ملخصات مشاركات المؤتمرات

#	عنوان البحث (Title)	ملخص البحث (abstact)	اسم الباحث المشارك (Presnting Author)	الحدث العلمي (Scientific Event)	السنة Year
1	Effective Food Safety Risk Communication via Social Media in Times of Crisis: A Systematic Review	Abstract:Background: Social media has transformed crisis communication, enabling rapid information dissemination during food safety emergencies. However, evidence on effective strategies remains fragmented across disciplines and platforms. Objectives: To systematically review and synthesize empirical evidence on the effectiveness of social media for food safety risk communication during crisis events (2015–2025). Methods: Following PRISMA 2020 guidelines, we searched PubMed and Scopus for peer-reviewed studies examining social media communication effectiveness during food safety crises. Studies were assessed using the Mixed Methods Appraisal Tool (MMAT) 2022 for methodological quality. We conducted thematic synthesis of qualitative findings and applied GRADE-CERQual to assess confidence in each theme. Findings: From 44 unique records, 16 underwent full-text assessment, yielding 6 included studies (USA: n=4; North America: n=1; Europe: n=1). Studies examined Facebook, Twitter/X, YouTube, and mixed platforms during outbreaks, contamination events, and recalls. Thematic synthesis identified five key themes: (1) timing and speed of communication (moderate confidence); (2) platform-specific engagement patterns (high confidence); (3) message content and framing (high confidence); (4) sentiment and trust dynamics (moderate confidence); and (5) data-driven crisis communication (moderate confidence). Initial illness reports generated significantly more attention than delayed recall announcements. Different platforms served distinct purposes: Facebook for dialogue, YouTube for reach and counter-messaging. Content quality, actionable recommendations, and strategic framing were critical for effectiveness. Conclusion: Timing, platform selection, and message content are critical determinants of effective food safety risk communication on social media. Evidence supports early communication, platform-matched strategies, and data-driven adaptive messaging. Research gaps include standardized outcome measures, experimental comparisons, and studies from non-Western contexts.	(Nisreen M. Abdulsalam) د.نسرين عبدالسلام	China International Food Safety & Quality (CIFSQ) Conference	2025

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2	Phased Integration of Additional Risk Minimization Measures (aRMMs) into Hospital Information Systems in Saudi Arabia: A National Safety Initiative (oral presntation)	Background: Additional Risk Minimization Measures (aRMMs) are required for certain high-risk medicinal products when routine risk minimization measures, such as product labeling, are insufficient to ensure safe use. These measures typically include educational materials targeting healthcare professionals and patients to highlight safety concerns and outline actions to minimize risks. In Saudi Arabia, aRMMs are distributed through physical and electronic channels. To improve accessibility and usability, the Saudi Food and Drug Authority (SFDA) launched a nationwide initiative to integrate aRMMs directly into Hospital Information Systems (HIS) across selected healthcare institutions. Objective: To describe the phased integration of aRMMs into HIS in Saudi hospitals, aimed to enhance patient safety and improve the accessibility of aRMMs. Methods: The initiative was implemented in three phases between 2023 and 2025, targeting 12 hospitals: • Phase I (2023): Pilot integration in three tertiary hospitals in Riyadh and Dhahran. • Phase II (2024): Expansion of three additional hospitals in Riyadh and Khamis Mushait. • Phase III (2025): Ongoing scale-up to six hospitals, including private sector institutions in Riyadh, Taif, and Madinah. Results: In Phase I, hospitals successfully integrated Additional Risk Minimization Measures (aRMMs) into Hospital Information Systems (HIS). Core features included Electronic Health Record (EHR)-linked portals that enabled prescribers to access aRMM details at the point of prescribing, mandatory pop-up alerts for high-risk medications, embedded instructions within the prescribing interface, and SMS messages sent to patients with links to educational materials upon dispensing. During Phase II, aRMM integration was expanded and refined. Educational content was linked to specific medications, allowing prescribers to access relevant materials directly during the prescribing process. Automated alerts were triggered when high-risk drugs were selected. In addition, QR codes linked to patient-specific educational content were printed on medication labels. One hospital incorporated all aRMM-related content into its internal INTRANET system to improve visibility across departments. Phase III is currently in progress, with active onboarding of additional public and private hospitals. Participating hospitals reported improved prescriber awareness and easier access to aRMMs at the point of care. Patient communication was also considered effective. Further improvements in engagement and adherence are anticipated through future integration of aRMM content into patient-facing digital platforms. Conclusion: This national initiative presents a scalable, technology-driven model to enhancing medication safety. Further evaluation is underway to assess its effectiveness in reducing adverse events and improving safety outcomes.	(Aljawharah Albabtain) الجوهرة أبابطين	ISoP Annual Meeting	2025

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3	Evaluating the Readiness of Saudi Oncology Real-World Data for Standardization and Quality Enhancement	Background: Data standardization and quality are essential in generating reliable real-world evidence (RWE), which support regulatory and clinical decision-making, particularly in cancer drug treatments.However, studies evaluating the standardization and quality of oncology real-world data (RWD), both internationally and in Saudi Arabia, remain uncommon. Objectives: This study represents the first phase of an initiative to assess the readiness of Saudi multicenter oncology real-world data (RWD) for standardization. Additionally, data quality assessment was conducted with a focus on completeness and accuracy—two essential quality dimensions that determine the reliability of fitness-for-purpose. Methods: Data were sourced from a centralized database, the Saudi Real-World Evidence Network (SRWEN), pertained to electronic health records (EHRs) from five Saudi tertiary healthcare centers. Patients (≥18 years old) diagnosed with common (breast, thyroid, colorectal) and rare (gastric, hepatocellular and renal) forms of cancer between 2016 and 2023, were included. Readiness for standardization was evaluated by assessing the level of alignment of the existing extracted variables vs. available elements outlined in the framework of Minimal Common Oncology Data Elements (mCODE) initiative (the latter was designed to establish and maintain standardized, computable oncology data formats). Percentage completeness (i.e., the extent to which the variables in the SRWEN contained complete data entries), and accuracy of the available variables was assessed and compared across cancer types and centers. All outcomes were analyzed descriptively using RStudio (Version 1.2.5033). Results: A total of 20,671 patients were identified (15,683 [67.0%] with common cancer). Data alignment with the mCODE framework varied across centers. Core elements (e.g., patient demographics, cancer diagnosis dates, and comorbidities), were generally available. However, data on cancer clinical status, location, staging, and medications were inconsistently reported across cancer types and centers. Completeness was higher in common vs. rare cancer. Demographic information and diagnosis dates were generally complete. Certain variables, such as cancer clinical status, exhibited extremely low completeness (below 1%). Overall data accuracy was high, with rates exceeding 80% across evaluated domains. Conclusions: The findings reveal considerable variability in oncology data format across centers within the SRWEN. While data accuracy is generally high, critical gaps in completeness exist, particularly concerning clinical status and outcomes. Addressing these issues is essential for enhancing RWD's utility in supporting research and regulatory decisions in cancer care.	إبراهيم عسيري (Ibrahim Asiri)	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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4	Opioid-related Emergency Department Visits: An Interrupted Time Series Analysis of Visits Patterns Pre, and Post COVID-19 Lockdown	Background: Studies have shown that lockdowns related to COVID-19 have been associated with increased rates of opioid and psychotropic related emergency department (ED) visits. Whether COVID-19 lockdowns have had a similar impact in Saudi Arabia remains unknown. Objectives: To analyze patterns of ED visits related to opioids and psychotropics use disorders before and after COVID-19 lockdown in a Saudi population. Methods: This study employed an interrupted time series analysis. Data from the Saudi Real-World Evidence Network (SRWEN) and the Ministry of Health's Online Toxicology Analysis Request and Result (OTAAR) platform, were used to construct the times series. Adults (≥18 years old) with ED visits related to opioids or psychotropics, from 2018 – 2022, who had a positive toxicology test, or had use of medications (naloxone, flumazenil) were included in the study. The impact of the lockdown, period March 2020 to June 2020, on rates of opioids and psychotropics related ER visits was analyzed using the ARIMA. Sensitivity analyses were conducted to assess the robustness of the findings. All analyses were conducted using RStudio 1.4.553. Results: Between February 2018 and April 2022, the Saudi Real-World Evidence Network (SRWEN) recorded a total of 3,820 (88%) opioid-related and 536 (12%) psychotropic-related emergency department visits. According to data from the Online Toxicology Analysis Request and Result (OTAAR) platform, positive toxicology tests accounted for 769 (9%) opioid cases and 5,326 (57%) psychotropic cases. The ARIMA model for opioid-related ED visits using the SRWEN data revealed an immediate increase (pulse effect) in the rate by 14.75 (95% CI: 9.65 to 19.86) representing an acute response to the COVID-19 lockdown, and a slope change of -0.6 opioid-related ED visits per month (95% CI: -0.08 to -0.03). However, OTAAR data revealed no significant changes in pulse or slop. Conclusions: We found that COVID-19 lockdown was associated with an abrupt increase in opioid-related ER visits followed by a steep decrease in the pattern. This study findings support policies aimed at mitigating opioid- and psychotropic-related misuse during public health emergencies and serve as a baseline for researchers to further investigation of these patterns.	رسيل الربع (Raseel A. AlRoba)	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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5	The Effectiveness of the Safety Communication for Concurrent Benzodiazepine-Opioid Therapy: A Retrospective Real-World Analysis	Background: Regulatory agencies commonly use safety communication as a tool to minimize patient harm by providing recommendations for certain precautionary measures. For example, the Saudi Food and Drug Authority (SFDA) issued a safety communication concerning the potential risk of respiratory depression related to concomitant use of benzodiazepines and opioids and provided recommendation to avoid such combination unless medically necessary. While such communication may offer important information to minimize harm, their effectiveness needs to be examined. Thus, monitoring trends or changes in practice may provide an important mechanism to reflect on the extent of effectiveness of such regulatory actions. Objectives: To examine the impact of the safety communications issued by SFDA on the prevalence of concomitant use of opioids and benzodiazepines before and after the safety communication. Methods: A multicenter retrospective cohort study utilizing data from Real-world Evidence Research Network comprised adult (≥18 years old) users of benzodiazepines and opioids from 2016 throughout 2020. This study employed an interrupted time series analysis using ARIMA model to examine changes in concomitant benzodiazepine and opioid prescriptions before and after the safety communication. Results: A total of 43,906 concomitant benzodiazepines and opioids prescriptions were identified for 32,035 patients. The prevalence of concomitant prescriptions for benzodiazepines and opioids slightly decreased from 22.5% (22,846 episodes) to 20.4% (21,096 episodes) after the safety communication. The result from the ARIMA model show that the estimated step change was 9.3 in prescriptions (95% CI: -154.5 – 173.2) while the estimated change in slope was -1.7 prescriptions per month (95% CI: -29.4 – 26.1). Conclusions: In this study, we observed no significant changes in prevalence and trends in concomitant prescriptions of benzodiazepines and opioids. The findings of this study could be used as a benchmark for SFDA to track trends in the application of safety communication over time and to evaluate the performance of various safety communication strategies.	رسيل الربع (Raseel A. AlRoba)	International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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

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7	Andexanet Alfa and Potential Risk of Thrombotic Events	Background: Andexanet alfa (AA), a recombinant factor Xa inhibitor, is approved by the Saudi Food & Drug Authority (SFDA) for the management of adult patients with life-threatening or uncontrolled bleeding while on apixaban or rivaroxaban. Thrombotic events (TEs) are labeled in the product information as uncommon adverse effects. Objectives: To evaluate the potential association and frequency of TEs with AA. The signal was evaluated following to the completion of the post-marketing requirement trial; ANNEXA-I trial in the United States. Methods: We conducted a systematic literature search in November 2024, using several search engines, including PubMed, Embase, Cochrane library, and Google Scholar, for English language articles on human investigating the association between AA and the risk of TEs. The search terms included 'Andexanet alfa' OR 'Andexxa' OR 'Ondexxya' AND 'Atrial thrombosis' OR 'Myocardial infarction' OR 'cerebrovascular accident' OR 'ischaemic stroke' OR 'pulmonary embolism' OR 'deep vein thrombosis' OR 'thromboembolism' OR 'thrombotic event' OR 'thrombosis'. Moreover, we conducted a search in the World Health Organization (WHO) database "VigiBase" and in the local database of the National Pharmacovigilance Center (NPC) to retrieve case reports up to November 2024. Finally, the causality assessment of the cases was performed using the WHO-Uppsala Monitoring Center (UMC) causality system. Results: Six studies were identified. Two meta-analysis studies demonstrated a significantly higher risk of TEs with AA compared to usual care (UC), with risk ratio of 1.47 (95% CI 1.01–2.15) and 1.74 (95% CI 1.09–2.77), respectively. One single-arm clinical trial reported a TE incidence of approximately 10% with AA. One post-marketing clinical trial reported significantly higher incidence of TE with AA compared to UC (P = 0.048). Two retrospective observational studies with multiple limitations did not show a significant increase in the TE risk. In VigiBase, 153 global cases were reported and 17 cases with completeness score > 0.7 were assessed; 11 cases were probably related, 5 cases were possibly related, and 1 was un-assessable. No local cases were reported to the SFDA. Conclusions:Current evidence suggests potential association between AA and TEs with an estimated incidence of ≈10%. Consequently, the PI of AA has been updated to reflect this information. Also, given the emergent and serious nature of this AE, a direct healthcare professional communication was requested from the marketing authorization holder.	(Solaiman Alhawas)سليمان الحواس	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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8	Towards Accurate Data Linkage: A Comparison of Deterministic, Probabilistic, and Machine Learning Approaches Applications in Multiple Sclerosis	Background: Data linkage in pharmacoepidemiological research is commonly employed to ascertain exposure and outcomes, or to obtain more information about confounding variables. However, to protect patient confidentiality usually unique patient identifiers are not provided; thus, makes data linkage between various sources challenging. The Saudi Real-Evidence Researches Network (RERN) aggregates EHRs from various hospitals, which may require a robust linkage technique. In this research, we compared the performance of deterministic, probabilistic, and machine learning (ML) methods to link two data sources for 2,247 multiple sclerosis MS patients. Objectives: To compare deterministic, probabilistic, and ML-based linkage approaches' performances in linking de-identified MS patient data from RERN and Ministry of National Guard Health Affairs (MNGHA) EHRs. Methods: We used two data sources to link de-identified MS patients' records from two data sources for the years 2016 through 2023. We applied a simulation-based validation framework before linking real-world data. Deterministic linkage was based on predefined rules, while probabilistic linkage was based on a similarity-score matching. We applied both similarity-score and classification approach in ML¬¬¬¬— models including neural networks, logistic regression, and random forest. Performance of each approach was assessed using confusion matrix focusing on sensitivity, positive predictive value (PPV), F1-score, and computational efficiency. Results: Deterministic linkage achieved high precision (F1 score, 97.2%) and the percentage of matched from 46.6% to 86.6%. Probabilistic linkage with one-to-one matching achieved an overall mean F1-score of 93.9% with more matched pairs (65.5-95.4%). ML methods achieved high accuracy (up to 99.37%) at the expense of high computational resources and lower marched pairs (35.1-89.6%. Conclusions: Probabilistic linkage offers high linkage capacity by recovering matches missed by deterministic methods, proving to be both flexible and efficient method, especially in real-world scenarios where unique identifiers are lacking. Probabilistic linkage achieved a great balance between recall and precision, enabling better integration of various data sources that could be useful in MS research.	عهود المدني Ohoud Almadani	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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9	Refine Risk Minimization Strategies in Saudi Arabia	Introduction: The continuous evaluation of Additional Risk Minimization Measures (aRMMs) is essential for enhancing medication safety and public health outcomes. Understanding the perspectives of healthcare professionals (HCPs) and patients is crucial for optimizing the design and effectiveness of aRMMs. This study aimed to assess and improve the clarity, usability, and accessibility of aRMMs by gathering direct feedback from stakeholders. Objective: The primary objective of this study was to enhance the effectiveness of aRMMs by identifying areas for improvement based on HCP and patient feedback. The study sought to optimize aRMM content and design to ensure better comprehension and adherence while addressing recognized gaps in current materials. Methodology: We conducted Several focus group discussions between April to December, 2024 with each session lasting around 90 minutes. Structured questions were used to assess aRMM effectiveness, clarity, design, and accessibility. Participants included HCPs and patients, and discussions were guided by predefined criteria. These discussions across selected medical centers around Saudi Arabia were facilitated by Regional Pharmacovigilance Officers (RPVOs). We selected four aRMMs (HCP Guide, Patient Guide, Patient alert card) from different therapeutic areas (Hematology, and Cardiology) based on risk severity, therapeutic group, patient population. Collected feedback was analyzed to identify common themes, areas for improvement, and actionable recommendations. Results: Twenty participants (HCP & Patients) were involved in the focus group discussions, provided valuable insights into improving the effectiveness of aRMMs. Participants emphasized the need to simplify medical terminology and ensure consistency in language, making the materials more accessible to both HCPs and patients. Many highlighted that reducing text-heavy content, particularly with patient guides, would enhance readability. Additionally, visual enhancements such as tables, graphs, and pictograms were preferred over lengthy textual descriptions, as they aid comprehension and engagement. The integration of digital tools, including QR codes linking to educational videos or mobile-friendly resources, was suggested to improve accessibility and user experience. Standardizing aRMM templates across different brands was also identified as a key improvement to ensure consistency and clarity. Furthermore, maintaining bilingual alignment between Arabic and English versions was highlighted as crucial for effective communication. These recommendations collectively aim to enhance the usability of aRMMs, improve adherence, and ultimately contribute to pharmacovigilance practice. Conclusion: The study findings provide a strong foundation for optimizing aRMMs by making them more accessible and user-friendly. Recommendations emphasize digitalization, visual enhancements, and simplification to improve risk communication and medication safety. Continuous engagement with HCPs and patients is essential for refining aRMM strategies and ensuring their long-term effectiveness.	(Fadi Alanazi) فادي العنزي	22nd DIA Japan Annual Meeting	2025

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10	Risk of Newborn Congenital Abnormalities after Exposure to Misoprostol during Pregnancy: A Systematic Review and Meta-Analysis	Background: Misoprostol is used to prevent and treat stomach and duodenal ulcers. However, prenatal exposure to misoprostol is contraindicated due to the increased risk of birth defects, abortion, premature labor or uterine rupture when administered to pregnant women. Objectives: To quantify the risk of embryotoxicity associated with misoprostol exposure during pregnancy. Methods: A systematic literature search was conducted in Medline, and Embase databases from inception to October 2024. We included studies that assessed the association between misoprostol exposure during pregnancy and the risk of congenital abnormalities in newborns. Studies were excluded if Misoprostol was administered primarily for abortion induction or lacked comparator group .The safety outcome was the occurrence of congenital abnormalities in newborns. Results: Six studies were included in the final analysis with of 6,499 pregnant females. The odds ratio (OR) for newborn congenital abnormalities range from 1.22 to 6.05. The pooled OR for newborn congenital abnormalities was estimated to be 1.88 (95% CI, 1.23 to 2.88). Conclusions: Our study shows that exposure to misoprostol during pregnancy raised the risk of congenital malformations by 88%.	(Fares Alrubaish) فارس الربيش	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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11	Insights from PBRERs Assessments: The SFDA Experience from 2022 to 2024	Introduction: Pharmacovigilance plays a critical role in safeguarding public health by continuously evaluating the risk-benefit profile of medicinal products. As part of its regulatory mandate, the Saudi Food and Drug Authority (SFDA) assess Periodic Benefit-Risk Evaluation Reports (PBRERs) submitted by Marketing Authorization Holders (MAH). These reports provide a comprehensive review of cumulative safety data and highlight emerging risks. Over the past three years, the SFDA enhanced PBRER assessment methodologies and regulatory actions to strengthen pharmacovigilance practices, improve compliance, and align with international standards. Objectives: This review aims to analyze SFDA's assessment of PBRERs over the past three years, focusing on assessment outcomes. Methods: PBRERs were prioritized for full or summary review based on predefined risk-based prioritization criteria. Full reviews were reserved for high-priority submissions, including the first submission for a new chemical entity (NCE) or biological products, underwent a full review due to their complexity and clinical significance. Summary evaluations focused on the benefit-risk balance, emerging safety information, and global regulatory actions. When a regulatory action was warranted, SFDA issued appropriate measures such as label update requests from MAHs, internal referrals for potential safety signals evaluations, or notifications relevant departments regarding risk minimization measures, medication errors, or drug quality issues. Results: From 2022 to 2024, SFDA received and assessed 1,390 PBRERs submitted by MAHs. In 2022, we received 456 PBRERs. of them, 18 reports were excluded due to medicine withdrawal by the MAH. A total of 438 PBRERs were assessed (25 full reviews and 413 summary reviews). The outcomes included 1 internal signal evaluation, 55 label updates, 9 PBRERs triggering interdepartmental notifications, and 373 reports with no recommended regulatory action. In 2023, 440 PBRERs were received, of which 33 reports were excluded due to medicine withdrawal by the MAH. Assessments were conducted on the remaining 407 PBRERs, including 36 full reviews and 371 summary reviews. These evaluations resulted in 1 internal signal evaluation, 37 label updates, and 19 notifications issued to relevant departments. Additionally, 350 reports closed with no regulatory action. In 2024, 494 PBRERs were received. Following the exclusion of 7 reports due to medicine withdrawal, 487 PBRERs were assessed (33 full reviews and 454 summary reviews). These evaluations resulted in 5 internal potential signal evaluations, 68 label updates, 15 interdepartmental notifications, and 399 reports with no recommended regulatory action. Conclusion: There are a substantial number of recommendations after PBRERs Assessments such as label updates and internal referrals highlight the important role of PBRERs in identifying emerging safety concerns. These findings reinforce the SFDA's ongoing efforts to enhance drug safety and align pharmacovigilance practices with international standards.	لى الحسيني (Lama J. Alhusayni)	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

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12	Detection and Molecular Characterization of Aflatoxin and Ochratoxin Produce Aspergillus Species In Capsicum Spices In Saudi Arabia	Capsicum is a common spice used in food flavouring. However, they are prone to mycotoxin contamination. Mycotoxins are natural toxins produced by filamentous fungi and can pose serious risks to human health. Fungal contamination was assessed in 130 randomly collected samples following ISO 21527–2:2008 standards. Results revealed that 84.6% of the samples exceeded the acceptable fungal count limit (102 CFU/g) according to Gulf Cooperation Council (GCC) standards (GSO1016:2015). The predominant fungal isolates were Aspergillus (51.1%), notably Aspergillus flavus (38.8%) and Aspergillus niger (37.7%). Molecular characterization focused on crucial genes associated with aflatoxin (AF) and ochratoxin (OT) biosynthesis, 14.4% of the isolates exhibited all targeted AF genes. The mycotoxin analysis, conducted on 34.6% of samples via liquid chromatography-mass spectrometry (LC-MS), detected AFB1 in 28.8% (0.2–13.8 µg/kg) and OTA in 35.5% (6.87–59.00 µg/kg) of the tested samples. This study demonstrates the need of implementing rules governing the methods of storing, shipping, and packing spices in Saudi Arabia, which may help to minimizes the prevalence of toxigenic fungus and mycotoxins. This was the first study in KSA that focused on Aspergillus in Capsicum products.	منال الموسى (Manal Almusa)	The 1st International Forum on Mycology and Biotechnology	2025
13	Adverse Drug Events Associated with Pembrolizumab in Pediatric Oncology: Analysis of Global and Local Individual Case Safety Reports	Background: Pembrolizumab is a programmed cell death protein 1 (PD-1) inhibitor approved by Saudi food and Drug Authority (SFDA) for pediatric patients aged 3 and older with relapsed or refractory classical Hodgkin lymphoma and those 12 and older with melanoma. Understanding its safety profile in pediatric populations is essential for optimizing treatment and ensuring patient safety. Objectives: To describe reported adverse drug events (ADEs) associated with pembrolizumab in pediatric patients. Methods: AA descriptive analysis was conducted using data retrieved from the World Health Organization (WHO) 'VigiBase (1967 to January 2025) and the SFDA's National Pharmacovigilance Center. Inclusion criteria encompassed all individual case safety reports (ICSRs) for pediatric patients receiving pembrolizumab, excluding cases ≥18 years. Results: 130 ICSRs associated with pembrolizumab in pediatric patients were identified. Indications were reported in 50 cases (38%): lymphoma (17 cases), stage IV melanoma (16), sarcoma (10), and hepatocellular carcinoma (7). Most patients were aged 12-17 years (54.6%), with 20% aged 2-11 years; 50.8% were female. The United States accounted for 36.2% of reports, with 41.5% submitted by physicians. Common ADEs: Lack of efficacy/effectiveness (13%), death and product quality issues (7% each), and pain (5%). Arthralgia and diarrhea were reported in 3.1% of cases each. Serious cases comprised 61.5% of reports. Local Data: One case reported: a 12-year-old female with aggravated hyperthyroidism; due to missing temporal relationship information, this case was un-assessable. Conclusions: This study highlights emerging safety concerns associated with pembrolizumab in pediatric patients, emphasizing the need for continued monitoring and strengthened pharmacovigilance efforts to protect this vulnerable population.	نورا العرف Nora S. Alorf	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025

ملخصات مشاركات المؤتمرات

#	عنوان البحث (Title)	ملخص البحث (abstact)	اسم الباحث المشارك (Presnting Author)	الحدث العلمي (Scientific Event)	السنة Year
14	Potential Risk of Acute Pancreatitis with GLP-1 Receptor Agonists	Introduction: The risk of acute pancreatitis has been reported with the use of all GLP 1 receptor agonists, raising important safety concerns. Objective: Given the severity of this adverse event, this review aims to evaluate the necessity of implementing additional risk minimization measures (specifically targeted at the risk of acute pancreatitis associated with these medications. Methods: We conducted a systematic search across multiple databases, including PubMed, Embase Google Scholar, and ClinicalTrials gov, from inception to April for eligible English publications Additionally, on March, 2025 we retrieved global cases from the World Health Organization (database VigiBase and the local adverse drug events database at the Saudi Food and Drug Authority (regarding reported cases of GLP 1 receptor agonist induced acute pancreatitis Finally, we reviewed regulatory documents submitted to the SFDA, particularly the "Periodic Benefit Risk Evaluation Report". Results: Our search identified two interventional studies, seven observational studies, and ten published case reports on the risk of acute pancreatitis linked to GLP 1 receptor agonists. Six local cases were recorded three with liraglutide, two with dulaglutide, and one with semaglutide Only one case each of dulaglutide and liraglutide showed a possible relationship due to reasonable temporal associations the others were unassessable due to insufficient data In VigiBase 8 889 cases were associated with GLP 1 receptor agonists, with 100 cases having a completeness score of 0 8 (including liraglutide, tirzepatide and lixisenatide Cases. Conclusions: Given the findings from our review, the SFDA recommended issuing a Direct Healthcare Professional Communication (from marketing companies to inform healthcare providers about serious adverse events linked to GLP 1 receptor agonists, especially the risk of pancreatitis.	هدير الجهني Hadir I. Aljohani	The Real-World Evidence Summit of the ISPOR	2025
15	Medication Use Evaluations for Medication Safety Profile and Risk Minimization Measures Assessment: A National Multicenter Study	Background:Pharmacovigilance increasingly relies on real-world data sources to detect safety signals and assess the effectiveness of additional Risk Minimization Measures (aRMMs) post-marketing. Medication Utilization Evaluation (MUE) presents a valuable, underutilized tool for capturing safety information from electronic health records (EHRs). Several studies have highlighted challenges in the implementation and adherence to aRMMs in clinical practice. Objectives:To assess healthcare provider adherence to aRMMs and collect safety information for Fingolimod, Clozapine, Perfenidone, and Bosentan using MUEs. Methods: Design: A cross-sectional study. Setting: 19 hospitals were invited across the Kingdom to participate in the study. Exposures: The index date was the first recorded prescription of Bosentan, Clozapine Fingolimod, or Pirfenidone between February 2021 and December 2022. Main outcome measures: The primary outcome was the proportion of patients who received laboratory screening according to SFDA-approved aRMMs (liver function tests for Bosentan, Fingolimod, and Pirfenidone or blood count for Clozapine). Other data collected included demographics, prescription patterns, and reported Adverse Drug Reactions (ADRs). Statistical analysis: Statistical Analysis was performed using Jamovi software version 1.2.2.0. Results:ATotal of 411 patients were included from ten hospitals (figure 1). The overall adherence to aRMMs for Fingolimod, Clozapine, Pirfenidone and Bosentan was 7.3%,12.2%, 36.4% and 29%, respectively. Drug induced liver injury was observed with Fingolimod, Perfenidone and Bosentan use in 9, 3 and 4 patients, respectively. Liver failure (n=11) and was observed with Fingolimod use. Conclusion:This study highlights poor adherence to aRMMs among healthcare providers for the aforementioned drugs. SFDA will cooperate with their stakeholders to improve the implementation of aRMMs. The study indicates the benefits of using MUE as a post-marketing tool for pharmacovigilance.	وعد الغامدي Waad Alghamdi	المؤتمر السنوي للجمعية الدولية لعلم الأوبئة الدوائية International Society for Pharmacoepidemiology (ISPE) Annual Meetings	2025