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 – الأوربي I 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	الها 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