Iraqi Pharmacovigilance Center
المـركز العـــراقي لليقظـة الدوائيـة

وزارة الصحة العراقية
Iraqi Ministry of Health
Founded 1920 تأسست

PHARMACOVIGILANCE BULLETIN

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A publication issued periodically by the Iraqi Pharmacovigilance Center to enhance awareness and disseminate crucial information within your workplace. We invite your contributions, including articles and case studies from Iraq on pharmacovigilance, to promote a safer pharmaceutical environment. Join us in shaping the future of drug safety.

In This Issue:

The Editorial Team:

This bulletin was designed and prepared by: **Ban Abdulameer Al Shimran** (Pharmacovigilance/ MOH)
Supervised by: **Dr. Manal Mohammed Younus** (Head of Pharmacovigilance/ MOH)

If you have any inquiries or if you wish to contact us directly, use the following contact information: **E-mail**: pv@ifda.iq, **phone number & WhatsApp**: 07807820490

The First Annual #MedSafetyWeek Celebration

Under the patronage of the Minister of Health, Prof. Dr. Saleh Mehdi Al-Hasnawi, and supervised by Pharmacist Noufal Kareem Abdul-Hadi, Director General of the Technical Affairs Directorate, the Iraqi Pharmacovigilance Center proudly hosted the inaugural MedSafetyWeek Celebration.

This milestone event, held in Dijla Village, aspires to establish itself as a hallmark of an annual tradition dedicated to advancing pharmacovigilance and patient safety in Iraq.

The celebration brought together a diverse audience, including high-ranking officials, prominent healthcare figures, higher education representatives, pharmacovigilance officers from health institutions, and marketing authorization holders (MAHs). The gathering aimed to recognize and celebrate the collective efforts and achievements that contributed to the success of MedSafetyWeek across Iraq. The event also garnered extensive media coverage, with multiple networks reporting on the discussions and key highlights.

Dr. Manal M. Younus delivered a presentation that charted the significant milestones in Iraq's pharmacovigilance journey over the past 15 years. From its establishment in 2010 to the development of guidelines for both MAHs and healthcare professionals (HCPs), the creation and decentralization of a national database for public sector health institutions, implementation of risk minimization measures, capacity-building initiatives, combating substandard and falsified medicines, and the publication of research work.

As part of the celebration, an award ceremony recognized top-performing institutions in pharmacovigilance and the most impactful campaigners of MedSafetyWeek. The Directorates of **Thiqar, Basra, Al-Russafa, Babel, and Missan** were acknowledged as the highest-performing regional centers, while the **Medical City Directorate, Ibn-Alatheer Hospital (Ninawa), and Thiqar Directorate** were celebrated as top campaigners.

Informative presentations and engaging panel discussions featured pharmacovigilance data, achievements, and challenges across both public and private health sectors. These sessions underscored the importance of collaborative efforts across all health system disciplines to enhance pharmacovigilance practices and achieve patient safety.

We sincerely thank everyone who joined us, especially those who traveled from afar. Your presence honored us and contributed to the success of this event.

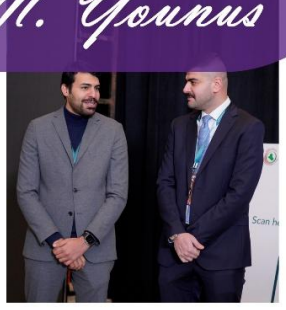
A special thanks to our dedicated colleagues who work tirelessly behind the scenes, upholding the highest standards of pharmacovigilance.

While we wished for everyone to celebrate with us, we remain hopeful for the future. Our goal is to make future gatherings larger, more inclusive, and to cover even more important topics.

We are grateful for your active participation and enthusiasm, which made this event a success. May this be the start of more collaborations, and we look forward to an even better celebration next year, God willing.

Thank you for your support and for making this occasion truly special

- Manal M. Younus



2- MedSafetyWeek 2024 Highlights

Under the slogan "Prevent Adverse Drug Reactions Through Pharmacovigilance," the **Iraqi Pharmacovigilance Center (Ministry of Health), and the Kurdistan Medicine Agency KMCA**, joined with Uppsala Monitoring Centre, for the seventh year in a row in the MedSafetyWeek campaign from November 4th to 10th, besides 97 countries to promote medication safety and ADR reporting. The campaign is mainly comprised of social media activities. According to UMC's evaluation report, analysis of social media activity showed that Iraq was the thirteenth most active country.

2025 MSW Statistics: Iraq

Local Participants:
- +16 Directorates of Health
- +150 Health Institutions
- +10 External Stakeholders

Social Media Stats:
- +2000 Shares
- +200K Views
- 4 Languages (Arabic, Kurdish, Turkish, English)

1- Distribution of Printed Materials: Posters and brochures were placed in hospitals, healthcare centers, and community pharmacies.
2- Institutional Lectures and Workshops: Sessions were conducted for medical, nursing, and administrative staff, as well as outpatients and visitors.
3- Public Engagement: Staff interacted directly with patients in waiting areas and outpatient clinics to emphasize safe medication use and adverse drug reaction reporting. Awareness sessions were held in community locations such as **markets, malls, and nursing homes**.
4- Pharmacy Outreach: Volunteers visited private pharmacies outside official hours to distribute campaign materials and speak with citizens.
5- Multimedia: Awareness videos were shown in hospitals, primary healthcare centers, and on street billboards (with **Al-Raya Advertisements**).
6- Media Broadcasts: In some provinces, such as **Kirkuk**, local radio and TV stations aired messages on preventing adverse reactions.
7- Collaboration with Digital Services: Medical City DoH with Local pharmacy wholesalers' app **"Kabsula",** integrated campaign content and push notifications for users. The app has +25,000 pharmacist users.
8- Surveys and Feedback: In **Basra**, surveys were distributed to assess knowledge gaps in pharmacovigilance among healthcare workers and patients. Over 100 responses were collected.
9- Co-ordinated posting campaign was organized on "X" (formerly Twitter) under **#MedSafetyWeek** to make it a trending hashtag.
10- Text Message Alerts: Medical City DoH, coordinated a sponsored campaign with **Asiacell co.**, to send text messages to raise public awareness.
11- School Involvement: Awareness lectures on safe medication use, risks of random drug intake, and the need to inform HCPs about any side effects.
12- **Universities** such as **Al-Mustansiriyah University**, **Al-Mashreq University** in Baghdad, hosted lectures on medication errors and electronic reporting. Thiqar DoH and **Mazaaya University College of Pharmacy** also organized a widespread student activity in collaboration with local pharmacies.
• Activities extended to **University of Al-Qadisiyah**, **University of Basra College of Medicine**, **Imam Ja'far Al-Sadiq** University and others for broader student and faculty engagement.

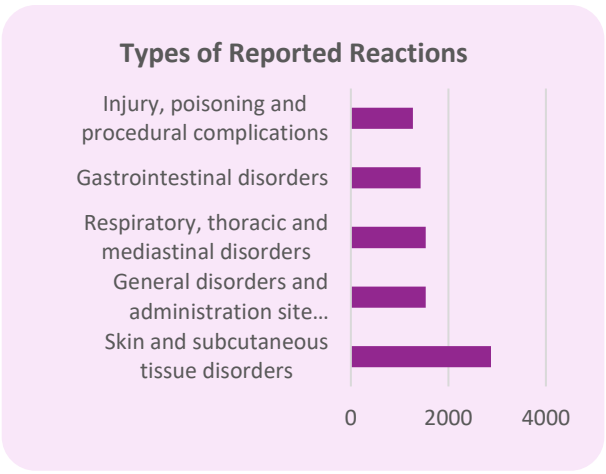
Best Field Activity Competition: Iraqi PV Center announced the competition and outlined the rules. Over 30 participating institutions were evaluated, and the top three winners were revealed during the central Medicines Safety Week (MSW) celebration in December:
1- Medical City Directorate of Health/ PV Section
2- Ibn-AlAtheer Hospital/ Ninawa
3- Thiqar Health Directorate/ PV Section

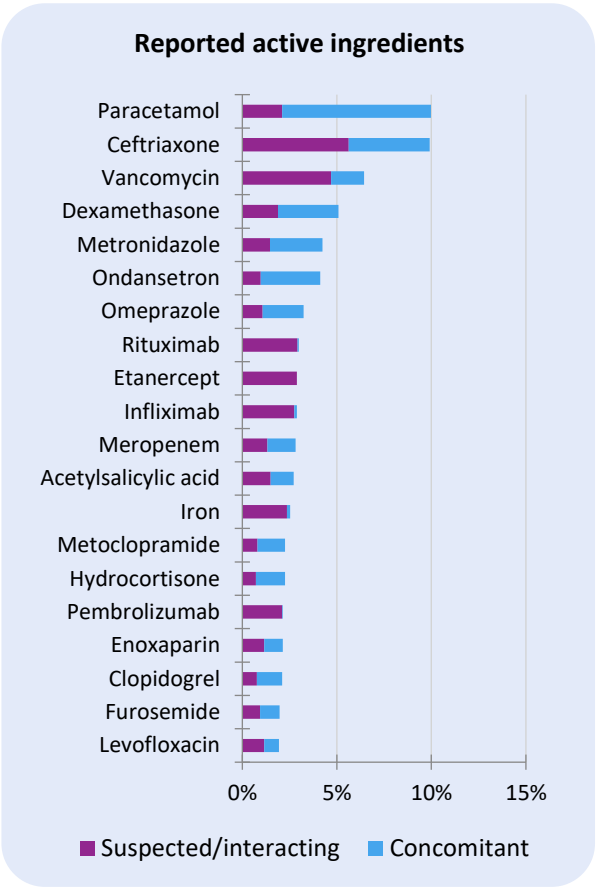
3- A Year in Review: The 2024 National ADR Database Report

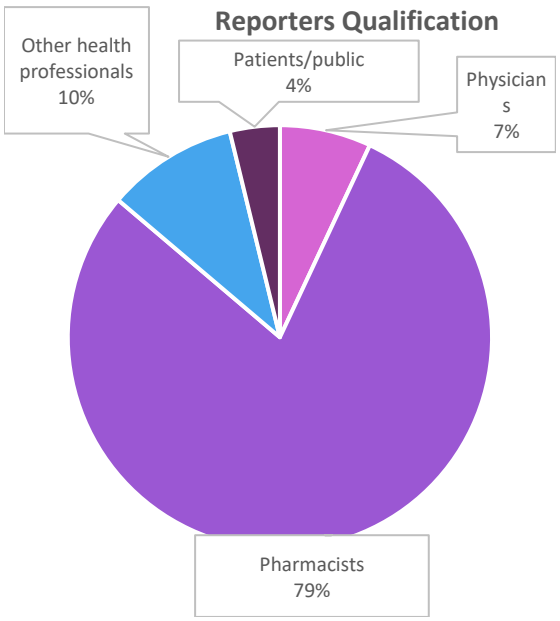
VigiFlow, the national ADR database, currently receives individual case safety reports from the regional centers and pharmacovigilance units across public health institutions nationwide, as well as from Marketing Authorization Holders (MAHs) in Iraq. In 2024, **a total of 8,320 reports** were received. This year saw a slight increase in the number of reports submitted by healthcare professionals (HCPs) other than pharmacists, although pharmacists remain the primary contributors. This improvement reflects ongoing efforts to enhance the quality of the system and promote inclusivity among HCPs.

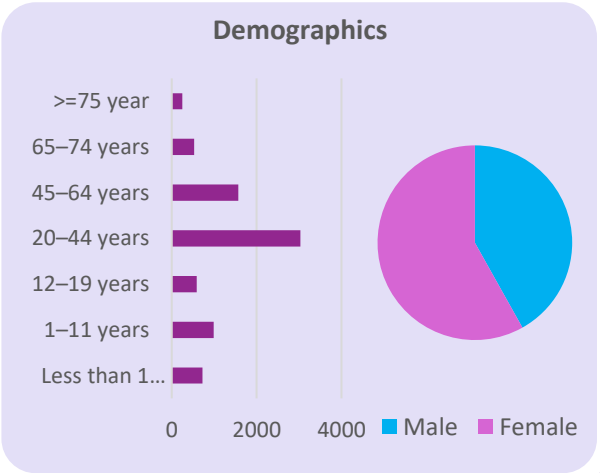
Approximately **31.6%** of the reported cases were **classified as serious**, while **15.3% of total were deemed preventable,** falling under the category of medication errors. The following figures provide a detailed analysis of these reports:

Seriousness Criteria	Percentage
Death	3.5%
Life-threatening	36.7%
Caused/prolonged hospitalization	29.8%
Resulted in permanent disability	6.3%
Congenital birth defect	0.7%
Other significant medical events	23%









Cont. 3- A Year in Review: The 2024 National ADR Database Report

A higher female-to-male ratio is a consistent trend in spontaneous reporting systems around the world. This could be attributed to multiple biological, social, and behavioral factors. For children less than 11 years of age, the opposite is true.

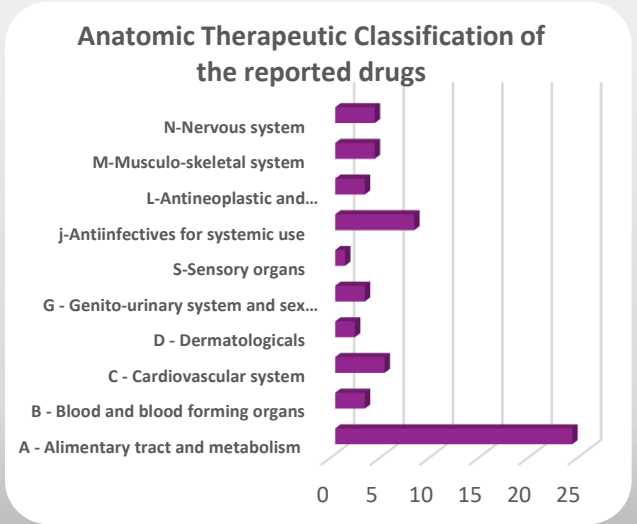
Anti-infective and infusion-administered medications are predominant in the reports reflecting the challenges associated with their administration, and possibly its use in high-risk patients. The majority of the adverse events were allergic in nature involving skin and subcutaneous tissue disorders, mostly non-serious in nature.

Medication errors, although still under-reported, its detection has risen tremendously over the past year. These mainly included: Incorrect administration rate, Labelled drug-drug interactions, prescribing issues, and lack of monitoring tests as labelled by medications.

After health institutions enter reports and delegate them to the regional center, they are assessed at two levels in VigiFlow. The regional pharmacovigilance officer (Health Directorate) first evaluates completeness and causality, then forwards the report to the Ministry of Health. The MOH PV officer reviews report quality and submits valid cases to VigiBase for analysis. If a potential signal is detected (an unknown or insufficiently documented drug-event relationship), the IPvC assesses it and coordinates with relevant bodies for confirmation and risk minimization.

Substandard and Falsified Report

The Iraqi Pharmacovigilance Center currently serves as the authority responsible for issuing alerts regarding substandard and falsified (SF) medicines. Last year, the center issued **36 alerts related to falsified medicines** based on received reports, accounting for 41% of the total reports since 2016. Additionally, **40 alerts were issued for substandard medicines**. These SF medicine alerts were also shared with the WHO Global Surveillance and Monitoring System (GSMS) for SF products. Among the most commonly reported categories were medicines related to the alimentary tract and metabolism, as well as anti-infective drugs.



4- Quality Over Quantity: Insights from Iraq's Pharmacovigilance System

By: Ahmed Sami Abbas (Iraqi Pharmacovigilance Center / Ministry of Health)

The quality of spontaneous Individual case safety reports is measured by many factors: completeness, accuracy, timeliness, and relevance. To enhance reporting quality, Iraq's pharmacovigilance system has undertaken continuous improvement efforts, guided by an annual evaluation plan aligned with WHO Pharmacovigilance (PV) Indicators. This evaluation plan assesses the performance of regional centers using a range of adapted indicators and is revised annually to raise performance standards.

Evolution of Quality Measurement

The focus initially centered on report quantity, measured by population density. Over time, it shifted to quality, progressing from VigiGrade completeness scores in the early years to clinical quality and causality assessment in subsequent years.

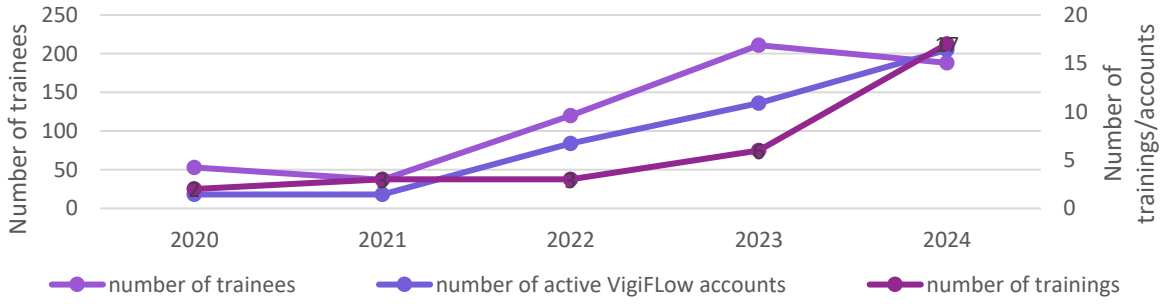
Strategic Interventions

1.Expanding VigiFlow Access: Over the past five years, the number of active VigiFlow accounts has grown significantly, facilitating broader and more effective reporting.

2.Dedicated Roles: PV officers now exclusively handle PV tasks with clearly defined responsibilities.

3.Capacity-Building Through Training: PV officers at regional centers and major reporting hospitals underwent specialized training. These programs emphasized:

1. Submitting detailed case narratives.
2. Ensuring the inclusion of essential and appropriate data for robust causality assessment.
3. Inclusion of preventability assessment using P-method in the level of the PV officers at the regional centers and health institutions

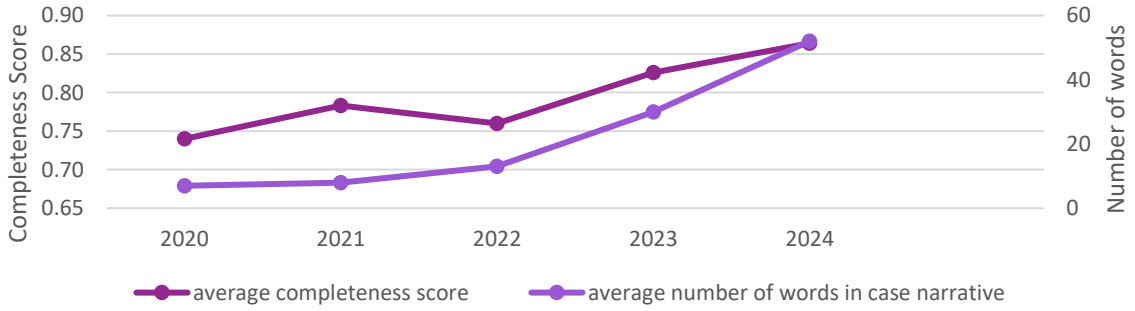


Measuring Impact

To quantify these advancements, the following metrics were tracked:

1.Average Completeness Scores: Derived from VigiGrade,

2.Case Narrative Detail: The average number of words per case narrative reflects the depth and quality of information provided.



Conclusion

Iraq's pharmacovigilance system has transitioned from prioritizing report quantity to focusing on quality. By expanding access to VigiFlow, providing specialized training, and refining evaluation metrics, the system has achieved substantial progress.

5- GLP-1 Analogues in Obesity Management: A National Perspective

By: Tamara Emad (Medical City Directorate/ Pharmacovigilance Section)
Ban Al-Shimran (Iraqi Pharmacovigilance Center)

Obesity is defined as a BMI above 30 kg/m² and is linked to numerous health risks, including heart disease and diabetes. Losing at least 5% of body weight can significantly lower these risks. Glucagon-like peptide 1 (GLP-1) is a hormone that promotes insulin secretion, reduces glucagon release, slows gastric emptying, and decreases food intake, although it is rapidly broken down by enzymes in its natural form. To extend GLP-1's therapeutic benefits, the following synthetic GLP-1 agonists have been developed:

Trade Name	Active Constituent	Global Authorization	Iraq*	Labelled Dosing
Saxenda®	Liraglutide	Dec. 2014 for chronic weight management (FDA) Mar. 2015 for weight management (EMA)	Authorized	3.0 mg, daily
Ozempic®	Semaglutide	Dec. 2017 for type 2 diabetes. (FDA) 2018 for type 2 diabetes (EMA)	Authorized	0.5 mg, 1 mg, or 2 mg once weekly
Mounjaro ®	Tirzepatide	May 2022 for type 2 diabetes (FDA) September 2022 for type 2 diabetes. (EMA)	Not Authorized	2.5, 5, 7.5, 10, 12.5, or 15 mg once weekly (titrated)
Victoza®	Liraglutide	January 2010 for type 2 diabetes (FDA) 2009 for type 2 diabetes (EMA)	Authorized	1.2 mg or 1.8 mg once daily (after initial 0.6 mg start)
Wegovy®	Semaglutide	Jun. 2021 for chronic weight management (FDA) Jan. 2022 for weight management (EMA)	Authorized but not available	2.4 mg once weekly (titrated from lower starting doses)

* According to the latest national comprehensive drugs list (End of 2024)

All of the above are injectable **prescription-only**. they are not approved for – and should not be used for – cosmetic weight loss. They are prescription medications that when used along with a reduced-calorie diet and increased physical activity, may help adults with obesity, or overweight who also have weight-related medical problems, lose weight and keep it off. GLP-1–based therapies (and related dual GIP/GLP-1 agonists) carry several important safety concerns, including alerts about the following:

Thyroid C-Cell Tumors
(Contraindication)
personal/family history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN2)

Pancreatitis
(Contraindication)
Monitor for persistent severe abdominal pain.

Renal Impairment
precipitated by volume depletion, e.g. severe vomiting and diarrhea

Pregnancy
(Not Recommended)

Gallbladder Disease
Gallstones and cholecystitis

Hypoglycemia
when combined with other agents

Gastrointestinal (GI) Side Effects: especially during initial dose titration.

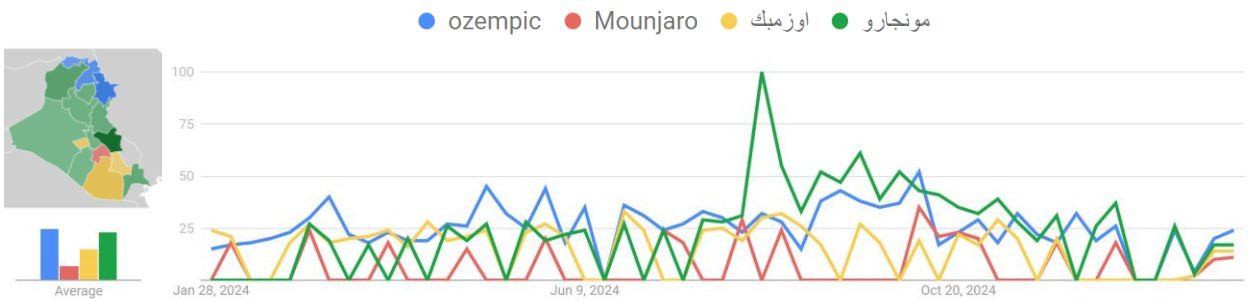
Iraq

Google Trends Analysis:

We used Google Trends data (http://google.com/trends) over a one-year period (January 2024 to January 2025), focusing on the terms "Ozempic" and "Mounjaro" in both English and Arabic (أوزمبيك, مونجارو) within Iraq. Results show a notable rise in public interest for these weight-loss injections, particularly from mid-2024 onward. Saxenda on the other hand had the lowest trend.

Interestingly, there were minimal or no searches for "side effects" or "dangers" in association with these drug names, suggesting that while people are eager to learn about the benefits, they may not be equally informed—or concerned—about potential risks. This trend may be partially driven by social media discussions and celebrity endorsements, which often highlight rapid weight-loss stories without delving into the safety profile.

Cont. 5- GLP-1 Analogues in Obesity Management: A National Perspective



Quality Concerns

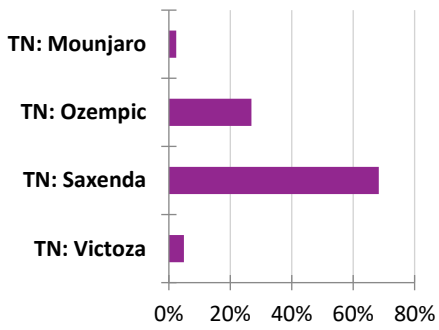
Numerous unlicensed online sources, pages, and advertisements offer all of these products without requiring a prescription or medical consultation. Among them, Mounjaro appears to be the most prominently advertised and widely sold.

Only three obesity medications are currently (Jan. 2025) authorized in Iraq—**Orlistat 120 mg, Liraglutide 6 mg/ml pen, and Semaglutide 2.27 mg/ml & 3.2 mg/ml**. Despite this, Mounjaro is appearing on the market without authorization, alongside multiple falsified products (including Ozempic and Saxenda) flagged by the WHO and the Iraqi Pharmacovigilance Center. These counterfeit or unlicensed items pose significant health risks because they are not subject to regulatory inspections and may contain no medicine, the wrong medicine, or unsafe mixtures, all of which can lead to serious harm.

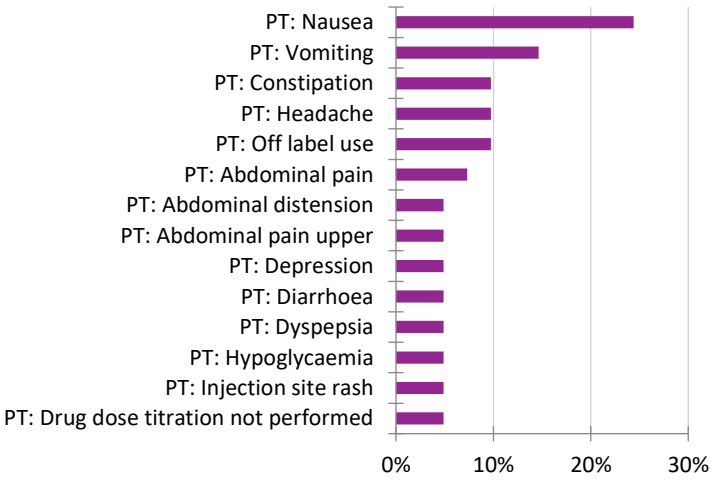
National ADR Database

A Vigilyze search showed an all time report count of 41 received regarding these products in Iraq from variable reporter types, and only 18 of them were during 2024. 56% were Gastrointestinal disorders, 27% were injury, poisoning, and procedural complications (including dosing errors, lack of prescription, exposure during pregnancy, and counterfeit product administration). Thirty-four percent were serious.

Drug (WHODrug)



Reported preferred terms (MedDRA)



Call for Action!

Pharmacovigilance in Iraq applies to **both public and private** healthcare settings, urging healthcare professionals, pharmacists, and patients to promptly report adverse effects and issues related to these medications to the Iraqi Pharmacovigilance Center. Moreover, patient education on using only **legally procured products** after proper medical consultation is crucial.

Ongoing Monitoring: While established issues like pancreatitis and gallbladder disease remain under active surveillance, newer concerns—including suicidal ideation, diabetic retinopathy, and severe gastrointestinal motility disorders—have emerged with GLP-1 therapies. Regulatory bodies continue gathering data to assess these risks and may update product labels if causal relationships are confirmed.

References:
1. World Health Organization. Obesity and overweight .
2. Wojtara M et al. Glucagon-like peptide-1 receptor agonists for chronic weight management. Adv Med. 2023 Sep 20;2023:9946924.
3. European Medicines Agency Products SmPCs
4. World Health Organization. WHO issues warning on falsified medicines used for diabetes treatment and weight loss.

6- New Melatonin Use Recommendations by the Iraqi Pharmacovigilance Center

By: Ban Al-Shimran (Iraqi Pharmacovigilance Center)

Melatonin, a hormone naturally produced by the pineal gland, regulates the sleep-wake cycle and is widely used in its synthetic form as a sleep aid, particularly for managing insomnia and jet lag. Known for its minimal side effects when used correctly, melatonin is considered a safer alternative to traditional sedatives. It is non-addictive, has a low risk of dependency, and does not disrupt sleep architecture, making it a preferred choice for both adults and children under medical supervision.

→ **Global Overview:** Melatonin's regulation, however, varies globally. In the United Kingdom and many European countries, melatonin is classified as a prescription-only medication, requiring healthcare supervision to minimize misuse and ensure safety. This strict regulation also helps prevent counterfeit products and ensures melatonin's use is appropriate for validated conditions and in low doses.

In contrast, melatonin is sold over the counter in the United States as a dietary supplement. This leniency raises concerns about product consistency and quality. A **2023 Journal of the American Medical Association (JAMA) study** found alarming inconsistencies in melatonin gummy products, with some exceeding declared dosages by up to 347%. Such variability poses serious risks, particularly for children, increasing the likelihood of unintentional overconsumption.

→ **In Iraq,** the Pharmacovigilance (PV) Center has received numerous reports of adverse events linked to melatonin use, including excessive sedation, numbness, nightmares, and depressive symptoms, with some cases involving pediatric patients and products combined with herbal components. A review uncovered **widespread misuse**, including inappropriate indications and excessive durations of use, along with the availability of **unregulated products** of questionable quality in the local market and sold online by **unlicensed sources**.

Recommendations

In response, the Iraqi PV Center, in collaboration with the Ministry of Health's Specialized Advisory Committees, issued formal recommendations for melatonin use in Iraq:

1. **Avoid Herbal Combinations for Children Under 12:** Products combining melatonin with herbal extracts, such as Passiflora incarnata, should not be given to children under 12 years of age.
2. **Restricted Use for Individuals Under 18:** Melatonin should not be given OTC to individuals under 18 without consultation from a specialist. Complete avoidance is recommended for children under 3 years of age is preferred.
3. **Purchase from Trusted Sources:** only purchase melatonin products from licensed pharmacies. Ensure the product bears the Ministry of Health's official sticker to verify registration and safety compliance.
4. **Proper Administration Guidelines:** Use the lowest effective dose, ideally less than 5 mg per day. Administer 30–60 minutes before bedtime, at least two hours after the last meal. Limit use to a maximum of one week unless advised otherwise by a physician.
5. **Concurrent Use with Certain Medications:** exercise caution when using melatonin alongside drugs affecting the nervous system, such as: Antidiabetic medications, Antihypertensives, Oral contraceptives, Warfarin. Patients should always mention this to their physician.

These recommendations places the **pharmacist in a central role** as the sole dispensers of melatonin, pharmacists act as gatekeepers to ensure only high-quality, Ministry-approved products are provided. They are responsible for determining which patients may safely use melatonin OTC, providing appropriate counseling, and referring those who require specialist oversight. Pharmacists also play a vital role in public awareness campaigns, educating the community about melatonin's benefits, risks, and proper use.

References:
1. NHS. Common questions about melatonin [Internet].
2. Cohen PA, et al.. Quantity of melatonin and CBD in melatonin gummies sold in the US. *JAMA*. 2023 Apr 25;329(16):1401-1402.
3. Skrzelowski et al. Melatonin Use in Pediatrics: Evaluating the Discrepancy in Evidence Based on Country and Regulations Regarding Production. The Journal of Pediatric Pharmacology and Therapeutics. 26. 4-20. 10.5863/1551-6776-26.1.4.
4. European Medicine Agency

7- Eco-Pharmacovigilance and Mercury: Iraq's Progress Post-Minamata Convention

By: Ayoob Nouri Ayoob (Specialized Centers Section/ Basra)

Eco-pharmacovigilance can be defined as science and activities concerning detection, assessment, understanding, and prevention of adverse effects or other problems related to the presence of pharmaceuticals in the environment, which affect human and other animal species.

Historically, mercury was used in treatments for syphilis, antiseptics, dental amalgams, and skin-lightening products. However, its adverse effects, including neurological, renal, and dermatological disorders, have led to its phased elimination.

Mercury in cosmetics, especially in skin-lightening creams and soaps, is a major concern. These products are widely available in some regions despite bans and contain mercury levels far exceeding safe limits. Exposure can result in kidney damage, psychosis, peripheral neuropathy, and other health issues. Furthermore, mercury from such products and medical waste often enters waterways, where it becomes methylated into highly toxic methylmercury. This substance accumulates in fish and can harm pregnant women and fetuses, causing neurodevelopmental deficits.

The **Minamata Convention on Mercury** Is a global treaty adopted in 2013 in response to the devastating effects of mercury pollution, epitomized by the Minamata Disease tragedy in Japan.

As of December 2024, the Minamata Convention on Mercury has 151 parties. These parties are nations or regional organizations that have ratified or acceded to the convention, committing to its goals of reducing mercury pollution to protect human health and the environment.

Iraq's Actions Post-Minamata:

Signature Date: October 10, 2013
Ratification Date: September 16, 2021
Entry into Force: December 15, 2021
Iraq is the 134th party of Minamata Convention

•**Phasing Out Dental Amalgams**: Mercury-containing dental fillings are being replaced with safer alternatives, as part of Iraq's commitment to mercury elimination.


كومارى عيراق
وه زاره تى ته ندروستى
REPUBLIC OF IRAQ
MINISTRY OF HEALTH

جمهورية العراق
وزارة الصحة
دائرة الأمور الفنية
قسم تقدير الإحتياج

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الى/ وزارة صحة اقليم كردستان / المديرية العامة للامور الصحية (دوائر صحة اربيل ،السليمانية ، دهوك)
دائرة صحة بغداد (الرصافة / الكرخ)
قسم الصيدلة
دائرة مدينة الطب
دوائر الصحة في المحافظات كافة
دائرة العيادات الطبية الشعبية

م/ اتفاقية مناماتا بشان الزئبق / مستلزمات طب الاسنان العامة

تحية طيبة ...

تنفيذا لالتزامات العراق تجاه الاتفاقية انفا ، تحذف مادة Amalgam capsule و المدرجة ضمن مستلزمات الاسنان العامة بالرمز الوطني DNS-DE00-001 و اعتبارا من احتياج العام 2026 و للاعوام اللاحقة .

للتفضل بالاطلاع و اعادة النظر باحتياجكم من المواد البديلة المرققة ربطا و مواد ومستلزمات العمل بالحشوات انفا و اجابتنا خلال 15 يوما من تاريخ صدور كتابنا اعلاه ليتسنى لنا اجراء اللازم ... مع الاحترام

م/ قائمة عدد (1).

الصيدلاني
نوفل كريم عبد الهادي
المخول بصلاحيات مدير عام
دائرة الأمور الفنية
2024/ 11 / ١٩

References:

1. U.S. Food and Drug Administration (FDA)
2. The Journal of the American Dental Association (JADA)
3. World Health Organization (WHO)
4. Minamata Convention on Mercury www.mercuryconvention.org

8- Selected Cases from the National Database:

Disclaimer!

The following cases were collected through spontaneous pharmacovigilance reporting and processed by the Iraqi Pharmacovigilance Center; they are not peer reviewed. These case summaries are provided **for educational and informational purposes only**. They **do not constitute clinical guidance or establish a standard of care**. Due to under-reporting, incomplete data, and potential reporter bias, these cases may not reflect the true incidence of adverse events. Additionally, **causality cannot be definitively confirmed** based on spontaneous reports alone.

8.1 Cerebral Vein Thrombosis in a Patient on Combined Danazol and Norethisterone Therapy

By: Ph. Sara Abdulhadi Saleh & Shahlaa Saleh Mohammed (Al-Falluja Teaching Hospital)

A 40-year-old female patient with a history of ovarian cysts and endometriosis was prescribed danazol (Ectopal, 400 mg twice daily) and norethisterone (Aminor, 5 mg, initially once daily and later increased to twice daily). After four months of therapy, she began experiencing severe headaches, which were misdiagnosed as sinusitis and migraines. Despite treatment with pain relievers, her condition worsened, leading to severe headache and abnormal body movements, which prompted her admission to the emergency department.

At the hospital, she was diagnosed with meningitis, cerebral vein thrombosis (CVT), and status epilepticus. Although initial brain CT scans were unremarkable, elevated D-dimer levels (9945 ng/ml) and clinical symptoms confirmed the diagnosis of CVT. The patient received anticonvulsants, antibiotics, antivirals, and anticoagulants. Despite intensive care, her condition rapidly deteriorated, and following few days, she succumbed to complications, including severe hypotension, bradycardia, apnea, and ultimately death.

Insights and Takeaways:

- **The current Endometriosis treatment guidelines** *(Ref: UpToDate)* **do not recommend combining** hormonal therapies.
    - Both Danazol and Norethisterone are associated with an increased risk of thromboembolism. Danazol is reserved for refractory, while norethisterone acetate is preferred as a standalone therapy for its better safety and tolerance.
- Being vigilant and **recognizing the potential symptoms early** can be life-saving (e.g. persistent headaches or neurological disturbances).
    - The patient's early symptoms (e.g. headache) are non-specific and difficult to diagnose leading to initial diagnosis of sinusitis and migraine which resulted severe progression and delayed management.
- Before initiating hormonal therapy, patients should undergo a thorough **evaluation of risk factors**, including obesity, personal or family history of thromboembolism, and other predisposing conditions.
    - This patient had predisposing factors (e.g., obesity at 83 kg, prolonged hormonal therapy for endometriosis).
- **Close and regular patient monitoring** and screening for these events (e.g., coagulation parameters, D-dimer) is crucial baseline and during treatment.
    - No drug monitoring prior to the event was documented for this patient
- The national ADR database has recorded 16 cases of embolic and thrombotic events (mostly pulmonary embolism and DVT), associated with hormone replacement therapy, 9 of which were in 2024. Although, this may reflect increased reporting or drug use rather than a trend.

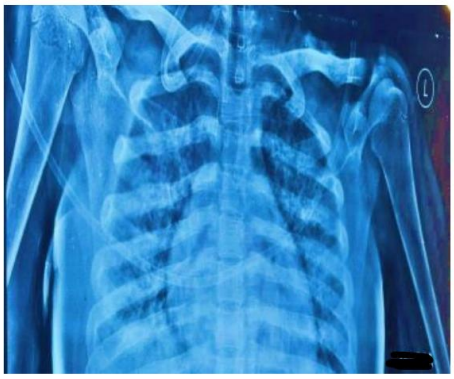
Cont. 8- Selected Cases from the National Database:

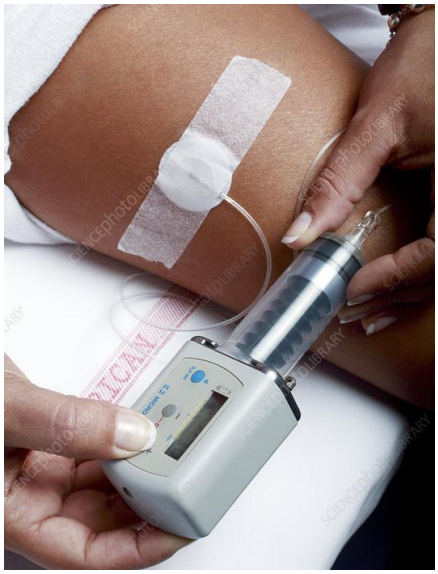
8.2 Deferoxamine Overdose in a Patient with β-Thalassemia Major

By: Clinical Pharmacist Practitioner Shahad Ali Sadik (Al-Kindy Teaching Hospital / Baghdad)

A 20-year-old female (weight: 45 kg, height: 155 cm) with a history of β-thalassemia major since 18 months of age presented to the emergency department with fever, pruritus, intermittent shivering, sweating, reduced oral intake, and left loin pain. She had been receiving scheduled blood transfusions every 2-3 weeks and subcutaneous deferoxamine (1,000 mg every other day) for chronic iron overload. Two days prior to admission, she was administered an intravenous dose of deferoxamine (5,000 mg in 200 mL of normal saline over 6 hours).

The following day, the patient developed dyspnea, tachypnea, epistaxis, and hemoptysis. Laboratory results revealed severe anemia (Hb: 7.7 g/dL, PCV: 15.1%), elevated C-reactive protein (CRP: 192 mg/L), coagulopathy (D-dimer: 3848 ng/mL, PTT: 48 seconds), and signs of renal dysfunction (serum creatinine: 1.4 mg/dL, blood urea: 105 mg/dL). Imaging studies, including Echo study **(QR Code on the right),** a chest CT scan identified bilateral pleural effusion, patchy consolidation, and severe pulmonary hypertension. The patient was managed with supportive care, including oxygen therapy and correction of coagulopathy.





Insights and Takeaways:

Deferoxamine overdose can lead to acute respiratory distress syndrome (ARDS), a rare but potentially fatal complication, particularly with high doses or rapid intravenous infusion. The recommended dose for chronic iron overload is 40–50 mg/kg/day, infused over 8–12 hours, with a maximum rate of 15 mg/kg/hour. In this case, the infusion exceeded these parameters, contributing to the adverse effects.

This case highlights the critical importance of adhering to recommended dosing regimens and infusion rates for deferoxamine.

This case also illustrates the complex challenges faced by thalassemia patients, who require lifelong management involving frequent blood transfusions and chelation therapy to manage chronic iron overload. These treatments not only come with a risk of severe adverse effects, such as those observed in this case, but also require meticulous dosing and administration protocols that demand ongoing monitoring and expertise from healthcare providers. This also demonstrates the financial burden this poses on the Ministry of Health due to both direct and indirect costs associated with Thalassemia that is unfortunately increasing in prevalence.

Cont. 8- Selected Cases from the National Database:

8.3 Aspirin in Pregnancy and Postpartum Hemorrhage Complications

By: Mina Soadad (Iraqi Pharmacovigilance Center/ Ministry of Health)

A 27-year-old G3P2A0 woman with a history of gestational hypertension and a previous episode of thrombocytopenia during COVID-19 treatment underwent an elective cesarean section under general anesthesia. She had been prescribed **low-dose aspirin (81 mg daily) for preeclampsia prevention** since the first trimester, following clinical guidelines. However, aspirin was discontinued 12 hours before the procedure.

Two hours postoperatively, the patient experienced massive bleeding from the wound site and vagina, unresponsive to uterotonics and antifibrinolytics (Oxytocin, Carbetocin (200 mcg IV), Methylergonovine (200 mcg IV, Misoprostol (3200 mcg rectally over 8 hours). Persistent uterine atony necessitated a hysterectomy.

Insights and Takeaways:

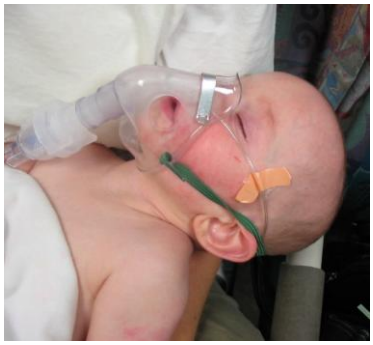
- Low-dose aspirin is effective in reducing maternal and neonatal morbidity when used for preeclampsia prevention during pregnancy. However, **its association with an increased risk of postpartum hemorrhage (PPH),** as highlighted in studies like a Swedish cohort, necessitates individualized risk assessment.
- The timing of aspirin discontinuation before delivery, particularly in cesarean sections where surgical bleeding risks are higher, remains a complex area of research.
- The patient failed to mention that she received aspirin, the physician hence administered oxytocin prophylactically but not escalated to therapeutic doses.
- Aspirin use alone was unlikely the sole cause of the hemorrhage, as multiple factors contributed, including uterine atony, anatomic abnormalities, exhausted myometrium, infections, and a family history of hematologic disorders.
- The case emphasizes the importance of thorough perioperative planning, **involving clinical pharmacists to review medications prior to surgery.** A standardized medication review checklist for clinical pharmacists before surgery is recommended to enhance patient safety

8.4 Medication Errors with Salbutamol Nebulizer in Pediatric Patients

By: Ayoob Nouri Ayoob & Farah Akram Qassim (Basra Maternity and Children Hospital)

Medication errors with nebulized salbutamol are a significant yet preventable issue in pediatric care. Common errors detected by the pharmacovigilance officers included:

1. **Improper dilution with distilled water instead of sterile saline**, which caused airway irritation and worsened bronchospasm due to the hypotonicity of distilled water.
2. **Inadequate sterilization of nebulizer equipment**, such as tubing and masks, led to cross-infections, with pathogens like *Pseudomonas aeruginosa* identified in improperly cleaned devices.
3. **Improper mask placement,** often referred to as the "blow-by" method, resulted in reduced aerosol delivery and compromised treatment effectiveness.
4. **Inaccurate dosing** also contributed to adverse effects, with over-dosing beyond the recommended pediatric range (1.25–2.5 mg every 6–8 hours for children aged 2–12 years) leading to tachyca--rdia and nervousness.
5. Additionally, the use of **multi-dose solutions containing benzalk--onium chloride** caused bronchoconstriction, especially with frequent administration.



To address these errors, PV officers plan to include regular training for healthcare workers and caregivers to improve proper nebulizer use, ensure accurate dosing, and adhere to infection control protocols to enhance patient safety.

8.5 Noradrenaline extravasation victims

By: Clinical Pharmacist Practitioner Abdulrahman Abdul-Aziz Salman & Shahad Ali Sadik (Al-Kindy Teaching Hospital / Baghdad)

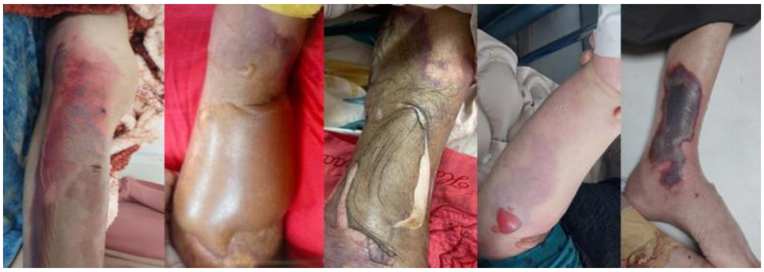
Reports from the pharmacovigilance unit at the hospital have highlighted several cases of noradrenaline-induced extravasation, leading to serious complications. Documented reactions included infusion site extravasation, extravasation injuries, and dry gangrene, with some cases classified as life-threatening and one case resulting in death. The affected patients exhibited varying degrees of tissue damage, with outcomes ranging from ongoing unresolved conditions to fatality.

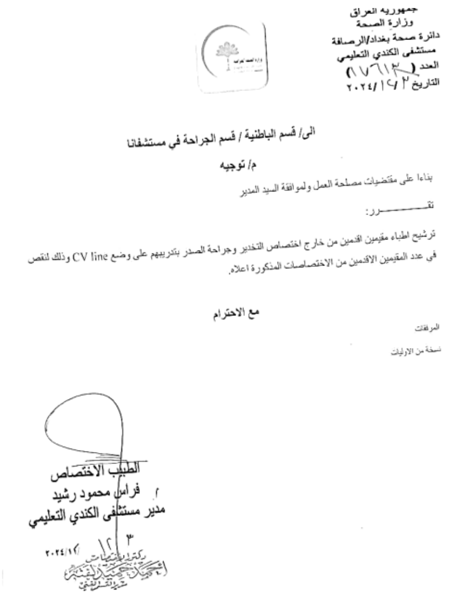
In response to these incidents, the Pharmacy and Therapeutics (P&T) Committee, in collaboration with the hospital's pharmacovigilance unit, convened to address the risks associated with noradrenaline administration. The committee implemented critical risk minimization measures, including limiting the duration of peripheral infusions to less than 24 hours, mandating the use of an infusion pump with a Y-line for administration, and ensuring continuous monitoring of peripheral cannulas every 24 hours. These interventions aim to enhance the safe administration of noradrenaline, reduce the risk of extravasation, and improve patient outcomes.

It is important to grade the severity of extravasation for patient management. It is graded as follows: grade 1 (intact skin), grade 2 (blanched skin, erythema), grade 3 (necrosis/ulceration causing severe tissue damage warranting surgical intervention), grade 4 (life-threatening warranting immediate intervention), and grade 5 (death). Among the current treatment options, phentolamine is considered the standard for management of extravasation. Other options include topical nitroglycerin and subcutaneous terbutaline.

Detailed protocols for administration of norepinephrine via peripheral line catheters should be developed, including the following recommendations:
- Assessment of veins >4 mm on ultrasound
- Use of size 20 or 18-gauge IV cannula
- Avoiding hand/wrist/antecubital fossa positions
- Peripheral IV access checks by nursing staff every 2 hours
- Maximum time of peripheral IV use of 72 hours

Furthermore, **nursing education on high-risk medication monitoring** and encouraging physicians to implement hospital protocols for peripheral vasopressor administration and extravasation management are essential.




جمهورية العراق
وزارة الصحة
دائرة صحة بغداد/الرصافة
مستشفى الكندي التعليمي
العدد (١٧٦١٣)
التاريخ ٢٠٢٤/١٢/٣

الى/ قسم الباطنية / قسم الجراحة في مستشفانا

م/ توجيه

بناءا على مقتضيات مصلحة العمل ولموافقة السيد المدير

تقـــــــــــرر:

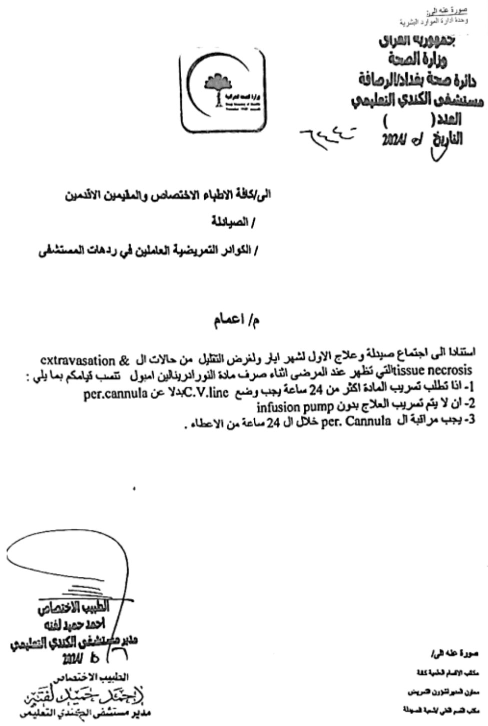
ترشيح اطباء مقيمين القدمين من خارج اختصاص التخدير وجراحة الصدر بتدريبهم على وضع CV line وذلك لنقص في عدد المقيمين الاقدمين من الاختصاصات المذكورة اعلاه.

مع الاحترام

المرفقات

نسخة من الاوليات

الطبيب الاختصاص
فراس محمود رشيد
مدير مستشفى الكندي التعليمي
٢٠٢٤/١٢/٣


صورة عنه الى/
وحدة ادارة الموارد البشرية

جمهورية العراق
وزارة الصحة
دائرة صحة بغداد/الرصافة
مستشفى الكندي التعليمي
العدد ( )
التاريخ / 2024

الى/كافة الاطباء الاختصاص والمقيمين الاقدمين
/ الصيادلة
/ الكوادر التمريضية العاملين في ردهات المستشفى

م/ اعمام

استنادا الى اجتماع صيدلة وعلاج الاول لشهر ايار ولغرض التقليل من حالات ال extravasation & tissue necrosisالتي تظهر عند المرضى اثناء صرف مادة النورادرينالين امبول تتسب قيامكم بما يلي :
1- انا تطلب تسريب المادة اكثر من 24 ساعة يجب وضع C.V.lineبدلا عن per.cannula
2- ان لا يتم تسريب العلاج بدون infusion pump
3- يجب مراقبة ال per. Cannula خلال ال 24 ساعة من الاعطاء .

الطبيب الاختصاص
احمد حميد لفتة
مدير مستشفى الكندي التعليمي
2024/ 6

References:

1. Pradhan R. R., "Inadvertent extravasations of norepinephrine", Clin Case Rep.,10, e06516, 2022, doi: 10.1002/ccr3.6516.
2. Shrestha N., Acharya U., Pramesh S. S., Subhash P. A., Bipin K. and Subodh S. D., "Topical nitroglycerin for management of peripheral extravasation of vasopressors: a case report", Oxford Medical Case Reports, 8, 289–291, 2020,
3. Cardenas-Garcia J., Schaub K. F., Belchikov Y. G., Narasimhan M., Koenig S. J., and Mayo P. H., "Safety of peripheral intravenous administration of vasoactive medication", J. Hosp. Med., 10 (9), 581-585, 2015.

Cont. 8- Selected Cases from the National Database:

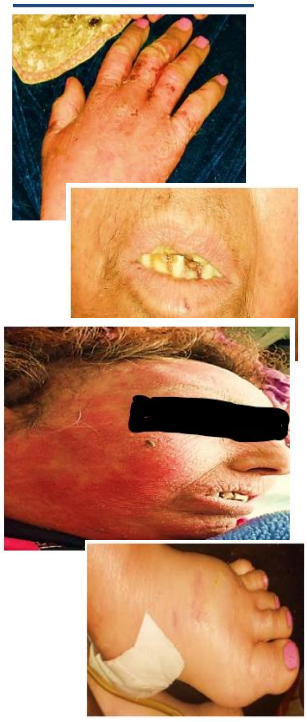
8.6 Steroid-Induced Cushing's Syndrome and Psychosis in an Abuser

By: Clinical Pharmacist Practitioner Shahad Ali Sadik (Al-Kindy Teaching Hospital / Baghdad)

A 45-year-old female (weight: 70 kg, height: 159 cm) with a past medical history of psoriasis presented to the emergency department with sudden-onset shortness of breath (6-hour duration), agitation, generalized redness, swelling, pain, confusion, and auditory hallucinations. Her medication history revealed prolonged misuse of corticosteroids, including dexamethasone 0.5 mg (three times daily) and high doses of topical steroid-containing preparations (Nystacort and Dermodin creams, 2 tubes each daily) for two years.

Laboratory tests showed elevated white blood cell count (WBC: 32.08 × 10^3/µL, neutrophils: 29.95 × 10^3/µL), hyperglycemia (RBS: 410 mg/dL), hypokalemia (serum K: 2 mmol/L), hypoalbuminemia (serum albumin: 1.9 g/dL), and metabolic alkalosis (pH: 7.52, HCO_3: 25 mmol/L). Imaging studies, including a chest CT, revealed bilateral lower lobe consolidations and cavitation, suggesting possible fungal or bacterial infection. A brain CT showed two hypo-dense areas in the right frontal and occipital regions. Echocardiography identified mild left ventricular hypertrophy, small pericardial effusion, and grade 1 diastolic dysfunction.

She was diagnosed by the specialist physician and then managed with supportive care, including oxygen therapy, infection control, electrolyte correction, and psychiatric evaluation.



Insights and Takeaways:

Steroid misuse is a significant issue in Iraq, driven by societal preferences for lighter skin tones and a "moon face" appearance. This case highlights the severe adverse effects of their prolonged abuse.

Adverse Effects of Steroids Noted in This Case:

- **Cutaneous**: Generalized redness and swelling likely due to steroid-induced rosacea.
- **Metabolic**: Hyperglycemia, hypokalemia, hypoalbuminemia, and metabolic alkalosis.
- **Infections**: Increased susceptibility to fungal and bacterial infections, evidenced by chest CT findings.
- **Psychiatric**: Agitation, confusion, auditory hallucinations.

The widespread availability of corticosteroids in Iraq and a lack of awareness about their irreversible side effects contribute to their misuse. According to a 2021 study conducted in Iraqi community pharmacies, topical corticosteroids are among the most commonly misused preparations.

8.7 Albumin Overdose and Fatal Outcome in a Neonate

A 6-day-old term neonate with congenital heart disease, admitted to the NICU for respiratory distress syndrome, developed peripheral edema on the third day of hospitalization. Albumin (15 mL) was prescribed alongside meropenem and furosemide. Due externally procured albumin (from outside the hospital) by the family in a 50 mL vial, which had double the concentration of the prescribed formulation. The unadjusted dose led to an albumin overdose when administered as a slow IV infusion.

The neonate subsequently developed harlequin color syndrome, pulmonary hemorrhage, apnea, and severe respiratory distress. Despite cardiopulmonary resuscitation and additional medications, the patient passed away. This case highlights systemic gaps in medication availability, lack of multidisciplinary review for substituted drugs, and the need for stringent dosing protocols to prevent errors in vulnerable neonatal patients.

9. Miscellaneous Activities

9.1 Piloting Vigiflow as a Database for Blood Products Problems in Iraq

In 2023, a strategic collaboration was endorsed between the Iraqi Pharmacovigilance Center and the Iraqi National Blood Transfusion Center. This significant step aims to improve the monitoring of blood products and their derivatives by activating Vigiflow as a comprehensive data management system to manage and document potential issues related to blood products in Iraq.

Vigiflow is designed to be served as a national database for adverse events related to medicines and vaccines. The collected reports from healthcare institutions, healthcare providers, and pharmaceutical companies, are collected and stored to enable detailed analysis to support decisions related to safety and effectiveness.

A phased plan was developed to implement this initiative effectively. The first step involved updating the existing hemovigilance reporting form to ensure it captured all essential elements for reporting. Gradually, Vigiflow accounts will be provided to blood banks across the country. The agreed next step was to establish a centralized account for the National Blood Bank and train its staff on report entry processes. Following this, piloting an account in a major hospital blood bank in Baghdad to evaluate the system's applicability and accessibility. The expected outcome of this collaboration is to enhance the safety monitoring of blood products and streamline the collection and analysis of related reports. Notably, Iraq is the leading the way to use Vigiflow for this purpose. The results of this very challenging experience will be shared with the Uppsala Monitoring Center, which oversees and maintains Vigiflow and VigiBase.

9.2 Active Surveillance : Ceftriaxone Infusion-Associated Hypersensitivity

Ceftriaxone has consistently been the most reported drug in Iraq's pharmacovigilance database. Despite sensitivity testing protocols in health institutions, hypersensitivity reactions linked to its intravenous infusion remain a concern, sparking controversy among healthcare professionals and the public. Unsubstantiated claims of low-quality products have circulated, while the root cause—whether due to over-reporting, excessive usage, or genuinely higher-than-expected reaction rates—remained unclear.

To address this, the Iraqi Pharmacovigilance Center initiated a three-month active surveillance study to evaluate the incidence and factors contributing to these reactions. Ten hospitals across Baghdad (Al-Rusafa and Al-Karkh), Basra, Anbar, Diyala, Karbala, Missan, Nineveh, Kirkuk, and Diwaniya were selected based on high ceftriaxone use and pharmacovigilance expertise. Notable researchers ensured rigorous data collection under the supervision of health directorate and Ministry of Health pharmacovigilance sections.

The study's findings have been finalized and will soon be published as a scientific paper, offering critical insights into ceftriaxone's safety profile and guiding evidence-based recommendations.

9. Miscellaneous Activities

9.3 Training Courses

Nationwide Pharmacovigilance Units Training:

As part of the National Pharmacovigilance Center's annual training plan, two courses were conducted in the second half of 2024—one for **Ninawa, Slaheddien, and Kirkuk** DoHs and institutions, and another for the **Al-Karkh** Directorate in Baghdad, and in **Al-Hussein Military Hospital**. These sessions aimed to enhance the skills and knowledge of pharmacovigilance officers in critical PV practices.

The courses covered pharmacovigilance essentials, from a refresher on basic principles to advanced topics such as VigiFlow proficiency, quality ICSRs, medication error reporting, and PV unit operations.

Following the training, a marked improvement in the volume and quality of reports was observed. Building on this success, the National PV Center will continue these activities in 2025, targeting institutions in the central region and Middle Euphrates.

Ministry of Health Training:

A specialized PV training course was provided to regulatory authority personnel and decision makers in the Iraqi Ministry of Health, aiming to enhance pharmacovigilance practices and strengthen the national drug safety system. This five-day course covered key topics, including pharmaceutical companies, national manufacturers, healthcare institutions, and regulations on falsified, substandard, and smuggled medicines—focusing on strategies to combat them.

Research Course:

In collaboration with the **Ministry of Health's National Center for Training and Human Development**, the Iraqi Pharmacovigilance Center organized a specialized training course in late July as part of its capacity-building efforts to enhance the research skills of pharmacovigilance officers across Iraqi institutions. The course covered evidence-based decision-making, critical appraisal skills, and introduced participants to the components of a research protocol and the principles of research design.

9.4 Clinical Research Course

The **Ministry of Health** has partnered with **AbbVie** to launch the Clinical Research Advancement Integrated Signature Program (CRISP) for its employees. The **PV Center** also strived to enroll pharmacovigilance officers in the program. A registration process was initiated, prioritizing officers with postgraduate degrees and those with over two years of pharmacovigilance experience. Through this collaboration, participants will develop expertise in clinical trials, study design, protocol development, and data interpretation, enabling them to enhance pharmacovigilance practices and contribute effectively to prospective clinical trials.

CRISP
CLINICAL RESEARCH ADVANCEMENT INTEGRATED SIGNATURE PROGRAM

Call For Reporting

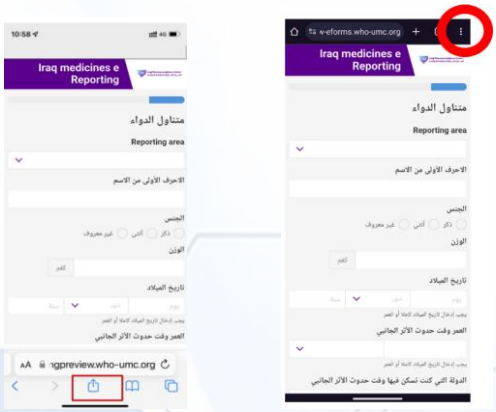
Become an alert health professional
Connect the undesirable medical event with drug exposure
REPORT IT!

1- Scan QR

Everyone Can Report!

Use the electronic pharmacovigilance form to report and document any adverse reactions or drug-related problems observed in patients.

2- Download as an App



Download the form as an app on iOS and Android
1- Click Add to Home Screen → Install
2- The form icon will appear
You can fill as many reports offline and send them when internet is available later

3- Select Reporting Area

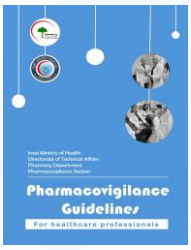
Public Sector: Name of institution where the case is detected

Private Sector: Governorate

4- Start Reporting!

Document all the available information about the case in the relevant fields.

Refer to the Pharmacovigilance Guidelines for Healthcare professionals:



5- Outcome

All reports are treated anonymously, handled scientifically and objectively, and participate in the analysis and necessary follow-up actions in collaboration with relevant official authorities.

Remember: if the reaction is not documented in the package insert, it does not mean that the reaction cannot occur with that particular suspected medicine.