al-Harbi

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61	Integrating Risk Minimization Measures of Medications into Hospital Information Systems: Insights from three Hospitals in Saudi Arabia	Background: 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. Objective: 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. Methods: 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. Results: 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. 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. Conclusion: 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.	ISoP Mid-Year Symposium 2024	2024	Wed AlGhannam, Fadi Alanazi, Najd Alabdulrahman, Naser Aljaser, and Fawaz Alharbi

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62	Exploring Healthcare Providers' Perspectives on Risk Minimization Measures' Content	Background: The purpose of Additional Risk Minimization Measures (aRMMs) is to prevent or lessen the likelihood or severity of adverse reactions that may result from exposure to a medicine. As of 2022, the Saudi Food and Drug Authority has approved 265 aRMMs in English and Arabic languages. The continuous evaluation of RMMs is a crucial part of products' risk management systems, and assessing healthcare professionals' perception of their understandability is recommended for the overall improvement of risk communication means. Objective: The aim of this study was to obtain healthcare professionals' opinions on aRMMs of three sampled products in terms of design, content, and layout, and to identify opportunities for improvement. The study also aimed to assess the understandability and actionability of the aRMMs. Methodology: A cross-sectional, multi-center survey-based study was conducted among healthcare professionals who had previously received aRMMs of three sampled products (nilotinib, valproate, and baricitinib) which were selected according to pre-defined criteria. The self-administered online survey consisted of 25 questions designed to explore gaps in the current approved aRMMs' design, content, and layout. The survey was published online in English and distributed via mailing lists and to Pharmacovigilance Regional-Center offices in multiple medical centers across Saudi Arabia. Results: A total of 40 healthcare professionals responded to the survey. Of these, 76% were physicians and 24% were pharmacists. All participants agreed that the educational material's purpose was completely evident, and the material clearly identified the action that the healthcare professional or patient should take. A majority of the healthcare professionals (87%) agreed that the material uses common, everyday language, that the medical terms were defined properly, and that the information was presented in a logical sequence. Conclusion: Involving Healthcare professionals in the continuous assessment of aRMMs can provide valuable insight. According to the survey results regarding educational materials, healthcare professionals have an overall positive perception towards the content of the educational materials that are part of the aRMMs. It is evident that development opportunities exist for simplifying the language used and incorporating more everyday language. This approach will enhance the accessibility and comprehension of educational materials, making them more effective. Further studies are required to incorporate more HCPs in Saudi Arabia to assess their utilization of aRMM tools.	ISoP 2023 Annual Meeting	2023	Fadi Alanazi, Wed AlGhannam, Naser Aljaser, and Fawaz Alharbi

إسم الباحث المشـــــارك	سنـــــة المشـــاركة	إسم المؤتمر	ملخص البحث (abstact)	عنوان البحث (Title)	#
Aljawharah Albabtain, Naser Aljaser, Fawaz Alharbi	2023	ISoP 2023 Annual Meeting	Background: Sodium valproate is an antiepileptic medication. Teratogenicity is one of the most serious risks in children of women exposed to valproate during pregnancy. The Saudi Food and Drug Authority (SFDA) have approved additional risk minimization measure, which is a "pregnancy prevention program (PPP)" to minimize this risk and raise the awareness among healthcare professionals. This program includes tools such as patient card, patient guide, health care provider guide, and an acknowledgement form. Aim: To evaluate the effectiveness of the Additional Risk Minimization Measures (aRMMs) in improving the knowledge and the practices of targeted HCPs about the indications and safe use of sodium valproate. Method: A cross-sectional, multi-center, survey-based study targeted healthcare professionals (HCPs)who had previously listed to receive aRMMs of sodium valproate in Saudi Arabia. The web-based Survey was distributed by email between March and December of 2021. Descriptive statistics were performed to represent demographic characteristics and knowledge level and practices using Excel 2016 program. Results: Only 42 of 813 HCPs responded to the e-survey, and 26% (11) of them acknowledged receiving the educational materials of sodium valproate. Furthermore, 98% (41) of HCPs were aware of the potential risk of "teratogenicity," and 86% (36) of HCPs provided adequate patient counseling before using sodium valproate regarding potential risk of teratogenicity. Additionally, 60% (25) of HCPs requested a pregnancy test for a female of childbearing potential prior to prescribing sodium valproate and 64% (27) of HCPs confirmed that their female patients in childbearing age used effective contraception methods. Conclusion: The impact of aRMMs of valproate was not optimal. However, the results should be interpreted carefully due to the low sample size. Further epidemiological studies are needed to assess the effectiveness of aRMM implementation of sodium valproate in Saudi Arabia.	Impact of Additional Risk Minimization Measures in Reducing the Risk of Teratogenicity in Sodium Valproate: A Cross-sectional Study Among Healthcare Providers in Saudi Arabia	63
Nada Alageel, Amal Alshatri, Naser Aljaser, Fawaz Alharbi	2023	ISoP 2023 Annual Meeting	Background: Ivabradine is a heart rate lowering agent approved in Saudi Arabia in 2007 for treatment of angina pectoris and chronic heart failure. In 2015, SFDA withdrew the marketing authorization of Ivabradine due to serious cardiac adverse events. After that, in 2017, ivabradine was re-registered under SFDA-approved restrictions, in which Ivabradine was restricted to the indication of chronic heart failure with implemented additional risk minimization measures (aRMMs) (registry, prescriber and patient guides. A registry was requested in order to follow up patients who taking Ivabradine as part of the risk minimization activities and to support that ivabradine is only used in patient who are eligible for receiving the treatment and in which the benefits of ivabradine therapy outweighs its risks. Objective: To assess the compliance of ivibradine prescribers to instructions in approved aRMMs in Saudi Arabia. Methods: A retrospective cohort study was conducted using data from drug registry. Patients was included if they initiated ivabradine treatment between November 2018 until end of July 2022. Patient information were obtained from registry forms that received from marked authorization holder (MAH) or health institutions in Saudi Arabia. We assessed prescriber adherence to the following instructions: left ventricular ejection fraction ≤ 35% at time of therapy initiation, Heart rete (HR) greater than or equal to 70 bpm at time of initiation, the initiation dose does not exceed 5 mg twice a day, the maintenance dose does not exceed 7.5 mg twice a day, and no concomitant use of verapamil or diltiazem at treatment initiation or during 6-month follow-up. Results: 652 patients enrolled in our registry. Mean age was 55.1 years old. 68% of patients aged <75 years old and 6% of patients aged ≥75 years old. None of patients exceeded 7.5-mg bid as maintenance dose Ivabradine was not used concurrently with verapamil or diltiazem in any patients except two patients (0.3%), (one on diltiazem and the other one on verapamil). Conclusion: The study shows that aRMMs for ivabradine are implemented successfully in Saudi Arabia.	Assessment the effectiveness of implementing Registry as Risk Minimization Measures of Ivabradine in Saudi Arabia	64

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65	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. 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. 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. 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. 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.	ISoP 2023 Annual Meeting	2024	Atheer Aldayel, Maram Aljebreen, Amal Alshatri, Naser Al Jaser, Fawaz Alharbi

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66	Improving Medication Safety in Saudi Healthcare System: The Role of Regional Pharmacovigilance Officers (RPVOs) in Implementing Additional Risk Minimization Measures	BBackground: 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. Objectives: 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). Methods: 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. Results: 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. 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. 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. Conclusion: 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.	ISoP 2023 Annual Meeting	2024	Aseel Alshayji, Naser Al Jaser, Fawaz Alharbi

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67	Standardized Approach to obtain Patients feedback on Risk Minimization Measures Shape and Content	Background: 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. Objective: To obtain patients' opinions and feedback about three aRMMs (patient guide) of semaglutide, ranibizumab and mycophenolate in regards to design, content and layout. Methods: 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. Results: 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. Conclusion: 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.	ISPE's 16th Asian Conference on Pharmacoepidemiology	2024	Naser Aljaser, Mariam Alghamdi,, Fadi Alanazi,, and Fawaz Alharbi

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68	Marketing Authorization Holders' (MAHs): The pharmacovigilance (PV) performance pattern according to their geographic classification.	Titel Marketing Authorization Holders' (MAHs): The pharmacovigilance (PV) performance pattern according to their geographic classification. Introduction: Saudi Food & Drug Authority (SFDA) initiated the PV inspection department as an independent section under NPC at the end of 2018. This section aimed to monitor the PV activities and enhance PV activities by inspecting the performance of the registered MAHs, whether they follow it as stated in the Saudi GVP or not. During the inspection process, the inspection team noticed a distinguish pattern in the pharmacovigilance (PV) performance according to the MAHs geographic classification (1,2,3). Aim: To understand the performance pattern based on the MAH classification with respect to the overall pattern over time. Methods: A retrospective observational study of the inspected MAHs reports in the Saudi market from December 2018 to December 2021. All registered MAHs in the Saudi market, either global, regional, or local companies, were included. The MAHs were selected based on The MAH's portfolio, ADRs reporting rate, the QPPV turnover, Compliance history, , and no more than five years from the last inspection. Results: The results showed that among all inspections (n=63), 57% were global MAHs (n=36), 25% were regional MAHs (n=16), and 18% were local MAHs. The average number of findings reported per inspection for overall inspections started from 5.5 in 2018 and reached 8.3 in 2021 (a 51% increase). The average number of findings reported per inspection for global MAHs inspections started from 5.5 in 2018 and reached 12.5 in 2021 (a 127% increase). The regional MAHs inspections started from 22.4 per inspection in 2019 and reached 18.2 in 2021 (an 18.75% decrease). For local MAHs inspections, it started from 8.5 per inspection in 2019 and reached 14.5 in 2021 (70.5% increase). Conclusions: This study has identified factors contributing to developing distinguish patterns in the pharmacovigilance (PV) performance between these classifications. The pharmacovigilance inspection department will use these data to create an educational plan to deliver the targeted recommendation for each MAHs category. References 1. Saudi Food and Drug Authority, 2015. Guideline on Good Pharmacovigilance Practices (GVP). Riyadh: Saudi Food and Drug Authority: National Pharmacovigilance Center. 2. National pharmacovigilance center, 2021. Pharmacovigilance Inspections Report December 2018– December 2020. Riyadh. 3. National pharmacovigilance center, 2022. Pharmacovigilance Inspections Report 1st Jan 2021 to 31st Dec 2021. Riyadh.	21st ISoP Annual Meeting	2022	Amal Arafah

إسم الباحث المشـــــارك	سنـــــة المشـــاركة	إسم المؤتمر	ملخص البحث (abstact)	عنوان البحث (Title)	#
Amal Arafah	2023	22nd ISoP Annual Meeting	Title: Management and Reporting of Adverse Reaction by Marketing Authorization Holders: Challenges and Opportunities Observations of Pharmacovigilance Inspection Author(s): A. Arafah, A. AlOtaibi Affiliation(s): Pharmacovigilance system inspection department, Saudi Food & Drug Authority, Riyadh, Saudi Arabia. Text: Background: Adverse Events reporting had special attention from the executive president of the Saudi Food & Drug Authority (SFDA) since early 2018. Accordingly, reporting adverse events became one of the remarkable indicators for well-established and supported systems in Saudi Arabia. Since 2018 to date, the inspection program of SFDA have identified that management and reporting of adverse events activities as the most violated Guideline on Good Pharmacovigilance Practices (GVP) module at inspected marketing authorization holders (MAHs). Aim: To identify the gaps by assessing the performance pattern of the inspected MAHs in managing and reporting adverse reaction activities, and suggest the opportunity for change. Methodology: A retrospective observational study documenting various inspectional findings of eighty inspection visits from December 2018 to December 2022. All inspected MAHs were included to measure the performance & compliance of MAHs toward the management and reporting of adverse events activities through the number of findings of that section. Statistical analysis used in the study included descriptive analysis, including frequency/percentages for categorical variables analyzed using Microsoft Excel software. Results: The total number of inspection findings detected in management and reporting of adverse reactions was 226 out of 1066 (21%); among them 29% (n=65) of the total result was seen in data collection methods, 23% (n=52) in assessments of seriousness, causality, and expectedness, 20% (n=46) in literature screening, and 15% (n=35) in submissions and follow up processes. The major findings were the dominant finding among all the results, representing 65% of the total findings. The findings were divided by 49% (n=111) for global MAHs, 35% (n=79) for regional MAHs, and 16% (n=36) for local MAHs. The global and regional MAHs were similar in the topics ranking to the total findings; however, the regional added the quality control process as a one of the significant findings (10%, n=8). On the other side, the local MAHs were different which recorded literature screening as reported (25%, n=9), followed by data collection methods and submissions and follow-up processes at the percentage (19%, n=7), medical review (17%, n=6), and assessments of seriousness, causality, and expectedness (11%, n=4) Conclusions: The study has identified variations in the pharmacovigilance performance, developing distinguished patterns between these classifications. The inspection team considers the significant variation to address these topics in the annual educational sessions that the national pharmacovigilance center department plans to deliver the targeted recommendation for each MAH category. References/ Further sources of information (maximum 6 References): 1. Saudi Food and Drug Authority, 2015. Guideline on Good Pharmacovigilance Practices (GVP). Riyadh: Saudi Food and Drug Authority: National Pharmacovigilance Center. 2. National pharmacovigilance center, 2021. Pharmacovigilance Inspections Report December 2018– December 2020. Riyadh. 3. National pharmacovigilance center, 2022. Pharmacovigilance Inspections Report 1st Jan 2021 to 31st Dec 2021. Riyadh. 4. National pharmacovigilance center, 2023. Pharmacovigilance Inspections Report 1st Jan 2022 to 31st Dec 2022. Riyadh.	Management and Reporting of Adverse Reaction by Marketing Authorization Holders: Challenges and Opportunities Observations of Pharmacovigilance Inspection	69

#	عنوان البحث (Title)	ملخص البحث (abstact)	إسم المؤتمر	سنـــــة المشـــاركة	إسم الباحث المشـــــارك
70	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 Background: 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. Objective: 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. Method: 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. Results: 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. Conclusion: 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. References: 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. 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.	23rd ISoP Annual Meeting	2024	Amal Arafah

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71	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. 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. 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. 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.	2024 ISPE Annual Meeting	2024	Hammad A. Al Dali
72	Critical Vs Major finding; According to the classification of MAH in Saudi Arabia	Introduction: Pharmacovigilance system inspections are designed to review the procedures, systems, personnel, and facilities in place and determine their compliance with regulatory pharmacovigilance obligations. The objective is monitor activities and protect public health by ensuring the continued safety of medicines that authorized in Saudi Arabia. Aim/Objective: To count and review the inspection findings that documented through inspections visits for local, regional and global MAHs, then to find what are the main characteristics and differences of those findings. Methods: Using the Pharmacovigilance inspection database to review the inspection findings that conducted between December 2018 to December 2022 for all inspection visits of local, regional and global MAHs that registered in Saudi Arabia. Results: This study analyzed 80 pharmacovigilance inspections of Marketing Authorization Holders (MAHs) in Saudi Arabia, revealing 135 critical and 704 major findings. The most findings were identified in global MAHs (55 critical, 305 major), followed by regional (61 critical, 277 major), and local MAHs (19 critical, 122 major). For global and regional MAHs, the top critical findings were in data collection methods and system oversight, while major findings were most common in assessments of seriousness, causality, and expectedness, and dataset used for signal detection. Local MAHs showed the most critical findings in data collection methods and system oversight, whereas major findings were concentrated in areas such as backup and disaster recovery processes, periodicity of data review, and the audit and corrective and preventive actions process. Conclusion: In conclusion, this study illustrates that pharmacovigilance inspections revealed a higher number of critical findings in global MAHs and major findings in various areas across different types of MAHs in Saudi Arabia. The prevalent issues across all MAHs included data collection methods and system oversight, indicating areas that require significant improvement to ensure drug safety and compliance with pharmacovigilance regulations	22nd ISoP Annual Meeting	2023	Abdullatif alotaibi

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73	Comprehensive Analysis of Pharmacovigilance Inspections Practices: Focus on QPPV Responsibilities 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. 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. 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. 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. 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	2024 ISPE Annual Meeting	2024	Hammad A. Al Dali
74	Potential Risk of Dry Mouth: Local Case Report Triggers Review of Levofloxacin Safety	Background: Dry mouth also refers medically to Xerostomia is the patient's subjective feeling of dry mouth while hyposalivation is the objective measure. Xerostomia occurs when secretion is reduced to a bout half the normal quantity, but may also be a result of changes in the composition of the saliva. In such cases, the saliva may become viscous, stringy and / or frothy. [1][2] Levofloxacin is abroad-spectrum, third-generation fluoroquinolone antibiotic used to treat bacterial infections. In 1996, levofloxacin received the first approval by U.S.FDA. [3]Recently, the signal detection team in Saudi Arabia received a local case-report of dry mouth reported with the use of levofloxacin, which triggers this investigation. Aim: To evaluate the risk of dry mouth associated with the use of levofloxacin and to suggest regulatory recommendations if required. Methods: Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between dry mouth and levofloxacin use. Results: While only one case report found in Saudi vigilance database, we found 857 global cases resulted in WHO database at march 2023 (figure1-2). Authors applied WHO-UMC causality assessment criteria on cases with completeness score1.0 (n=30). [4]Among them, 29 cases of Dry mouth were either probably or possibly linked to levofloxacin. Moreover, the authors also looked or more supportive evidence from literature. A search for eligible publication using terms “levofloxacin” and “Dry mouth” was done at that point of time. As a result, evidence from literature found supportive for this signal, the risk of dry mouth was reported in a published randomized double-blind controlled trial.[5] Conclusion: Based on this comprehensive review, the cumulative evidence identified from assessed cases and literature are sufficient to suggest causal association between levofloxacin and dry mouth. Health care professionals and health regulators must be aware of the potential risk in drug recipients and we suggest monitoring signs and symptoms in treated patients.	22nd ISoP Annual Meeting	2023	Mohammed Fouda

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75	Uveitis Associated with Elasomeran Use: Adverse Events- Signal Review	Background: 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. Aim: The purpose of this review is to evaluate the risk of uveitis in association with Elasomeran use. Methods: 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. 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. 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.	23nd ISoP Annual Meeting	2024	Abdulaziz alakeel

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76	Descriptive Analysis of Good Clinical Practice Inspection Findings from the Saudi Food and Drug Authority	Abstract Introduction 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. Objectives 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. Methods 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. Results 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. Conclusion 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. 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. Keywords: Clinical trial, regulatory, inspection, investigation, good clinical practice, Saudi Food and	Society of Clinical Research Associates	2024	اميمة عرب و محمد الضعيان

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77	Safety of Switching from a Reference Biologic to Its Biosimilar: A Systematic Review and Meta-Analysis	Abstract Background: Biosimilars are designed to closely resemble their reference biologics in terms of quality, safety, and efficacy, with only minor variations in clinically inactive components and manufacturing methods. Evaluating the safety of switching between these products is critical for healthcare providers and patients. Concerns may arise when transitioning patients from a reference biologic to a biosimilar or between different biosimilars. Objective: This systematic review and meta-analysis aims to evaluate the frequency of adverse events associated with switching from a reference biologic to its biosimilar, using data derived from randomized controlled trials (RCTs). Methods: A comprehensive search was conducted in MEDLINE and Cochrane Central databases from their inception to December 2024. Studies included RCTs that reported adverse reactions related to switching between reference-to-reference biologics and reference-to-biosimilar biologics. Record screening, data extraction, and risk of bias assessment were performed independently by two reviewers. Random effects models were applied to pool crude outcome data. Results: The search identified 668 abstracts, with an additional 14 studies found through hand-searching review articles. Of these, 12 trials involving 1326 participants in the reference–reference group and 1176 participants in the reference–biosimilar group met the inclusion criteria. The frequency of adverse events, serious adverse events, and treatment-related adverse events did not differ significantly between the reference–reference and reference–biosimilar groups: relative risk (RR) = 0.96 (95% confidence interval [CI], 0.85–1.08), RR = 1.06 (95% CI, 0.68–1.65), and RR = 1.03 (95% CI, 0.66–1.59), respectively. Heterogeneity was generally low to moderate across outcomes, and subgroup analyses based on disease type and reference product showed no differences. Conclusions: Switching between reference biologics and biosimilars demonstrates a comparable safety profile, suggesting that both options are viable. However, the findings are limited by the small number of trials and the scope of patient populations and products studied. PROSPERO registration number: CRD42021267205. Keywords: reference; biosimilar; biologics; interchangeability; switching; safety; adverse events	ISPOR	2022	سارة الجاهلي سمر الشويرخ احمد الخالدي عبير الذيبان
78	Hospitalization Endpoint in Clinical Trials of Outpatient Settings: using Anti-SARS-COV-2 Therapy as an Example	Abstract Purpose: 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. Methods: 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. Results: 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. Conclusion: 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.	-----	2024	Alhanouf Yousef Alnafisah, Ahmed Fawaz Alkhalidi, Hanin Aljohani, Manal Almutairi, Adel Alharf, Hadeel Alkofide

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79	Responses of Pharmaceutical Companies to Literature Review Inquiries from a Regulatory Authority: A Retrospective Analysis	Introduction: In support of new marketing authorizations and variations for novel pharmaceutical products, regulatory submissions generally consist of comprehensive modules that cover all phases of clinical development, including Phase I, II, and III trials. These comprehensive submissions are essential to ensure a thorough evaluation of the product's safety and efficacy. However, for certain submissions pertaining to products with known active substances or generics, regulatory guidelines permit applicants to submit only relevant literature references, thus exempting them from providing the complete set of documentation typically required for novel products. Although, the applicant is responsible for ensuring that the submitted literature is scientifically rigorous, directly relevant, and appropriately aligned with the specific product, including its dosage form, route of administration, and intended therapeutic indication. Objective: This study aims to evaluate the adequacy and regulatory compliance of company responses to literature inquiries issued by the Saudi Food and Drug Authority (SFDA), focusing on the effectiveness of these responses in meeting regulatory expectations. Methods: A retrospective document analysis was conducted, reviewing all literature inquiries and corresponding company responses filed in the electronic Common Technical Document (eCTD) from January 2021 till November 2023. Data of product submissions were collected from the Saudi Drug Registration (SDR) and Extedo Universal Review System (EURS). Dscriptive analysis was performed to assess the current literature review inquiries and company responses in terms of number of inquiries, type of products, submitted evidence, search strategies, and decision outcomes related to these submissions. Results: Among 28 evaluated products, 15 met the inclusion criteria. The companies responded to 18 literature inquiries as three products had at least two inquiries. Nine products were generics compared to six new products from known active substance. Despite most literature inquiries satisfying SFDA requirements, substantial gaps were observed in company compliance. Approximately 80% of the responses predominantly supported the active ingredient's efficacy and safety for the proposed indication, but 40% demonstrated limited search breadth. Furthermore, over half of the responses lacked explicit search strategies. Conclusion: The study reveals a significant discrepancy between the expectations of the SFDA and the quality of company responses to literature inquiries. The findings suggest an urgent need for regulatory guidance specific to literature reviews, aiming to standardize and improve the quality of submissions. Link of the abstract: ac3c884c-dbe8-44ec-b224-f827e9a00025.pdf.	International Society for Pharmacoeconomics and Outcomes Research (ISPOR)	2025	Zinah Alabdulkarim and Ahmed Alkhaldi

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80	Safety of Switching from a Reference Biologic to Its Biosimilar: A Systematic Review and Meta-Analysis	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. 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. 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. 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. 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. 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.	المؤتمر الآسـيوي السادس عشر لعلـم الوبائيـات الدوائية (ISPE's 16th Asian Conference on Pharmacoepidemiology (ACPE16)	2024	سارة التميمي

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81	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). Objective Reviewing the SFDA-registered drug for camels and their common practice of drug administration. 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. 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. 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. 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.	المؤتمـر الـدولي السـادس للجمعيـة الدولية لأبحاث وتنمية الإبل "دور الإبل في الأمـن الغـذائي والنمـو الاقتصادي" الأحساء	2024	Abdulelah Al-suwaydani نوره بن يوسف